

ACR BI-RADS® ATLAS

Breast Imaging Reporting and Data System

2013



Mammography

Ultrasound

Magnetic Resonance Imaging

Follow-up and Outcome Monitoring

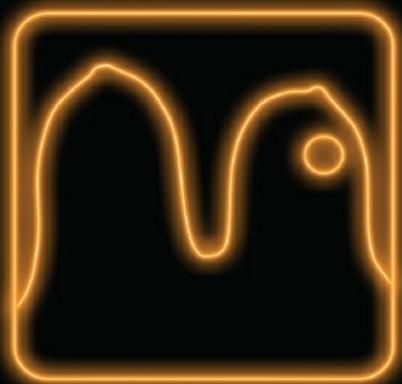
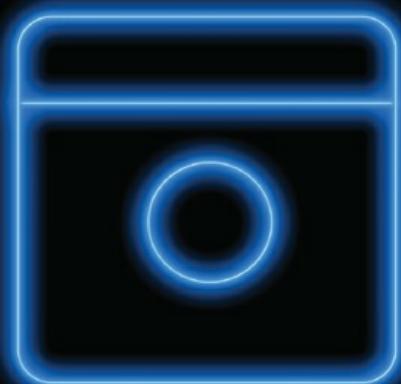
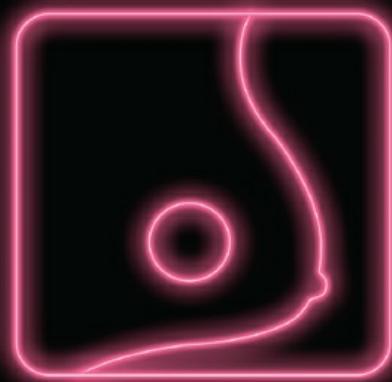
Data Dictionary

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Breast Imaging Reporting and Data System

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Breast Imaging Reporting and Data System
5th Edition



Mammography



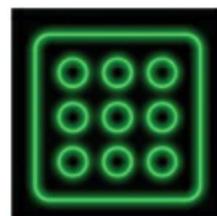
Ultrasound



Magnetic Resonance
Imaging



Follow-up and
Outcome Monitoring



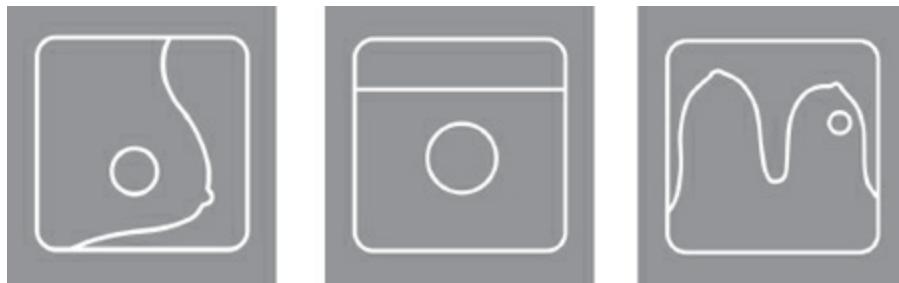
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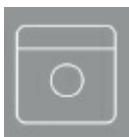
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PREFACE

The illustrated BI-RADS® Fifth Edition is an extension of the Fourth Edition of the BI-RADS® Atlas. The Fifth Edition, like its predecessor, includes sections on ultrasound and magnetic resonance imaging (MRI) of the breast. As you will see, the number of actual cases has been increased significantly throughout all sections of the atlas. The new edition has a total of approximately 600 images. Also, whenever possible the authors have placed an emphasis on ensuring consistency in terms and definitions among the three lexicons.

There are several changes and expanded definitions within the Fifth Edition. The ultrasound portion now includes and/or expands on anatomy, image quality, labeling, and tissue composition. MRI includes a section on breast implants and clearly defines troublesome issues such as background enhancement and foci. While all the lexicons within the BI-RADS® Atlas stress the importance of clear description of findings and BI-RADS® assessment categories and management, it is now possible to separate the BI-RADS® categories from management. For example, a solitary group of punctate calcifications will have a $\leq 2\%$ chance of malignancy and appropriately receive a BI-RADS® category 3 after workup, a probably benign finding. Previously this assessment was given with the management decision of short-term follow-up. However, there may be circumstances where the category 3 assessment is correct but perhaps a biopsy is done due to clinician and/or patient insistence. Such a scenario may now appropriately be described as category 3 without the attached management option of short-term follow-up. Of course, for the most part, the current management aligned with the BI-RADS® assessment categories will be appropriate but now the flexibility to separate the assessment categories from the management has been added.

A substantive change involving assessment category 3, which will impact the audit metrics for breast imaging, is defined. It is strongly encouraged that a category 3 be issued only after an appropriate workup. This modification has been implemented based on recent studies that have indicated that full diagnostic imaging evaluation will identify both benign and malignant lesions promptly instead of waiting for 6-month follow-up to obtain the diagnostic workup. Previously, for purposes of the audit, category 3 at screening had been considered a negative assessment. Now, to make our audits more consistent and useful as both a quality and teaching tool, **a category 3 assessment rendered from a screening exam, without workup, is considered a positive screening exam.** The rationale for making category 3 at screening positive is that it implies additional imaging evaluation prior to routine screening in 1 year. The rationale for considering category 3 after a diagnostic workup as negative is that biopsy is not recommended. Most importantly, the consistent and clearly

defined use of the assessment categories and management options will help clinicians understand disposition of their patients based on breast imaging evaluation. Knowing how we perform will also aid to identify deficiencies, facilitate research, and be of practical value to avoid adverse medicolegal consequences.

The figure legends will designate the defined feature in capital letters. Obviously, many of the illustrations will display several features, for example, "ROUND", circumscribed, high-density mass. All cases will be fully described using the lexicon terminology; so, many of the examples will highlight more than one feature. However, the capitalized terms will indicate the feature that was chosen for illustration. One must remember that management recommendations should be based on the most worrisome of the features. Thus, a group of pleomorphic and punctate calcifications may use all terms needed to describe the calcifications, but must include a statement recommending biopsy due to the presence of pleomorphic forms. This flexibility should also be applied when describing mass features. For example, many margins will be partially obscured by glandular tissue: but if at least 75% of the margin is circumscribed and the remainder is obscured, the mass can be classified on the basis of its circumscribed margins. On the other hand, a mass margin that is partially circumscribed and partially indistinct should be classified on the basis of its more worrisome indistinct margins.

The Fifth Edition of BI-RADS® is the culmination of years of collaborative efforts between the subsection heads and their committees, the American College of Radiology (ACR), and, importantly, input from users of these lexicons. It is designed for everyday practice and should make it possible to issue unambiguous breast imaging reports and meaningfully evaluate our performance. This will enable us to improve our practices and compare ourselves to other breast imaging facilities worldwide. We all sincerely hope that this document helps breast imagers everywhere better understand and evaluate our subspecialty.

BI-RADS®, now more than ever, is intended to be a dynamic and evolving document that will adapt to changes in the practice of breast imaging and be of practical use to radiologists. In addition to the traditional bound format, the Fifth Edition of the Atlas will take advantage of advances in electronic publishing to offer its material in an e-book, available online, and as an app for greater portability and expanded features. BI-RADS® in these digital media will be able to address changes in practice and advances in technology efficiently and regularly. Therefore, the BI-RADS® committee encourages comments and/or suggestions from its users and requests these in writing to the ACR. However, prior to submitting comments or suggestions, please visit the ACR BI-RADS® web page at, <http://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/BIRADSFAQs.pdf>, which displays committee-approved responses to suggestions already submitted.

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PREFACE

This mammography section of the BI-RADS® Atlas 2013 Edition is an extension of the fourth edition and includes illustrations of each feature described. The mammography section is part of the BI-RADS® Atlas, which also includes sections on ultrasound (US) of the breast and magnetic resonance imaging (MRI) of the breast.

There are numerous changes, clarifications, additions, and expanded definitions in this edition of the mammography section that are covered in the Guidance chapter and in pertinent individual parts of the section. The lexicon of mammography terms and the reporting format are meant to standardize the language used in mammography reports. In particular, consistent use of BI-RADS® assessment categories coupled with use of concordant management recommendations will help clinicians understand disposition of their breast imaging patients and aid in auditing breast imaging practices.

The features we use to describe mammographic findings are illustrated in the BI-RADS® 2013 edition. The presentation of each feature is accompanied by mammographic examples. The legend beneath each example indicates in capital letters the specific feature illustrated. If, as often is the case, an illustration depicts more than one feature, the legend indicates all the features using lexicon terminology, so that each such example serves to highlight more than one feature. However, the capitalized term indicates the feature that the mammogram was chosen to illustrate, such as "ROUND, circumscribed, high density mass." Where possible, pathology of what is described is included.

Sometimes, a single descriptor will not be adequate to characterize a finding. This is often true with the features of calcifications and masses. Furthermore, a group of calcifications may include several different types, for example, "punctate" and "amorphous." If one type predominates, a single descriptor would be best; if not, multiple descriptors may be preferred. One must remember that management recommendations should usually be based on the most worrisome of the features. For calcifications, this may be the distribution or the morphology. While more than one feature may be described, a single management recommendation should be made based on the most suspicious feature(s). Thus, a group of fine pleomorphic and punctate calcifications may use all terms needed to describe the calcifications with a statement recommending biopsy due to the presence of fine pleomorphic forms. One may also describe the finding as "a group of microcalcifications with fine pleomorphic forms; biopsy is recommended." This flexibility should also be used when describing the margin of masses. In many cases, the margin of a mass will be partially obscured by glandular tissue. If at least 75% of the margin is circumscribed, the mass may

be classified as “circumscribed,” even if the remainder is obscured. If, however, a mass margin is partially circumscribed (i.e., < 75%) and partially indistinct, it should be classified on the basis of its indistinct margin.

For several findings in the lexicon for which more than one descriptor was used in past editions, only one descriptor remains in the 2013 edition. These changes were made to simplify reporting. To ease the transition, the eliminated descriptor term appears in the heading for each such finding, within parentheses, as (historically, “eliminated term”). Eliminated terms will appear only in the edition within which they were eliminated, not in subsequent editions.

The Guidance chapter, first introduced in the fourth edition in response to many questions and suggestions concerning terminology and auditing, has been greatly expanded in the 2013 edition. In this chapter we explain in detail the proper use of BI-RADS® assessment categories, the introduction to the mammography report of a separate management recommendation section immediately following the BI-RADS® assessment section, how to achieve concordance between assessment and management recommendations, and how to report the few clinical scenarios when assessment and management recommendations are not fully concordant.

All mammography reporting system vendors licensed to use BI-RADS® terminology in their software will have access to the files for the fifth edition of the atlas in sufficient time to update their applications within the 180 days stipulated by the signed license agreement they have with the ACR. Users should verify that their equipment has been updated with the most recent software or request updates from their vendors to ensure that their automated reporting is up to date and accurate.

All mammographic images in the 2013 edition are displayed with the right breast on the left, nipple facing to the left, in concert with standard display of all radiographic images. This represents a change from previous BI-RADS® editions, when screen-film mammography was the prevalent technology and at a time when only half of interpreting physicians viewed mammographic images using this orientation (the other half preferred the opposite orientation because it allowed the observer to face the emulsion [dull] side of films, thereby reducing glare). Now that digital mammography has become the prevalent technology, the argument for “opposite-orientation” display is increasingly becoming moot. A major goal of BI-RADS® is to promote consistency and uniformity in reporting breast imaging examinations, so the acceptance of uniform-display orientation is meant to facilitate this goal. However, those interpreting physicians who have recently switched or will switch from opposite- to standard-orientation display should take precautions to avoid right-left confusion.

The BI-RADS® Atlas Fifth Edition is designed for everyday practice and should make it possible to issue meaningful and unambiguous breast imaging reports. BI-RADS® was always intended to be a dynamic and evolving document that would adapt to changes in

the practice of breast imaging and be of practical use to interpreting physicians. Therefore, the Committee on BI-RADS® welcomes any comments and/or suggestions from its users and requests that these be submitted in writing or electronically to the ACR. However, prior to submitting comments or suggestions, please first visit the ACR BI-RADS® web page at <http://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/BIRADSFAQs.pdf>, which displays committee-approved responses to suggestions already submitted.

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INTRODUCTION

The ACR BI-RADS® is a quality assurance tool designed to standardize reporting, reduce confusion in breast imaging interpretations and management recommendations, and facilitate outcomes monitoring. Through a medical audit and outcomes monitoring, BI-RADS® provides important structure for collecting peer-review and quality assurance data that may improve the quality of patient care.

All interpreting physicians and referring health care providers should be aware of the benefits and limitations of breast imaging technologies. There are two major categories of women who may benefit from breast imaging studies.

Screening

The major role for mammography is the earlier detection of breast cancer in asymptomatic women. The efficacy of mammographic screening has been established by randomized controlled trials in which significant breast cancer mortality reduction has been achieved by the ability of mammography to depict ductal carcinoma *in situ* and infiltrating cancers at a smaller size and earlier stage than in control groups not offered screening. Data are also accumulating that indicate the adjunctive use of US and MRI is useful in the screening setting for certain groups of high-risk women, which is covered in detail in the US and MRI sections of the BI-RADS® Atlas. Although mammography can detect the majority of breast cancers, there are some that elude detection by imaging yet may be palpable. Thus, despite the paucity of studies demonstrating the efficacy for the clinical breast examination (CBE), the committee feels this remains an important component of screening. In addition, although breast cancer mortality reduction has not been demonstrated for breast self-examination, it seems prudent to encourage its use, if only as a means to promote awareness of good breast health practices that include screening with mammography. By definition, mammographic screening involves the performance of the mediolateral-oblique and craniocaudal projections. Its goal is to identify the small subset of women who require further diagnostic imaging evaluation among the much larger group of well women for whom periodic screening is recommended. In some clinical practice settings, additional mammographic images and/or adjunctive breast imaging studies will be undertaken immediately to solve a question raised on a screening examination. In the more common setting, involving the batch reading of screening examinations, the patient will be recalled for further evaluation to answer a question raised on the screening study.

Diagnostic Breast Evaluation

Mammography and other breast imaging modalities, such as US and MRI, also are useful in the evaluation of women who have signs or symptoms that may suggest breast cancer. However, ***there is no test or group of tests that ensure that a woman does not have breast cancer.*** Physical examination evaluates different tissue characteristics than mammography and provides a unique set of information concerning the tissues being studied. Just as decisions must be made based on mammographic suspicion in the face of a normal clinical examination, management decisions also must be made based on clinical findings in the face of a negative mammogram. Because it is a well-established fact that mammography does not reveal all breast cancers, some of which may be palpable, a statement indicating diminished accuracy of mammography in the dense breast is often warranted.

In addition, a finding of clinical concern that has no mammographic correlate must be evaluated independently of the mammographic findings. US is often helpful in this setting; given the combination of a negative mammogram and negative sonogram, the likelihood of malignancy has been shown to range from 0.1% to 4%.^{1, 2, 3, 4, 5, 6} A statement in the report should be included indicating the need for final management based on findings at clinical breast examination, in which the laterality, clock-face position, and distance from the nipple of the symptomatic lesion are described (to the extent known) in order to aid the referring clinician in identifying the site at which CBE should be targeted. However, universal (nontailored) disclaimers are unnecessary since it is well established that a negative mammogram does not exclude cancer and a clinically suspicious area should be biopsied even if the mammogram is negative.

Despite the fact that biopsy may be performed for a suspicious palpable abnormality, mammography is still important to evaluate the area in question as well as to screen the remaining ipsilateral and the contralateral breast for clinically occult cancer. It also is important for women and their physicians to understand that mammography screening is not perfect and that any noncyclic breast change should be brought to the physician's attention regardless of how soon this occurs following negative mammography and clinical breast examinations.

The ACR BI-RADS® — Mammography is divided into three sections with two additional appendices.

SECTION I: Breast Imaging Lexicon — Mammography

SECTION II: Reporting System

SECTION III: Guidance

APPENDIX A: Mammographic Views

APPENDIX B: ACR BI-RADS® — Mammography Lexicon Classification Form

The following is a brief summary of each section.

I. Breast Imaging Lexicon — Mammography

The terminology used to describe mammographic findings has evolved over many years, and the diversity of this terminology may cause confusion. The descriptive terms and definitions that follow have been approved by the ACR Committee on BI-RADS®, and it is hoped that all those involved in breast imaging will adopt these terms and use them exclusively so that reports will be clear, concise, and standardized. It is believed that these terms provide a reasonably complete evidence-based categorization of mammographic lesions. Any proposed substantive changes should be submitted to the ACR for review by the Committee on BI-RADS®, as indicated in the Preface.

II. Reporting System

The reporting system is designed to provide an organized approach to image interpretation and reporting. It does not absolutely require use of computer-based reporting software, but such use is strongly recommended. Not only does this facilitate clear, concise, and standardized reporting, but it also permits simultaneous data collection for the maintenance of a database used for future outcomes review (audit). This will allow individual interpreting physicians and mammography facilities to monitor their own results and appraise the accuracy of image interpretation so that they can adjust interpretive thresholds appropriately. The ideal computer-based reporting software has not yet been developed, but it is strongly recommended that use of software should involve a minimum of data entry. The interpreting physician's attention should be focused on the evaluation of images, not on interaction with a software program. The simplest input utilizes a single screen for normal examinations and only limited interaction for abnormal examinations. The goals are to maximize the image viewing time and minimize the distractions inherent in reporting. If practical, we recommend use of a scribe to enter the data. Note that use of ACR-approved computer-based reporting software is required for participation in the ACR National Mammography Database (NMD) (<https://nrdr.acr.org/Portal/NMD/Main/page.aspx>), a quality assurance initiative designed to conveniently and accurately produce clinically meaningful audits, with outcomes reported for individual interpreting physicians and for an entire mammography facility, accompanied by comparison to concurrent benchmark data from similar interpreting physicians, similar facilities, and all NMD facilities.

Report Organization

Use of approved terminology is key to the production of an understandable breast imaging report. The BI-RADS® approach to reporting mammography examinations categorizes the overall composition of the breast and then describes noncalcified lesions by their basic shape, border characteristics, and density. Calcifications are described according to size, morphology, and distribution. The findings are then evaluated, and an

assessment is rendered that includes the degree of suspicion for malignancy at mammography. Finally, the report indicates the pertinent management recommendation(s). Thus, the mammography report should be divided into:

1. INDICATION FOR EXAMINATION

2. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION

3. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

4. COMPARISON TO PREVIOUS EXAMINATION(S), IF DEEMED APPROPRIATE BY THE INTERPRETING PHYSICIAN

5. ASSESSMENT

6. MANAGEMENT

Note that if mammography and US/MRI examinations are performed concurrently, the findings at each imaging modality should be reported in separate paragraphs. Also, a single overall assessment of the findings of both (all) examinations is recommended in addition to the mammography and other-modality assessments. The Guidance chapter describes in detail how to integrate the mammography and adjunctive-examination assessments into an overall assessment.

III. Guidance

Over the years of continued BI-RADS® usage, the committee has received many questions and reports of problems related to the various sections that comprise BI-RADS®. It was decided to address these concerns, introduce changes in terminology and assessments, and explain the reasons for these changes in a single guidance chapter. New or expanded definitions and terminology in the lexicon and the explanation for their inclusion are more fully described in the Guidance chapter. At present, some of the changes do not have supportive data; however, the committee believes that inclusion is necessary to make the lexicon a more practical document. As was the case with previous BI-RADS® editions, data accrue in the mammography literature, and as this occurs, evidence-based changes are made. An example of this is the inclusion of developing asymmetry in the lexicon and its assessment as suspicious for malignancy. There now is scientific evidence that this mammographic finding is associated with malignancy in approximately 15% of cases identified at mammo-graphy screening,⁷ a much higher frequency than the approximately 1% likelihood of malignancy associated with focal asymmetry identified at baseline mammography screening.

APPENDICES

Appendix A contains a table of standardized terminology and abbreviations for

mammography views. Appendix B contains a form for easily noting the findings of an Mammography examination with the appropriate BI-RADS® terminology in a simple checklist. This form also contains the BI-RADS® assessment categories.

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2. Dennis MA, Parker SH, Klaus AJ, Stavros AT, Kaske TI, Clark SB. [Breast biopsy avoidance: the value of normal mammograms and normal sonograms in the setting of a palpable lump](#). *Radiology* 2001; 219(1):186–191.
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REVISIONS

I. BREAST IMAGING LEXICON — MAMMOGRAPHY

Table 1. BI-RADS® Mammography Lexicon Overview

Breast Tissue	Terms	
Breast composition	a. The breasts are almost entirely fatty b. There are scattered areas of fibroglandular density c. The breasts are heterogeneously dense, which may obscure small masses d. The breasts are extremely dense, which lowers the sensitivity of mammography	
Findings	Terms	
A. Masses	1. Shape	a. Oval b. Round c. Irregular
	2. Margin	a. Circumscribed b. Obscured c. Microlobulated d. Indistinct e. Spiculated
	3. Density	a. High density b. Equal density c. Low density d. Fat-containing
B. Calcifications	1. Typically benign	a. Skin b. Vascular c. Coarse or "popcorn-like" d. Large rod-like e. Round f. Rim g. Dystrophic h. Milk of calcium i. Suture
	2. Suspicious morphology	a. Amorphous b. Coarse heterogeneous c. Fine pleomorphic d. Fine linear or fine-linear branching
	3. Distribution	a. Diffuse b. Regional c. Grouped d. Linear e. Segmental
C. Architectural distortion		
D. Asymmetries	1. Asymmetry 2. Global asymmetry 3. Focal asymmetry 4. Developing asymmetry	
E. Intramammary lymph node		
F. Skin lesion		

G. Solitary dilated duct

H. Associated features

1. Skin retraction
2. Nipple retraction
3. Skin thickening
4. Trabecular thickening
5. Axillary adenopathy
6. Architectural distortion
7. Calcifications

I. Location of lesion

1. Laterality
2. Quadrant and clock face
3. Depth
4. Distance from the nipple

A. MASSES

A mass is 3-dimensional and occupies space. It is seen on two different mammographic projections. It has completely or partially convex-outward borders and (when radiodense) appears denser in the center than at the periphery. If a potential mass is seen only on a single projection, it should be called an asymmetry until its 3-dimensionality is confirmed ([Section D on Asymmetries](#) and also the [Guidance chapter](#)).

A. MASSES

1. SHAPE

a. Oval

An oval mass is elliptical or egg-shaped (may include two or three undulations).

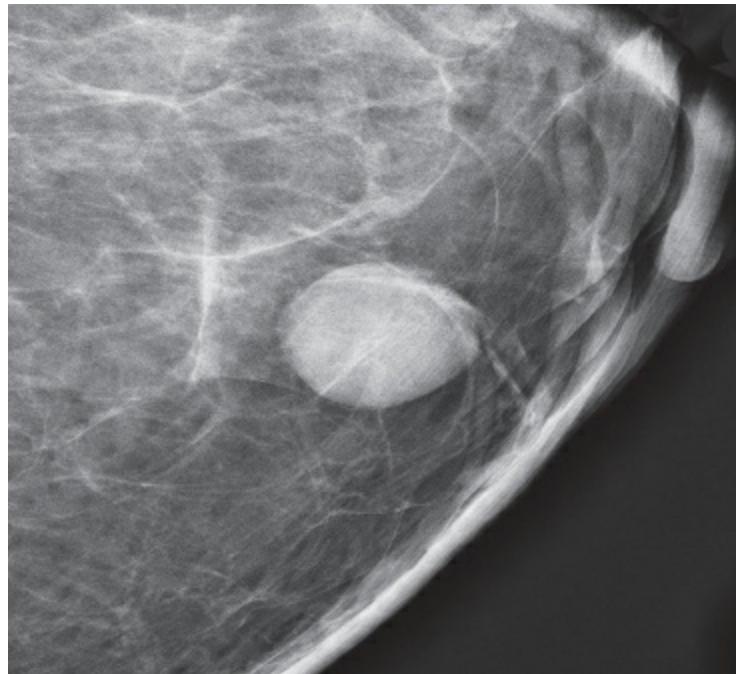


Figure 1 – SHAPE: OVAL. Circumscribed mass almost completely surrounded by fatty tissue. Outcome: complicated cyst versus cystic and solid mass at US; confirmed as benign cyst at diagnostic aspiration.

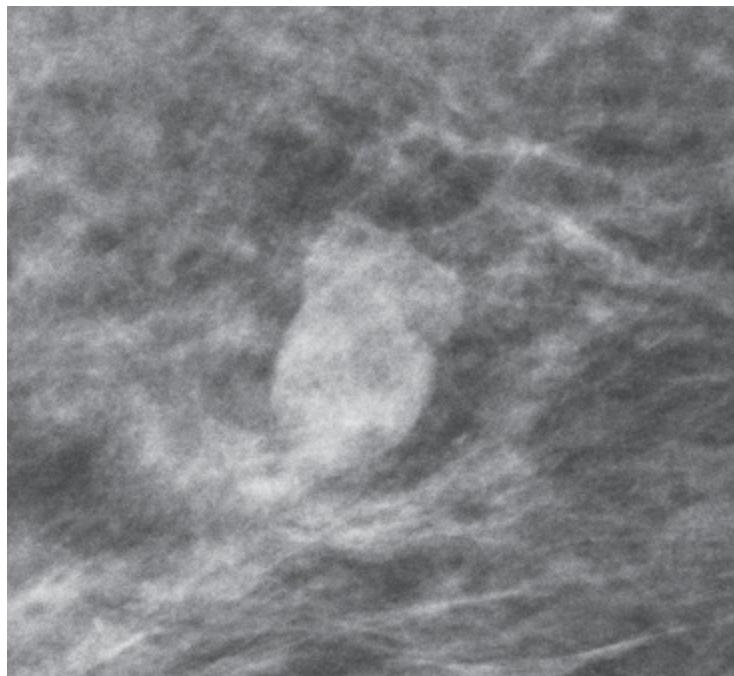


Figure 2 – SHAPE: OVAL. Circumscribed mass with two undulations, almost completely surrounded by fatty tissue. Core biopsy: fibroadenoma.

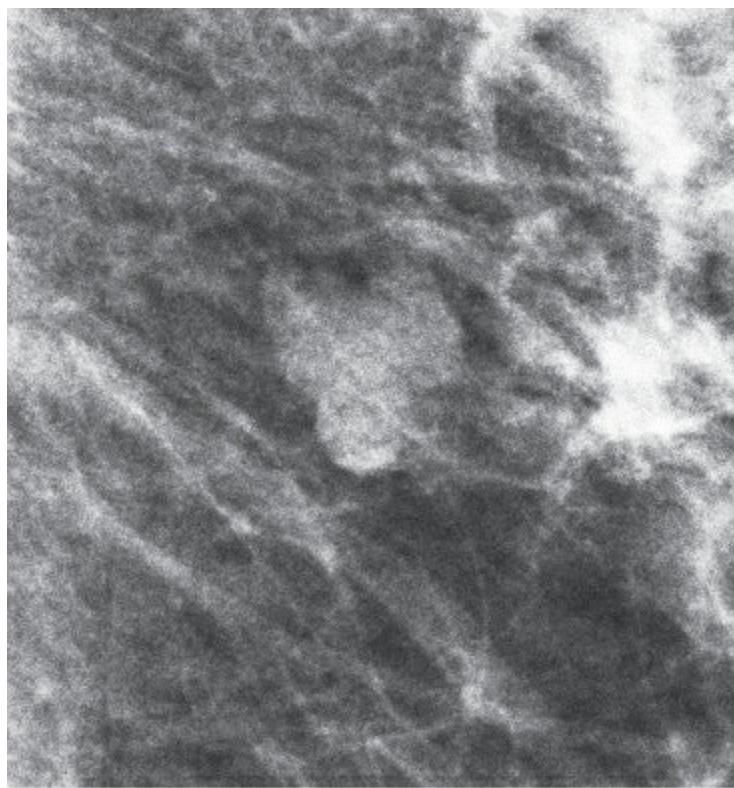


Figure 3 – SHAPE: OVAL. Circumscribed mass with three undulations, almost completely surrounded by fatty tissue. Core biopsy: fibroadenoma.

A. MASSES

1. SHAPE

b. Round

A round mass is spherical, ball-shaped, circular, or globular in shape.

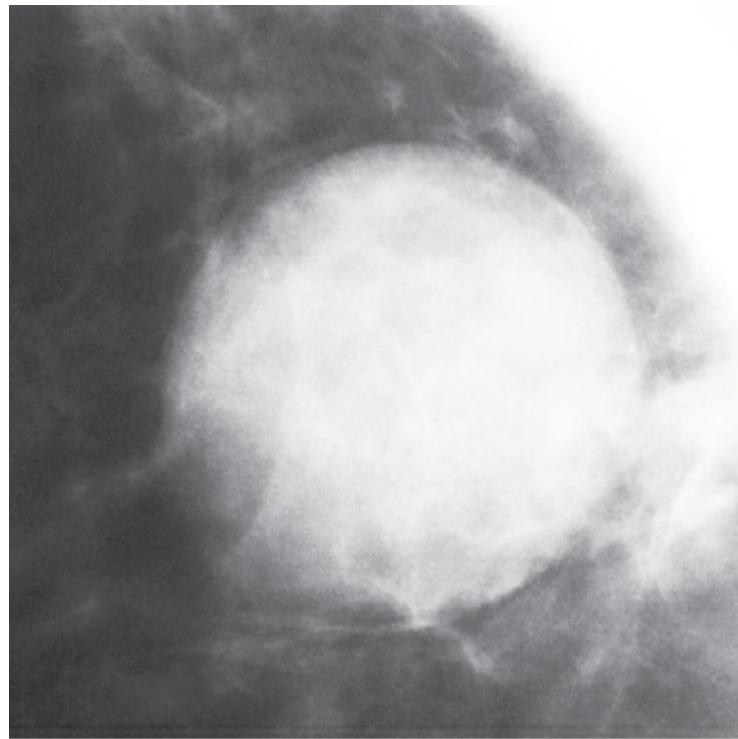


Figure 4 – SHAPE: ROUND. Circumscribed mass, completely surrounded by fatty tissue. Outcome: simple cyst at US.

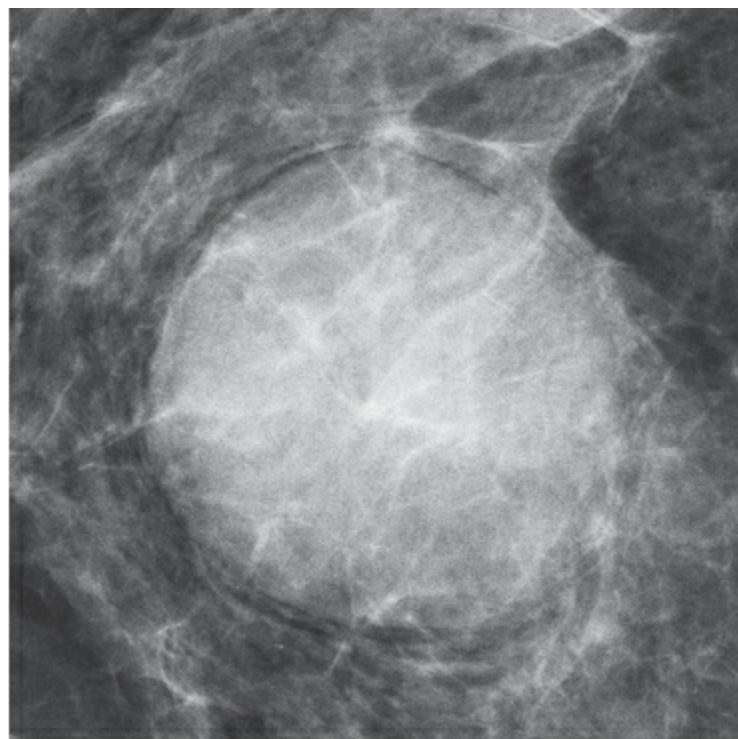


Figure 5 – SHAPE: ROUND. Although more than half of the margin of the mass is circumscribed, it also is obscured by adjacent dense tissue from approximately 1:00 to 5:30 (> 25%). Therefore, the margin should be classified as obscured. Core biopsy: fibroadenoma.

A. MASSES

1. SHAPE

c. Irregular

The shape of the mass is neither round nor oval. For mammography, use of this descriptor usually implies a suspicious finding.

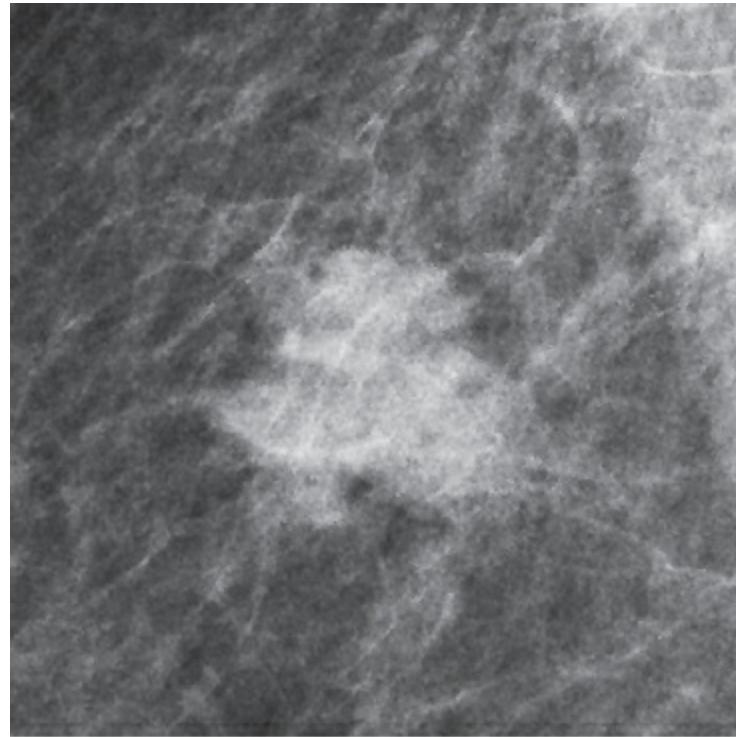


Figure 6 – SHAPE: IRREGULAR. Mass with primarily obscured margin. Despite the possibility that this mass may have only three undulations (suggesting oval shape), its primarily obscured margin does not permit this determination, hence its characterization as irregular in shape. Core biopsy: invasive ductal carcinoma (IDC).

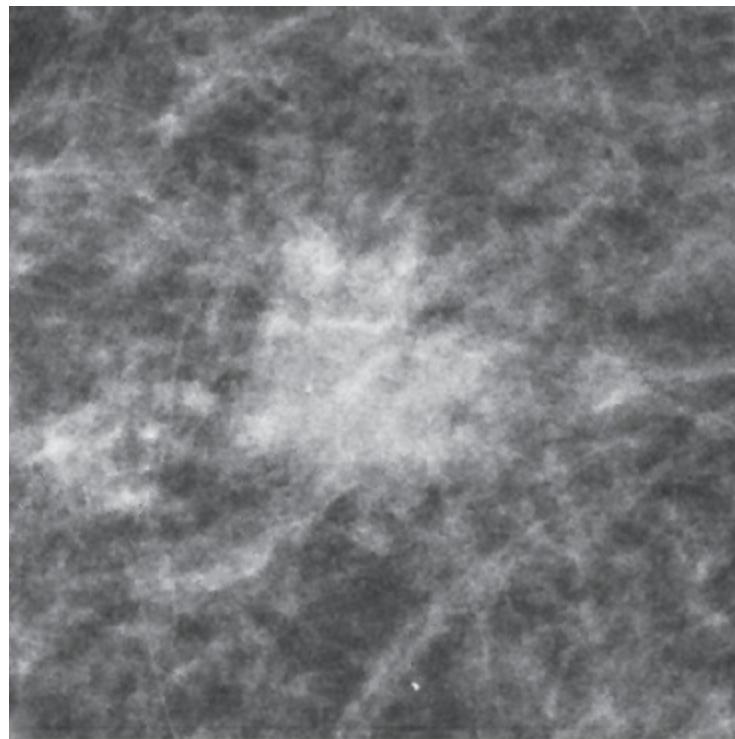


Figure 7 – SHAPE: IRREGULAR. Mass with partially indistinct and partially obscured margin. Core biopsy: fibroadenoma.

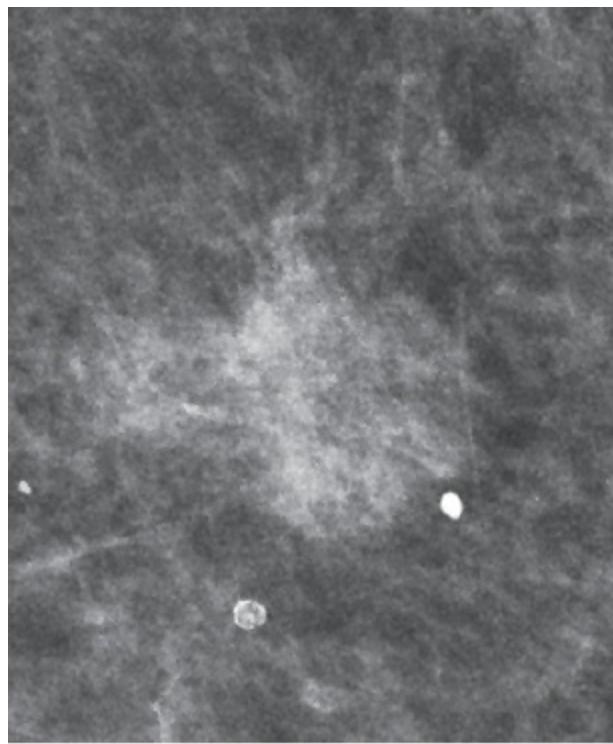


Figure 8 – SHAPE: IRREGULAR. Mass with primarily indistinct and partially spiculated margin. Core biopsy: invasive ductal carcinoma.

A. MASSES

2. MARGIN

The margin is the edge or border of the lesion. The descriptors of margin, like the

descriptors of shape, are important predictors of whether a mass is benign or malignant.

a. Circumscribed (historically, “well defined” or “sharply defined”

The margin is sharply demarcated with an abrupt transition between the lesion and the surrounding tissue. For mammography, if part of the margin is obscured, at least 75% of the margin must be well defined for a mass to qualify as circumscribed. A mass for which **any** portion of the margin is indistinct, microlobulated, or spiculated should be classified on the basis of the latter (the most suspicious component).

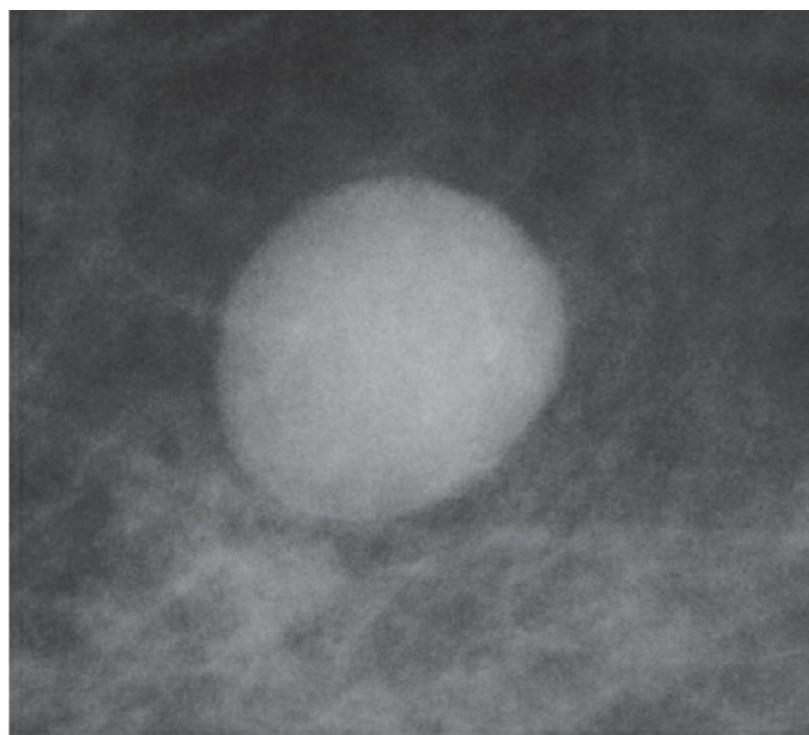


Figure 9 – MARGIN: CIRCUMSCRIBED. Oval CIRCUMSCRIBED mass, completely surrounded by fatty tissue. This mass was assessed as probably benign after diagnostic mammography and US, with subsequent demonstration of 3-year stability at surveillance mammography. Presumptive diagnosis: fibroadenoma. Previously published as Figure 1 (p. 774) in Leung JWT, Sickles EA. The probably benign assessment. *Radiol Clin North Am* 2007; 45[5]:773–789.

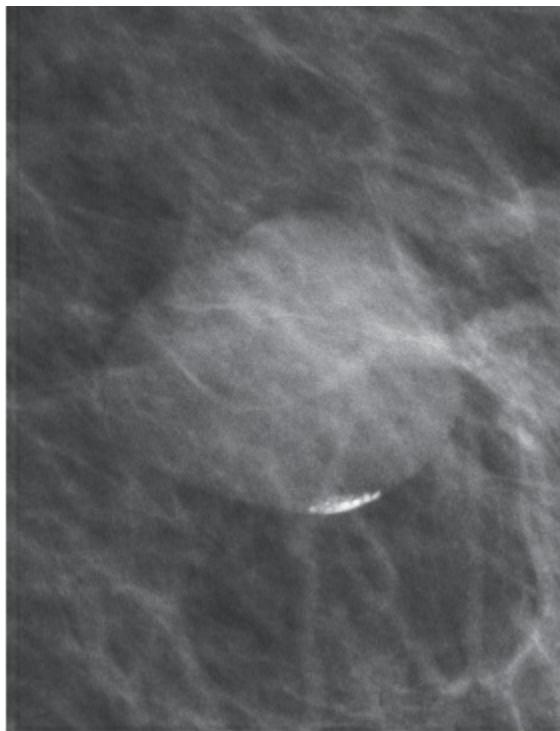


Figure 10 – MARGIN: CIRCUMSCRIBED. Oval CIRCUMSCRIBED mass, almost completely surrounded by fatty tissue. Note the calcification sedimented at the bottom of the mass on this MLO view, representing milk of calcium. Outcome: simple cyst at US.

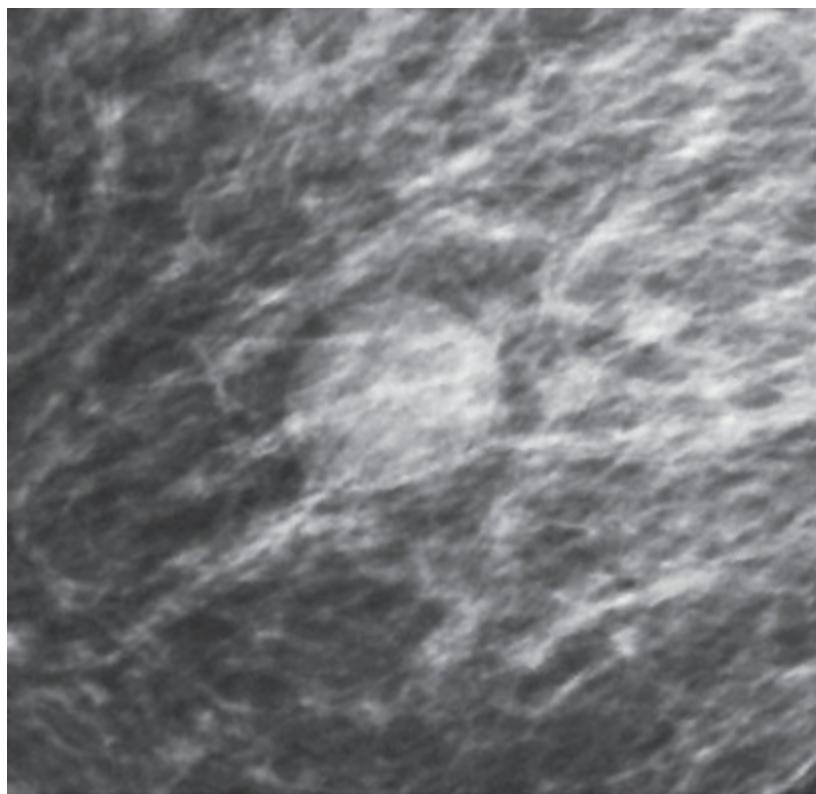


Figure 11 – MARGIN: CIRCUMSCRIBED. Round CIRCUMSCRIBED mass, almost completely surrounded by fatty tissue. If one is unsure that at least 75% of the margin of a mass is circumscribed at mammography screening, spot-compression mammograms (with or without magnification) should be obtained to aid in this determination. Core biopsy: fibroadenoma.

A. MASSES

2. MARGIN

b. Obscured

An obscured margin is one that is hidden by superimposed or adjacent fibroglandular tissue. This is used primarily when some of the margin of the mass is circumscribed, but the rest (> 25%) is hidden.

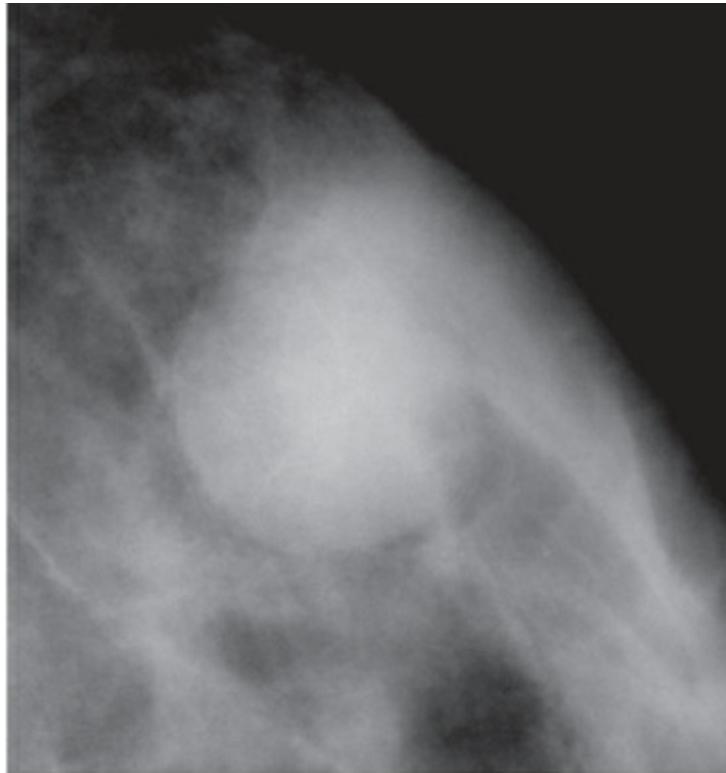


Figure 12 – MARGIN: OBSCURED. Oval mass, with margin mostly circumscribed but also OBSCURED from 11:00 to 3:00 (> 25%). Therefore, the margin should be classified as obscured rather than circumscribed, based on this screening mammogram. However, after diagnostic mammography and US, the mass was assessed as probably benign, with subsequent demonstration of 3-year stability at surveillance mammography. Presumptive diagnosis: fibroadenoma.

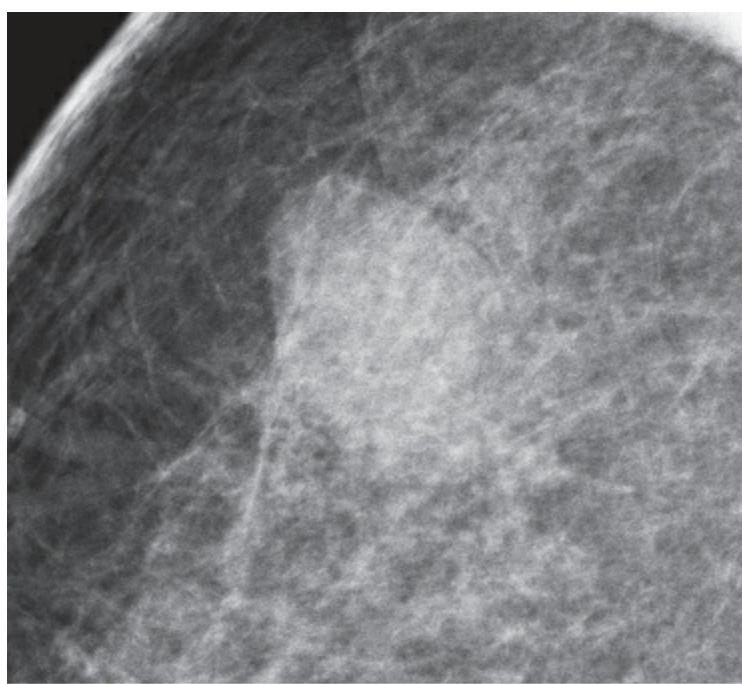


Figure 13 – MARGIN: OBSCURED. Oval mass with half circumscribed and half (> 25%) OBSCURED margin. Core biopsy: fibroadenoma.

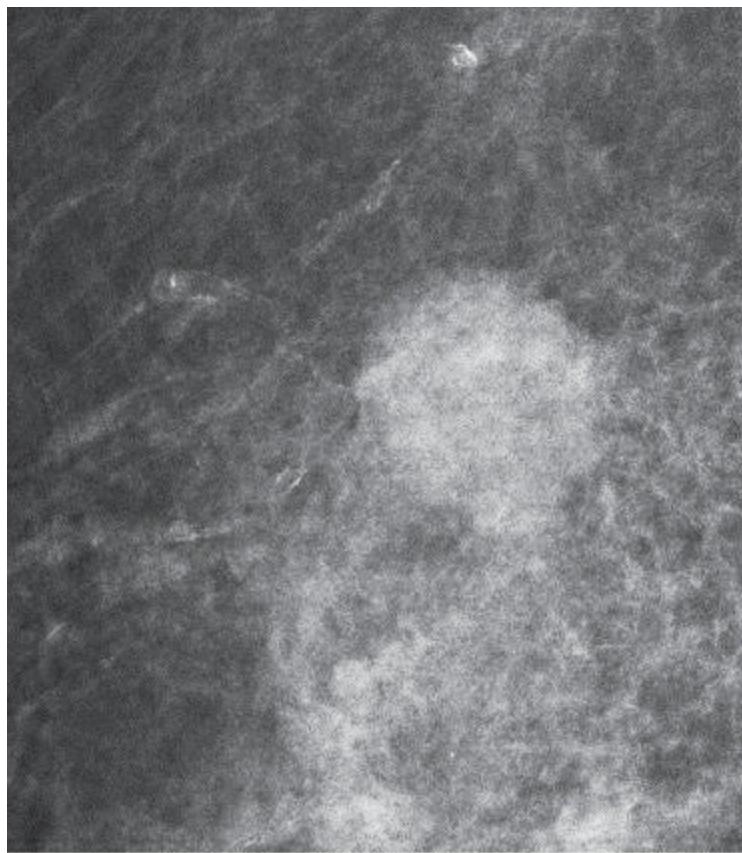


Figure 14 – MARGIN: OBSCURED. Round mass with partially circumscribed but mostly OBSCURED margin. Core biopsy: invasive ductal carcinoma, high grade.

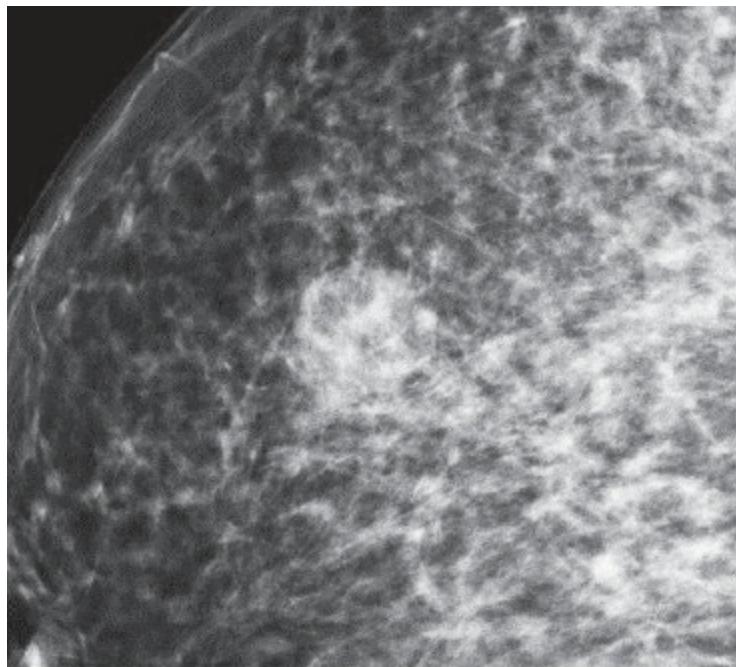


Figure 15 – MARGIN: OBSCURED. Mass with partially circumscribed but mostly OBSCURED margin. Because so much of the margin is obscured, it is difficult to characterize the shape of this mass.
Core biopsy: fibroadenoma.

A. MASSES

2. MARGIN

c. Microlobulated

The margin is characterized by short cycle undulations. For mammography, use of this descriptor usually implies a suspicious finding.



Figure 16 – MARGIN: MICROLOBULATED. Irregular mass with MICROLOBULATED margin. Core biopsy: apocrine metaplasia.

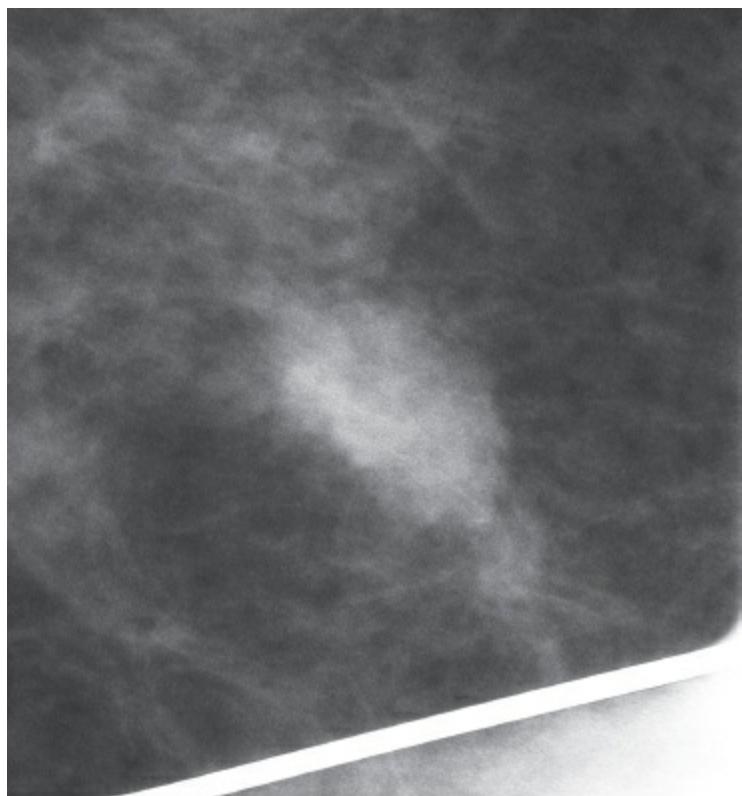


Figure 17 – MARGIN: MICROLOBULATED. Irregular mass with partially obscured but mostly MICROLOBULATED margin. Core biopsy: fibroadenoma.

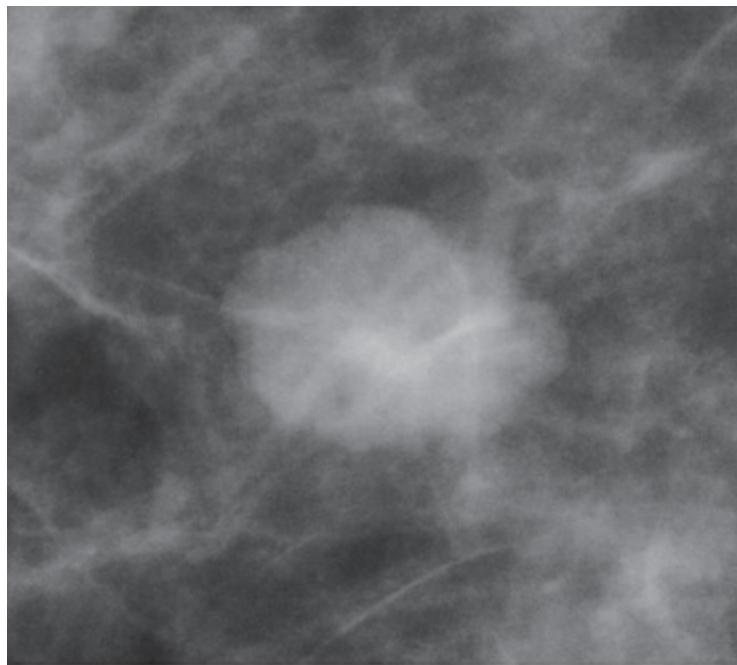


Figure 18 – MARGIN: MICROLOBULATED. Irregular mass with MICROLOBULATED margin. Note that although almost the entire margin is well defined (mass almost completely surrounded by fatty tissue), the depiction of numerous short-cycle undulations should prompt classification of the margin as microlobulated (more worrisome) rather than circumscribed. Core biopsy: invasive ductal carcinoma.

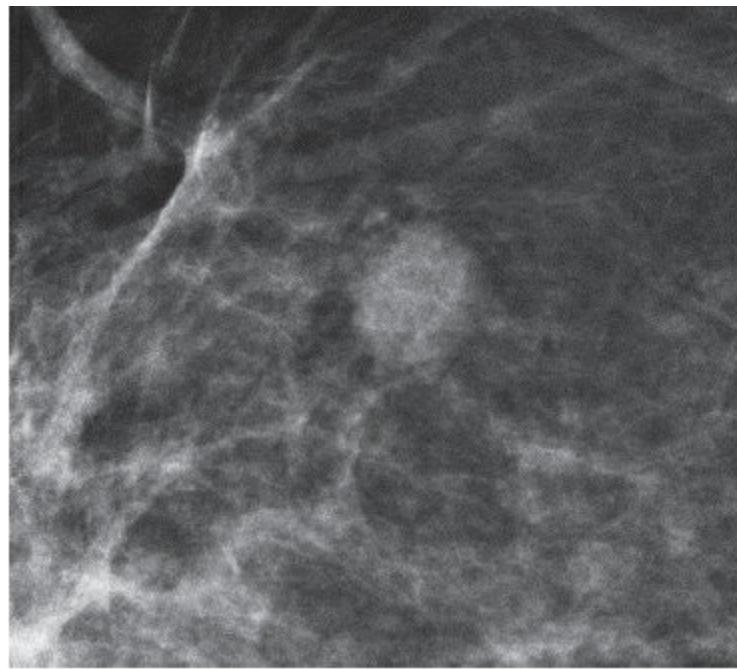


Figure 19 – MARGIN: MICROLOBULATED. Irregular mass with MICROLOBULATED margin. Note that although the shape of the mass is elliptical, the depiction of numerous short-cycle undulations should prompt classification of the shape as irregular rather than oval (which should have only two or three undulations). Core biopsy: invasive ductal carcinoma.

A. MASSES

2. MARGIN

d. Indistinct (historically, "ill defined")

There is no clear demarcation of the entire margin, or of any portion of the margin, from the surrounding tissue. For mammography, this descriptor should not be used when the interpreting physician believes it is likely due to immediately adjacent breast tissue. Use of this descriptor usually implies a suspicious finding.

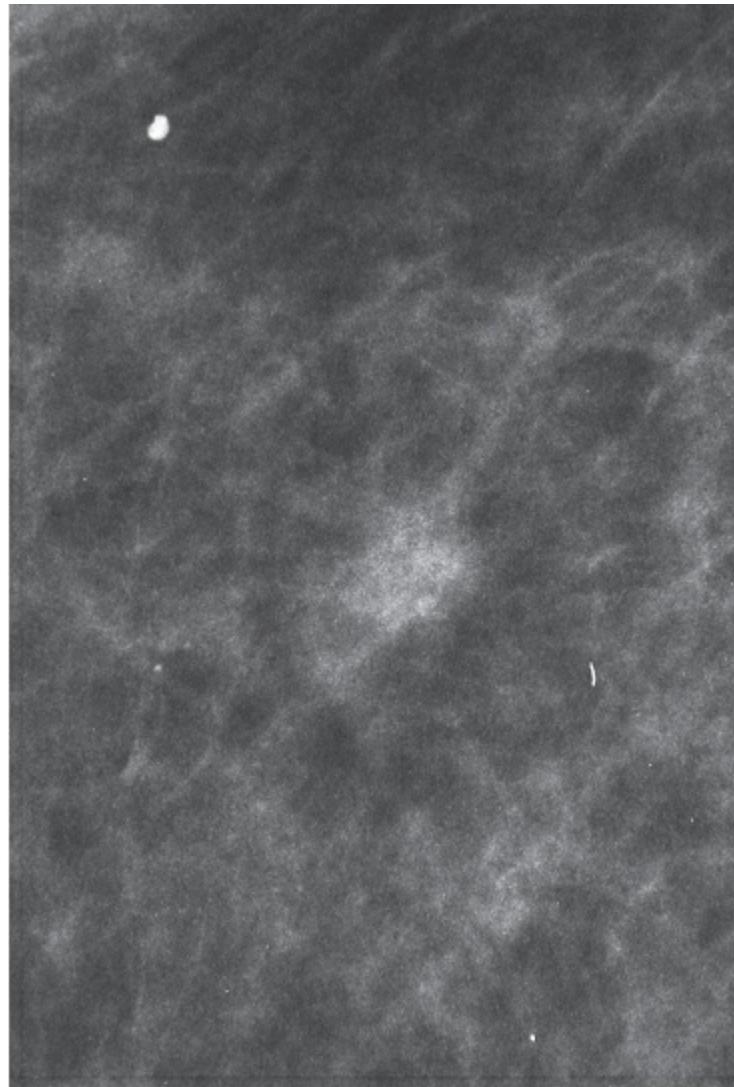


Figure 20 – MARGIN: INDISTINCT. Because almost the entire margin is so indistinct, it is difficult to determine the shape of this mass. Core biopsy: pseudoangiomatous stromal hyperplasia (PASH).

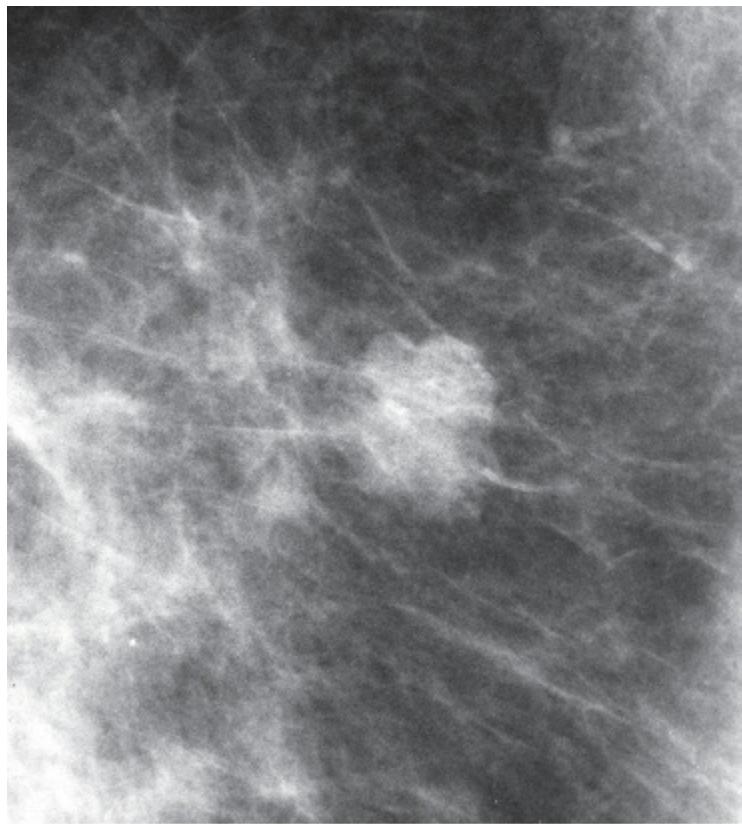


Figure 21 – MARGIN: INDISTINCT. This mass is almost completely surrounded by fatty tissue. Note that although most of the margin is circumscribed, other portions are not well defined, hence, classification of the margin as indistinct. Core biopsy: invasive ductal carcinoma.

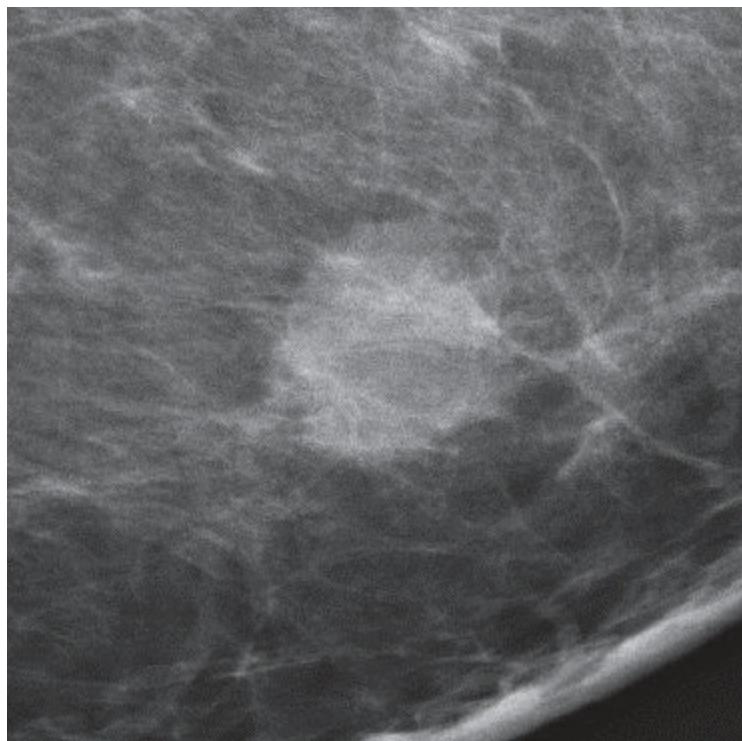


Figure 22 – MARGIN: INDISTINCT. Round INDISTINCT mass. The margin of this mass is not well defined, and, because it is almost entirely surrounded by fatty tissue, it should be classified as indistinct rather than obscured. Note that there is subtle suggestion that some of the margin is spiculated. Core biopsy: invasive ductal carcinoma.

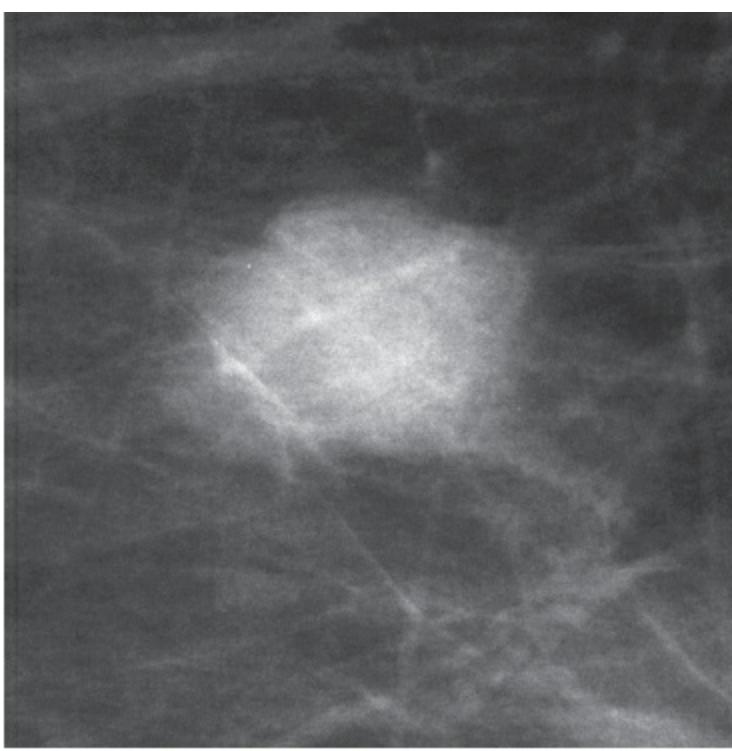


Figure 23 – MARGIN: INDISTINCT. Irregular INDISTINCT mass, almost completely surrounded by fatty tissue. Although part of the margin is circumscribed, the margin is not well defined from approximately 7:30 to 10:30, prompting classification as indistinct. Also note that although the shape of the mass is elliptical, the depiction of at least five undulations should prompt classification of the shape as irregular rather than oval (which should have only two or three undulations). Core biopsy: mucinous carcinoma.

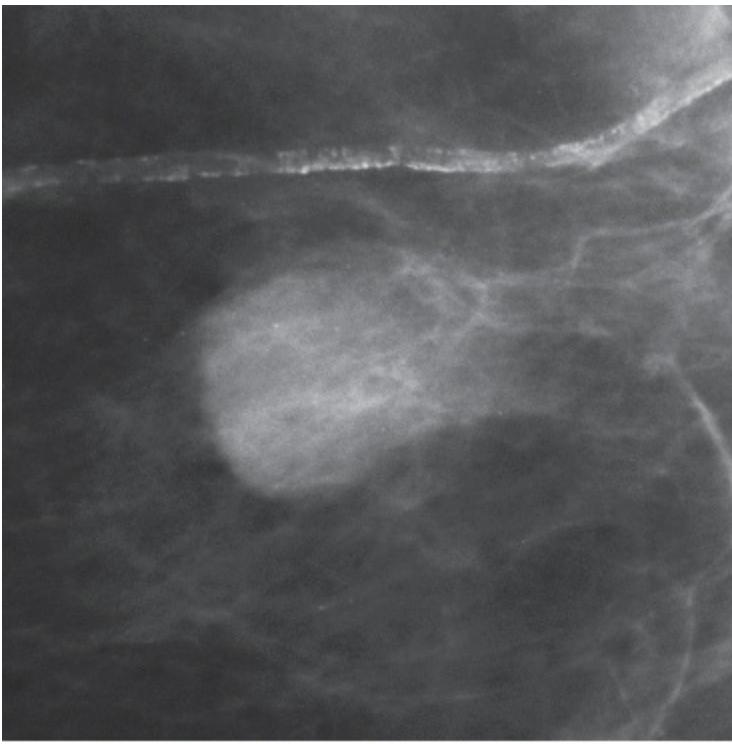


Figure 24 – MARGIN: INDISTINCT. Irregular INDISTINCT mass, almost completely surrounded by fatty tissue. Close inspection shows almost the entire margin to be indistinct rather than circumscribed. Core biopsy: invasive ductal carcinoma with ductal carcinoma in situ.

A. MASSES

2. MARGIN

e. Spiculated

The margin is characterized by lines radiating from the mass. Use of this descriptor usually implies a suspicious finding.

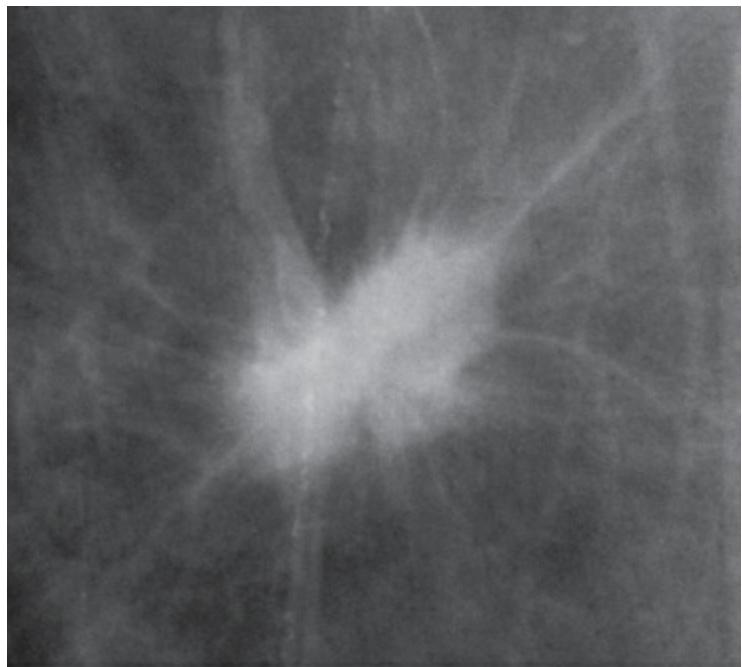


Figure 25 – MARGIN: SPICULATED. Irregular SPICULATED mass.
Core biopsy: invasive ductal carcinoma.

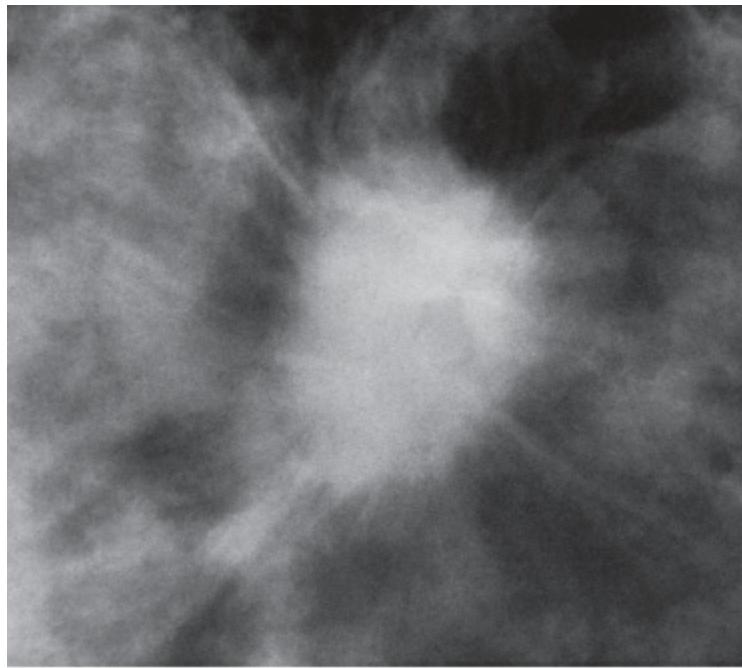


Figure 26 – MARGIN: SPICULATED. Oval SPICULATED mass. Core
biopsy: invasive ductal carcinoma.



Figure 27 – MARGIN: SPICULATED. Because so much of the margin is not well defined, it is difficult to determine whether the shape of this mass is oval or irregular. Core biopsy: invasive lobular carcinoma.



Figure 28 – MARGIN: SPICULATED. Round SPICULATED mass.
Core biopsy: fat necrosis.

A. MASSES

3. DENSITY

This is used to define the x-ray attenuation of the mass relative to the expected attenuation of an equal volume of normal fibroglandular breast tissue. Most breast cancers that present as a mass are of equal or higher density than an equal volume of normal fibroglandular tissue. The likelihood of malignancy for a high-density mass (70%) is reported to be significantly greater than that for equal- and low-density masses (22%). It is rare (although not impossible) for breast cancer to be lower in density. However, breast density is a subjective evaluation that is least reliable among the mammographic features of masses (i.e., shape and margin). Breast cancers are never fat-containing (radiolucent), although they may entrap fat.

REFERENCES

1. Woods RW, Sisney GS, Salkowski LR, Shinki K, Lin Y, Burnside ES. [The mammographic density of a mass is a significant predictor of breast cancer](#). Radiology 2010; 258(2):417–428.

Abstract:

Purpose:

To determine whether the mammographic density of noncalcified solid breast masses is associated with malignancy and to

measure the agreement between prospective and retrospective assessment.

Materials and Methods:

The institutional review board approved this study and waived informed consent. Three hundred forty-eight consecutive breast masses in 328 women who underwent image-guided or surgical biopsy between October 2005 and December 2007 were included. All 348 biopsy-proved masses were randomized and assigned to a radiologist who was blinded to biopsy results for retrospective assessment by using the BI-RADS® (retrospectively assessed data set). Clinical radiologists prospectively assessed the density of 180 of these masses (prospectively assessed data set). Pathologic result at biopsy was the reference standard. Benign masses were followed for at least 1 year by linking each patient to a cancer registry. Univariate analyses were performed on the retrospectively assessed data set. The association of mass density and malignancy was examined by creating a logistic model for the prospectively assessed data set. Agreement between prospective and retrospective assessments was calculated by using the κ statistic.

Results:

In the retrospectively assessed data set, 70.2% of high-density masses were malignant, and 22.3% of the isodense or low-density masses were malignant ($P < .0001$). In the prospective logistic model, high-density (odds ratio, 6.6), irregular shape (odds ratio, 9.9), spiculated margin (odds ratio, 20.3), and age ($\beta = 0.09$, $P < .0001$) were significantly associated with the probability of malignancy. The κ value for prospective-retrospective agreement of mass density was 0.53.

Conclusion:

High mass density is significantly associated with malignancy in both retrospectively and prospectively assessed data sets, with moderate prospective-retrospective agreement. Radiologists should consider mass density as a valuable descriptor that can stratify risk.

A. MASSES

3. DENSITY

a. High Density

X-ray attenuation of the mass is greater than the expected attenuation of an equal volume of fibroglandular breast tissue.

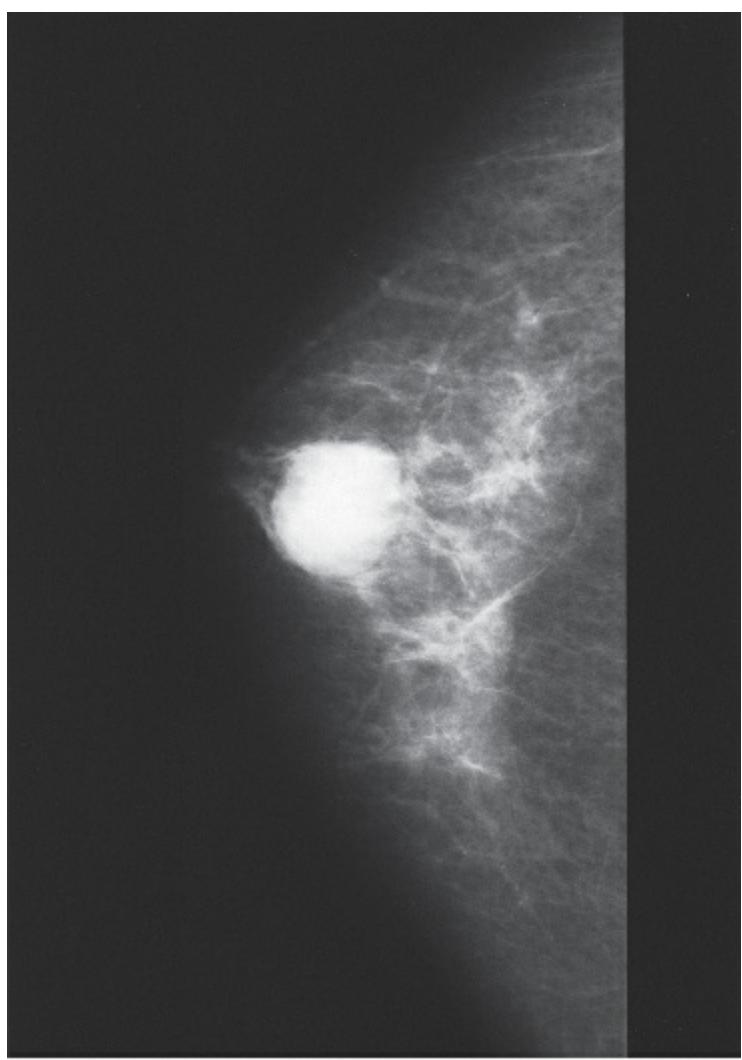


Figure 29 – DENSITY: HIGH DENSITY. Oval, mostly circumscribed, partially obscured, HIGH DENSITY mass. Excisional biopsy: benign phyllodes tumor.

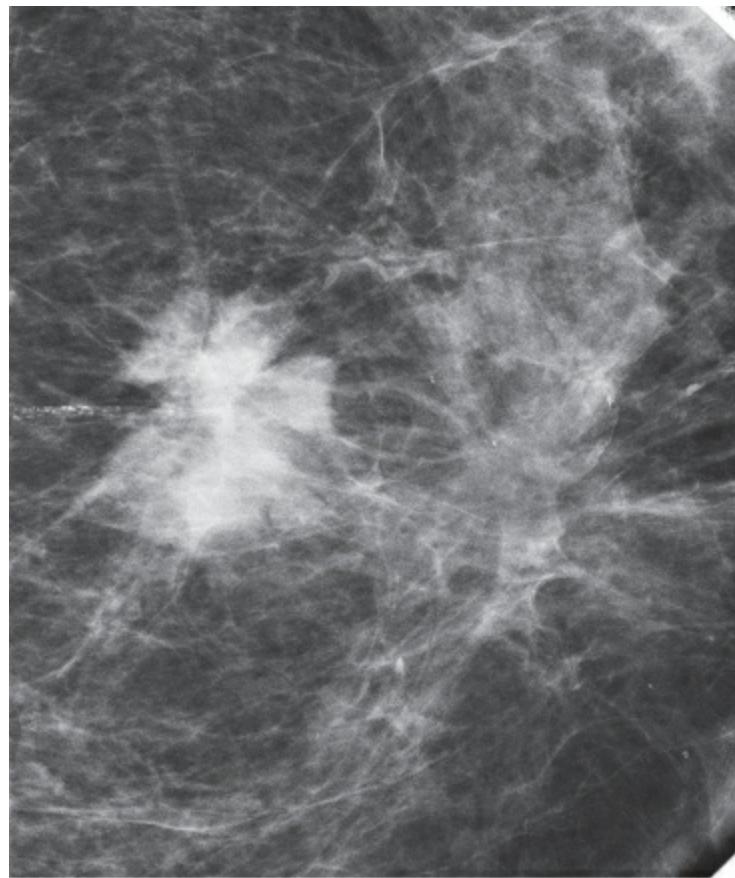


Figure 30 – DENSITY: HIGH DENSITY. Irregular, somewhat spiculated, HIGH DENSITY mass. Core biopsy: invasive ductal carcinoma.

A. MASSES

3. DENSITY

b. Equal Density (historically, “isodense”)

X-ray attenuation of the mass is the same as the expected attenuation of an equal volume of fibroglandular breast tissue.

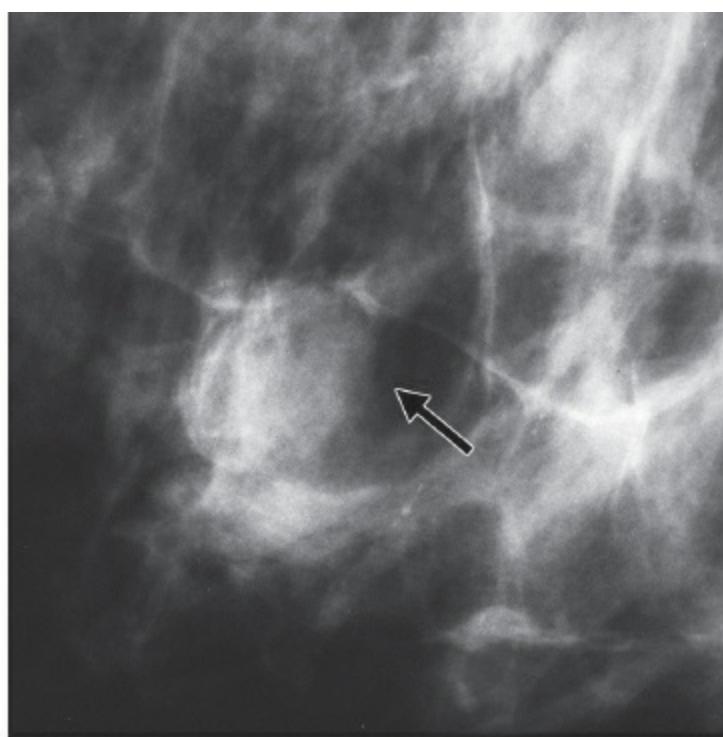


Figure 31 – DENSITY: EQUAL DENSITY. Oval, partially circumscribed, mostly obscured, EQUAL DENSITY mass (arrow). Core biopsy: fibroadenoma.

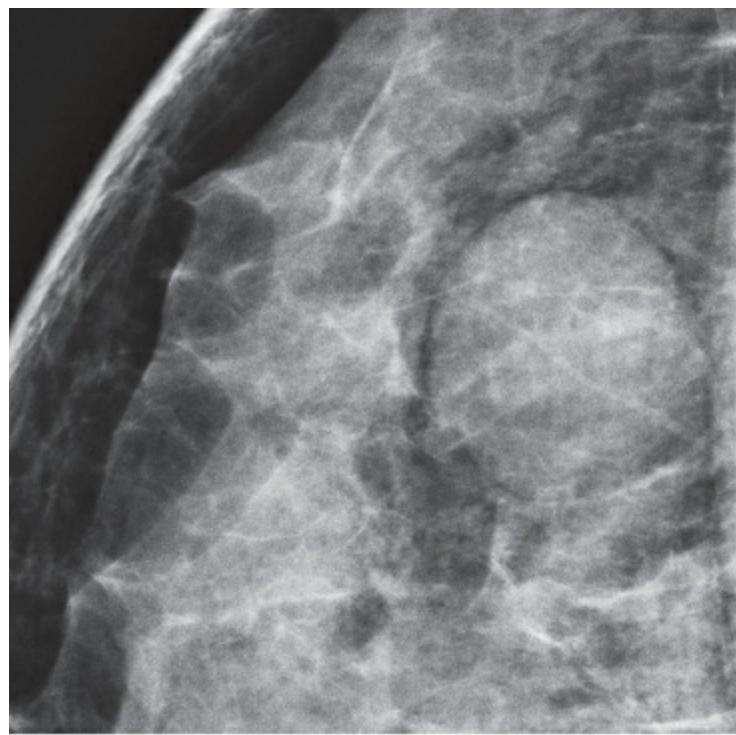


Figure 32 – DENSITY: EQUAL DENSITY. Oval, half-circumscribed, half-obscured, EQUAL DENSITY mass. Outcome: simple cyst at ultrasound.

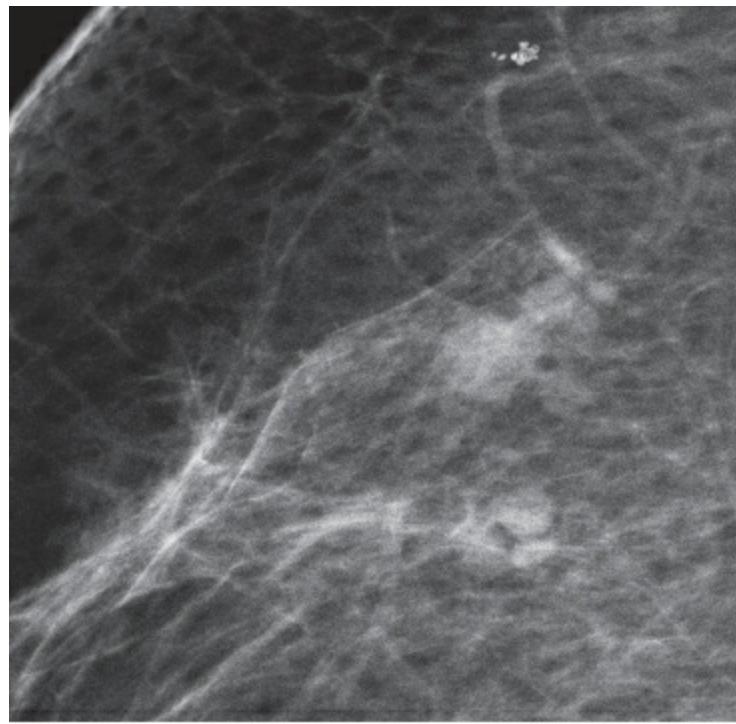


Figure 33 – DENSITY: EQUAL DENSITY. Round, indistinct, EQUAL DENSITY mass. The mass is almost completely surrounded by fatty tissue. Also note the small intramammary lymph nodes slightly below the mass and the grouped skin calcifications at the top of the image. Core biopsy: invasive ductal carcinoma.

A. MASSES

3. DENSITY

c. Low Density

X-ray attenuation of the mass is less than the expected attenuation of an equal volume of fibroglandular breast tissue. A low-density mass may be a group of microcysts. If such a finding is identified at mammography, it may very well not be malignant but appropriately may be worked up.

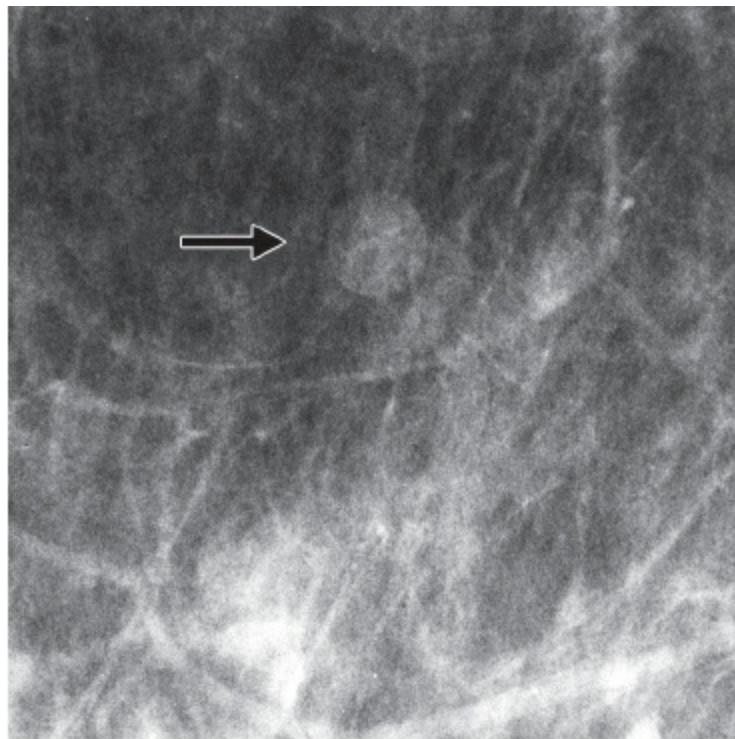


Figure 34 – DENSITY: LOW DENSITY. Round, circumscribed, LOW DENSITY mass (arrow), almost completely surrounded by fatty tissue. Outcome: simple cyst at US.

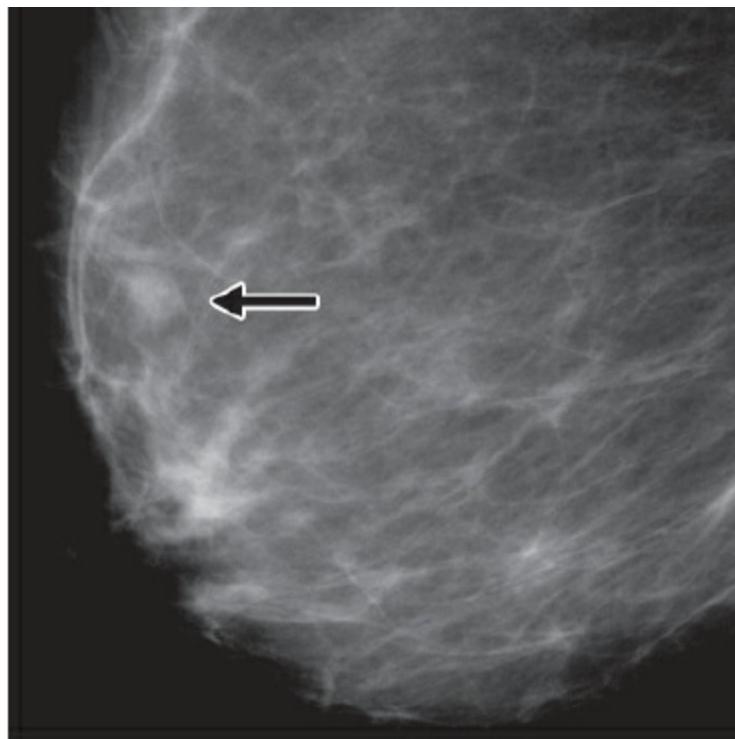


Figure 35 – DENSITY: LOW DENSITY. Oval, mostly obscured, LOW DENSITY mass (arrow). Core biopsy: ductal carcinoma in situ.

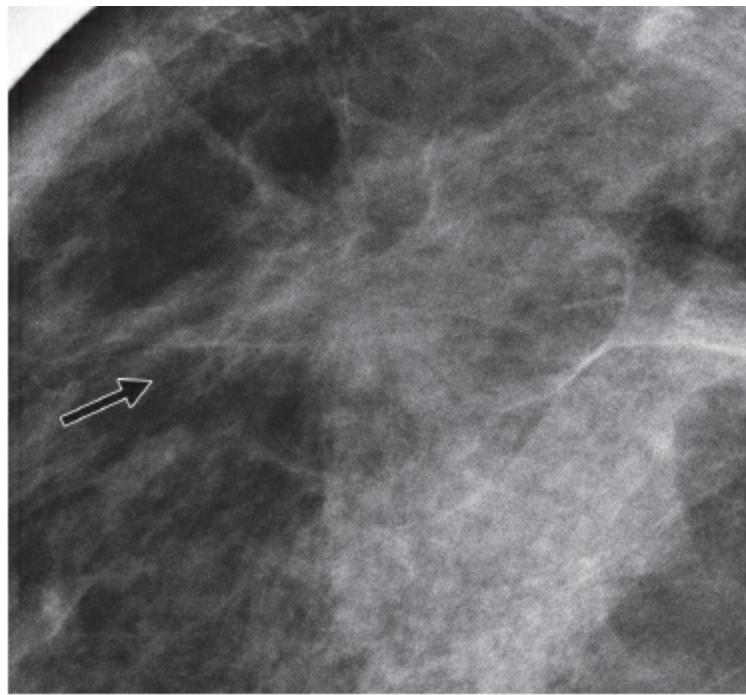


Figure 36 – DENSITY: LOW DENSITY. Irregular, partially obscured and partially spiculated, LOW DENSITY mass (arrow). Core biopsy: invasive ductal carcinoma.

A. MASSES

3. DENSITY

d. Fat-Containing

This includes all masses containing fat, such as oil cyst, lipoma, or galactocele, as well as mixed-density masses such as hamartoma. A fat-containing mass will almost always represent a benign mass.



Figure 37 – DENSITY: FAT-CONTAINING. Irregular, primarily circumscribed, FAT-CONTAINING mass, almost completely surrounded by dense tissue. The depiction of numerous (more than three) undulations should prompt classification of the shape of this mass as irregular rather than oval. Presumptive diagnosis for such a large solitary mass: lipoma.

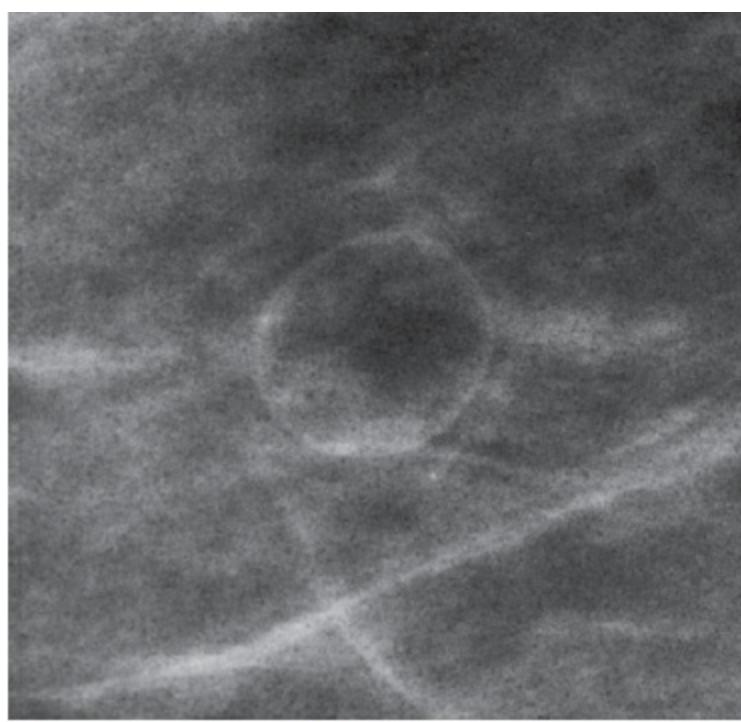


Figure 38 – DENSITY: FAT-CONTAINING. Oval, circumscribed, FAT-CONTAINING mass, almost completely surrounded by fatty tissue. Note the thin radiodense rim (pseudocapsule) that serves as the only indicator of the mass (visible because of fat both inside and outside of the mass). Presumptive diagnosis for such a small mass, especially if multiple: oil cyst (fat necrosis).

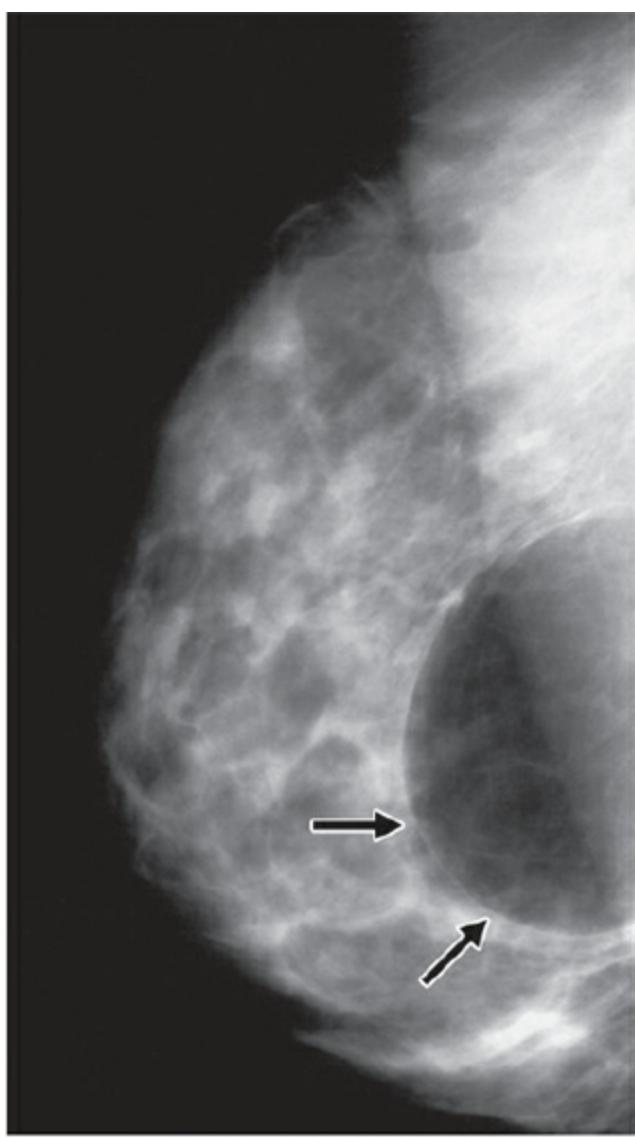


Figure 39 – DENSITY: FAT-CONTAINING. Oval, circumscribed, FAT-CONTAINING mass. Note that where the mass is adjacent to fatty tissue (between arrows), a thin radiodense rim (pseudocapsule) is visible. Presumptive diagnosis for such a large solitary mass: lipoma.

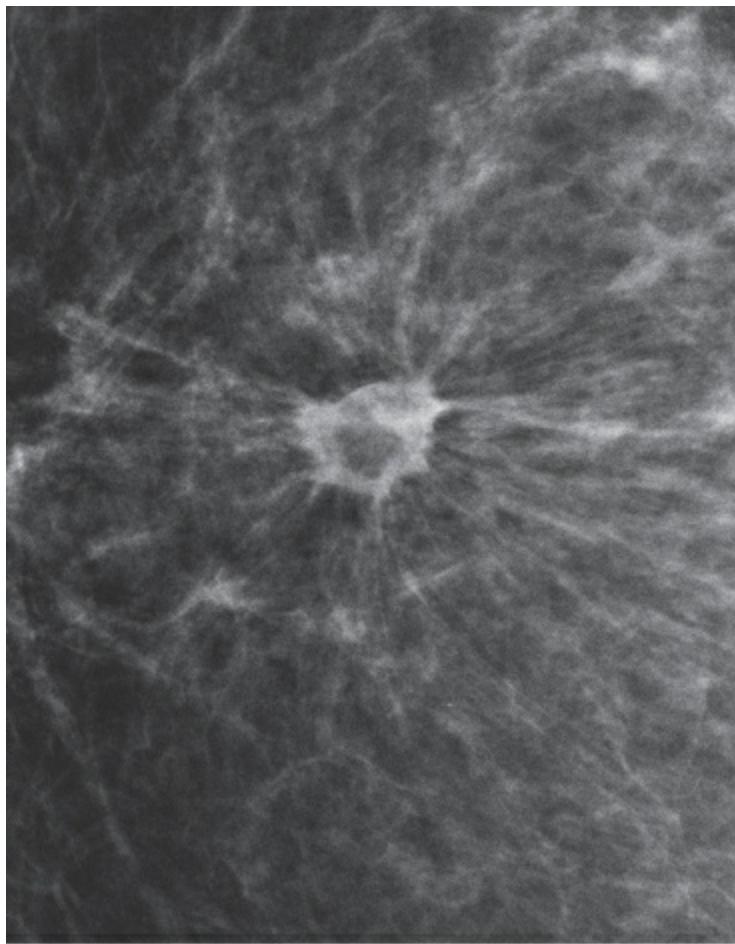


Figure 40 – DENSITY: FAT-CONTAINING. Rim of dense tissue with spiculated margin surrounds a circumscribed, FAT-CONTAINING mass. History of recent surgical biopsy at this site. Presumptive diagnosis: oil cyst (fat necrosis).

B. CALCIFICATIONS

Calcifications that are assessed as benign at mammography are typically larger, coarser, round with smooth margins, and more easily seen than malignant calcifications. Calcifications associated with malignancy (and many benign calcifications as well) are usually very small and often require the use of magnification to be seen well. When a specific, typically benign etiology cannot be assigned, a description of calcifications should include their morphology and distribution. Calcifications that are obviously benign need not be reported, especially if the interpreting physician is concerned that the referring clinician or patient might infer anything other than absolute confidence in benignity were such calcifications described in the report. However, typically benign calcifications should be reported if the interpreting physician is concerned that other observers might misinterpret them as anything but benign were such calcifications not described in the report.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

a. Skin

These are usually lucent-centered and pathognomonic in their appearance. Skin calcifications are most commonly seen along the inframammary fold, parasternally, overlying the axilla, and around the areola. The individual calcific particles usually are tightly grouped, with individual groups < 5 mm in greatest dimension. Atypical forms may be confirmed as skin deposits by performing additional mammographic views tangential to the overlying skin. Also note that if suspicious-appearing calcifications are adjacent to a skin surface on a given mammographic view, they actually may be dermal (hence benign) in nature, so that tangential-view mammography with or without magnification should be done prior to any intervention.

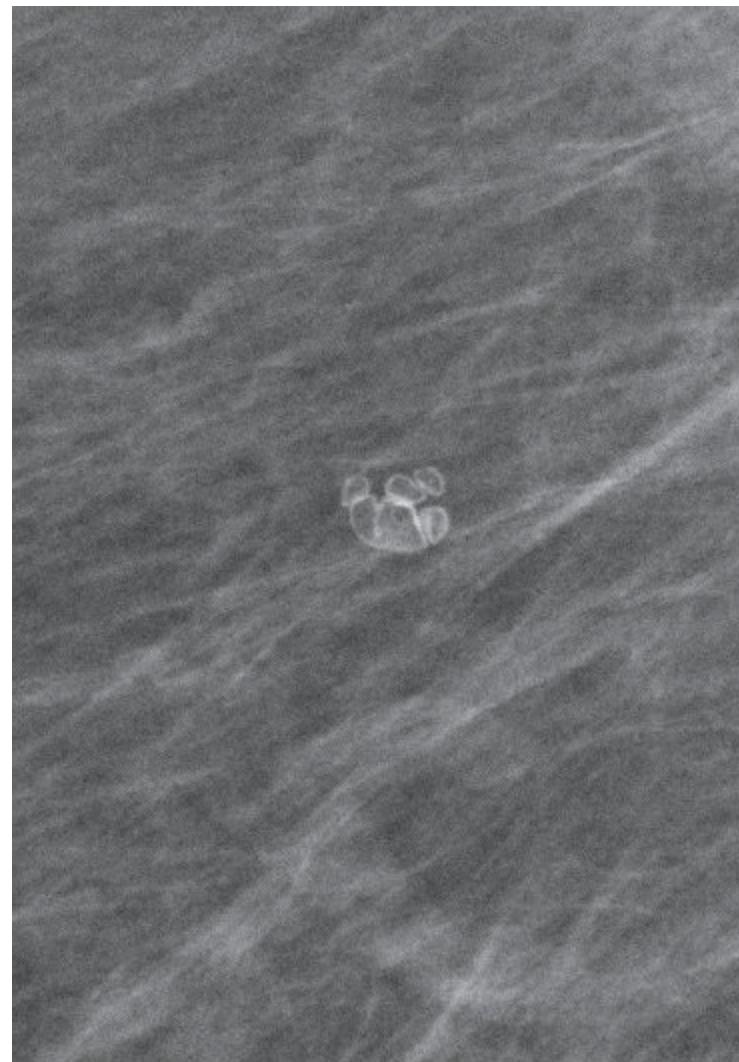


Figure 41 – TYPICALLY BENIGN: SKIN. Tightly grouped, lucent-centered SKIN calcifications, a characteristically benign appearance.

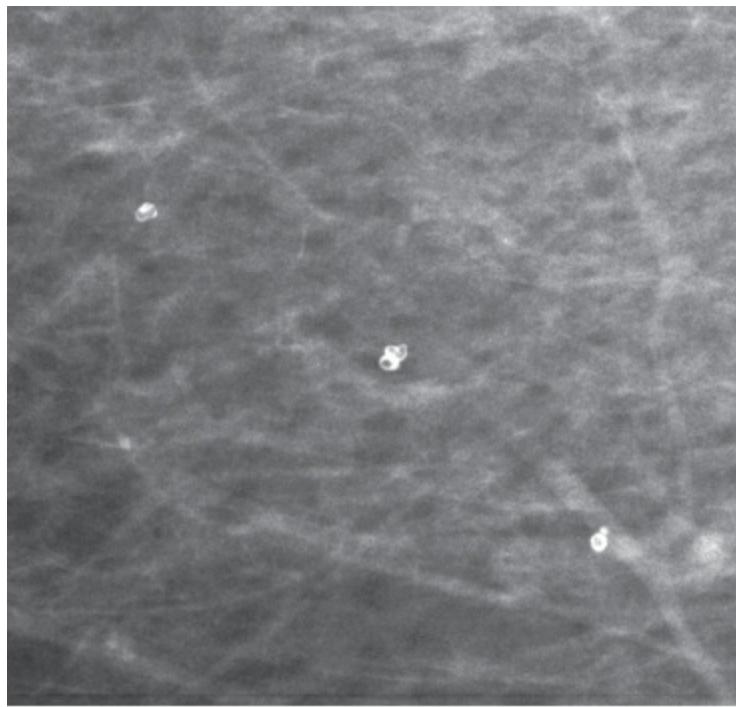


Figure 42 – TYPICALLY BENIGN: SKIN. Three small collections of tightly grouped, lucent-centered SKIN calcifications, a characteristically benign appearance.

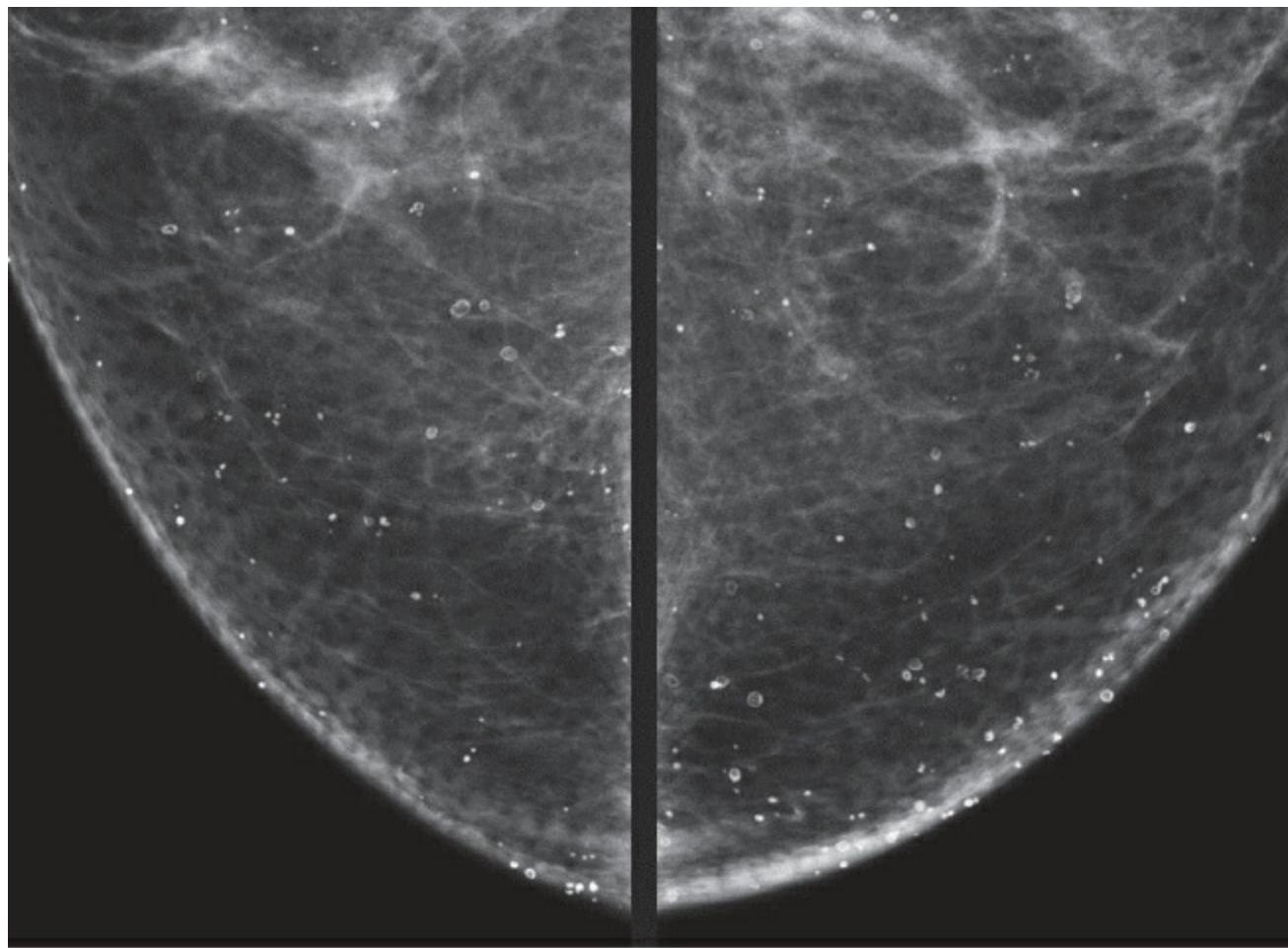


Figure 43 – TYPICALLY BENIGN: SKIN. SKIN calcifications in parasternal location on paired craniocaudal views. Note that some calcifications display typical radiolucent centers, whereas others that are projected tangentially are seen to be located within the skin.

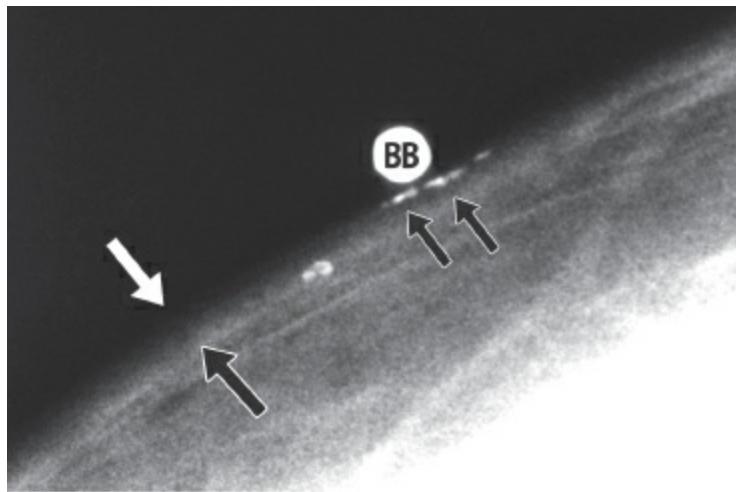


Figure 44 – TYPICALLY BENIGN: SKIN. Tangential view mammogram with round metallic marker (BB) placed directly overlying a tight group of amorphous calcifications demonstrates these to be SKIN calcifications (small arrows). These calcifications do not have the lucent-centered morphology typical of skin calcifications, but their intradermal location is diagnostic. Large arrows demarcate the skin. Note that any tight grouping of suspicious-appearing calcifications close to a skin surface on at least one mammographic image should prompt tangential-view mammography to establish or exclude intradermal location, prior to an attempt at tissue diagnosis.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

b. Vascular

These are parallel tracks, or linear tubular calcifications that are clearly associated with blood vessels. While most vascular calcification is not difficult to identify, if only a few discontinuous calcific particles are visible in a single location and if association with a tubular structure is questionable, then additional spot-compression magnification views may be needed to further characterize their nature.

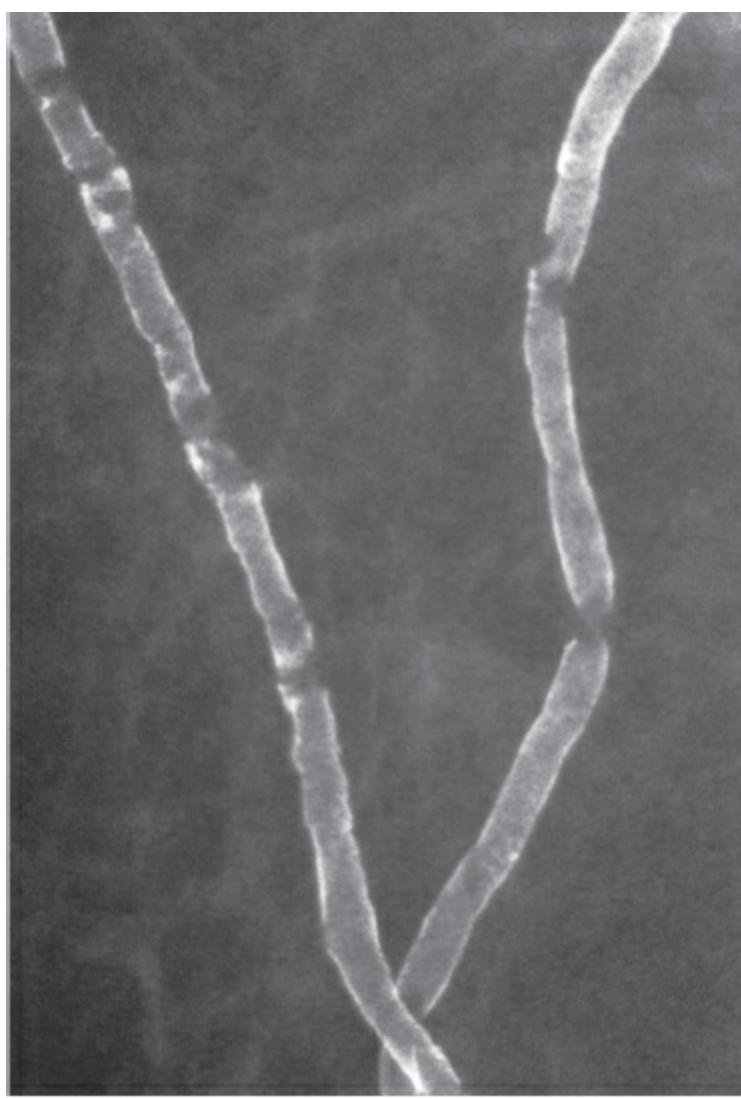


Figure 45 – TYPICALLY BENIGN: VASCULAR. Fully developed VASCULAR calcification in two adjacent blood vessels. Note the characteristically benign parallel tracks of calcification in the walls of the blood vessels.

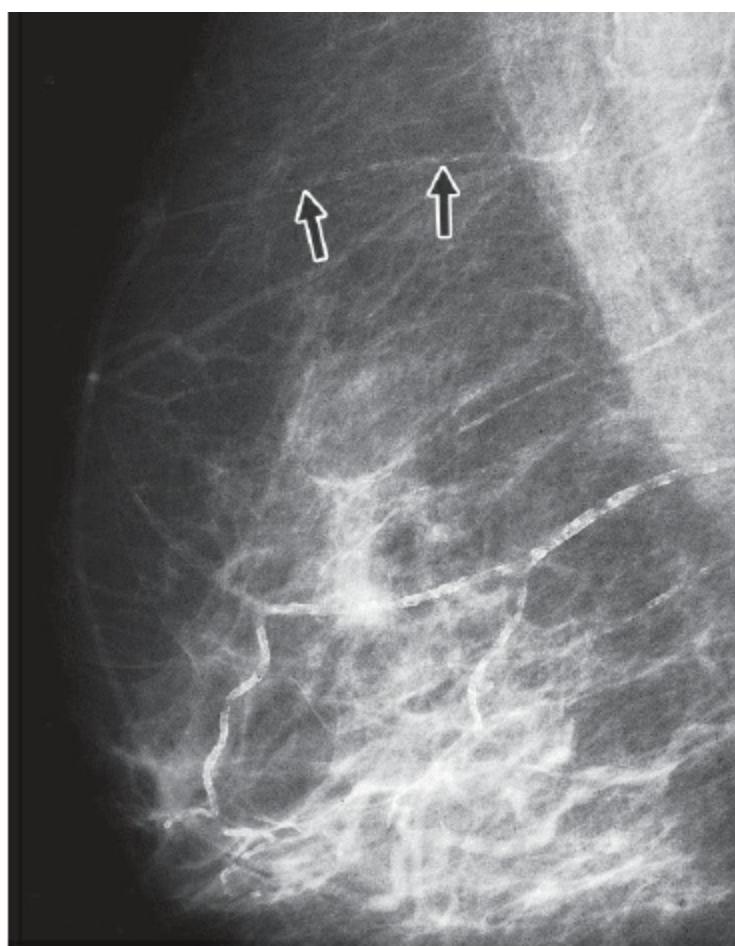


Figure 46 – TYPICALLY BENIGN: VASCULAR. Extensive VASCULAR calcification, producing typically benign parallel tracks of calcification in several blood vessels. Note the partially developed vascular calcification projected over the far superior aspect of the breast (arrows), also typically benign because discontinuous linear calcifications are seen to be located at the margin of a tubular structure (blood vessel).



A



B



c

Figure 47 – TYPICALLY BENIGN: VASCULAR. Early VASCULAR calcification. Enlarged view of screening mammogram (a) depicts a linear distribution of calcifications, intraductal versus vascular. Spot-compression magnification mammogram (b) shows that the linearly distributed calcifications are located in one wall of a tubular structure (blood vessel), hence, vascular and typically benign. At digital mammography, early vascular calcification often is more readily visible (c).

B. CALCIFICATIONS

1. TYPICALLY BENIGN

c. Coarse or “Popcorn-Like”

These calcifications are classic, large ($> 2\text{--}3 \text{ mm}$ in greatest diameter), and produced by an involuting fibroadenoma.

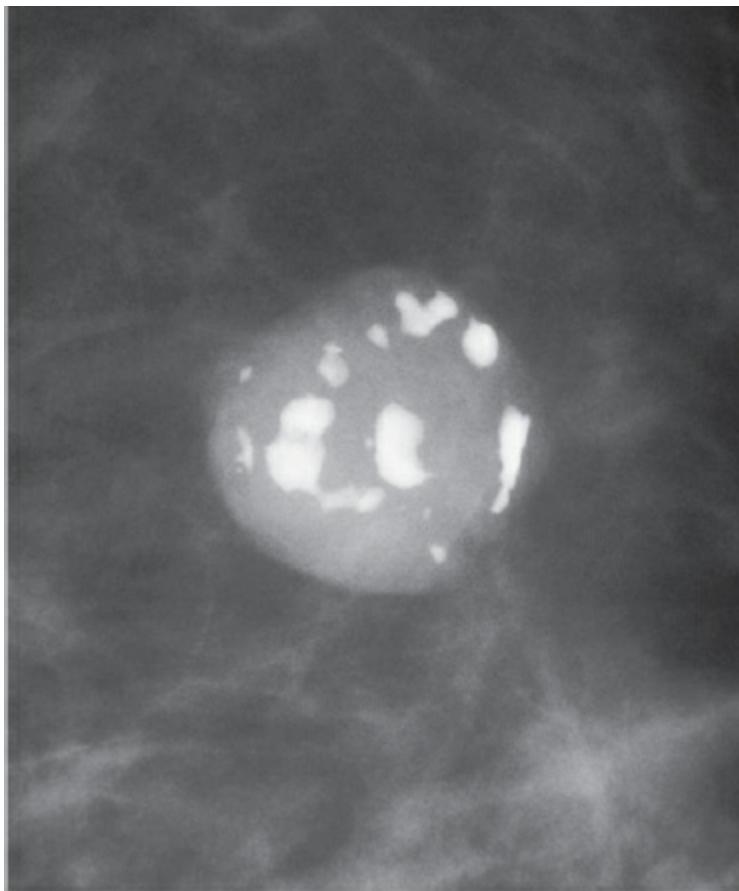


Figure 48 – TYPICALLY BENIGN: COARSE or POPCORN-LIKE.
Calcifications, not sufficiently extensive to appear confluent, nonetheless typically benign, especially because many of the calcifications are seen to be located peripherally in a circumscribed mass. Presumptive diagnosis: fibroadenoma.

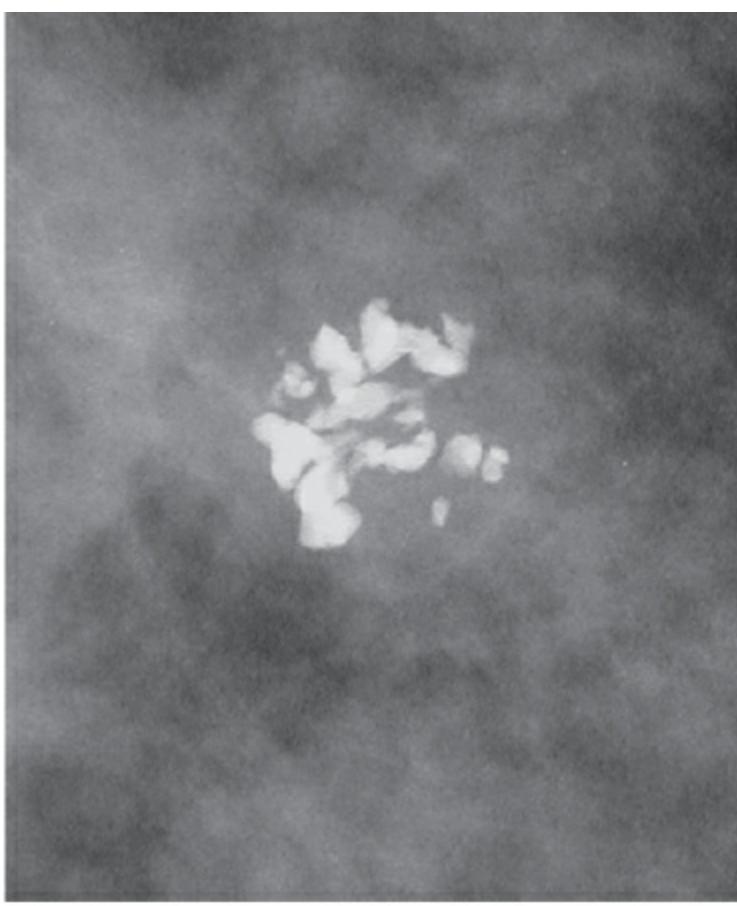


Figure 49 – TYPICALLY BENIGN: COARSE or POPCORN-LIKE.
Calcifications, many of which appear confluent, typically
benign. Note that the margin of the underlying mass is
obscured by surrounding dense tissue. Presumptive diagnosis:
fibroadenoma.

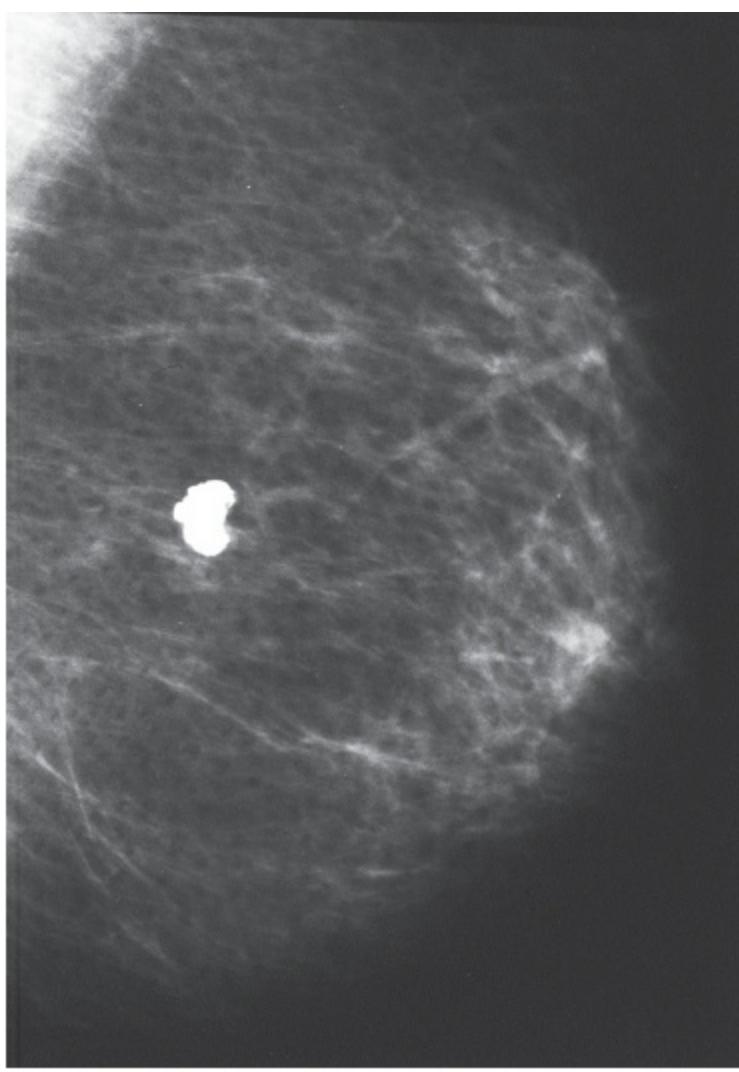


Figure 50 – TYPICALLY BENIGN: COARSE or POPCORN-LIKE.
Large COARSE calcification, typically benign, representing the end stage of POPCORN-LIKE calcifications that have become almost completely calcified. When so densely calcified, the underlying mass usually is not visible, even if surrounded by fatty tissue, because calcification occupies almost the entire mass. Presumptive diagnosis: fibroadenoma (a densely calcified oil cyst of fat necrosis usually still displays some internal radiolucency).

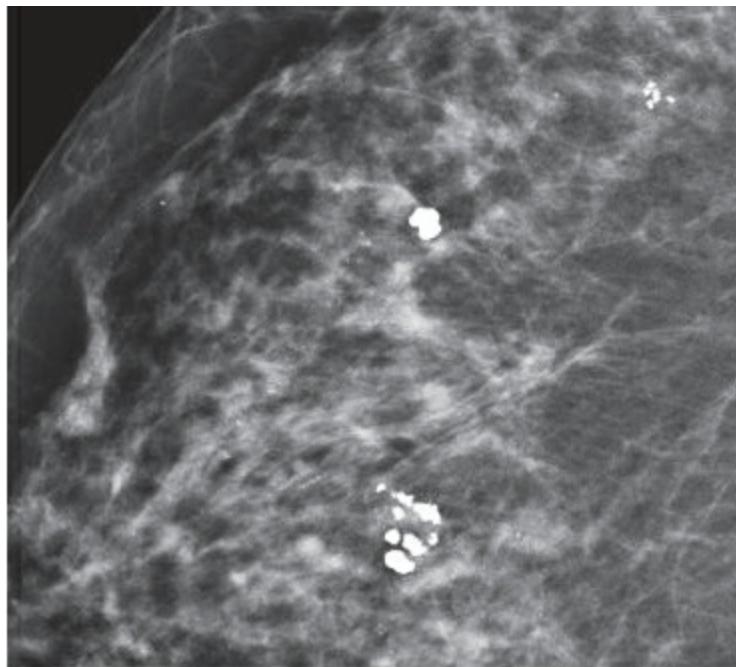


Figure 51 – TYPICALLY BENIGN: COARSE or POPCORN-LIKE.
Three examples of COARSE (POPCORN-LIKE) calcifications, in different stages of development. The middle calcification is the most completely calcified. The upper group of calcifications is the least completely calcified, nonetheless typically benign because these calcifications are somewhat coarse and coexist with the other more fully developed calcifications. Presumptive diagnosis: three fibroadenomas.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

d. Large Rod-Like

These benign calcifications associated with ductal ectasia may form solid or discontinuous smooth linear rods, most of which are 0.5 mm or larger in diameter. A small percentage of these calcifications may have lucent centers if the calcium is in the wall of the duct (periductal), but most are intraductal, when calcification forms within the lumen of the duct. All large rod-like calcifications follow a ductal distribution, radiating toward the nipple, occasionally branching. The calcifications usually are bilateral, although they may be seen in only one breast, especially when few calcific particles are visible. These calcifications usually are seen in women older than 60 years.



Figure 52 – TYPICALLY BENIGN: LARGE ROD-LIKE. Calcifications, primarily intraductal, occasionally branching, typically benign.

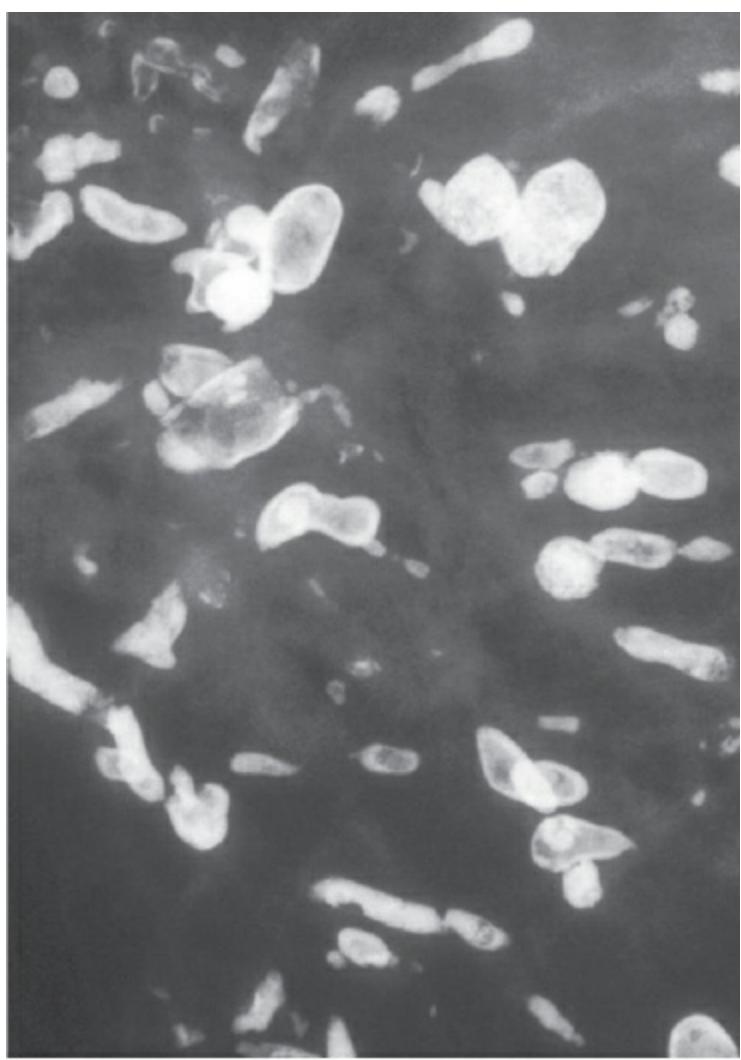


Figure 53 – TYPICALLY BENIGN: LARGE ROD-LIKE. Calcifications, primarily in the walls of ducts (periductal), typically benign.

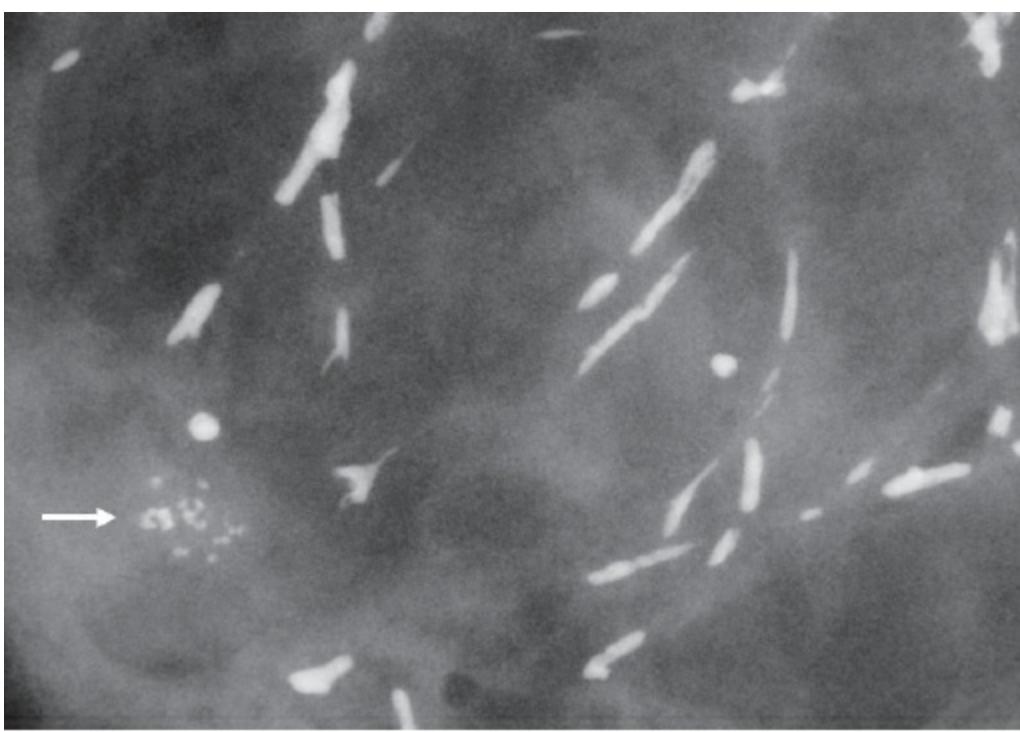


Figure 54 – TYPICALLY BENIGN: LARGE ROD-LIKE. Calcifications, primarily intraductal, typically benign. Also note the small group of fine pleomorphic calcifications at the lower left of the image field (*arrow*), distinguished by differences in size, morphology, and distribution. Core biopsy: benign ductal ectasia and ductal carcinoma in situ (6 mm, high nuclear grade).

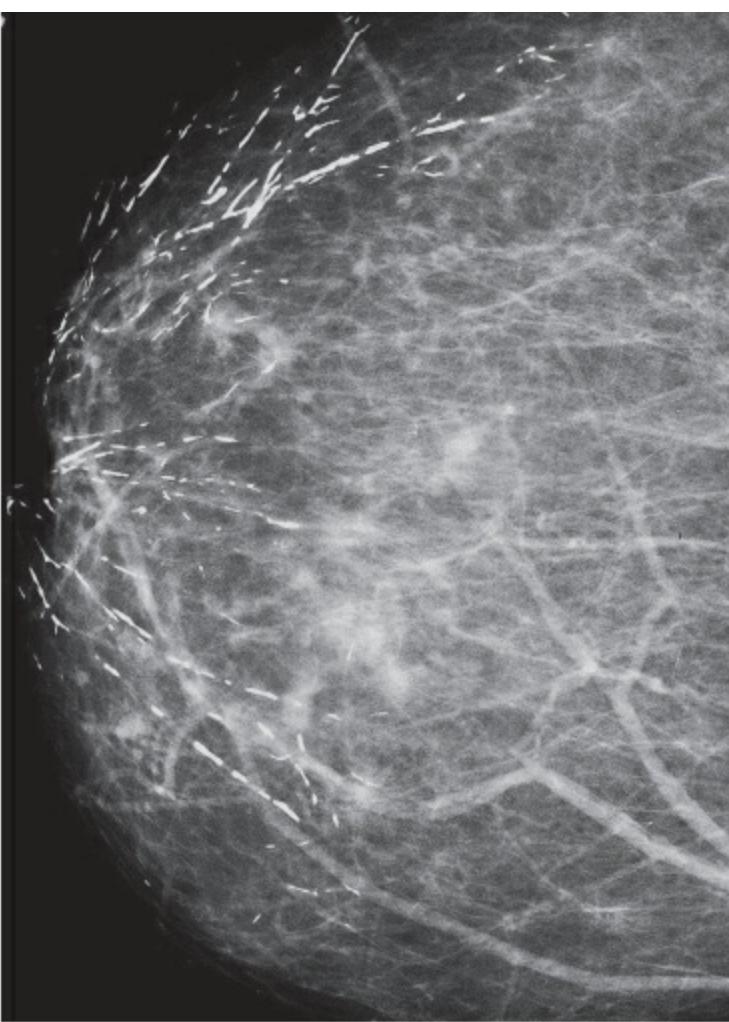


Figure 55 – TYPICALLY BENIGN: LARGE ROD-LIKE. Extensive LARGE ROD-LIKE calcifications, primarily intraductal, typically benign. Note the diffuse distribution of calcifications, radiating toward the nipple.

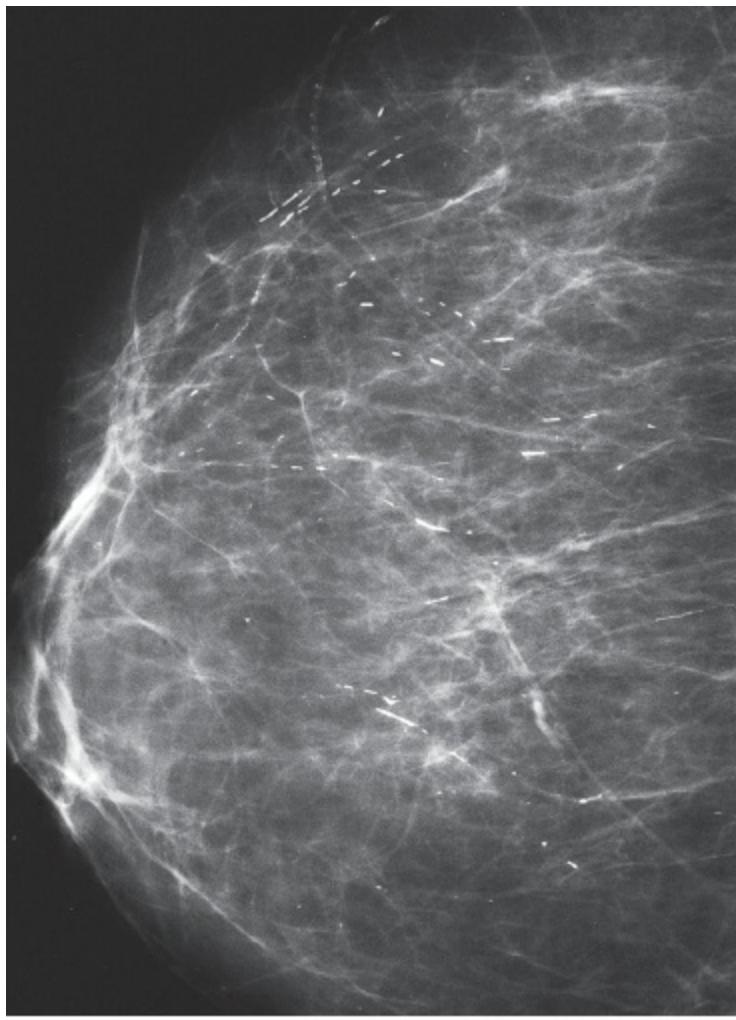


Figure 56 – TYPICALLY BENIGN: LARGE ROD-LIKE. Calcifications, primarily intraductal, typically benign. Also note the vascular calcification at the top of the image field, also typically benign.

REFERENCES

1. Graf O, Berg WA, Sickles EA, et al. Large rodlike calcifications at mammography: analysis of morphologic features. *AJR* 2013; 200(2):299–303.

Abstract:

Objective:

The purpose of this article is to prospectively determine the prevalence and morphologic features of typically benign large rod-like calcifications at mammography and to provide evidence-based data for this descriptor in a future version of the BI-RADS® lexicon.

Subjects and Methods:

In the 1-year period of 2011, large rod-like calcifications were detected in 239 of 7,935 (3%) consecutive women undergoing screening or diagnostic mammography. Analysis of morphologic features was performed in 165 of the 239 women (69%; mean age, 71.1 years; range, 39–86 years), who had a minimum number of six calcific particles and in whom benignity was assessed by lack of suspicious change compared with prior mammograms. Two of the 165 women had undergone a mastectomy previously.

Results:

The mean length of the longest calcification was 4.2 (SD, 2.4) mm (median, 3.5 mm; range, 1–14 mm). The mean width of the widest calcification was 0.6 (SD, 0.5) mm (median, 0.5 mm; range 0.2–3 mm). Bilaterality was found in 131 of 163 women (80.4%) with two breasts, periductal calcifications were found in 18 of 165 women (10.9%), and branching calcifications were found in another 18 women (10.9%). One hundred fifty-five of 165 women (93.9%) had almost entirely fat or scattered areas of fibroglandular tissue; 10 women (6.1%) had heterogeneously dense or extremely dense tissue.

Conclusion:

Our results partially contradict the current description (size, diameter, and bilaterality versus unilaterality) of large rod-like calcifications in the BI-RADS® lexicon (fourth edition).

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Content for this descriptor has been modified in the current version of the lexicon (2013 edition).

B. CALCIFICATIONS

1. TYPICALLY BENIGN

e. Round (Punctate is a subset of Round) (see Guidance chapter)

When multiple, they may vary in size, and therefore in opacity. They may be considered benign when diffuse and small (< 1 mm), and are frequently formed in the acini of lobules. When smaller than 0.5 mm, the term “punctate” should be used.

An isolated group of punctate calcifications may warrant probably benign assessment and mammographic surveillance if no prior examinations are available for comparison, or image-guided biopsy if the group is new, increasing, linear, or segmental in distribution, or if adjacent to a known cancer.

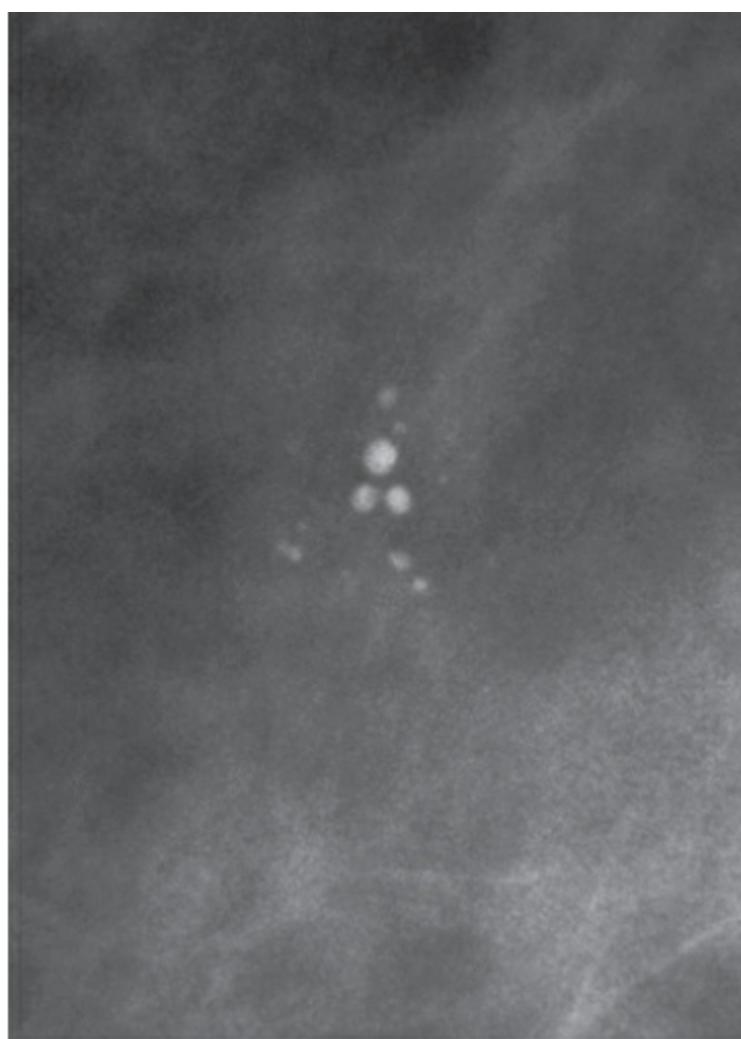


Figure 57 – TYPICALLY BENIGN: ROUND. Grouped ROUND (punctate) calcifications. Assessed as probably benign with subsequent demonstration of 3-year stability at surveillance mammography. Presumptive diagnosis: benign calcifications. Previously published as Figure 4 (p. 776) in Leung JWT, Sickles EA. The probably benign assessment. *Radiol Clin North Am* 2007; 45[5]:773–789.



Figure 58 – TYPICALLY BENIGN: ROUND. Regional ROUND (punctate) calcifications. Assessed as probably benign with subsequent demonstration of 3-year stability at surveillance mammography. Presumptive diagnosis: benign calcifications.

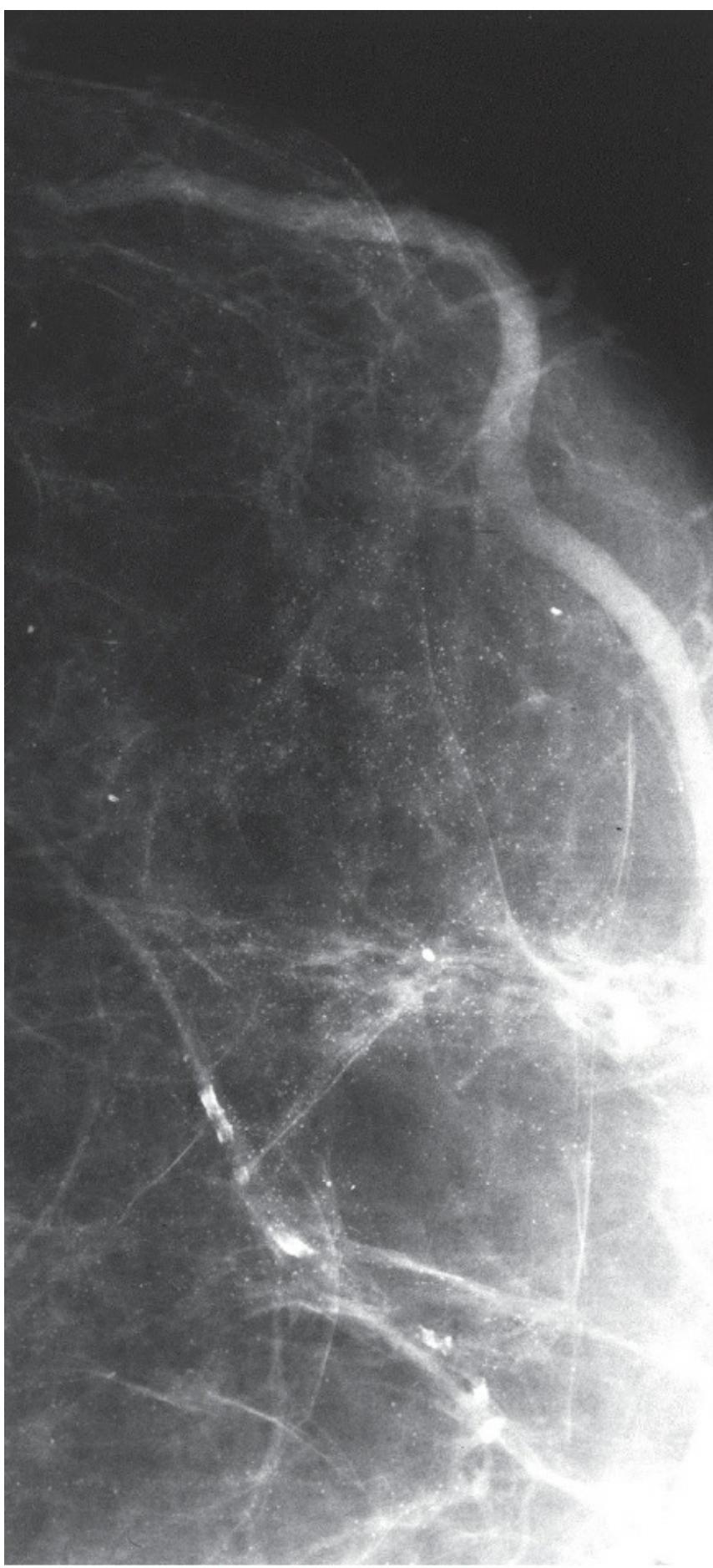


Figure 59 – TYPICALLY BENIGN: ROUND. Diffuse ROUND (punctate) calcifications, typically benign. Similar calcifications seen elsewhere in the same breast and in the contralateral breast. Note the vascular calcification, also typically benign, at the bottom of the image field.

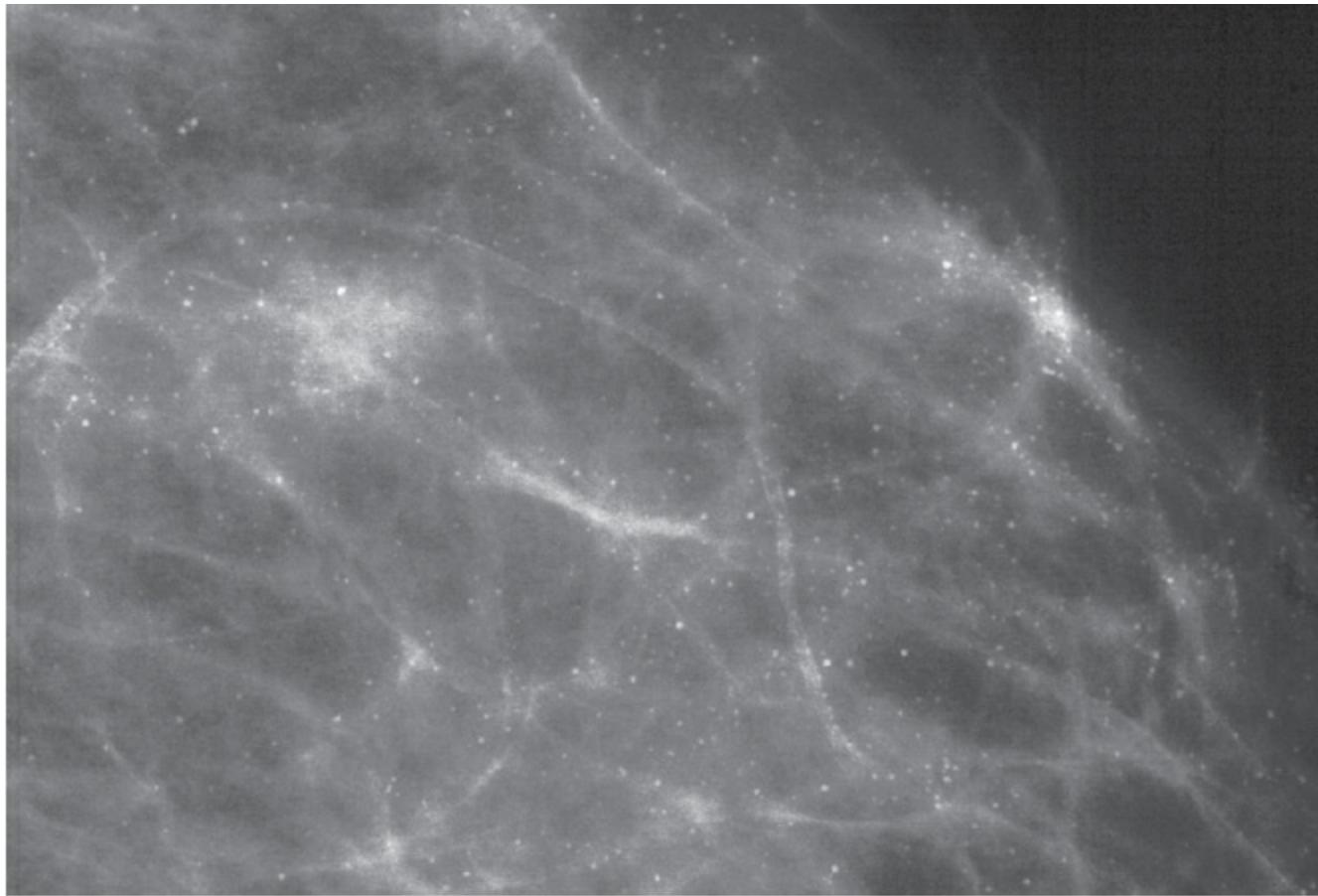


Figure 60 – TYPICALLY BENIGN: ROUND. Diffuse, ROUND (punctate) calcifications, typically benign. Similar calcifications seen elsewhere in the same breast and in the contralateral breast. Previously published as Figure 12 (p. 779) in Leung JWT, Sickles EA. The probably benign assessment. *Radiol Clin North Am* 2007; 45[5]:773–789.

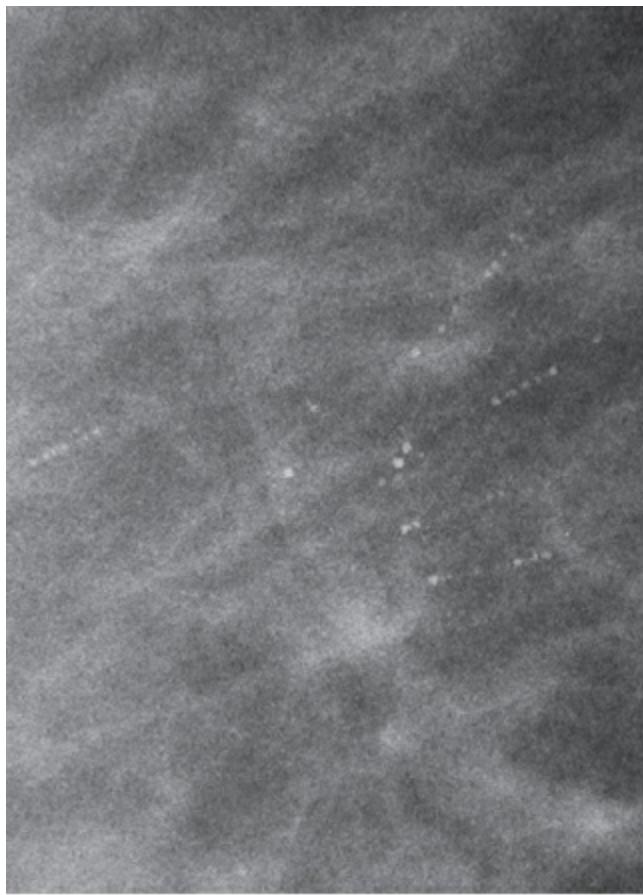


Figure 61 – TYPICALLY BENIGN: ROUND. Segmental ROUND (punctate) calcifications. Although punctate morphology usually prompts a benign or probably benign assessment, the segmental distribution in this case prompts a suspicious assessment instead. Core biopsy: ductal carcinoma in situ (DCIS). Previously published as Figure 6 (p. 776) in Leung JWT, Sickles EA. The probably benign assessment. *Radiol Clin North Am* 2007; 45(5):773–789.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

f. Rim (historically, “eggshell”, “lucent-centered”) (see Guidance chapter)

These are thin benign calcifications that appear as calcium deposited on the surface of a sphere. The calcific deposits are usually less than 1 mm in thickness when viewed on edge. These are benign nongrouped calcifications that range from smaller than 1 mm to larger than a centimeter or more. The calcifications are round or oval, with smooth surfaces and lucent centers. Fat necrosis and calcifications in the walls of cysts are the most common rim calcifications, although more extensive (and occasionally thicker-rimmed) calcifications in the walls of oil cysts or simple cysts may be seen.

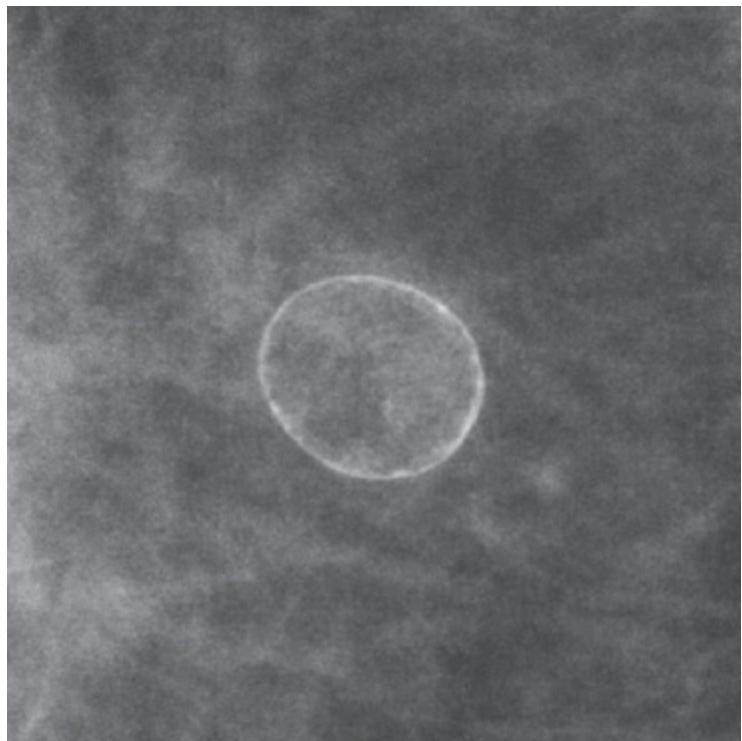


Figure 62 – TYPICALLY BENIGN: RIM. RIM calcification, typically benign.

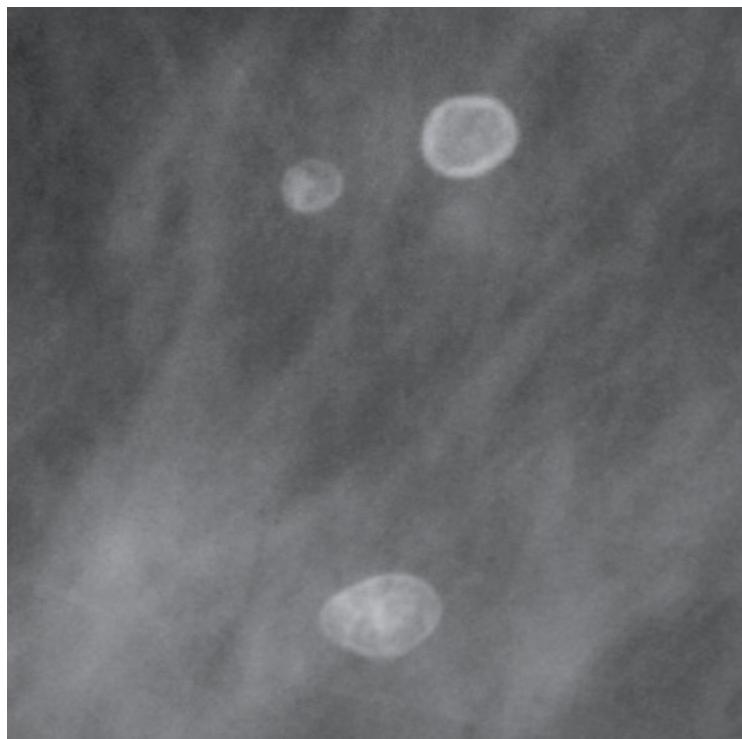


Figure 63 – TYPICALLY BENIGN: RIM. RIM calcifications, typically benign, showing varying degrees of calcified-rim thickness.
Previously published as Figure 2a (p. 290) in Sickles EA. Breast calcifications: mammographic evaluation. *Radiology* 1986; 160[2]:289–293.

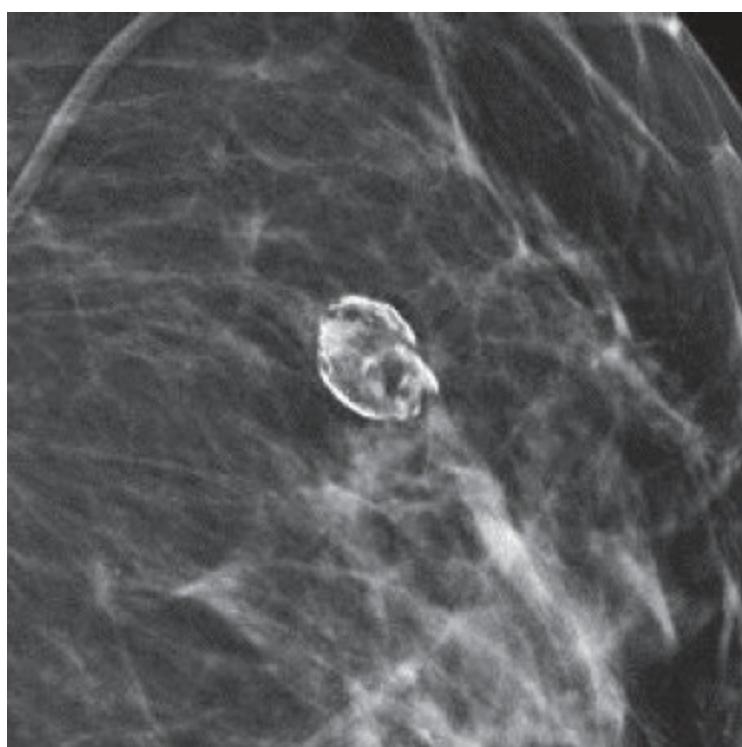


Figure 64 – TYPICALLY BENIGN: RIM. RIM calcification, typically benign. Some of the calcified rim is imaged en face, hence, projected over the radiolucent center of the calcification.

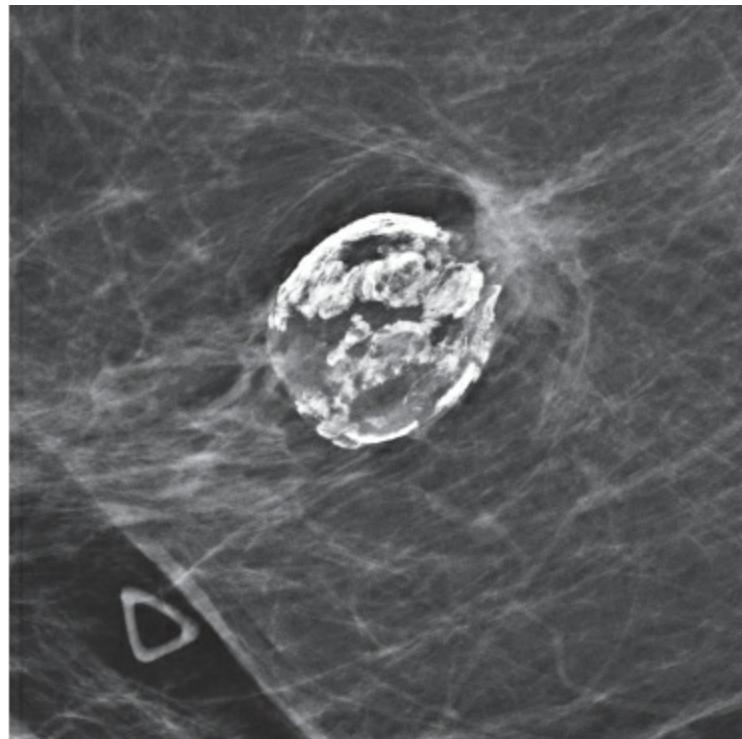


Figure 65 – TYPICALLY BENIGN: RIM. RIM calcification, typically benign. Much of the thickly calcified rim is imaged en face, hence, projected over the radiolucent center of the calcification. A triangle-shaped radiopaque marker indicates the location of a palpable mass that likely represents the large calcification.

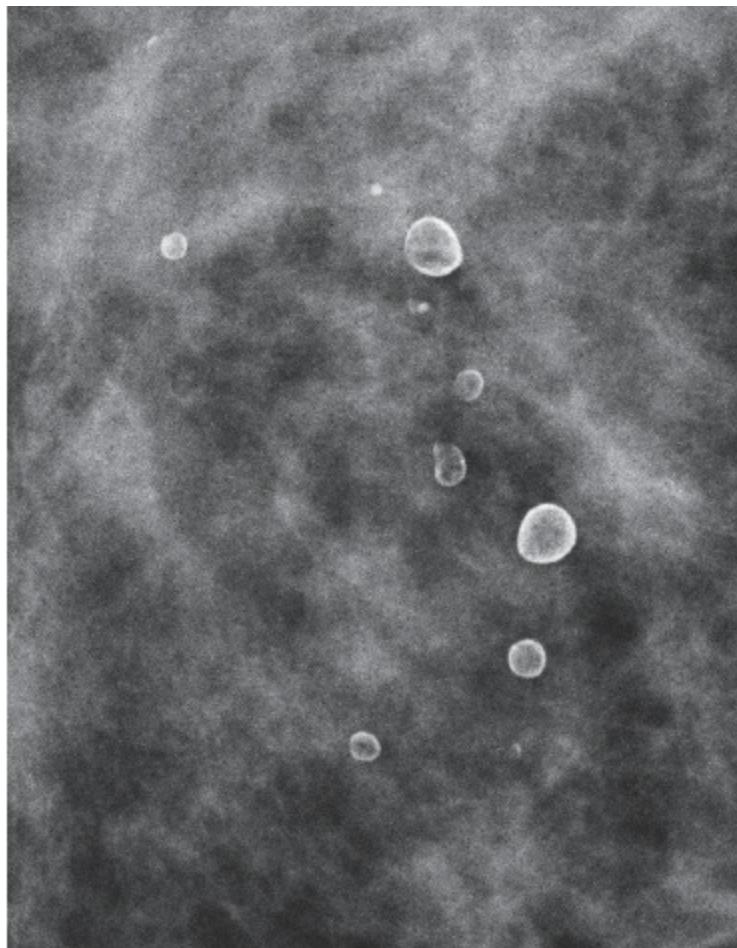


Figure 66 – TYPICALLY BENIGN: RIM. RIM calcifications, typically benign, showing variation in size and in degree of calcified-rim thickness.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

g. Dystrophic (see Guidance chapter)

These typically form in the irradiated breast or in the breast following trauma or surgery. The calcifications are irregular in shape, and they are usually > 1 mm in size. They often have lucent centers.

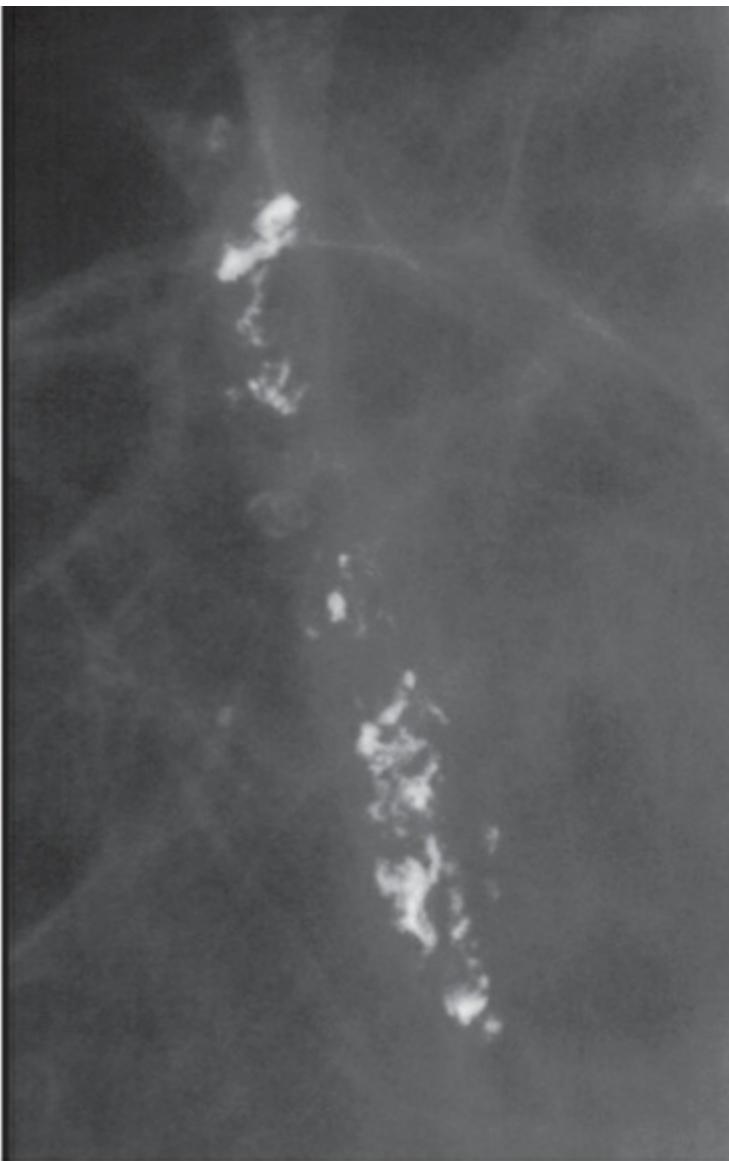


Figure 67 – TYPICALLY BENIGN: DYSTROPHIC. Dystrophic calcifications, typically benign, within the plane of dissection in a surgical scar.



Figure 68 – TYPICALLY BENIGN: DYSTROPHIC. DYSTROPHIC calcifications, typically benign, at the site of previous surgical excision marked by several metallic clips.

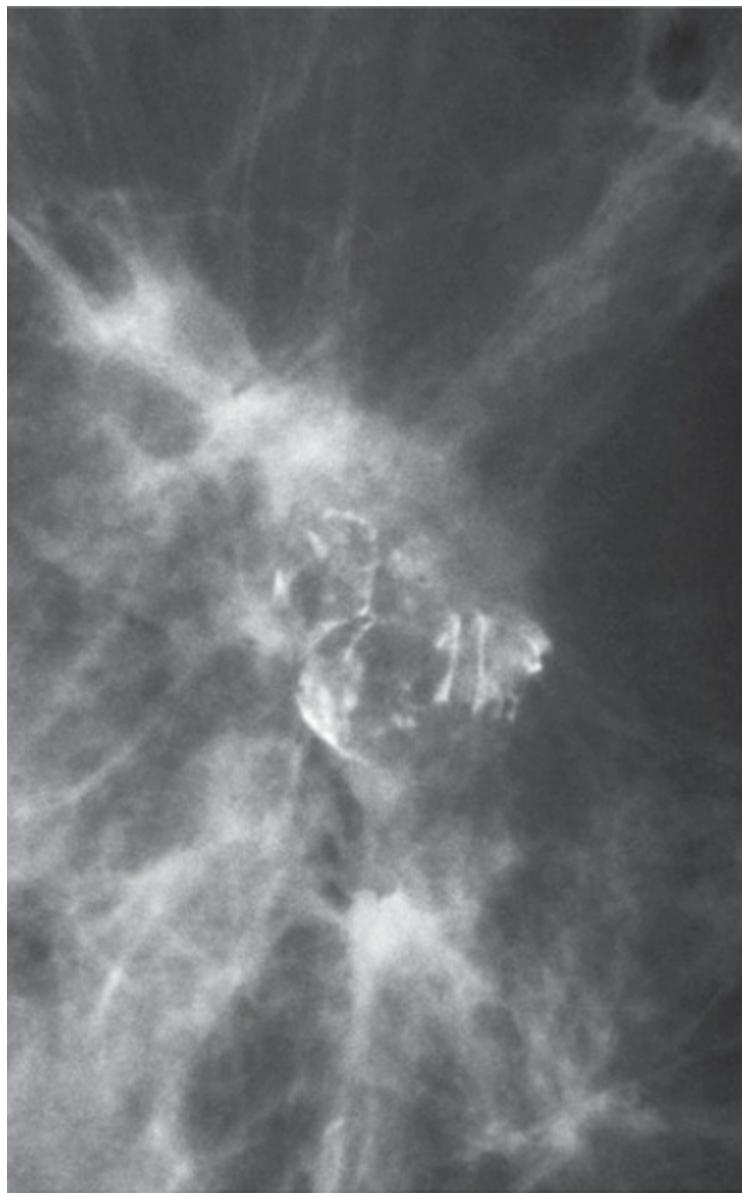


Figure 69 – TYPICALLY BENIGN: DYSTROPHIC. Dystrophic calcifications, typically benign, less extensive than usual, at the site of a surgical scar that also displays some architectural distortion. Previously published as Figure 6 (p. 291) in Sickles EA. Breast calcifications: mammographic evaluation. *Radiology* 1986; 160[2]:289–293.

B. CALCIFICATIONS

1. TYPICALLY BENIGN

h. Milk of Calcium

This is a manifestation of sedimented calcifications in macro- or microcysts, usually but not always grouped. On the craniocaudal image they are often less evident and appear as round, smudgy deposits, while occasionally on MLO and especially on 90° lateral (LM/ML) views, they are more clearly defined and often semilunar, crescent shaped, curvilinear (concave up), or linear, defining the dependent portion of cysts. The most important feature of these calcifications is the apparent change in shape of

the calcific particles on different mammographic projections (CC versus occasionally the MLO view and especially LM/ML views). At times milk of calcium calcifications are seen adjacent to other types of calcifications that may be associated with malignancy, so it is important to search for more suspicious forms, especially those that do not change shape from the 90° lateral projection to the CC projection.

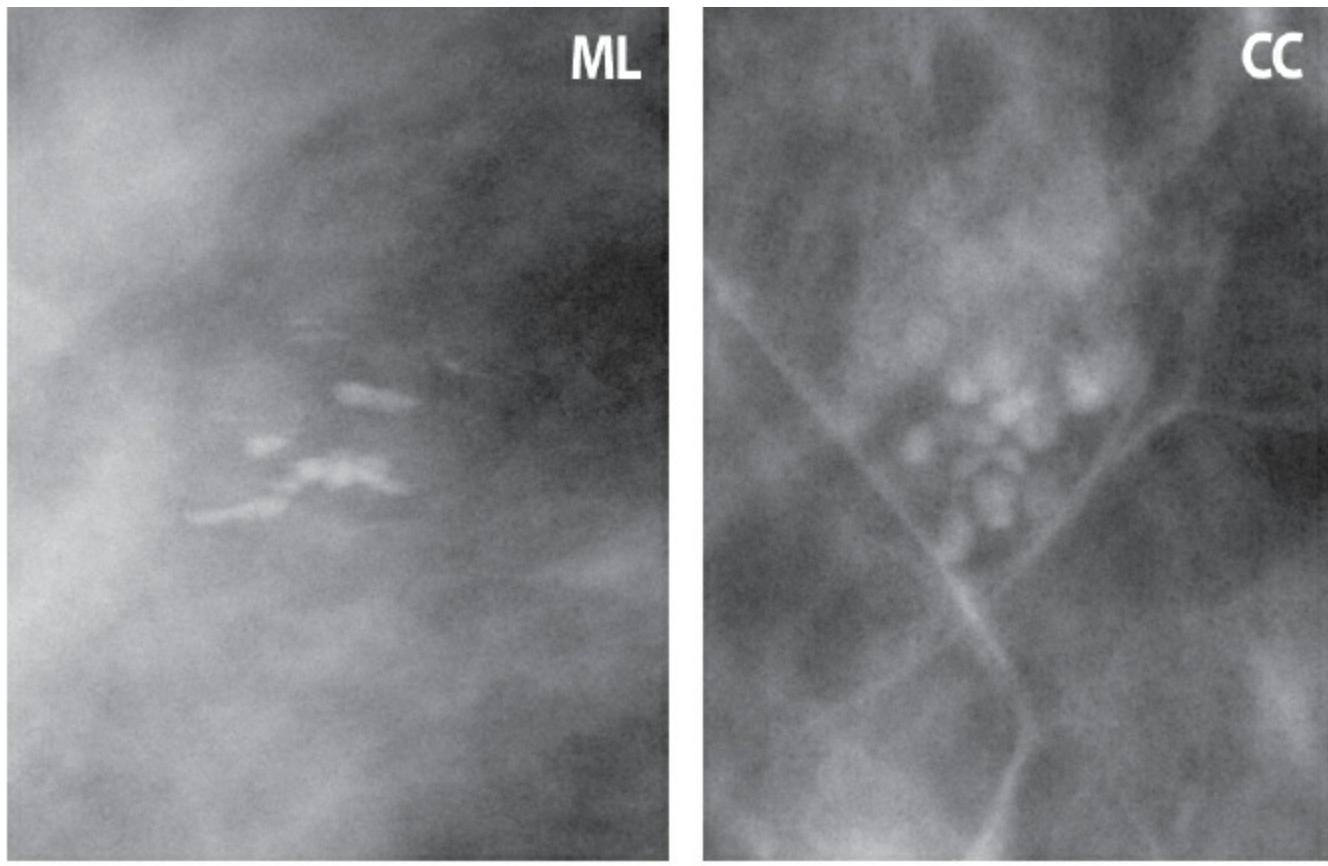


Figure 70 – TYPICALLY BENIGN: MILK OF CALCIUM. Grouped MILK OF CALCIUM calcifications, typically benign. The calcifications appear to be linear and crescent-shaped on ML view but smudgy on CC view (sedimented at the bottom of a group of tiny cysts).

ML

CC

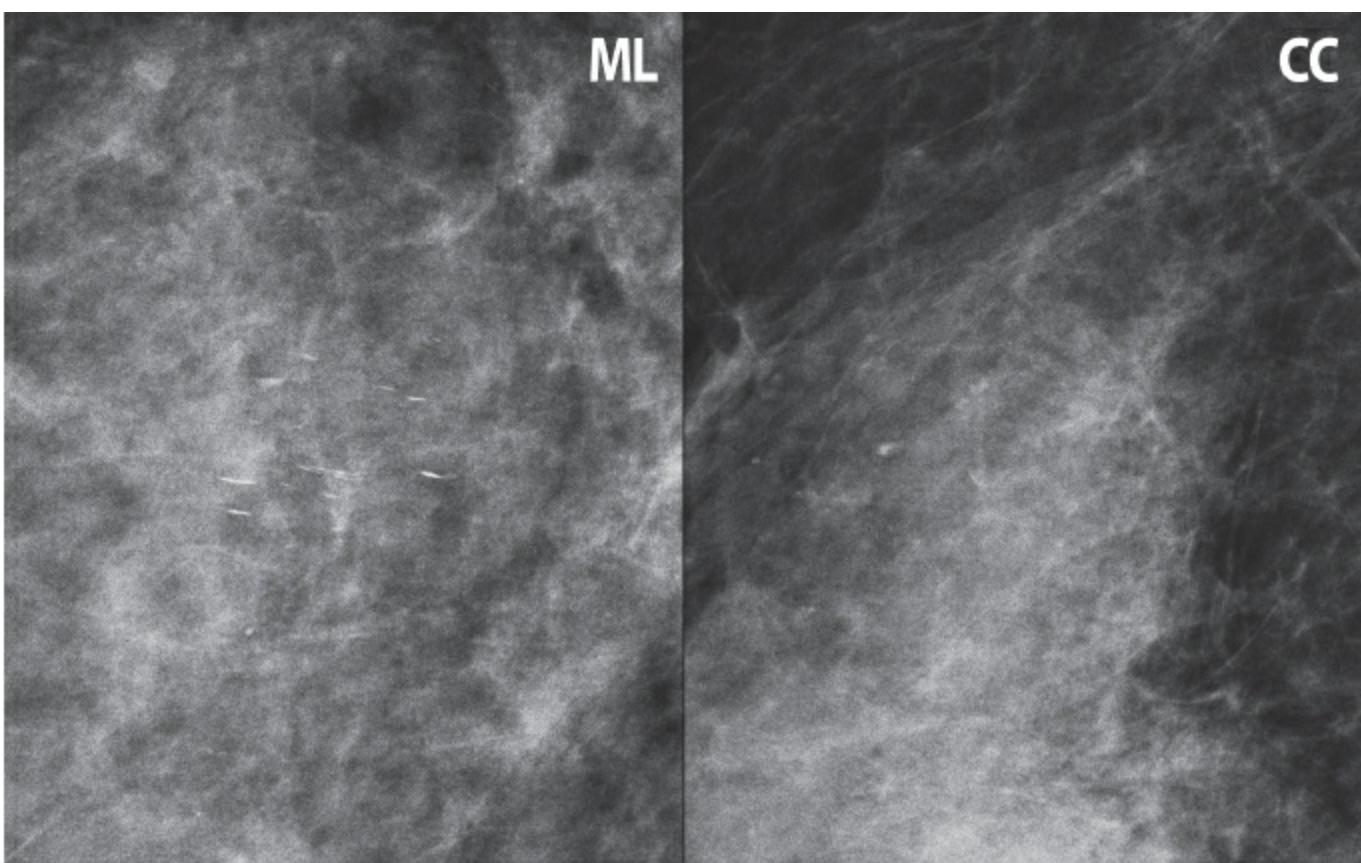


Figure 71 – TYPICALLY BENIGN: MILK OF CALCIUM. Regional MILK OF CALCIUM calcifications, typically benign. Most of the calcifications appear to be linear (a few others are semilunar) on ML view, with only a few barely visible as smudges on CC view (sedimented at the bottom of tiny cysts).

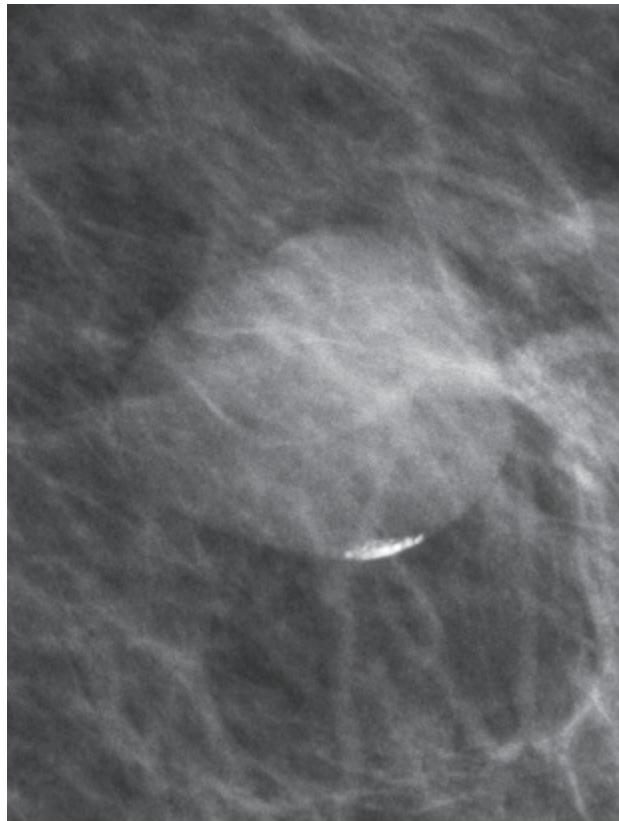
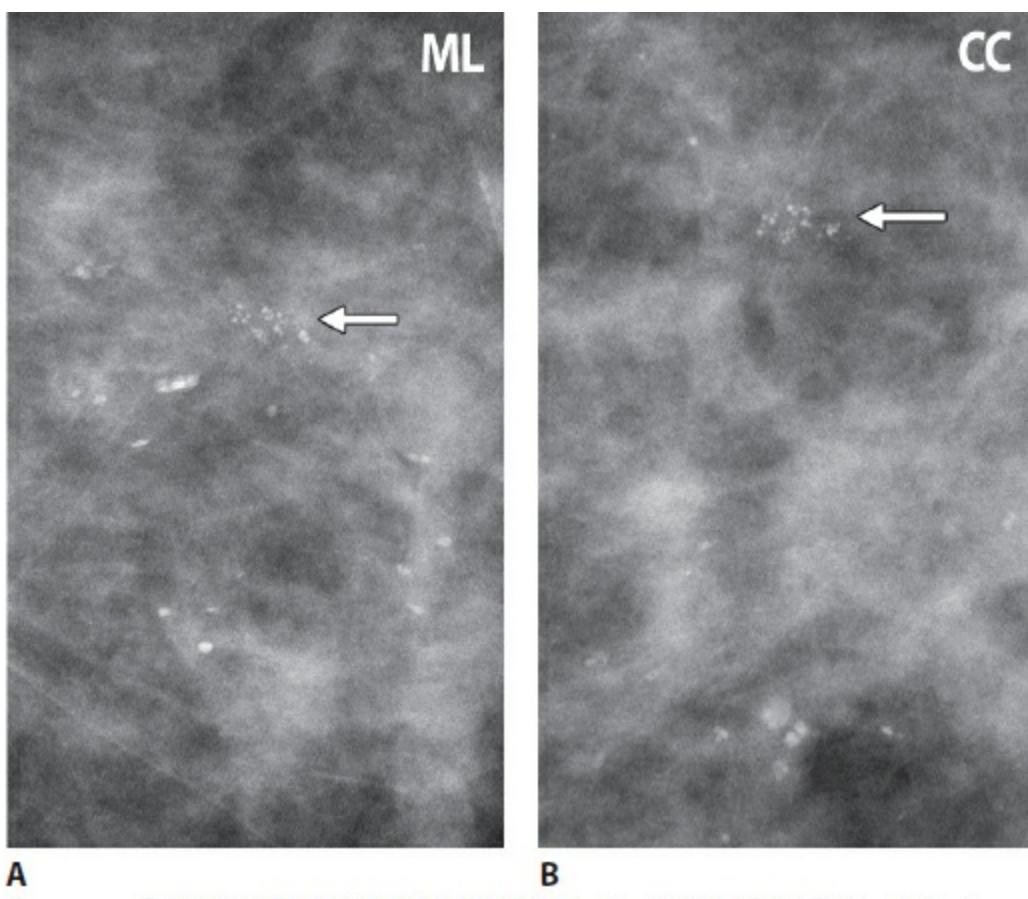


Figure 72 – TYPICALLY BENIGN: MILK OF CALCIUM. MILK OF CALCIUM calcifications, typically benign, sedimented at the bottom of a large cyst, which itself is displayed as an oval, circumscribed mass.



A

B

Figure 73 – TYPICALLY BENIGN: MILK OF CALCIUM. Regional MILK OF CALCIUM calcifications, typically benign. Some calcifications appear to be crescent-shaped or semilunar on ML view but smudgy on CC view (sedimented at the bottom of tiny cysts). Also note other grouped amorphous calcifications that are similar in morphology on both views (*arrows*); these grouped calcifications are not compatible with milk of calcium due to their similar morphology on orthogonal views, hence assessed as suspicious. Core biopsy: ductal carcinoma in situ (DCIS).

B. CALCIFICATIONS

1. TYPICALLY BENIGN

i. Suture

These represent calcium deposited on suture material. They are typically linear or tubular in appearance and, when present, knots are frequently visible.

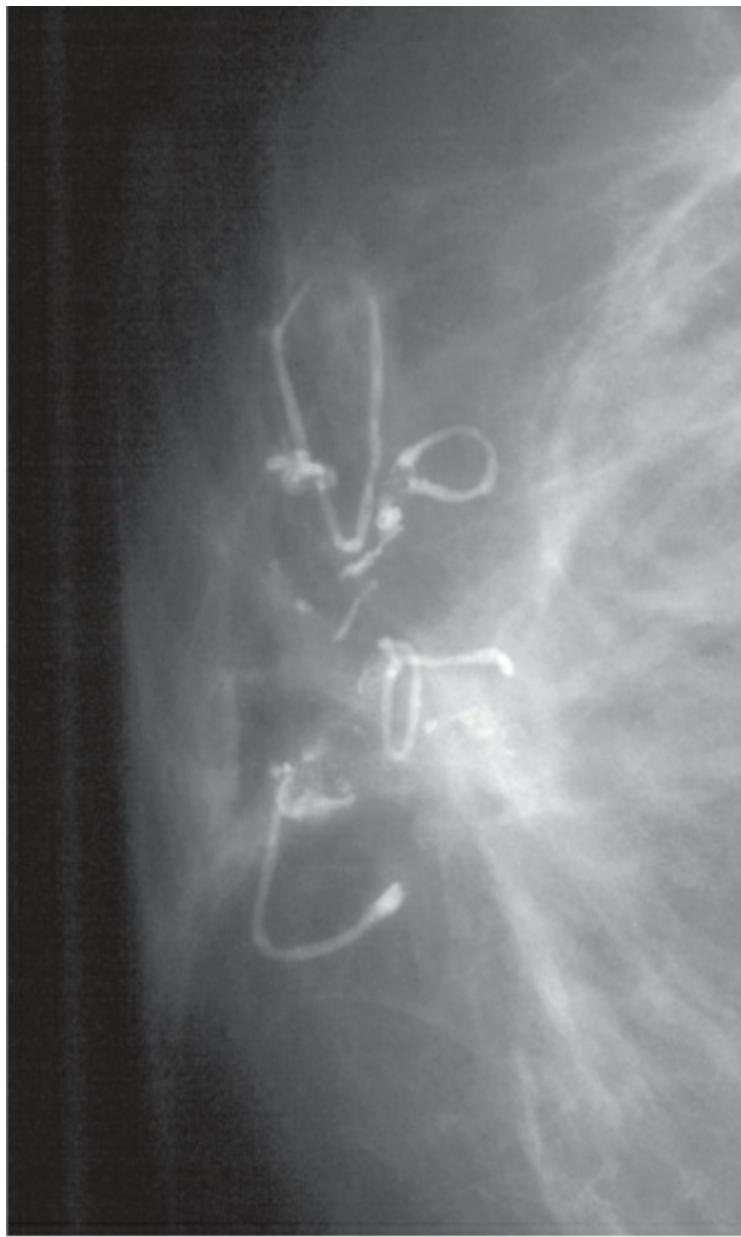


Figure 74 – TYPICALLY BENIGN: SUTURE. SUTURE calcifications, typically benign. Note the calcified loops and knots of the sutures. There also is some architectural distortion at the surgical site.



Figure 75 – TYPICALLY BENIGN: SUTURE. SUTURE calcifications, typically benign. Note the two calcified knots and partially calcified loops.

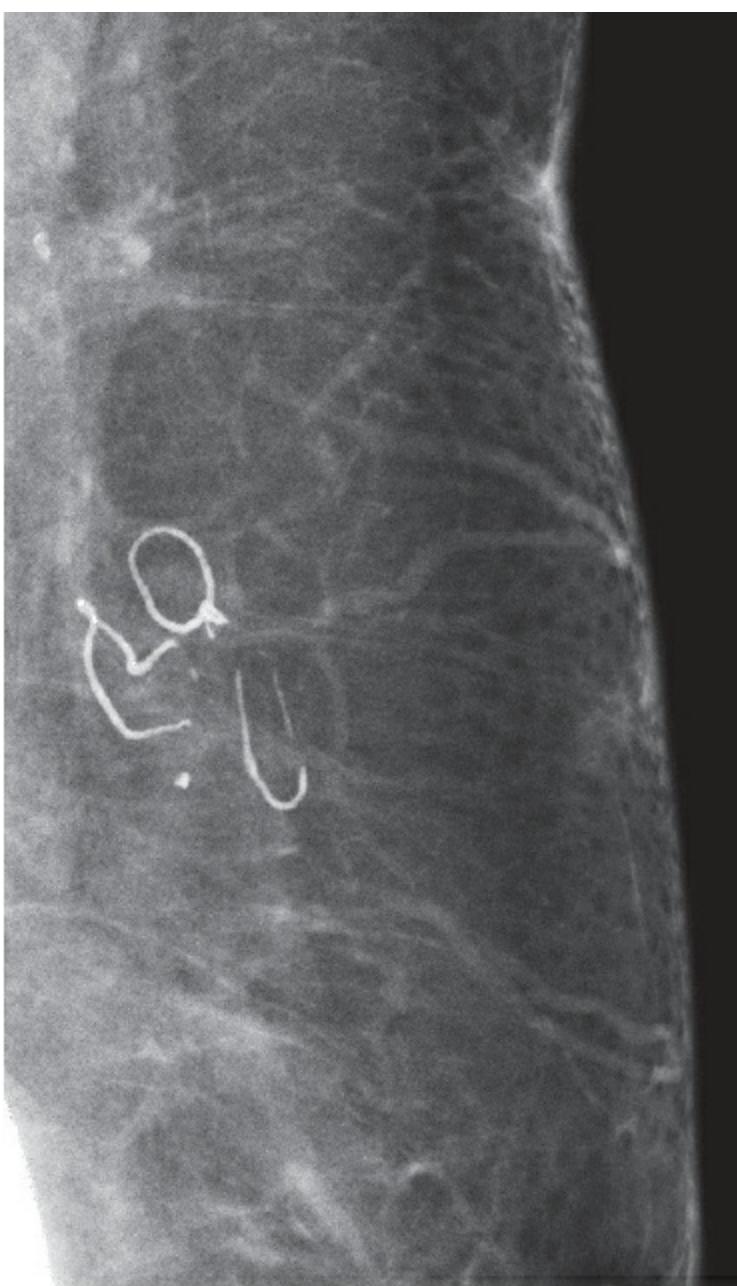


Figure 76 – TYPICALLY BENIGN: SUTURE. SUTURE calcifications, typically benign. Note the two completely calcified sutures, one with intact loop and knot, the other with loop and untied knot. There also is a third partially calcified suture, with calcification involving most of the loop.

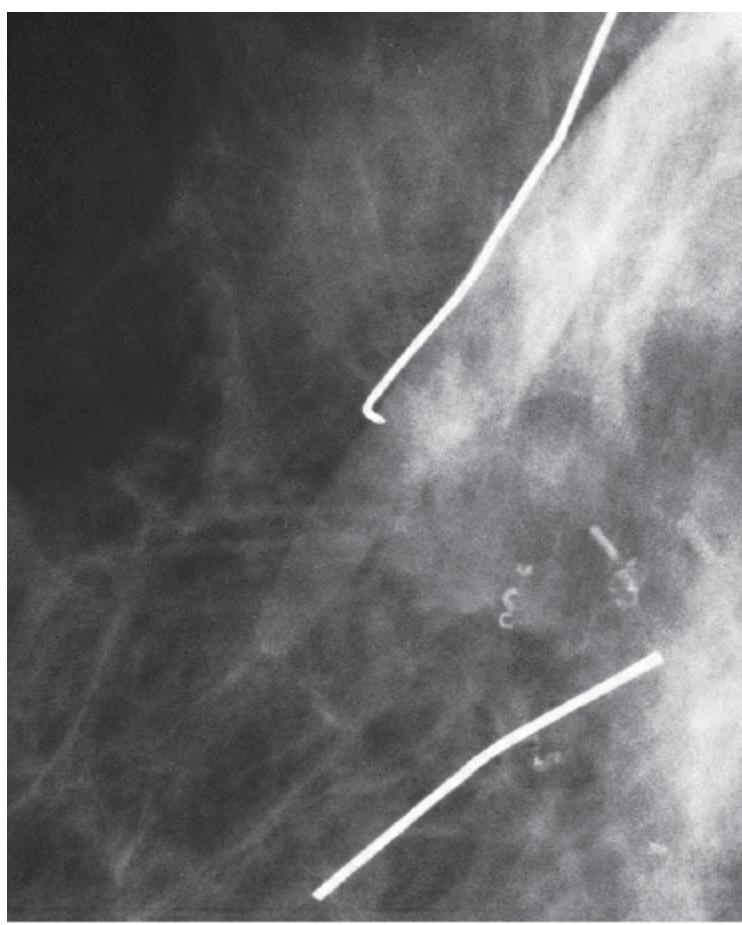


Figure 77 – TYPICALLY BENIGN: SUTURE. SUTURE calcifications, typically benign. These partially calcified sutures are disrupted. Metallic wires placed on the skin surface overlying surgical scars.

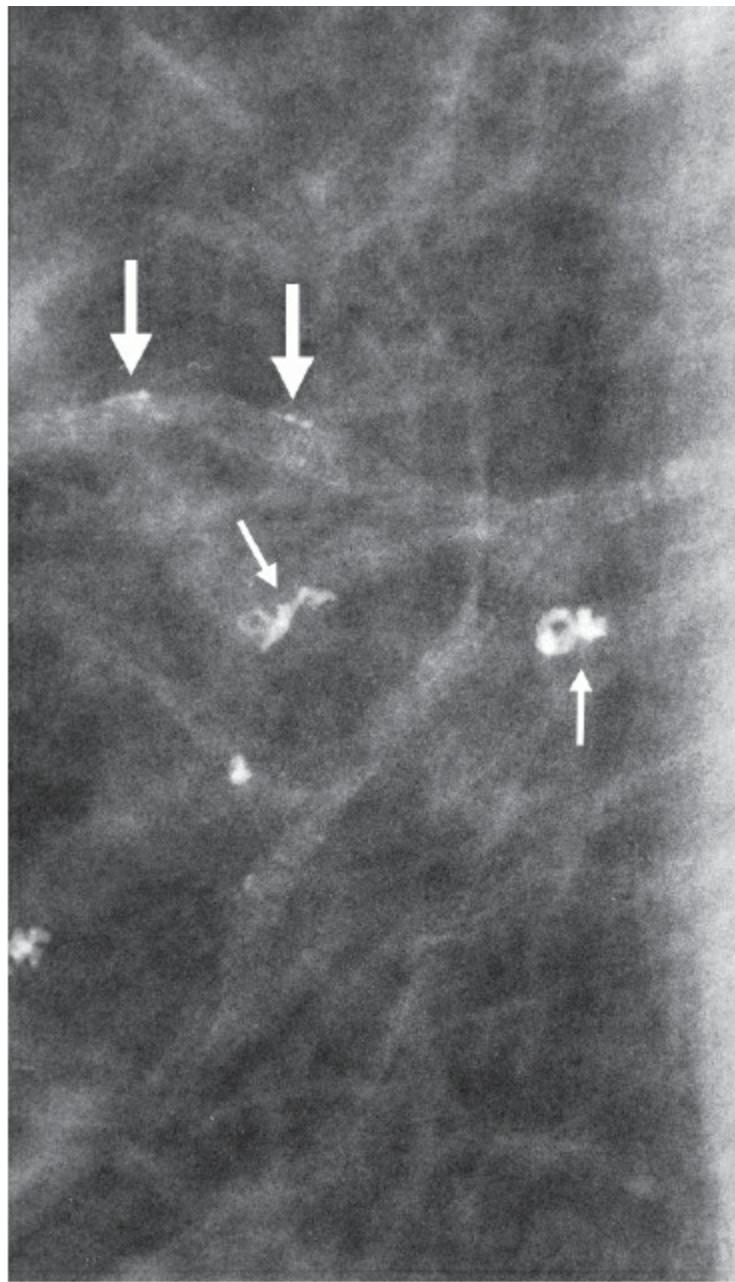


Figure 78 – TYPICALLY BENIGN: SUTURE. SUTURE calcifications, typically benign, one of which is intact, the other disrupted (*small arrows*). Note the early vascular calcification, seen as a few linear calcifications within one wall of a branched blood vessel (*large arrows*), also typically benign.

B. CALCIFICATIONS

2. SUSPICIOUS MORPHOLOGY

Classification of breast calcifications by morphology is useful in predicting the likelihood of malignancy. There are four descriptors of calcification morphology that usually indicate sufficient suspicion of malignancy to prompt a recommendation for biopsy. [Table 2](#) displays the results of several single-institution consecutive-case series involving suspicious mammographic calcifications classified by BI-RADS® morphology descriptors.

Table 2. Likelihood of Malignancy as a Function of BI-RADS® Descriptors of Calcification Morphology^a

Morphology Descriptor	Liberman et al. ¹	Berg et al. ²	Burnside et al. ³	Bent et al. ⁴	Total
Amorphous	9/35 (26)	30/150 (20)	4/30 (13)	10/51 (20)	53/266 (21)
Coarse	N/A ^b	N/S ^c	1/14 (7)	2/10 (20)	3/24 (13)
Heterogeneous					
Fine Pleomorphic	N/A ^b	N/S ^c	10/34 (29)	14/50 (28)	24/84 (29)
Fine Linear or Fine-Linear Branching	26/32 (81)	N/S ^c	10/19 (53)	16/23 (70)	52/74 (70)

^a Data are presented as cancer cases/all cases biopsied, with percentage of cancer cases in parentheses.

^b N/A = not applicable. This study, published in 1998, reported 98 cancers among 241 cases of pleomorphic calcifications (41%). The fourth edition of BI-RADS® (published later, in 2003) subdivided the pleomorphic descriptor into coarse heterogeneous and fine pleomorphic descriptors.

^c N/S = not specified. This study involved only amorphous calcifications.

B. CALCIFICATIONS

2. SUSPICIOUS MORPHOLOGY

a. Amorphous (historically, “indistinct”) (See Guidance chapter)

These are so small and/or hazy in appearance that a more specific particle shape cannot be determined. Amorphous calcifications in a grouped, linear, or segmental distribution are suspicious and generally warrant biopsy. Bilateral, diffuse, amorphous calcifications usually may be dismissed as benign, although baseline magnification views may be helpful. The positive predictive value (PPV) of amorphous calcifications is reported to be approximately 20% ([Table 2](#)). Therefore, calcifications of this morphology appropriately should be placed into BI-RADS® assessment category 4B (PPV range > 10% to ≤ 50%). (See [the Guidance chapter](#) for a discussion of the optional use of subcategories of assessment category 4.)



Figure 79 – SUSPICIOUS MORPHOLOGY: AMORPHOUS. Grouped AMORPHOUS calcifications. Core biopsy: sclerosing adenosis.

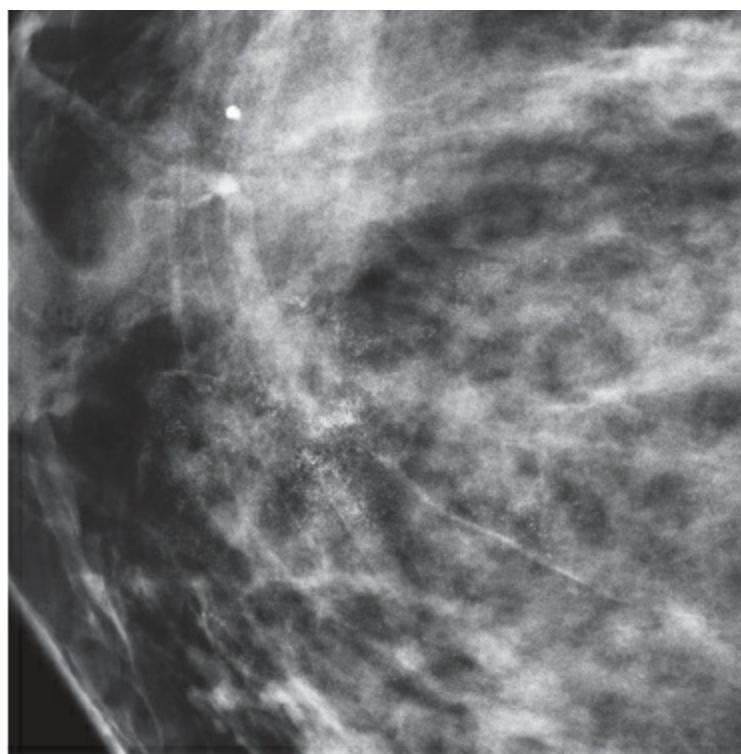


Figure 80 – SUSPICIOUS MORPHOLOGY: AMORPHOUS. Regional AMORPHOUS calcifications, spanning 3 cm. Core biopsy: calcifications in benign ducts.



Figure 81 – SUSPICIOUS MORPHOLOGY: AMORPHOUS. Linear AMORPHOUS calcifications. Note that although amorphous calcification morphology is reported to have a PPV of approximately 20% (category 4B assessment), linear distribution is reported to have a much higher PPV of approximately 60% ([Table 3](#), see page 71). Therefore, these calcifications should be assessed as category 4C (PPV range > 50% to < 95%). Core biopsy: calcifications in benign ducts.



Figure 82 – SUSPICIOUS MORPHOLOGY: AMORPHOUS.
Segmental AMORPHOUS calcifications. As occurs frequently, more than one suspicious morphology is visible, in this case, some of the calcifications are fine pleomorphic. Note that although amorphous calcification morphology is reported to have a PPV of approximately 20% (category 4B assessment), segmental distribution is reported to have a much higher PPV of approximately 6.2% (Table 3, see page 71). Therefore, these calcifications should be assessed as category 4C (PPV range > 50% to < 95%). Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

2. SUSPICIOUS MORPHOLOGY

b. Coarse Heterogeneous (see Guidance chapter)

These are irregular, conspicuous calcifications that are generally between 0.5 mm and 1 mm and tend to coalesce, but are smaller than dystrophic calcifications. They may be associated with malignancy, but more frequently are present in a fibroadenoma, or in areas of fibrosis, or trauma representing evolving dystrophic calcifications. Numerous bilateral groups of coarse heterogeneous calcifications usually may be dismissed as benign, although baseline magnification views may be helpful. However, a single group of coarse heterogeneous calcifications has a positive predictive value of slightly less than 15% (Table 2); therefore, this finding should be placed in BI-RADS® assessment category 4B (PPV range > 10% to ≤ 50%).

(See the Guidance chapter for a discussion of the optional use of subcategories of assessment category 4.)

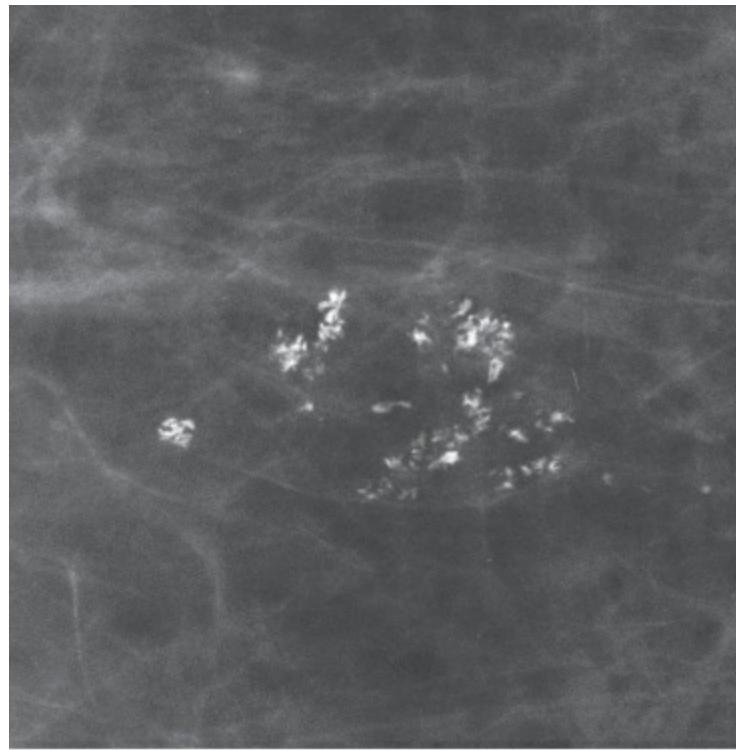


Figure 83 – SUSPICIOUS MORPHOLOGY: COARSE HETEROGENEOUS. Grouped COARSE HETEROGENEOUS calcifications. Core biopsy: fibroadenomatoid change.

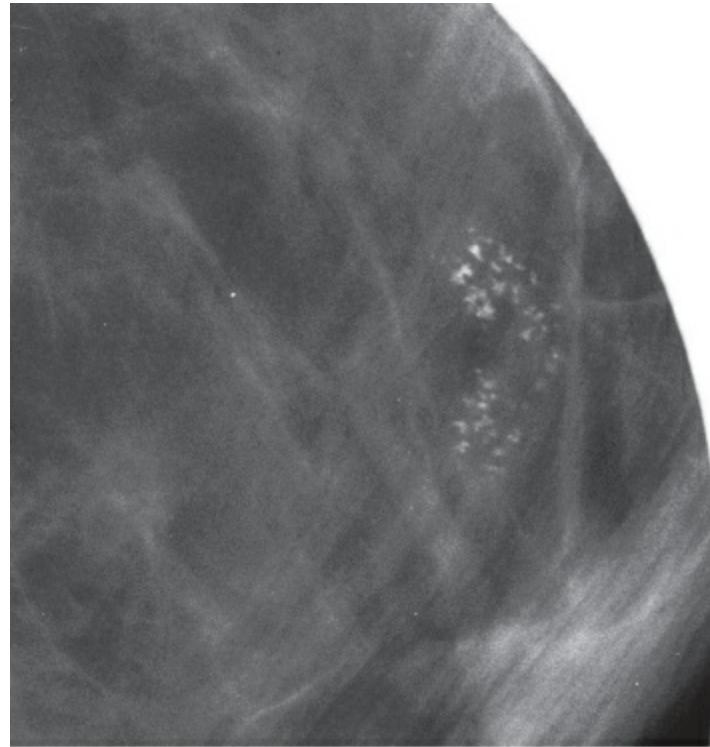


Figure 84 – SUSPICIOUS MORPHOLOGY: COARSE HETEROGENEOUS. Grouped COARSE HETEROGENEOUS calcifications. Core biopsy: fibrosis.

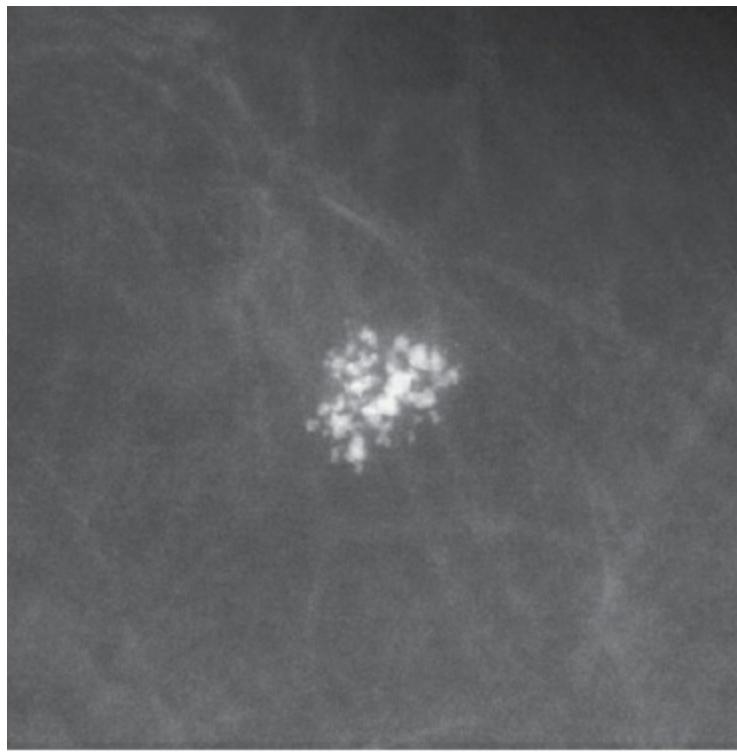


Figure 85 – SUSPICIOUS MORPHOLOGY: COARSE HETEROGENEOUS. Grouped COARSE HETEROGENEOUS calcifications. Core biopsy: fibroadenoma.

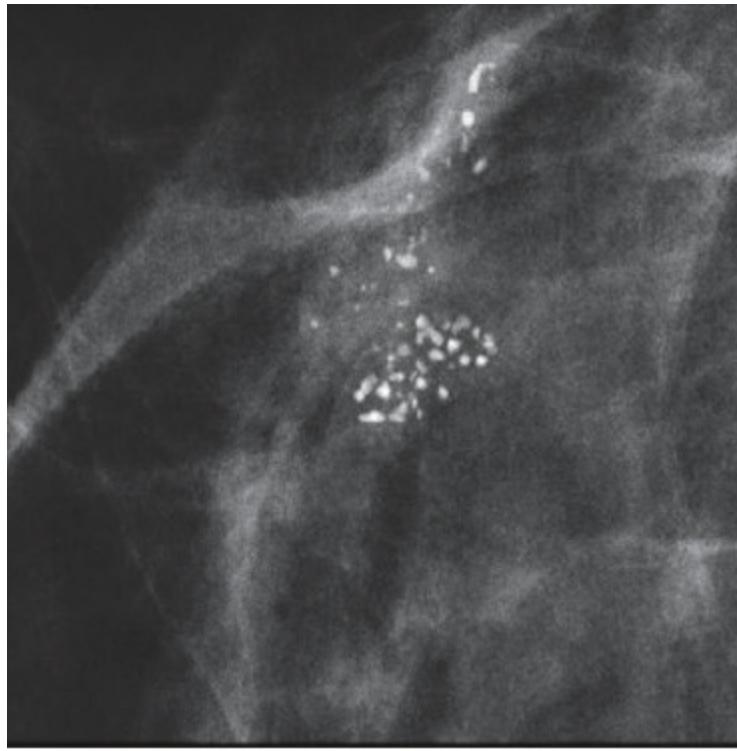


Figure 86 – SUSPICIOUS MORPHOLOGY: COARSE HETEROGENEOUS. Grouped COARSE HETEROGENEOUS calcifications. Core biopsy: ductal carcinoma in situ.

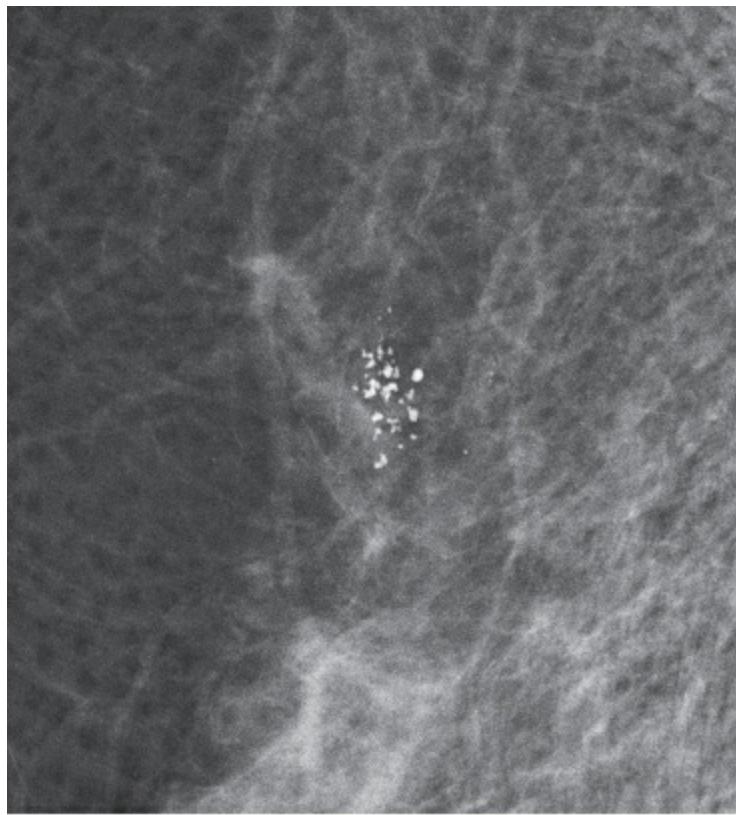


Figure 87 – SUSPICIOUS MORPHOLOGY: COARSE HETEROGENEOUS. Grouped COARSE HETEROGENEOUS calcifications. Core biopsy: fat necrosis.

B. CALCIFICATIONS

2. SUSPICIOUS MORPHOLOGY

c. Fine Pleomorphic (see Guidance chapter)

These calcifications are usually more conspicuous than amorphous forms and are seen to have discrete shapes. These irregular calcifications are distinguished from fine linear and fine-linear branching forms by the absence of fine-linear particles. Fine pleomorphic calcifications vary in size and shape and are usually < 0.5 mm in diameter. They have a somewhat higher PPV for malignancy (29%) than amorphous or coarse heterogeneous calcifications ([Table 2](#)), but also should be placed in BI-RADS® assessment category 4B (PPV range > 10% to ≤ 50%). (See the [Guidance chapter](#) for a discussion of the optional use of subcategories of assessment category 4.)

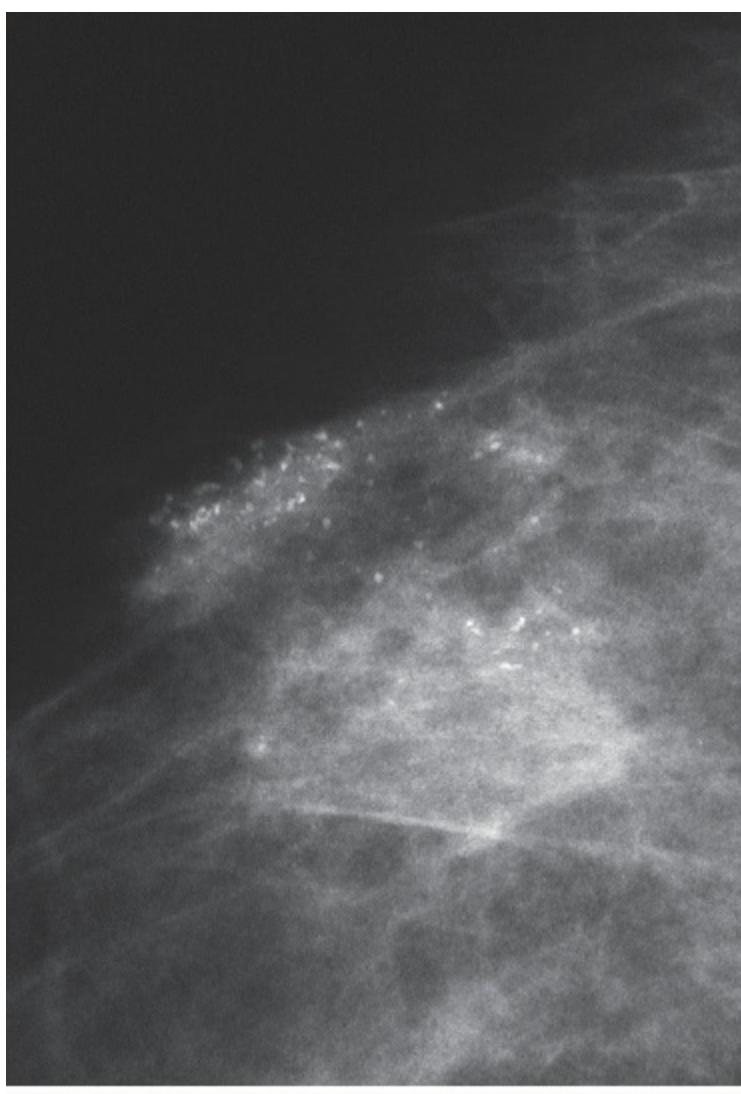


Figure 88 – SUSPICIOUS MORPHOLOGY: FINE PLEOMORPHIC.
Grouped FINE PLEOMORPHIC calcifications. Core biopsy:
calcifications in benign ducts.

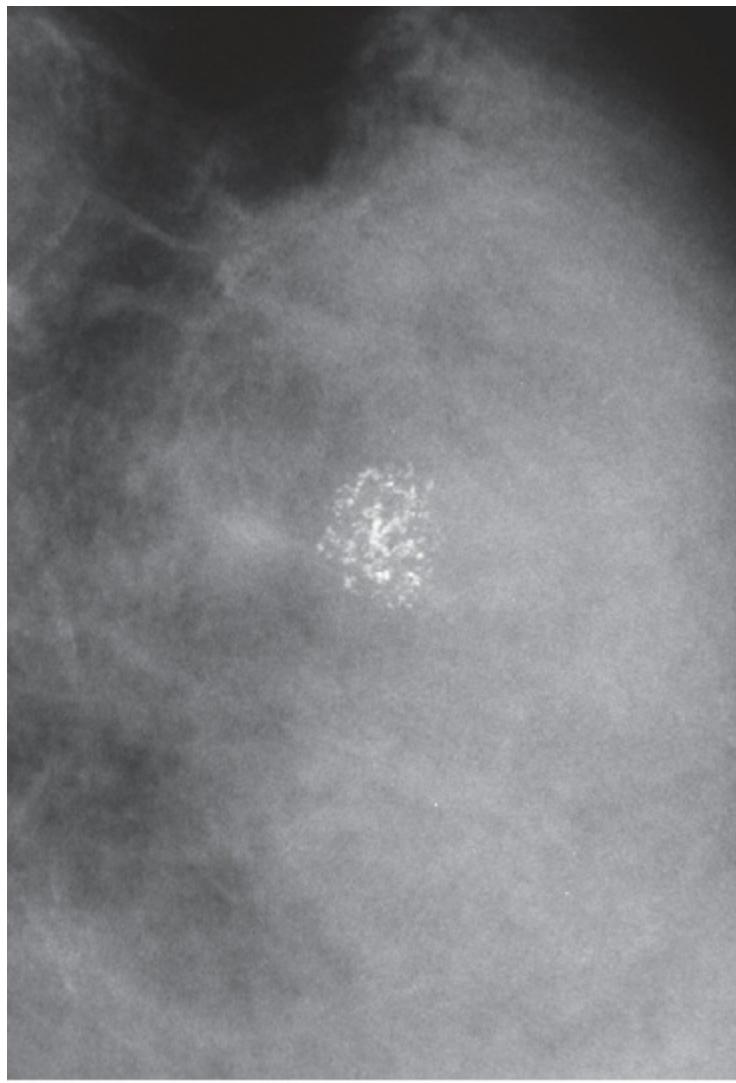


Figure 89 – SUSPICIOUS MORPHOLOGY: FINE PLEOMORPHIC.
Grouped FINE PLEOMORPHIC calcifications. Core biopsy:
sclerosing adenosis.

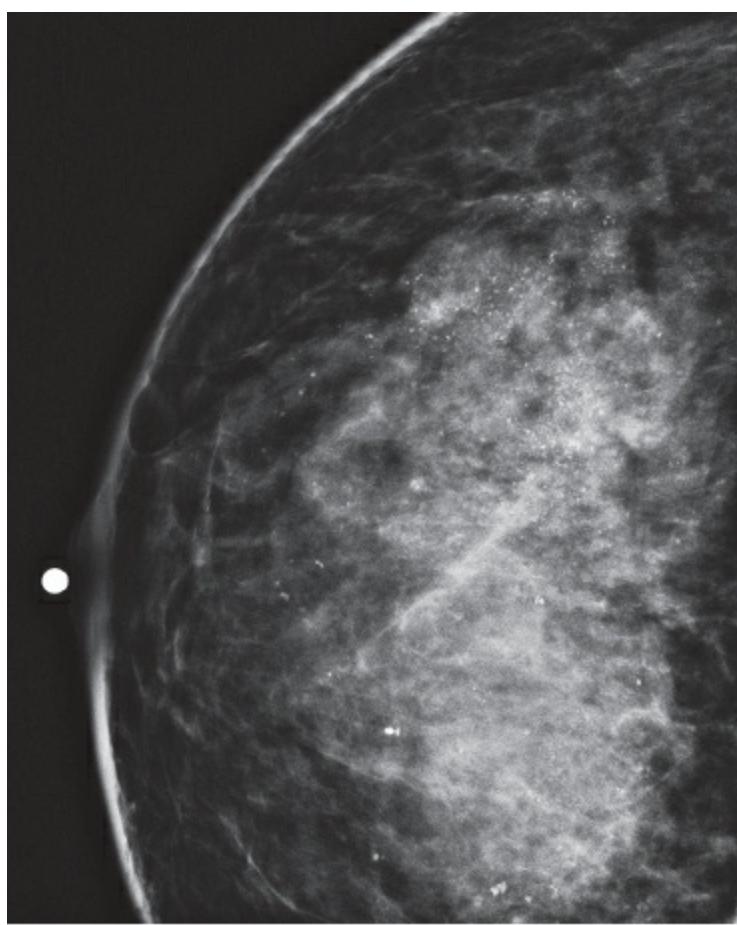


Figure 90 – SUSPICIOUS MORPHOLOGY: FINE PLEOMORPHIC.
Regional FINE PLEOMORPHIC calcifications. Core biopsy: ductal carcinoma in situ.

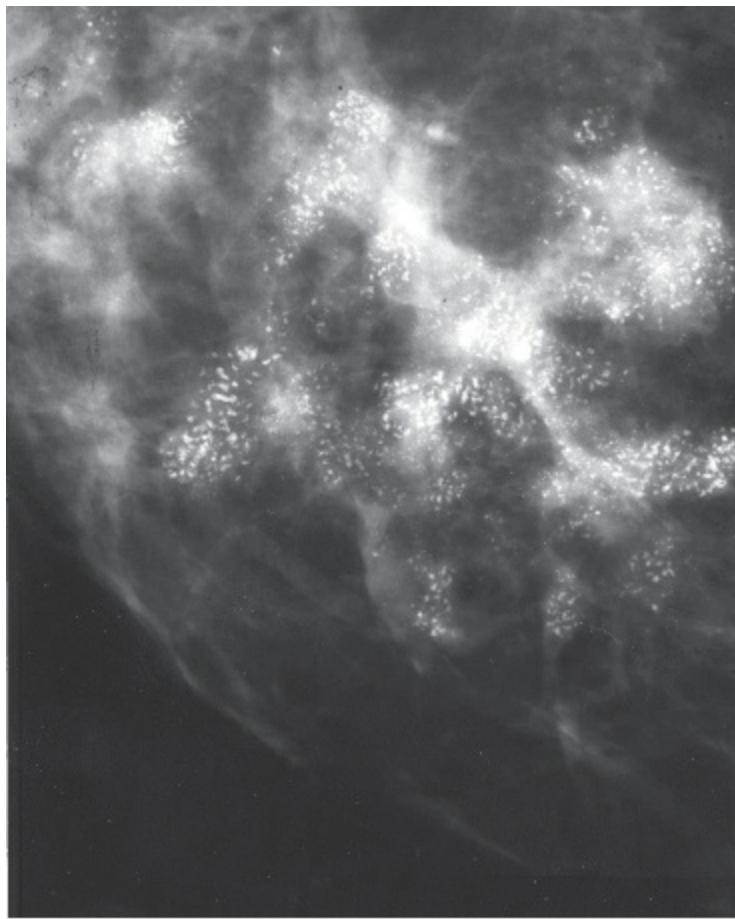


Figure 91 – SUSPICIOUS MORPHOLOGY: FINE PLEOMORPHIC.
Segmental FINE PLEOMORPHIC calcifications. Note that although fine pleomorphic calcification morphology is reported to have a PPV of approximately 30% (category 4B assessment), segmental distribution is reported to have a much higher PPV of approximately 60% ([Table 3](#), see page 71). Therefore, these calcifications should be assessed as category 4C (PPV range > 50% to < 95%). Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

2. SUSPICIOUS MORPHOLOGY

d. Fine Linear or Fine-Linear Branching (see Guidance chapter)

These are thin, linear, irregular calcifications, which may be discontinuous and which are < 0.5 mm in caliber. Occasionally, branching forms may be seen. Their appearance suggests filling of the lumen of a duct or ducts involved irregularly by breast cancer. Among the suspicious calcifications, fine linear and fine-linear branching calcifications have the highest PPV (70%) ([Table 2](#)). Therefore, these calcifications should be placed in BI-RADS® assessment category 4C (PPV range > 50% to < 95%) regardless of their distribution. (See the [Guidance chapter](#) for a discussion of the optional use of subcategories of assessment category 4.)

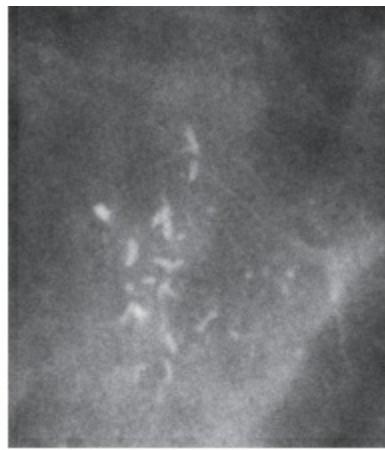


Figure 92 – SUSPICIOUS MORPHOLOGY: FINE LINEAR or FINE-LINEAR BRANCHING. Grouped FINE LINEAR calcifications, a few of which appear to be FINE-LINEAR BRANCHING calcifications. Core biopsy: fat necrosis.

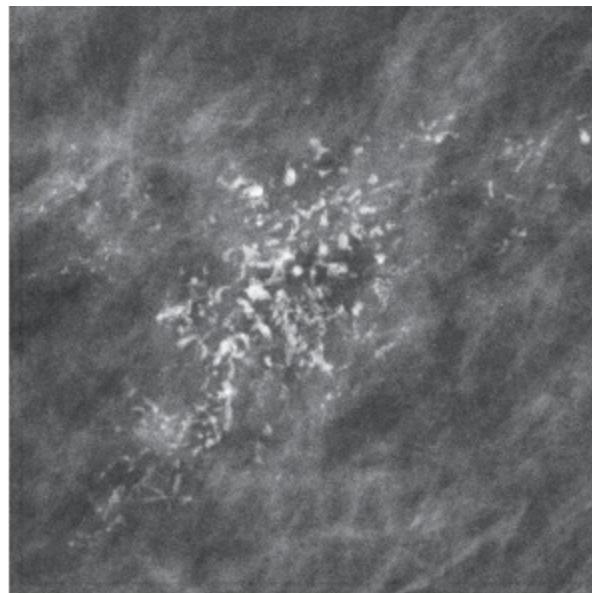


Figure 93 – SUSPICIOUS MORPHOLOGY: FINE LINEAR or FINE-LINEAR BRANCHING. Regional FINE LINEAR calcifications, a few of which appear to be FINE-LINEAR BRANCHING calcifications. Core biopsy: ductal carcinoma in situ.

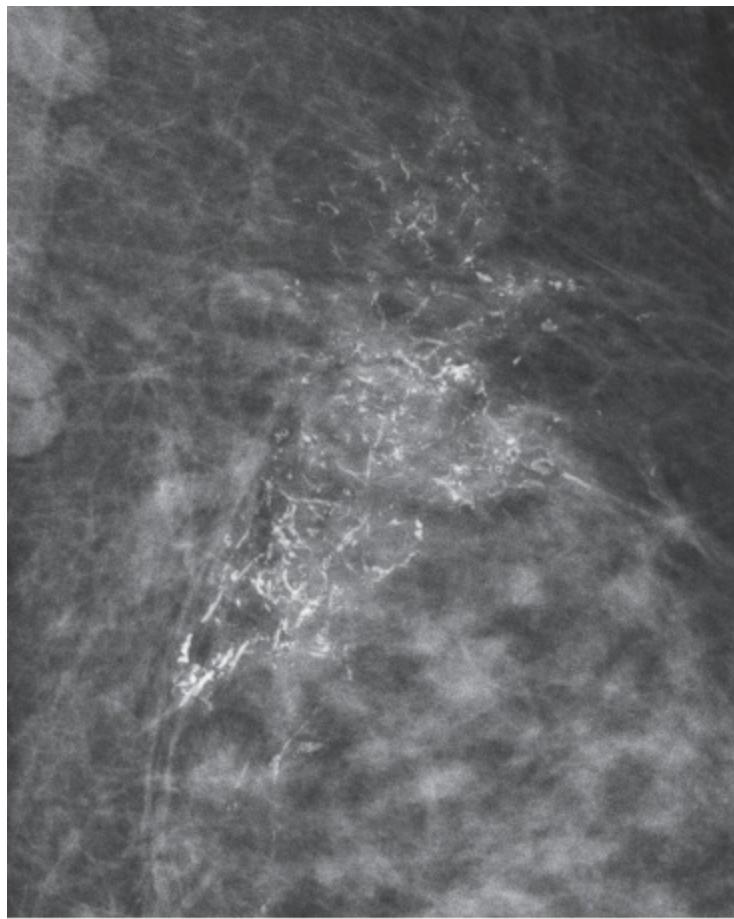


Figure 94 – SUSPICIOUS MORPHOLOGY: FINE LINEAR or FINE-LINEAR BRANCHING. Segmental FINE LINEAR calcifications, a few of which appear to be FINE-LINEAR BRANCHING calcifications. Core biopsy: ductal carcinoma in situ.

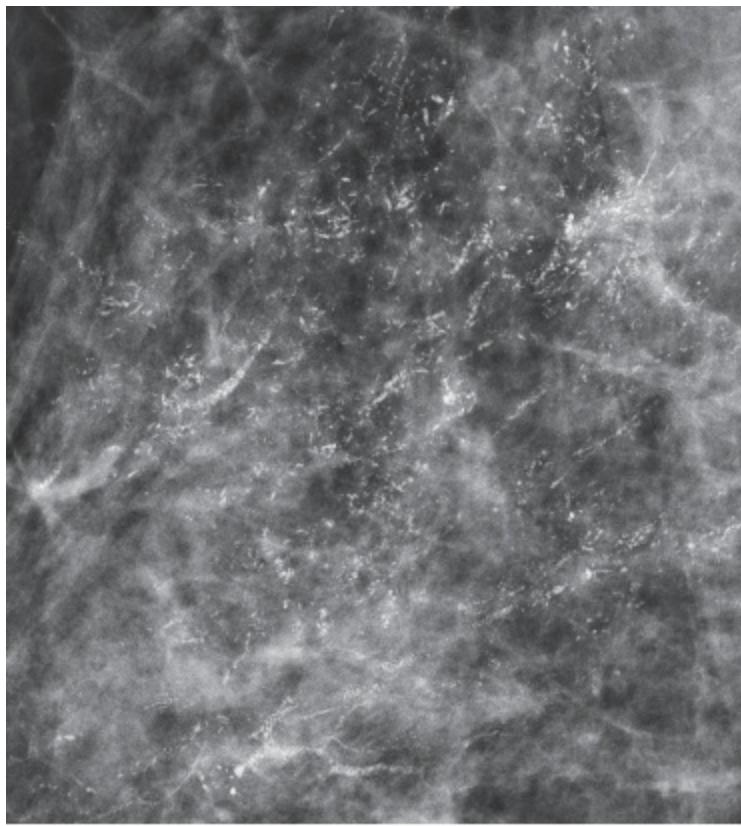


Figure 95 – SUSPICIOUS MORPHOLOGY: FINE LINEAR or FINE-LINEAR BRANCHING. Segmental FINE LINEAR calcifications. Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

3. DISTRIBUTION

These descriptors are used to indicate the arrangement of calcifications in the breast. Multiple similar groups may be described in the report when there is more than one group of calcifications that are similar in morphology and distribution. In evaluating the likelihood of malignancy for calcifications, distribution is at least as important as morphology. [Table 3](#) displays the results of several single-institution consecutive-case series involving suspicious mammographic calcifications classified by BI-RADS® distribution descriptors.

Table 3. Likelihood of Malignancy as a Function of BI-RADS® Descriptors of Calcification Distribution^a

Distribution Descriptor	Liberman et al. ¹	Burnside et al. ³	Bent et al. ⁴	Total
Diffuse	0/1 (0)	0/1 (0)	0/0 (0)	0/2 (0)
Regional	6/13 (46)	0/1 (0)	0/9 (0)	6/23 (26)
Grouped	93/254 (37)	14/76 (18)	19/81 (23)	126/411 (31)
Linear	13/19 (68)	8/11 (73)	14/28 (50)	35/58 (60)
Segmental	17/23 (74)	3/8 (38)	9/16 (56)	29/47 (62)

^a Data are presented as cancer cases/all cases biopsied, with percentage of cancer cases in parentheses.

B. CALCIFICATIONS

3. DISTRIBUTION

a. Diffuse (historically, "scattered")

These are calcifications that are distributed randomly throughout the breast. Punctate and amorphous calcifications in this distribution are almost always benign, especially if they are bilateral.

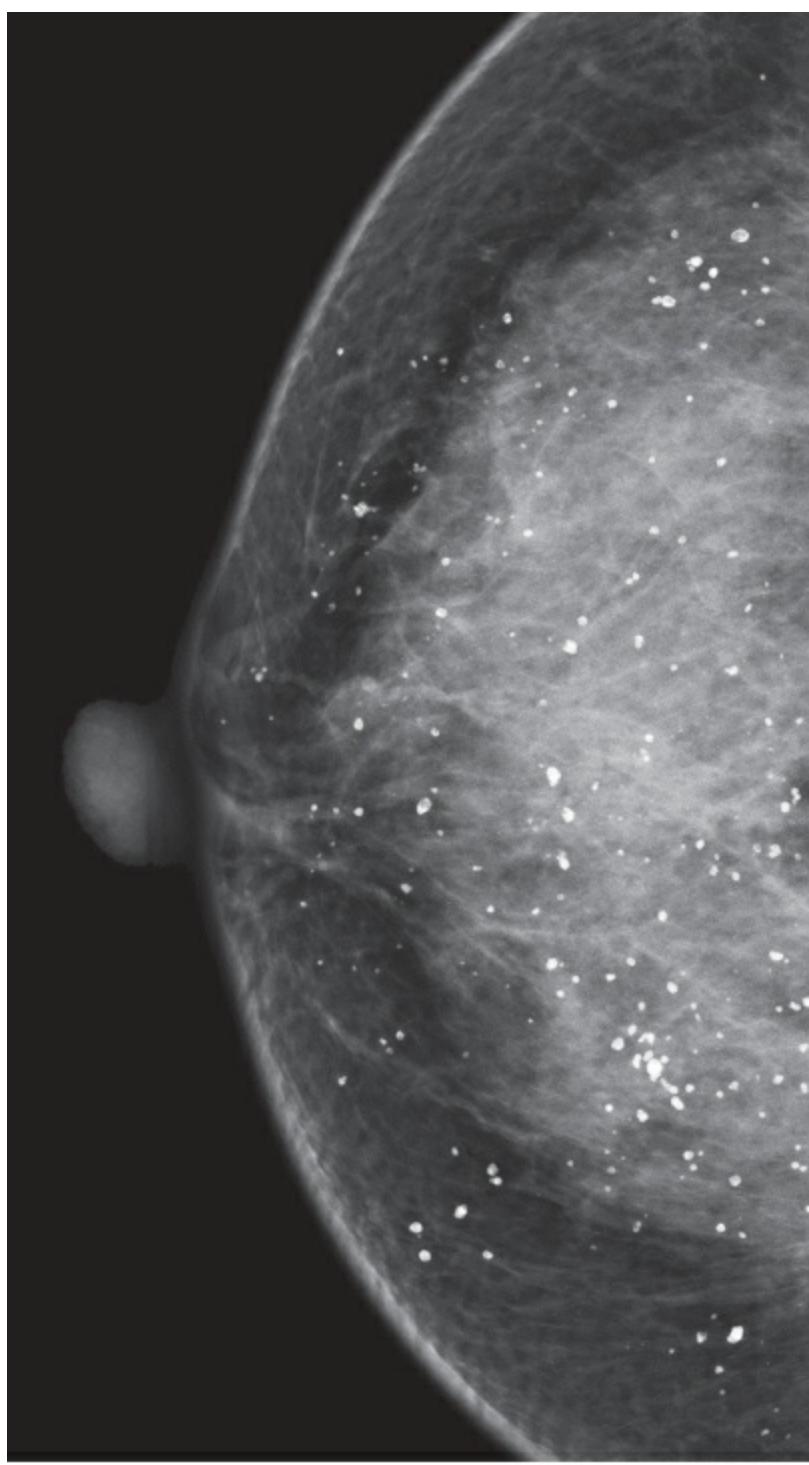


Figure 96 – DISTRIBUTION: DIFFUSE. DIFFUSE, primarily round calcifications. Although many of these numerous calcifications have radiolucent centers, not even one calcific particle projects over the skin surface, making it unlikely that these are skin calcifications. Similar diffuse calcifications were present in the contralateral breast. Multiplicity, bilaterality, diffuse distribution, and absence of suspicious morphology should prompt a benign assessment (category 2).

B. CALCIFICATIONS

3. DISTRIBUTION

b. Regional (see Guidance chapter)

This descriptor is used for numerous calcifications that occupy a large portion of breast tissue (> 2 cm in greatest dimension), not conforming to a duct distribution. Because this distribution may involve most of a quadrant or even more than a single quadrant, malignancy is less likely. However, overall evaluation of regional calcifications must include particle shape (morphology) as well as distribution.



Figure 97 – DISTRIBUTION: REGIONAL. REGIONAL round and punctate calcifications, as well as rim calcifications. This patient had a past history of seat belt injury to this breast. Presumptive diagnosis: fat necrosis.

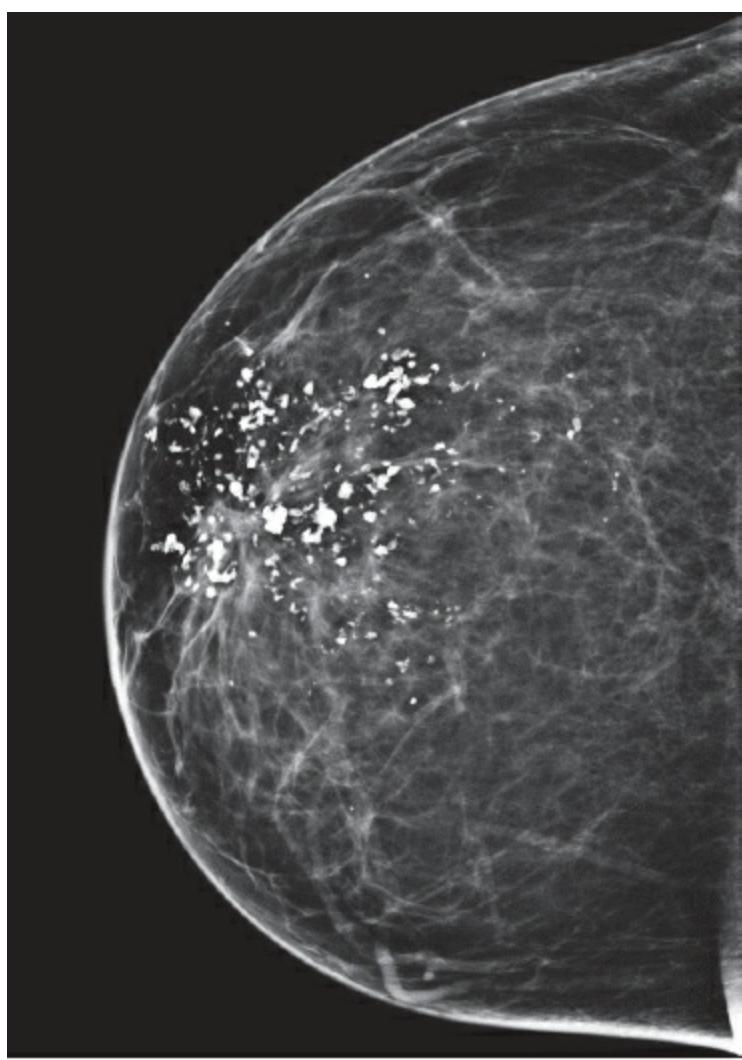


Figure 98 – DISTRIBUTION: REGIONAL. REGIONAL dystrophic calcifications. This patient had a past history of seat belt injury to this breast. Presumptive diagnosis: fat necrosis.

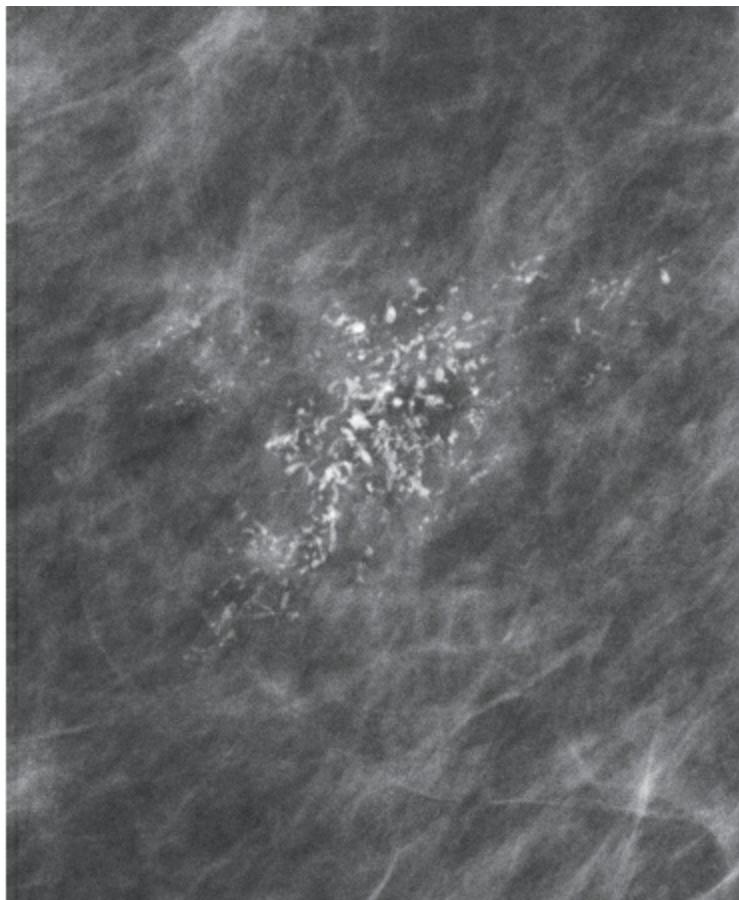


Figure 99 – DISTRIBUTION: REGIONAL. REGIONAL fine linear calcifications, a few of which appear to be fine-linear branching calcifications. Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

3. DISTRIBUTION

c. Grouped (historically, “clustered”) (see Guidance chapter)

This term should be used when relatively few calcifications occupy a small portion of breast tissue. The lower limit for use of this descriptor is usually when five calcifications are grouped within 1 cm of each other or when a definable pattern is identified. The upper limit for use of this descriptor is when larger numbers of calcifications are grouped within 2 cm of each other.

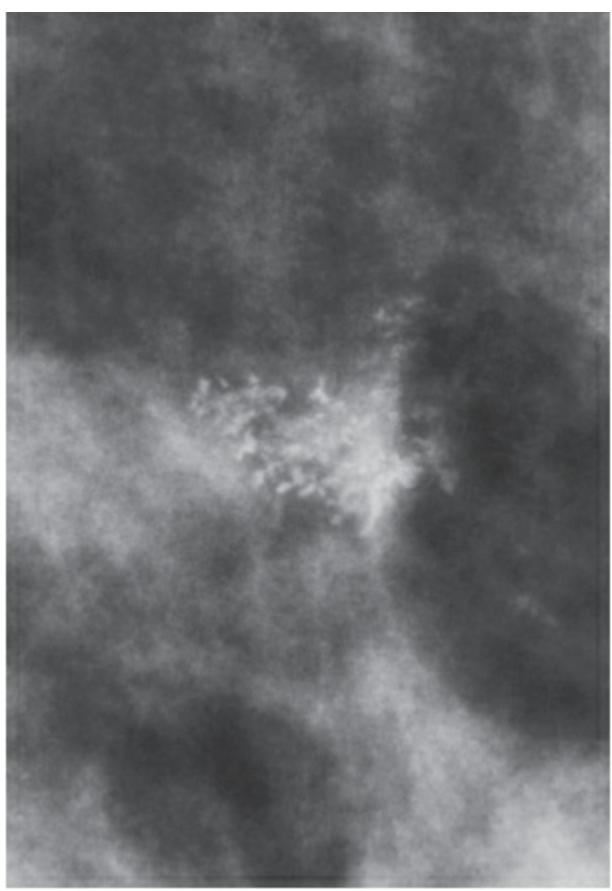


Figure 100 – DISTRIBUTION: GROUPED. GROUPED fine pleomorphic calcifications. Core biopsy: calcifications in benign ducts.

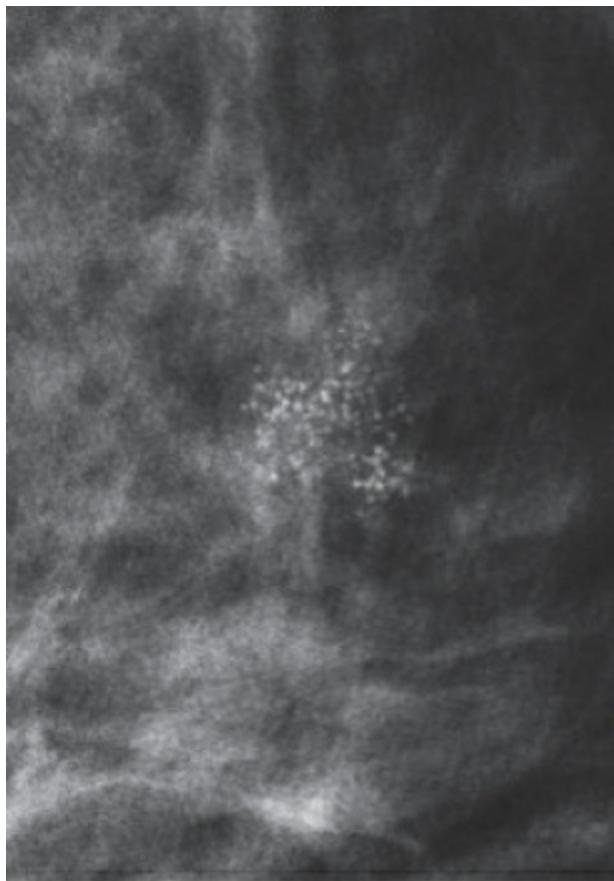


Figure 101 – DISTRIBUTION: GROUPED. GROUPED amorphous calcifications. Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

3. DISTRIBUTION

d. Linear

These are calcifications arrayed in a line. This distribution may elevate suspicion for malignancy, as it suggests deposits in a duct. Note that both vascular and large rod-like calcifications also are usually linear in distribution, but that these typically benign calcifications have a characteristically benign morphology.

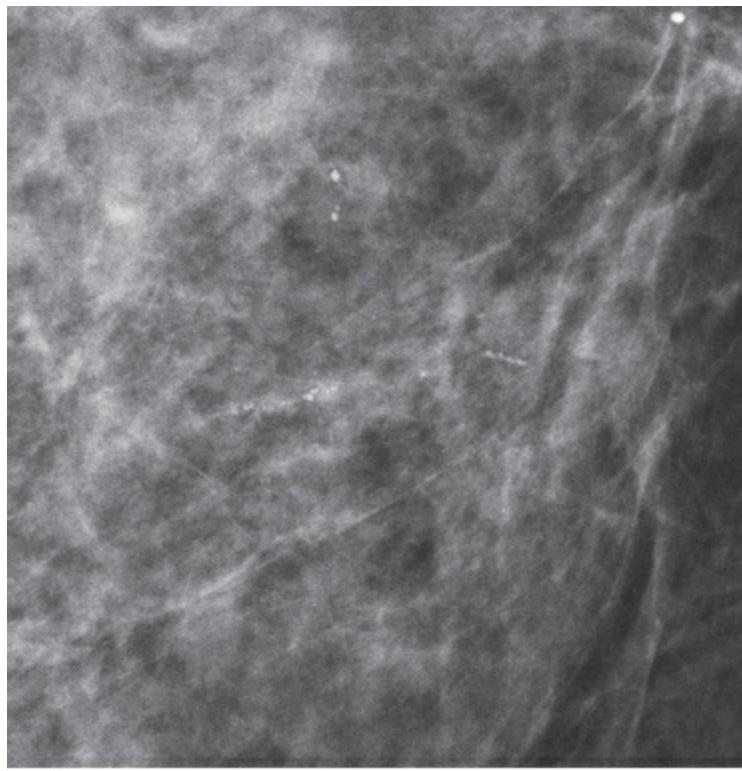


Figure 102 – DISTRIBUTION: LINEAR. LINEAR, amorphous calcifications. Core biopsy: atypical ductal hyperplasia; excisional biopsy: atypical ductal hyperplasia.

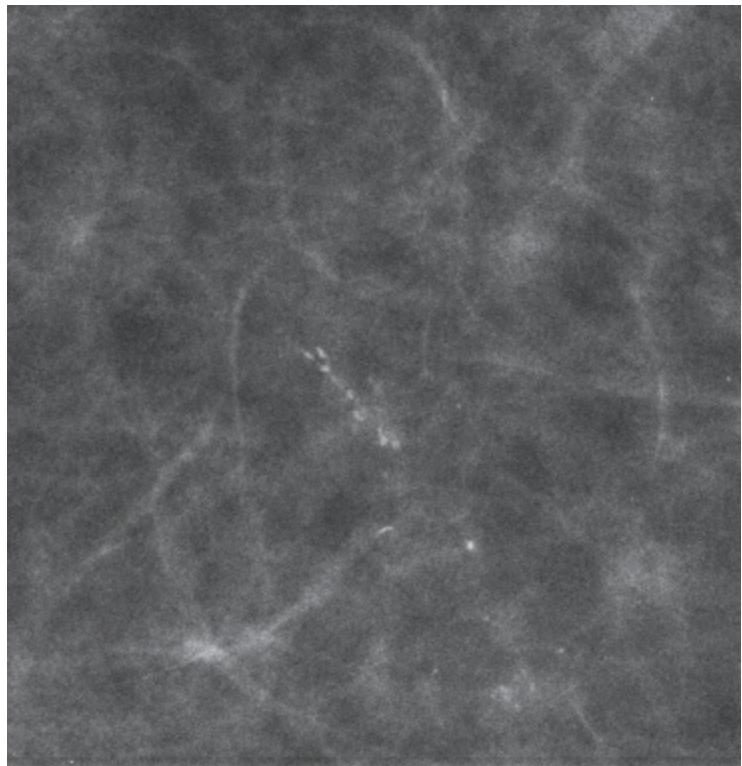


Figure 103 – DISTRIBUTION: LINEAR. LINEAR, fine pleomorphic calcifications. Core biopsy: sclerosing adenosis.

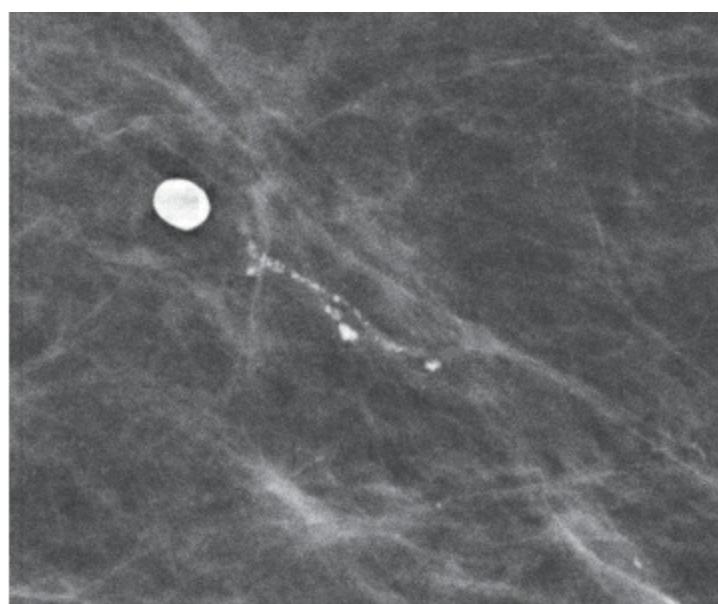


Figure 104 – DISTRIBUTION: LINEAR. LINEAR, fine pleomorphic calcifications. Core biopsy: ductal carcinoma in situ.

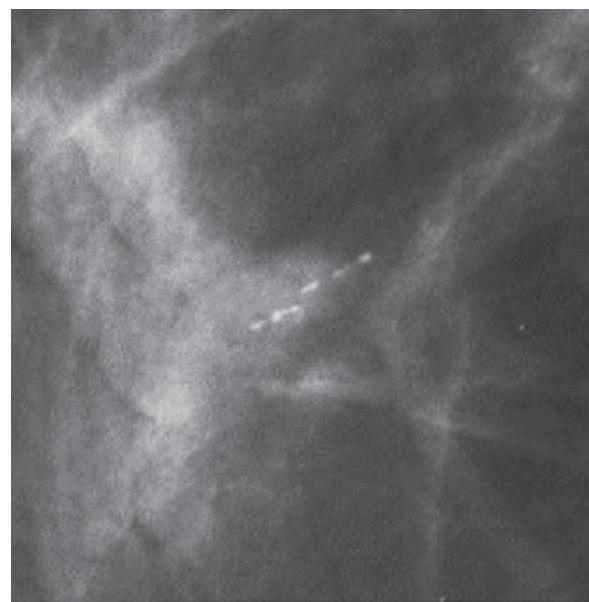


Figure 105 – DISTRIBUTION: LINEAR. LINEAR, fine linear calcifications. Core biopsy: ductal carcinoma in situ.

B. CALCIFICATIONS

3. DISTRIBUTION

e. Segmental

Calcifications in a segmental distribution are of concern because they suggest deposits in a duct or ducts and their branches, which raises the possibility of extensive or multifocal breast cancer in a lobe or segment of the breast. Although benign causes of segmental calcifications exist (e.g., large rod-like), the smooth, rod-like morphology and large size of benign calcifications distinguish them from finer,

more pleomorphic or heterogeneous malignant calcifications. A segmental distribution may elevate the degree of suspicion for calcifications such as punctate or amorphous forms.

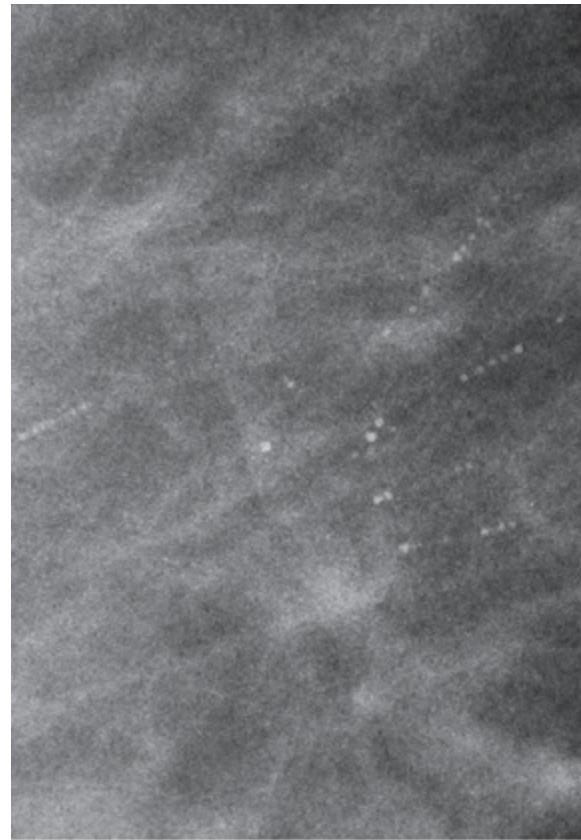


Figure 106 – DISTRIBUTION: SEGMENTAL.
SEGMENTAL round (punctate) calcifications.
Although punctate morphology usually prompts a benign or probably benign assessment, the segmental distribution in this case prompts a suspicious assessment instead. Core biopsy: ductal carcinoma in situ. Previously published as Figure 6 (p. 776) in Leung JWT, Sickles EA. The probably benign assessment. *Radiol Clin North Am* 2007; 45[5]:773–789.

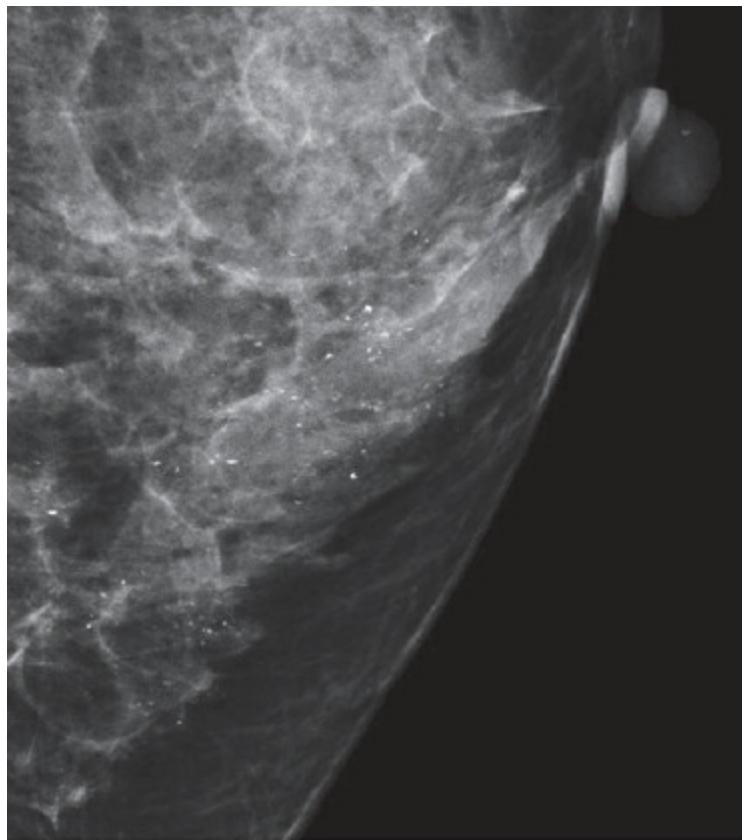


Figure 107 – DISTRIBUTION: SEGMENTAL. SEGMENTAL fine pleomorphic calcifications. Core biopsy: atypical ductal hyperplasia; excisional biopsy: atypical ductal hyperplasia.



Figure 108 – DISTRIBUTION: SEGMENTAL. SEGMENTAL fine linear calcifications. Core biopsy: ductal carcinoma in situ.

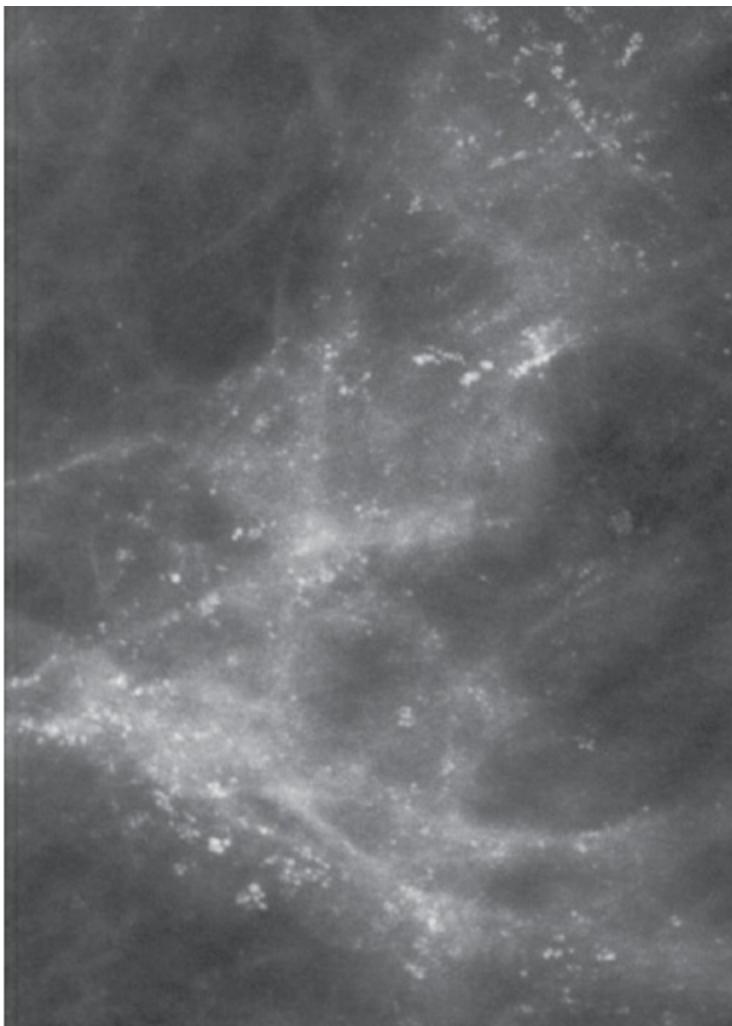


Figure 109 – DISTRIBUTION: SEGMENTAL. SEGMENTAL fine pleomorphic calcifications, occupying a wedge-shaped area with the apex of the wedge pointing toward the nipple. Core biopsy: ductal carcinoma in situ.

REFERENCES

1. Liberman L, Abramson AF, Squires FB, Glassman JR, Morris EA, Dershaw DD. [The Breast Imaging Reporting and Data System: positive predictive value of mammographic features and final assessment categories](#). *AJR* 1998; 171(1):35–40
2. Berg WA, Arnoldus CL, Teferra E, Bhargavan M. [Biopsy of amorphous breast calcifications: pathologic outcomes and yield at stereotactic biopsy](#). *Radiology* 2001; 221(2):495–503
3. Burnside ES, Ochsner JE, Fowler KJ, et al. [Use of microcalcification descriptors in BI-RADS 4th edition to stratify risk of malignancy](#). *Radiology* 2007; 242(2):388–395
4. Bent CK, Bassett LW, D'Orsi CJ, Sayre JW. [The positive predictive value of BI-RADS microcalcification descriptors and final assessment categories](#). *AJR* 2010; 194(5):1378–1383

C. ARCHITECTURAL DISTORTION

The parenchyma is distorted with no definite mass visible. For mammography, this includes thin straight lines or spiculations radiating from a point, and focal retraction, distortion, or straightening at the anterior or posterior edge of the parenchyma. Architectural distortion may also be associated with asymmetry or calcifications. In the

absence of appropriate history of trauma or surgery, architectural distortion is suspicious for malignancy or radial scar, and tissue diagnosis is appropriate.

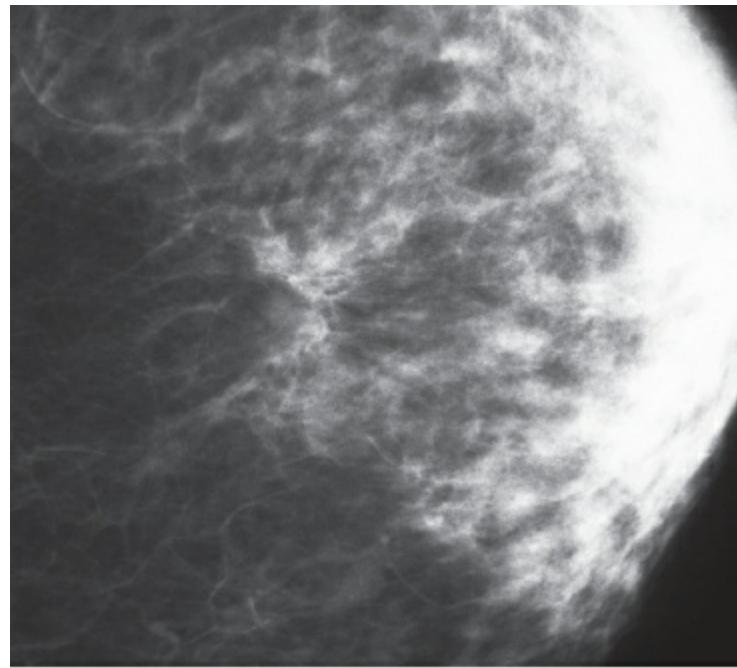


Figure 110 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with primarily fatty tissue at the point of origin.
Core biopsy: scar tissue.

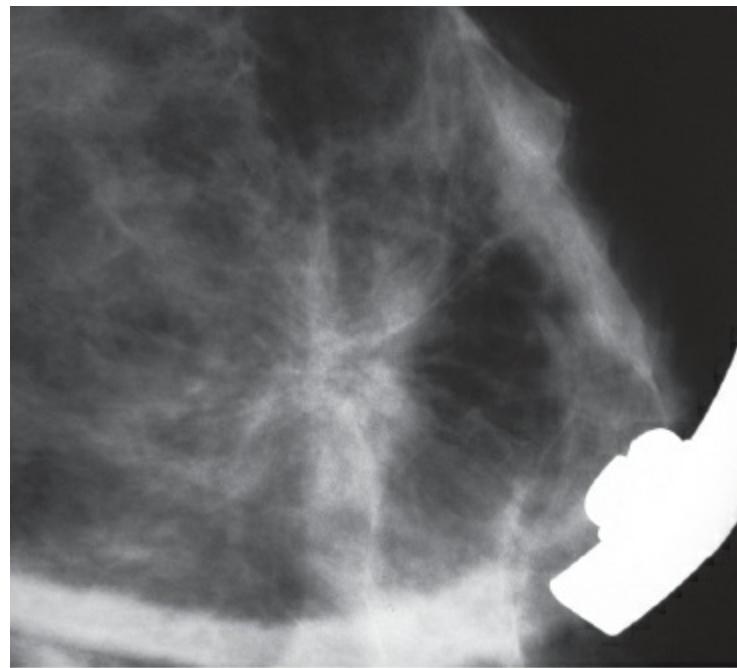


Figure 111 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with radiolucency at the point of origin. There was no history of previous surgery or trauma at this location.
Core biopsy and excisional biopsy: radial scar.

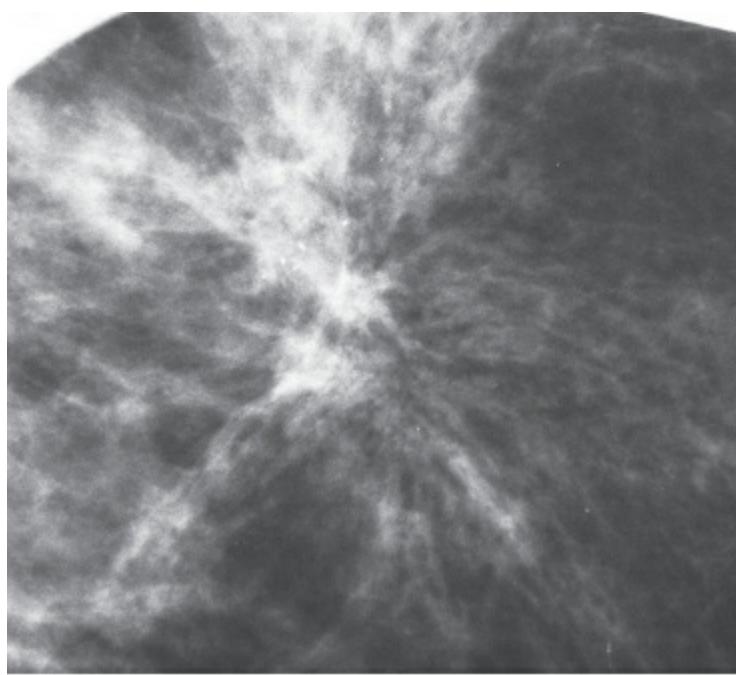


Figure 112 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with primarily fatty tissue at the point of origin. Note a few associated punctate calcifications. Core biopsy: radial scar and invasive lobular carcinoma.



Figure 113 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with primarily fatty tissue at the point of origin. Core biopsy: invasive ductal carcinoma.

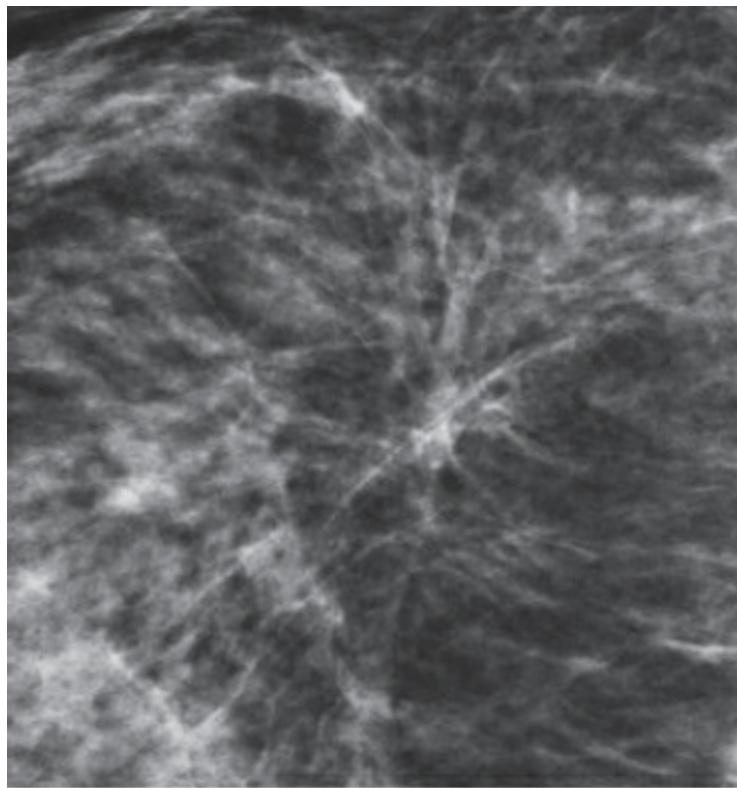


Figure 114 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with primarily fatty tissue at the point of origin.
Core biopsy: radial scar without atypia.

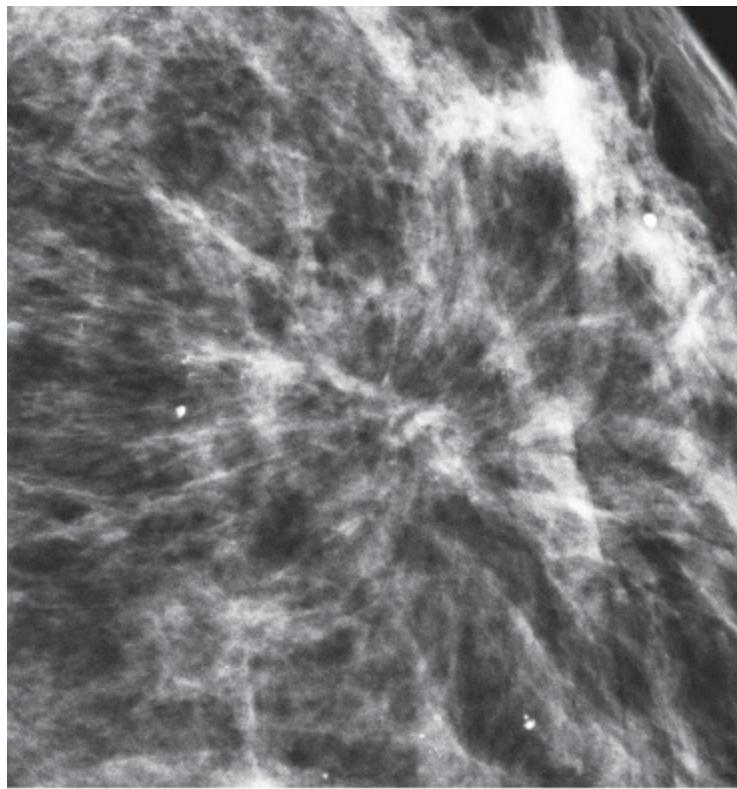


Figure 115 – ARCHITECTURAL DISTORTION. Manifested by thin radiating lines with primarily fatty tissue at the point of origin.
Core biopsy: invasive lobular carcinoma.

D. ASYMMETRIES (Guidance chapter)

The several types of asymmetry involve a spectrum of mammographic findings that represent unilateral deposits of fibroglandular tissue not conforming to the definition of a radiodense mass. The asymmetry, unlike a mass, is visible on only one mammographic projection. The other three types of asymmetry, although visible on more than one projection, have concave-outward borders and usually are seen to be interspersed with fat, whereas a radiodense mass displays completely or partially convex-outward borders and appears to be denser in the center than at the periphery.

D. ASYMMETRIES

1. ASYMMETRY ([Guidance chapter](#))

This is an area of fibroglandular-density tissue that is visible on only one mammographic projection. Most such findings represent summation artifacts, a superimposition of normal breast structures, whereas those confirmed to be real lesions (by subsequent demonstration on at least one more projection) may represent one of the other types of asymmetry or a mass.

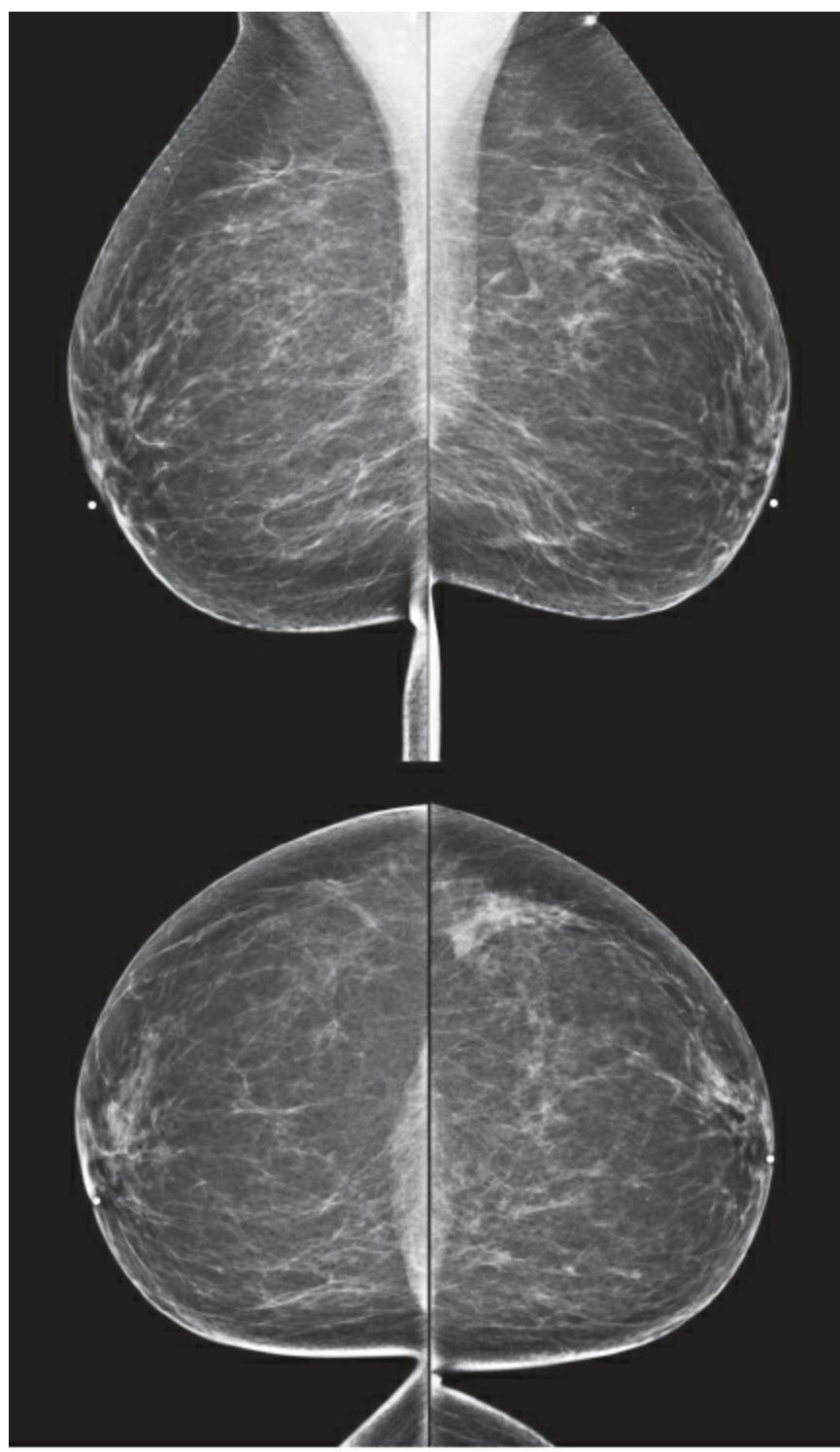


Figure 116 – ASYMMETRY. Note the asymmetric area of dense tissue in the lateral aspect of the left breast seen only on the CC view. Long-term stability was observed by comparison with previous examinations. Presumptive diagnosis: benign asymmetric fibroglandular-density breast tissue.

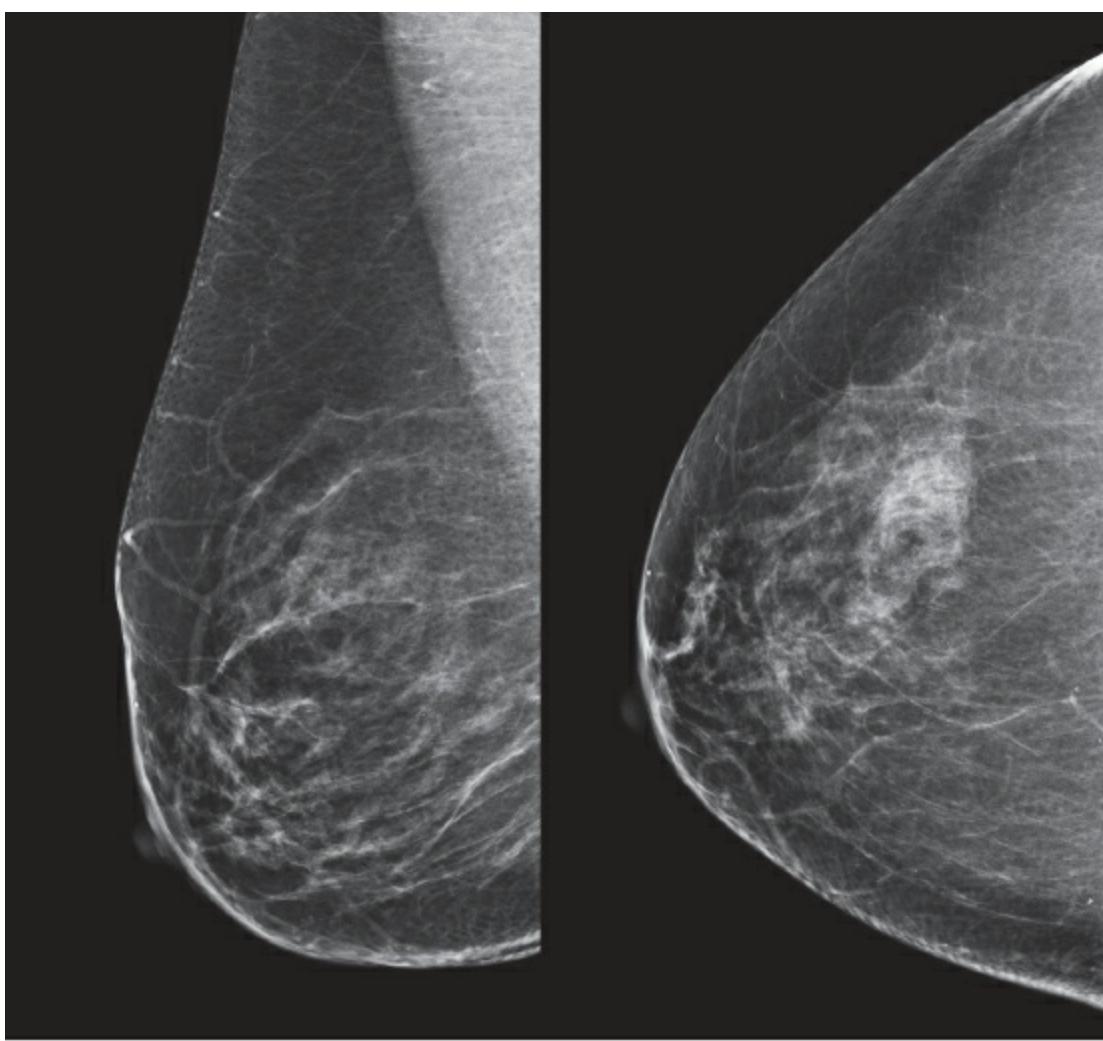


Figure 117 – ASYMMETRY. Note the area of dense tissue in the lateral aspect of the right breast seen only on the CC view. Outcome: presumed to represent summation artifact. No asymmetry was visible at subsequent screening examination 1 year later.

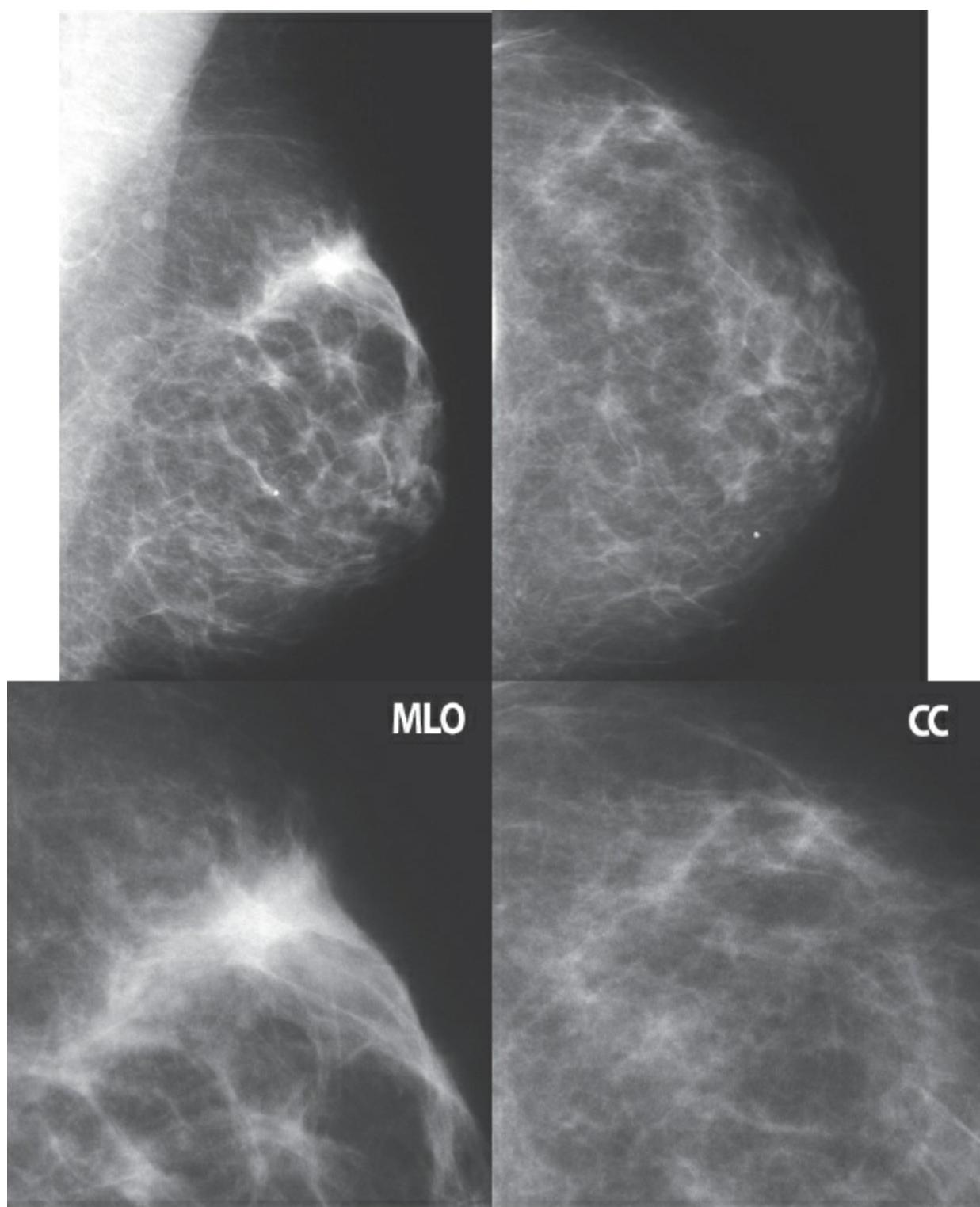
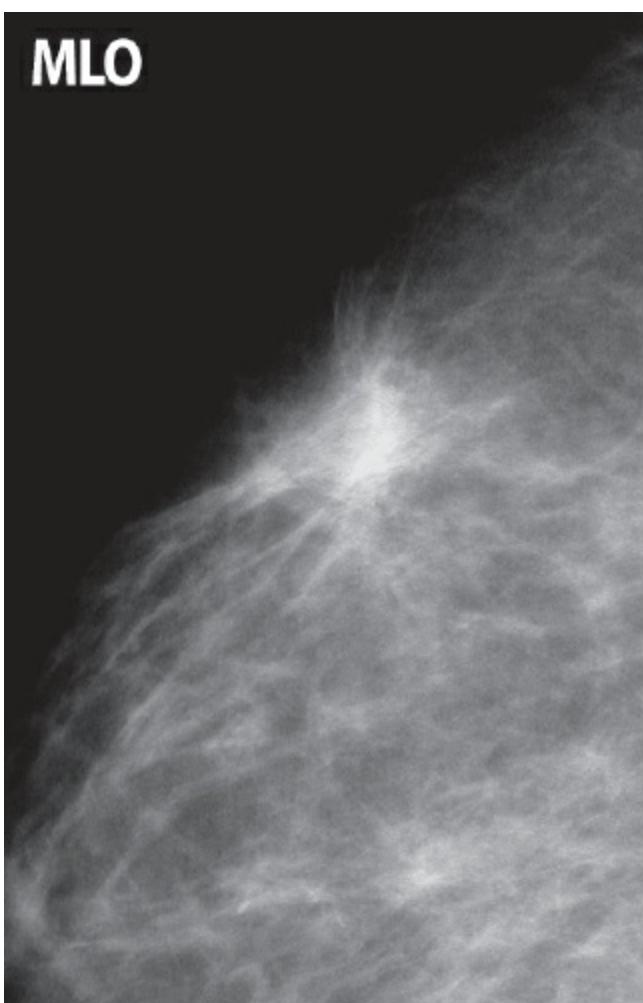


Figure 118 – ASYMMETRY. Note the area of dense tissue in the superior aspect of the left breast seen only on the MLO view. Outcome: summation artifact. No asymmetry was visible on a repeat MLO view obtained at recall imaging. Previously published as Figure 2 (p. 767) in Sickles EA. The spectrum of breast asymmetries: imaging features, workup, management. *Radiol Clin North Am* 2007; 45[5]:765–771.

MLO



CC

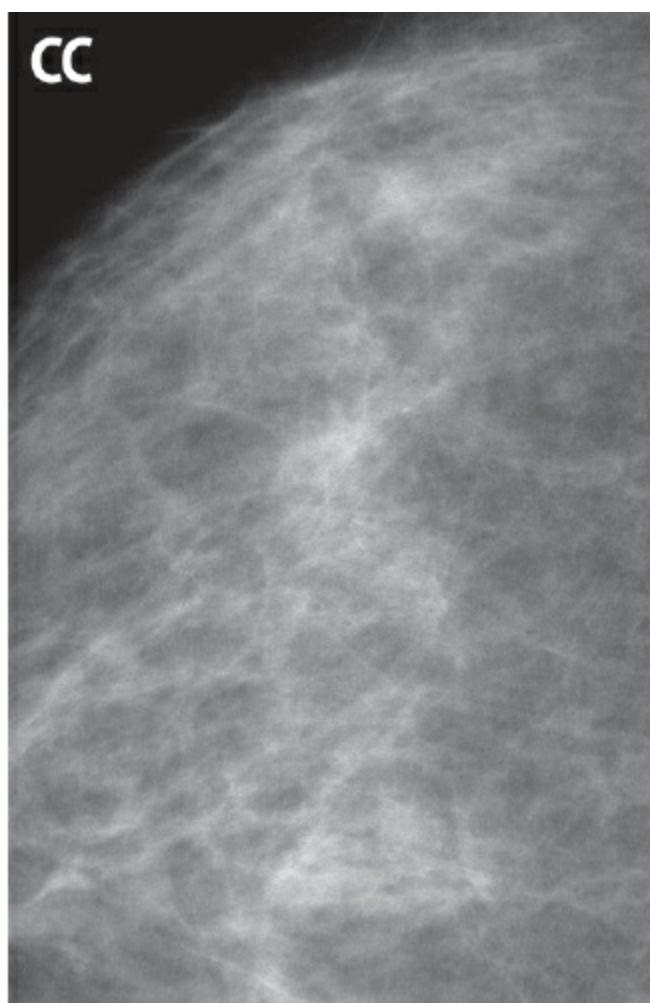


Figure 119 – ASYMMETRY. Note the area of dense tissue in the superior aspect of the right breast seen only on the MLO view. Outcome: presumed to represent summation artifact. No asymmetry was visible at subsequent screening examination 1 year later.

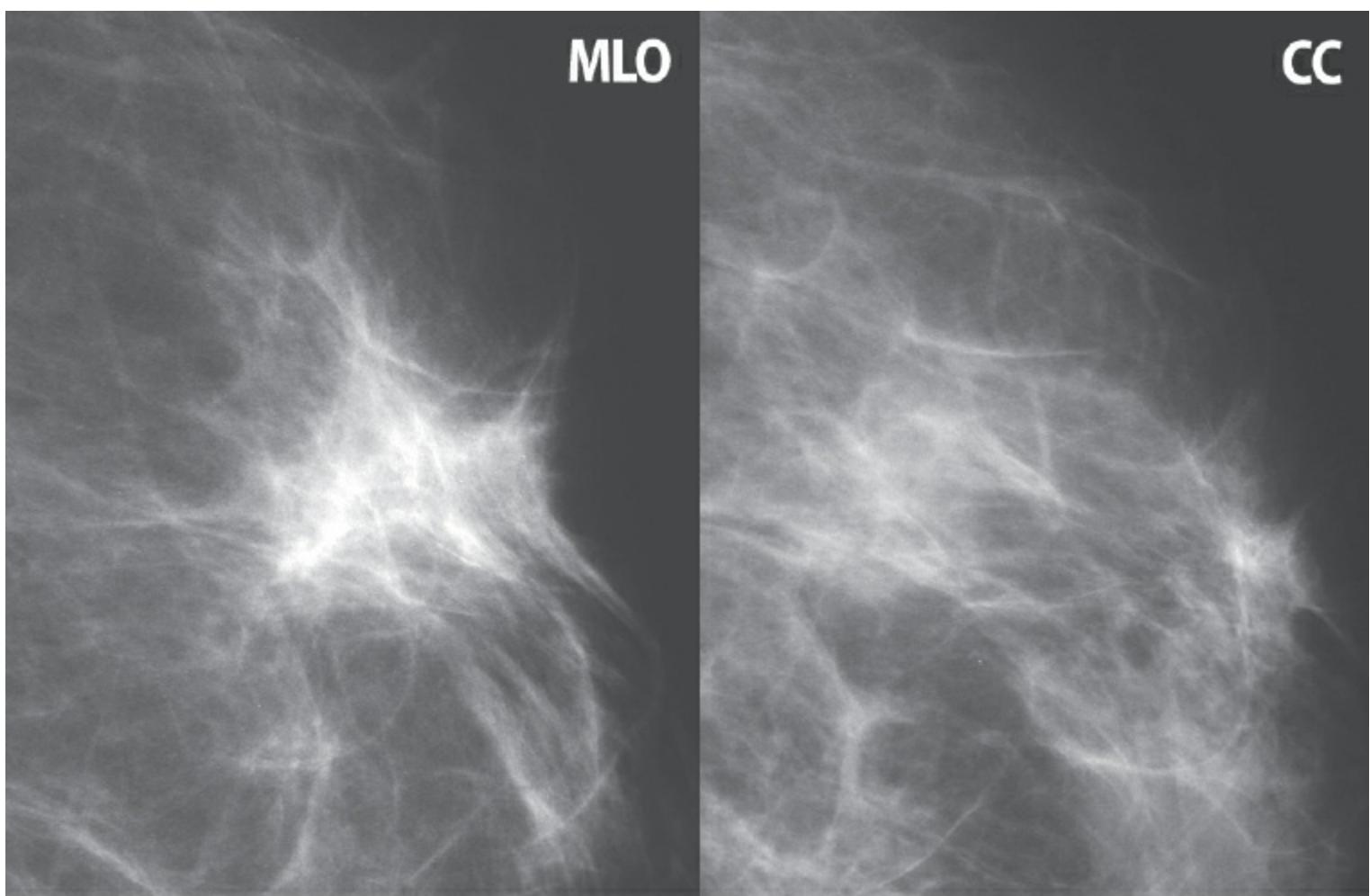


Figure 120 – ASYMMETRY. Note the area of dense tissue in the superior aspect of the left breast seen only on the MLO view. Outcome: presumed to represent summation artifact. No asymmetry was visible at subsequent screening examination 1 year later.

REFERENCES

1. Sickles EA. [Findings at mammographic screening on only one standard projection: outcomes analysis](#). *Radiology* 1998; 208(2):471–475.

Abstract:

Purpose:

To determine the radiographic and clinical outcomes of findings seen at mammographic screening on only one standard projection.

Materials and Methods:

To identify prospectively marked benign-appearing and abnormal findings that were seen on only one standard projection, 68,836 consecutive 2-view mammographic screening studies were reviewed. Subsequent outcomes analysis included determination of the frequency of occurrence, mammographic features, workup performed, and final imaging assessment. For imaging findings that prompted tissue sampling, histopathologic diagnosis was recorded. To identify breast cancers among the remaining findings, screening cases were linked with a regional tumor registry.

Results:

Of the 61,273 screening studies available for review, 2,023 (3.3%) involved prospectively identified findings seen on only one standard projection. One thousand eighty-six (53.7%) studies with 1-view-only findings were judged to represent superimposition of normal breast structures (summation artifact) simply from the standard projections obtained at screening; findings in an additional 587 (29%) studies were characterized as representing superimposition of normal structures after

recall for further diagnostic imaging. None of these 1,673 cases was subsequently found to be cancer. Cancers were identified in 36 one-view-only studies: 6 involved ductal carcinoma in situ; 18, invasive ductal carcinoma; and 12, invasive lobular carcinoma (a large percentage [33%], since only 10% of all cancers are invasive lobular carcinoma).

Conclusion:

Findings seen on only one standard projection are common among lesions identified at mammographic screening. More than 80% can be correctly assessed as representing superimposition of normal structures, either without or with the aid of additional imaging studies. Among those findings that truly are cancer, a disproportionately high percentage is invasive lobular carcinoma.

D. ASYMMETRIES

2. GLOBAL ASYMMETRY ([Guidance chapter](#))

Global asymmetry is judged relative to the corresponding area in the contralateral breast and represents a large amount of fibroglandular-density tissue over a substantial portion of the breast (at least one quadrant). There is no mass, distorted architecture, or associated suspicious calcifications. Global asymmetry usually represents a normal variant.

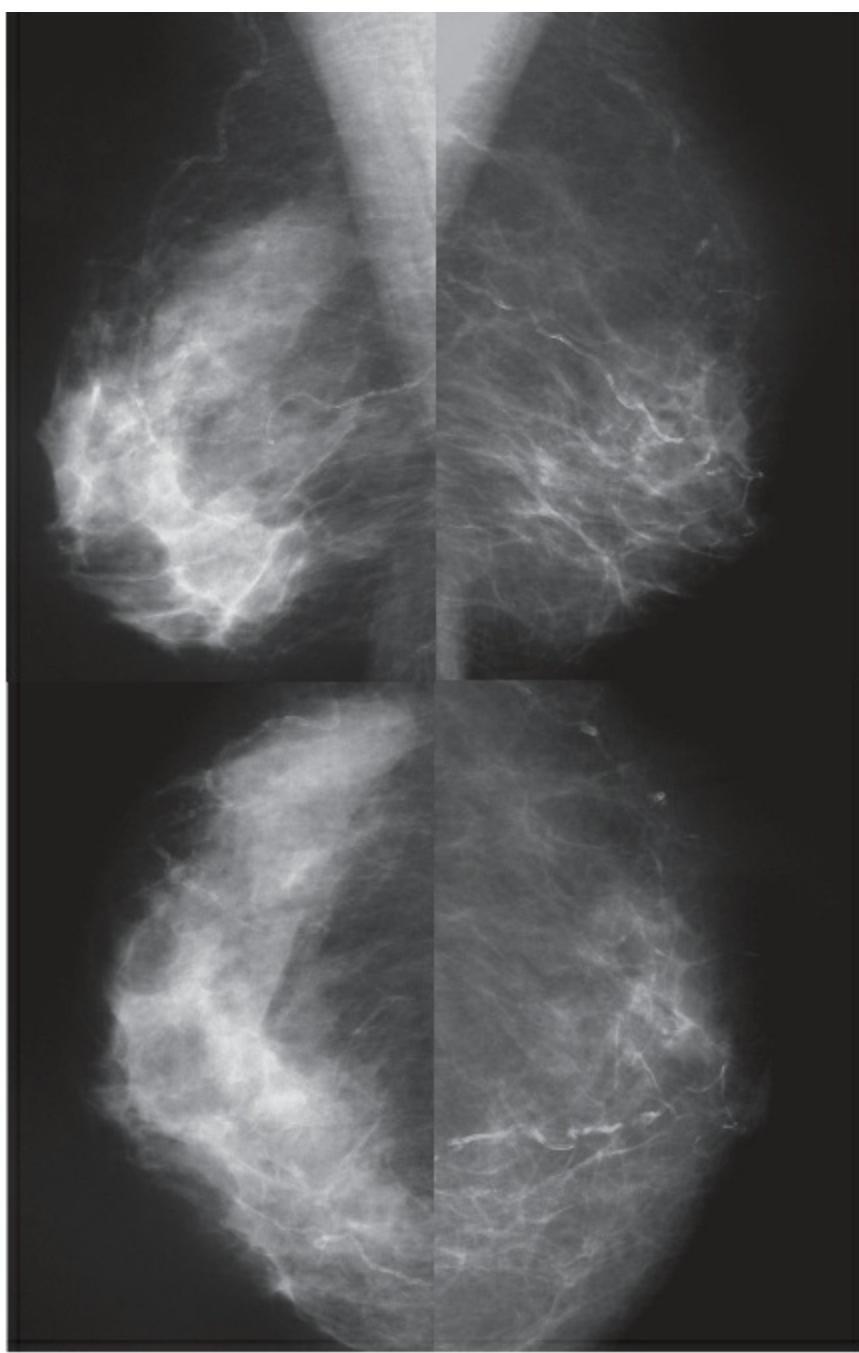


Figure 121 – GLOBAL ASYMMETRY. The large volume of asymmetric dense tissue occupies at least one quadrant of the right breast. There also is vascular calcification in both breasts, typically benign. Outcome: presumed benign. There was no accompanying history of a palpable correlate to the global asymmetry. Long-term stability also was observed by comparison with previous examinations. Previously published as Figure 3 (p. 767) in Sickles EA. The spectrum of breast asymmetries: imaging features, workup, management. *Radiol Clin North Am* 2007; 45[5]:765–771.

D. ASYMMETRIES

3. FOCAL ASYMMETRY (Guidance chapter)

A focal asymmetry is judged relative to the corresponding location in the contralateral breast, and represents a relatively small amount of fibroglandular-density tissue over a confined portion of the breast (less than one quadrant). It is visible on and has a similar

shape on different mammographic projections (hence, a real finding rather than superimposition of normal breast structures), but it lacks the convex-outward borders and the conspicuity of a mass. Rather, the borders of a focal asymmetry are concave-outward, and it is usually seen to be interspersed with fat.

Note that occasionally what is properly described as a focal asymmetry at screening (a finding visible on standard MLO and CC views) is determined at diagnostic mammography to be two different findings, each visible on only one standard view (hence, two asymmetries), each of which ultimately is judged to represent the superimposition of normal breast structures. Also, not infrequently, what is properly described as a focal asymmetry at screening is determined at diagnostic evaluation (mammography and/or US) to represent a mass.

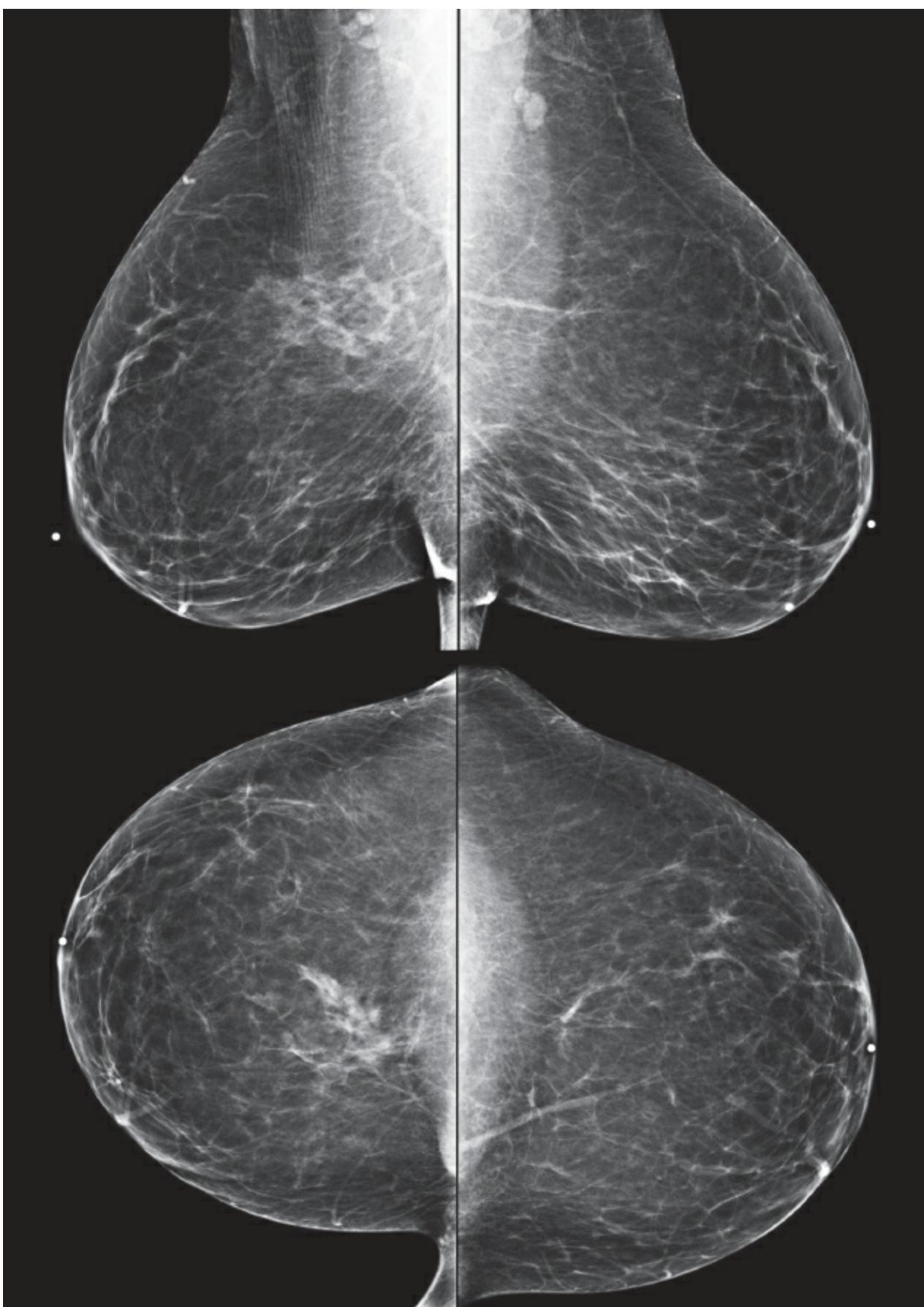


Figure 122 – FOCAL ASYMMETRY. The asymmetric dense tissue occupies less than the entire upper inner quadrant of the right breast. Round metallic markers indicate the location of both nipples. Outcome: presumed benign. Long-term stability was observed by comparison with previous examinations.

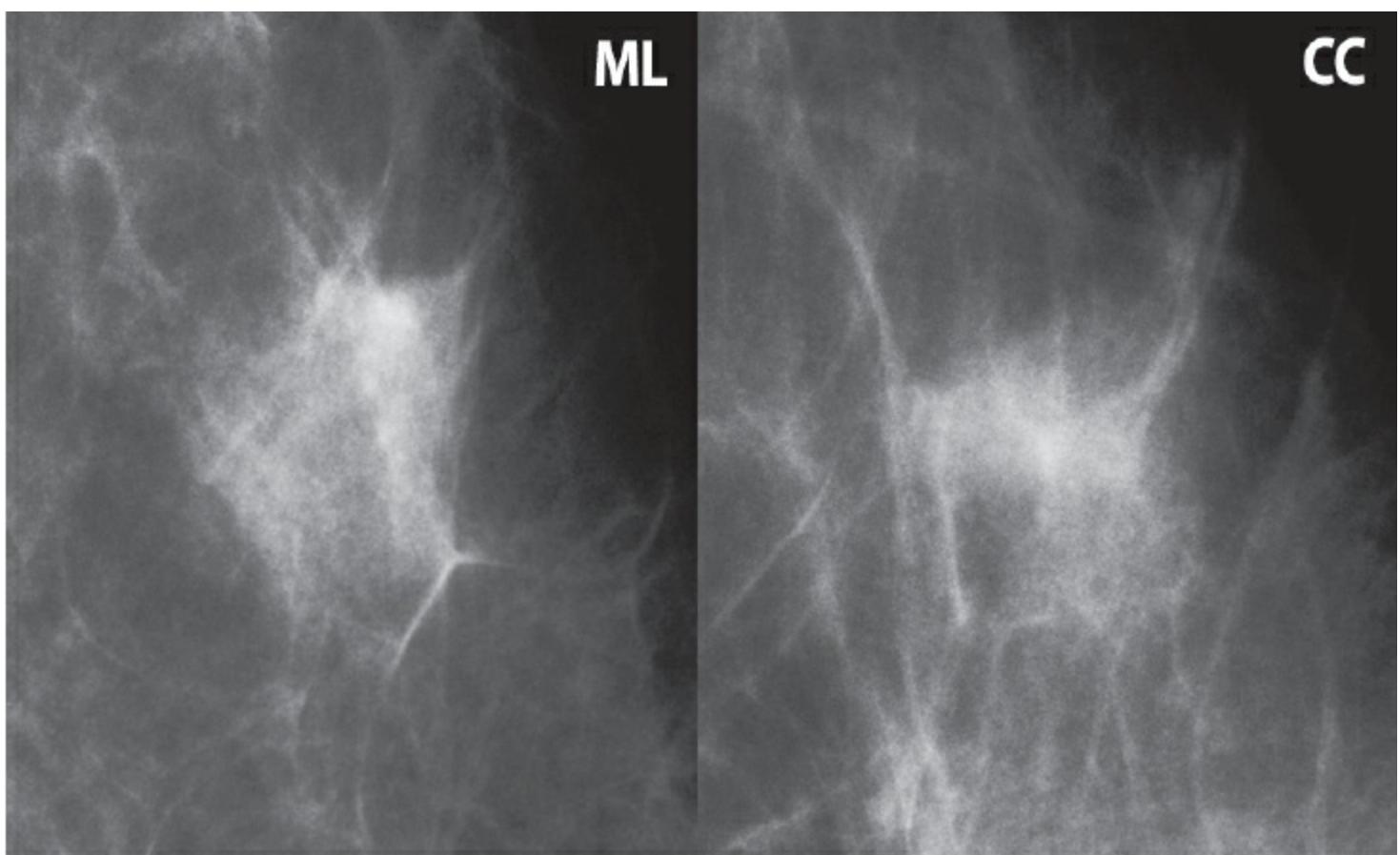


Figure 123 – FOCAL ASYMMETRY. Asymmetric dense tissue occupying less than a quadrant of one breast was identified at baseline screening examination. The displayed spot-compression magnification ML and CC views show that the finding has concave-outward borders, is interspersed with fat, and has no associated mass, architectural distortion, or calcifications. There was no correlate at directed US examination. This finding was assessed as probably benign, with subsequent demonstration of 3-year stability at surveillance mammography. Presumptive diagnosis: benign asymmetric fibroglandular-density breast tissue. Previously published as Figure 4B (p. 768) in Sickles EA. The spectrum of breast asymmetries: imaging features, workup, management. *Radiol Clin North Am* 2007; 45[5]:765–771.

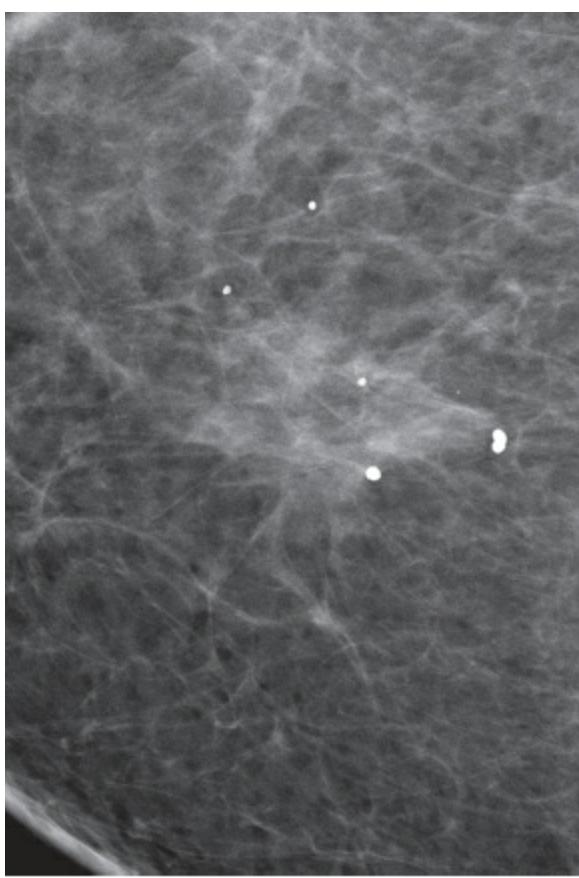


Figure 124 – FOCAL ASYMMETRY. Asymmetric dense tissue occupying less than a quadrant of one breast was identified at baseline screening examination. The finding has concave-outward borders, is interspersed with fat, and has no associated mass, architectural distortion, or abnormal calcifications. There was no correlate at directed US examination. This finding was assessed as probably benign after full diagnostic imaging workup, but slight interval enlargement at 6-month follow-up examination then prompted a suspicious assessment. Stereotactic core biopsy: invasive ductal carcinoma.

D. ASYMMETRIES

4. DEVELOPING ASYMMETRY ([Guidance chapter](#))

This is a focal asymmetry that is new, larger, or more conspicuous than on a previous examination. Approximately 15% of cases of developing asymmetry are found to be malignant (either invasive carcinoma, DCIS, or both), so these cases warrant further imaging evaluation and biopsy unless found to be characteristically benign (e.g., simple cyst at directed US). Absence of a sonographic correlate, especially for a small (< 1 cm) developing asymmetry, should not avert biopsy.

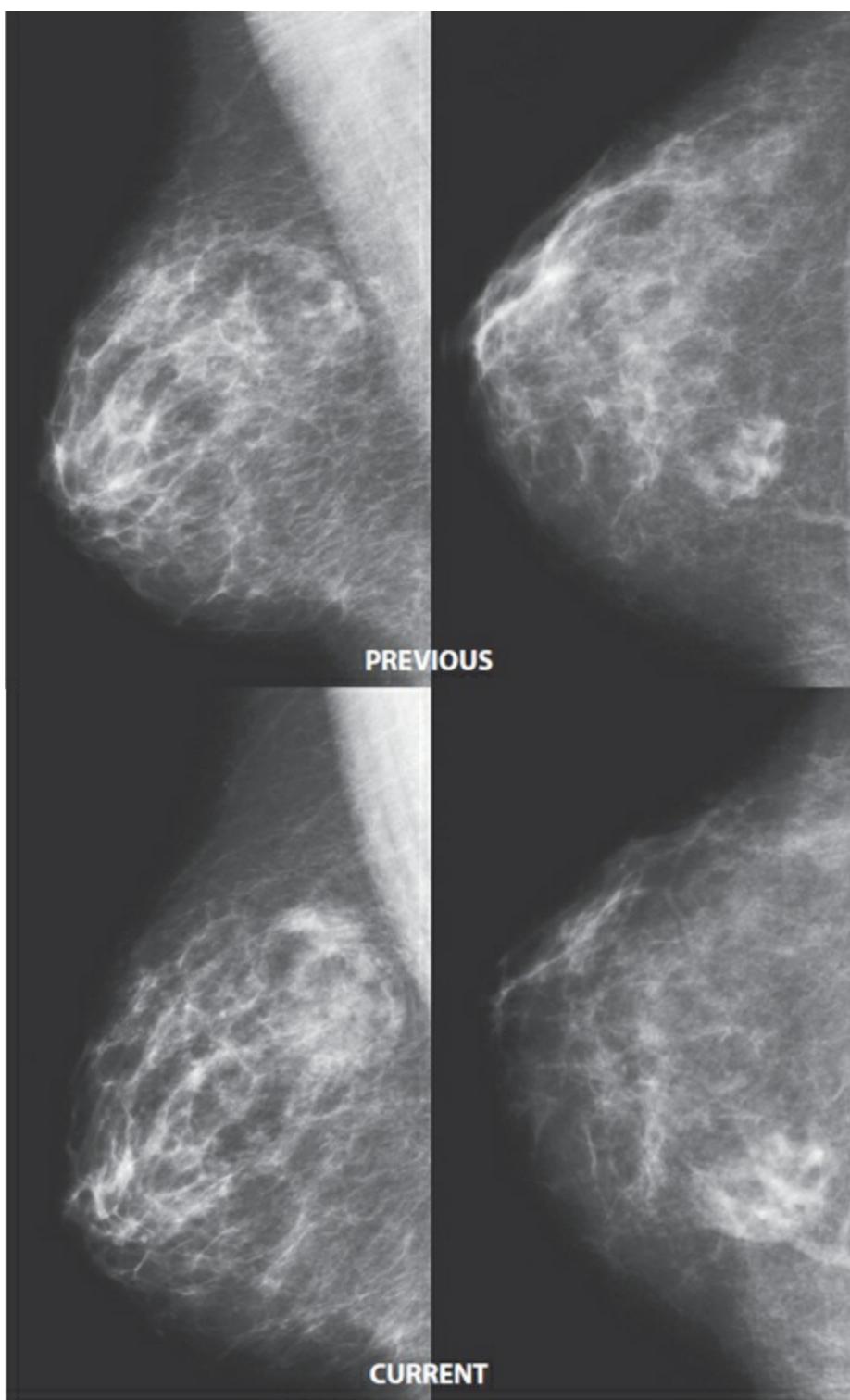


Figure 125 – DEVELOPING ASYMMETRY. The asymmetric dense tissue in the upper inner quadrant of the right breast is larger on current examination than on the previous examination. Core biopsy: pseudoangiomatous stromal hyperplasia (PASH).

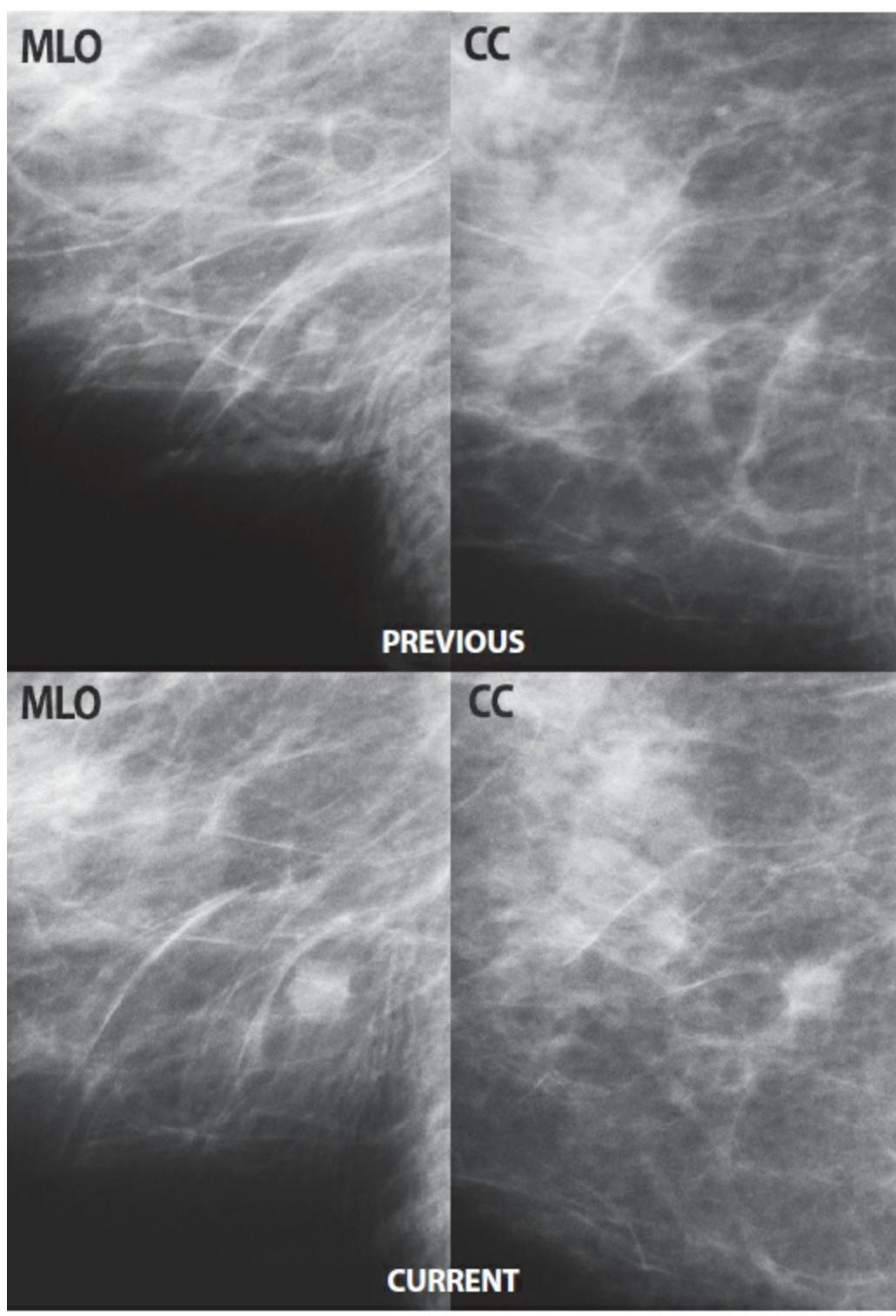


Figure 126 – DEVELOPING ASYMMETRY. The asymmetric dense tissue in the lower inner quadrant of the right breast is larger on current examination than on the previous examination. Core biopsy: invasive ductal carcinoma. Previously published as Figures 5C and 5D (p. 769) in Sickles EA. The spectrum of breast asymmetries: imaging features, workup, management. *Radiol Clin North Am* 2007; 45[5]:765–771.

REFERENCES

1. Leung JWT, Sickles EA. Developing asymmetry identified on mammography: correlation with imaging outcome and pathologic findings. *AJR* 2007; 188(3):667–675.

Abstract:

Objective:

Developing asymmetry on mammography is a focal asymmetric deposit that has appeared or increased in size or conspicuity since a previous examination. We examined the frequency, imaging outcome, and pathologic significance of developing asymmetry.

Materials and Methods:

This study was performed in a retrospective cohort manner. We searched for all cases of developing asymmetry consecutively entered into our mammography database from April 1985 to April 2005. We examined radiology records to determine whether sonography and MRI were used as adjunctive diagnostic tools and examined pathology records to determine tissue diagnosis.

Results:

Developing asymmetry was present in 292 (0.16%) of 180,801 consecutive screening examinations and 32 (0.11%) of 27,330 consecutive diagnostic examinations. After exclusion for absent data, the study consisted of 281 screening and 30 diagnostic cases. In the 281 cases of screening-detected developing asymmetry, biopsy was recommended and was performed in 84 (29.9%) of cases. Thirty-six cases of cancer were identified, resulting in a positive predictive value of 12.8%, obtained by division of the number of cases of cancer by the number of examinations with abnormal mammographic findings (PPV_1), and a PPV_2 of 42.9%, obtained by division of the number of cases of cancer by the number of mammographic examinations in which findings led to a recommendation for biopsy. Biopsy was recommended and performed in 26 (86.7%) of the 30 cases of diagnostic mammography. Eight cases of cancer were identified, resulting in a PPV_1 of 26.7% and a PPV_2 of 30.8%. Of the 44 cancers detected at screening and diagnostic mammography, 21 had available sonographic data. Five (23.8%) of these 21 cases of cancer had no correlate at sonographic examination. MRI was performed in only two cases, both with benign diagnoses.

Conclusion:

Developing asymmetry is an uncommon finding. When this sign is identified on screening and diagnostic mammography, the likelihood of malignancy is sufficiently high to justify recall and biopsy. Normal sonographic findings do not exclude malignancy in the case of developing asymmetry.

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E. INTRAMAMMARY LYMPH NODE

Intramammary lymph nodes are circumscribed masses that are reniform and have hilar fat. They are generally ≤ 1 cm. They may be > 1 cm and characterized as normal when fat replacement is pronounced. They frequently occur in the lateral and usually upper portions of the breast closer to the axilla, although they may occur anywhere in the breast. They often are seen adjacent to a vein, because the lymphatic drainage of the breast parallels the venous drainage.

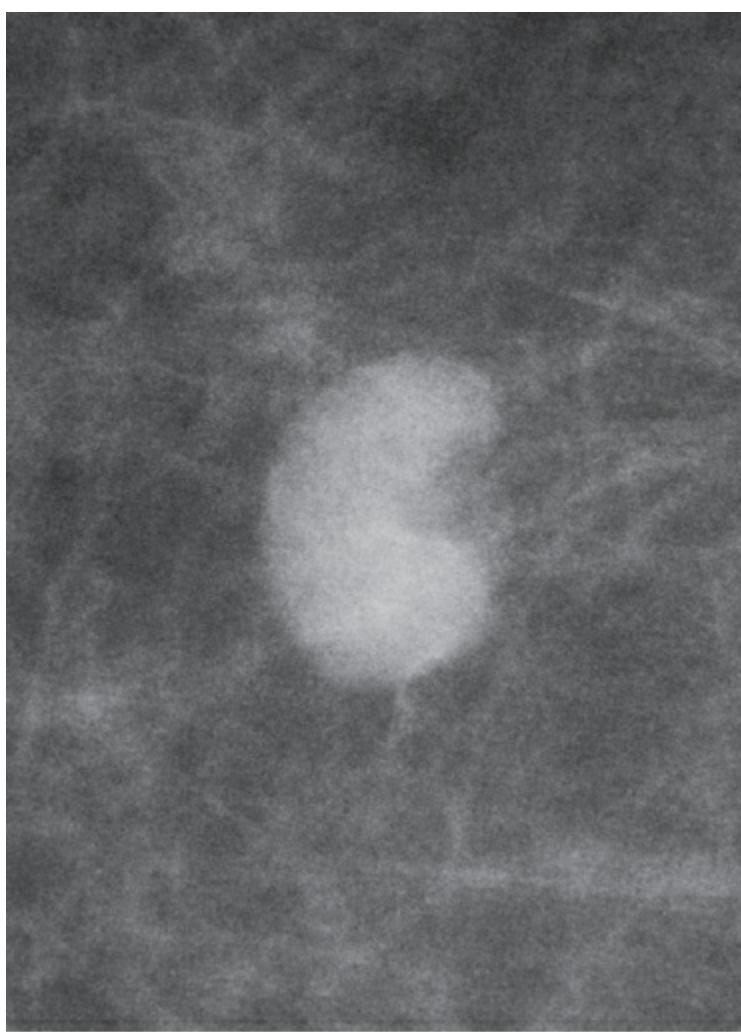


Figure 127 – INTRAMAMMARY LYMPH NODE. Note the fatty hilum projected tangentially, at the periphery of the oval circumscribed mass. These mammographic features are typically benign.

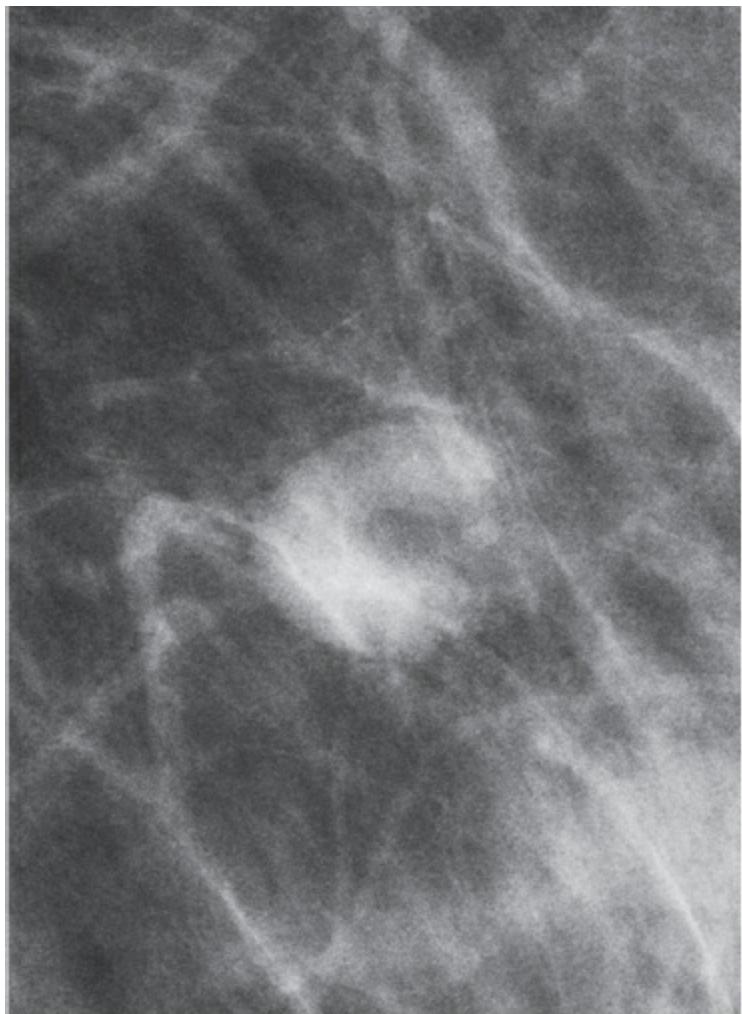


Figure 128 – INTRAMAMMARY LYMPH NODE. Note the fatty hilum projected tangentially, at the periphery of the oval circumscribed mass. These mammographic features are typically benign.



Figure 129 – INTRAMAMMARY LYMPH NODE. Note the fatty hilum projected en face, at the center of the oval circumscribed mass. These mammographic features are typically benign.

F. SKIN LESION ([Guidance chapter](#))

This finding may be described in the mammography report or annotated on the mammographic image when it projects over the breast (especially on two different projections), and may be mistaken for an intramammary lesion. A raised skin lesion sufficiently large to be seen at mammography should be marked by the technologist with a radiopaque device designated for use as a marker for a skin lesion.

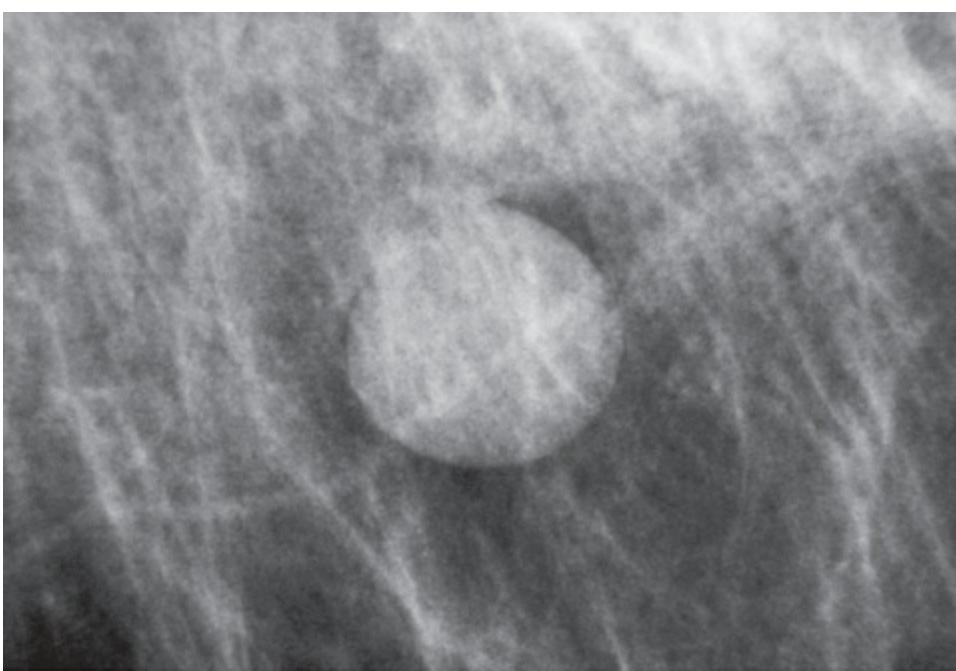


Figure 130 – SKIN LESION. Raised SKIN LESION. Note the area of radiolucency surrounding the mostly circumscribed margin of the mass, representing air trapped during breast compression. These mammographic features are typically benign.

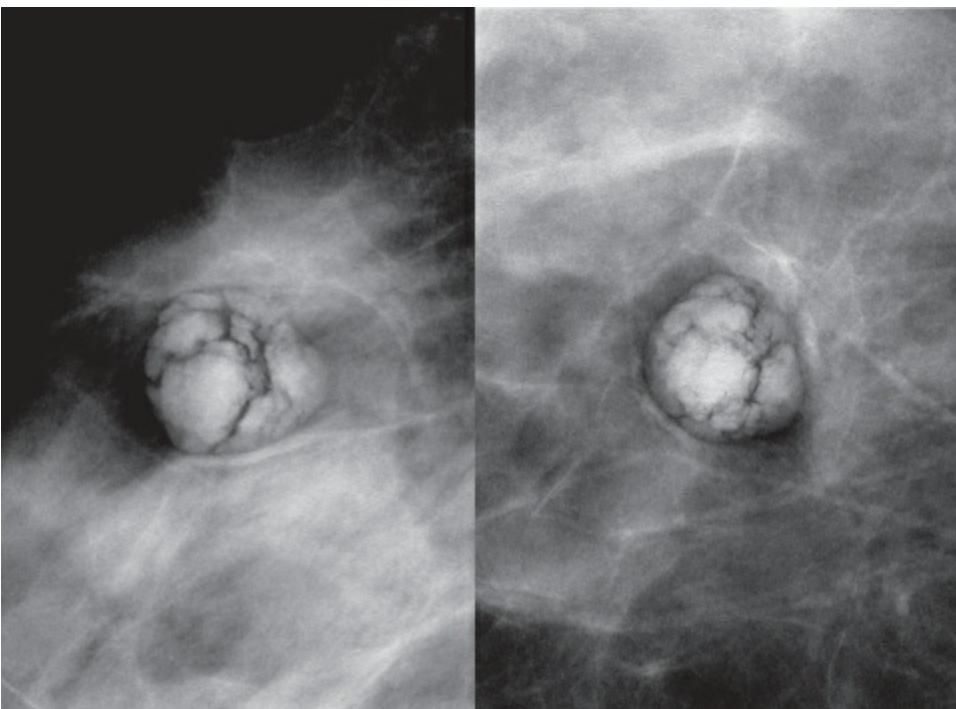


Figure 131 – SKIN LESION. Raised SKIN LESION. Air is trapped around this raised skin lesion and within some of its crevices. These mammographic features are typically benign. A raised skin lesion depicted with air trapped in its crevices usually represents a seborrheic keratosis.

G. SOLITARY DILATED DUCT (Guidance chapter)

This is a unilateral tubular or branching structure that likely represents a dilated or otherwise enlarged duct. It is a rare finding. Even if unassociated with other suspicious clinical or mammographic findings, it has been reported to be associated with

noncalcified DCIS.

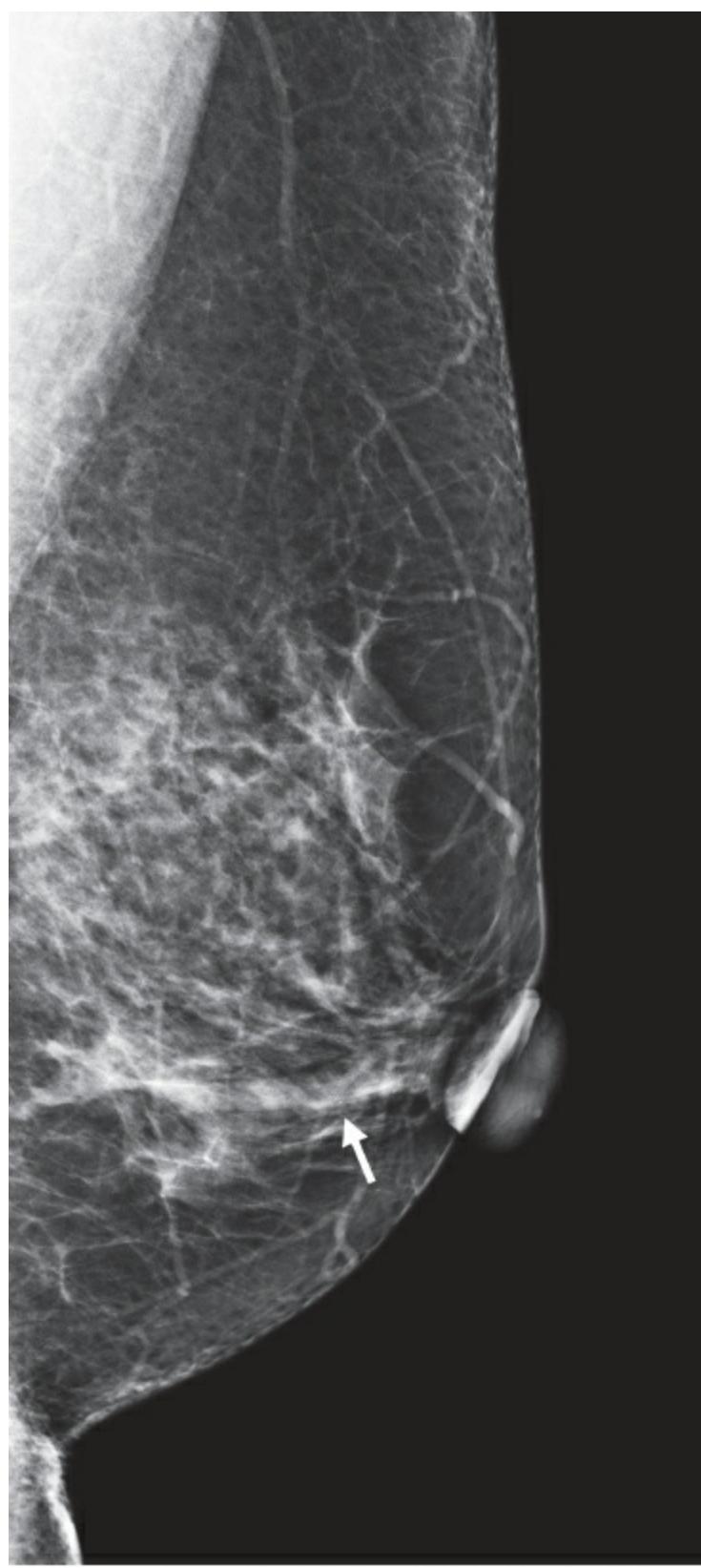


Figure 132 – SOLITARY DILATED DUCT. Excisional biopsy: intraductal papilloma (arrow).



Figure 133 – SOLITARY DILATED DUCT (arrow). Excisional biopsy: intraductal papilloma.



Figure 134 – SOLITARY DILATED DUCT. There also is vascular calcification, typically benign. Core biopsy of solitary dilated duct: ductal carcinoma in situ. Previously published as Figure 1A (p. 380) in Chang CB, Lvoff NM, Leung JW, et al. Solitary dilated duct identified at mammography: outcomes analysis. *AJR* 2010; 194[2]:378–382.



Figure 135 – SOLITARY DILATED DUCT. Containing calcifications. Core biopsy: ductal carcinoma in situ.

REFERENCES

1. Chang CB, Lvoff NM, Leung JW, et al. [The solitary dilated duct identified at mammography: outcomes analysis](#). *AJR* 2010; 194(2):378–382.

Abstract:

Purpose:

To review clinical and pathological outcomes for cases of solitary dilated duct (SDD) identified at mammography.

Materials and Methods:

Institutional review board approval and waiver of informed consent were obtained for this HIPAA-compliant retrospective single-institution study. For all screening mammography examinations during a 22-year period and all diagnostic mammography examinations during the last 10 of these years, the interpreting physician recorded the principal finding of each abnormal mammographic examination during image interpretation. Only examinations with the recorded finding of SDD were studied. We examined radiology records to determine imaging follow-up, pathology records to determine histological diagnosis, and performed linkage with our regional tumor registry to identify cancers not biopsied at our institution.

Results:

The finding of SDD was recorded for 9 of 235,209 consecutive screening (0.0038%) and for 12 of 29,267 consecutive diagnostic mammography examinations (0.041%). Five screening and five diagnostic cases were stable at follow-up (minimum interval, 2 years) and did not undergo biopsy; tumor registry linkage showed no subsequent cancer diagnosis. Biopsy was performed for 4 of 9 screening (44%) and 7 of 12 diagnostic (58%) cases. One cancer each (ductal carcinoma in situ) was identified from the screening and diagnostic populations, yielding positive predictive values of 11% (1/9) and 8% (1/12), respectively.

Conclusion:

SDD is a rare mammographic finding, this series being the largest reported to date. Although few cases are studied, SDD appears to have a greater than 2% likelihood of malignancy, sufficiently high to suggest that a suspicious (BI-RADS® 4A) assessment may be appropriate.

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H. ASSOCIATED FEATURES

Used with masses, asymmetries, or calcifications or may stand alone as findings when no other abnormality is present.

H. ASSOCIATED FEATURES

1. SKIN RETRACTION

The skin is pulled in abnormally.



Figure 136 – SKIN RETRACTION. Note the double skin line (indicating skin retraction) anterior and medial to the irregular high-density mass. Core biopsy: invasive ductal carcinoma.

H. ASSOCIATED FEATURES

2. NIPPLE RETRACTION

The nipple is pulled in. This should not be confused with nipple inversion, which is often bilateral and which in the absence of any suspicious findings and when stable for a long period of time, is not a sign of malignancy. However, if nipple retraction is new, suspicion for underlying malignancy is increased.

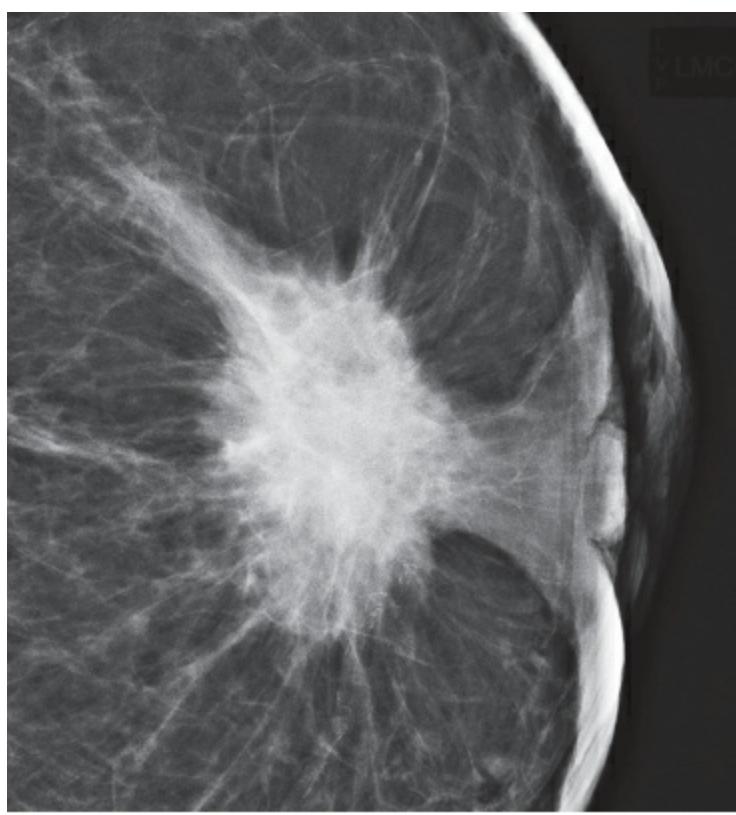


Figure 137 – NIPPLE RETRACTION. Adjacent to a spiculated high-density mass. There also is associated skin thickening. Core biopsy: invasive ductal carcinoma.

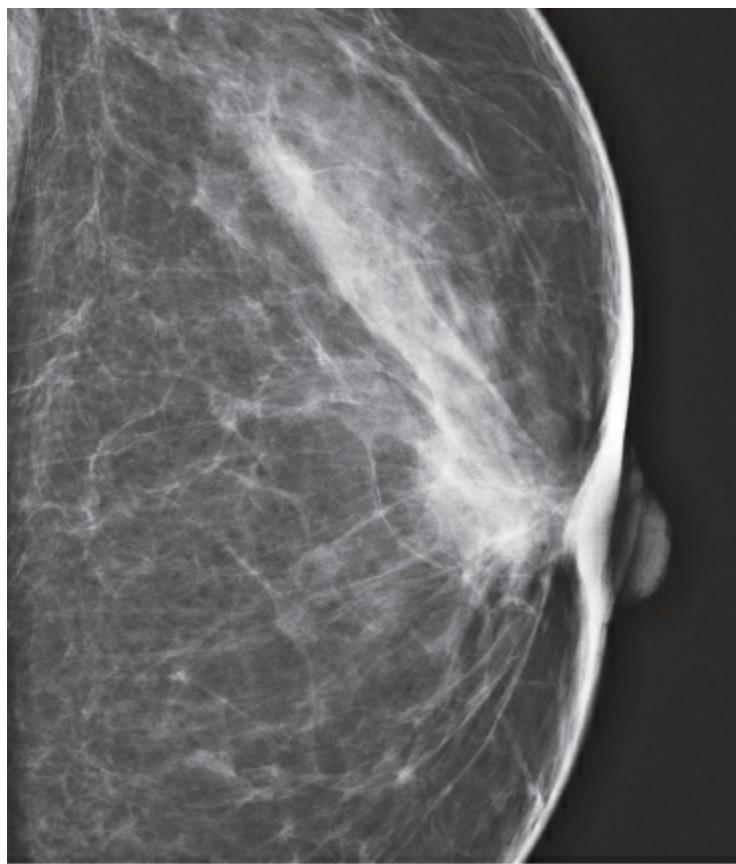


Figure 138 – NIPPLE RETRACTION. Slight NIPPLE RETRACTION adjacent to an irregular indistinct mass. There also is associated slight skin thickening. Core biopsy: invasive ductal carcinoma.

H. ASSOCIATED FEATURES

3. SKIN THICKENING

Skin thickening may be focal or diffuse, and is defined as being greater than 2 mm in thickness. This finding is of particular concern if it represents a change from previous mammography examinations. However, unilateral skin thickening is an expected finding after radiation therapy.

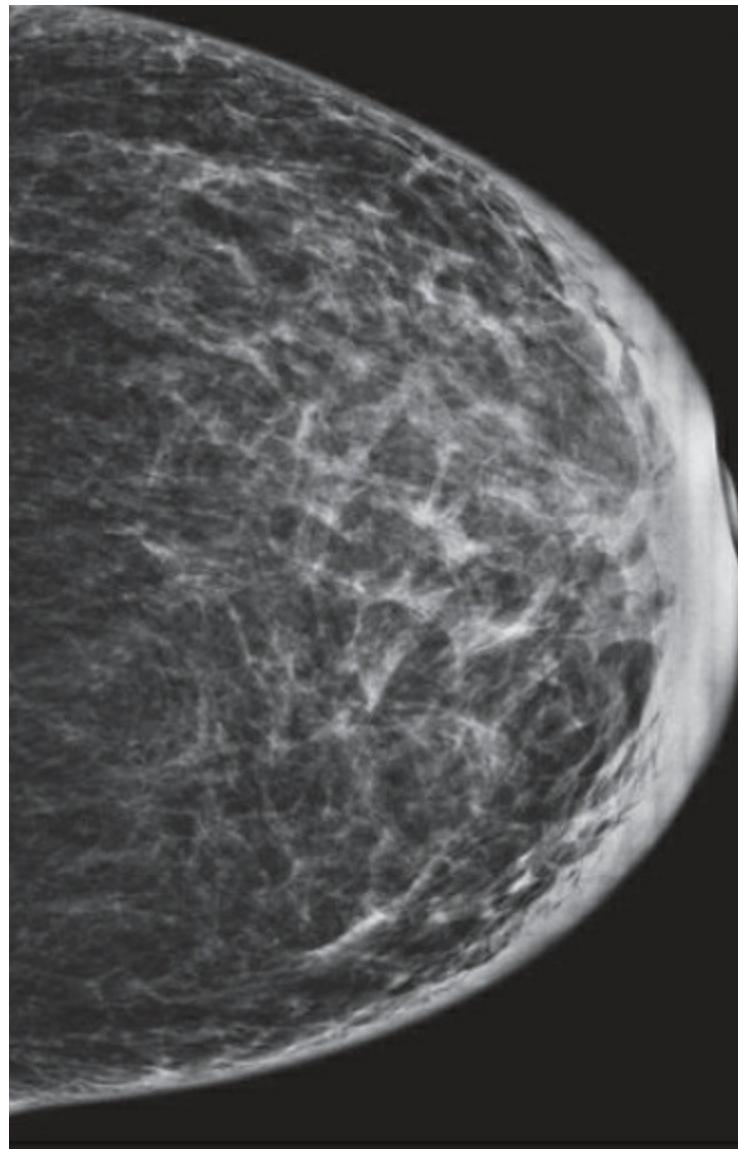


Figure 139 – SKIN THICKENING. Diffuse SKIN THICKENING in a woman with known congestive heart failure. There also is trabecular thickening. Given the provided clinical history, these are typically benign findings.

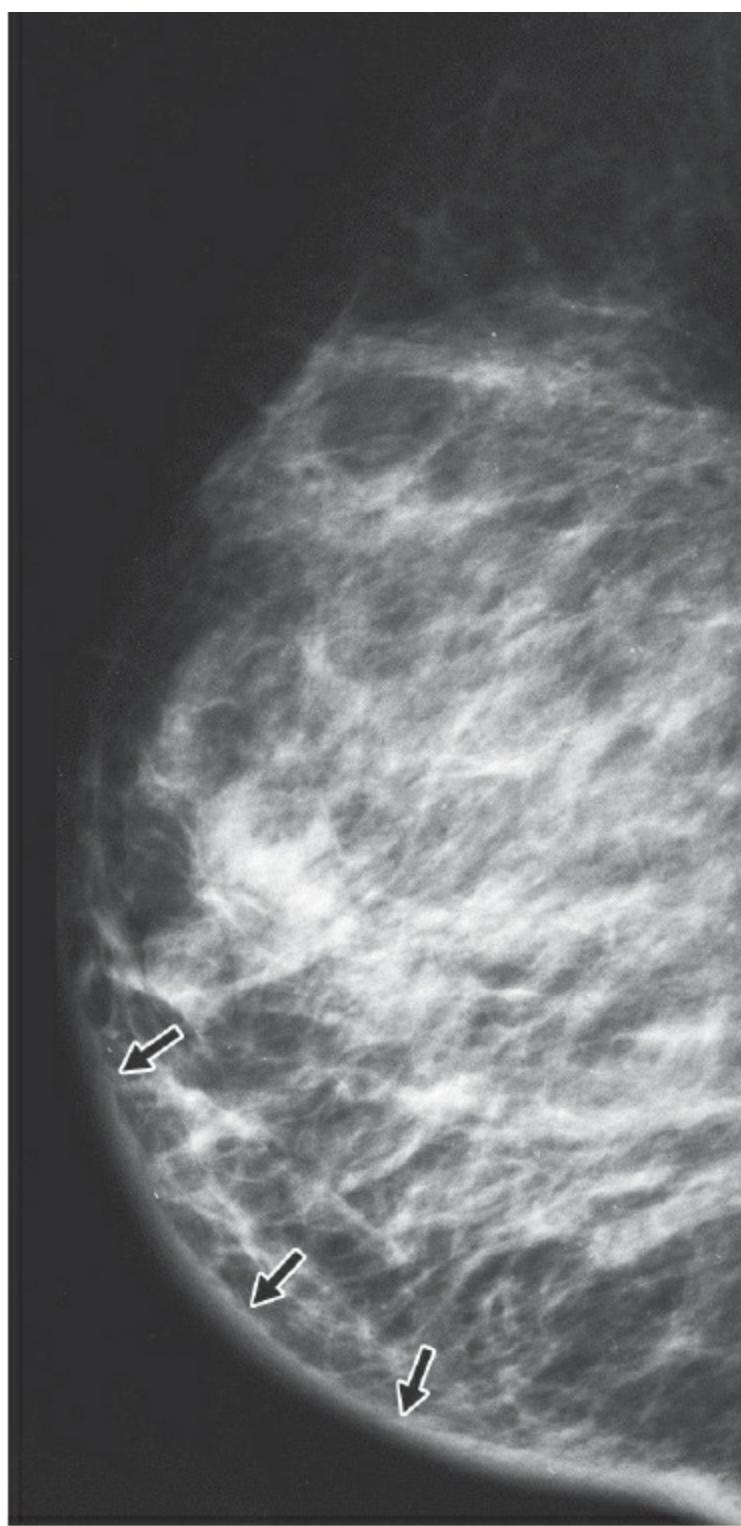


Figure 140 – SKIN THICKENING. Focal SKIN THICKENING, involving the inferior half of the breast (arrows), in a woman known to have undergone breast radiation therapy 1 year ago. There also is trabecular thickening. Given the provided clinical history, these are typically benign findings.

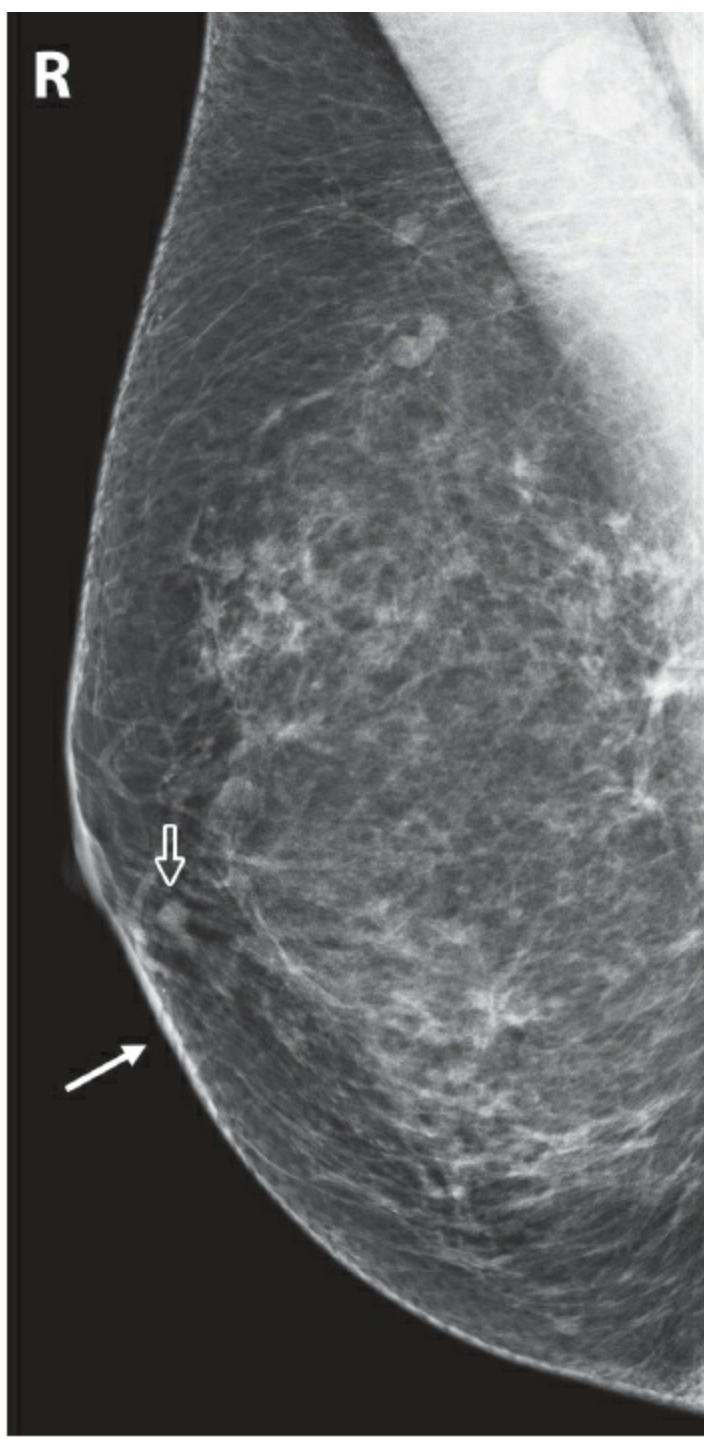
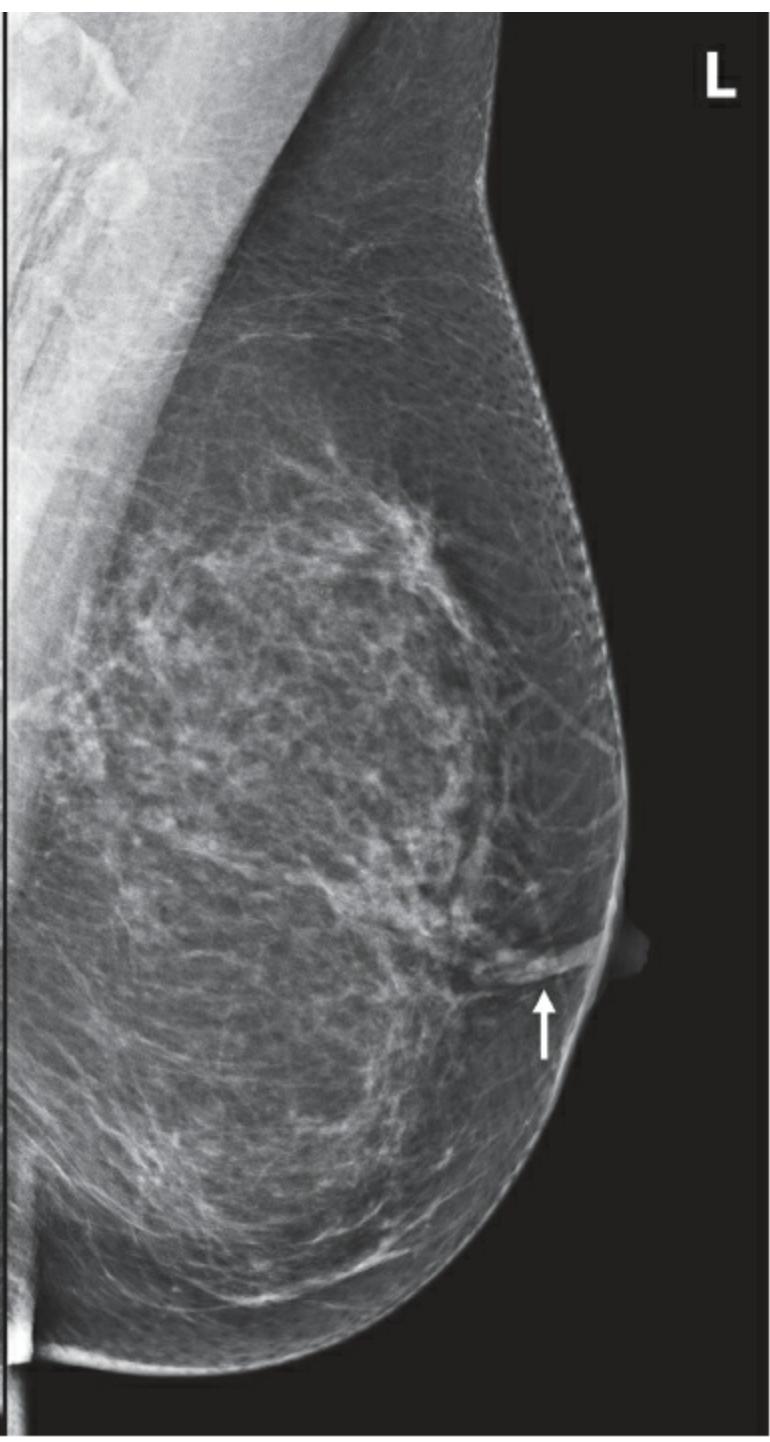
R**L**

Figure 141 – SKIN THICKENING. Focal SKIN THICKENING (arrow) involving the areola and adjacent skin inferior to the right nipple. Note the small partially indistinct mass (open arrow) in retroareolar location, adjacent to the uppermost part of thickened skin. There also is a solitary dilated duct (arrow) in the left breast, anechoic (filled with fluid) at directed US examination. Core biopsy of the mass: invasive ductal carcinoma. Presumptive diagnosis for the solitary dilated duct: benign fluid-filled duct.

H. ASSOCIATED FEATURES

4. TRABECULAR THICKENING

This is a thickening of the fibrous septa of the breast.

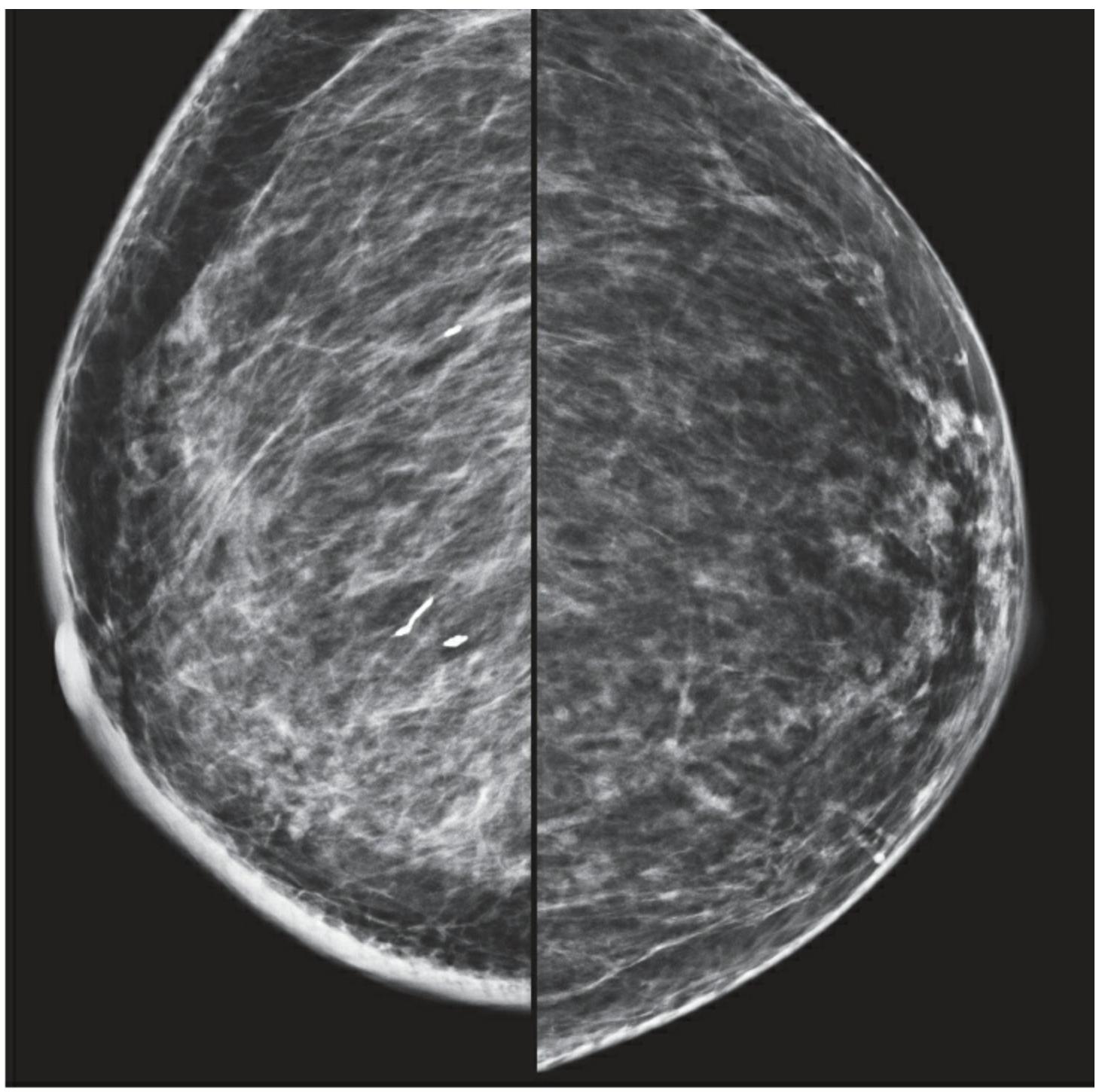


Figure 142 – TRABECULAR THICKENING. Right breast, most readily apparent immediately deep to the associated skin thickening, which is most extensive in the inferior aspect of the image. This woman was known to have undergone right breast radiation therapy 1 year ago. There also are a few dystrophic calcifications in the right breast. Given the provided clinical history, these are typically benign findings.

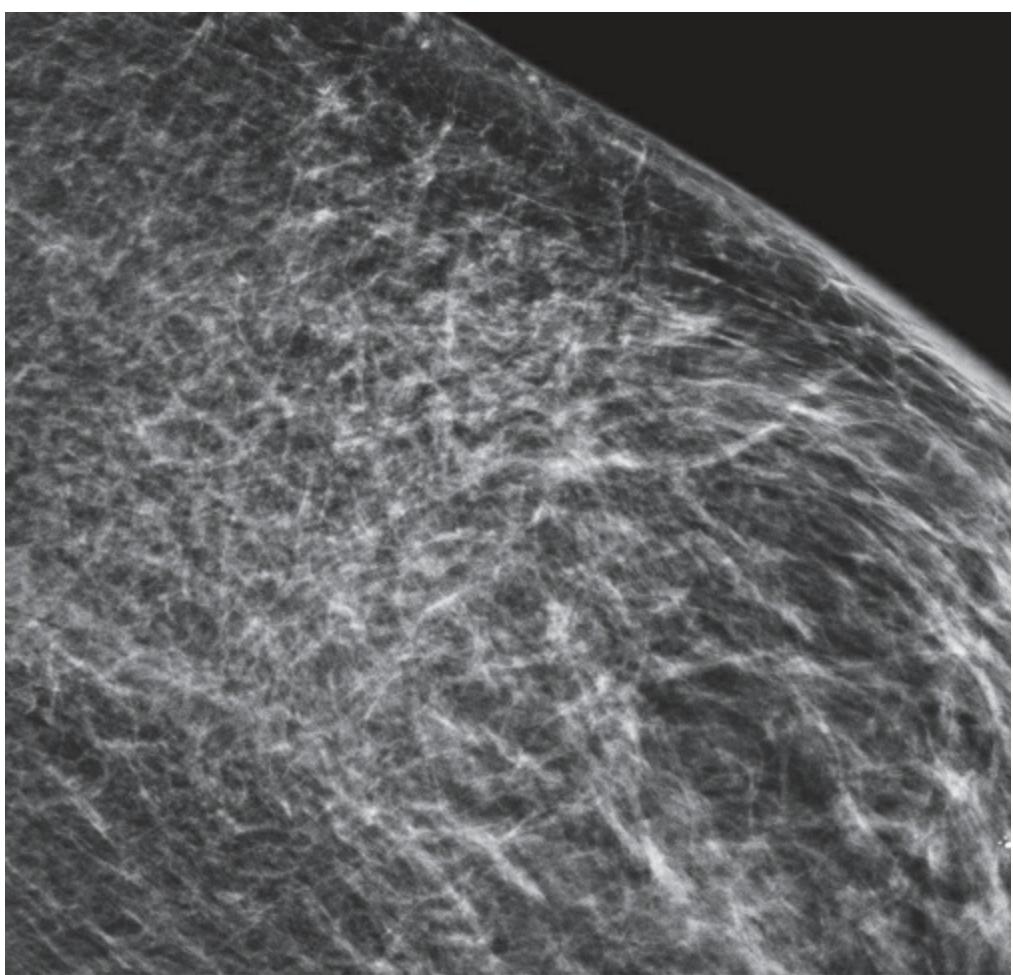


Figure 143 – TRABECULAR THICKENING. In a woman with known congestive heart failure. There also is focal skin thickening at the right side of the image field. Given the provided clinical history, these are typically benign findings.

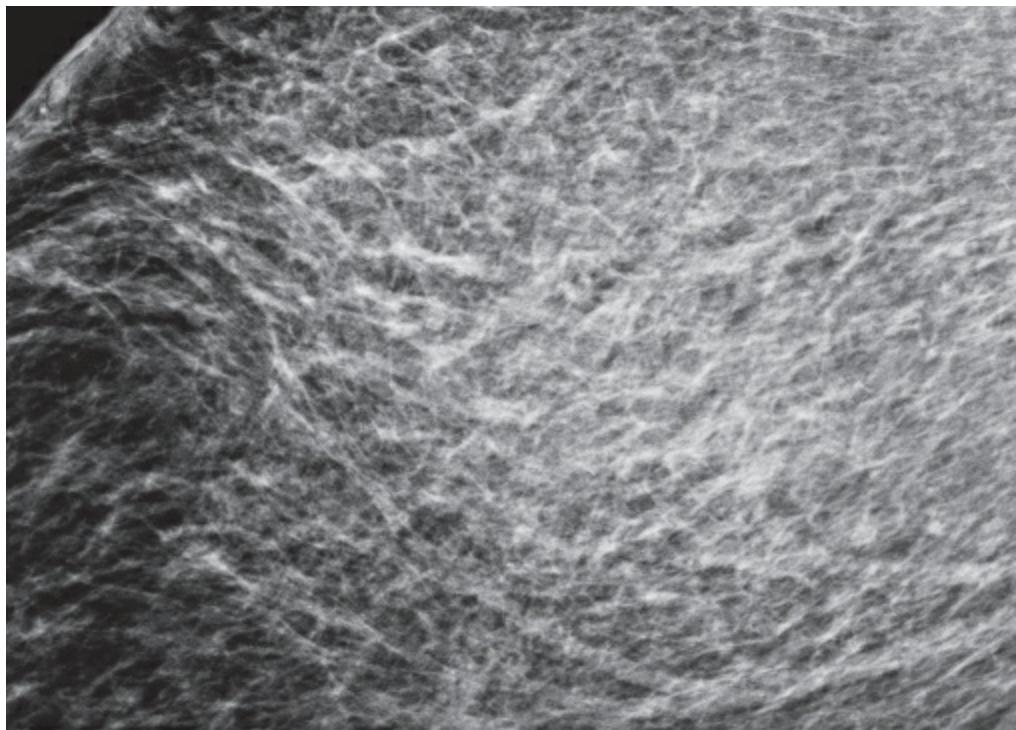


Figure 144 – TRABECULAR THICKENING. In a woman with known congestive heart failure. The associated diffuse opacity is a manifestation of edema within the breast. Given the provided clinical history, these are typically benign findings.

H. ASSOCIATED FEATURES

5. AXILLARY ADENOPATHY ([Guidance chapter](#))

Enlarged axillary lymph nodes may warrant comment, clinical correlation, and additional evaluation, especially if they are new or considerably larger or rounder when compared to previous examination. A review of the patient's medical history may elucidate the cause for axillary adenopathy, averting recommendation for additional evaluation. When one or more large axillary nodes are substantially composed of fat, this is a normal variant.

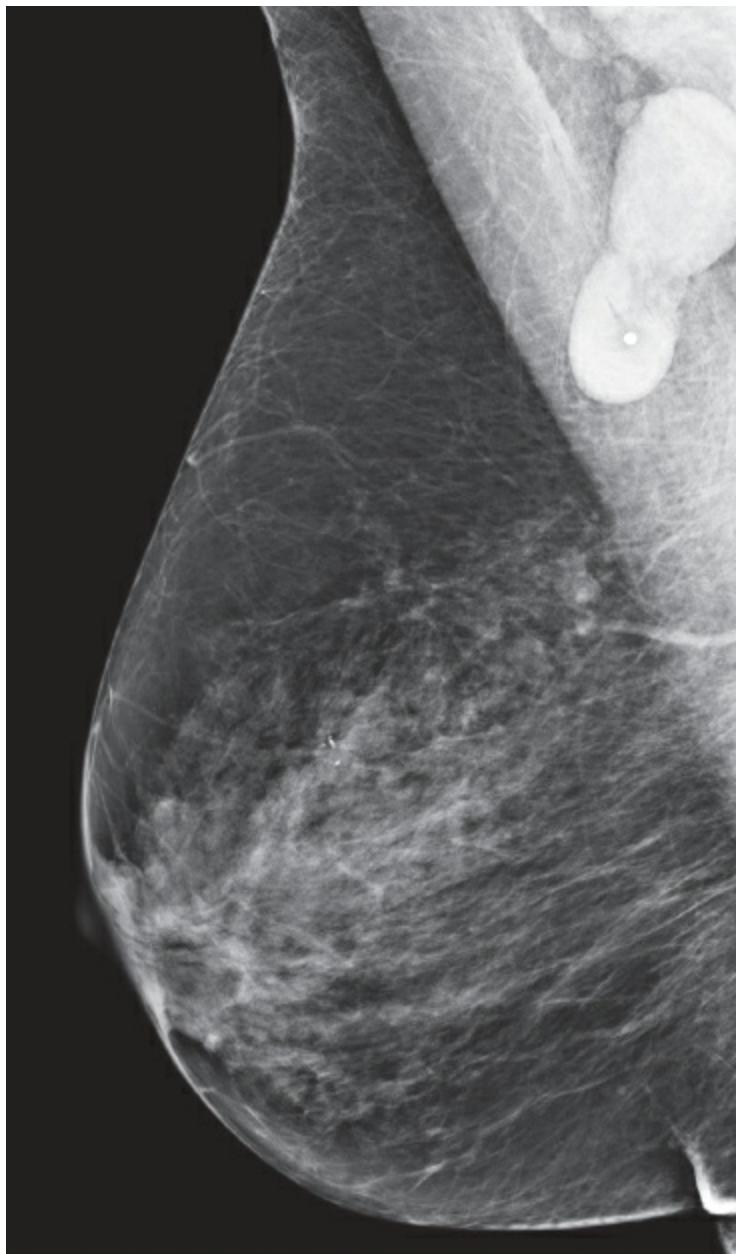


Figure 145 – AXILLARY ADENOPATHY. There are two adjacent enlarged dense axillary lymph nodes. Presumptive diagnosis: involvement with lymphoma, in a woman with known lymphoma, in relapse.



Figure 146 – AXILLARY ADENOPATHY. There is an oval circumscribed high-density mass in the axilla, representing an enlarged axillary lymph node. A round metallic marker indicates the location of the nipple. Presumptive diagnosis: reactive hyperplasia, in a woman with known rheumatoid arthritis.



Figure 147 – AXILLARY ADENOPATHY. There are multiple enlarged dense lymph nodes in both axillae. Presumptive diagnosis: leukemic infiltration, in a woman with known chronic lymphocytic leukemia, in relapse.

H. ASSOCIATED FEATURES

6. ARCHITECTURAL DISTORTION

As an associated feature, architectural distortion may be used in conjunction with another finding to indicate that the parenchyma is distorted or retracted adjacent to the finding (see definitions of architectural distortion, [Section C](#)).

H. ASSOCIATED FEATURES

7. CALCIFICATIONS

As an associated feature, this may be used in conjunction with one or more other finding(s) to describe calcifications within or immediately adjacent to the finding(s) (see descriptors of calcifications, [Section B](#)).

I. LOCATION OF LESION

The location of a suspicious lesion should be described using standard clock-face clinical orientation, as extrapolated from image location. The breast is viewed as the face of a clock with the patient facing the observer. Use of both clock-face position and quadrant location is encouraged because clinicians use these location descriptors interchangeably; this also provides an internal consistency check for possible right-left confusion (e.g., description of a right breast lesion in the upper outer quadrant at 2:00 is inconsistent and must be changed before verifying a mammography report). The side is given first, followed by the quadrant, clock-face location, and the depth of the lesion. Depth descriptors arbitrarily divide the breast into anterior, middle, and posterior thirds. In addition, description of the distance of the lesion from the nipple provides a more precise indication of its depth. This may be particularly helpful in determining whether an imaging finding matches the location of a palpable mass or in directing US examination or a postimaging clinical breast examination. The following is an example of a lesion location description:

right, upper outer quadrant, 10:00, anterior third, 3 cm from nipple

Full description of lesion location should be limited to examinations for which biopsy is recommended.

I. LOCATION OF LESION

1. LATERALITY

Indicate right or left breast.

2. QUADRANT AND CLOCK FACE

Use upper outer quadrant, upper inner quadrant, lower outer quadrant, or lower inner quadrant. Twelve o'clock lesions may be described as upper central, 6 o'clock lesions as lower central, and lesions at 3:00 or 9:00 as either outer central or inner central depending on laterality. Central is directly behind the nipple-areolar complex on all projections. Retroareolar indicates central location in the anterior third of the breast close to the nipple. Axillary tail indicates upper outer quadrant location adjacent to the axilla but within the breast mound. The clock-face notation for a lesion in a given

quadrant will depend on whether the lesion is in the right or left breast. Note that central, retroareolar, and axillary tail descriptors are used instead of quadrant descriptors and do not require indication of clock-face location.

3. DEPTH

Indicate depth in the breast (anterior, middle, posterior third). See [Figure 148](#).

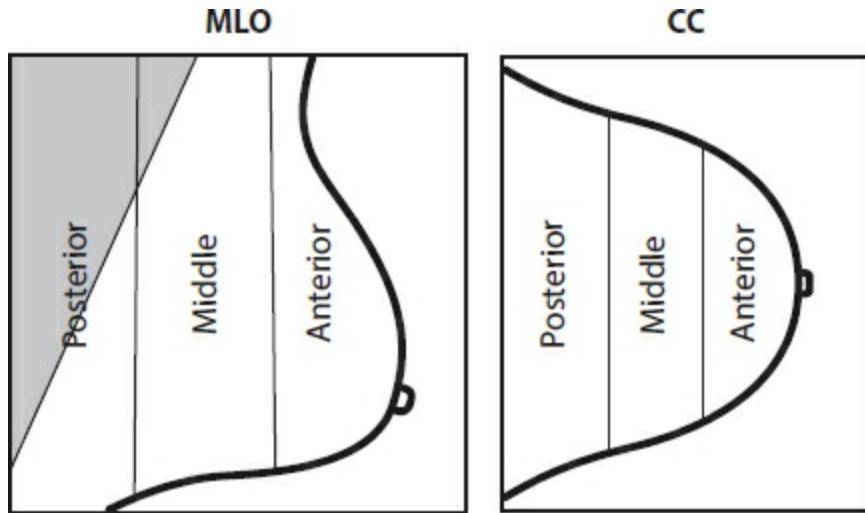


Figure 148 – Depth Diagrams

4. DISTANCE FROM THE NIPPLE

II. REPORTING SYSTEM

A. REPORT ORGANIZATION ([Guidance chapter](#))

The reporting system should be concise and organized using the following structure. A statement indicating that the current examination has been compared to previous examination(s) should be included (specify date[s]). If this is not included, it should be assumed that no comparison has been made, although it is preferable to indicate that no comparison was made.

Table 4. Report Organization

Report Structure
1. Indication for examination
2. Succinct description of the overall breast composition
3. Clear description of any important findings
4. Comparison to previous examination(s), if deemed appropriate by the interpreting physician
5. Assessment
6. Management

1. INDICATION FOR EXAMINATION

Provide a brief description of the indication for examination. This may be screening for an asymptomatic woman, recall of a screening-detected finding, evaluation of a clinical finding (specify the finding and its location), or follow-up of either a probably benign lesion or cancer treated with breast conservation. If an implant is present, both standard and implant-displaced views should be performed, and this should be stated in the mammography report.

2. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION

This is an overall assessment of the volume of attenuating tissues in the breast, to help indicate the relative possibility that a lesion could be obscured by normal tissue and that the sensitivity of examination thereby may be compromised by dense breast tissue. A few coalescent areas of dense tissue may be present in breasts with as little as 10% dense tissue, whereas primarily fatty areas may be present in breasts with as much

as 90% dense tissue.

Since mammography does not depict all breast cancers, clinical breast examination is a complementary element of screening. Findings at clinical breast examination should not be ignored and may have increased importance in the dense breast.

The available data do not support the use of mammographic breast density for determining screening frequency.

The following four categories of breast composition are defined by the visually estimated content of fibroglandular-density tissue within the breasts. Please note that the categories are listed as **a**, **b**, **c**, and **d** so as not to be confused with the numbered BI-RADS® assessment categories. If the breasts are not of apparently equal density, the denser breast should be used to categorize breast density. The sensitivity of mammography for noncalcified lesions decreases as the BI-RADS® breast density category increases. The denser the breast, the larger the lesion(s) that may be obscured. There is considerable intra- and inter-observer variation in visually estimating breast density between any two adjacent density categories. Furthermore, there is only a minimal and insignificant difference in the sensitivity of mammography between the densest breast in a lower-density category and the least dense breast in the next-higher-density category. These factors limit the clinical relevance of breast density categorization for the individual woman.

Table 5. Breast Tissue

Breast Composition Categories
a. The breasts are almost entirely fatty
b. There are scattered areas of fibroglandular density
c. The breasts are heterogeneously dense, which may obscure small masses
d. The breasts are extremely dense, which lowers the sensitivity of mammography

a. The breasts are almost entirely fatty.

Unless an area containing cancer is not included in the image field of the mammogram, mammography is highly sensitive in this setting.

b. There are scattered areas of fibroglandular density (historically, there are scattered fibroglandular densities).

It may be helpful to distinguish breasts in which there are a few scattered areas of fibroglandular-density tissue from those in which there are moderate scattered areas of fibroglandular-density tissue. Note that there has been a subtle change in the wording of this category, to conform to BI-RADS® lexicon use of the term “density” to describe the degree of x-ray attenuation of breast tissue but not to represent discrete

mammographic findings.

c. The breasts are heterogeneously dense, which may obscure small masses.

It is not uncommon for some areas in such breasts to be relatively dense while other areas are primarily fatty. When this occurs, it may be helpful to describe the location(s) of the denser tissue in a second sentence, so that the referring clinician is aware that these are the areas in which small noncalcified lesions may be obscured. Suggested wordings for the second sentence include:

"The dense tissue is located anteriorly in both breasts, and the posterior portions are mostly fatty."

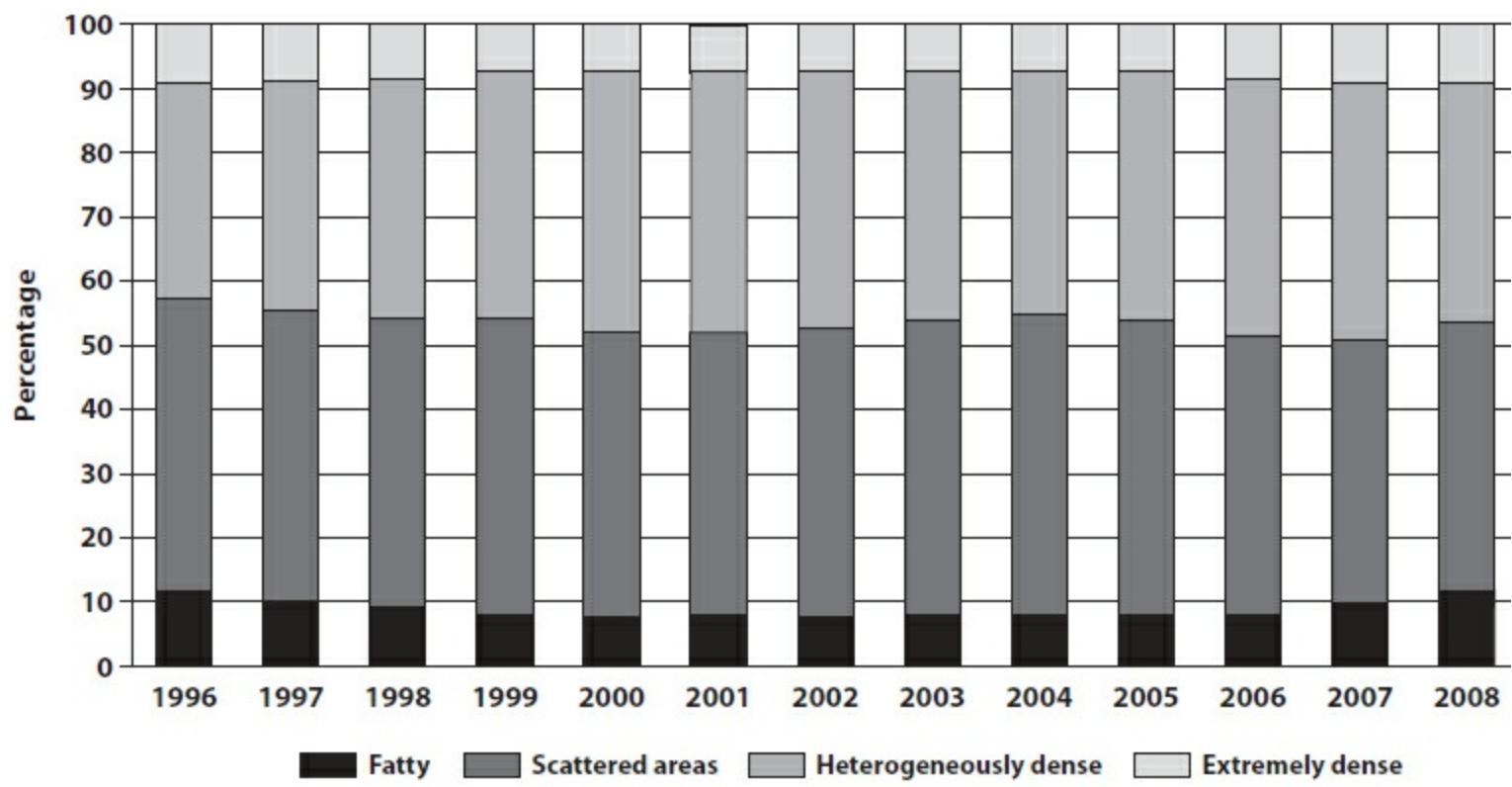
"Primarily dense tissue is located in the upper outer quadrants of both breasts; scattered areas of fibroglandular tissue are present in the remainder of the breasts."

d. The breasts are extremely dense, which lowers the sensitivity of mammography.

The sensitivity of mammography is lowest in this density category.

The fourth edition of BI-RADS®, unlike previous editions, indicated quartile ranges of percentage dense tissue (increments of 25% density) for each of the four density categories, with the expectation that the assignment of breast density would be distributed more evenly across categories than the historical distribution of 10% fatty, 40% scattered, 40% heterogeneously, and 10% extremely dense. However, it has since been demonstrated in clinical practice that there has been essentially no change in this historical distribution across density categories, despite the 2003 guidance provided in the BI-RADS® Atlas ([Figure 149](#)).

Figure 149 – U.S. Radiologists’ Use of BI-RADS® Breast Density Descriptors, 1996–2008



Data from 3,865,070 screening mammography examinations interpreted by radiologists who participate in the Breast Cancer Surveillance Consortium (BCSC), a group of seven population-based mammography registries covering geographically, ethnically, and socioeconomically diverse areas of the United States. Data collection for this work was supported by the National Cancer Institute-funded BCSC cooperative agreement (U01CA63740, U01CA86076, U01CA86082, U01CA63736, U01CA70013, U01CA69976, U01CA63731, U01CA70040). We thank the BCSC investigators, participating women, mammography facilities, and radiologists for the data they have provided for this study. A list of the BCSC investigators and procedures for requesting BCSC data for research purposes are provided at: <http://breastscreening.cancer.gov/>.

The absence of change in clinical practice of the assignment of breast density across categories may reflect the reality that a few coalescent areas of dense tissue may be present in breasts with as little as 10% dense tissue, whereas primarily fatty areas may be present in breasts with as much as 90% dense tissue.

The fifth edition of BI-RADS® no longer indicates ranges of percentage dense tissue for the four density categories. This is done to emphasize the text descriptions of breast density, which reflect the masking effect of dense fibroglandular tissue on mammographic depiction of noncalcified lesions, because the Committee on BI-RADS® concludes that the association of subjectively estimated breast density with changes in the sensitivity of mammography is clinically more important than the relatively smaller effect of percentage breast density as an indicator for breast cancer risk.

The Committee on BI-RADS® indeed is aware of recent and continuing investigations of

percentage breast density as an indicator for breast cancer risk, and by eliminating percentage ranges we do not intend to compromise or impede any such research. We simply recognize the reality that interpreting physicians will continue to use density categories in mammography reports as they have done over the past many years, independent of BI-RADS® guidance on percentage breast density. We further recognize that both subjective estimates and planimetry measurements of breast density based on area as depicted on (2-D) mammograms are imprecise indicators of the volume of dense tissue, which may be measured using (3-D) cross-sectional breast imaging modalities.¹ We await publication of robust volume-based breast density data, using validated percentage cut points (not necessarily quartiles) that are readily and reproducibly determined at imaging, before again indicating percentage ranges for BI-RADS® density categories. We also urge avoidance of numbers to classify breast density instead of BI-RADS® terminology in order to avoid confusion with BI-RADS® assessment categories, which are numbered.

Some breasts may appear more or less dense when imaged using full-field digital mammography compared to screen-film mammography. Superior depiction of the skin line by digital mammography provides the observer with a more accurate (and usually larger) estimate of the extent of the subcutaneous fat. However, no change in the distribution across density categories has been observed when comparing full-field digital mammography with screen-film mammography.²

BREAST COMPOSITION ILLUSTRATIONS

- a. The breasts are almost entirely fatty.

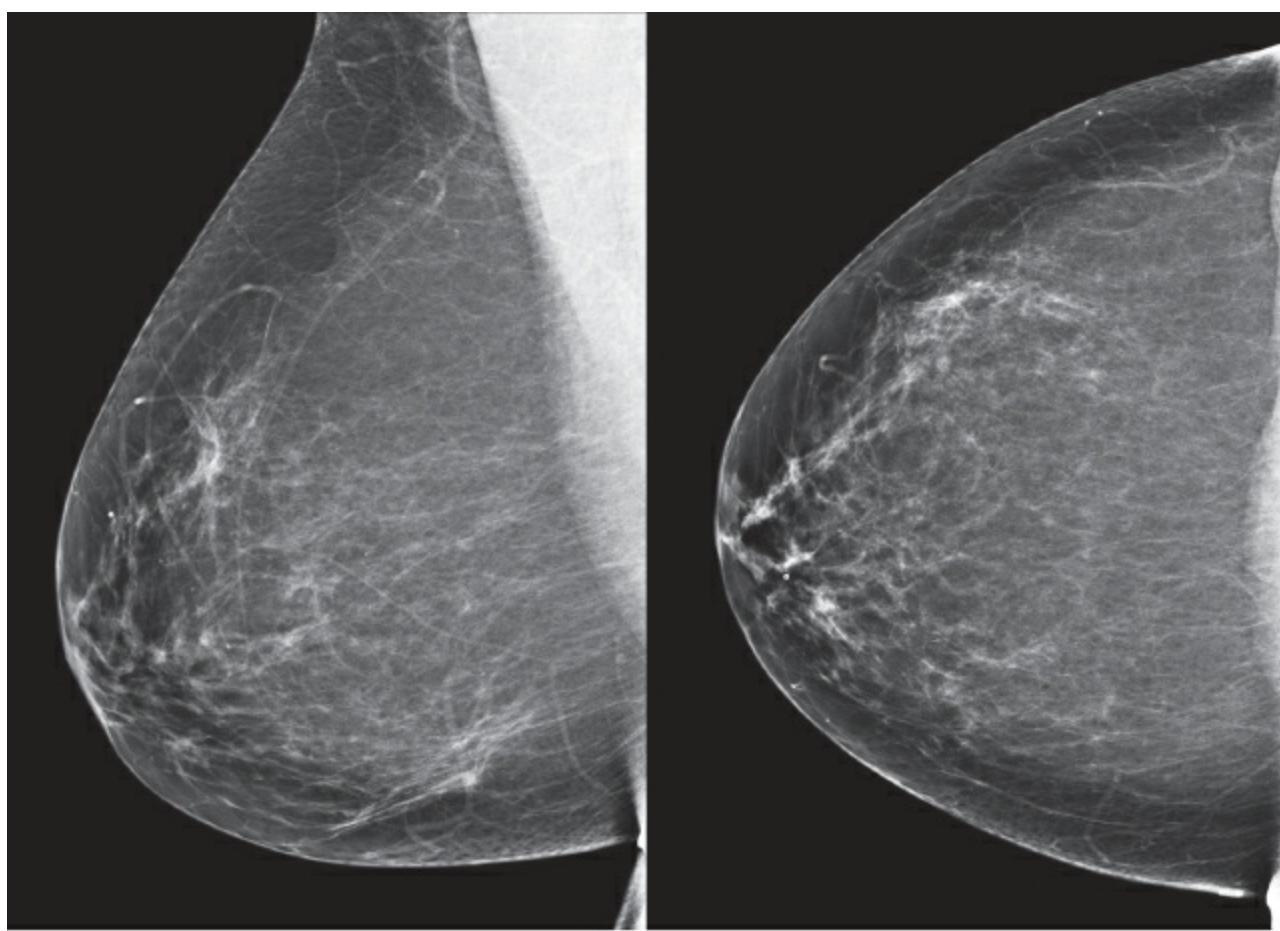


Figure 150 — The breasts are almost entirely fatty.

BREAST COMPOSITION ILLUSTRATIONS

- b. There are scattered areas of fibroglandular density.

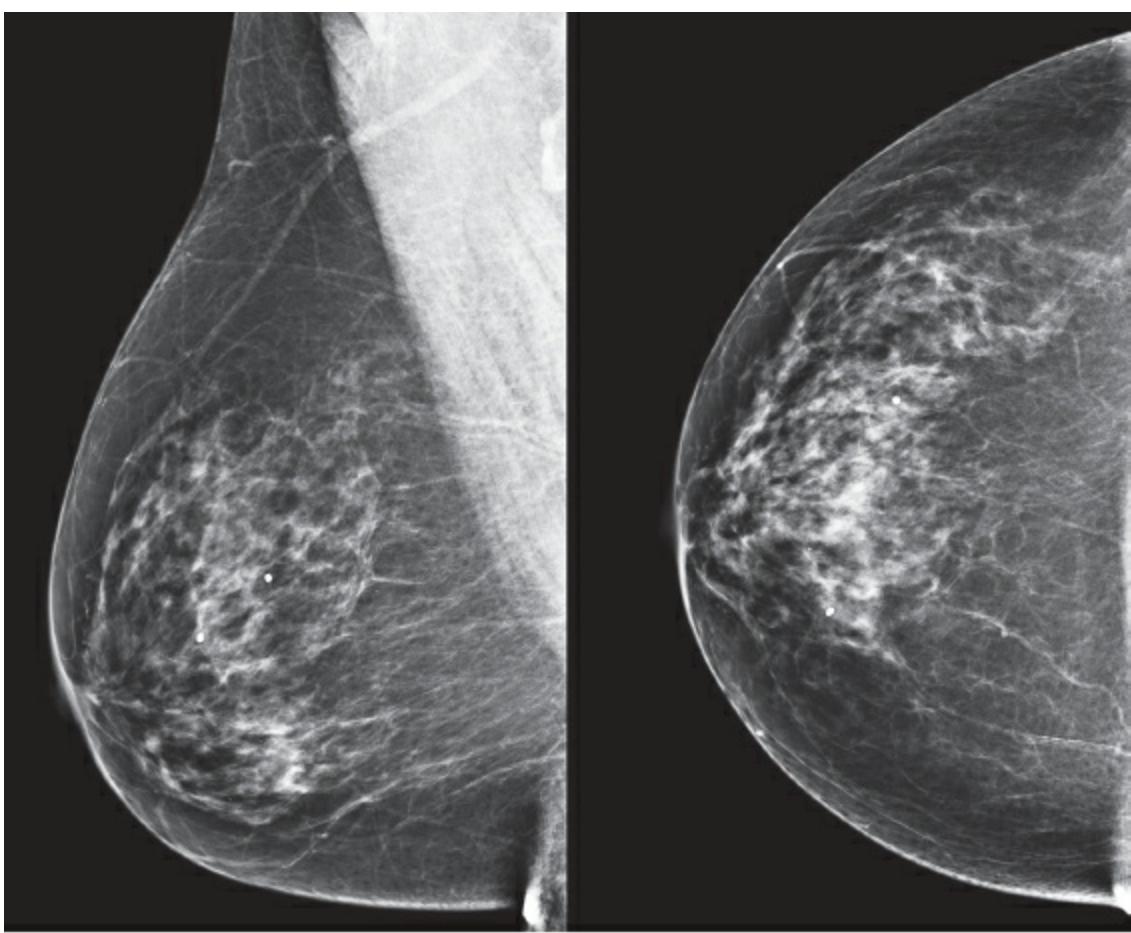


Figure 151— There are scattered areas of fibroglandular density.

BREAST COMPOSITION ILLUSTRATIONS

- c. The breasts are heterogeneously dense, which may obscure small masses.

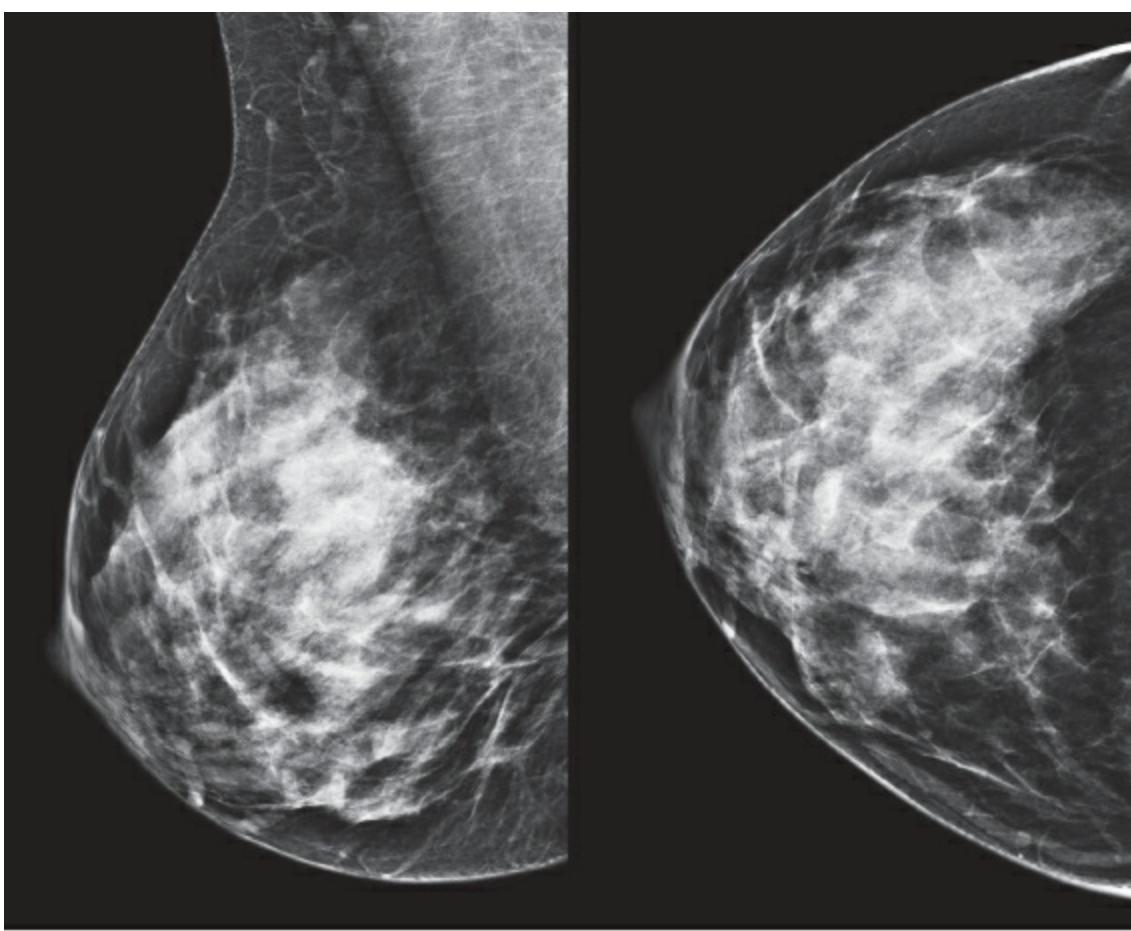


Figure 152 — The breasts are heterogeneously dense, which may obscure small masses.

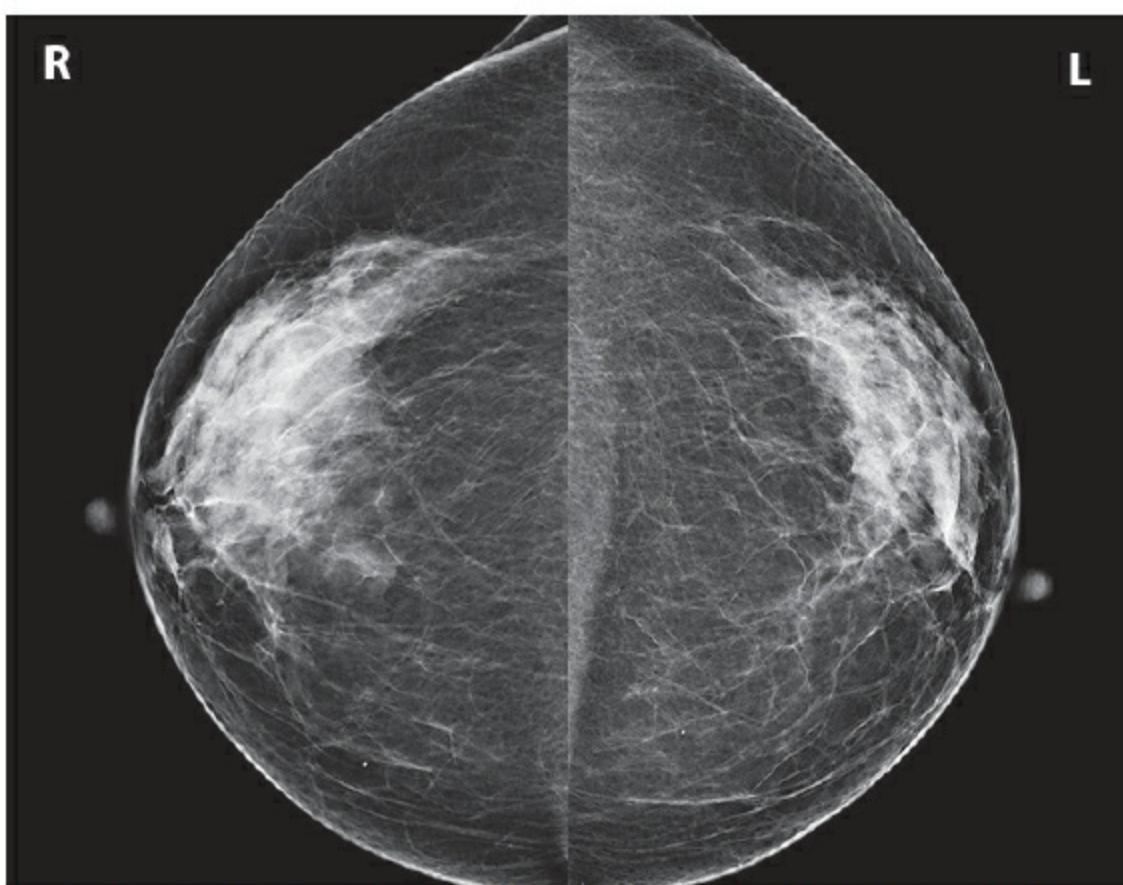


Figure 153 — Breast density is classified using the denser breast. In this case, because the fibroglandular tissue in the upper outer right breast is sufficiently dense to obscure small masses, the examination should be classified as HETEROGENEOUSLY DENSE, even though far less than 50% of the volume of this (denser) breast contains fibroglandular-density tissue.

d. The breasts are extremely dense, which lowers the sensitivity of mammography.

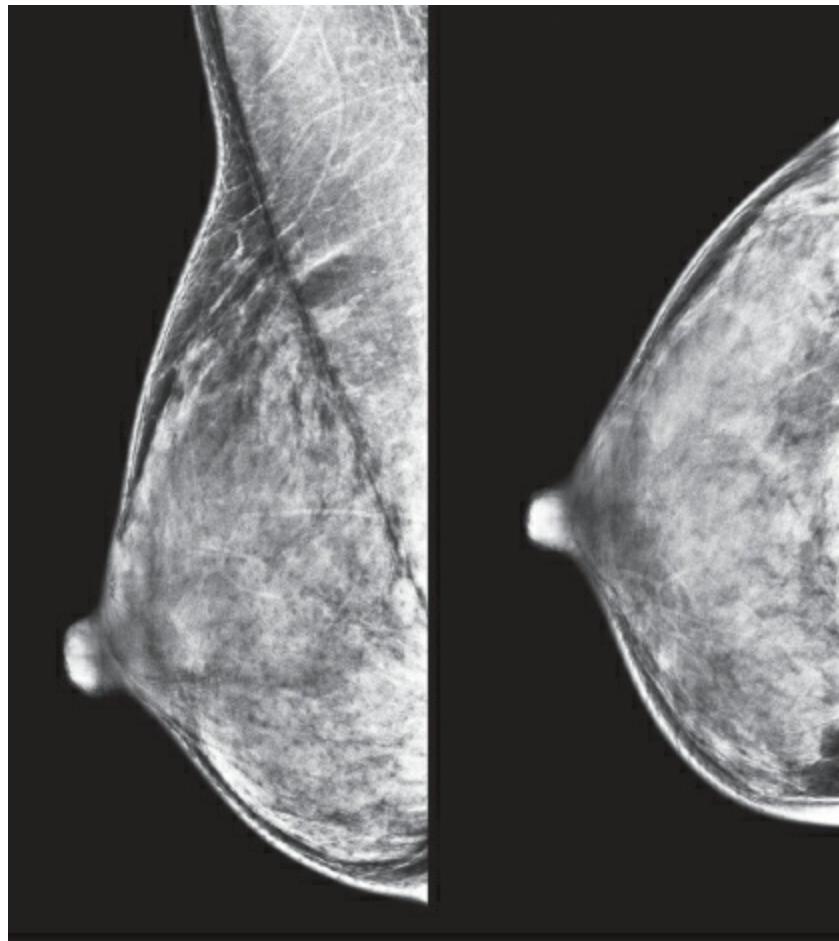


Figure 154 — The breasts are extremely dense, which lowers the sensitivity of mammography.

3. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

(It is assumed that most important findings are either of concern at screening, inherently suspicious, new, or seen to be larger/more extensive when compared to previous examination.)

a. **Mass:**

Size

Morphology (shape, margin)

Density

Associated calcifications

Associated features

Location

b. Calcifications:

Morphology — describe typically benign type or describe shape of particles

Distribution (may not be appropriate for typically benign calcifications)

Associated features

Location

c. Architectural Distortion:

Associated calcifications

Associated features

Location

d. Asymmetries (asymmetry, global asymmetry, focal asymmetry, developing asymmetry):

Associated calcifications

Associated features

Location

e. Intramammary lymph node (rarely important):

Location

f. Skin lesion (rarely important):

Location

g. Solitary dilated duct (rarely present):

Location

4. COMPARISON TO PREVIOUS EXAMINATION(S), IF DEEMED APPROPRIATE BY THE INTERPRETING PHYSICIAN

Comparison to previous examination may assume importance if the finding of concern requires an evaluation of change or stability. Comparison is not important when a finding has unequivocally benign features. Comparison may be irrelevant when the finding is inherently suspicious for malignancy.

5. ASSESSMENT

The incorporation of an assessment category in the overall summary of the mammography report is mandated by the Food and Drug Administration, Quality Mammography Standards; Final Rule.³ Whereas FDA-mandated assessments are not linked to management recommendations, BI-RADS® assessment categories are designed to be concordant with specific management recommendations. The linking of assessment categories with concordant management recommendations further enhances sound medical practice.

All final assessments (BI-RADS® categories 1, 2, 3, 4, 5, and 6) should be based on thorough evaluation of the mammographic features of concern or after determination that an examination is negative or benign.

An incomplete (category 0) assessment is usually given for screening examinations when additional imaging evaluation is recommended before it is appropriate to render a final assessment. There may be rare situations in the screening setting in which a category 4 or 5 assessment is used, but this practice is discouraged because it may compromise some aspects of outcome analysis.

A recall (category 0) assessment should include specific suggestions for the next course of action (spot-compression magnification views, US, etc.).

6. MANAGEMENT

If a suspicious abnormality is identified, the report should indicate that a biopsy should be performed in the absence of clinical contraindication. This is an assessment for which the interpreting physician has sufficient concern that biopsy is warranted based on imaging findings. The recommended language ("biopsy should be performed in the absence of clinical contraindication") provides for the unusual circumstance in which either the patient or her physician might reasonably wish to defer a biopsy.

Interpretation is facilitated by recognizing that most examinations may be categorized under a few headings. These are listed in [Table 6](#) and numeric codes are included for computer use.

B. ASSESSMENT CATEGORIES

Table 6. Concordance Between BI-RADS® Assessment Categories and Management Recommendations

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete – Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	Recall for additional imaging and/or comparison with prior examination(s)	N/A
Category 1: Negative	Routine mammography screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine mammography screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance mammography (Figure 155, see page 152)	> 0% but ≤ 2% likelihood of malignancy
Category 4: Suspicious Category 4A: <i>Low suspicion</i> for malignancy Category 4B: <i>Moderate suspicion</i> for malignancy Category 4C: <i>High suspicion</i> for malignancy	Tissue diagnosis	> 2% but < 95% likelihood of malignancy > 2% to ≤ 10% likelihood of malignancy > 10% to ≤ 50% likelihood of malignancy > 50% to < 95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

a. Mammographic Assessment Is Incomplete

Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison

For this assessment category, the text may be shortened to “Incomplete — Need Additional Imaging Evaluation” or “Incomplete — Need Prior Mammograms for Comparison”, as appropriate. Refer to [Table 8](#) in Frequently Asked Question #1 in the Guidance chapter for a listing of FDA-approved equivalent wording for assessment categories.

There is a finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this assessment category may be used in a diagnostic mammography report, such as when US equipment or personnel are not immediately available, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. A recommendation for additional imaging evaluation includes the use of spot-compression (with or without magnification), special mammographic views, and US. Category 0 should not be used for diagnostic breast imaging findings that warrant further evaluation with

MRI. Rather, the interpreting physician should issue a final assessment in a report that is made before the MRI examination is performed. Refer to [Frequently Asked Question #8](#) in the Guidance chapter for further discussion.

In most circumstances and when feasible, if a mammography examination is not assessed as negative or benign, the current examination should be compared with prior examination(s). The interpreting physician should use judgment on how vigorously to attempt obtaining prior examinations, given the likelihood of success of such an endeavor and the likelihood that comparison will affect the final assessment. In this context, it is important to note that comparison with previous examination(s) may be irrelevant when a finding is inherently suspicious for malignancy.

Category 0 should be used for prior image comparison only when such comparison is required to make a final assessment. When category 0 is used in the context of awaiting prior examinations for comparison, there should be in place a tracking procedure guaranteeing with 100% reliability that a final assessment will be made within 30 days (preferably sooner) even if prior examinations do not become available. Some mammography practices may reasonably choose never to use category 0 in the context of awaiting prior examinations simply because they do not have a 100% reliable tracking procedure. If a mammography examination is assessed as category 0 in the context of awaiting prior examinations and then the prior examinations do become available, an addendum to the initial mammography report should be issued, including a revised assessment. For auditing purposes, the revised assessment should replace the initial assessment (see the Follow-up and Outcome Monitoring section).

b. Mammographic Assessment Is Complete — Final Assessment Categories

Category 1: Negative (see Guidance chapter)

There is nothing to comment on. This is a normal examination.

Category 2: Benign (see Guidance chapter)

Like category 1, this is a normal assessment, but here the interpreter chooses to describe a benign finding in the mammography report. Involuting calcified fibroadenomas, skin calcifications, metallic foreign bodies (such as core biopsy and surgical clips), and fat-containing lesions (such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas) all have characteristically benign appearances and may be described with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcification, implants, or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy. On the other hand, the interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1).

Note that both category 1 and category 2 assessments indicate that there is no mammographic evidence of malignancy. Both should be followed by the management recommendation for routine mammography screening. The difference is that category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas category 1 should be used when no such findings are described (even if such findings are present).

Category 3: Probably Benign (see Guidance chapter, including [Figure 155](#))

A finding assessed using this category should have a $\leq 2\%$ likelihood of malignancy, but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding. A probably benign finding is not expected to change over the suggested period of imaging surveillance, but the interpreting physician prefers to establish stability of the finding before recommending management limited to routine mammography screening.

There are several prospective clinical studies demonstrating the safety and efficacy of periodic mammographic surveillance instead of biopsy for specific mammographic findings.^{4, 5, 6, 7, 8, 9} Three specific findings are validated as being probably benign (noncalcified circumscribed solid mass, focal asymmetry, and solitary group of punctate calcifications). All the previously cited studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (category 3) assessment; hence, it is recommended not to render such an assessment in interpreting a screening mammography examination. The practice of rendering category 3 assessments directly from screening examination also has been shown to result in adverse outcomes: 1) unnecessary follow-up of many lesions that could have been promptly assessed as benign, and 2) delayed diagnosis of a small number of cancers that otherwise may have been smaller in size and less likely to be advanced in stage.¹⁰ Also, all the previously cited studies^{4, 5, 6, 7, 8, 9} exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by robust scientific data, although there are two single-institution studies that do report successful outcomes for palpable lesions.^{11, 12} Finally, because evidence from previously cited studies indicates the need for biopsy rather than continued surveillance when a probably benign finding increases in size or extent,^{4, 5, 6, 7, 8, 9} it is not prudent to render a category 3 assessment when a finding that otherwise meets “probably benign” imaging criteria is either new or has increased in size or extent.

Refer to [Figure 155](#) at the end of the Guidance chapter for an illustration of the recommended algorithm for follow-up examinations during the entire mammographic surveillance period. While the vast majority of probably benign findings are managed with an initial short-interval follow-up (6 months) examination followed by additional examinations until long-term (2- or 3-year) stability is demonstrated, there may be occasions in which a biopsy is done instead (patient

preference or overriding clinical concern).

Category 4: Suspicious ([Guidance chapter](#))

This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy. The ceiling for category 3 assessment is a 2% likelihood of malignancy and the floor for category 5 assessment is 95%, so category 4 assessments cover the wide range of likelihood of malignancy in between. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this category. By subdividing category 4 into 4A, 4B, and 4C, as recommended in Guidance chapter and using the cut points indicated therein, it is hoped that patients and referring clinicians will more readily make informed decisions on the ultimate course of action.

Category 5: Highly Suggestive of Malignancy ([Guidance chapter](#))

These assessments carry a very high probability ($\geq 95\%$) of malignancy. This category initially was established to involve lesions for which 1-stage surgical treatment was considered without preliminary biopsy, in an era when preoperative wire localization was the primary breast interventional procedure. Nowadays, given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery is rarely, if ever, performed. Rather, current oncologic management almost always involves tissue diagnosis of malignancy via percutaneous tissue sampling to facilitate treatment options, such as when sentinel node biopsy is included in surgical management or when neoadjuvant chemotherapy is administered prior to surgery. Therefore, the current rationale for using a category 5 assessment is to identify lesions for which any non-malignant percutaneous tissue diagnosis is automatically considered discordant, resulting in the recommendation for repeat (usually surgical) biopsy.

Category 6: Known Biopsy-Proven Malignancy ([Guidance chapter](#)):

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy but prior to complete surgical excision), in which there are no mammographic abnormalities other than the known cancer that might need additional evaluation.

C. WORDING THE REPORT

The current examination should be COMPARED TO PRIOR EXAMINATION(S) when appropriate. The INDICATION FOR EXAMINATION, such as screening or diagnostic, should be stated. The report should be organized with a brief description of the COMPOSITION of the breast and any pertinent FINDINGS, followed by the ASSESSMENT and MANAGEMENT RECOMMENDATIONS. ***Any verbal discussions between the interpreting physician and the referring clinician or patient should be documented in the original report or in an addendum***

to the report.

The report should be succinct, using terminology from the latest approved lexicon without embellishment. Definitions of lexicon terms for mammographic findings **should not** appear in the report narrative. Following the impression section and the (concordant) management recommendation section of the report, both the assessment category number **and** FDA-approved terminology for the assessment category should be stated. Other aspects of the report should comply with the **ACR Practice Guideline for Communication: Diagnostic Radiology**.¹³

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III. GUIDANCE

Many substantive changes were incorporated in the fourth and 2013 editions to improve the clinical utility of the BI-RADS® Atlas and to supply a unified base for research involving breast imaging. This chapter expands on these changes as they appear in each section of the BI-RADS® Atlas and provides more complete explanations for the changes. ***What follows is intended for guidance and is not meant to imply required standards of practice.***

It is important to review the beginning text of the [Follow-up and Outcome Monitoring section](#) and its [Frequently Asked Questions](#) to fully understand how auditing definitions will affect the outcomes (performance metrics) for screening examinations as well as the benchmarks that are derived from these outcomes.

A. MAMMOGRAPHY LEXICON

For several findings in the lexicon for which more than one descriptor was used in past editions, only one descriptor remains in the 2013 edition. These changes were made to simplify reporting. To ease the transition, the eliminated descriptor term appears in the heading for each such finding, within parentheses, as (historically, “eliminated term”). Eliminated terms will appear only in the edition within which they were eliminated, not in subsequent editions.

1. Asymmetry Versus Mass

All types of asymmetry have different border contours than true masses and also lack the conspicuity of masses. Indeed, asymmetries appear similar to other discrete areas of benign fibroglandular tissue except that they are unilateral, with no mirror-image correlate in the opposite breast. An asymmetry demonstrates concave-outward borders and usually is interspersed with fat, whereas a mass demonstrates completely or partially convex-outward borders and (when radiodense) appears denser in the center than at the periphery. As a descriptor of specific mammographic findings, use of the term “asymmetry” rather than “density” avoids potential confusion, insofar as density also is used to describe the attenuation characteristics of masses.

There has been only one change in the 2013 edition concerning the lexicon descriptors for masses. It was confusing in previous editions to have the term “lobular” (two or three large undulations) as a descriptor of shape and the term “microlobulated” (many small undulations) as a descriptor of margin. Adding to the confusion was the fact that lobular shape usually is associated with a benign mass, whereas a microlobulated margin usually implies a suspicious mass. In the 2013 edition, the shape descriptor “lobular” has been eliminated; “microlobulated” remains a descriptor of margin. The shape of masses with two or three undulations now are to be described as oval, along with smooth-contoured elliptical or egg-shaped masses. This change is consistent with the observation that almost all such macrolobulated masses indeed are oval; it also serves to distinguish all oval masses (usually benign in appearance) from masses with microlobulated margins (which usually are assessed as suspicious).

Also concerning masses, it is useful to note that for mammography, descriptors of margin include the term “obscured” because adjacent dense fibroglandular tissue may impair the visibility of the margin of a mass. This does not apply to either US or MRI, which are tomographic modalities that display masses unimpaired by the presence of adjacent dense fibroglandular tissue.

2. Calcifications

In the 2013 edition, among the descriptors of typically benign calcifications, the term "lucent-centered" has been eliminated by incorporating it into the remaining term "rim." The historical term "eggshell" also has been eliminated, to simplify reporting. This leaves "rim calcification" as the only acceptable lexicon term. One reason for these changes is that all the terms describe calcific particles displaying calcium in the rim and radiolucency in the center. Furthermore, there is no need to distinguish between different types of rim calcification on the basis of the thickness of the calcified rim, given that all rim calcifications are typically benign.

It may be confusing to have both "round" and "punctate" as calcification descriptors when both refer to particles that are round in shape, but the 2013 edition emphasizes that these two descriptors have distinguishing features. One difference relates to size, with punctate defined as calcific particles < 0.5 mm and round as particles ≥ 0.5 mm. Another difference from benign round calcifications is that an isolated group of the smaller, punctate calcifications may warrant 1) a probably benign assessment and mammographic surveillance if no prior examinations are available for comparison, or 2) imaging-guided biopsy if punctate calcifications are new, increasing, linear, or segmental in distribution, or adjacent to a known cancer.

Coarse heterogeneous calcifications are between 0.5 mm and 1 mm in size and variable in size and shape, but are smaller than the similarly shaped > 1 mm dystrophic calcifications that occur in response to injury. When present as multiple bilateral groupings, coarse heterogeneous calcifications are almost always due to fibroadenomas or fibrosis, and benign assessment may be appropriate. Over time, these tend to coalesce into typically benign calcifications. However, when present as a solitary isolated group, coarse heterogeneous calcifications have a small but substantial likelihood of malignancy, demonstrating malignancy in slightly fewer than 15% of cases (see [Table 2](#)), especially when occurring together with even smaller, fine pleomorphic calcifications. Among the several types of grouped calcifications that vary in size and shape, there is a continuum from "fine pleomorphic to coarse heterogeneous to coarse or popcorn-like to dystrophic," based on the increasing size of the largest, most coalescent calcific particles in the group. Assessment may be challenging at or close to the cut points for particle size (0.5 mm, 1 mm) between these different types of calcifications. However, within the continuum of variable-shaped grouped calcifications, the likelihood of malignancy increases as the size of the calcific particles decreases.

Another change in the 2013 edition concerning calcifications involves a clarification of the definitions of grouped and regional distribution. Problems with the definitions used in previous editions were: 1) the upper limit in size for grouped distribution was 1 cm^3 , whereas the lower limit in size for regional distribution was more than 2 cm^3 in size, leaving an unexplained 1 cm^3 gap; and 2) the sizes for grouped and regional distribution were described in terms of volume, but interpreting physicians rarely make volume measurements. The 2013 edition redefines the upper limit in size for grouped

distribution as 2 cm while retaining > 2 cm as the lower limit for regional distribution, thus eliminating the gap. Furthermore, the 2013 edition describes the measurement of size in terms of greatest linear dimension, to correspond to the measurement made most frequently by interpreting physicians.

However, the major change concerning calcifications in the 2013 edition is elimination of the subdivision of suspicious calcifications into groups called intermediate concern (amorphous and coarse heterogeneous) and higher probability of malignancy (fine pleomorphic and fine linear or fine-linear branching). Subsequent to publication of the fourth edition, two clinical studies have been published based on BI-RADS® calcification descriptors,^{1,2} the data from which are incorporated into Tables 2 and 3) in the Lexicon along with two other previously published studies.^{3,4} The combination of data from all these studies indicates relatively small differences in the likelihood of malignancy among amorphous, coarse heterogeneous, and fine pleomorphic calcifications, all being substantially lower than 50%. So, rather than retaining the previously described terms “intermediate concern” and “higher probability of malignancy”, the 2013 edition indicates that the three calcification types with a lower likelihood of malignancy should be assessed as category 4B, whereas fine linear or fine-linear branching calcifications should be assessed as category 4C (see below, in the section on Assessment Categories, for a discussion of the use of subcategories of category 4).

3. Asymmetries

The BI-RADS® Atlas describes four types of asymmetries: asymmetry, global asymmetry, focal asymmetry, and developing asymmetry. The term “asymmetry” is used to define a discrete but asymmetric area of fibroglandular tissue that is visible on only one mammographic projection. This finding is usually identified at screening mammography, when only one mediolateral oblique and one craniocaudal view are obtained of each breast. When such a finding reaches the interpreting physician’s threshold for recall, additional mammographic view(s) should be obtained to establish or exclude the diagnosis of summation artifact (superimposition of normal breast structures). This is because research has demonstrated that more than 80% of screening-detected asymmetries represent summation artifact.⁵

Global asymmetry is a real finding (visible on two different mammographic projections), involving a large portion of the breast that is defined as at least a quadrant. In the absence of a palpable correlate, global asymmetry usually is a normal variant or due to contralateral excision of a large volume of dense fibroglandular tissue and is assessed as benign (BI-RADS® category 2) with a recommendation for routine screening.

A focal asymmetry differs from global asymmetry only in the volume of the breast involved, occupying less than a quadrant. Despite its smaller size, focal asymmetry is of

more concern than global asymmetry because a small (especially < 1 cm) focal asymmetry may be nonpalpable yet malignant. Robust clinical research indicates that there is a 0.5%–1% likelihood of malignancy for a solitary focal asymmetry identified at screening, with no associated architectural distortion, microcalcifications, or underlying mass identified at subsequent diagnostic mammography and US examination.^{6, 7, 8, 9, 10, 11} Therefore, it is reasonable to assess such a finding as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging and surveillance imaging.

Note that occasionally what is properly described as a focal asymmetry at screening (a finding visible on standard MLO and CC views) is determined at diagnostic mammography to be two different findings, each visible on only one standard view (hence, two asymmetries), each of which ultimately is judged to represent superimposition of normal breast structures. Also, not infrequently, what is properly described as a focal asymmetry at screening is determined at diagnostic evaluation (mammography and/or US) to represent a mass.

Comparison to previous examination(s) is critical in evaluating asymmetries. Research indicates an essentially 0% likelihood of malignancy for focal asymmetries that are stable at imaging over at least a 2- to 3-year interval.^{6, 7, 8, 9, 10, 11} However, more recent research has demonstrated that when a focal asymmetry is new or appears larger or more conspicuous than on a previous examination, the likelihood of malignancy is substantial.¹² Based on this evidence, the term “developing asymmetry” has been added to the lexicon. A developing asymmetry requires additional imaging evaluation in the absence of a history of surgery, trauma, or infection at the site of the finding. Unless shown to be characteristically benign (e.g., representing a simple cyst at US), it is reasonable to assess an unexplained developing asymmetry as suspicious (BI-RADS® category 4) with a recommendation for tissue diagnosis.

4. Solitary Dilated Duct

Solitary dilated duct is another discrete mammographic finding for which recent research suggests a change in assessment and management from what was recommended previously.¹³ Although rarely encountered, the frequency of malignancy is reported to be approximately 10% when a solitary dilated duct is identified (without associated mass, architectural distortion, or microcalcifications). Therefore, although previous editions of the BI-RADS® Atlas indicated that this finding is usually of minor clinical significance, one should now consider additional imaging evaluation leading to tissue diagnosis unless a benign etiology is demonstrated.

5. Breast Composition

The 2013 edition eliminates quartile ranges of percent dense tissue to define the

descriptors of breast composition, reflecting the clinical experience that interpreting physicians did not use the quartile ranges that were introduced in the fourth edition. Documentation of this clinical experience and a full discussion of the rationale behind eliminating quartile ranges is found in the [breast composition](#), portion of the Reporting System.

6. Descriptors for Lesion Location

The 2013 edition expands the descriptors used to describe lesion location, allowing for more precision in indicating the site(s) of abnormal finding(s). This facilitates correlation of what is seen at mammography with the findings at other breast imaging modalities and at clinical breast examination.

7. Comparison to Previous Examinations

The 2013 edition adds the statement that comparison with previous examination(s) may be irrelevant when a finding is inherently suspicious for malignancy, serving as recognition of the clinical reality that subsequent management should be based on current rather than previous imaging findings. This provides justification for simplifying abnormal reports by omitting comments about the presence or absence of interval change for findings that clearly require prompt action.

8. Use of Radiopaque Markers

A raised skin lesion sufficiently large to be seen at mammography may be marked by the technologist with a radiopaque device designed for use as a marker for a skin lesion. Because this marker is placed directly on top of or surrounding the skin lesion, both the device and the skin lesion will be seen in the same location on mammographic images obtained in any projection. This approach enables the interpreting physician to discount the importance of the underlying mammographic finding, which represents the benign skin lesion.

Similarly, the technologist may use a radiopaque device to mark the location of a palpable lesion in the breast. The technologist should place the marker at the location on the skin that is expected to overlie the palpable lesion when the breast is compressed in a given mammographic projection.¹⁴ Visibility of the marker on the mammogram may serve as an indicator that the palpable lesion has been included in the image field. This approach also assists the interpreting physician in correlating the presence or absence of any visible mammographic finding(s) with the palpable lesion. However, the deeper within the breast that a palpable lesion is located, the greater the likelihood that the marker will be projected distant from the palpable lesion, potentially confounding mammographic interpretation. For this reason, it is recommended that the technologist remove the marker after the first exposure and replace it at another location on the skin so as to overlie the palpable lesion when the

next exposure is obtained in a different mammographic projection.

Finally, because the clinical significance of a palpable lesion is greater than that of a raised skin lesion, because the radiopaque devices used to mark both palpable and skin lesions are available in several different shapes, and because there has been no consensus in establishing the use of specific-shaped markers to represent palpable versus skin lesions, the following two practices are recommended.

1. To properly inform interpreting physicians within a given mammography facility, the facility should adopt a policy requiring consistent use of two different shapes of radiopaque devices for palpable and skin lesions, respectively.
2. To properly inform interpreting physicians outside the facility, there should be an indication of the type of underlying lesion marked by every radiopaque device (palpable versus skin lesion), either as a permanent annotation on the appropriate mammographic image(s) or as a description in the mammography report.

B. REPORT ORGANIZATION

1. Assessment-Management Concordance

In previous editions of the BI-RADS® Atlas, management recommendations were included in the text used to describe several of the assessment categories. In the 2013 edition, we have removed the management recommendations from this text in order to provide more flexibility for several specific clinical scenarios (described in detail in the immediately subsequent paragraphs) for which a seemingly discordant management recommendation might be appropriate for a given assessment. However, ***except for these few scenarios, the management recommendation should be fully concordant with the assessment***, as indicated in [Table 6](#). Assessment-management concordance is a hallmark of appropriate interpretation. To do otherwise invites confusing the referring clinician and/or the patient, with the potential for producing incorrect treatment.

The most common clinical scenario in which the appropriate management recommendation may appear to be discordant with the proper BI-RADS® assessment category occurs when there are no imaging findings in a patient who has a palpable breast abnormality. In this situation, it would seem that the breast imaging report should indicate a negative (BI-RADS® category 1) assessment, because there are indeed no imaging findings to describe. However, to cover the possibility that a palpable cancer might not be visible at breast imaging, the interpreting physician may want to suggest surgical consultation or tissue diagnosis, management recommendations that are discordant with a negative assessment. The correct approach to reporting in this scenario is to provide a negative (BI-RADS® category 1) assessment with a concordant

management recommendation for routine mammography screening, but to follow this with a sentence recommending surgical consultation or tissue diagnosis if clinically indicated. The presence of certain other mammographically occult clinical findings also may require a recommendation for prompt action by the referring clinician, such as suspected Paget disease of the nipple without a suspicious finding at imaging and a skin lesion suspect for melanoma or skin cancer.

Another seemingly discordant clinical scenario involves the simple (characteristically benign) cyst that is either tender or painful, for which therapeutic aspiration is recommended for symptomatic relief, given that the recommendation for an interventional procedure is discordant with a benign assessment. The correct approach to reporting in this scenario is to provide a benign (BI-RADS® category 2) assessment with a concordant management recommendation for routine mammography screening, but to follow this with a sentence recommending aspiration to relieve the discomfort produced by the cyst.

Still another scenario that involves an assessment-management discordance occurs in the woman who has a ruptured implant but no imaging findings suggestive of malignancy. The seemingly appropriate benign assessment would be discordant with a recommendation for surgical consultation leading to implant removal and possible replacement with a new implant. The correct approach to reporting in this scenario is to provide a benign (BI-RADS® category 2) assessment with a concordant management recommendation for routine mammography screening, but to follow this with a sentence recommending surgical consultation that addresses proper treatment for the ruptured implant. The presence of certain other benign imaging findings also may require a recommendation for prompt action by the referring clinician, such as breast abscess, edema of the breast (when not suspicious for malignancy), new hematoma, new clinically relevant foreign body, and some manifestations of gynecomastia in a male patient.

It should be clear from the previous examples that the correct approach to reporting for all seemingly discordant interpretive scenarios is that a) the assessment category should reflect the imaging findings of the case, b) a concordant management recommendation should be provided for this assessment, but c) an additional sentence should recommend the additional (apparently discordant) management appropriate for the scenario. This approach provides the flexibility in reporting to allow for both concordant and discordant components of management to be associated with the imaging-appropriate assessment.

2. Assessment When More Than One Breast Imaging Examination Is Reported Together

BI-RADS® initially was designed as a mammographic tool. Beginning with the fourth edition, BI-RADS®—Mammography was combined with BI-RADS®—US and BI-RADS®—

MRI. Obviously, both US and MRI have features that are unique to each imaging modality, but, when possible, the same lexicon descriptors that are used for mammography also are employed for US and MRI. In the 2013 edition, one change has been made in the mammography section, so that all three sections use the same terminology whenever possible. Specifically, the mammography section has been changed to add distance from the nipple as a descriptor of lesion location, to parallel the descriptors used in the US and MRI sections. Note that the goal here is simply to provide an additional location descriptor for mammographic lesions; it is recognized that distance from the nipple is likely to vary somewhat among the different breast imaging modalities because the breast is compressed at mammography and the patient is supine at US and prone at MRI.

The terms used for assessment categories and management recommendations are the same for all imaging modalities. When more than one type of examination is performed concurrently (on the same day), it is preferable that the examinations be reported together, with the findings for each examination described in separate paragraphs, with an overall assessment and management recommendations for the combined examinations. In general, when the assessments for two examinations differ, the overall assessment (and concordant management recommendations) should reflect the more abnormal of the individual assessments (whatever management is expected to come first, supplemented by likelihood of malignancy), according to the following hierarchy of increasing abnormality: categories 1, 2, 3, 6, 0, 4, 5 ([Table 7](#)).

Exceptions to this rule occur when the characteristically benign features of a given imaging finding on one examination supersede the less specifically benign features of the same finding on the other examination (for example, partially circumscribed noncalcified mass at mammography, superseded by simple cyst at US). These exceptions are described in detail in the section on frequently asked questions that appears later in this chapter.

C. ASSESSMENT CATEGORIES

BI-RADS® assessments are divided into incomplete (category 0) and final assessment categories (categories 1, 2, 3, 4, 5, and 6). An incomplete mammography assessment, usually rendered at batch-read screening mammography, requires further evaluation with additional mammographic views, US, and/or comparison mammography examination(s). If the additional evaluation involves only comparison with previous mammography examination(s) that then leads to a final assessment, the incomplete screening assessment is replaced by this final assessment. If the additional evaluation includes a diagnostic imaging examination, a final assessment is rendered for the diagnostic examination, but the screening mammography examination remains assessed as category 0.

Table 7. Abnormality Hierarchy

BI-RADS Assessment Category	Degree of Abnormality
1	Lowest
2	
3	
6	
0	
4	
5	Highest

The FDA regulations¹⁵ require that a single assessment be rendered for every mammographic examination. Mammography facilities that wish to provide an assessment separately for each breast may do so within the impression or body of the report, provided that a single overall assessment for the examination is clearly stated at the end of the entire report. This overall assessment should be based on the assessment rendered for the more abnormal of the two breasts, based on the same hierarchy of increasing abnormality described previously (categories 1, 2, 3, 6, 0, 4, 5). For example, if there is a probably benign assessment for one breast and a suspicious assessment for the opposite breast, the overall assessment should be suspicious (BI-RADS® category 4). Note that in July 2003 the FDA approved an alternative standard that allows for the separate assessment of findings for each breast without the need to also provide an overall assessment.¹⁶ [<http://www.fda.gov/RadiationEmittingProducts/MammographyQualityStandardsACTandProgram/Regualtions/ucm259285> .] The conditions for use of this alternative standard are that:

- a single medical report for both breasts will be sent to the referring clinician (or to the patient if there is no referring clinician);
- a single lay report will be sent to the patient, containing information based on what would have been the overall assessment for both breasts; and
- even though separate assessments are made for each breast, the interpretation will count as only one examination towards meeting the MQSA experience requirements and will be billed as a single examination.

The following paragraphs explain in detail the proper use of the several BI-RADS® assessment categories.

1. Categories 1 and 2

The use of assessment categories 1 and 2 (negative and benign, respectively) has been further clarified in the lexicon of the 2013 edition. Both of these categories are associated with the same management recommendation, routine mammography screening. The difference is that category 1 should be used when no specific benign findings are described in the text of the report, whereas category 2 should be used when at least one benign finding is described. Note that this difference relates to whether benign findings are ***described in the report***, not whether such findings are visible at examination. Some radiologists prefer to describe certain benign findings while others do not, so it is possible for the same examination (or unchanged examinations) to be assessed as either category 1 or 2. Because it may be confusing for the referring clinician or patient who reads a report that indicates no interval change from a previous examination but includes a current category 1 versus previous category 2 assessment, or vice versa, it is recommended that all radiologists who work at a given mammography facility collectively agree on whether and when to describe benign findings in the report, hence, when to use category 2 versus category 1.

2. Category 3

The use of assessment category 3, probably benign, has been clarified in the lexicon of the 2013 edition. It is emphasized that this is ***not*** an indeterminate category used simply when the radiologist is unsure whether to render a benign (BI-RADS® category 2) or suspicious (BI-RADS® category 4) assessment, but one that is reserved for specific imaging findings known to have a greater than essentially 0% but \leq 2% likelihood of representing malignancy. For mammography, there is robust literature describing three findings (noncalcified circumscribed solid mass, focal asymmetry, and solitary group of punctate calcifications) that have likelihoods of malignancy in the defined (\leq 2%) probably-benign range, for which short-interval (6-month) follow-up mammography and then periodic mammographic surveillance represents appropriate management.^{6, 7, 8, 9, 10, 11} Use of assessment category 3 for mammographic findings other than these three should be considered only if the radiologist has personal experience to justify a watchful-waiting approach, preferably involving observation of a sufficient number of cases of an additional mammographic finding to suggest a likelihood of malignancy within the defined (\leq 2%) probably-benign range. Two large-scale studies performed in the United States have validated that in the usual-care setting, category 3 assessments indeed are associated with a likelihood of malignancy of $<$ 2%.^{17, 18}

The 2013 edition also emphasizes the recommendation that category 3 assessments should be made only after completion of a full diagnostic breast imaging examination, rather than at screening mammography. There are two major advantages to the recommended approach. The first is more prompt identification of truly benign findings (simple cysts, some intramammary lymph nodes, some cases of grouped skin calcifications, etc.). A large-scale BCSC study has shown that recall imaging significantly

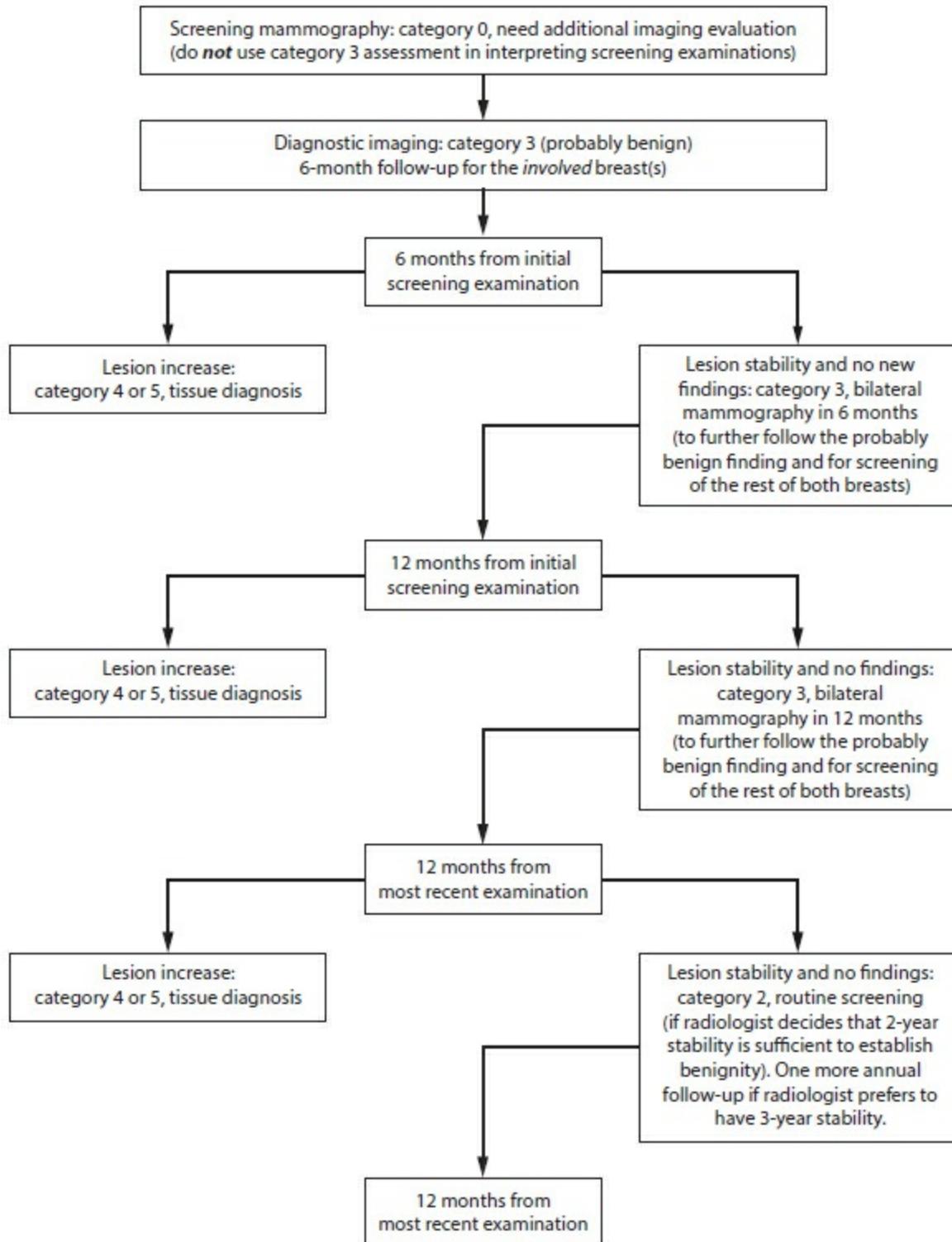
increases the identification of characteristically benign lesions, thus promptly establishing a benign diagnosis, reducing anxiety, and obviating short-interval follow-up examination.¹⁸ The second is more prompt identification of some rapidly growing cancers (the same BCSC study also suggested that recall imaging leads to the prompt diagnosis of some aggressively growing cancers by identifying these tumors when they are smaller and more likely to be node-negative, rather than 6 months later at initial short-interval follow-up examination.¹⁸) Discouraging the use of category 3 assessments at screening mammography is not limited to BI-RADS® recommendations. The first pay-for-performance initiative within Medicare's Physician Quality Reporting System (PQRS) that concerns breast imaging involves reporting the percentage of screening mammography examinations that are assessed as category 3, with the stated goal of reducing this to "approaching 0%" in clinical practice.¹⁹

For category 3 assessments, the initial short-term follow-up interval is usually 6 months, involving the breast(s) containing the probably benign finding(s). Assuming stability at this 6-month examination, a category 3 assessment again will be rendered with a management recommendation for a second short-interval follow-up examination in 6 months, but now involving both breasts if the opposite breast will be due for routine annual screening. Again assuming stability at this second short-interval follow-up, the examination is once more assessed as category 3, but now the recommended follow-up interval usually is lengthened to 1 year due the already-observed 12-month stability. Note that although the 1 year follow-up coincides with the routine screening interval in the United States, a category 3 assessment still should be rendered to indicate that the period of mammographic surveillance is still underway. According to the literature⁶, after 2–3 years of stability, the final assessment category should be changed to benign (BI-RADS® category 2), although diagnostic (rather than screening) follow-up may be appropriate if, for example, continued spot-compression magnification views will be needed. A flow-chart algorithm describing appropriate protocols for short-interval follow-up and surveillance mammography for category 3 assessments is presented in [Figure 155](#).

Note that at any short-interval or surveillance mammography examination, if the probably benign lesion is seen to decrease or disappear, the appropriate assessment is benign (BI-RADS® category 2) or negative (BI-RADS® category 1), respectively, accompanied by a recommendation for routine mammography screening. Also, it may be appropriate for a more experienced interpreter of a follow-up examination to render a benign or negative rather than probably benign assessment for a stable finding that he or she recognizes as being characteristically benign or a normal variant. Also, one may encounter the scenario in which patient or referring clinician concern causes a probably benign finding to be biopsied. In this potentially confusing scenario, the correct approach to reporting is to render a probably benign (BI-RADS® category 3) assessment with a concordant management recommendation for short-interval or surveillance mammography, but to follow this with a sentence indicating that tissue

diagnosis will be performed instead, due to patient or referring clinician concern. Finally, one may encounter the scenario of a developing asymmetry or similar suspicious finding in the clinical setting of recent breast trauma or suspected infection, causing the interpreting physician to recommend repeat mammography in 1 month rather than prompt biopsy. In this potentially confusing scenario, the correct approach is to render a suspicious (BI-RADS® category 4) assessment rather than a probably benign (BI-RADS® category 3) assessment, with a concordant management recommendation for biopsy followed by additional text indicating that biopsy will be deferred for 1 month, at which time it will be performed unless prebiopsy mammography shows interval resolution of the suspicious finding. These last two scenarios are yet other examples of how, by removing management recommendations from the text of BI-RADS® assessment categories, we have provided the needed flexibility to allow for both the concordant and discordant components of management to be associated with an imaging-appropriate assessment, as well as to produce accurate medical audit data for the interpreting physician's performance.

Figure 155. Surveillance Imaging (BI-RADS® Category 3) Algorithm



There is still another reason for eliminating management recommendations from the text of BI-RADS® assessment categories. Consider the potential confusion if the fourth-edition terminology “probably benign short-interval follow-up recommended” were used for a 12-month follow-up category 3 assessment that appropriately is accompanied by a management recommendation of 1 year follow-up. By using 2013-edition terminology (“probably benign”), there is no apparent discordance with the recommendation for 1 year surveillance mammography.

3. Category 4

Category 4 is used for the vast majority of findings prompting breast interventional procedures, ranging from diagnostic aspiration of some complicated cysts to biopsy of fine linear and fine-linear branching calcifications. According to BI-RADS® definitions expressed in terms of likelihood of malignancy, the cut points between category 3 versus category 4 assessments and category 4 versus category 5 assessments are 2% and 95%, respectively. Many institutions have, on an individual basis, subdivided category 4 to account for the vast range of lesions subjected to interventional procedures and corresponding broad range of likelihood of malignancy. This allows a more meaningful practice audit, is useful in research involving receiver-operating characteristic (ROC) curve analysis, and is an aid for clinicians and pathologists. The ***optional*** division of category 4 into three subdivisions, ***internally*** at the facility level, helps to accomplish these goals.

Since the publication of the fourth edition, in which subdivision of category 4 assessments was proposed, several articles have been published that support this approach.^{2, 20, 21} We believe that the scientific literature is now sufficiently strong to indicate specific cut points for the subdivisions of category 4 assessments and encourage future research to validate the clinical relevance of using these cut points.

4. Category 4A

Category 4A may be used for a finding needing intervention but with a low suspicion for malignancy. A malignant finding is not expected, and a recommendation for 6-month or routine follow-up after a benign percutaneous tissue diagnosis is appropriate. The range of likelihood of malignancy for category 4A assessments is > 2% to ≤ 10%. ***Examples of findings placed in this category may include a partially (< 75%) circumscribed solid mass with US features suggestive of a fibroadenoma, palpable solitary complicated cyst, and probable abscess.*** Some particularly risk-tolerant patients may even choose to decline a recommended biopsy for category 4A lesions, if they are willing to accept the risk that up to 10% of such lesions actually are malignant.

5. Category 4B

Category 4B includes lesions with a moderate suspicion for malignancy. Findings in this category warrant careful radiologic and pathologic correlation after percutaneous tissue diagnosis. Recommended follow-up with a benign result will depend on concordance. The range of likelihood of malignancy for category 4B assessments is > 10% to ≤ 50%. ***Examples of findings placed in this category may include a group of amorphous or fine pleomorphic calcifications and an otherwise nondescript solid mass with indistinct margin*** (for amorphous calcifications, see Figures 79 and 80; for fine pleomorphic calcifications, see Figures 88 and 89; and for mass with indistinct margin, see Figure 20).

6. Category 4C

Category 4C includes findings that have a high suspicion for malignancy but that are not highly suggestive of malignancy (category 5). The range of likelihood of malignancy for category 4C assessments is > 50% to < 95%, more likely malignant than benign and therefore properly termed “high suspicion.” **Examples of findings placed in this category are a new indistinct, irregular solid mass and a new group of fine linear calcifications** (for indistinct irregular solid mass, see Figures 4 and 5; for fine linear calcifications, see Figures 102 and 105).

Given the consistent use of the subdivisions of category 4, pathologists may initiate further histological evaluation of benign results for category 4C lesions, and the referring clinician may be better able to understand the radiology follow-up recommendations for findings placed in each subdivision of category 4.

Also note that whereas the fourth edition indicated the terse and somewhat vague “consider biopsy” as management for all category 4 assessments, the fifth edition provides the more directed management recommendation, “biopsy should be performed in the absence of clinical contraindication.” This new text unequivocally specifies tissue diagnosis as the interpreting physician’s management recommendation for category 4 assessments, appropriately and effectively transferring the burden of establishing a contraindication to this recommendation to the referring clinician.

Refer to Frequently Asked Question #4 later in this section for further discussion of FDA regulations concerning the use of subdivisions of Category 4.

7. Category 5

Category 5 (highly suggestive of malignancy) was established at a time when most nonpalpable breast lesions underwent preoperative wire localization prior to surgical excision. Category 5 assessments were used for those lesions that had such characteristic features of cancer that 1-stage surgical treatment might be performed immediately following frozen-section histological confirmation of malignancy. Today, breast cancer diagnosis for imaging-detected lesions almost always involves percutaneous tissue sampling, **so the current rationale for using a category 5 assessment is to identify lesions for which any nonmalignant percutaneous tissue diagnosis is automatically considered discordant**, resulting in the recommendation for repeat (usually surgical) biopsy.

The likelihood of malignancy for category 5 assessments is ≥ 95%, so use of this assessment category is reserved for classic examples of malignancy. **Examples of findings placed in this category are an irregular, spiculated, high-density mass with**

associated microcalcifications and new fine linear and branching calcifications in segmental distribution. Note that there is no single mammographic feature that is associated with a likelihood of malignancy of $\geq 95\%$. Just as for breast US and MRI examinations, it takes a combination of suspicious imaging findings to justify a category 5 assessment.

Also note that whereas the fourth edition simply indicated as management that “appropriate action should be taken” for category 5 assessments, the fifth edition provides the more directed management recommendation, “biopsy should be performed in the absence of clinical contraindication.” As for category 4 assessments, this new text unequivocally specifies tissue diagnosis as the interpreting physician’s management recommendation for category 5 assessments, appropriately and effectively transferring the burden of establishing a contraindication to this recommendation to the referring clinician.

8. Category 6

This assessment category was added to the fourth edition for use in the special circumstance when breast imaging is performed after a tissue diagnosis of malignancy but prior to complete surgical excision. Unlike the more common situations when BI-RADS® categories 4 and 5 are used, a category 6 assessment will not be associated with recommendation for tissue diagnosis of the target lesion because biopsy already has established the presence of malignancy. Category 6 is the appropriate assessment, prior to complete surgical excision, for second opinions of previously biopsied findings already shown to be malignant, after attempted complete removal of the target lesion by percutaneous core biopsy, and for the monitoring of response to neoadjuvant chemotherapy.

Category 6 also should be used for breast imaging examinations performed after attempted complete surgical excision when the pathology report indicates positive resection margins, given the assumption that residual tumor is present. The purpose of breast imaging in this situation is to indicate the specific location of any area(s) suspicious for a residual tumor that should be included in planned re-excision, not to help determine whether re-excision is needed. The use of category 6 is appropriate because additional surgery likely will be performed anyway, even in the absence of suspicious breast imaging findings. However, a category 6 assessment is appropriate in this scenario only if there is at least one mammographic feature suggestive of residual tumor. On the other hand, if there are no mammographic findings other than those indicating postsurgical scarring, a benign (BI-RADS® category 2) assessment should be rendered, supplemented by an extra sentence stating that the pathology report suggests the possibility of a residual tumor despite the absence of a mammographic correlate. This latter circumstance represents still another assessment-management discordance for which the assessment should reflect the imaging findings, with an additional management recommendation to cover the discordance.

Also note that whereas the fourth edition simply indicated as management that “appropriate action should be taken” for category 6 assessments, the fifth edition provides the more directed management recommendation, “surgical excision when clinically appropriate.” This new text unequivocally specifies surgical excision as subsequent management, also taking into account the clinical reality that the timing of excision (when clinically appropriate) will be determined by someone other than the interpreting physician.

A category 6 assessment should not be rendered in several clinical scenarios in which patients with known biopsy-proven malignancy have breast imaging examinations. For example, the use of category 6 is not appropriate for breast imaging examinations performed following surgical excision of a malignancy (lumpectomy) when the pathology report indicates no tumor at the margins of resection. In this clinical setting, tissue diagnosis will not be performed unless breast imaging demonstrates residual or new suspicious findings. Therefore, if a post-lumpectomy examination demonstrates surgical scarring but no visible residual malignancy, the appropriate assessment is benign (BI-RADS® category 2). On the other hand, if there are, for example, residual or new suspicious calcifications, the appropriate assessment is category 4 or 5.

There is one other potentially confusing situation involving the use of assessment category 6. This occurs prior to complete surgical excision of a biopsy-proven malignancy, when breast imaging demonstrates one or more possibly suspicious findings other than the known cancer. Because subsequent management should first evaluate the as yet undetermined finding(s), involving additional imaging, imaging-guided tissue diagnosis, or both, it must be made clear that besides the known malignancy there is one or more finding requiring specific prompt action. The single overall assessment should be based on the most immediate action needed. Therefore, if a second-opinion report is being made and additional imaging is indicated, a category 0 assessment should be rendered and the recommended workup should be specified. If a finding or findings are identified for which tissue diagnosis is recommended, then a category 4 or 5 assessment should be rendered. If, at additional imaging for finding(s) other than the known malignancy, it is determined that tissue diagnosis is not appropriate, then a category 6 assessment should be rendered accompanied by the recommendation that subsequent management now should be directed to the cancer. As for any examination in which there is more than one finding, the management section of the report may include a second sentence that describes the appropriate management for the finding(s) not covered by the overall assessment.

Note that, as described in the Follow-up and Outcome Monitoring chapter, examinations with a category 6 assessment should not be included in breast imaging audits. Because the diagnosis of malignancy already has been established, inclusion of these cases would skew the data for many performance parameters, confounding the interpretation of audit results.

9. Category 0

Category 0 is utilized primarily in reporting batch-read screening mammography examinations. It is used to indicate the recommendation for additional imaging evaluation, for retrieval of previous examinations for comparison, or for a “technical repeat” examination. A recommendation for additional imaging evaluation includes the use of spot-compression (with or without magnification), special mammographic views, and US.

Unlike all previous editions, the 2013 edition discourages the use of category 4 or 5 assessments at screening, instead recommending that all abnormal screening reports utilize assessment category 0 (incomplete — need additional imaging evaluation). This new recommendation more closely reflects the binary nature of screening assessments (positive versus negative) and management recommendations (routine screening versus prompt action). Note that the presence of findings at screening that are sufficiently abnormal to justify tissue diagnosis does not eliminate the need for diagnostic breast imaging evaluation to more accurately indicate the extent of disease prior to biopsy. Indeed, the use of category 0 assessments in this clinical scenario maximizes the likelihood that appropriate additional diagnostic imaging will be performed prior to tissue diagnosis. The use of category 0 assessments for all abnormal screening examinations also will serve to clarify that the abnormal interpretation (recall) rate should reflect even those screening examinations with findings sufficiently abnormal to justify tissue diagnosis.

While comparison to previous examinations is known to decrease the frequency of recall,^{22, 23} comparison is not required for most mammography examinations. In the absence of any concerning findings, it was found that previous examinations were helpful in only 35 of 1,093 (3.2%) cases.²⁴ Therefore, assessment category 0 should be used for previous image comparison only when such comparison is required to make a final assessment. Most frequently, this would involve examinations that display a focal asymmetry that could be dismissed as either a normal variant or benign finding by demonstration of stability.

Also note that the 2013 edition contains a caution, not present in the fourth edition, on the use of category 0 assessments when awaiting prior mammograms for comparison. This caution emphasizes that the mammography facility utilizing such assessments should have in place a tracking procedure guaranteeing with 100% reliability that a more directive assessment will be made within 30 days (preferably sooner) even if prior examinations do not become available.

Further note that the 2013 edition contains another caution, absent in the fourth edition, that category 0 assessments should not be utilized for diagnostic breast imaging findings that warrant further evaluation with MRI. Rather, in this clinical scenario the interpreting physician should utilize one of the final assessment

categories in a report that is made before the MRI examination is performed. Refer to [Frequently Asked Question #8](#) for a more complete discussion of this issue.

Proper procedures for the auditing of category 0 assessments are described in detail in the Follow-up and Outcome Monitoring section of the atlas.

D. FREQUENTLY ASKED QUESTIONS

1. Under MQSA, is it necessary to include a numeric assessment code (i.e., 0, 1, 2, 3, 4, 5, or 6) in addition to the assessment category in all mammography reports?

No. FDA regulations require only that each mammography report include the text corresponding to the overall assessment category, not the numeric code. These categories are “Incomplete: Need Additional Imaging Evaluation,” “Negative,” “Benign,” “Probably Benign,” “Suspicious,” “Highly Suggestive of Malignancy,” and “Known Biopsy-Proven Cancer.” The FDA requires that the assessment category be written verbatim as described in their regulations (limited flexibility is allowed, using equivalent wording as detailed in [Table 8](#) below). ***Use of any wording not specifically listed in the table would be in violation of FDA regulations.*** Also, the FDA has approved an alternative standard to allow the assessment category “Post Procedure Mammograms for Marker Placement.” Although the ACR encourages the use of numeric codes along with the assessment category text, there are no requirements that the codes be assigned to their respective assessments.

Table 8. FDA-Approved Equivalent Wording for BI-RADS® Assessment Categories

BI-RADS® Assessment Category	BI-RADS® Numeric Code	FDA-Approved Equivalent Wording
Incomplete — Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	0	<ul style="list-style-type: none">• Incomplete: Needs Additional Imaging Evaluation• Incomplete: Additional Imaging Evaluation Needed• Incomplete: Need Additional Imaging Evaluation — Comparison with Prior Studies• Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison• Incomplete: Need Prior Mammograms for Comparison• Need Additional Imaging Evaluation (The term incomplete can be inferred in this example as this is the only BI-RADS® assessment category.)• Incomplete Mammogram: Need Additional Imaging Evaluation
Negative	1	<ul style="list-style-type: none">• Negative Mammogram
Benign	2	<ul style="list-style-type: none">• Benign Finding• Benign Findings• Benign Abnormality• Benign Abnormalities• Benign Mammogram
Probably Benign	3	<ul style="list-style-type: none">• Probaby Benign Finding• Probably Benign Findings• Probably Benign Abnormality• Probably Benign Abnormalities• Probably Benign — Short Interval Follow-up Suggested• Probably Benign Finding — Short Interval Follow-up Suggested• Probably Benign Mammogram
BI-RADS® Assessment Category	BI-RADS® Numeric Code	FDA-Approved Equivalent Wording
Suspicious	4	<ul style="list-style-type: none">• Suspicious Finding• Suspicious Findings• Suspicious Abnormality• Suspicious Abnormalities• Suspicious for Malignancy• Suspicious Finding — Biopsy Should Be Considered• Suspicious Abnormality — Biopsy Should Be Considered• Suspicious Mammogram
Highly Suggestive of Malignancy	5	<ul style="list-style-type: none">• Highly Suggestive for Malignancy• Highly Suggestive of Malignancy — Appropriate Action Should Be Taken
Known Biopsy-Proven Malignancy	6	<ul style="list-style-type: none">• Known Biopsy-Proven Cancer• Known Malignancy• Known Cancer

2. Is there a new numeric code in BI-RADS® for “Post Procedure Mammograms for Marker

Placement”?

No. There is no numeric code for the FDA-approved alternative standard for “Post Procedure Mammograms for Marker Placement.” This is not even a BI-RADS® final assessment category. This assessment may be used only for postprocedure mammograms obtained for the purpose of confirming the deployment and position of breast tissue markers, which typically have been placed at the time of core biopsy. In addition, this assessment should be excluded from auditing. Note that there is no FDA-approved equivalent wording for this assessment category other than “Post Procedure Mammograms for Marker Placement.”

3. *In my practice we commonly issue addenda and/or comparison reports after initial mammography reports have been issued. Are we required to provide a final assessment category with each of these reports? Must we also send the addendum or comparison report to the referring health care provider and a letter to the patient, even if there is no change in the final assessment category or recommended course of action?*

Yes, to both questions. FDA regulations require that the report issued after additional mammography (i.e., repeat, spot-compression, magnification, other additional views) or following comparison with prior mammography examinations must provide a final assessment category for the case. A report **must** be communicated to the referring health care provider or the self-referred patient. In addition, a lay summary of the addendum or comparison report must be provided to the patient, even if there is no change in the final assessment category or recommended course of action. For the specific case in which there is no significant change in a comparison report, a simple statement that the comparison has been performed and that there is no overall change (ensuring to include the unchanged final assessment) would satisfy the requirement, accompanied by a comparison lay summary informing the patient of that fact. For the specific case in which an addendum report is issued that merely states that the referring health care provider has been notified of the results of the patient’s examination, then the addendum lay summary may be a simple statement informing the patient of that fact.

4. *My practice uses the BI-RADS® category 4 subdivisions (4A – low suspicion for malignancy, 4B – moderate suspicion for malignancy, 4C – high suspicion for malignancy). May our reports use these subdivisions as assessment categories instead of the category 4 assessment (suspicious)?*

No. While you have the option of using one of the three subdivisions of category 4 in addition to a final assessment of Suspicious, the FDA will not allow you to use the subcategories instead of the Suspicious assessment category in the mammography report.

5. *Do mammography examinations performed on men require a BI-RADS® final assessment*

and/or numeric code?

Yes. All mammography examinations, regardless of the patient's gender, are required to have a final assessment category (not a numeric code) in the mammography report. However, management recommendations may differ from those made for women because annual screening mammography is not usually appropriate for men.

6. Under the Centers for Medicare and Medicaid Services (CMS) guidelines, we may now charge for screening and diagnostic mammography examinations done on the same patient on the same day. May we combine the two examinations into one report or must we issue two separate reports?

The mammography facility has the option of issuing either separate or combined reports. (You may want to check with your billing office; some third-party payers may require individual reports.) If two reports are issued, each must contain its own overall final assessment. The facility may report both examinations on the "same piece of paper." If the facility decides to issue a single combined report, the facility needs to be aware of the following:

1. A single combined report must contain a single overall final assessment.
2. The combined report should make it clear to the referring clinician that it is combining the results of the screening and diagnostic studies. This is also important if questions ever arise about whether the examinations were billed correctly.
3. It is critical to understand that issuing a single report with a single final assessment will skew the facility's audit results, unless (recommended) the examination is audited as both screening category 0 and diagnostic, using the final assessment category rendered.
4. Although some computerized reporting systems may consider this a single examination (rather than two), FDA would still allow the facility to count both examinations toward meeting the continuing experience requirement of the interpreting physician.

7. If the final assessment of a screening mammography examination is "Incomplete" (BI-RADS® category 0) and the woman then undergoes additional imaging evaluation, does the FDA require the mammography facility to revise or amend the original report if, as a result of the additional imaging, the assessment is changed to any of the final assessment categories?

First, for auditing purposes, the original screening assessment must remain category 0. However, if the additional imaging includes mammography (and therefore is covered under MQSA), the facility performing these additional mammographic views also **must**

issue a report (either separately or as an addendum to the original mammography report) that reflects the final assessment. The BI-RADS® Atlas provides further recommendations on this topic. “When more than one type of [diagnostic] examination is performed concurrently (on the same day), it is ***preferable*** that the examinations be reported together, with the findings for each examination described in a separate paragraph, with separate assessments for each examination followed by ***an overall assessment and management recommendations for the combined examinations.***”

8. A screening mammography examination received an “Incomplete” (BI-RADS® category 0) assessment due to an asymmetry. The subsequent diagnostic mammography examination is also assessed as BI-RADS® category 0, recommending additional US examination. A US examination then is performed showing no abnormal findings, but I want to further evaluate this patient with MRI, which occasionally depicts a cancer not seen at either mammography or US. Is it appropriate to also assess the US examination as BI-RADS® category 0, recommend additional MRI examination?

This question involves two non-recommended uses of BI-RADS® category 0. First, with few uncommon exceptions, category 0 should not be used for diagnostic mammography examinations. Therefore, if diagnostic mammography is performed concurrently with US, an overall BI-RADS® assessment category should be given (rather than a category 0 assessment for the mammography followed by a final assessment for the US). The overall assessment would depend on the mammographic and sonographic findings and whether these are or are not described in the diagnostic breast imaging report. Refer to the following examples.

- If no findings are described in either the mammography or US portions of a combined report, the appropriate overall assessment is negative (BI-RADS® category 1).
- If one or more specific benign findings are described in either the mammography or US portions of a combined report, the appropriate overall assessment is benign (BI-RADS® category 2).
- If diagnostic mammography depicts a focal asymmetry with no associated mass, calcifications, or architectural distortion; if there is no sonographic or palpable correlate to the mammographic finding; and if there are no prior mammography examinations available for comparison, it may be appropriate to render a probably benign (BI-RADS® category 3) assessment.
- If diagnostic mammography indicates the presence of a suspicious abnormality despite absence of a sonographic correlate (or vice versa), the appropriate overall assessment is suspicious (BI-RADS® category 4).

Second, BI-RADS® category 0 **should not be used for diagnostic breast imaging findings that warrant further evaluation with MRI.** Rather, the radiologist should issue a final assessment for the combined diagnostic mammography and US examinations in a report that is made **before** the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations in the combined mammography/US report. This provides the following advantages:

- If the recommended MRI examination is not performed, the combined diagnostic breast imaging report will stand as issued.
- If MRI is performed as recommended, it would not be necessary to re-interpret the mammography and US examinations. A negative or benign MRI assessment would sustain a similar assessment made at diagnostic mammography and US. If the MRI examination shows more abnormal findings than those identified at mammography and US, the MRI assessment would supersede that made for mammography and US.

Also note that breast MRI is not appropriate follow-up in many situations, including:

- Instead of biopsy of a suspicious finding at mammography and/or US.
- As an alternative to short-interval follow-up of probably benign findings at mammography and/or US.
- To further evaluate findings that should be recognized as benign at mammography and/or US, such as gynecomastia or multiple bilateral, mostly circumscribed masses. Also most lymph nodes and fat necrosis may be characterized as benign at mammography and/or US.

MRI is rarely helpful in further evaluation of possible architectural distortion that is too vague to target for stereotactic or sonographic biopsy.

9. Axillary adenopathy is seen at screening mammography with no suspicious findings in the breasts. What should the BI-RADS® final assessment be?

In the absence of a known infectious or inflammatory cause, isolated **unilateral** axillary adenopathy should receive a suspicious (BI-RADS® category 4) assessment. Unilateral axillary adenopathy suggests occult breast carcinoma or, much less commonly, lymphoma, metastatic melanoma, ovarian cancer, or other metastatic cancer. Consequently, a careful search of the ipsilateral breast images is warranted. Bilateral axillary US should be performed to confirm that the finding is asymmetric/unilateral. Clinical evaluation for infection or inflammation in the ipsilateral breast, axilla, arm, and hand is recommended at the time of US, as mastitis, breast abscess, an infected skin

lesion, and cat-scratch fever are all potential sources of benign unilateral axillary adenopathy. If a benign cause is elucidated, a benign (BI-RADS® category 2) assessment would be appropriate. In the absence of a known infectious or inflammatory source, a suspicious (BI-RADS® category 4) assessment would be appropriate, with the intent to biopsy after further evaluation and review of clinical history. It is then appropriate to proceed with US-guided fine-needle aspiration (FNA) or core biopsy of the axillary adenopathy, and it may be advisable to perform ipsilateral whole-breast US at that visit to search for an occult primary breast carcinoma.

Bilateral axillary adenopathy would be assessed as benign (BI-RADS® category 2) in some situations and as suspicious (BI-RADS® category 4) in others. Bilateral axillary adenopathy is frequently reactive/infectious in origin, such as with inflammatory conditions (sarcoidosis, systemic lupus erythematosis, psoriasis, etc.) and HIV. In such situations, the appropriate assessment is benign (BI-RADS® category 2). Patients with known lymphoma or leukemia may also have bilateral axillary adenopathy. In this situation, the BI-RADS® assessment should be based on findings in the breasts themselves, but the report also should indicate the presence of adenopathy and the known underlying disease. For example, a report might indicate a negative or benign assessment, followed by "with bilateral axillary adenopathy presumed due to known lymphoma." It may be helpful to contact the referring health care provider or review the electronic medical record to clarify whether or not there is such a history before issuing a final report. If there is no known explanation for bilateral adenopathy, and particularly if it is new, then it may be a sign of lymphoma-leukemia, and a suspicious (BI-RADS® category 4) assessment is warranted, with a recommendation for US-guided FNA or core biopsy. Note that ideally, biopsy specimens should be kept in saline or RPMI 1640 if lymphoma is suspected, to facilitate fluorescence-activated cell sorting.

10. Are there BI-RADS® assessment categories and management recommendations available for breast PET scans and dedicated breast gamma camera imaging examinations? Are there plans to include these in the BI-RADS® Atlas in the future?

No. Because these breast imaging modalities are so new, the BI-RADS® Atlas does not have assessment categories and management recommendations for breast PET scans and dedicated breast gamma camera imaging examinations at this time. The atlas will be updated with new modalities as they become more established and widely available. In the interim, the same assessment categories for mammography, US and MRI may be used for these and other new-modality examinations, so long as recommendations for patient management are clearly stated in the imaging report.

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APPENDIX A

Mammographic Views

A suspicious lesion must always be triangulated so that its three-dimensional location within the breast is known. This requires it to be visible on two different mammographic projections. Triangulation is more precise if the lesion is visible on orthogonal views. The updated terminology and abbreviations for mammographic views are displayed in [Table 9](#) on the next page.

Table 9. Standardized Terminology and Abbreviations for Mammography Views

Projection/View	Labeling Code
Mediolateral oblique	MLO
Mediolateral	ML
Lateromedial	LM
Lateromedial oblique	LMO
Craniocaudal	CC
Craniocaudal exaggerated laterally	XCCL
Craniocaudal exaggerated medially	XCCM
Caudocranial (from below)	FB
Superolateral-to-inferomedial oblique	SIO
Inferomedial-to-superolateral oblique	ISO
Cleavage	CV
Axillary tail	AT
Tangential	TAN
Step-oblique view - 15 degree	MLO15
Step-oblique view - 30 degree	MLO30
Step-oblique view - 45 degree	MLO45
Step-oblique view - 60 degree	MLO60
Step-oblique view - 75 degree	MLO75
Spot-compression	S...
Magnification	M...
Rolled lateral	...RL
Rolled medial	...RM
Rolled superior	...RS
Rolled inferior	...RI
Implant displaced	...ID

Nipple in profile	...NP
Anterior compression	...AC
Inframammary fold	...IMF
Axillary tissue	...AX
Stereo scout	...SC
Stereo-	...ST-
Stereo+	...ST+
Pre-fire-	...PRF-
Prefire+	...PRF+
Postfire-	...POF-
Postfire+	...POF+
Postbiopsy-	...POB-
Postbiopsy+	...POB+
Postbiopsy	...POB

Note:

XX... — used as a prefix before the projection (e.g., LSMML)

...XX — used as a suffix after the projection (e.g., LCCRL)

APPENDIX B

ACR BI-RADS® — Mammography Lexicon Classification Form

For each of the following categories, select the term that best describes the dominant lesion feature.

BREAST TISSUE**Breast Composition (select one)**

- a. The breasts are almost entirely fatty
- b. There are scattered areas of fibroglandular density
- c. The breasts are heterogeneously dense, which may obscure small masses
- d. The breasts are extremely dense, which lowers the sensitivity of mammography

FINDINGS

A. Masses: A mass is 3-D and occupies space; it should be seen in two different mammographic projections. It has a completely or partially convex-outward contour and (if radiodense) is denser in the center than at the periphery.

1. Shape (select one)	<input type="checkbox"/> a. Oval	Elliptical or egg-shaped (may include 2 or 3 undulations)
	<input type="checkbox"/> b. Round	Spherical, ball-shaped, circular, or globular
	<input type="checkbox"/> c. Irregular	Neither round nor oval
2. Margin (select one)	<input type="checkbox"/> a. Circumscribed	At least 75% of the margin is sharply demarcated, with an abrupt transition between the lesion and surrounding tissue
	<input type="checkbox"/> b. Obscured	25% or more of the margin is hidden by superimposed or adjacent fibroglandular tissue
	<input type="checkbox"/> c. Microlobulated	A margin characterized by short-cycle undulations
	<input type="checkbox"/> d. Indistinct	No clear demarcation of the entire margin or any portion of it from the surrounding tissue
	<input type="checkbox"/> e. Spiculated	Margin is characterized by lines radiating from the mass
3. Density (select one)	<input type="checkbox"/> a. High density	X-ray attenuation of the mass is greater than the expected attenuation of an equal volume of fibroglandular breast tissue
	<input type="checkbox"/> b. Equal density	X-ray attenuation of the mass is the same as the expected attenuation of an equal volume of fibroglandular breast tissue
	<input type="checkbox"/> c. Low density	X-ray attenuation of the mass is less than the expected attenuation of an equal volume of fibroglandular breast tissue
	<input type="checkbox"/> d. Fat-containing	Includes all masses containing fat, such as oil cyst, lipoma, or galactocele as well as mixed-density lesions such as hamartoma

B. Calcifications (select one)

1. Typically benign (select all that apply)	<input type="checkbox"/> a. Skin	Usually lucent-centered and pathognomonic in appearance
	<input type="checkbox"/> b. Vascular	Parallel tracks or linear, tubular calcifications that are clearly associated with blood vessels
	<input type="checkbox"/> c. Coarse or "popcorn-like"	These calcifications are classic, large (> 2 to 3 mm in greatest diameter), and produced by an involuting fibroadenoma
	<input type="checkbox"/> d. Large rod-like	Associated with ductal ectasia, may form solid or discontinuous, smooth linear rods, usually ≥ 0.5 mm in diameter
	<input type="checkbox"/> e. Round	May vary in size and, therefore, also in opacity (when < 0.5 mm, the term "punctate" should be used)
	<input type="checkbox"/> f. Rim	Appear as calcium deposited on the surface of a sphere (usually < 1 mm in thickness when viewed on edge)
	<input type="checkbox"/> g. Dystrophic	Irregular in shape and usually > 1 mm in size; often with lucent centers
	<input type="checkbox"/> h. Milk of calcium	A manifestation of sedimented calcifications in macro- or microcysts, usually but not always grouped. On the CC image — often less evident and appear as round, smudgy deposits, while occasionally on MLO and especially on 90° lateral (LM/ML) views — more clearly defined and often semilunar, crescent shaped, curvilinear (concave up) or linear, defining the dependent portion of cysts. The most important feature of these calcifications is the apparent change in shape of the calcific particles on different mammographic projections (CC versus occasionally the MLO view and especially LM/ML views)
	<input type="checkbox"/> i. Suture	Typically linear or tubular in appearance; when present, knots are frequently visible
2. Suspicious morphology (select one)	<input type="checkbox"/> a. Amorphous	So small and/or hazy in appearance that a more specific particle shape cannot be determined
	<input type="checkbox"/> b. Coarse heterogeneous	Irregular, conspicuous calcifications that are generally between 0.5 mm and 1 mm and tend to coalesce but are smaller than dystrophic calcifications
	<input type="checkbox"/> c. Fine pleomorphic	Usually more conspicuous than amorphous forms and are seen to have discrete shapes — these irregular calcifications are distinguished from fine linear and fine-linear branching forms by the absence of fine-linear particles — they vary in size and shape and are usually < 0.5 mm in diameter
	<input type="checkbox"/> d. Fine linear or fine-linear branching	Thin, linear, irregular calcifications, which may be discontinuous and < than 0.5 mm in caliber — occasionally, branching forms may be seen

3. Distribution <i>(select one)</i>	<input type="checkbox"/> a. Diffuse	Distributed randomly throughout the breast
	<input type="checkbox"/> b. Regional	Used for numerous calcifications that occupy a large portion of breast tissue (> 2 cm in greatest dimension), not conforming to a duct distribution — may involve most of a quadrant or even more than a single quadrant
	<input type="checkbox"/> c. Grouped	Used when relatively few calcifications occupy a small portion of breast tissue — lower limit for use of this descriptor is 5 calcifications grouped within 1 cm of each other or when a definable pattern is identified — upper limit for use of this descriptor is for larger numbers of calcifications grouped within 2 cm of each other
	<input type="checkbox"/> d. Linear	Calcifications arrayed in a line
	<input type="checkbox"/> e. Segmental	Used when the distribution of calcifications suggests deposits in a duct or ducts and their branches

C. Architectural distortion: The parenchyma is distorted with no definite mass visible.

D. Asymmetries: Involve a spectrum of mammographic findings that represent unilateral deposits of fibroglandular tissue not conforming to the definition of a radiodense mass. *(select one)*

<input type="checkbox"/> 1. Asymmetry		An area of fibroglandular-density tissue that is visible on only one mammographic projection, frequently representing superimposition of normal breast structures (summation artifact)
<input type="checkbox"/> 2. Global asymmetry		Judged relative to the corresponding area in the contralateral breast and represents a large amount of fibroglandular-density tissue over a substantial portion of the breast (at least one quadrant) — there is no mass, distorted architecture, or associated suspicious calcifications
<input type="checkbox"/> 3. Focal asymmetry		Judged relative to the corresponding location in the contralateral breast and represents a relatively small amount of fibroglandular-density tissue over a confined portion of the breast (less than one quadrant) — having similar shape on different mammographic projections, with concave-outward borders, usually interspersed with fat
<input type="checkbox"/> 4. Developing asymmetry		A focal asymmetry that is new, larger, or more conspicuous than on a previous examination

E. Intramammary lymph node: Intramammary lymph nodes are circumscribed masses that are reniform and have hilar fat. They are generally 1 cm or smaller in size (but may be larger than 1 cm and characterized as normal when fat replacement is pronounced) and frequently occur in the upper portions of the breast closer to the axilla, although they may occur anywhere in the breast. They are often seen adjacent to a vein.

F. Skin lesion: This finding may be described in the mammography report or annotated on the mammographic image when it projects over the breast (especially on two different projections) and may be mistaken for an intramammary lesion.

G. Solitary dilated duct: This is a unilateral tubular or branching structure that likely represents a dilated or otherwise enlarged duct.

H. Associated features: Used with masses, asymmetries, or calcifications, or may stand alone as findings when no other abnormality is present. (*select all that apply*)

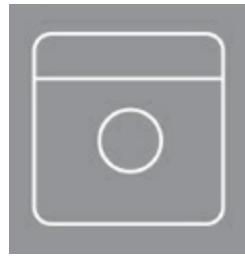
<input type="checkbox"/> 1. Skin retraction		The skin is pulled in abnormally
<input type="checkbox"/> 2. Nipple retraction		The nipple is pulled in (should not be confused with nipple inversion, which is often bilateral)
<input type="checkbox"/> 3. Skin thickening		May be focal or diffuse, and is defined as being > 2 mm in thickness
<input type="checkbox"/> 4. Trabecular thickening		A thickening of the fibrous septa of the breast
<input type="checkbox"/> 5. Axillary adenopathy		Enlarged axillary lymph nodes may warrant comment, clinical correlation and additional evaluation, especially if new or considerably larger or rounder when compared to previous examination
<input type="checkbox"/> 6. Architectural distortion		As an associated feature, architectural distortion may be used in conjunction with another finding to indicate that the parenchyma is distorted or retracted adjacent to the finding
<input type="checkbox"/> 7. Calcifications		As an associated feature, this may be used in conjunction with one or more other finding(s) to describe calcifications within or immediately adjacent to the finding(s) (see descriptors of calcifications, section B)

I. Location of lesion — The side is given first followed by the quadrant and clock-face position, then the depth of the lesion, and its distance from the nipple.

1. Laterality		Right or left breast
2. Quadrant and clock face	Use of both quadrant location and clock-face notation is encouraged	Use: quadrant location (upper outer, upper inner, lower outer, lower inner) and clock-face position, or Use: retroareolar, central, and axillary tail preceded by right, left, or both breasts
3. Depth		Indicate depth in the breast (anterior, middle, posterior third)
4. Distance from the nipple		Distance of the lesion from the nipple provides a more precise indication of its depth

ASSESSMENT CATEGORIES (select one)		
Incomplete Assessment	Management	Likelihood of Cancer
<input type="checkbox"/> Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	Recall for additional imaging and/or comparison with prior examination(s)	N/A
Final Assessment		
<input type="checkbox"/> Category 1: Negative	Routine mammography screening	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 2: Benign	Routine mammography screening	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance mammography	> 0% but ≤ 2% likelihood of malignancy
<input type="checkbox"/> Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
<input type="checkbox"/> Category 4A: <i>Low suspicion for malignancy</i>		> 2% to ≤ 10% likelihood of malignancy
<input type="checkbox"/> Category 4B: <i>Moderate suspicion for malignancy</i>		> 10% to ≤ 50% likelihood of malignancy
<input type="checkbox"/> Category 4C: <i>High suspicion for malignancy</i>		> 50% to < 95% likelihood of malignancy
<input type="checkbox"/> Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
<input type="checkbox"/> Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

This mammography lexicon classification form is for data collection and does not constitute a written mammography report.



ACR BI-RADS® Ultrasound

2013

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PREFACE

Ultrasound (US) characterization of mammographic and palpable abnormalities is indicated in the evaluation and management of breast disease. However, standardization of an effective, reliable technique for whole breast examination is a work in progress. In Europe and Asia, for many years, breast screening with US has been physician performed. In the United States, practice patterns are in flux, with the majority of breast sonograms performed by sonographers, usually directed to a particular area identified on other imaging modalities or by physical examination. Because we anticipate that US screening as a supplement to mammography will become more widely practiced in the United States, we offer guidance for training and performance as was provided in ACRIN 6666.^{1, 2, 3}

Effective use of the US lexicon is predicated on excellent sonographic technique and an understanding of breast anatomy. The descriptors comprising a lexicon for breast US are defined and exemplified in the sections that follow. Crucial to accurate assessment of masses is a method of lesion characterization achieved through analysis of multiple features rather than any single one. Some features are unique to US, such as orientation and echogenicity, and some are fundamental to interpreting breast masses with any imaging technique, such as shape and margin.

The descriptors that we recommend to designate findings are used in the illustrations throughout the second edition of the US lexicon. The legend beneath each example indicates in capital letters the primary illustrated feature. If, as is often the case, an illustration depicts more than one feature, the legend will indicate all of the features using lexicon terminology; however, the feature that the US image was chosen to illustrate will be the only term that is capitalized (e.g., “a small, oval, parallel, HYPERCHOIC mass”). Where possible, the pathology of what is described will be included.

The ACR Breast Imaging Reporting and Data System (BI-RADS®) for mammography has improved the assessment of masses, calcifications, and other mammographic findings, and the BI-RADS® final assessment phrases have been incorporated into the Mammography Quality Standards Act of 1992 (MQSA). The integration of US and mammographic findings promotes their clinical practicality.

In the late 1990s, the American College of Radiology (ACR) recognized the need for a US lexicon. Upon receipt of a grant from the Office on Women’s Health of the Department of Health and Human Services in 1998, to support protocol development for research in breast US [*Contract 282-97-0076, Federal Technology Transfer Program to Advance Novel Breast Imaging Technologies, U.S. Public Health Service Office on Women’s Health, U.S. Department of Health and Human Services*], the ACR convened an expert working group with national and international

representation. Research topics for protocol development included breast cancer screening with US, differentiation of benign from malignant solid masses, and the possible therapeutic applications of US. The need for consistent and standardized terminology became acute, particularly in designing studies of solid mass characteristics and of screening, in which criteria for probably benign masses required strict definition. Using techniques similar to those used for BI-RADS® mammography, agreement on terminology and assessment categorization was reached by consensus of this expert working group and its subcommittee.

Several feature descriptors are frequently used in analyzing mammographic findings, with the most worrisome feature the dominant consideration in selecting a final assessment category and management recommendation. Similarly, when mammography and US reports are combined, the most abnormal features should usually determine the assessment of the lesion.

Wherever possible and appropriate, the established descriptive terms in the lexicon for mammography were utilized for US interpretation. In the important feature categories of shape and margin, many of the descriptors work equally well for both. Since the publication of the first BI-RADS® US in 2003, there have been advances in US, such as elastography (included in Associated Features). Image quality, anatomy, the male breast, and a guidance chapter with frequently asked questions have also been added. This document will continue to change as breast US continues to evolve, with its roles for diagnostic and screening indications being further elucidated among those of other breast imaging modalities, such as mammography (including tomosynthesis), MRI, and molecular imaging.^{4,5}

This illustrated fifth edition of the BI-RADS® Atlas is designed for everyday practice and should make it possible to issue meaningful and unambiguous breast imaging reports. BI-RADS® was always intended to be a dynamic and evolving document that would adapt to changes in the practice of breast imaging and be of practical use to interpreting physicians. Therefore, the Committee on BI-RADS® welcomes any comments and/or suggestions from its users and requests that these be submitted in writing or electronically to the ACR. However, prior to submitting comments or suggestions, please first visit the ACR BI-RADS® website at <http://acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/BIRADSFAQs.pdf>, which displays committee-approved responses to suggestions already submitted.

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Ellen B. Mendelson, MD, FACP

Chair, Subcommittee on BI-RADS® Ultrasound

INTRODUCTION

The ACR BI-RADS® is a quality assurance tool designed to standardize reporting, reduce confusion in breast imaging interpretations and management recommendations, and facilitate outcomes monitoring. All interpreting physicians and referring health care providers should be aware of the benefits and limitations of breast imaging technologies.

The terminology used to describe breast US findings is still evolving, and the diversity of this terminology may cause confusion. The descriptive terms and definitions contained in the lexicon have been approved by the ACR Subcommittee on BI-RADS® Ultrasound. Employing these terms exclusively will help ensure that reports are clear, concise, and standardized. The subcommittee believes that these terms provide a reasonably complete evidence-based categorization of lesions depicted at US; however, as the field is still evolving, new terminology may be needed or existing terminology modified. If you would like to propose a substantive change, please submit it to the ACR for review by the Committee on BI-RADS®, using the contact information mentioned in the preface.

The ACR BI-RADS® — Ultrasound is divided into four sections with an appendix at the end.

SECTION I: General Considerations

SECTION II: Breast Imaging Lexicon — Ultrasound

SECTION III: Reporting System

SECTION IV: Guidance

APPENDIX: ACR BI-RADS® — Ultrasound Lexicon Classification Form

The following are brief summaries of each section.

I. General Considerations

This section discusses the anatomy of the breast, image quality issues and techniques, labeling and measurement of the images, and documenting results of the examination.

II. Breast Imaging Lexicon — Ultrasound

US is very useful for breast imaging. The lexicon offers a set of standardized terms along with copious examples of how and when to use these terms. The Subcommittee on BI-RADS® Ultrasound believes that widespread use of these descriptors will enable

radiologists everywhere to communicate results clearly and efficiently to other physicians and their patients.

III. Reporting System

Just as in mammography, utilizing the reporting system will provide an organized approach to image interpretation and reporting. Using a computer-based reporting software application is not required but is strongly recommended. This will facilitate clear, concise, and standardized reporting, and further enable simultaneous data collection for the maintenance of a database for future outcomes review (audit). Regular audits enable individual interpreting physicians and breast imaging facilities to monitor their own results and appraise the accuracy of image interpretation so that they can adjust interpretive thresholds appropriately. We strongly recommend using software that requires minimal data entry. The interpreting physician's attention should be focused on the evaluation of images not data input. The simplest input will need only a single screen for normal examinations and require limited interaction for abnormal examinations. If practical, we recommend use of a scribe to enter data.

Report Organization

Using the recommended terminology is the key to producing understandable breast imaging reports consistently. The BI-RADS® approach to reporting breast imaging examinations categorizes the overall composition of the breast and then describes masses by their shape, orientation, margin, echo patterns, and posterior features. Calcifications are described according to size and distribution. The findings are then evaluated and an assessment rendered that includes the degree of suspicion for malignancy. Finally, the report indicates the pertinent management recommendation(s). Thus, the breast US report should be divided into:

- 1. INDICATION FOR EXAMINATION**
- 2. STATEMENT OF SCOPE AND TECHNIQUE OF BREAST US EXAMINATION**
- 3. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION (screening only)**
- 4. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS**
- 5. COMPARISON TO PREVIOUS EXAMINATION(S), INCLUDING CORRELATION WITH PHYSICAL, MAMMOGRAPHY, OR MRI FINDINGS**
- 6. COMPOSITE REPORTS**
- 7. ASSESSMENT**
- 8. MANAGEMENT**

Note that breast US examinations are sometimes reported separately from mammography and sometimes reported as part of a combined examination. In either case, the structure of the report should follow some general guidelines to make it clear and concise.

IV. Guidance

Through the years of continued BI-RADS® usage, the committee has received many questions and reports of problems related to the various sections that comprise BI-RADS®. To address these concerns, to introduce changes in terminology and assessments, and to explain the reasons for these changes, we offer a guidance chapter.

APPENDIX

The appendix contains a form for easily noting the findings of an US examination with the appropriate BI-RADS® terminology in a simple checklist. This form also contains the BI-RADS® assessment categories.

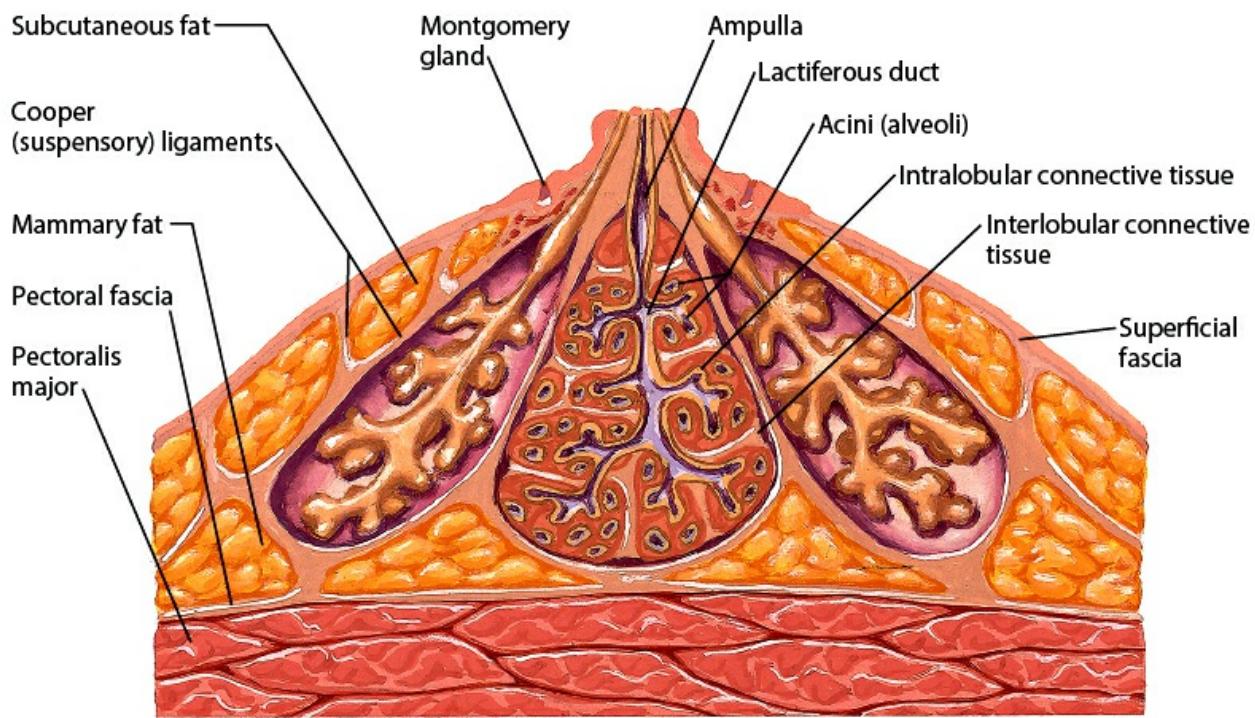
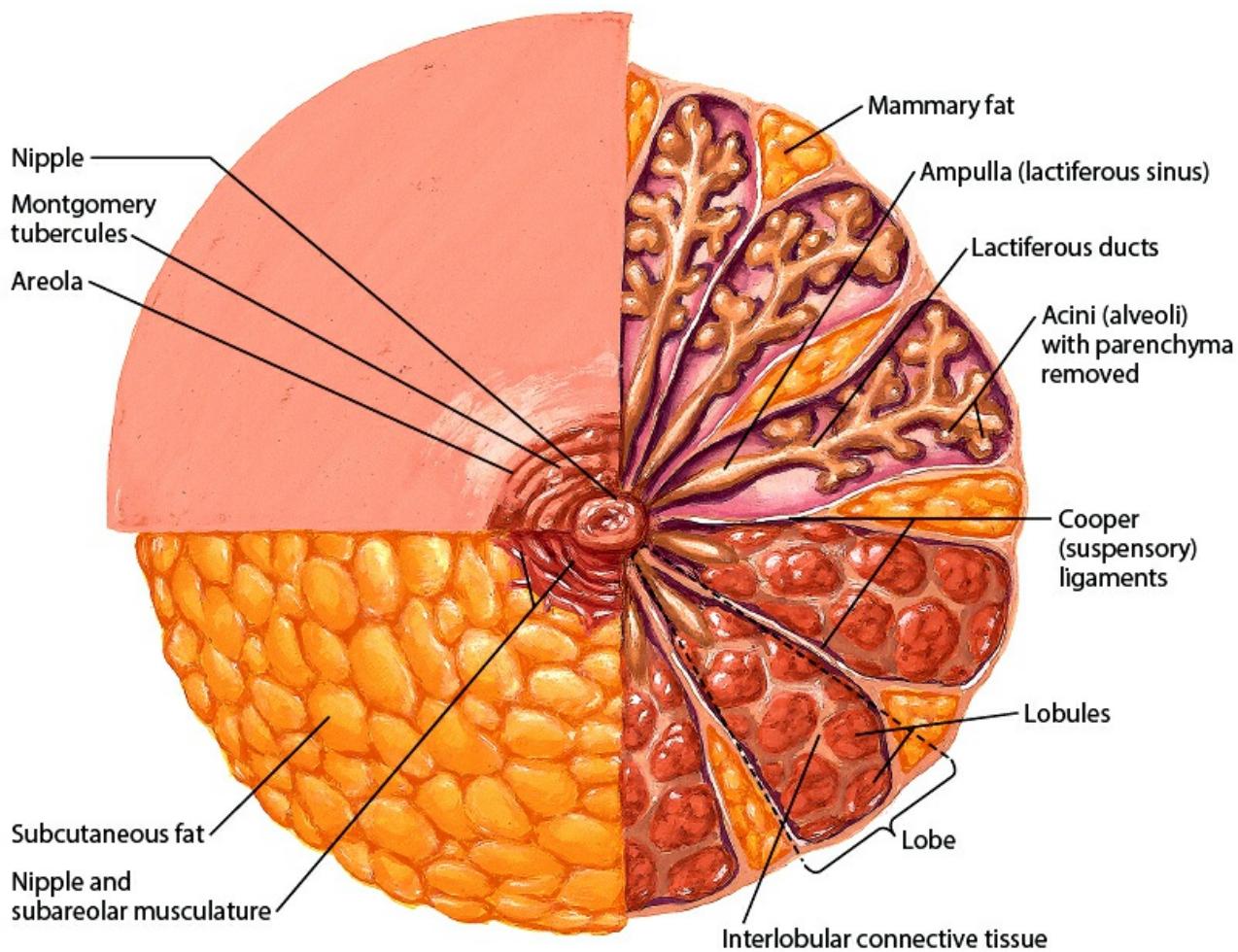
REVISIONS

I. GENERAL CONSIDERATIONS

A. BREAST ANATOMY

The breast is located on the chest wall between the second and the sixth ribs within layers of the superficial pectoral fascia. The fat and fibroglandular tissues of the breast are between the superficial layer of this fascia just beneath the skin and the deep fascial layer that lies just anterior to the pectoral muscle ([Figure 1](#)).

Anatomy of the Breast



Illustrations courtesy of Elsevier Inc.

Figure 1 — NORMAL BREAST ANATOMY. Diagram of breast of woman in supine (US) position. Anatomy of the breast in coronal plane (a) and axial plane (b).

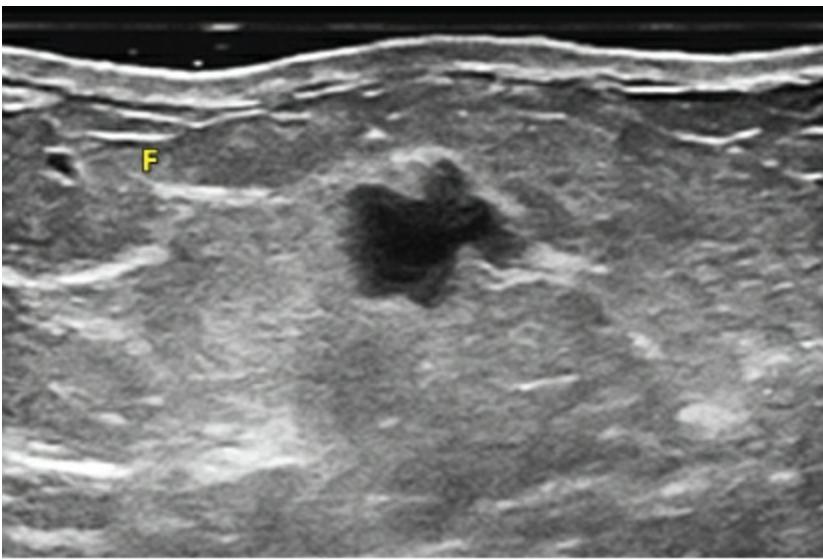


Figure 2 — ANATOMY: NORMAL SKIN COMPLEX. Two echogenic lines defining a hypoechoic layer whose total thickness is \leq 2 mm, except in the periareolar region or inframammary fold. A gel offset enables the upper layer of skin to be seen. Make certain that the focal zone is set superficially. Beneath the normal 2 mm skin complex and superficial fat lobules (F) is an 8 mm microlobulated invasive ductal carcinoma (IDC).

As few as seven or eight and as many as 20 lobes, loosely associated duct segments, are the anatomic components of the breast. Each segment starts in the fine peripheral branches and ends in a large collecting duct, its punctum visible on the nipple. The most peripheral ducts, the intralobular terminal ducts, end in the terminal duct-lobular units that give rise to common malignant and benign pathologies.

The subclavian and axillary arteries and their lateral thoracic, thoracoacromial, and internal mammary branches provide arterial supply to the breast. The venous plexus lies just beneath the nipple. Over 90% of the lymphatics of the breast drain into the ipsilateral axilla, with a small percentage of drainage into the internal mammary chain. In women who have had axillary dissections or mastectomies extending into the axilla, lymphatic drainage may cross to the contralateral axilla.

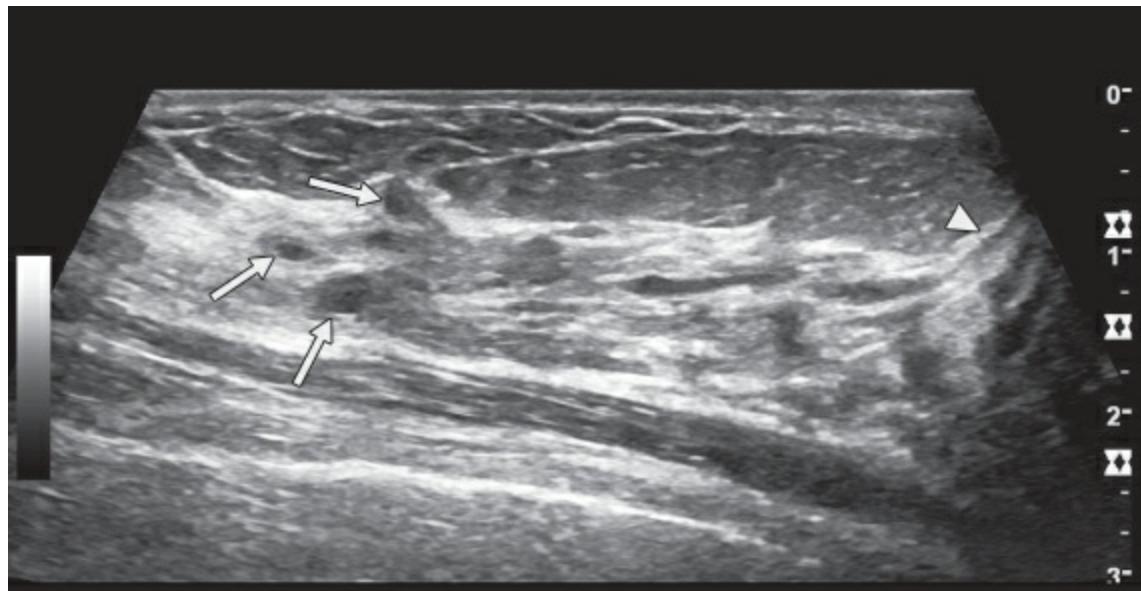
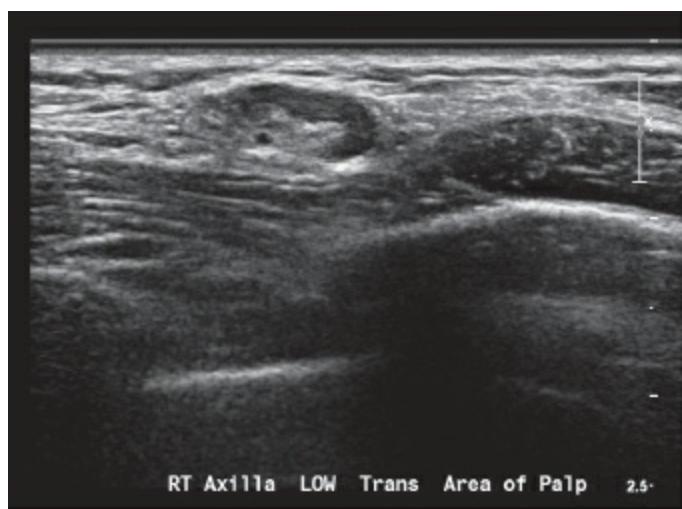


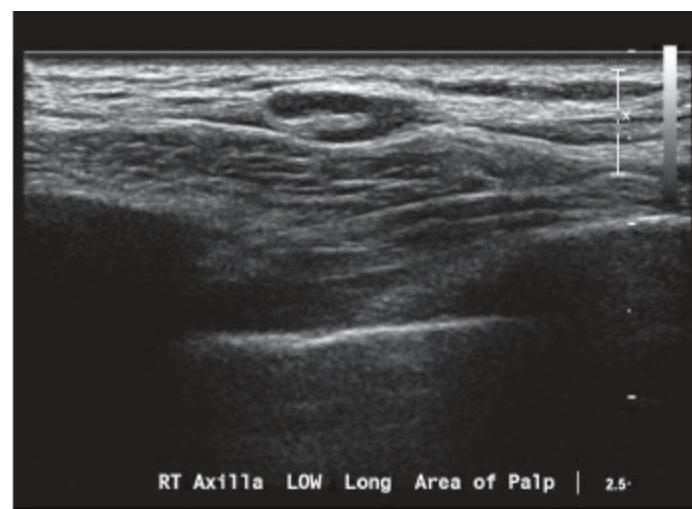
Figure 3 — IMAGE QUALITY: TRAPEZOIDAL ACQUISITION. Radial view shows the normal anatomy of a duct from its lobules (arrows) at the periphery, arching anteriorly (arrowhead) towards the nipple. The duct is within the fibroglandular zone of tissue beneath the hypoechoic fat lobules.

1. AXILLA

The axilla contains lymph nodes, the brachial plexus, and axillary artery and vein. The number and size of normal axillary lymph nodes varies widely from individual to individual. Side-to-side symmetry of size, shape, and number of nodes may help distinguish normal from abnormal. Nodes may be depicted in the axillae on mammograms; commonly two, three, or more can be identified as circumscribed oval (often reniform) masses with hilar fat and cortices of fibroglandular tissue density. With US, normal axillary or intramammary lymph nodes have echogenic fatty hila and cortices that are hypoechoic to anechoic.



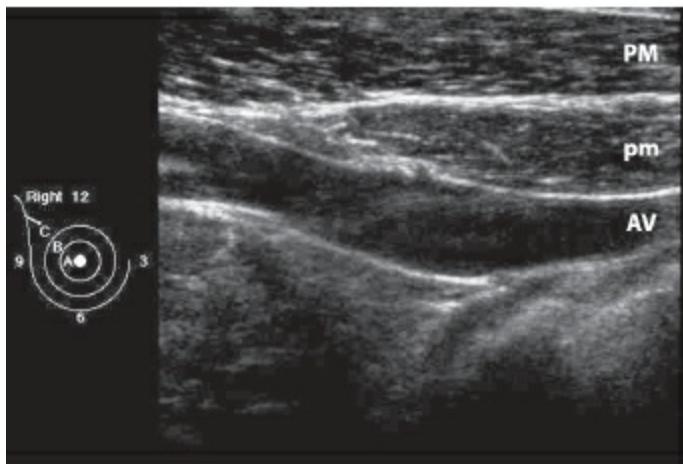
A



B

RT Axilla LOW Trans Area of Palp 2.5-

RT Axilla LOW Long Area of Palp | 2.5-



C

Figure 4 — NORMAL AXILLARY LYMPH NODE. Transverse (a) and longitudinal (b) views of a lymph node of normal size, cortical thickness, and echogenic hilus, resembling a miniature kidney. NORMAL AXILLA (c). Pectoralis major (PM) is shown anterior to pectoralis minor (pm) with axillary vein (AV) deep to both.

2. NIPPLE AND AREOLA

The nipple-areolar complex is quite variable, with areolar width narrow in some women or extending for 1 or 2 cm in others, making the nipple a more reliable landmark than the areola. Normal nipples can be prominent, flat, or inverted.

If an abnormality is suspected, or for interpretive confidence, look at the contralateral breast as you would for any other paired organ. The nipple's crevices and irregular surface cause posterior attenuation, and an offset pad or thick layer of gel can provide a medium for clear depiction (Figure 4a, b, and c). The skin of the areola tapers as the areola extends to either side of the nipple. The width of normal skin over the breast is 0.2 cm except for the region of the inframammary fold and the areola, where the skin is normally a little thicker.



A



B

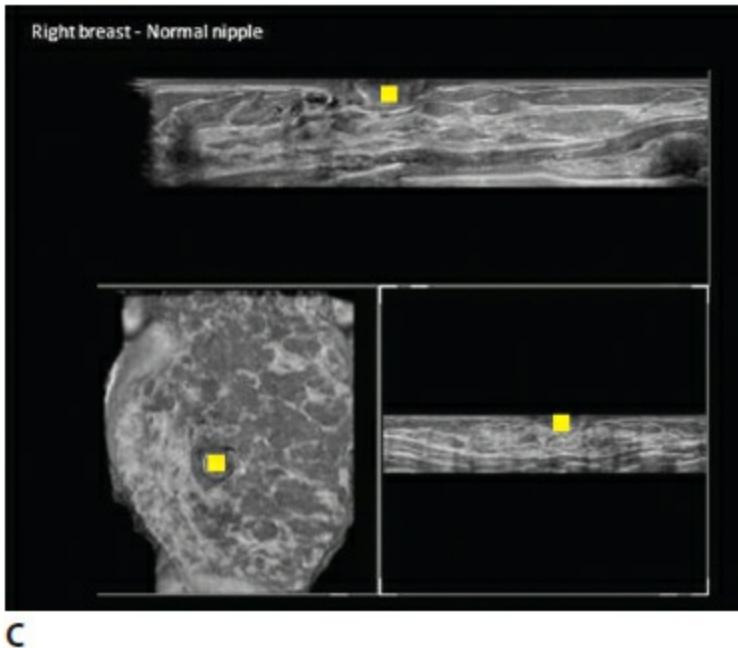
**C**

Figure 5 — ANATOMY: NIPPLE AND UNDERLYING BREAST TISSUE. Size and appearance of the nipple are variable, from retracted to flat to protuberant. A gel offset (*a* and *b*) enables the skin and superficial tissue to be seen. The nipple is normal (*a*). If there is concern for abnormality, as with any other paired organ, comparison with the normal side is helpful in decision making. Nipple is enlarged due to mucinous carcinoma contained within it (*b*). Automated supine whole breast scan (*c*). Upper image is B-mode acquisition (X-plane or transverse) centered over normal nipple (yellow square), with reconstructions in coronal (Z-plane) on left and sagittal (Y-plane), lower right image. The tissue beneath the nipple is not obscured by shadowing as it so often is with hand-held US.

3. GYNECOMASTIA

Hormonal effects of certain medications including anti-hypertensives, antidepressants, H₂ blockers, illicit drugs, and endocrine-active tumors stimulate development of rudimentary male breast tissue. Ducts and stroma are located in the retroareolar region, typically “flame-shaped” on mammograms extending posterolaterally from the nipple, and are often asymmetric.

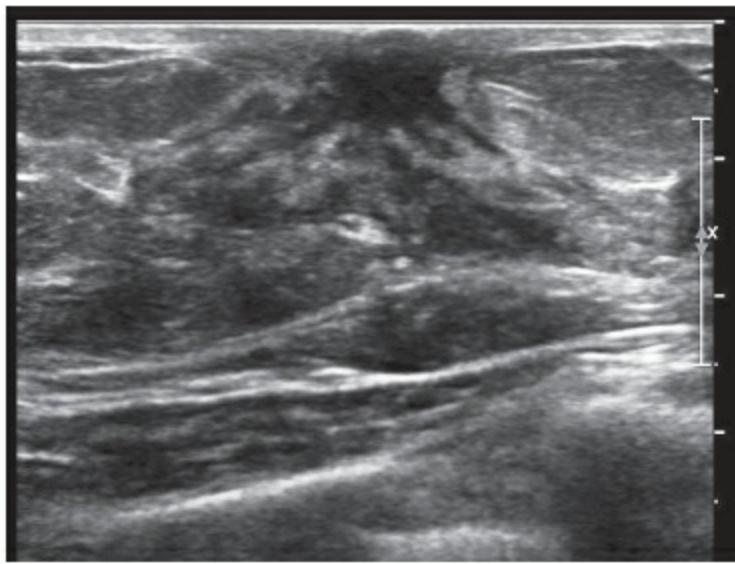
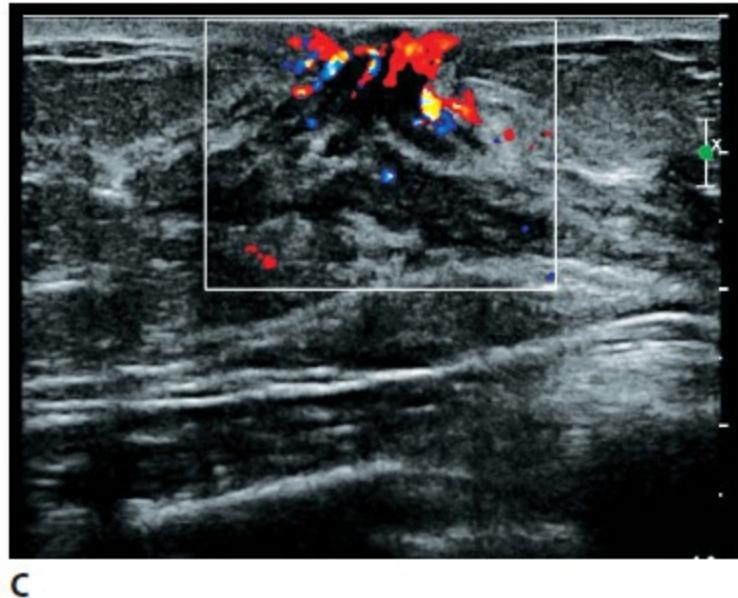
**A****B**

Figure 6—ANATOMY: GYNECOMASTIA.
71-year-old, hypertensive man with tender palpable nodule beneath the left nipple. Mediolateral oblique mammogram showing retroareolar fibroglandular tissue (a); B-mode (b) and color Doppler (c) images show hypoechoic mound of breast tissue with ducts radiating and tapering posteriorly, a characteristic US appearance of gynecomastia.



B. IMAGE QUALITY

1. TRANSDUCER FREQUENCY

As with all imaging modalities, the value of US for detection and diagnosis largely depends on the quality of the images. Handheld, high-frequency breast US can be particularly prone to operator dependence if a system's many image parameters are not optimally modulated. Poor US image quality can lead to serious misinterpretations such as mistaking a cancer for a cyst. The [ACR Practice Guideline for the Performance of a Breast Ultrasound Examination \(2011\)](#)⁴ recommends use of a broad bandwidth linear array transducer with a center frequency of at least 10 MHz. At the high-frequency end (between 12 and 18 MHz), these transducers provide high-resolution images. In their lower frequency ranges, tissue penetration of 5 cm is obtainable.

Higher frequency sound waves are more strongly attenuated by breast tissue than lower frequency waves. With proper positioning, most breasts in the supine or supine-oblique position are only a few centimeters thick, and high frequencies can provide optimal image quality for all of the breast tissue. However, when evaluating deep tissue in patients with particularly large breasts, it may be helpful to select lower frequency settings on multifrequency transducers, to use a lower frequency transducer, if available, or to apply greater compression for improvement of sound penetration and reduction of attenuation.

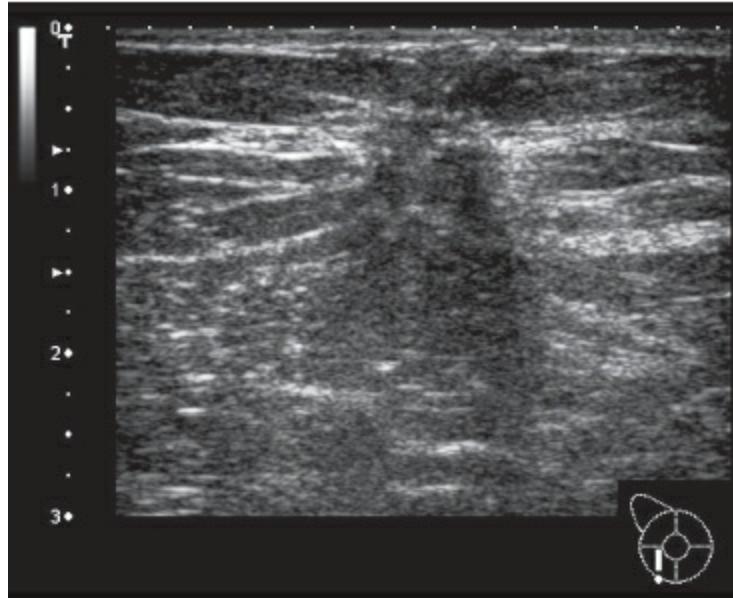
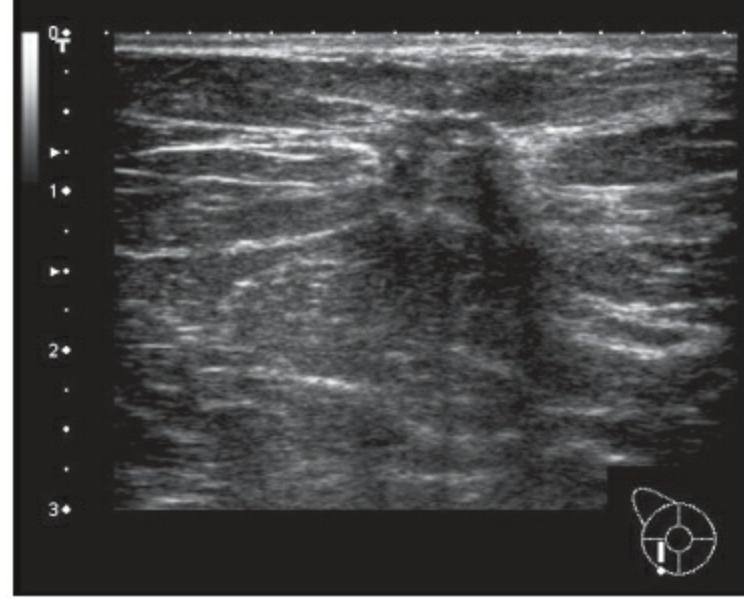
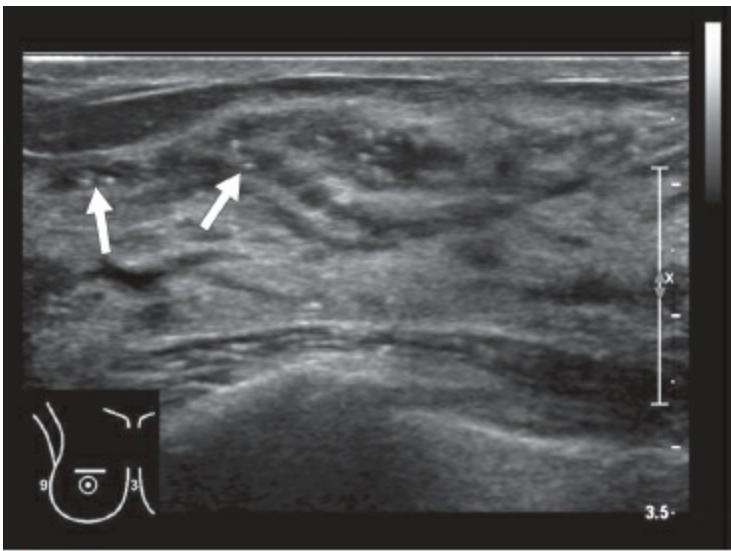
**A****B**

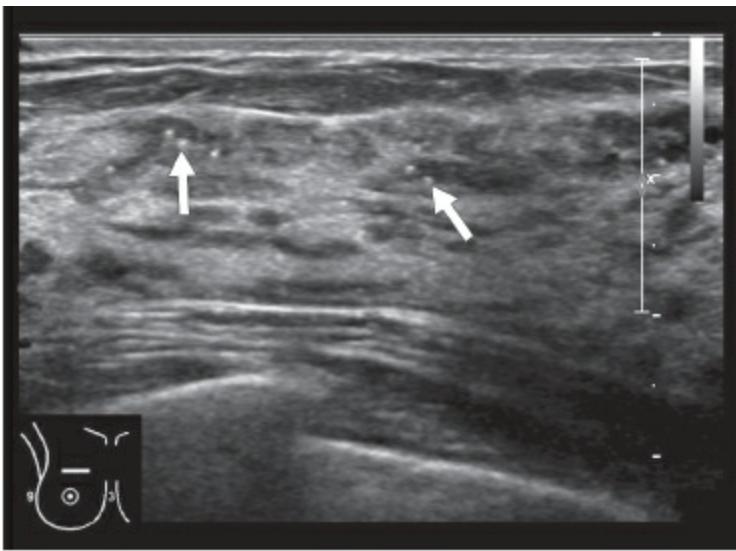
Figure 7 — IMAGE QUALITY: TRANSDUCER FREQUENCY. Margin and surrounding architectural distortion of this irregularly shaped carcinoma (longitudinal view) with transducer operating at 7.2 MHz (*a*) is less well characterized than same mass (*b*) imaged at 14 MHz. Cicatrization of the Cooper ligaments is more conspicuous and angular and the indistinct margin of the mass more confidently characterizable due to improved resolution of the higher frequency transducer.

**A****B****C**

Figure 8 — IMAGE QUALITY: DOPPLER SETTINGS. B-mode and color flow images with too much compression (*a*) causing vessels to be occluded. Image (*b*) has scanning without compression and allows depiction of some vascularity within lesion. Image (*c*), with the same Doppler frequency and scanning without compression shows more accurate depiction of slow flow vascular characteristics of the mass. Histopathology: invasive and intraductal carcinoma.



A

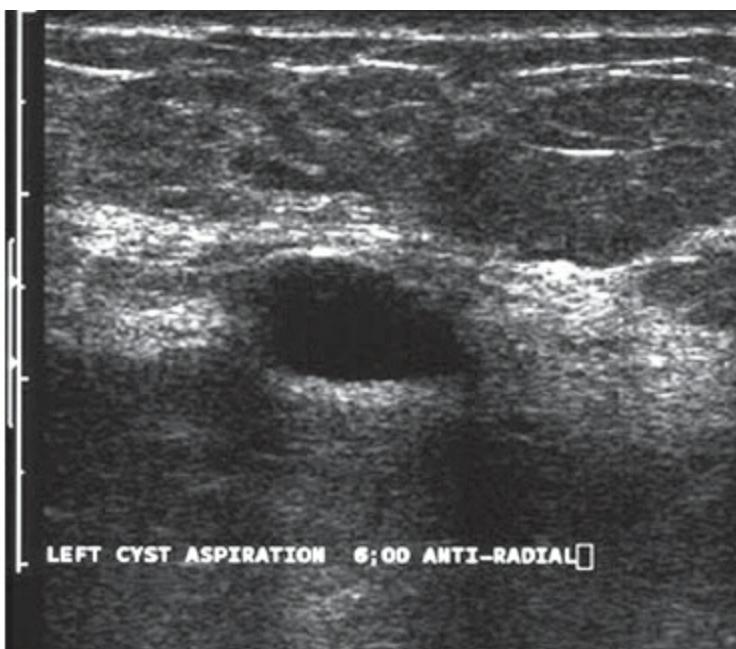


B

Figure 9 — IMAGE QUALITY: TRANSDUCER FREQUENCY. The image obtained with a linear transducer whose frequency range is 12–5 MHz is diagnostic (a) but greatly improved with a transducer whose frequency range is 17–5 MHz (b). In both images, the microcalcifications present within ducts (arrows) in the echogenic fibroglandular zone of tissue can be seen, but resolution of these particles and the ductal anatomy is better with the higher frequency probe.



A



B

Figure 10 — IMAGE QUALITY: TRANSDUCER FREQUENCY, RESOLUTION, AND CONTRAST SETTINGS. Confident interpretation of margin and shape of the mass is not possible in the image on the left (a) because of outdated technology: low transducer frequency, high contrast settings, and an inadequate gray scale. The same mass in the image on the right (b) appears to be better focused, and the higher resolution allows the characteristics of a simple cyst to be depicted. The BI-RADS® assessment based on image (b) would be benign (category 2), while in image (a) it might be suspicious (category 4). Annotation overlies the skin in image (a); no text should overlie an image unless the image is captured with and without annotation, as is suggested for lesion measurement. Note that image (b) is labeled for cyst aspiration, which would not have been necessary unless the patient was symptomatic (therapeutic aspiration). Image quality for (a) would be unacceptable at this time.

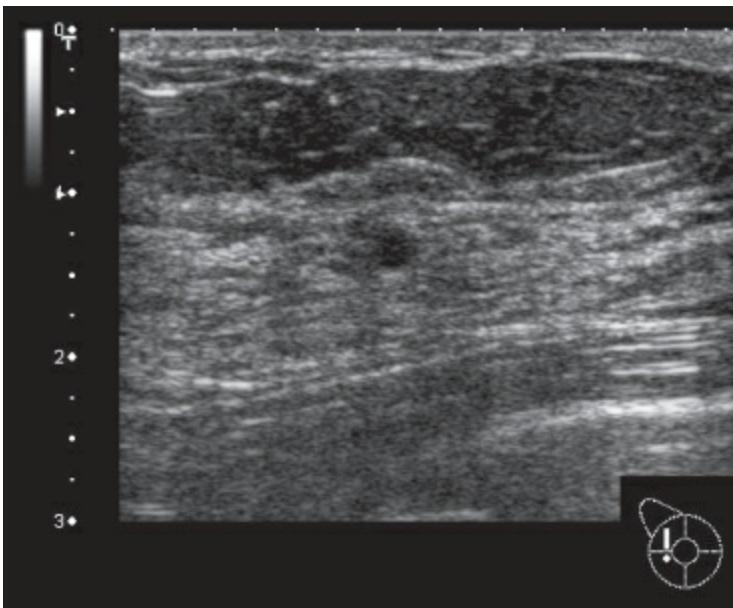
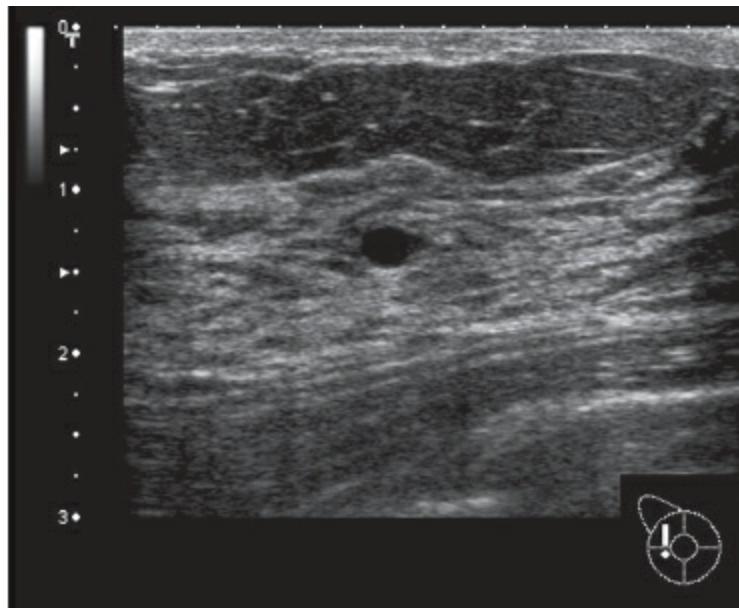
**A****B**

Figure 11 — IMAGE QUALITY: EFFECTS OF HIGHER FREQUENCY AND COMPRESSION. (a) Oval mass in sagittal view has indistinct margins at 7.2 MHz (linear transducer, frequency range 14–7 MHz). Diagnosis of simple cyst cannot be made, and the patient would most likely have undergone aspiration. Same mass (b) imaged with same transducer but operating at 14 MHz is identifiable as a simple cyst. Additional compression of the tissue with the probe helps to reduce refraction shadowing that is prominent in image (a). Improved image quality in (b) allowed BI-RADS® assessment as benign (category 2).

2. FIELD OF VIEW

The field of view (FOV) refers to the depth setting of tissue that will be displayed on the monitor. When searching for lesions, the field should be deep enough to include breast tissue and the pectoralis muscle posterior to it. The FOV should not include the pleura or lung.

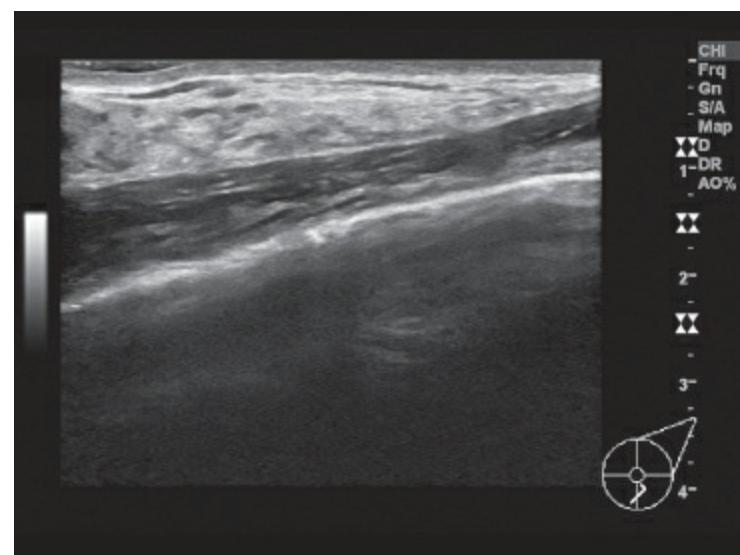


Figure 12 — IMAGE QUALITY: FOV. Single view of the left breast at 6:00 with breast tissue occupying only 50% of the FOV. From a depth of 2–4 cm, there is no information related to the breast. The focal zones (marked by **☒** icons) are also set too deeply.

When a lesion is found, temptation is to reset the field to a shallower depth or to zoom excessively. In both of these instances, the margin of the mass may be misinterpreted as indistinct. When the FOV is set too deeply, small lesions appear minified and cannot be characterized confidently.

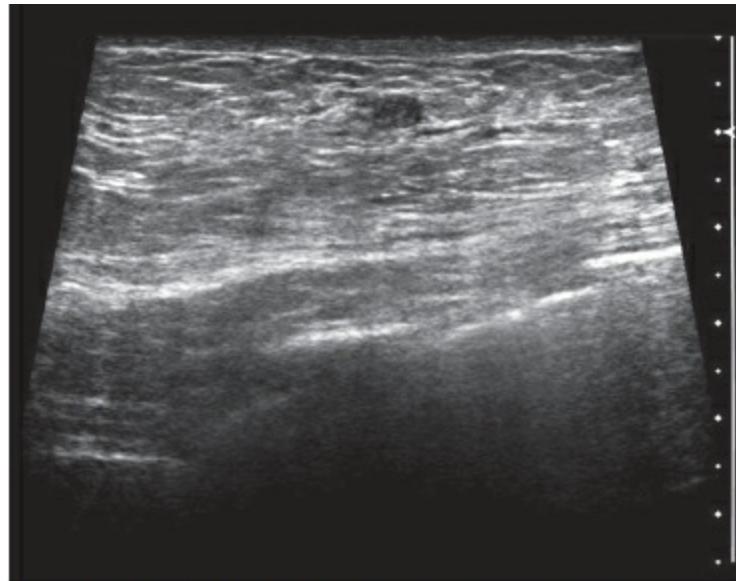


Figure 13 — IMAGE QUALITY: FOV. The lower portion of this trapezoidal image contains no information. Small, 0.4×0.3 cm, mass located 0.8 cm deep from the skin is poorly visualized in this sonogram set to a depth of 5.5 cm. Image appears minified.

For larger lesions, there are several methods that can be used to show the entire lesion in one image. Available with some transducers is “extended field-of-view imaging,” also called “panoramic imaging,” which may help to demonstrate the relationship of these lesions to surrounding the tissue. Extended FOV can also be useful to demonstrate the geographic relationship among multiple lesions or between a lesion and a structure such as the nipple. As with wide FOV automated US, freehand extended FOV is also useful for imaging multiple masses as well as large lesions.

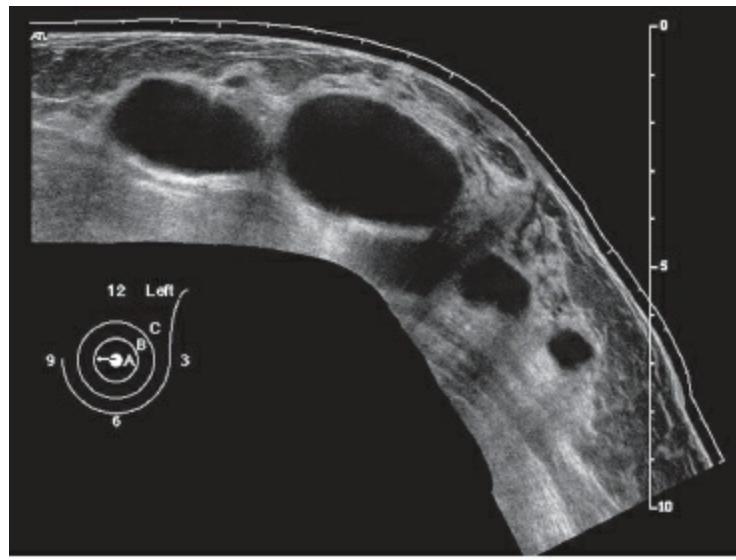


Figure 14 — IMAGE QUALITY: EXTENDED FOV. The FOV sweep shows numerous simple cysts within the fibroglandular tissue of this 46-year-old woman.

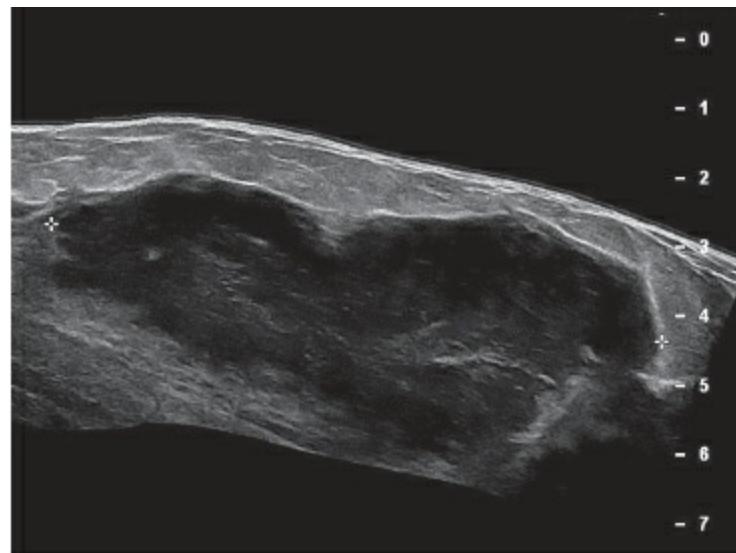


Figure 15 — IMAGE QUALITY: EXTENDED FOV. Extent of large 9 cm abscess is shown on this image using panoramic technique. On average, handheld high-resolution transducers in B-mode measure only 4–5 cm horizontally unless extended FOV functionality is used.

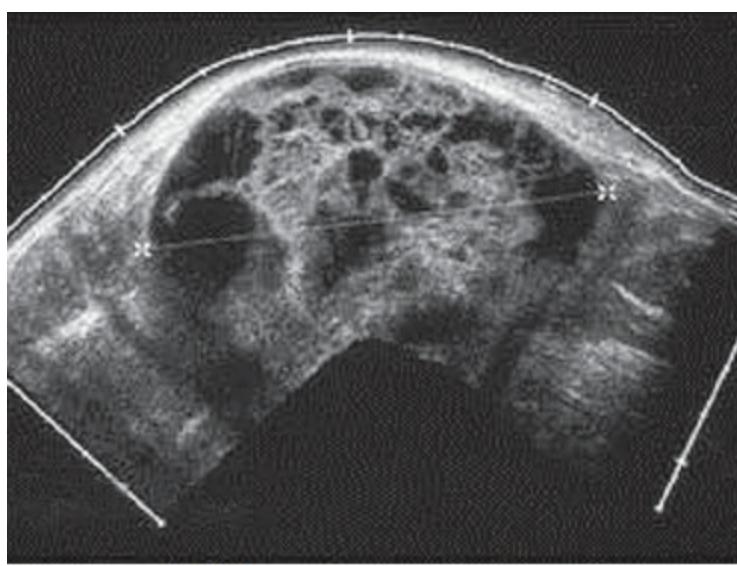
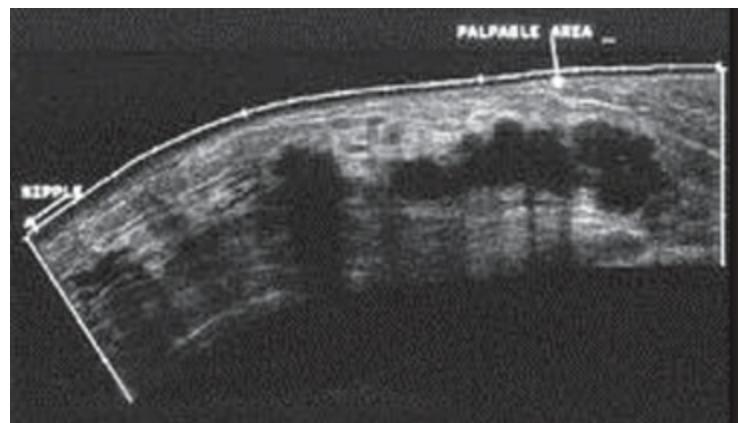
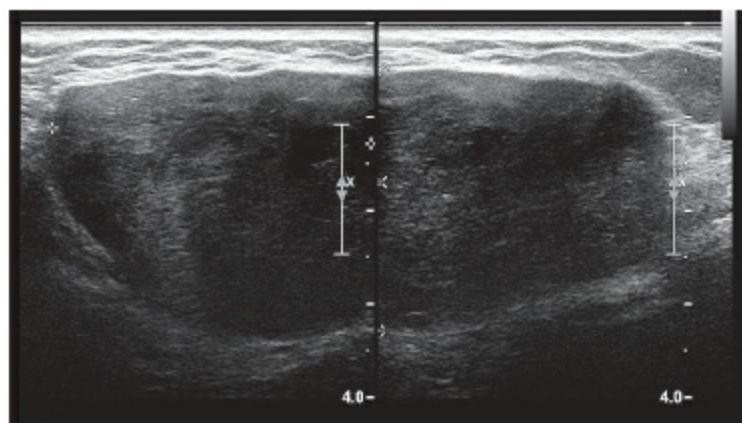


Figure 16 — IMAGE QUALITY: EXTENDED FOV. Complex cystic and solid mass shown in its entirety is a papillary ductal carcinoma in situ (DCIS).



A

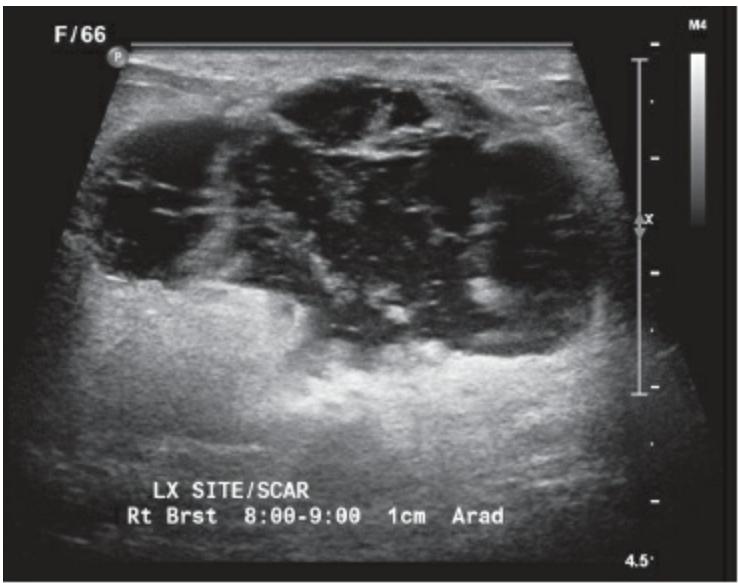


B

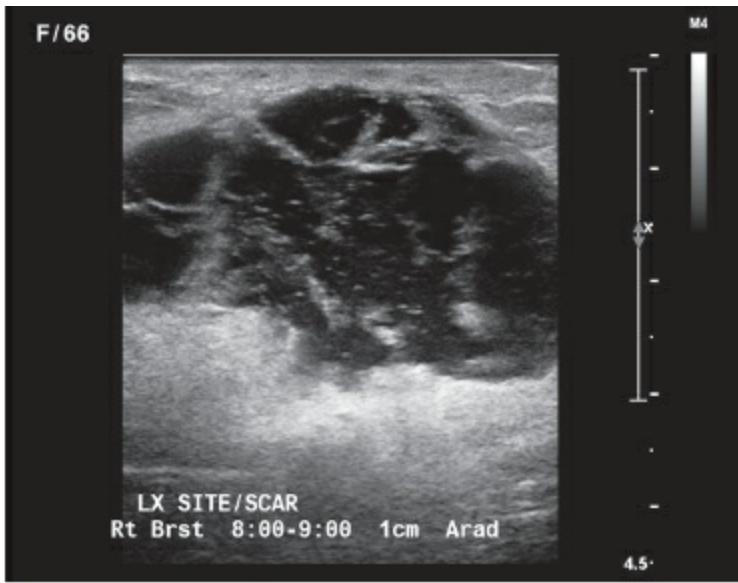
Figure 17 — IMAGE QUALITY: EXTENDED FOV shows infiltration of invasive lobular carcinoma throughout the fibroglandular tissue (a). Extended FOV imaging is useful for imaging large breast masses, for demonstrating distances between lesions, and for showing the relationship of lesions to other structures. Spliced image (b) of a 4 x 7 cm fibroadenoma is another method of US depiction of large abnormalities. This method is a workaround that approximates the size of the mass and shows less of the tissue surrounding it.

Some systems with dual screens enable image halves to be spliced. Approximately half of a large lesion or regional area of interest is captured and the image frozen; then the second image screen is activated and the other half captured. The edges of large lesions are approximated on a screen that shows both halves, and the entirety or most of the mass then is measured, albeit not precisely. Matching the anatomic landmarks provided by ducts, fat lobules, and depth from the skin facilitates accuracy. Wide FOV sweeps (panoramic displays) are more accurate and should be used whenever possible ([Figure 16](#)).

There are additional methods as well: images produced by some linear transducers can be widened at the base of the image, which then appears trapezoidal as opposed to rectangular.

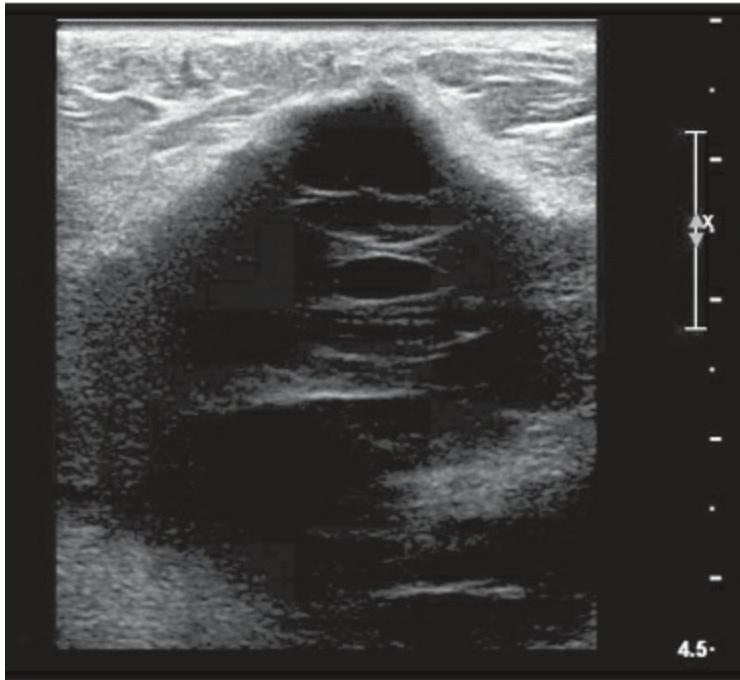


A

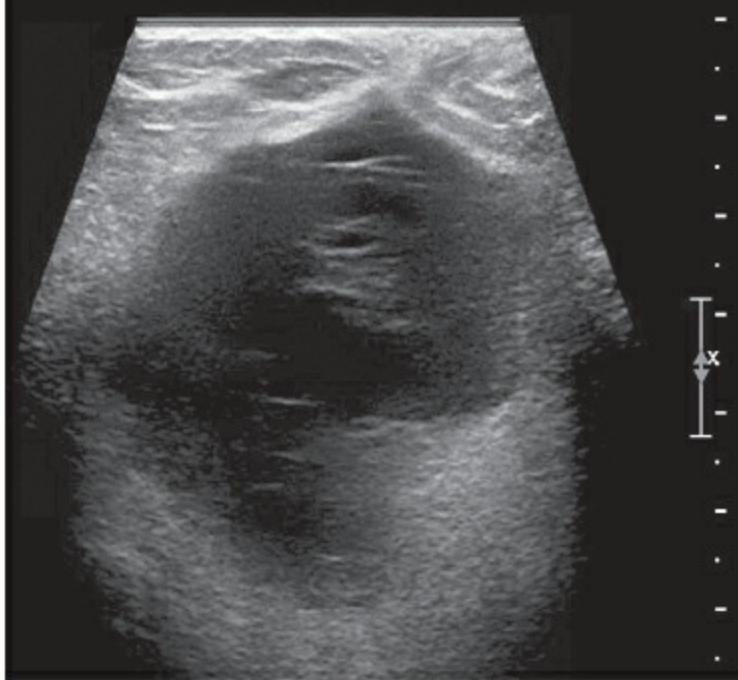


B

Figure 18 — IMAGE QUALITY: TRAPEZOIDAL ACQUISITION. Postsurgical fluid accumulation following lumpectomy for an invasive ductal carcinoma. Lateral aspects of this large collection are cut off on the rectangular image (a) but included in the wider base of the trapezoidal acquisition (b).



A



B

Figure 19 — IMAGE QUALITY: TRAPEZOIDAL ACQUISITION. Compared with the rectangular image (a), the posterior contour of this axillary postsurgical fluid collection is depicted better on the trapezoidal image (b), wider at the base of the image.

In addition, volumetric acquisitions of linear transducers with 14–15 cm footprints enable a broad sweep of tissue to be displayed in 3-dimensional.

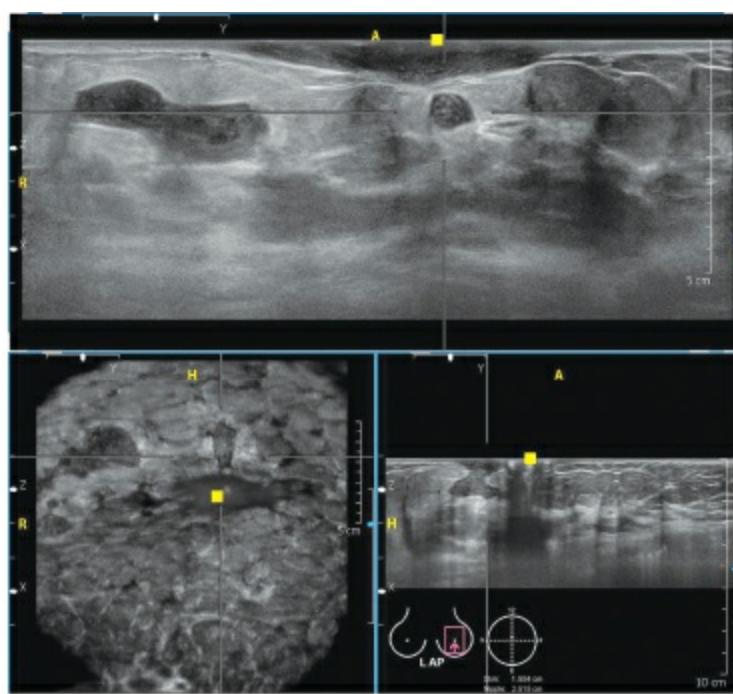


Figure 20 — IMAGE QUALITY: WIDE FOV, VOLUMETRIC ACQUISITION. Images of the right breast at 12:00 in a 29-year-old woman with chronic, sterile abscesses. Wide FOV B-mode transverse acquisition is illustrated above with coronal (lower left) and sagittal (lower right) images. The yellow square indicates location of the nipple, and the crosshairs are placed over a purulent collection shown in three orthogonal planes. Histopathology: granulomatous mastitis.

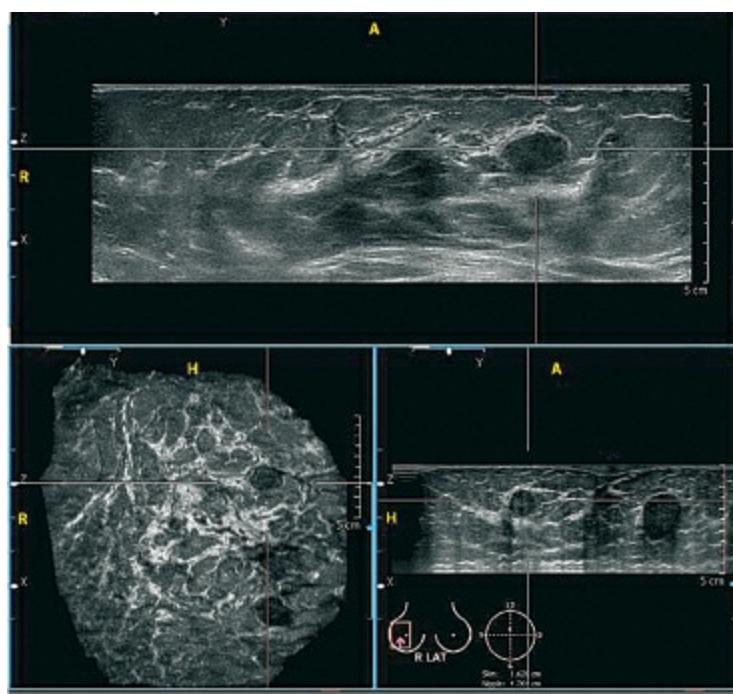
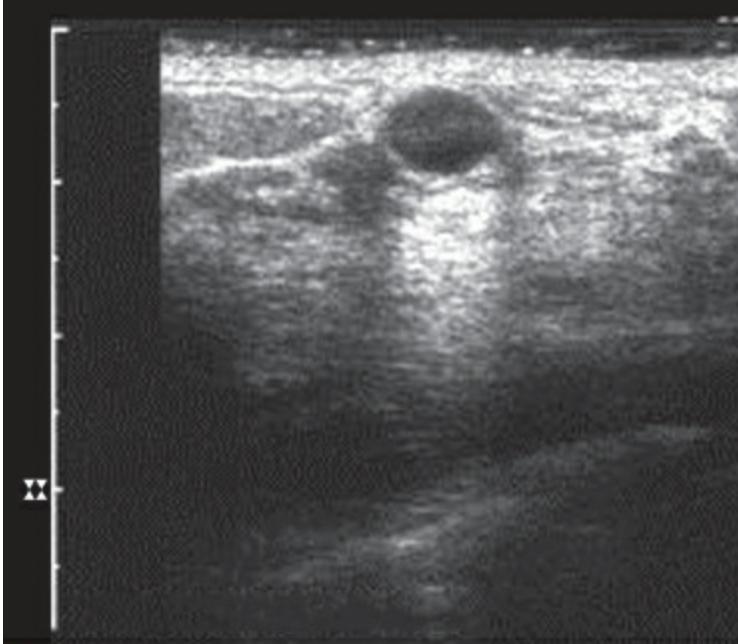


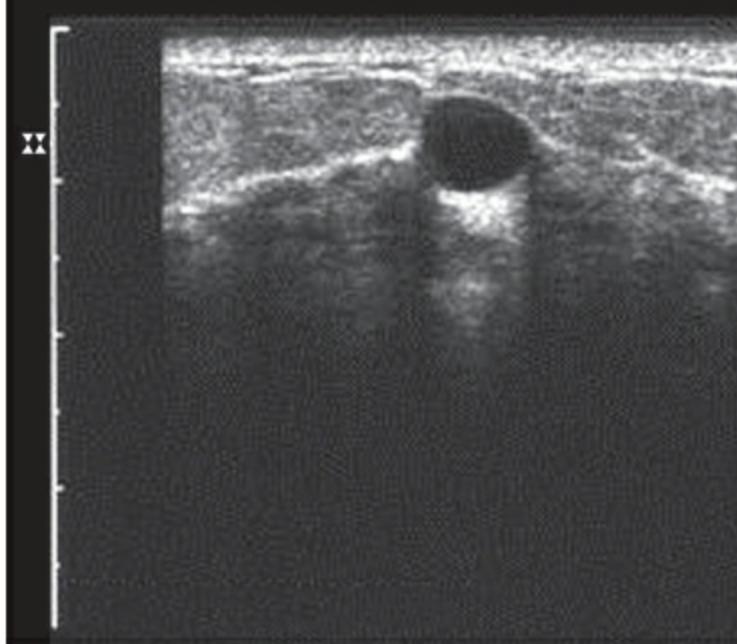
Figure 21 — IMAGE QUALITY: WIDE FOV, VOLUMETRIC ACQUISITION. Extended FOV, supine automated US examination, lateral view, of two of several benign masses in right breast of 42-year-old patient. Crosshairs intersect on a circumscribed, oval, parallel mass at 12:00. Top image is transverse, B-mode acquisition; lower left is coronal reconstruction with fibroglandular tissue white and fat darker gray; lower right, sagittal reconstruction. Wider acquisition fields allow more of the local anatomy to be depicted along with effect, if any, on the surrounding tissue (here, none). The volumetric acquisition also depicts the lesion in three orthogonal planes and can show distances between and relationships among multiple masses.

3. FOCAL ZONE

Variable focusing is available in many transducers. The focal zone(s) should be placed in the anterior-to-middle third of the region of interest between the skin and chest wall. When evaluating a lesion, the focal zone is optimally placed in the center of the lesion. Two to three focal zones or a single focal zone that has variable range will increase the resolution of the tissue imaged within that zone. However, in many systems, if more than three focal zones are used, the frame rate will be slowed significantly, losing the benefits of real-time scanning. Many systems have transducers that can be used with broad focal zone ranges that facilitate the rapidity of scanning large areas of the breast. If targeted scans are being done, a single zone or narrow range can be set at the midlevel of the mass or area of interest. Artifacts and blur caused by poor placement of the focal zones can cause misinterpretation of breast lesions.

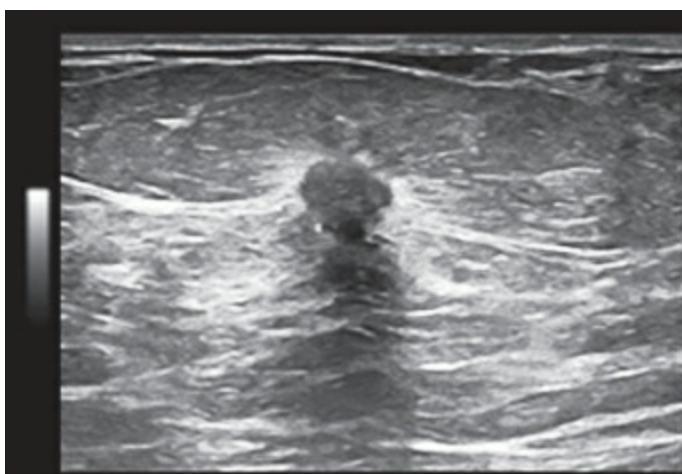


A

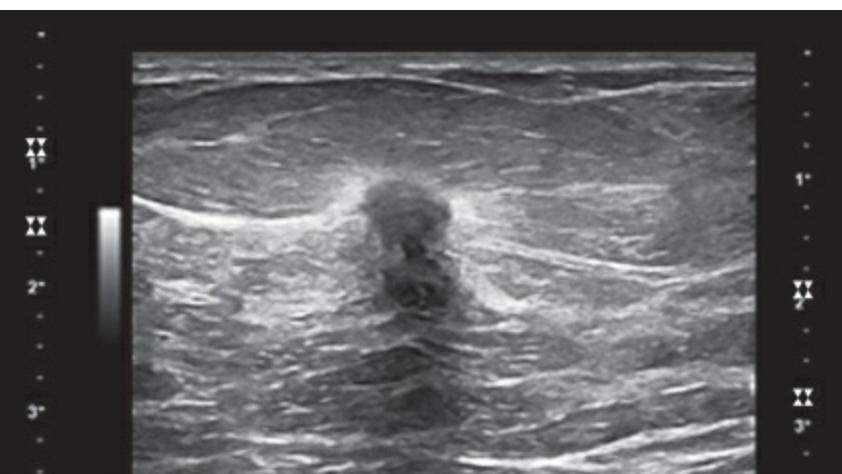


B

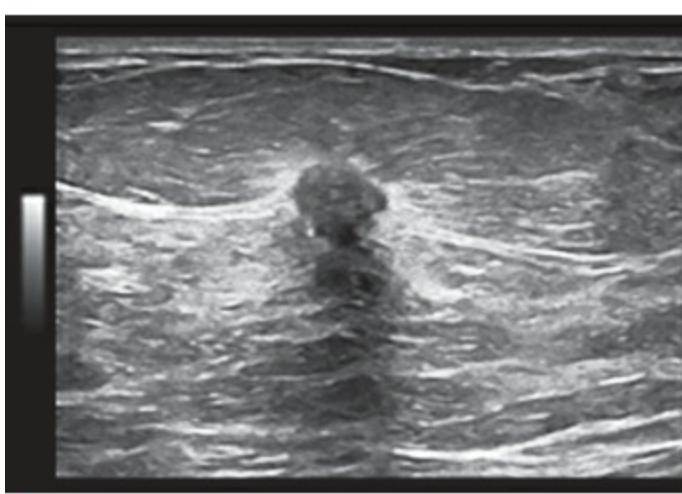
Figure 22 — IMAGE QUALITY: EFFECT OF FOCAL ZONE SETTINGS: Focal zone (marked by **XX** icons) inappropriately positioned below the mass causing echoes to appear within its anterior half (a); with focal zone set properly in the midportion of the mass (b), its anechogenicity is unquestioned. The echoes seen in (a) are confirmed as artifactual.



A



B



C

Figure 23 — IMAGE QUALITY: FOCAL ZONE PLACEMENT can affect conspicuity and clarity of lesion depiction. Three US images of a carcinoma that was readily visible at mammography (not shown) were performed with focal zone settings (marked by a pair of **XX** icons) at different levels. Although the small IDC is clearly identifiable on these three images, marginal features are best depicted when the focal zones are set at the depth of the lesion (a). When the focal zones are adjacent to the pectoral muscle (b), or set at the posterior aspect of the lesion (c), while the shadowing remains intense, marginal features are less distinct.

4. GRAY SCALE GAIN

US waves are absorbed by tissue; the deeper the tissue, the greater the absorption, with less of the beam available to create an image. Increasing the gain may help compensate for this by increasing the brightness of the image, but penetration of tissue for adequate depiction also depends on transducer frequency (greater penetration inversely proportional to frequency), focal zone settings, power increase, and the appropriate selection of FOV. Gray scale gain should be set so normal breast parenchyma varies in echogenicity using much of the gray scale range. The gain may be set too high if the tissue appears as varying shades of white, which can obscure some lesions and make some cysts appear solid. The gain may be set too low if the parenchyma appears dark gray to black, causing some very hypoechoic solid lesions to appear anechoic and be mistaken for simple cysts. As a reference setting for the gray scale, subcutaneous fat lobules should appear medium gray, never black.

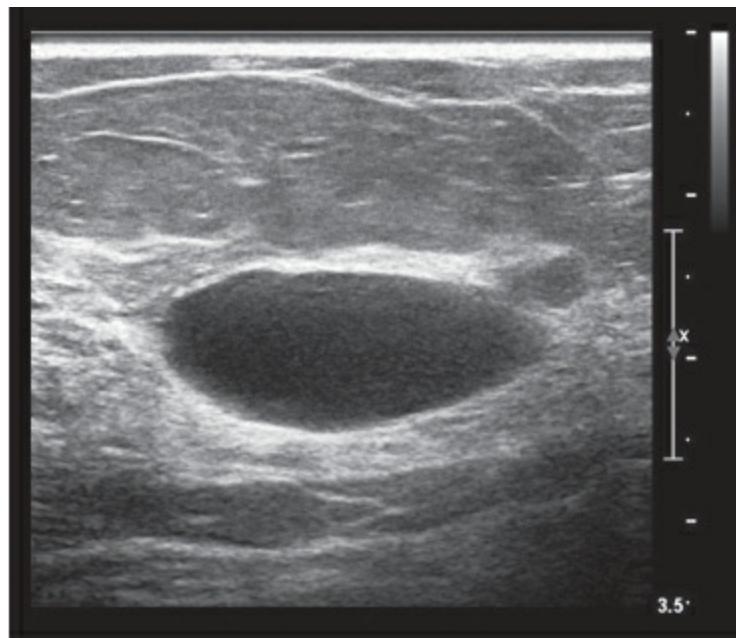
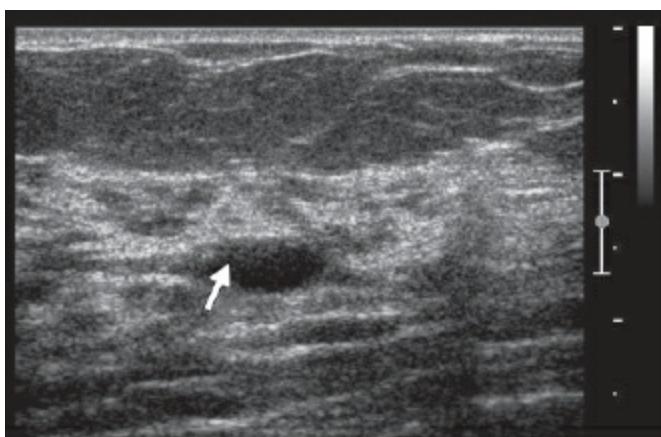


Figure 24 — IMAGE QUALITY: GRAY SCALE GAIN. Mass imaged with appropriate gain settings allows criteria for simple cyst to be applied. The center of the cyst appears anechoic, and surrounding fat and parenchyma are distinguished by the different shades of gray in this well-modulated image. A small complicated cyst is seen at the right margin of and anterior to the larger simple cyst.

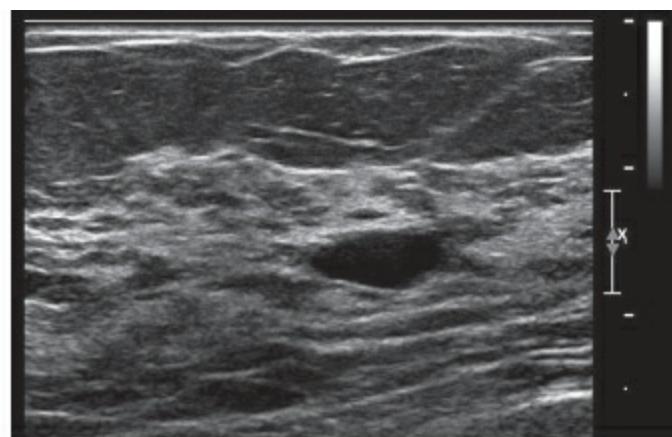
5. COMPOUND IMAGING

Real-time spatial compound imaging creates a single US frame by averaging several overlapping US images obtained at slightly different angles of insonation. The different angles are obtained by electronically steering the transducer array. The process can be repeated so rapidly that imaging occurs in real time, but the frame rate will slow as an increasing number of overlapping images is selected. Compound imaging reduces noise (speckle) and improves resolution in the center of the image. Architectural alterations may be easier to appreciate with compound imaging.

When masses are centered in an image obtained with spatial compounding, the margins are more confidently interpreted. The posterior features, shadowing and enhancement, may be less apparent but still discernible with spatial compounding, and enhancement may appear conical, reflecting the pattern of intersecting beam angles.

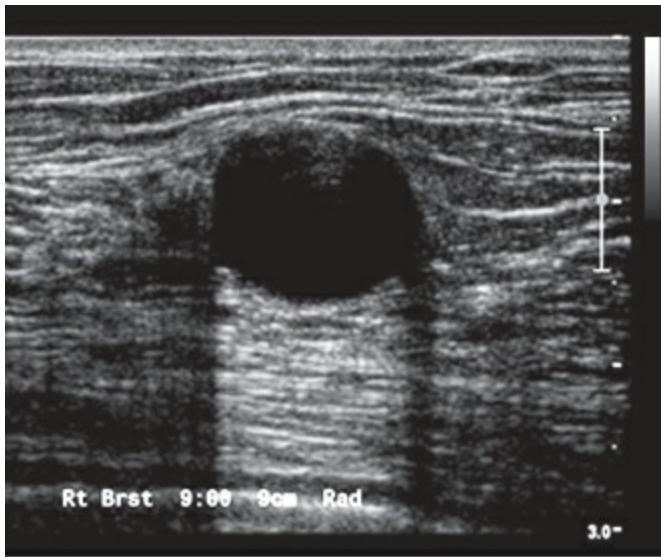


A

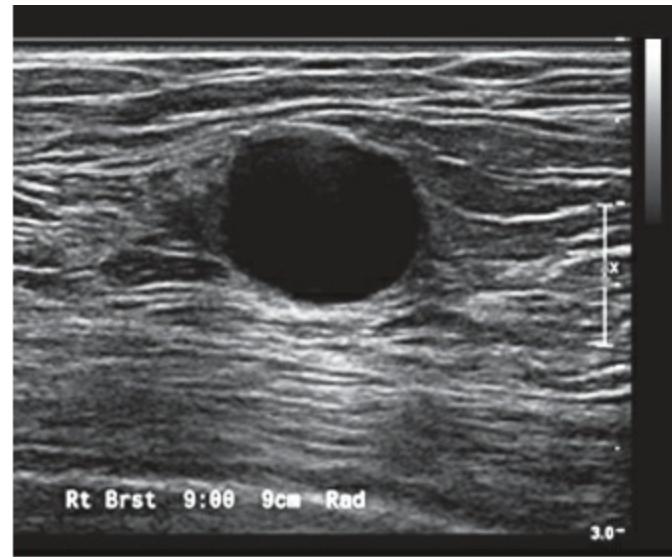


B

Figure 25 — IMAGE QUALITY: SPATIAL COMPOUNDING. US image in native mode (a) demonstrates reverberation artifact in anterior, nondependent wall of cyst (arrow). Spatial compounding technique (b) eliminates artifacts, making the cyst appear anechoic. In both of these images, the focal zone is set correctly.



A



B

Figure 26 — IMAGE QUALITY: SPATIAL COMPOUNDING. The tissue posterior to this simple cyst enhances brightly in a column in this image obtained in native mode (a) but refraction shadowing at the lateral margins of the cyst obscures the adjacent tissue. At the left anterior margin, the definition is not as sharp as it is in (b), obtained with spatial compounding. In (b) also, the lateral refraction shadows are nearly imperceptible, and the tissue lateral to the cyst is depicted clearly. Posterior enhancement is unmistakable; it is not as bright as that in (a) and is a more conical shape.

C. LABELING AND MEASUREMENT

1. LABELING

Breast US images should include the following labeling as described in the [ACR Practice](#)

Guidelines for the Performance of Breast Ultrasound Examination and the ACR Practice Guidelines for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures.^{4,6}

1. Facility name and location
2. Examination date
3. Patient's first and last name
4. Identifying number and/or date of birth
5. Designation of right or left breast
6. Anatomic location using clock-face notation (to the nearest hour) or a labeled diagram of the breast
7. Transducer orientation (e.g., radial, antiradial, oblique, transverse, sagittal)
8. Distance from the nipple to the abnormality or the area being scanned in centimeters (measure from the nipple as a standard reference point, not the edge of the very variable areola)
9. Sonographer's and/or physician's identification number, initials, or other symbol

2. MEASUREMENT

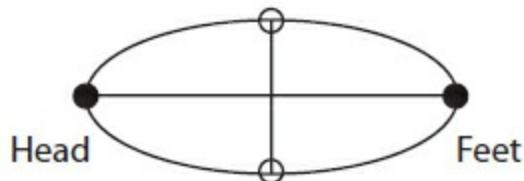
How To Measure

The sonologist or sonographer should seek the longest axis of a lesion, similar to what would be done for measuring a kidney or an ovary, and then obtain an orthogonal image with a measurement in the plane not present on the initial image. A common error is to use the rectangular frame of an image as the reference standard for measuring lesions (Figure 27). Often, a mass is not oriented horizontally or vertically but obliquely within the image. For solid or complex cystic and solid lesions, an image with color or power Doppler is also desirable. Although real-time scanning is optimal, video clips of the study may also contribute some interpretive confidence when the interpreter of the exam is not the performer, ***but video clips should not be a substitute for direct interpreter scanning if questions persist.***

1. Record measurements to the nearest **millimeter** or **centimeter** (be consistent with the use of distance units throughout the report). For example, 0.45 cm–0.49 cm should be rounded up to 0.5 cm, and 0.11–0.14 cm should be rounded down to 0.1 cm.

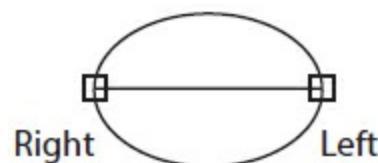
2. When possible, three measurements of a lesion should be given. The largest measurement should represent the longest axis of a lesion if there is one. The next measurement should be the one perpendicular to the first. The third measurement should be taken from a view orthogonal to the first image, and it should represent a plane different from the first two. For example, see diagram below.

A. Initial image of lesion



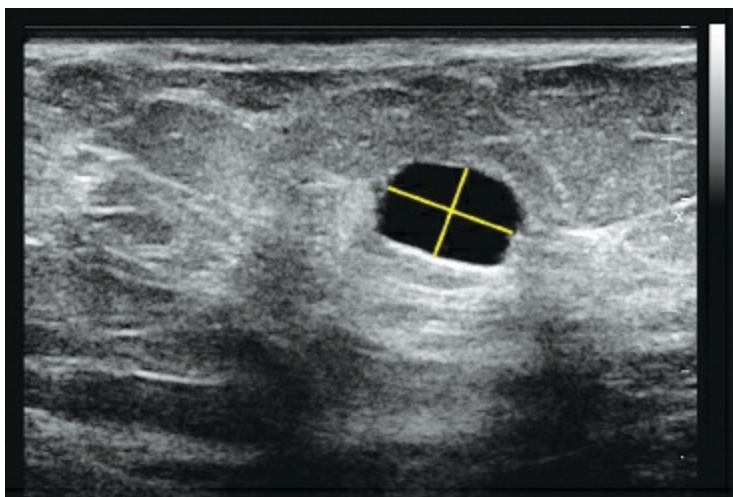
- Superior to Inferior
- Anterior to Posterior

B. Orthogonal view (turned 90°)

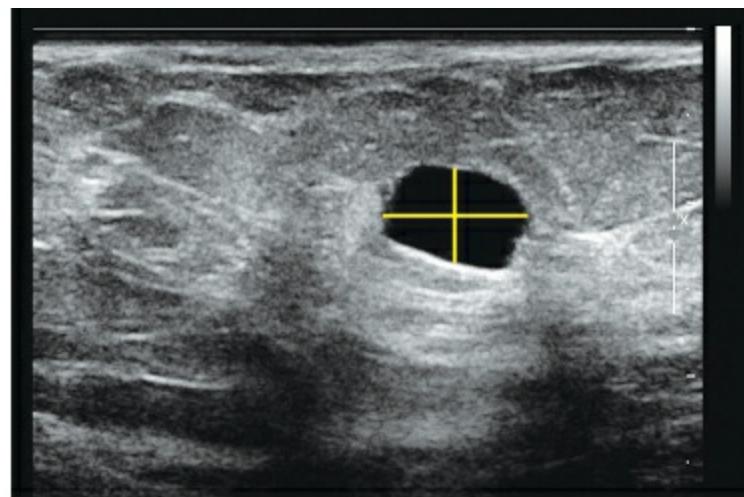


- Lateral to Medial

If it is necessary, the volume of a mass can be computed and reported by using a 3-D transducer (for 2-D US, two perpendicular images will allow three measurements to be made). If posterior shadowing is intense, the posterior margin of the mass may be obscured, and the anterior-posterior dimension may not be measurable.



A



B

Figure 27 — LABELING AND MEASUREMENT. This simple cyst and other obliquely situated masses should be measured as in (a), first finding the longest axis of the mass and then a measurement perpendicular to it. The measurements shown in (b) are incorrect; the rectangular image frame should not be the reference for measuring.

D. DOCUMENTATION

Cysts, Intramammary Lymph Nodes, and Multiple Benign Masses

When there are multiple cysts, representative images suffice. When several cysts are present, it is not necessary to document every cyst in two views; measuring the largest in each breast along only its longest axis is sufficient.⁷ If the US examination is directed to a

mammographic abnormality(ies) or if the cyst corresponds to an area of clinical concern to the patient, physician, or other health care provider, its measurements should be recorded as previously discussed. However, if a solitary asymptomatic simple cyst is identified at screening US, it should be fully evaluated by the operator at real-time scanning to establish its characteristically benign features, but it does not require complete documentation. One image along the longest axis of the cyst would be sufficient if the cyst is described in the report (benign assessment). No documentation is required if the cyst is not described in the report (negative assessment).

Although cysts can occur high in the axillary tail location or in accessory breast tissue within the axilla, such a location should suggest other etiologies, such as metastatic lymph nodes. Color or power Doppler and some elastographic methods can offer confirmation of the circumscribed, anechoic mass as a simple cyst.

Similar guidance is pertinent for the documentation of intramammary lymph node(s). If the US examination is directed to a mammographic abnormality(ies) or if the node corresponds to an area of clinical concern to the patient, physician, or other health care provider, full documentation of the lesion is appropriate. However, an asymptomatic, characteristically benign, intramammary lymph node, fully evaluated at real-time scanning or observed incidentally, does not require complete or even any documentation.

For US, as for mammography, benign (category 2) is the appropriate assessment for multiple bilateral solid masses, as long as all the masses are similar in appearance.⁷ If the interpreter prefers to document all masses rather than the largest in each quadrant or in each breast, reporting should be in the form of a list including clock-face locations of the masses, distance from the nipple, and three orthogonal measurements. When there are numerous masses in the same area, reporting the depth from the skin to the anterior aspect of a lesion also helps to differentiate it from others. ([Follow-Up and Outcome Monitoring section](#), regarding the effect that documenting nonstandard images has on the audit of screening examinations.)

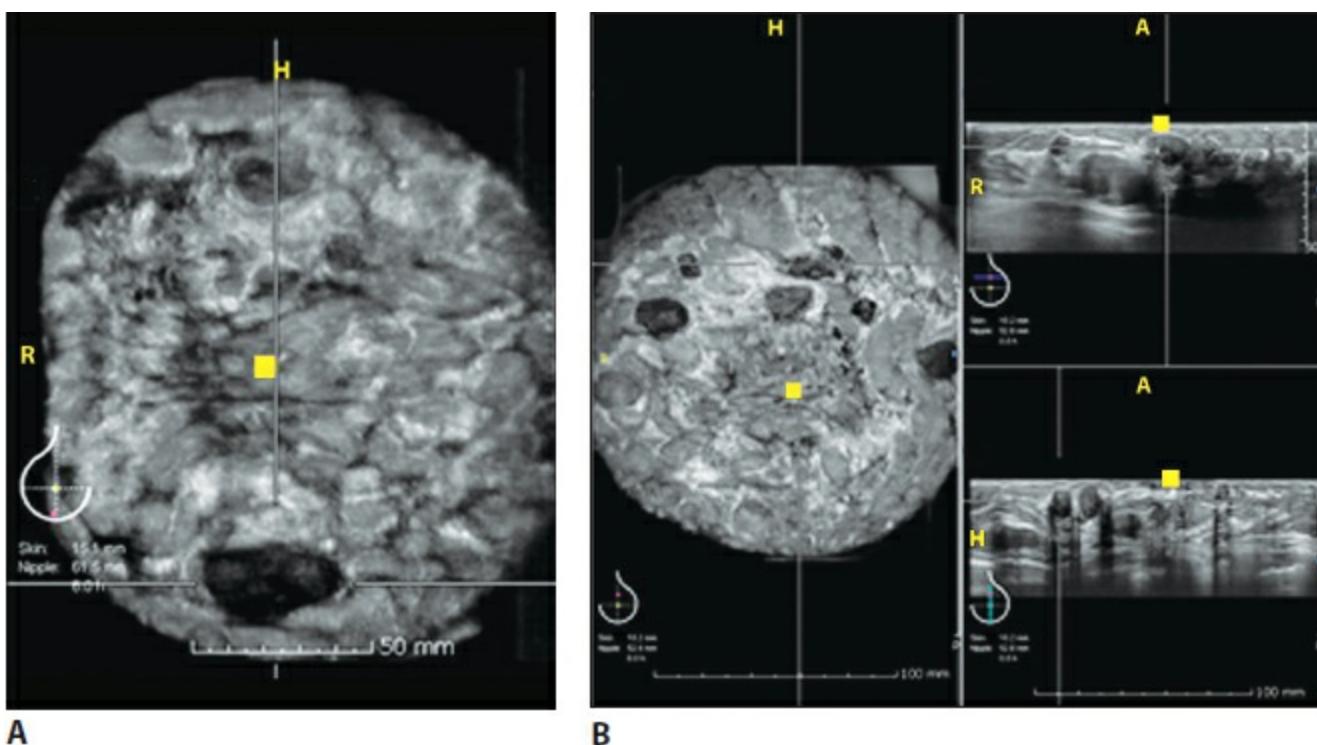


Figure 28 — DOCUMENTATION: MULTIPLE MASSES. Coronal views of the right (a) and left (b) breasts obtained with automated US show numerous circumscribed masses bilaterally. The transverse or axial acquisition is shown at the top right of (b) with the sagittal reconstruction at the lower right. Crosshairs correlate with lesion location on the three views. Diagrams and annotation at the lower corners of the coronal views indicate distance from the nipple, clock-face notation, and depth from the skin to the center of the crosshairs. DOCUMENTATION in a list is efficient and clear.

REFERENCES

1. American College of Radiology Imaging Network. Protocol 6666, screening breast ultrasound in high-risk women. (<http://www.acrin.org/TabID/153/Default.aspx>). Accessed November 4, 2013.
2. Berg WA, Blume JD, Cormack JB, et al. Combined screening with ultrasound and mammography vs mammography alone in women at elevated risk of breast cancer. *JAMA* 2008; 299:2151–2163.
3. Berg WA, Zhang Z, Lehrer D, et al. Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. *JAMA* 2012; 307:1394–1404.
4. American College of Radiology. ACR practice guideline for the performance of breast ultrasound examination. (http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/US_Breast.pdf). Accessed November 4, 2013.
5. American College of Radiology. ACR practice guideline for the performance of screening mammography. (http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Screening_Mammography.pdf) Accessed November 4, 2013.
6. American College of Radiology. ACR practice guideline for the performance of ultrasound-guided percutaneous breast interventional procedures. (http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/US_Guided_Breast.pdf). Accessed November 4, 2013.
7. Berg WA, Zhang Z, Cormack J, Mendelson E. Multiple bilateral circumscribed masses at screen breast US: consider annual follow-up. *Radiology* 2013; 268(3):673–683.

II. BREAST IMAGING LEXICON — ULTRASOUND

Table 1. BI-RADS® Ultrasound Lexicon Overview

Breast Tissue	Terms	
A. Tissue composition (screening only)	1. a. Homogeneous background echotexture – fat 2. b. Homogeneous background echotexture – fibroglandular 3. c. Heterogeneous background echotexture	
Findings	Terms	
B. Masses	1. Shape a. Oval b. Round c. Irregular 2. Orientation a. Parallel b. Not parallel 3. Margin a. Circumscribed b. Not circumscribed i. Indistinct ii. Angular iii. Microlobulated iv. Spiculated 4. Echo pattern a. Anechoic b. Hyperechoic c. Complex cystic and solid d. Hypoechoic e. Isoechoic f. Heterogeneous 5. Posterior features a. No posterior features b. Enhancement c. Shadowing d. Combined pattern	
C. Calcifications	1. Calcifications in a mass 2. Calcifications outside of a mass 3. Intraductal calcifications	
D. Associated features	1. Architectural distortion 2. Duct changes 3. Skin changes a. Skin thickening b. Skin retraction 4. Edema 5. Vascularity a. Absent b. Internal vascularity c. Vessels in rim 6. Elasticity assessment a. Soft b. Intermediate c. Hard	
E. Special cases	1. Simple cyst 2. Clustered microcysts 3. Complicated cyst 4. Mass in or on skin 5. Foreign body including implants 6. Lymph nodes – intramammary 7. Lymph nodes – axillary 8. Vascular abnormalities a. AVMs (arteriovenous malformations/pseudoaneurysms) b. Mondor disease 9. Postsurgical fluid collection 10. Fat necrosis	

A. TISSUE COMPOSITION

The wide normal variability in tissue composition seen on mammograms can also be observed on US images. Just as increasing breast density diminishes the sensitivity of mammography in the detection of small masses, heterogeneous background echotexture of the breast may affect the sensitivity of breast sonograms for lesion detection.

1. a. HOMOGENEOUS BACKGROUND ECHOTEXTURE — FAT

Fat lobules and uniformly echogenic bands of supporting structures comprise the bulk of breast tissue.



Figure 29—HOMOGENEOUS BACKGROUND ECHOTEXTURE — FAT.
Homogeneously fatty tissue in a 59-year-old patient is easily characterized and compared with mammography using extended FOV or other US techniques that widen the field. The patient's head would be at the left and feet at the right.

A. TISSUE COMPOSITION

2. b. HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR

A thick zone of homogeneously echogenic fibroglandular parenchyma is present beneath the thin hypoechoic layer of fat lobules. Many lesions, cancers, and fibroadenomas, for example, are found within the fibroglandular zone or at its junction with the layer of fat.



Figure 30 — HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR. The subcutaneous layer of fat is distinct from the more echogenic fibroglandular zone (*F*) that lies between it and the pectoral fascia and muscle beneath it.

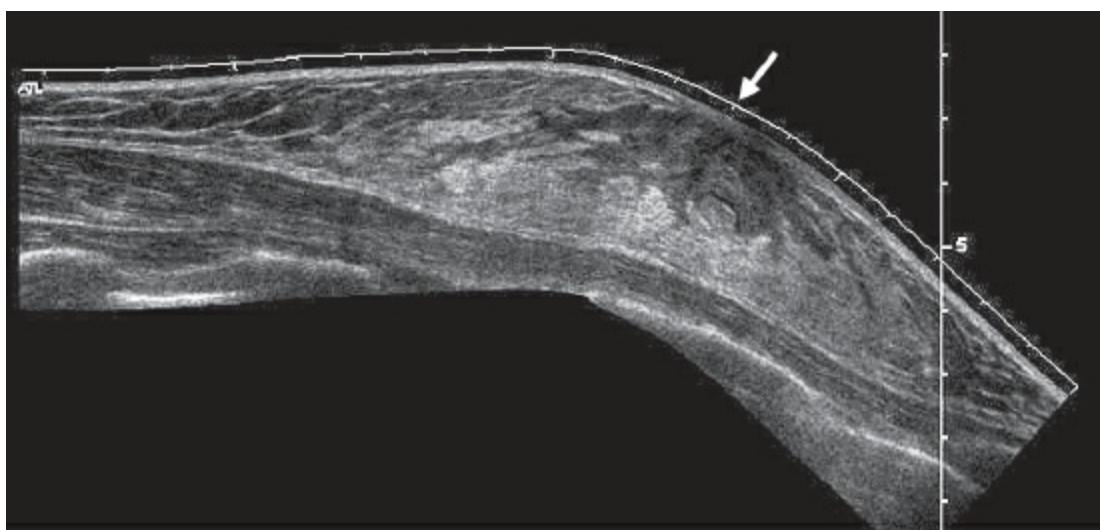


Figure 31 — HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR. The breast at puberty resembles gynecomastia with hypoechoic tissue immediately posterior to the nipple (arrow). Because these young patients ordinarily do not undergo mammography, it is important not to misinterpret the hypoechoic retroareolar breast bud as an abnormality requiring biopsy. This area should be recognized as normal for this age group; if it is removed surgically, the breast will not develop.

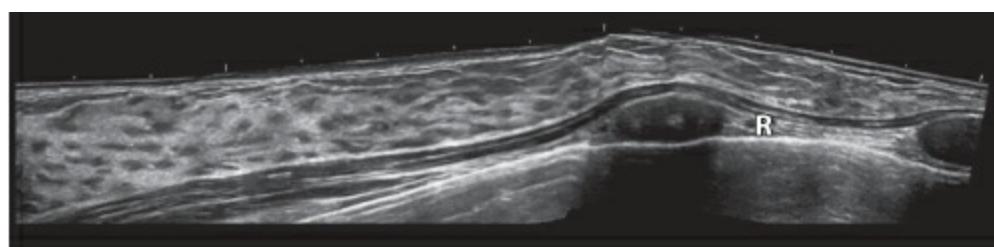


Figure 32 — HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR. Echogenic fibroglandular tissue with hypoechoic ducts beneath a layer of subcutaneous fat that is extremely thin. Rib (*R*).

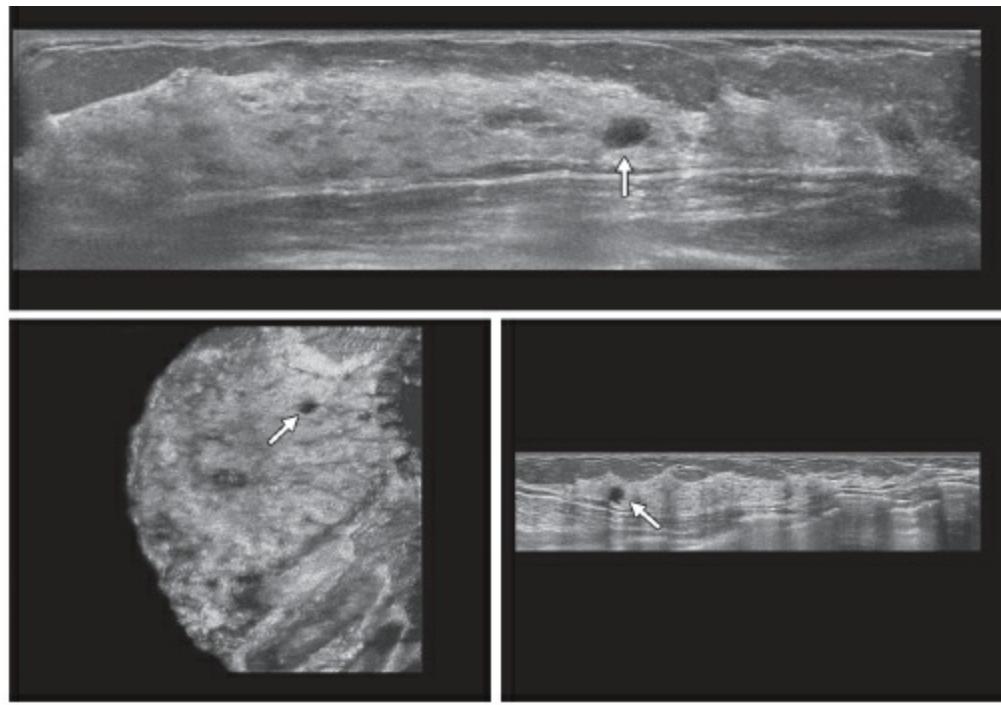


Figure 33 — HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR.
Automated US image (lateral view) of the left breast showing a small cyst (arrows) within the homogeneous echogenic fibroglandular zone on each view, the 14–5 MHz linear acquisition, 14.5 cm wide, at the top, with the coronal (left) and vertical (right) reconstructions below. A thin layer of subcutaneous fat overlies the fibroglandular zone.

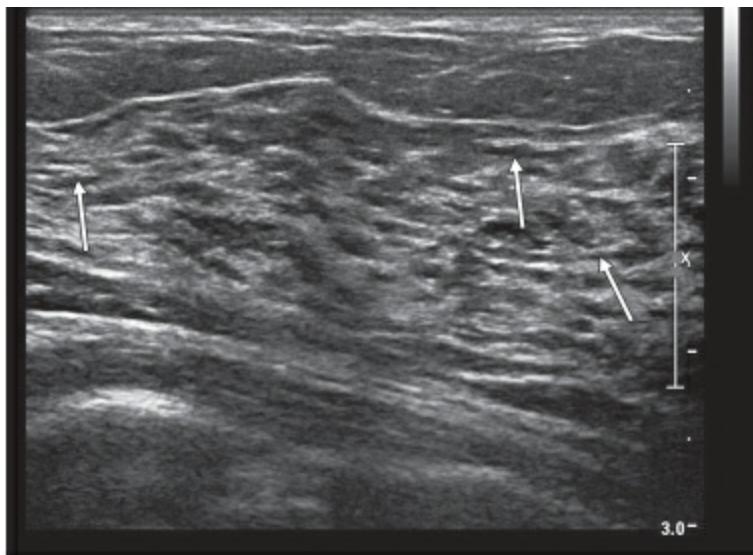


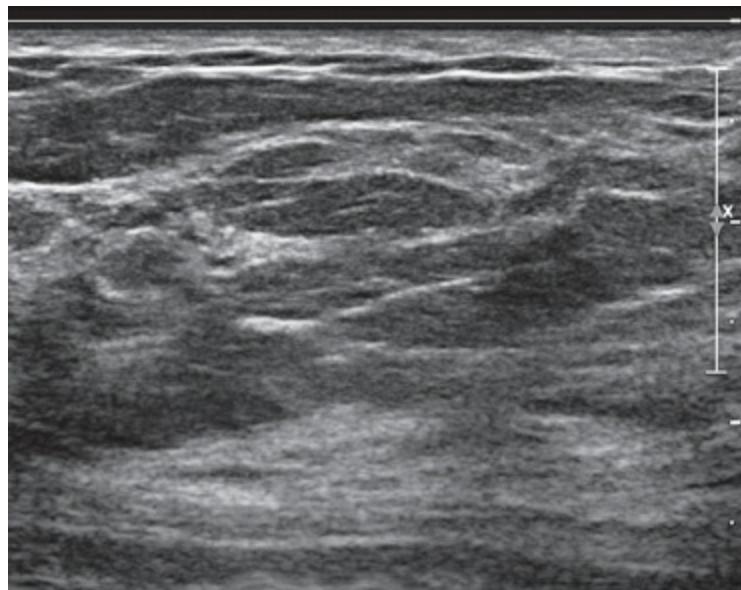
Figure 34 — HOMOGENEOUS BACKGROUND ECHOTEXTURE — FIBROGLANDULAR. Handheld image (linear transducer 17–5 MHz) with similar findings, but in greater detail, than the automated image above. The linear hypoechoic threadlike ducts (arrows) are seen throughout the fibroglandular tissue in the axillary tail of the right breast.

A. TISSUE COMPOSITION

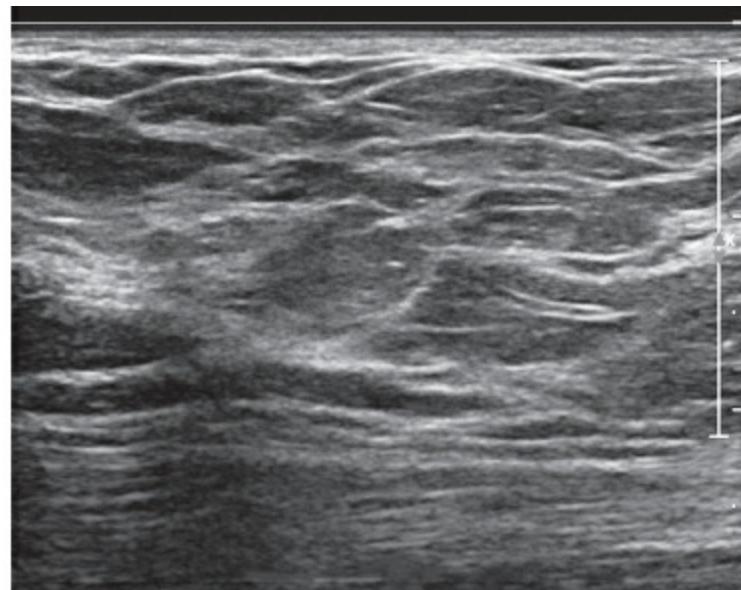
3. c. HETEROGENEOUS BACKGROUND ECHOTEXTURE

Heterogeneity can be either focal or diffuse. The breast echotexture is characterized

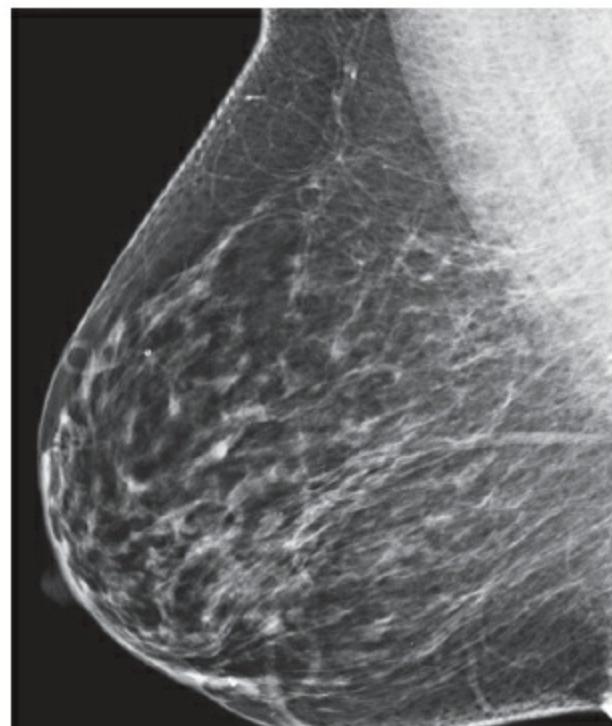
by multiple small areas of increased and decreased echogenicity. Shadowing may occur at the interfaces of fat lobules and parenchyma. This pattern occurs in younger breasts and those with heterogeneously dense parenchyma depicted mammographically. Whether and how this pattern affects the sensitivity of sonography merits study, but clinical experience suggests that the detection of small and subtle lesions may be confounded by heterogeneous background echotexture. Technical maneuvers may help resolve interpretive dilemmas that occasionally result in unnecessary biopsy.



A



B



C

Figure 35 — HETEROGENEOUS BACKGROUND ECHOTEXTURE. Two images, one at 10:00 in the right breast (a) and the other at 12:00 in the left breast (b), show an admixture of fat and fibroglandular tissue, not in separate homogeneous tissue layers as in the preceding images (Figs. 30–34). The mammographic correlate (c) is seen on a mediolateral oblique image of this 57-year-old woman's breast, described as scattered areas of fibroglandular density.

B. MASSES

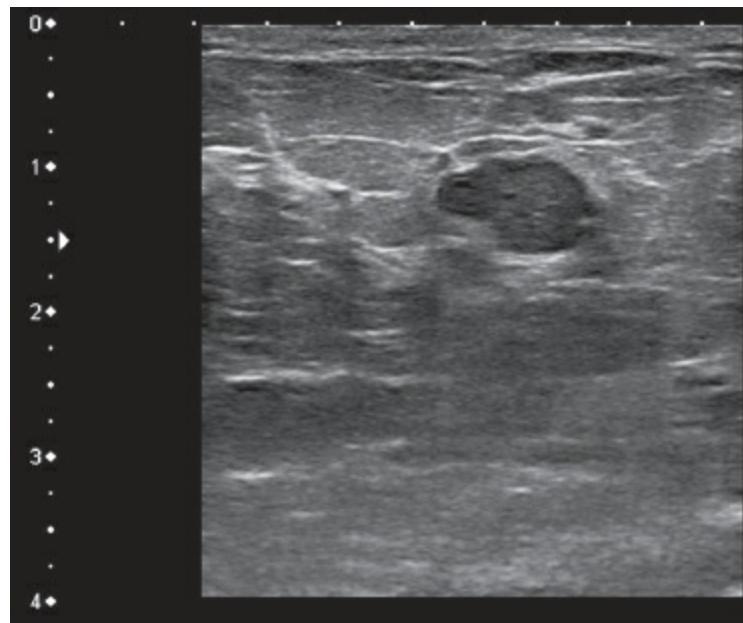
A mass is 3-D and occupies space. With 2-D US it should be seen in two different planes; with volumetric acquisitions it should be seen in three planes. Masses can be distinguished from normal anatomic structures, such as ribs or fat lobules, using two or more projections and real-time scanning.

B. MASSES

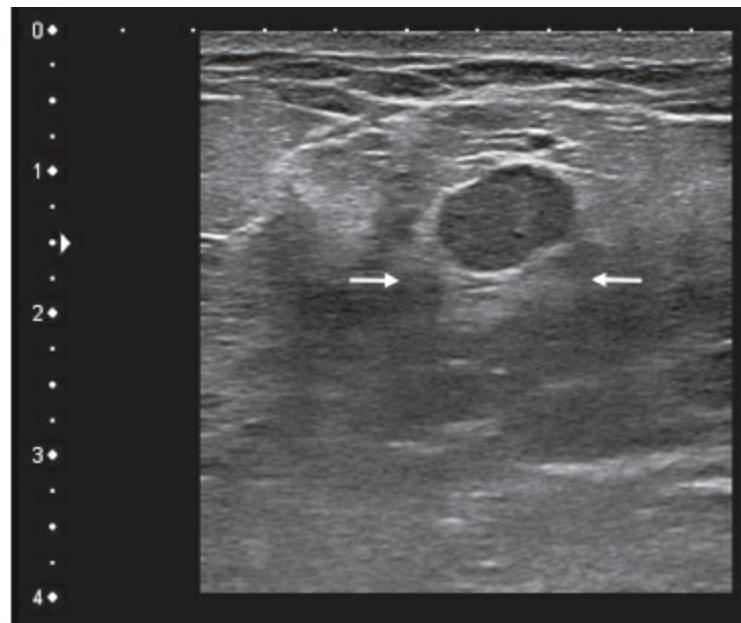
1. SHAPE

a. Oval

A mass that is elliptical or egg-shaped (may include two or three undulations, i.e., gently lobulated or macrolobulated).



A



B

Figure 36 — SHAPE: OVAL. Radial (a) and antiradial (b) images of an OVAL mass in a 32-year-old woman. Margin is circumscribed, and orientation (longest axis of mass) is parallel to the skin. Refractive edge shadowing is present at the edges of curved surfaces (arrows), particularly noticeable in (b). Applying increased probe pressure or slight alteration in patient's position or probe angle can minimize this effect. Combined features suggest benign etiology. Patient requested US-guided biopsy. Concordant histopathology was fibroadenomatous change, sclerosing adenosis, and calcifications.

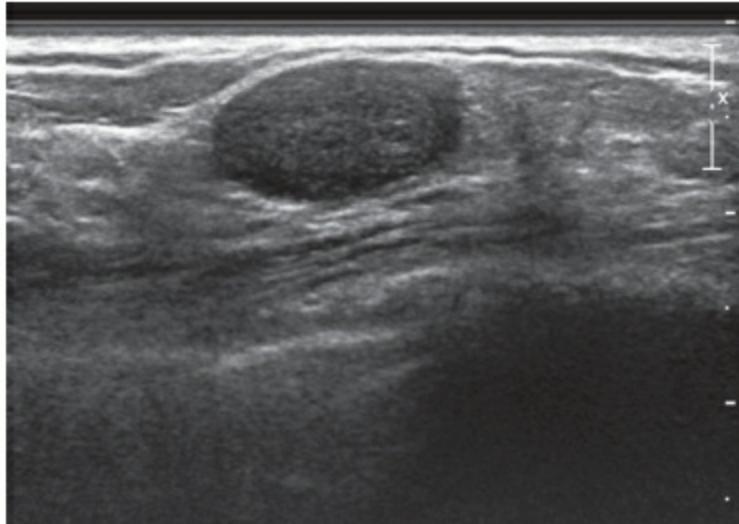
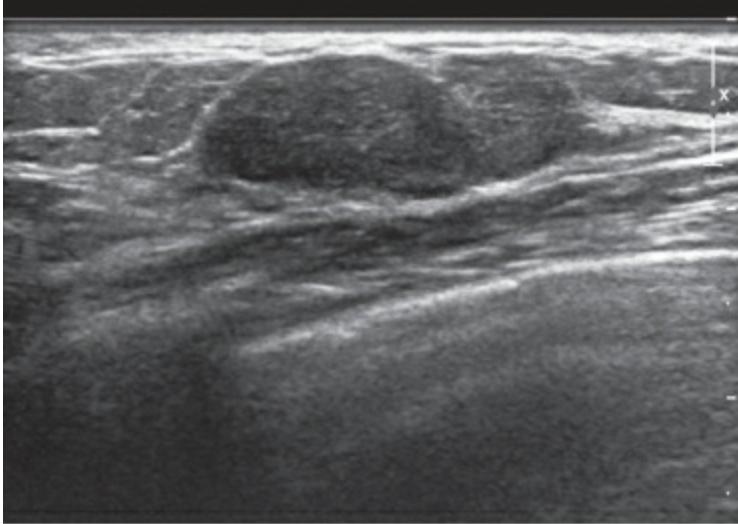
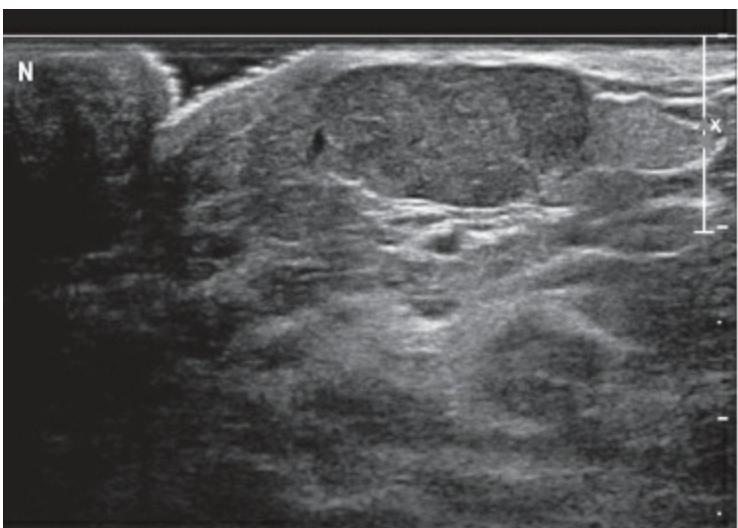
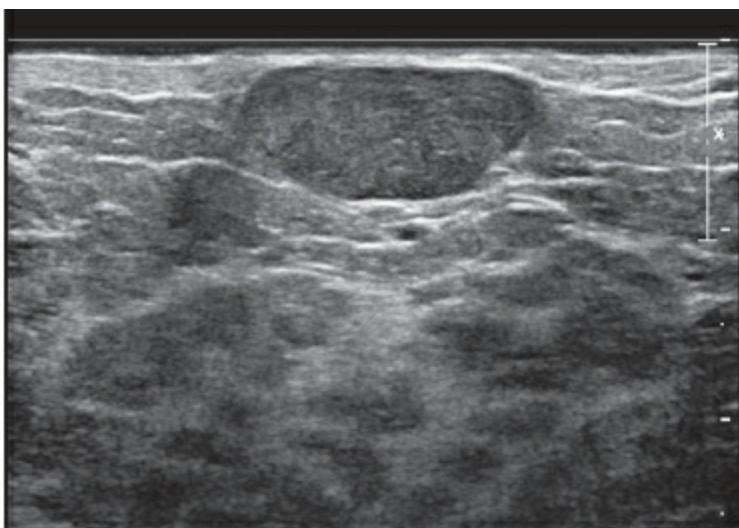


Figure 37 — SHAPE: OVAL. Orthogonal views of two adjacent, contiguous masses, each OVAL in shape, circumscribed, and parallel to the skin. Histopathology: fibroadenoma.



A



B



C

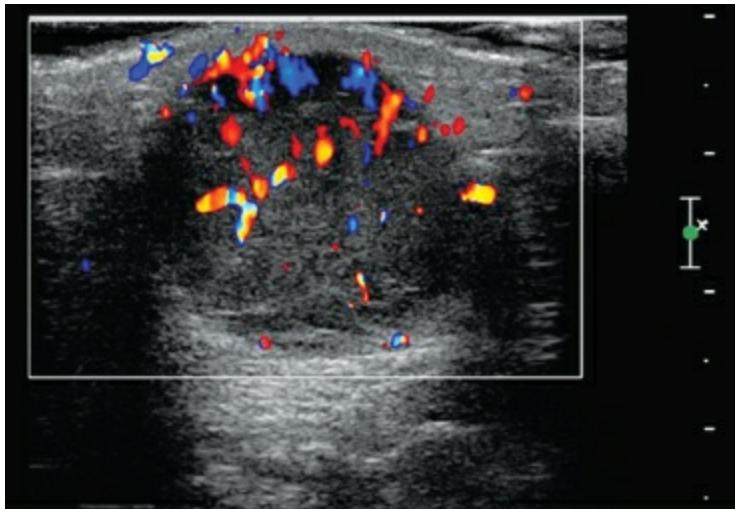
Figure 38 — SHAPE: OVAL. 28-year-old woman in third trimester of pregnancy with orthogonal views of a palpable mass (*a* and *b*) with features similar to those of the benign mass shown in Figure 26. US image (*c*) obtained 6 months after completion of lactation showed disappearance of the mass. Histopathology: lactating adenoma or lobular hyperplasia of pregnancy.

B. MASSES

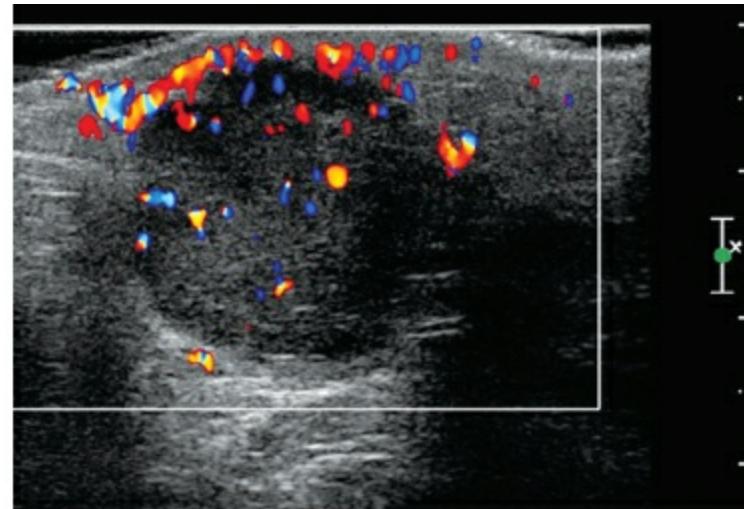
1. SHAPE

b. Round

A round mass is one that is spherical, ball-shaped, circular, or globular. It has an anteroposterior diameter equal to its transverse diameter; to qualify as a round mass, it must be circular in perpendicular projections. Masses with a round shape are not commonly seen at breast US.

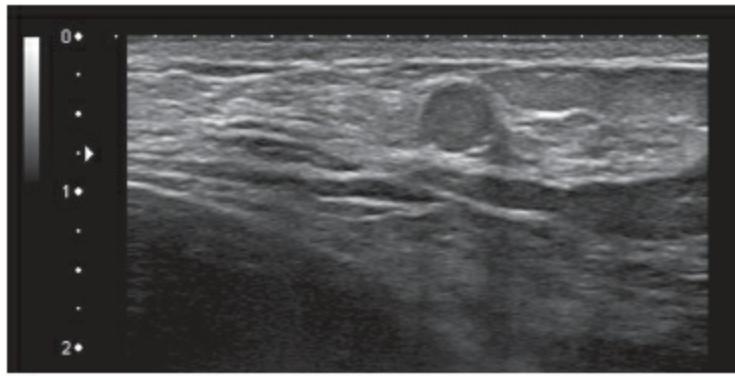


A

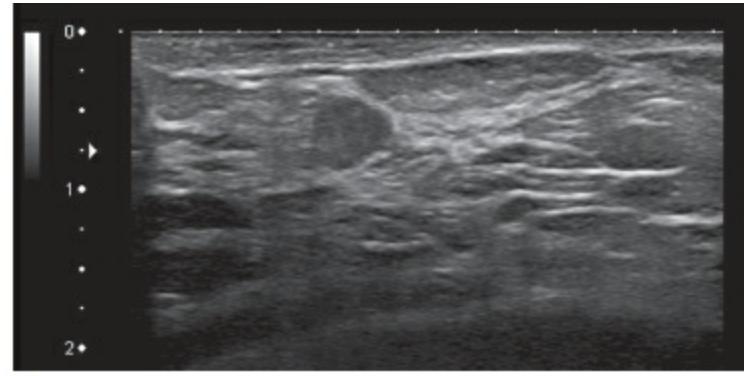


B

Figure 39 — SHAPE: ROUND. Axillary lymph node metastasis from esophageal carcinoma. Orthogonal, color flow images (*a* and *b*) in a woman who also has breast cancer. The mass is ROUND, is circumscribed, and enhances posteriorly. Vascularity is seen internally throughout the node and at its anterior rim. This lymph node, completely replaced by metastasis, has lost its reniform shape and hilar fat.



A



B

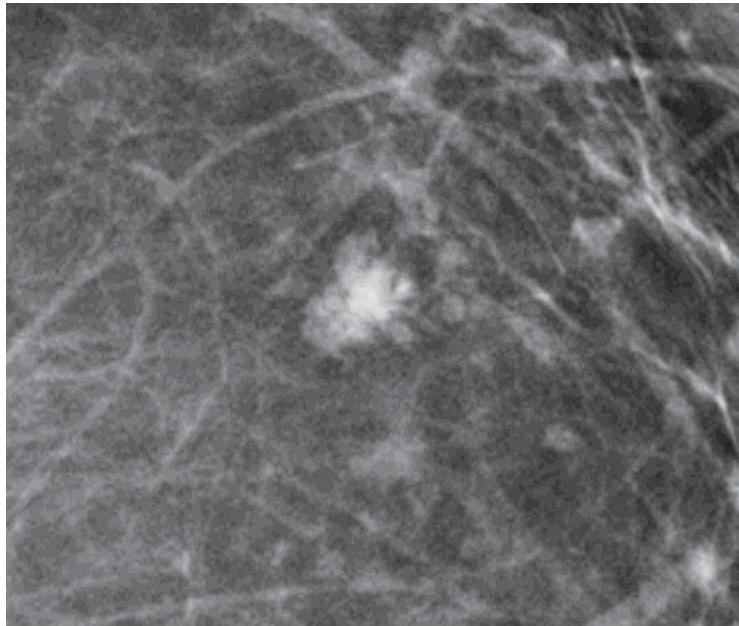
Figure 40 — SHAPE: ROUND. 37-year-old with pathogenic BRCA2 mutation and breast implants. Contrast-enhanced screening MRI depicted a suspicious mass. MRI-directed US also depicts this mass, as small, round, and circumscribed: (*a*) antiradial image; (*b*) radial image. Histopathology: intraductal papilloma.

B. MASSES

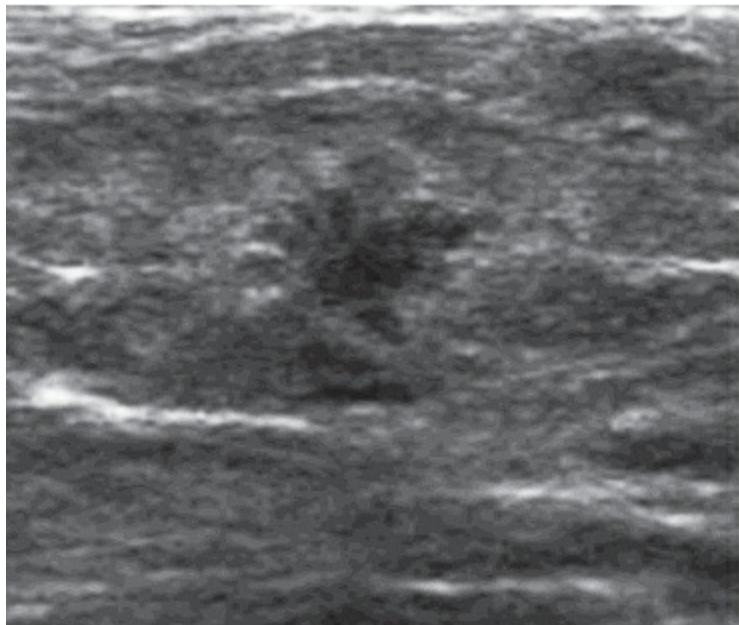
1. SHAPE

c. Irregular

The lesion shape is neither round nor oval.



A

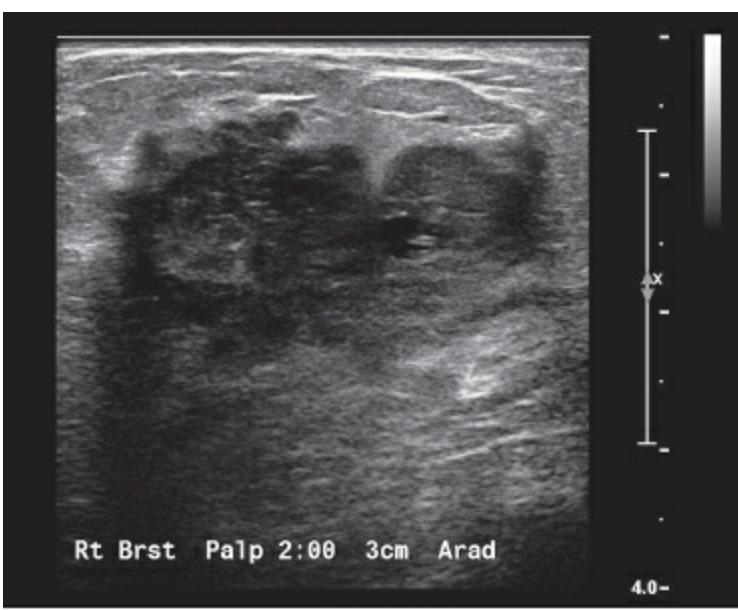


B

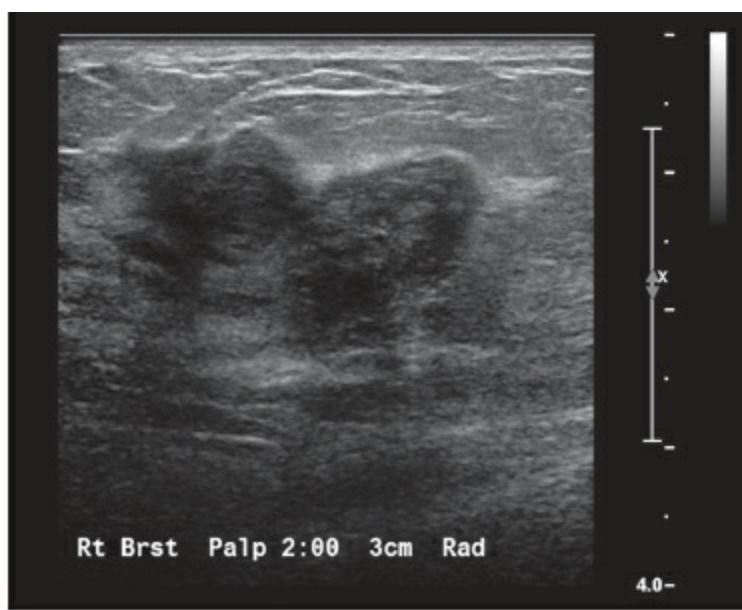
Figure 41 — SHAPE: IRREGULAR. Spot compression mammographic view of a mass with IRREGULAR shape (a) and perpendicular views of its sonographic correlate (b and c). The key findings are that the mass has an IRREGULAR shape, its margin is not circumscribed, and its orientation is not parallel. Histopathology is benign, high risk: complex sclerosing lesion, not upgraded at excision.



C

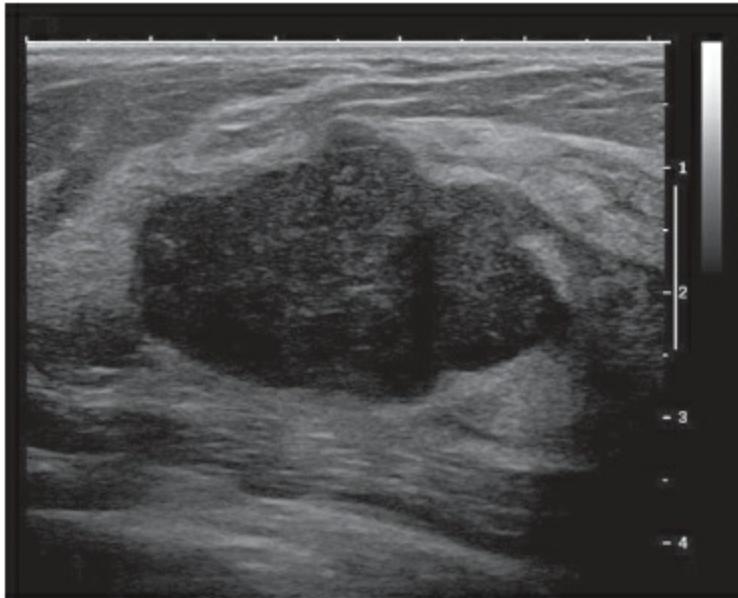


A

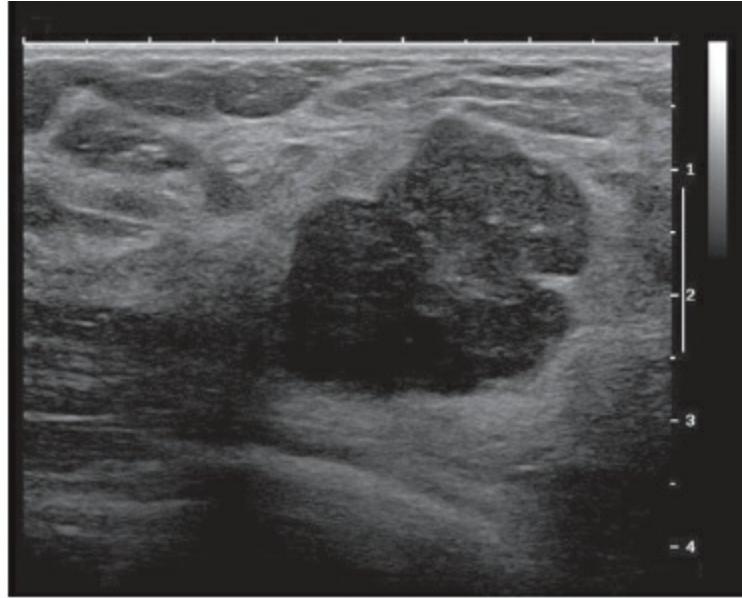


B

Figure 42 — SHAPE: IRREGULAR. This large mass in a 49-year-old woman is 4 cm in its longest dimension. Its shape is IRREGULAR, its margin is not circumscribed, and its orientation is parallel to the skin (a and b). Histopathology: invasive ductal carcinoma, grade 3.



A

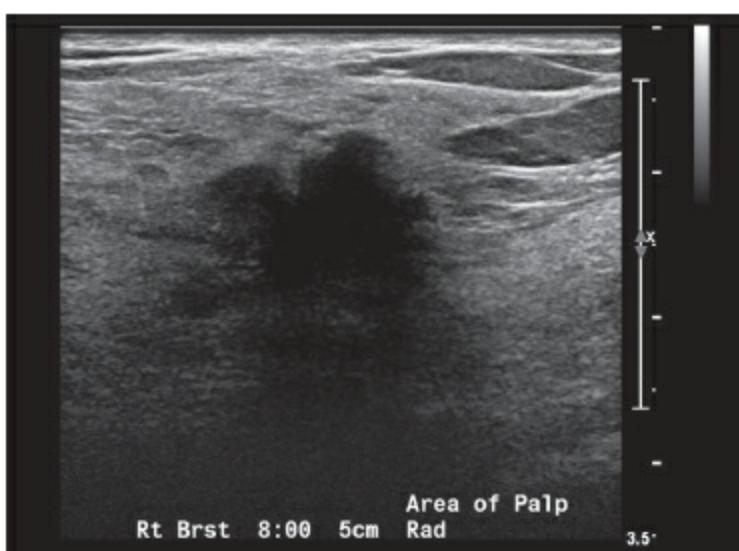


B

Figure 43 — SHAPE: IRREGULAR. A 42-year-old woman has a mass with an IRREGULAR shape and microcalcifications within; the margin is not circumscribed, and a long axis is parallel to the skin (a). Not uncommon in high-grade tumors is enhancement of the tissue posterior to the mass, well seen on (b). Histopathology: invasive ductal carcinoma, grade 3.



A



B

Figure 44 — SHAPE: IRREGULAR. Spiculated hypoechoic mass in a 35-year-old woman with type 1 diabetes has an IRREGULAR shape and is oriented parallel to the skin in the antiradial scan (a). The margin is not circumscribed (b). BI-RADS® assessment is category 4C— high suspicion for malignancy. As in this case, even if the patient is an insulin-dependent diabetic with juvenile onset, tissue sampling **must** be performed. Histopathology: diabetic mastopathy.

B. MASSES

2. ORIENTATION

This feature of masses is unique to US imaging. Orientation is defined with reference to the skin line. Obliquely situated masses may follow a radial pattern, and their long axes will help determine their classification as parallel or not parallel. Parallel or “wider-than-tall” orientation is a property of most benign masses, notably fibroadenomas; however, many carcinomas have this orientation as well. Orientation alone should not be used as the sole feature in assessing a mass for its likelihood of malignancy.

a. Parallel (historically, “wider-than-tall” or “horizontal”)

The long axis of the mass parallels the skin line. Masses that are only slightly obliquely oriented might be considered parallel.

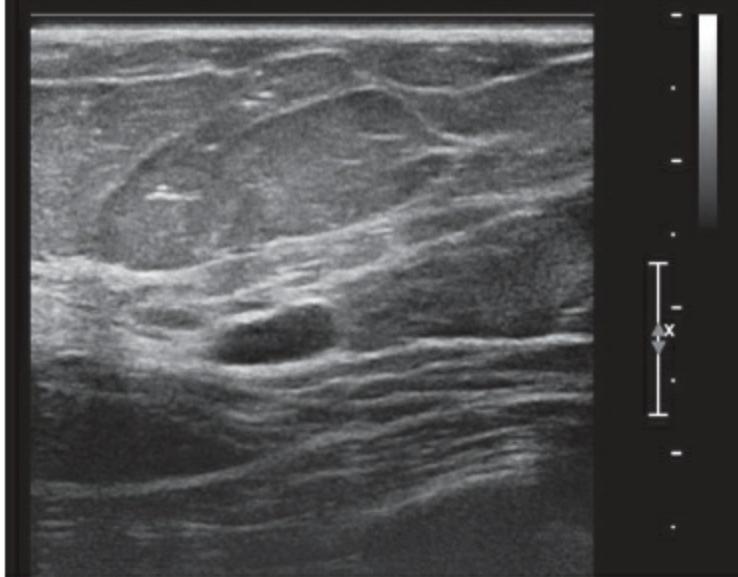
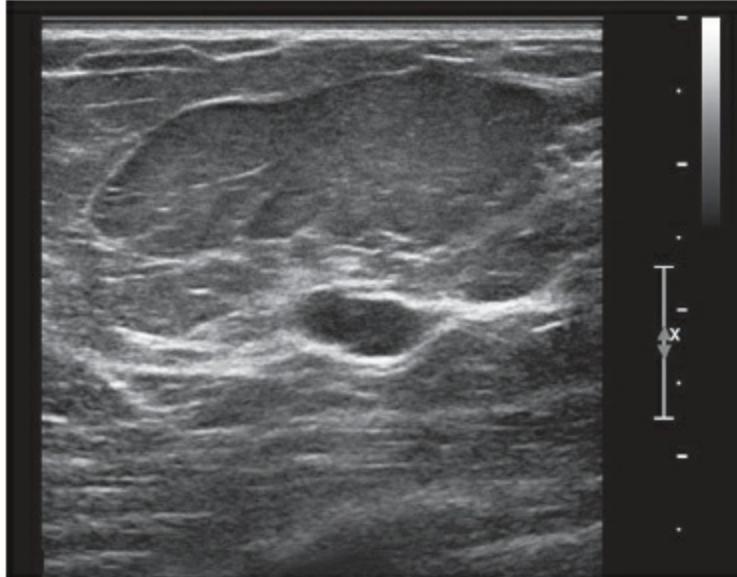
**A****B**

Figure 45 — ORIENTATION: PARALLEL. Radial (*a*) and antiradial (*b*) views of a PARALLEL mass, oval and circumscribed, benign features taken together, situated within a thin layer of echogenic fibroglandular tissue in a predominantly fatty breast. Histopathology: fibroadenoma in a 39-year-old patient.

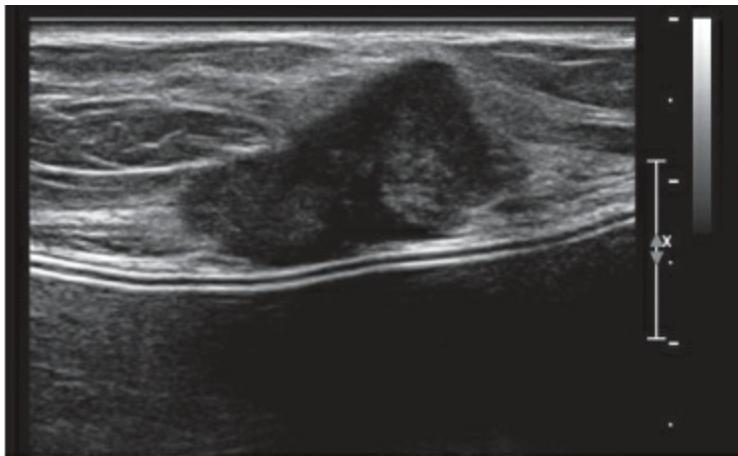
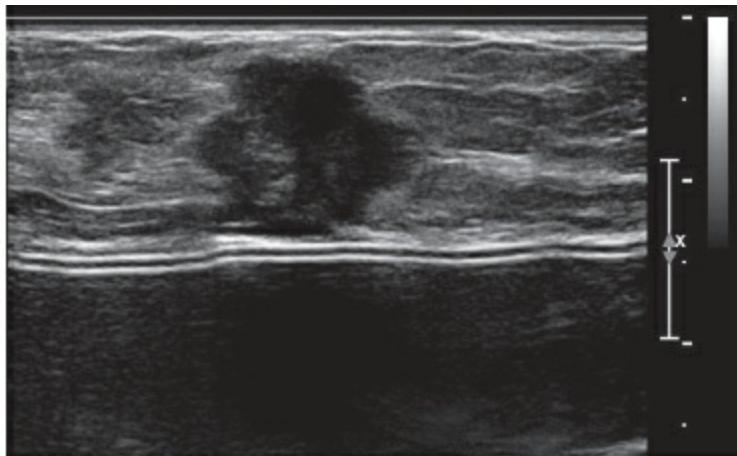
**A****B**

Figure 46 — ORIENTATION: PARALLEL. Longest axis of mass is parallel to the skin (*a*). Apparently nonparallel orientation is shown in the short axis view (*b*) of this mass in a 46-year-old woman with saline implants. When characterizing orientation, it should be from the view that depicts the longest axis of the lesion. The mass has an irregular shape, has a margin that is not circumscribed, and is located just anterior to the fibrous capsule of the implant. Echogenic flecks clumped within the mass are calcifications. Histopathology: invasive ductal carcinoma, grade 2.

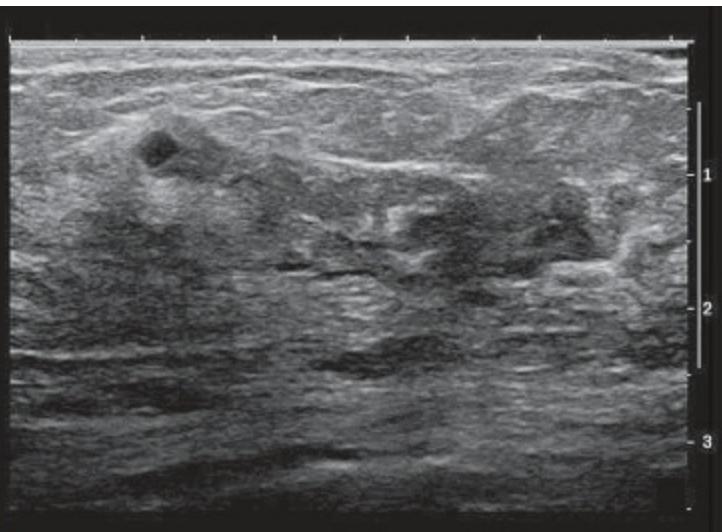
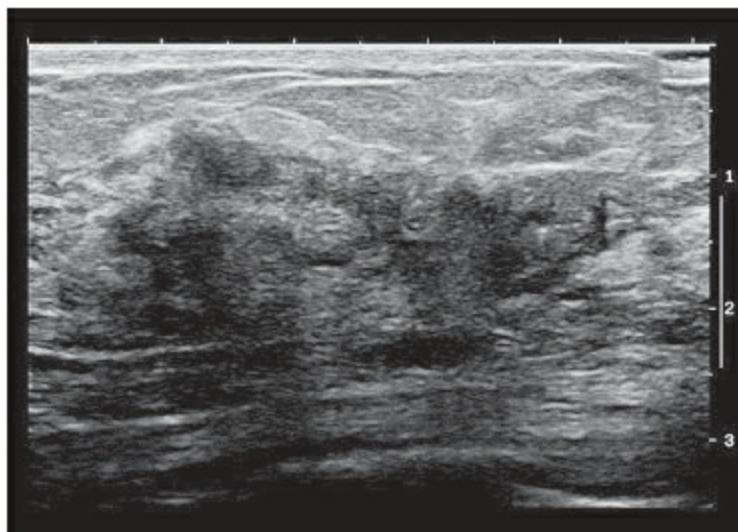
**A****B**

Figure 47 — ORIENTATION: PARALLEL. 52-year-old woman with a PARALLEL mass that has an irregular shape and not circumscribed (indistinct) margin on perpendicular views (a) and (b). The tumor extends through the fibroglandular zone of breast tissue. Portions of the mass show posterior shadowing; in other areas, there is no change in posterior features. Histopathology: invasive carcinoma (ductal and lobular features).

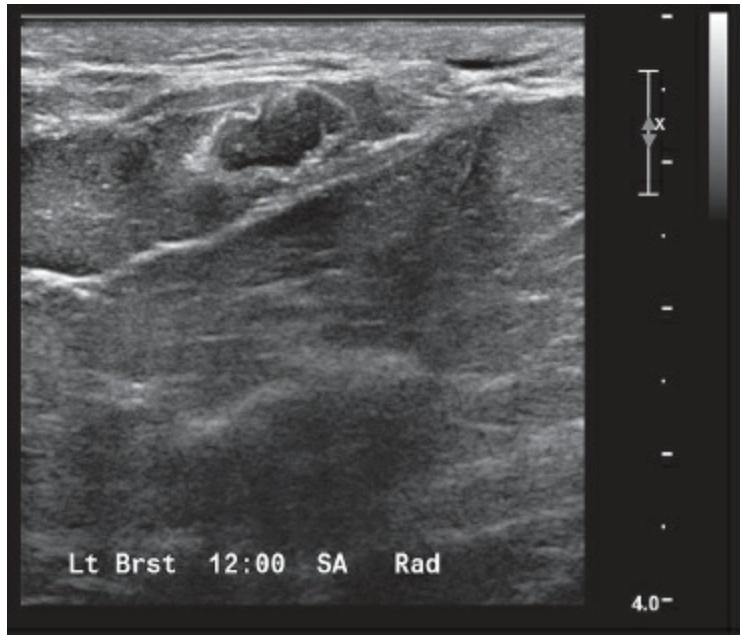
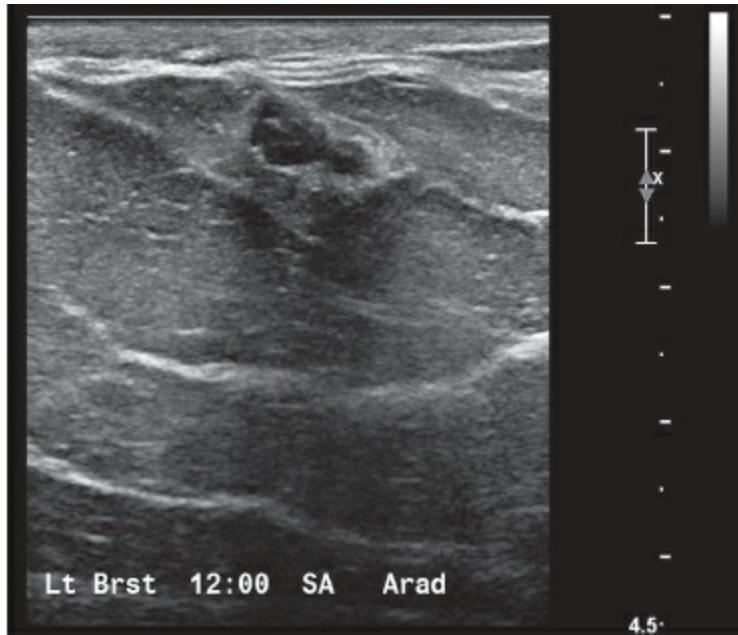
**A****B**

Figure 48 — ORIENTATION: PARALLEL. Two views (a and b) show obliquity in orientation, but the long axis is more PARALLEL than not. Obliquity may be due to proximity to the nipple and apex of the breast cone. Mass, surrounded by an echogenic rim, contains calcifications. Margin is not circumscribed (microlobulated), and assessment in this case is suspicious (category 4). Surrounding tissue is fatty, and there is posterior shadowing. Histopathology: nodular sclerosing adenosis.

B. MASSES

2. ORIENTATION

b. Not Parallel

The long axis of the mass is not parallel to the skin line. The anterior-posterior or vertical dimension is greater than the transverse or horizontal dimension. These masses can also be obliquely oriented to the skin line. Round masses are not parallel in their orientation.

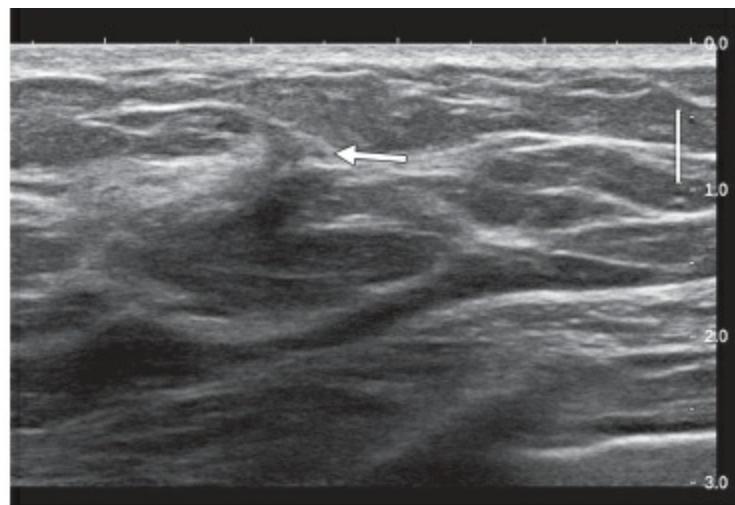
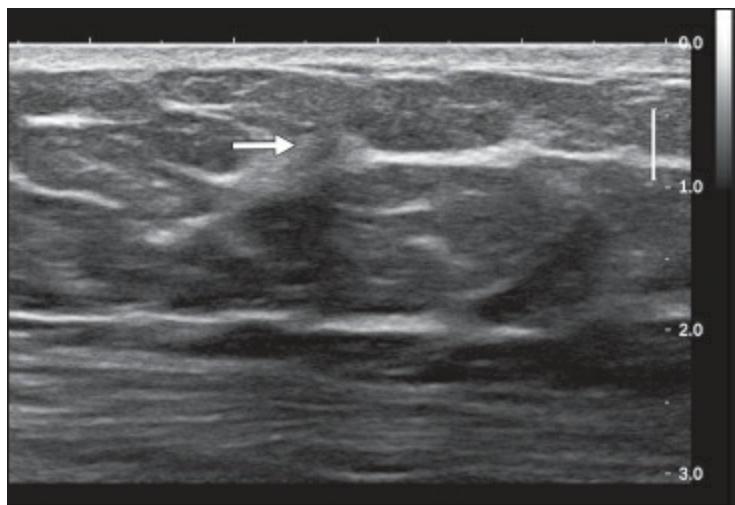
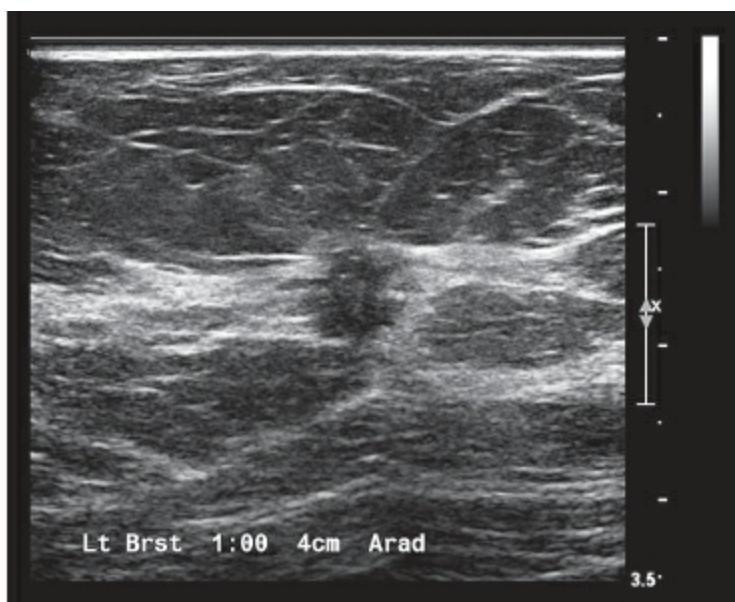
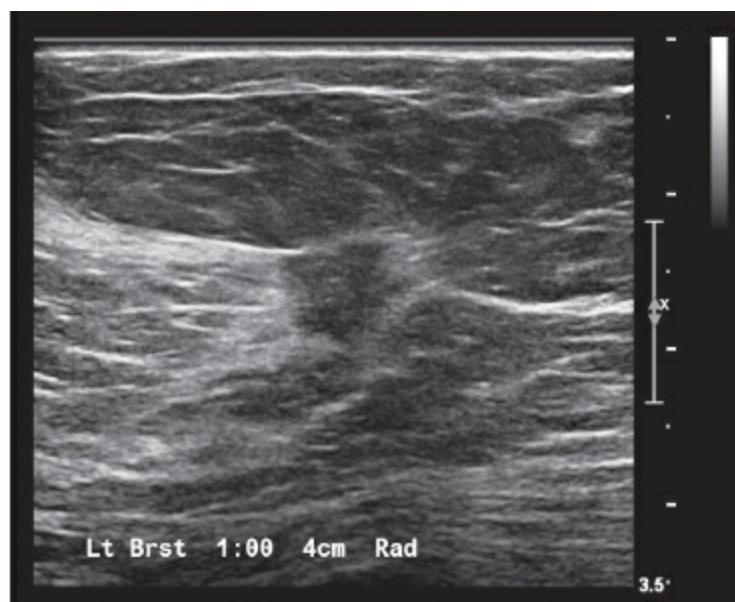


Figure 49 — ORIENTATION: NOT PARALLEL. Invasive ductal carcinoma (arrows) within the fibroglandular zone of a breast of predominantly fatty tissue composition is oriented NOT PARALLEL to the skin.



A



B

Figure 50 — ORIENTATION: NOT PARALLEL. The long axis of this isoechoic mass on the antiradial view (a) is NOT PARALLEL to the skin surface, whereas in (b) the long and short axes are equal: the mass is NOT PARALLEL. Invasive ductal carcinoma, grade 2, occupies nearly the entire thickness of the fibroglandular zone on orthogonal images.

B. MASSES

3. MARGIN

The margin is the edge or border of the lesion. The descriptors of margin, like the descriptors of shape, are important predictors of whether a mass is benign or

malignant.

a. Circumscribed (historically, “well-defined” or “sharply defined”)

A circumscribed margin is one that is well defined, with an abrupt transition between the lesion and the surrounding tissue. For a mass to be described as circumscribed at US, its entire margin must be sharply defined. Most circumscribed lesions have round or oval shapes.

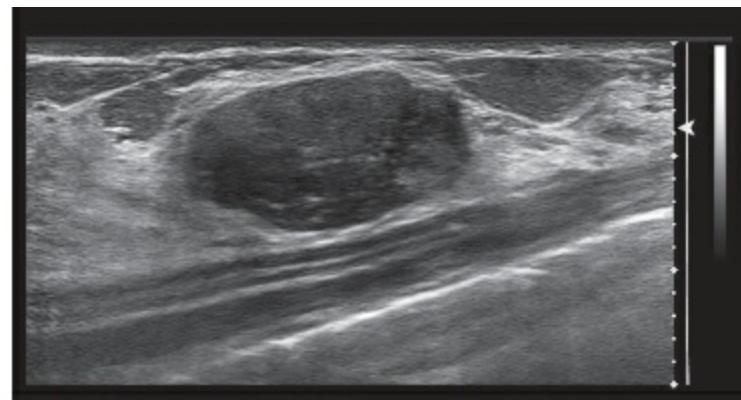
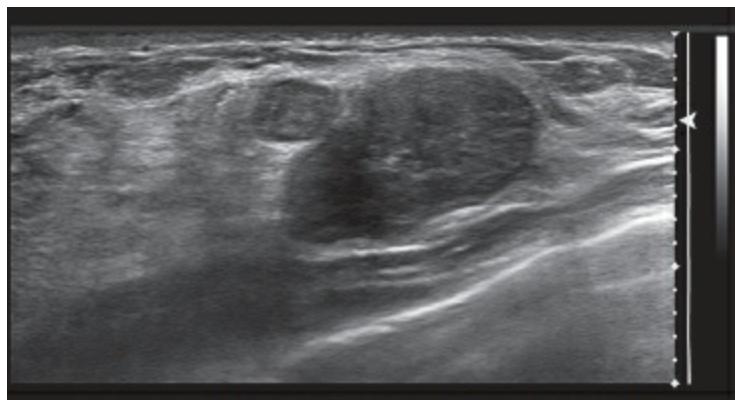


Figure 51 — MARGIN: CIRCUMSCRIBED. Two oval, parallel, CIRCUMSCRIBED masses, one much smaller and superficial, within the fibroglandular layer of tissue in a 32-year-old woman. Tissue composition is homogeneous background echotexture. Histopathology: fibroadenoma.



Figure 52 — MARGIN: CIRCUMSCRIBED. Oval, parallel, benign mass in a 28-year-old woman is a giant fibroadenoma. Giant fibroadenoma is defined as being ≥ 5 cm in its longest dimension. Extended FOV scan depicts the entire extent of the mass, here more than 9 cm on this medial-to-lateral image.

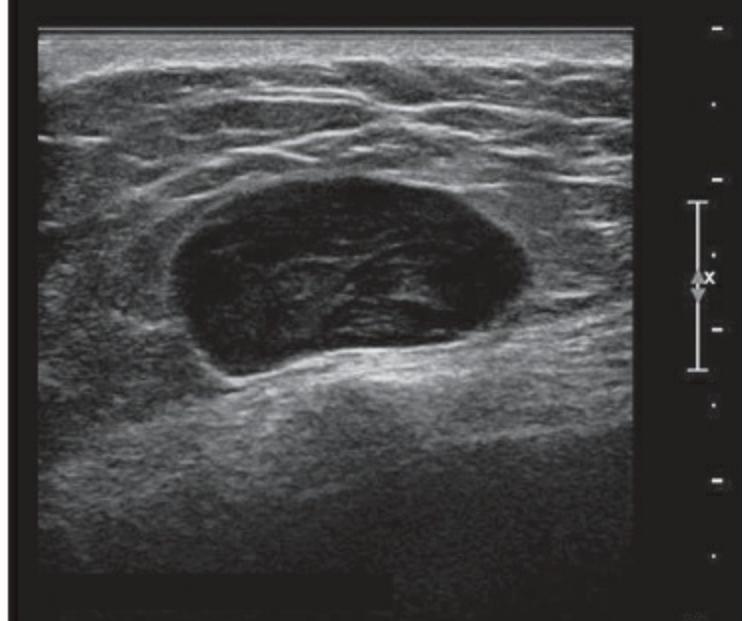
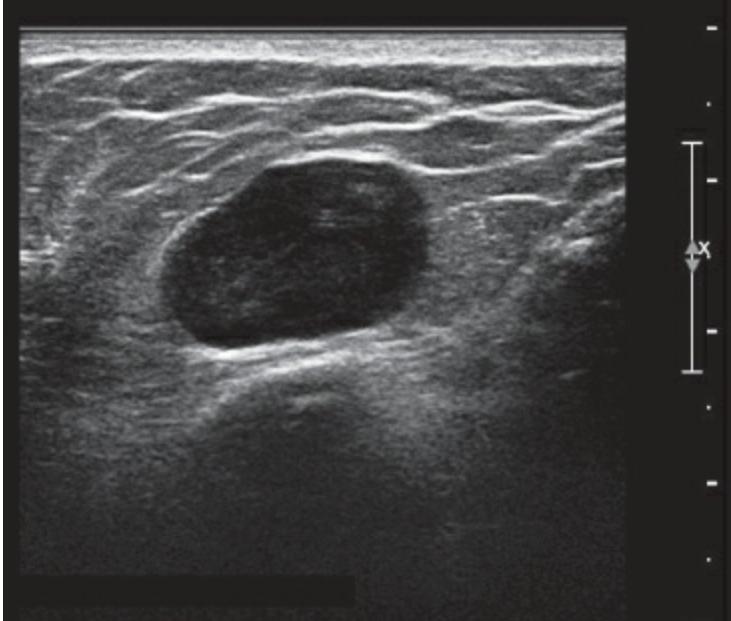


Figure 53 — MARGIN: CIRCUMSCRIBED. Oval, parallel, CIRCUMSCRIBED mass is metastatic leiomyosarcoma. Clinical history is essential in determining management of benign-appearing masses that require biopsy.

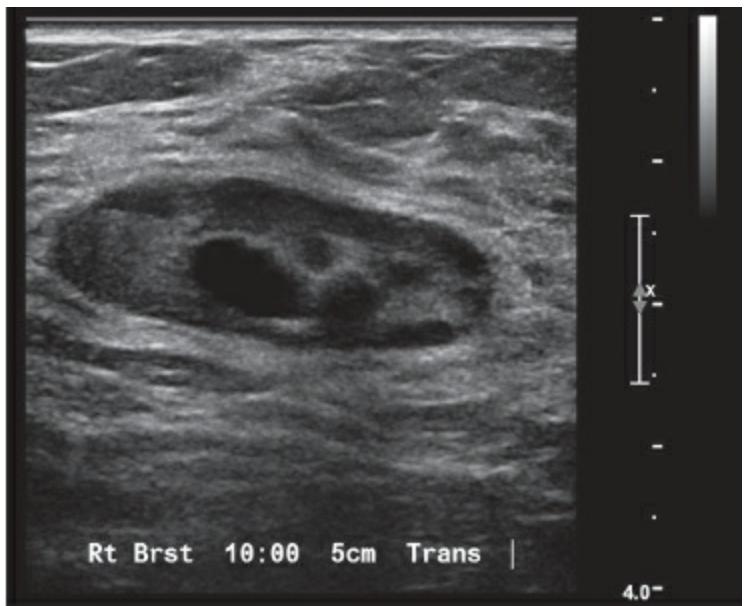
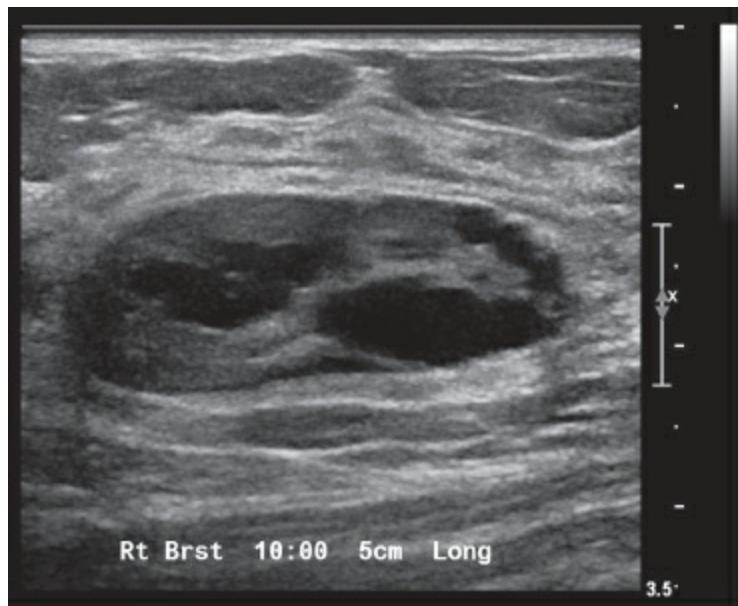


Figure 54 — MARGIN: CIRCUMSCRIBED. A complex cystic and solid mass palpable in a 39-year-old woman with extremely dense fibroglandular tissue. BI-RADS® assessment was suspicious — low suspicion (category 4A), likelihood of malignancy 2%–10%. Histopathology: pseudoangiomatous stromal hyperplasia (PASH), portions of cyst wall lined by benign epithelial hyperplasia and apocrine metaplasia. A complex fibroadenoma that contains cysts may also have this appearance.

B. MASSES

3. MARGIN

b. Not Circumscribed

If *any* portion of the margin is not circumscribed, the mass should be characterized as not circumscribed. A mass that is not circumscribed may further be described as

having ***indistinct, angular, microlobulated, or spiculated margins***, or any combination of these. “Irregular” is not used to group these marginal attributes because irregular describes the shape of a mass.

i. Indistinct

There is no clear demarcation of the entire margin or any portion of the margin from the surrounding tissue. The boundary is poorly defined, and the significant feature is that the mass is not circumscribed. The descriptor “indistinct” includes echogenic rim (historically, “echogenic halo”) because one may not be able to distinguish between an indistinct margin and one that displays an echogenic rim.

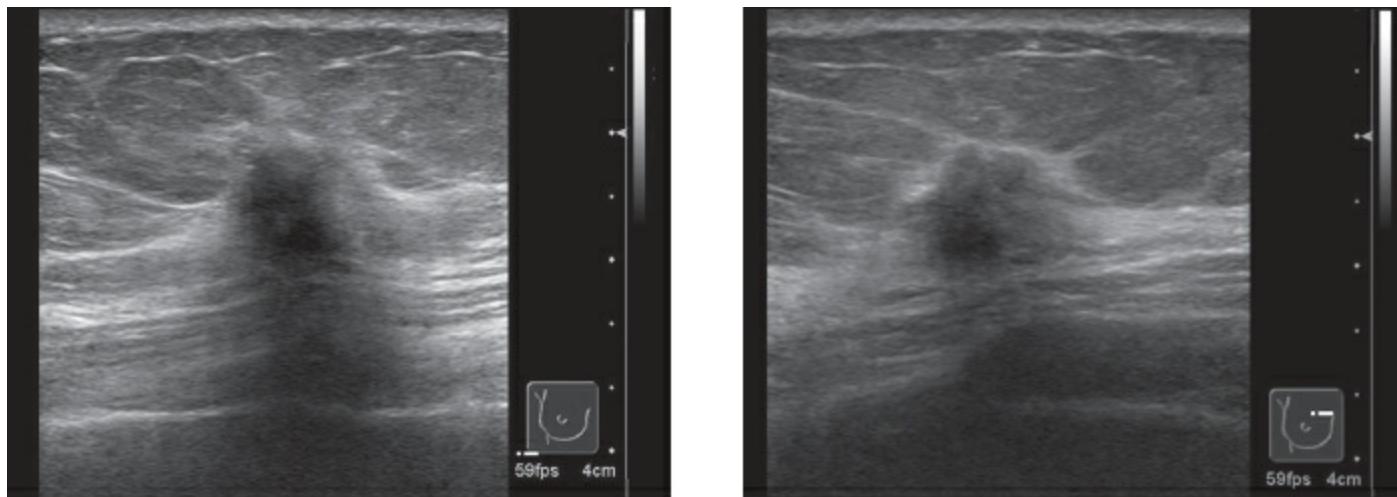


Figure 55 — MARGIN: NOT CIRCUMSCRIBED, INDISTINCT. The interface between the mass and the surrounding tissue is not circumscribed, with a predominantly INDISTINCT margin that also is partially angular and spiculated. Invasive ductal carcinoma, grade 2, that is hypoechoic, irregular in shape and not parallel to the skin.

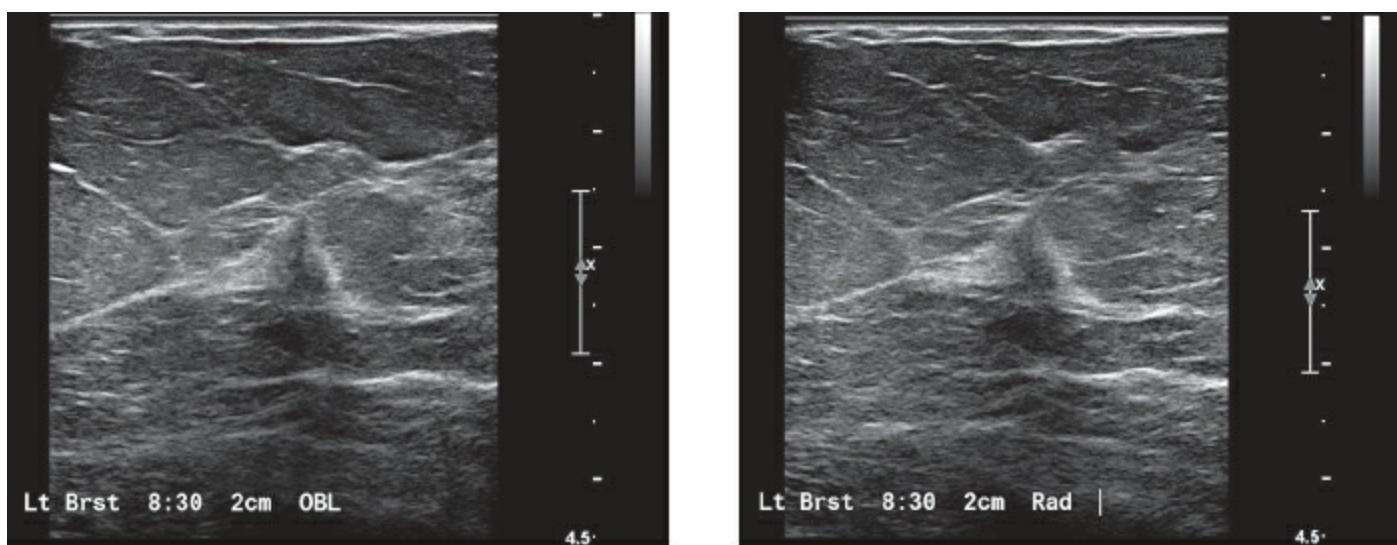


Figure 56 — MARGIN: NOT CIRCUMSCRIBED, INDISTINCT. Orthogonal views of an irregular mass in a 65-year-old woman, not parallel, with INDISTINCT margin. Histopathology: invasive ductal carcinoma and ductal carcinoma in situ, grade 2.

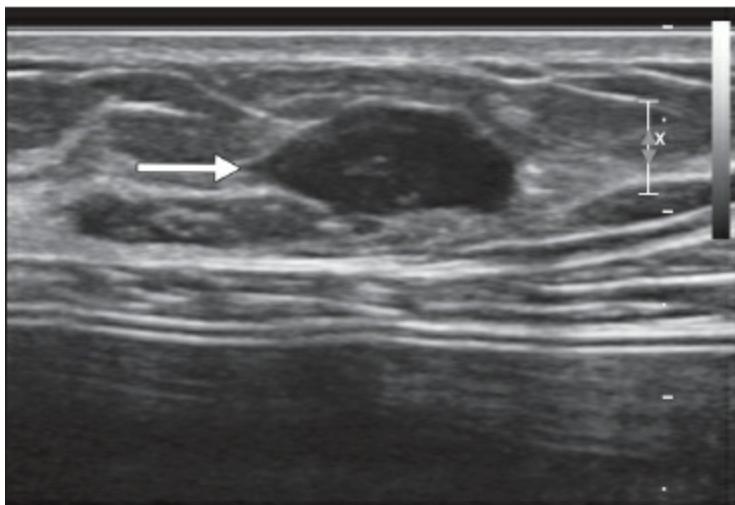
B. MASSES

3. MARGIN

b. Not Circumscribed

ii. Angular

Some or all of the margin has sharp corners, often forming acute angles, but the significant feature is that the margin of the mass is not circumscribed.



A



B

Figure 57 — MARGIN: NOT CIRCUMSCRIBED, ANGULAR. Orthogonal views of a mass in which the margin appears partially but not completely circumscribed. This palpable mass in an augmented 39-year-old patient might be described as oval and parallel, but it should not be given a probably benign assessment for the following reason: in (a), the margin is ANGULAR (arrow), and in (b), the margin is angular and has an echogenic rim (arrow), descriptors included in the NOT CIRCUMSCRIBED characterization. Histopathology: invasive ductal carcinoma, grade 3.

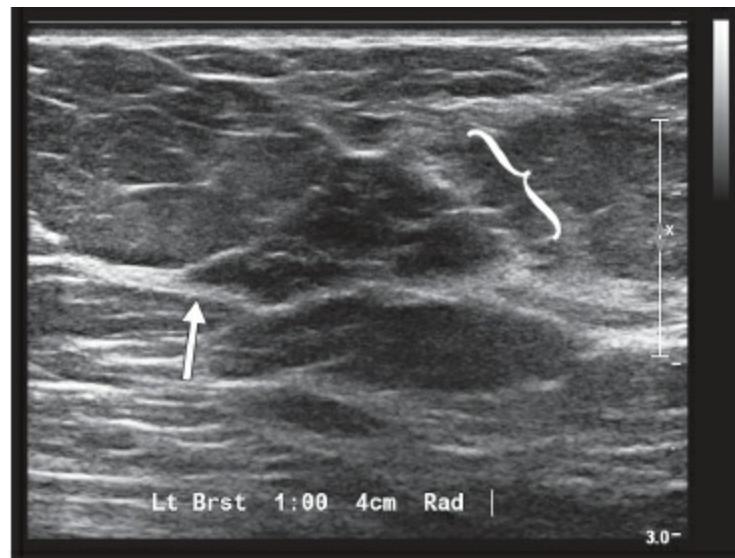


Figure 58 — MARGIN: NOT CIRCUMSCRIBED, ANGULAR. Heterogeneous mass with cystic components in a 64-year-old patient has an ANGULAR (arrow) and microlobulated (brace) margin. Assessment based on these sonograms would be suspicious — high suspicion (category 4C). Histopathology: invasive lobular carcinoma.

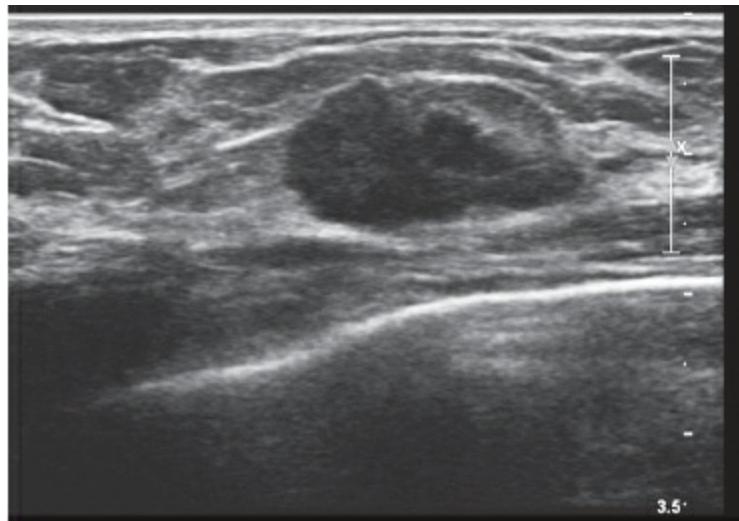
B. MASSES

3. MARGIN

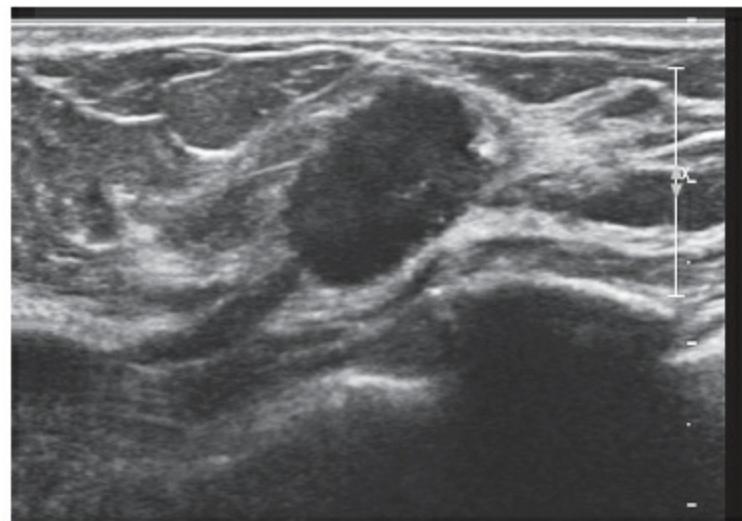
b. Not Circumscribed

iii. Microlobulated

The margin is characterized by short-cycle undulations, but the significant feature is that the margin of the mass is not circumscribed.

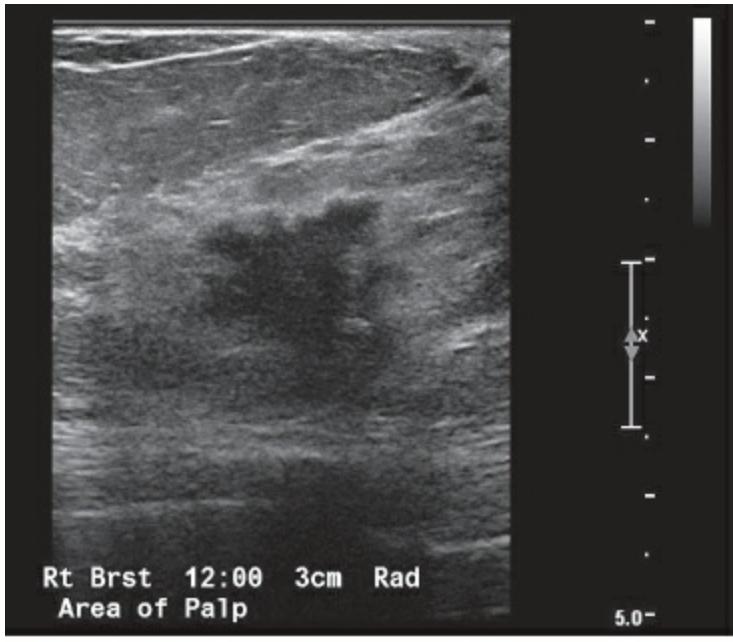


A

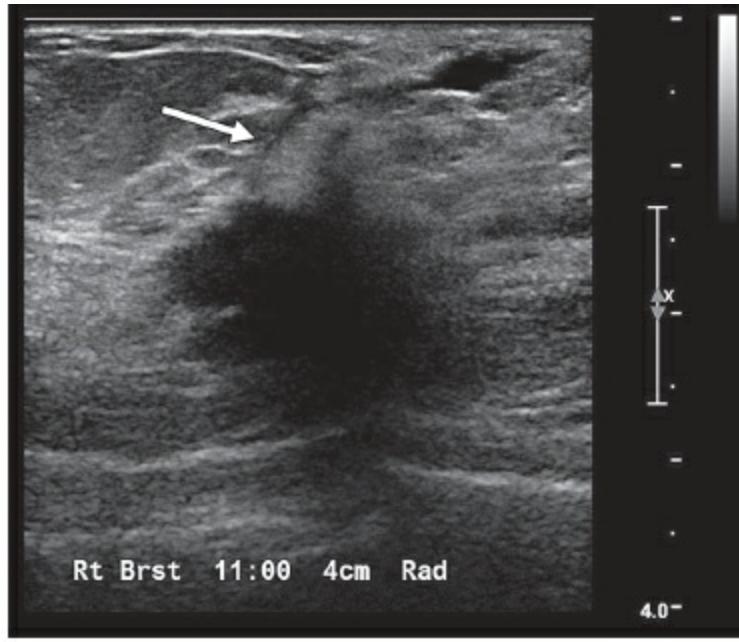


B

Figure 59 — MARGIN: NOT CIRCUMSCRIBED, MICROLOBULATED. A 56-year-old woman with a mass that is NOT CIRCUMSCRIBED, and a margin that is MICROLOBULATED. Invasive ductal carcinoma, grade 3.



A



B

Figure 60 — MARGIN: NOT CIRCUMSCRIBED, MICROLOBULATED. The margin of the mass is NOT CIRCUMSCRIBED, MICROLOBULATED anteriorly (a), ANGULAR (b), along with duct extension anteriorly (arrow). The carcinoma is located in this 61-year-old woman's fibroglandular zone. Invasive ductal carcinoma with micropapillary features, grade 3.

B. MASSES

3. MARGIN

b. Not Circumscribed

iv. Spiculated

The margin is characterized by sharp lines radiating from the mass, often a sign of malignancy, but the significant feature is that the margin of the mass is not circumscribed.

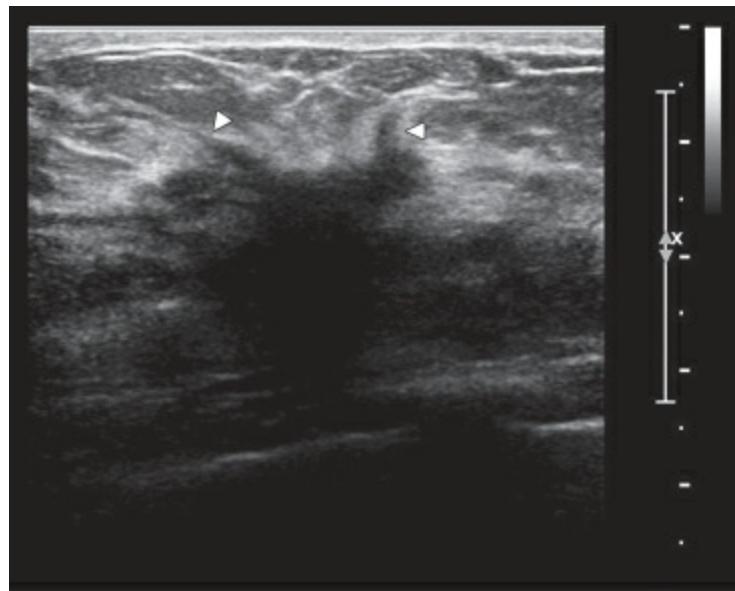
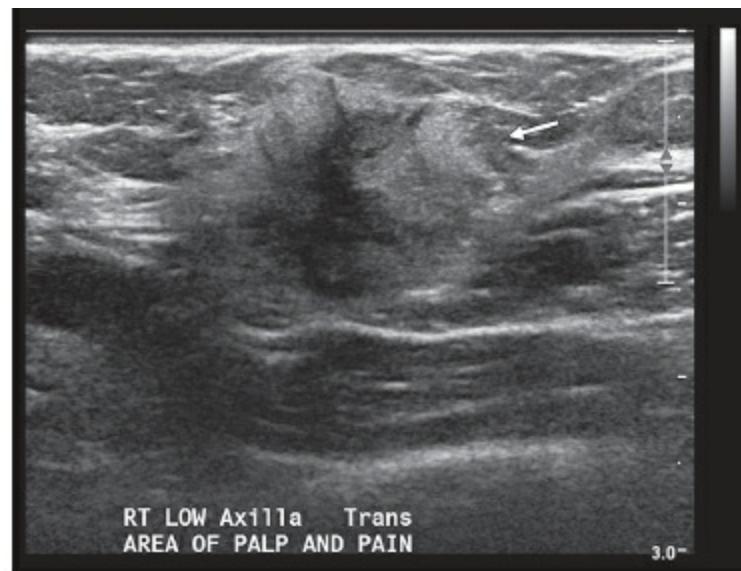


Figure 61 — MARGIN: NOT CIRCUMSCRIBED, SPICULATED. In a 37-year-old woman with a palpable thickening in her left breast, a SPICULATED (arrowheads) and indistinct mass is seen, parallel to the skin, with posterior shadowing and surrounding echogenic rim. Histopathology: invasive lobular carcinoma, grade 2.



A



B

Figure 62 — MARGIN: NOT CIRCUMSCRIBED, SPICULATED. A 31-year-old woman presented with a palpable, tender mass in her right axilla. Mass is irregular in shape with nonparallel orientation. Note the SPICULATED margin anteriorly (b). A single calcification is seen within the mass (a, thick arrow), and surrounding the central hypoechoic components is an echogenic rim (a and b, thin arrows). Histopathology: infiltrating ductal carcinoma, grade 3.

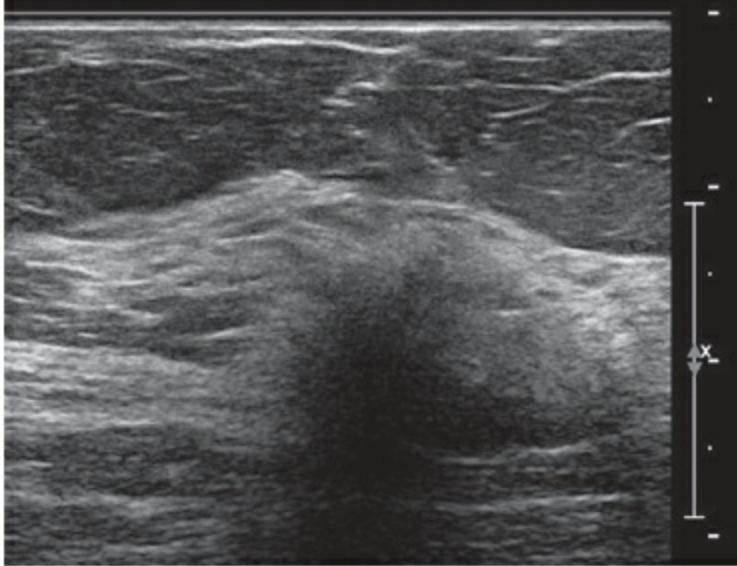
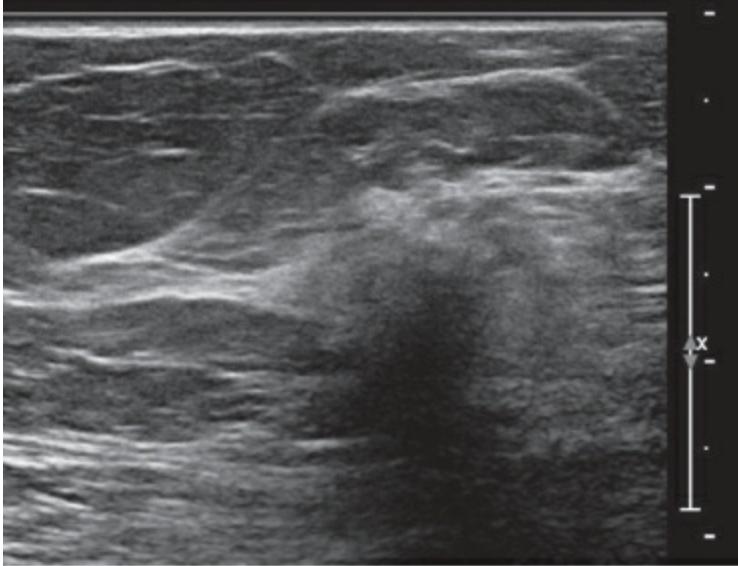


Figure 63 — MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Hypoechoic mass with posterior shadowing has short spicules extending from it anteriorly. Histopathology: invasive lobular carcinoma, grade 2.

B. MASSES

4. ECHO PATTERN

The echogenicity of most benign and malignant masses is hypoechoic compared with mammary fat. While many completely echogenic masses are benign, prospective assessment as benign is more reliable if it is based on margin descriptors. Although the echo pattern contributes with other feature categories to the assessment of a breast lesion, echogenicity alone has little specificity.

a. Anechoic

Without internal echoes.

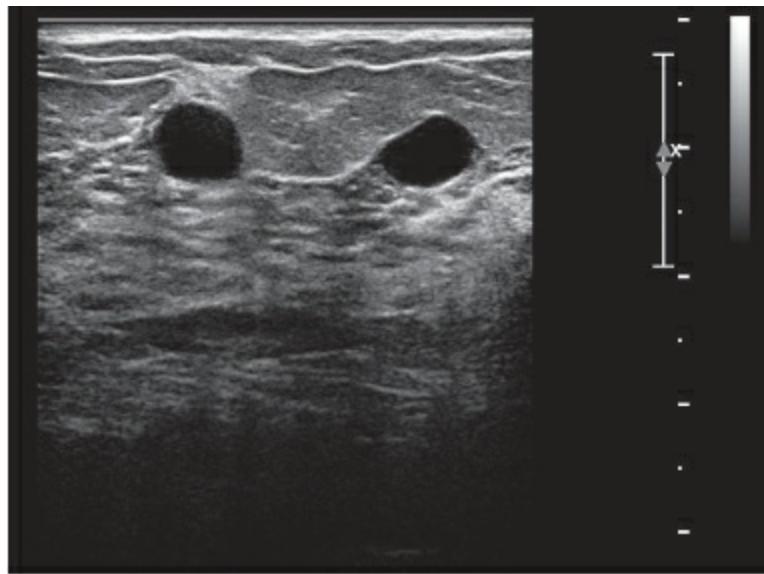


Figure 64 — ECHO PATTERN: ANECHOIC. Two small simple cysts, circumscribed and ANECHOIC, with some posterior enhancement. Assessment is benign (category 2).

B. MASSES

4. ECHO PATTERN

b. Hyperechoic

Hyperechogenicity is defined as having increased echogenicity relative to fat or equal to fibroglandular tissue.

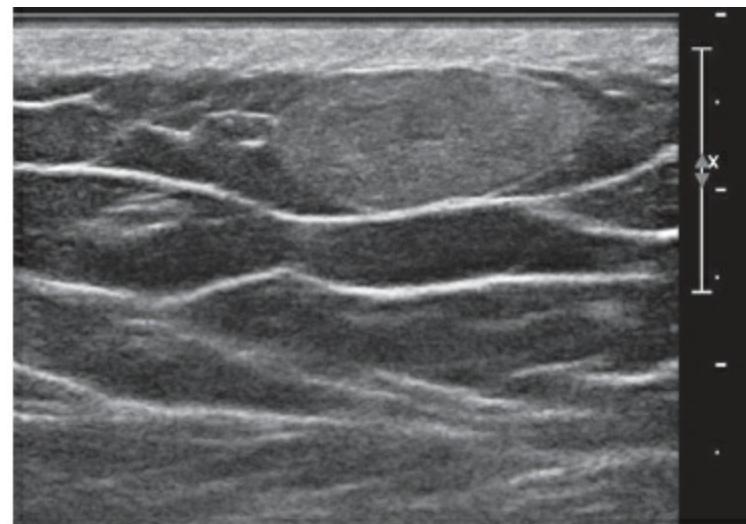
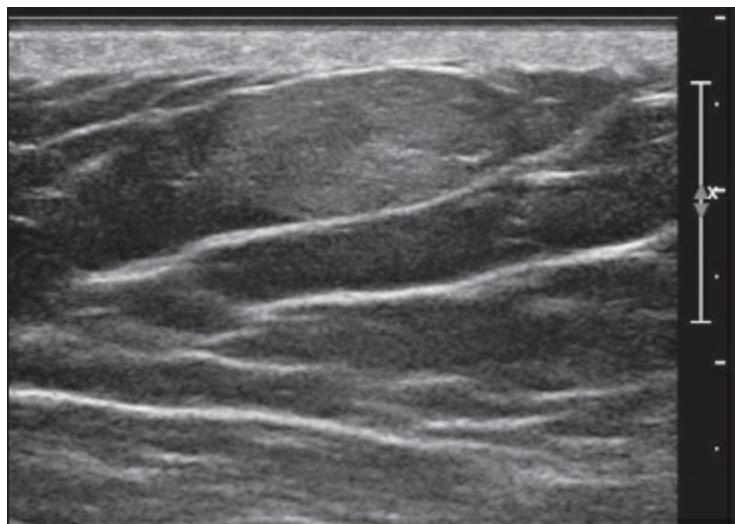
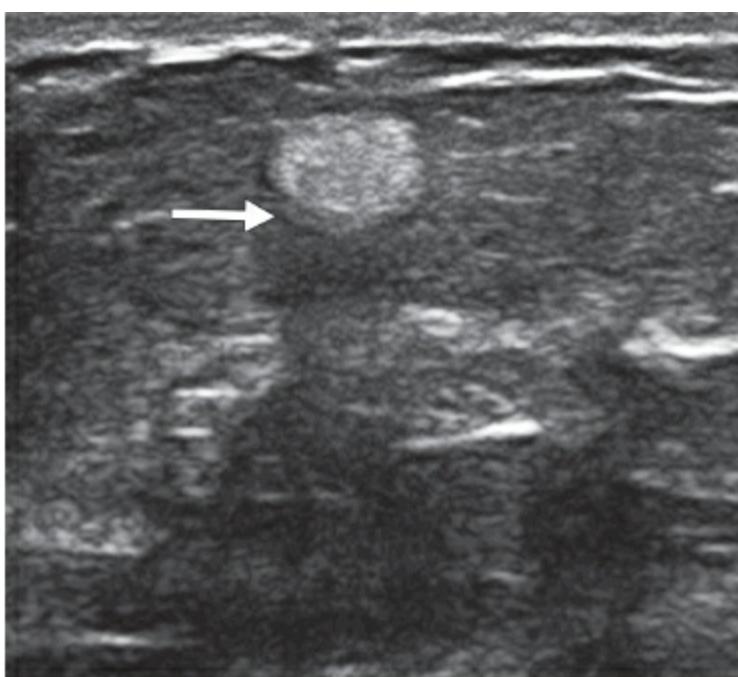
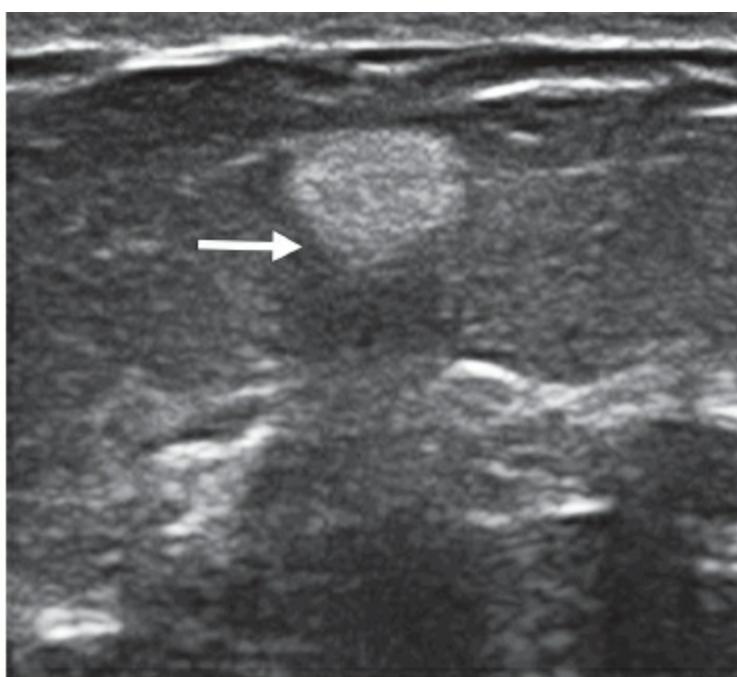


Figure 65 — ECHO PATTERN: HYPERECHOIC. Circumscribed, oval, parallel, HYPERECHOIC mass is a lipoma within a fat lobule. Lipomas are hyperechoic compared with fat lobules. A fibroadenoma superficially located might have a similar appearance, but mammography could help to differentiate between a lipoma, containing fat, and a fibroadenoma of water density.



A



B

Figure 66 — ECHO PATTERN: HYPERECHOIC. Small, oval, parallel, HYPERECHOIC mass located in subcutaneous fat layer with posterior shadowing. Marginal indistinctness was questioned on both views (arrows, *a* and *b*). Overall assessment was suspicious — low suspicion (category 4A), likelihood of malignancy, 2%–10%. Histopathology: hemangioma.

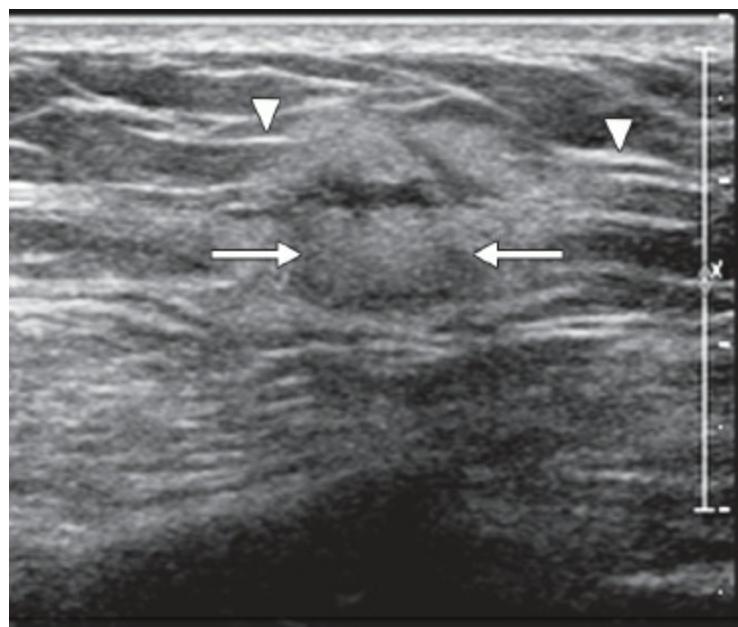
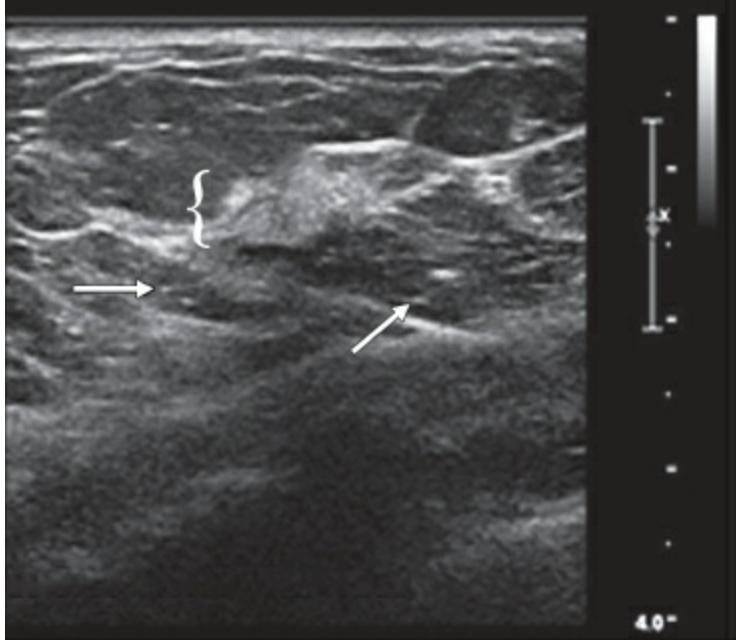
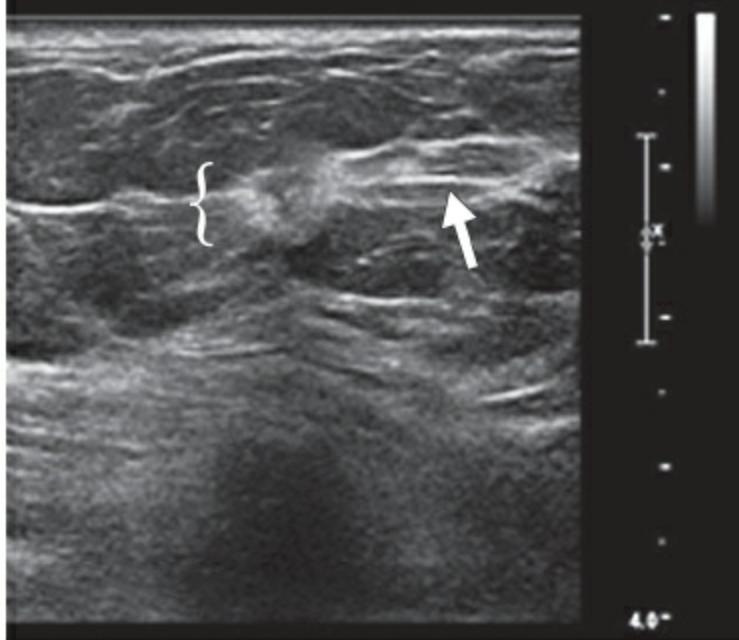


Figure 67 — ECHO PATTERN: HYPERECHOIC. Irregular mass with indistinct margins (arrows) and architectural distortion (arrowheads), with both HYPERECHOIC and anechoic features. Histopathology: invasive ductal carcinoma.



A



B

Figure 68 — ECHO PATTERN: HYPERCHOIC. Carcinoma similar in its characteristics to the preceding case but much smaller — ill-defined echogenic area surrounded by fat, containing small curvilinear hypoechoic areas (*brace*) — was detected on screening mammography in a 75-year-old woman. Calcifications (*thin arrows*) are present in and around the mass (*a*). The mass, small as it is, causes architectural distortion with straightening of the Cooper ligaments at the right lateral aspect of the mass (*b, thick arrow*). Histopathology: invasive and intraductal carcinoma, grade 2.

B. MASSES

4. ECHO PATTERN

c. Complex Cystic and Solid

A complex mass contains both anechoic (cystic or fluid) and echogenic (solid) components.



Figure 69 — ECHO PATTERN: COMPLEX CYSTIC AND SOLID. Partially cystic mass with solid component, assessed as suspicious — moderate suspicion (category 4B), likelihood of malignancy 10%–50%, unless known etiology of prior intervention, such as aspiration of a simple cyst with clot formation after the procedure. Histopathology: intracystic papillary carcinoma.



Figure 70 — ECHO PATTERN: COMPLEX CYSTIC AND SOLID. 32-year-old woman with right nipple discharge. This COMPLEX CYSTIC AND SOLID MASS posterior to the nipple, with its small central oval echogenic component and anechoic rim, resembles a lymph node. However, the linear extension at the right lateral border of the mass (arrow) is a duct, and the mass is assessed as suspicious (category 4). Histopathology: intraductal papilloma.

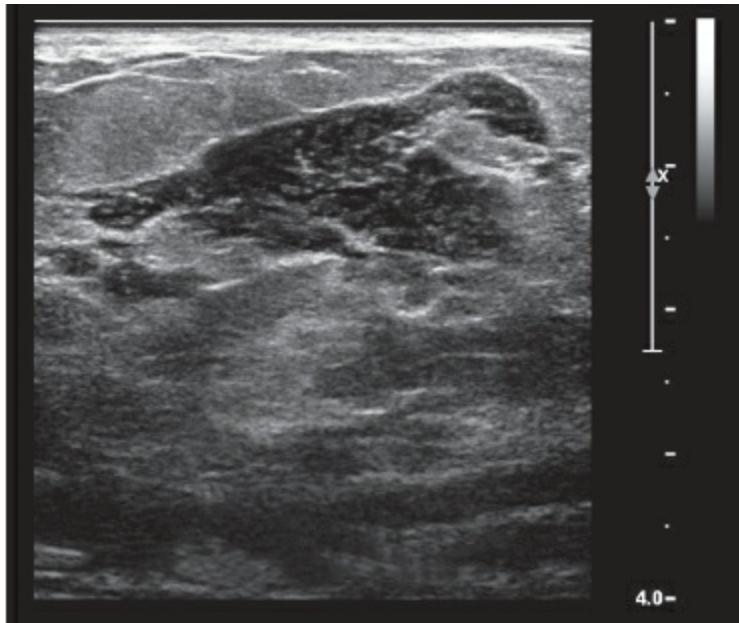
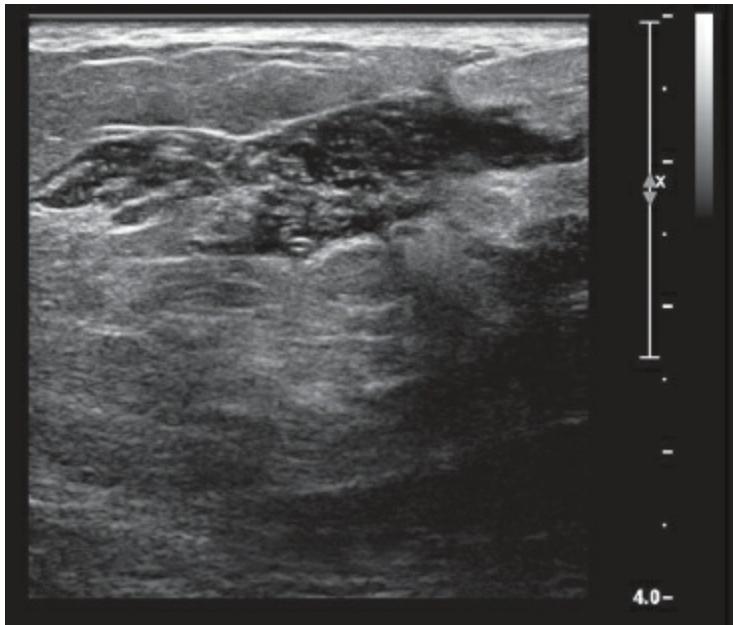


Figure 71 — ECHO PATTERN: COMPLEX CYSTIC AND SOLID. Irregular shape parallel to the skin, with cystic areas and septa, in a 19-year-old woman. Core biopsy histopathology: chronic granulomatous abscess.

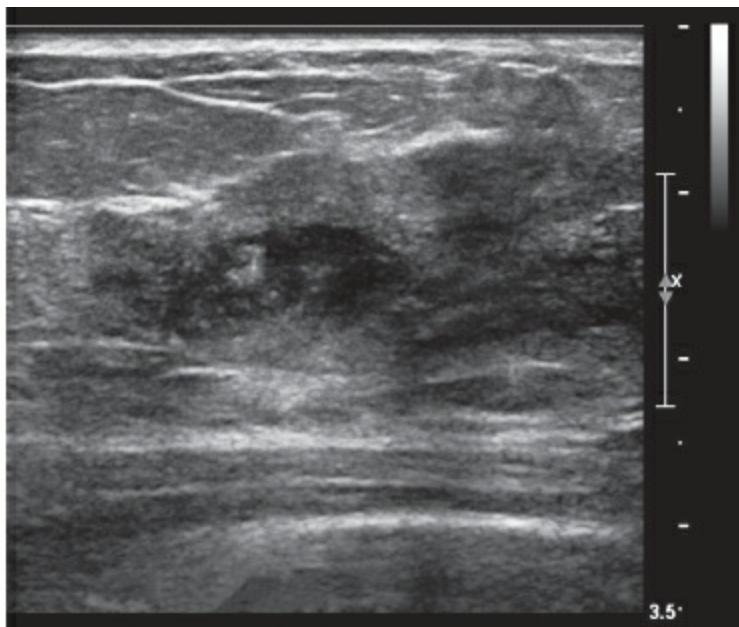
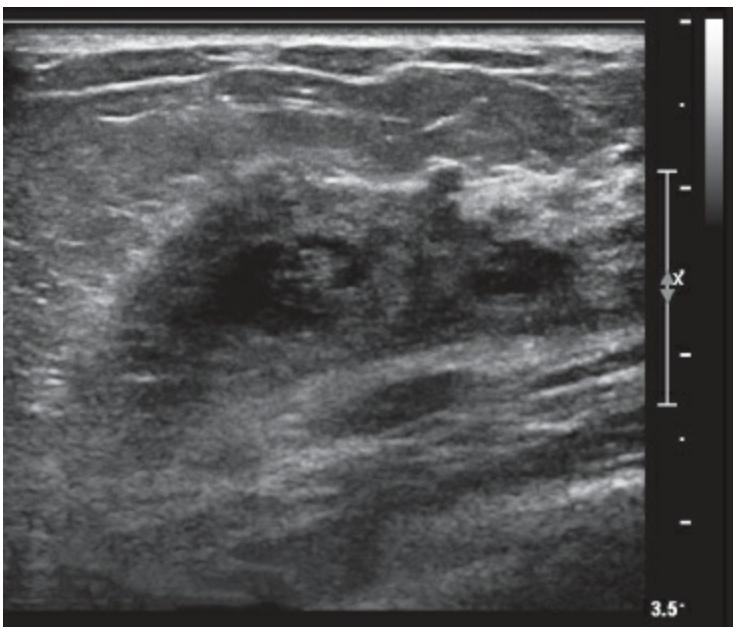


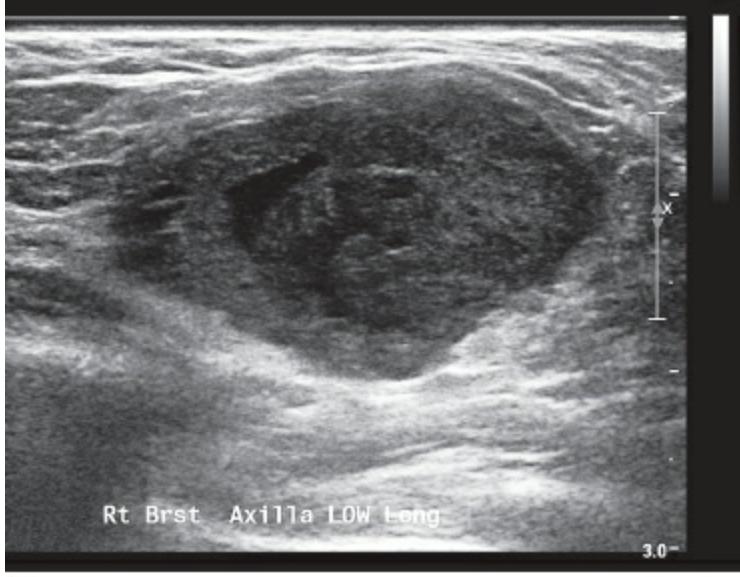
Figure 72 — ECHO PATTERN: COMPLEX CYSTIC AND SOLID. A 55-year-old woman with rheumatoid arthritis and a palpable mass at 1:00 in her left breast. Aspiration yielded a small amount of purulent material; core biopsy showed chronic inflammation.

B. MASSES

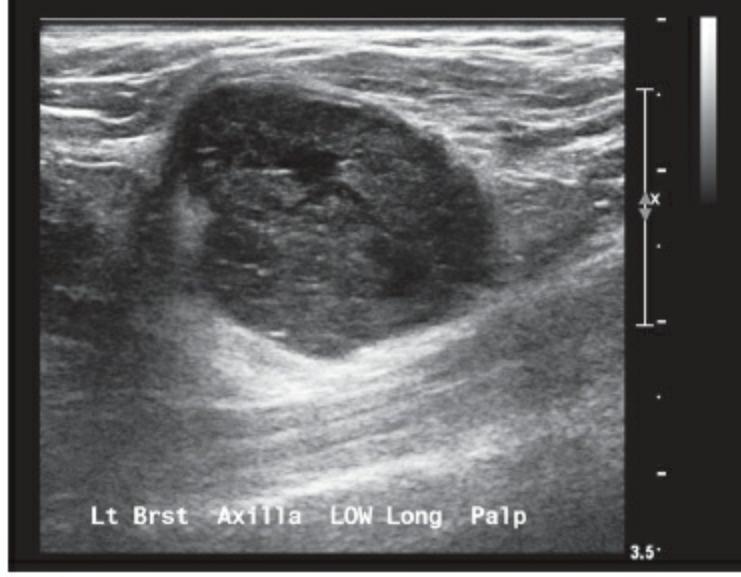
4. ECHO PATTERN

d. Hypoechoic

The term “hypoechoic” is defined relative to subcutaneous fat; hypoechoic masses, less echogenic than fat, are characterized by low-level echoes throughout (e.g., complicated cysts and fibroadenomas).

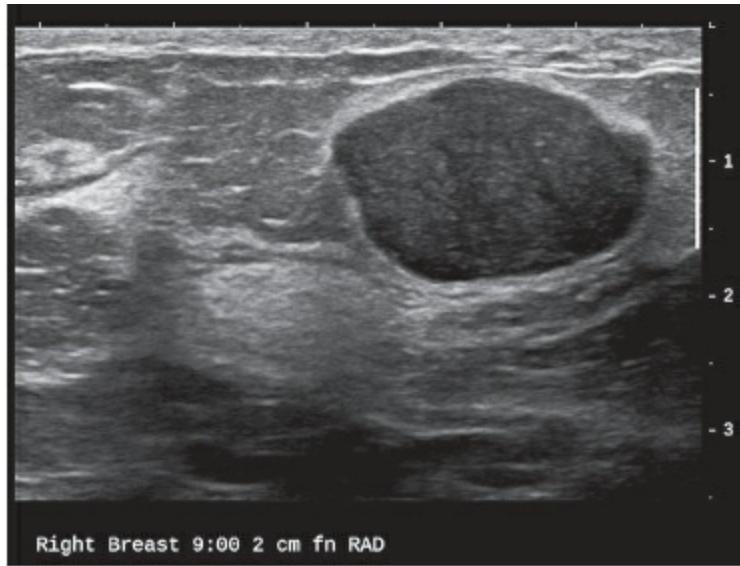


A



B

Figure 73 — ECHO PATTERN: HYPOECHOIC 32-year-old patient, 37 weeks pregnant, with palpable mass in the axillary tail of the left breast. Orthogonal views demonstrate an oval mass (*a* and *b*), which is HYPOECHOIC compared with the more anterior subcutaneous fat, as well as being parallel to the skin surface. The mass also is circumscribed, usually a benign feature, but it was assessed as suspicious (category 4) because it was *newly* palpable, hence a growing solid mass. Histopathology: invasive ductal carcinoma, grade 3.



A



B

Figure 74 — ECHO PATTERN: HYPOECHOIC. Radial (*a*) and antiradial (*b*) views of an oval, circumscribed, parallel mass. When evaluating echogenicity, comparison is with subcutaneous fat. Histopathology of US-guided biopsy was fibroepithelial lesion, and fibroadenoma at excision.

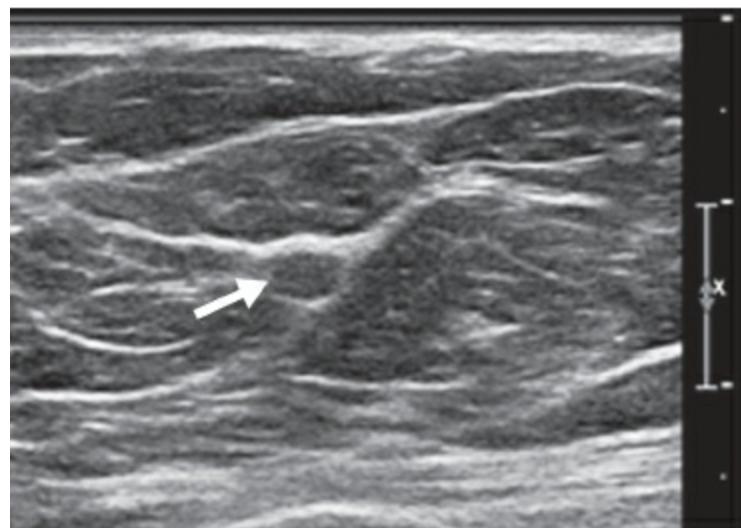
B. MASSES

4. ECHO PATTERN

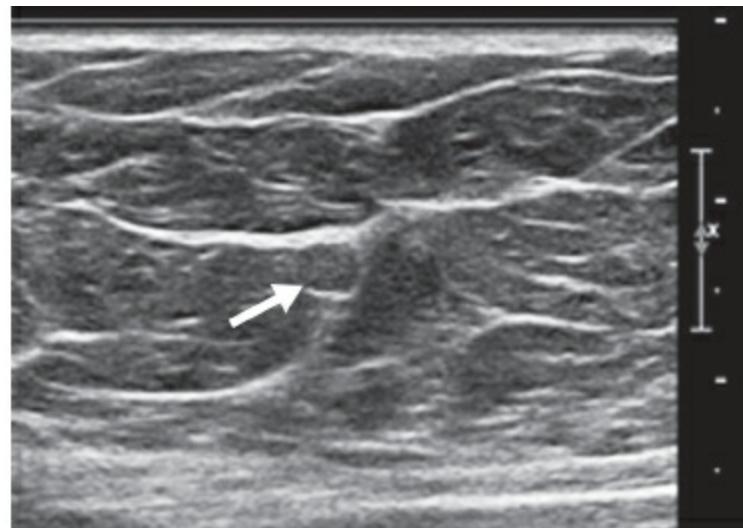
e. Isoechoic

Isoechogenicity is defined as having the same echogenicity as subcutaneous fat.

Isoechoic masses may be relatively inconspicuous, particularly when they are situated within an area of fat lobules. This may limit the sensitivity of US, especially at screening, in which the presence and location of such a mass are not known at the time of examination.



A



B

Figure 75 — ECHO PATTERN: ISOECHOIC. Orthogonal views of a small ISOECHOIC mass within fatty breast tissue (*a* and *b*, arrows). The mass had been identified on baseline screening mammography, and the patient was recalled for additional imaging including US. BI-RADS® assessment category 3, probably benign, was assigned. The patient requested biopsy. Histopathology: invasive ductal carcinoma with mucinous features, grade 1.

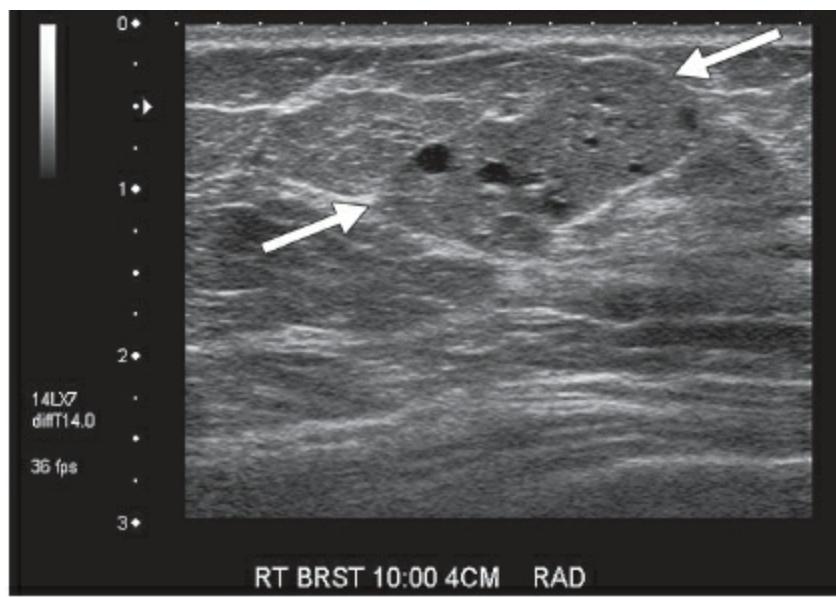


Figure 76 — ECHO PATTERN: ISOECHOIC. In this 44-year-old woman, an ISOECHOIC mass is situated obliquely within fat lobules of similar shape (arrows). The mass contains small cysts. Complex fibroadenomas, those containing a conglomeration of benign histologies, do not require excision. Excision is recommended for fibroepithelial lesions (FELs) and when the possibility of phyllodes tumor is raised in the pathology report. Histopathology: fibroadenoma with fibrocystic changes including sclerosing adenosis, apocrine metaplasia, microcysts, and duct epithelia hyperplasia without atypia (complex fibroadenoma).

B. MASSES

4. ECHO PATTERN

f. Heterogeneous

A mixture of echogenic patterns within a solid mass, heterogeneity has little prognostic value in differentiating benign from malignant masses, and it is not uncommon to observe heterogeneity in fibroadenomas as well as cancers. Clumped areas of different echogenicity may elevate the suspicion for malignancy, particularly in a mass in which the margins are not circumscribed and the shape is irregular.

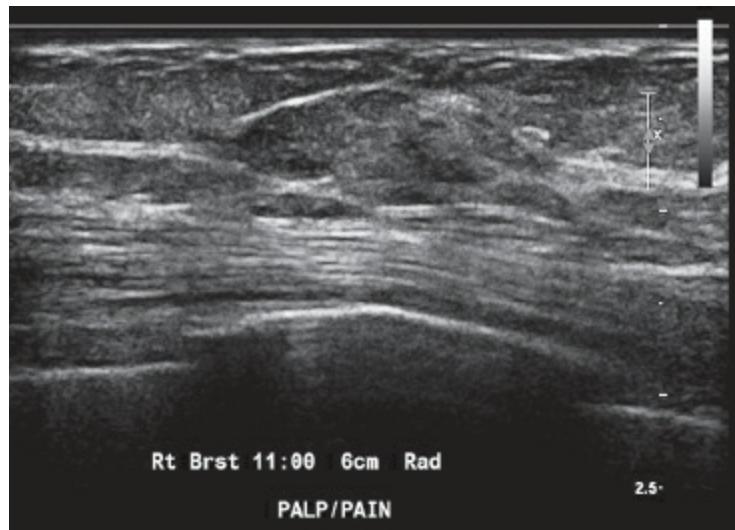


Figure 77 — ECHO PATTERN: HETEROGENEOUS. This palpable, painful new mass in a 75-year-old woman is circumscribed, oval, and parallel to the skin, with HETEROGENEOUS echotexture. Primarily because this solid mass was *new*, in an elderly woman, it was assessed as suspicious (category 4). Histopathology: low-grade mesenchymal tumor with periductal stromal proliferation and myxoid changes.

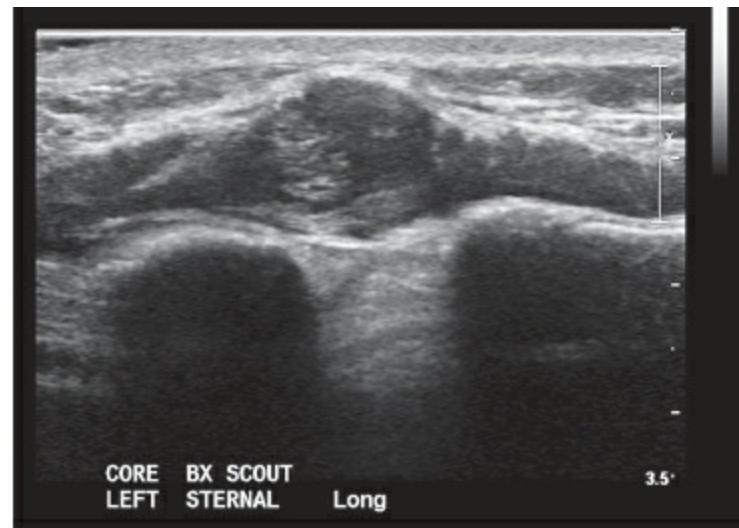


Figure 78 — ECHO PATTERN: HETEROGENEOUS. Palpable presternal mass in a 43-year-old man. It protrudes into the tissue overlying it, but no architectural distortion is present. Histopathology from US-guided core biopsy: granular cell tumor.

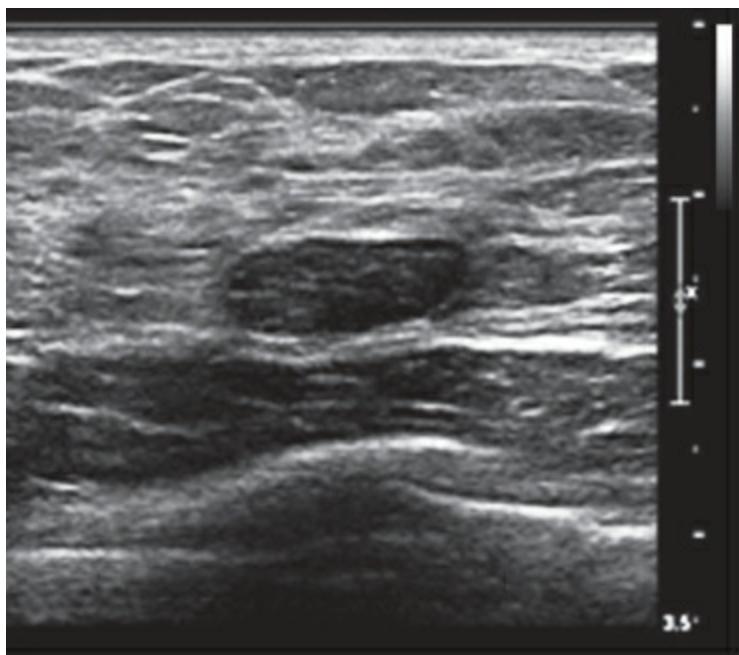
B. MASSES

5. POSTERIOR FEATURES

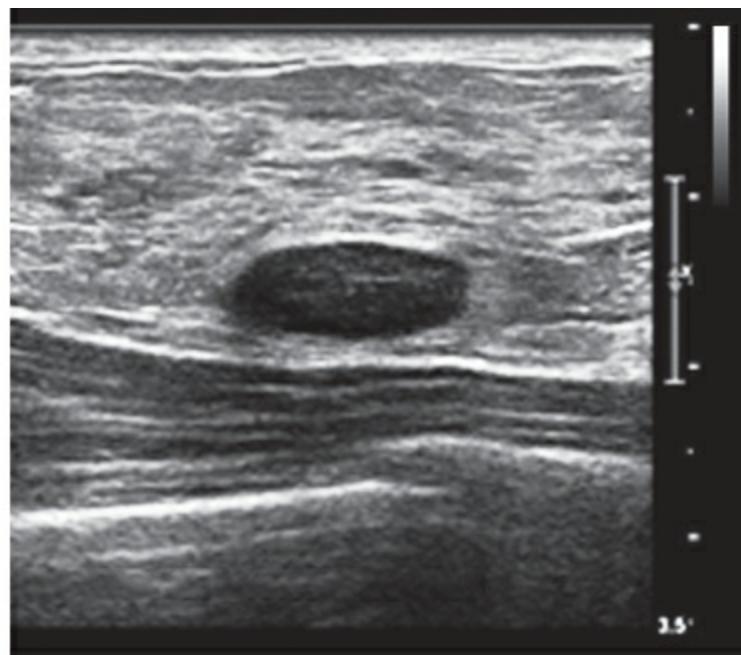
Posterior features represent the attenuation characteristics of a mass with respect to its acoustic transmission. Attenuation (shadowing) and enhancement are additional attributes of masses, mostly of secondary rather than primary predictive value.

a. No Posterior Features

No shadowing or enhancement is present deep to the mass; the echogenicity of the area immediately behind the mass is not different from that of the adjacent tissue at the same depth.



A



B

Figure 79 — POSTERIOR FEATURES: NO POSTERIOR FEATURES. Fibroadenoma located within fibroglandular tissue is adjacent to the pectoral muscle in this 35-year-old woman. Although proximity to the pectoral muscle may make enhancement or shadowing difficult to detect, there is no acoustic change on either antiradial (a) or radial (b) images of this benign mass.

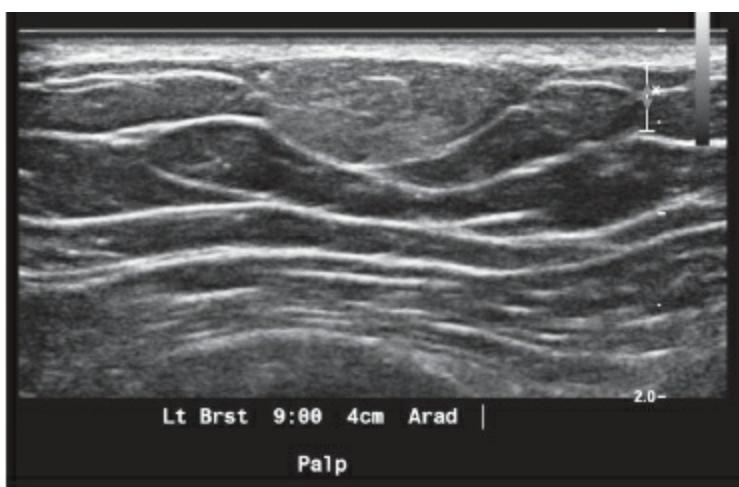
**A****B**

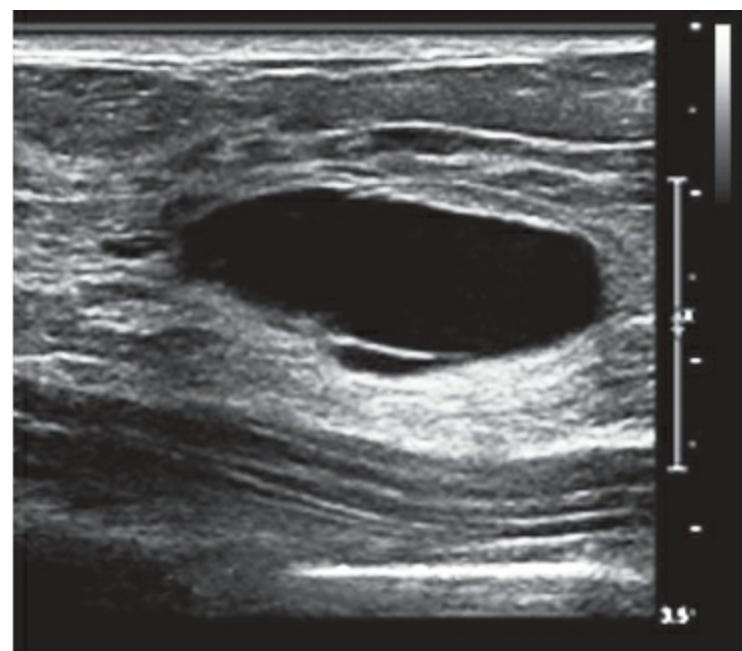
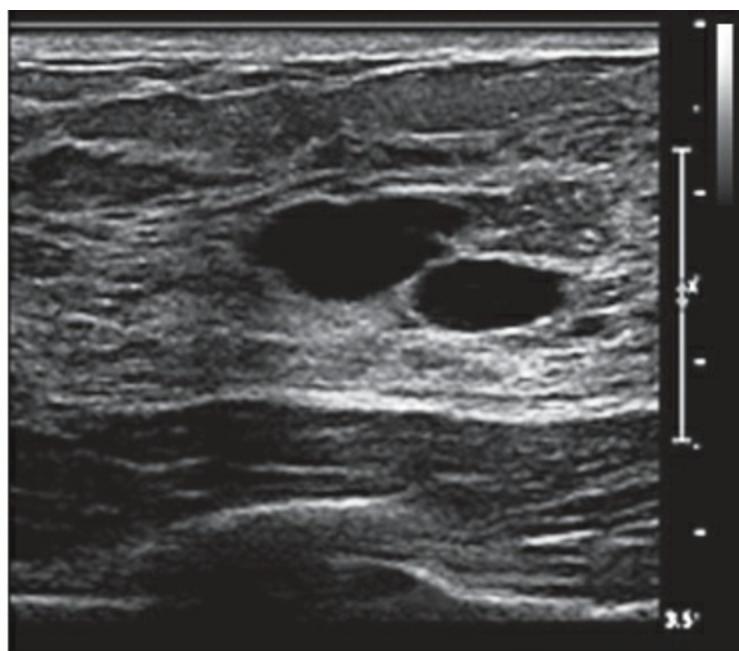
Figure 80 — POSTERIOR FEATURES: NO POSTERIOR FEATURES. Hyperechoic, circumscribed, oval mass (*a, b*) in a 67-year-old man. Increased echogenicity within a circumscribed mass is characteristic of lipomas; in women, mammography can differentiate the fat density of a lipoma from the soft tissue or water density of a fibroadenoma. Fibroadenomas and other lobular lesions are not ordinarily found in men.

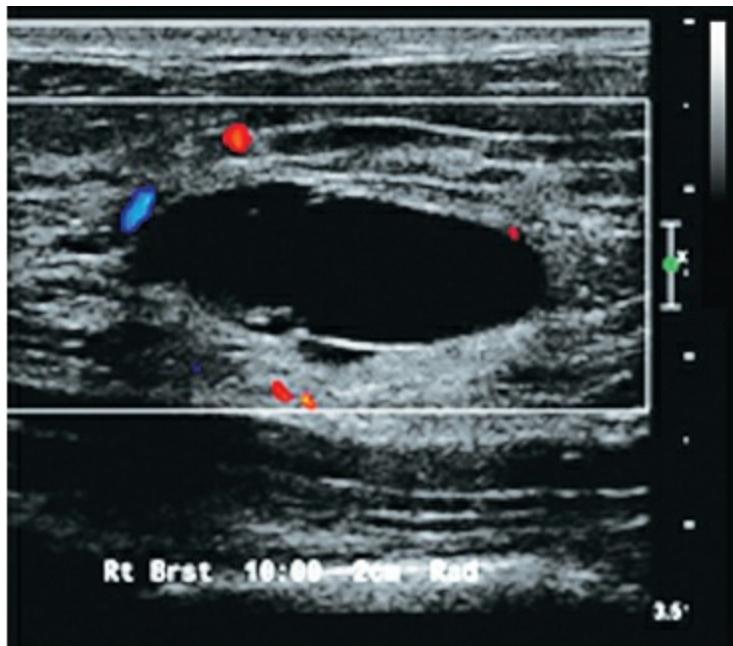
B. MASSES

5. POSTERIOR FEATURES

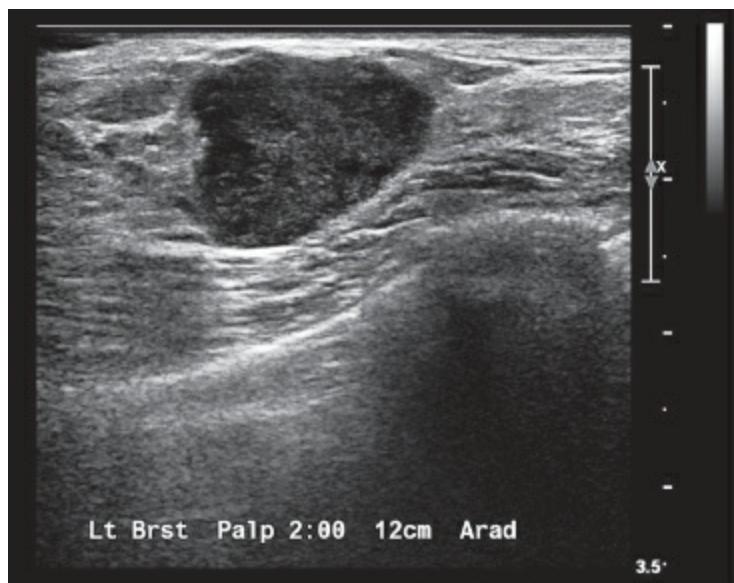
b. Enhancement

Sound transmission is unimpeded in its passage through the mass. Enhancement appears as a column that is more echogenic (whiter) deep to the mass. One criterion for cyst diagnosis is enhancement. Homogeneous solid lesions, including high-grade carcinomas, may also show enhancement.

**A****B**

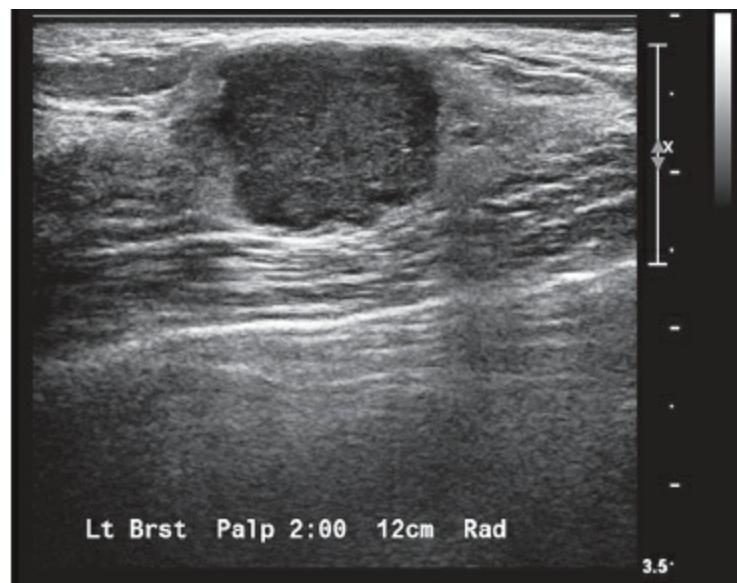


C



A

Figure 81 — POSTERIOR FEATURES: ENHANCEMENT. The criteria for diagnosing simple cysts are: oval or round shape (round less likely), anechogeticity, circumscribed margin, and POSTERIOR ENHANCEMENT. Simple cyst with a septum (a) and a cluster of simple cysts (b). Color Doppler applied to the cyst demonstrates it to be avascular (c). Flow may be seen in the tissue surrounding the cyst. Application of Doppler imaging may be helpful in establishing a mass as being fluid-filled due to lack of internal vascularity. However, for reliability, Doppler parameters must be optimized ([Image Quality section](#), see page 18).



B

Figure 82 — POSTERIOR FEATURES: ENHANCEMENT. Palpable mass, in a 28-year-old woman has an irregular shape (a) and a not circumscribed (indistinct) margin. The mass has strong POSTERIOR ENHANCEMENT. Assessment is suspicious — high suspicion (category 4C). Histopathology: invasive ductal carcinoma, grade 3.



A



B

Figure 83 — POSTERIOR FEATURES: ENHANCEMENT. Radial and antiradial views of an oval, circumscribed, parallel mass, with POSTERIOR ENHANCEMENT. The mass is predominantly hypoechoic with some heterogeneity, but its shape, margin, and orientation are all consistent with the benign etiology of this palpable, biopsy-proven fibroadenoma. Histopathology: fibroadenoma.

B. MASSES

5. POSTERIOR FEATURES

c. Shadowing

Shadowing is attenuation of the acoustic transmission. Sonographically, the area posterior to the mass appears darker. At the edges of curved masses, acoustic velocity changes and thin shadows are seen. This refractive edge shadowing is of no significance and should be distinguished from central shadowing, which is a property of the mass.

Shadowing is associated with fibrosis, with or without an underlying carcinoma. Postsurgical scars, fibrous mastopathy, and many cancers with or without a desmoplastic response will show posterior shadowing. Macrocalcifications can also attenuate sound. Similar to a vertical (taller-than-wide) orientation, shadowing is a feature more helpful when present than when absent. Many cancers will exhibit enhancement or no change in posterior features, particularly those that are high grade.

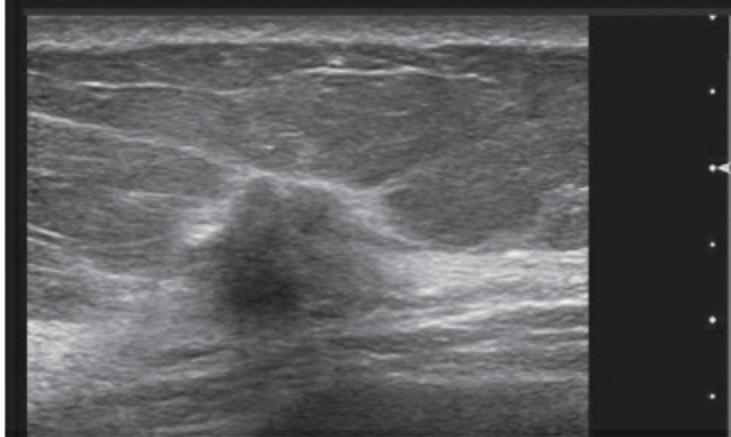
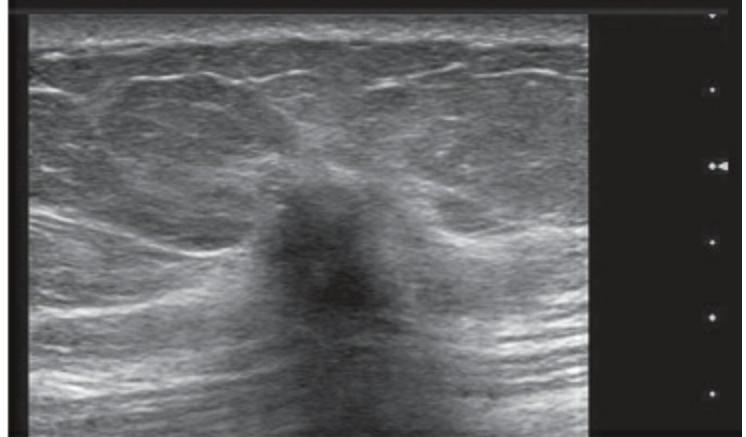
**A****B**

Figure 84 — POSTERIOR FEATURES: SHADOWING. Irregular, hypoechoic mass with a spiculated, indistinct, and angular margin, with POSTERIOR SHADOWING in a 56-year-old woman. Histopathology: invasive ductal carcinoma.

**A****B**

Figure 85 — POSTERIOR FEATURES: SHADOWING. Postsurgical scar in a 64-year-old patient following lumpectomy and radiation therapy for invasive carcinoma 11 years earlier, depicted as an irregular spiculated mass that produces intense POSTERIOR SHADOWING. Note that the entire posterior aspect of the mass is obscured on both views (a and b), with only partial visibility of the chest wall on the oblique view (b). Correct interpretation requires comparison with previous studies and correlation with unchanged mammograms. Assessment category 2: benign.

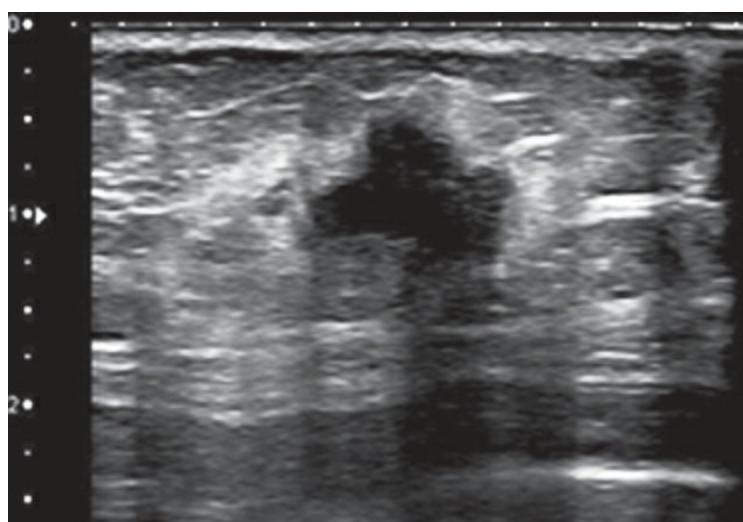
B. MASSES

5. POSTERIOR FEATURES

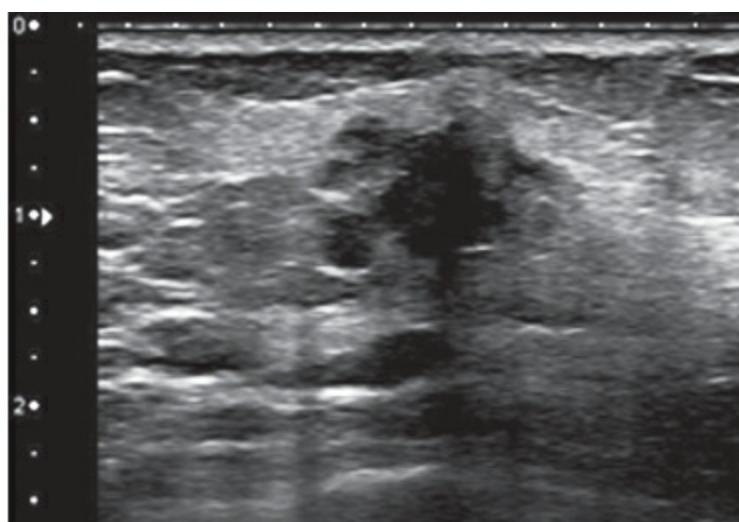
d. Combined Pattern

Some lesions have more than one pattern of posterior attenuation. For example, a fibroadenoma containing a large calcification may demonstrate shadowing posterior to the calcified area but enhancement of the tissues deep to the uncalcified portion. A combined pattern of posterior features also may be seen in lesions that are evolving. One such example is a post-lumpectomy seroma, which enhances posteriorly. As the fluid is resorbed and scarring develops, the features of fibrosis

become evident as spiculation of the margins and posterior acoustic shadowing.

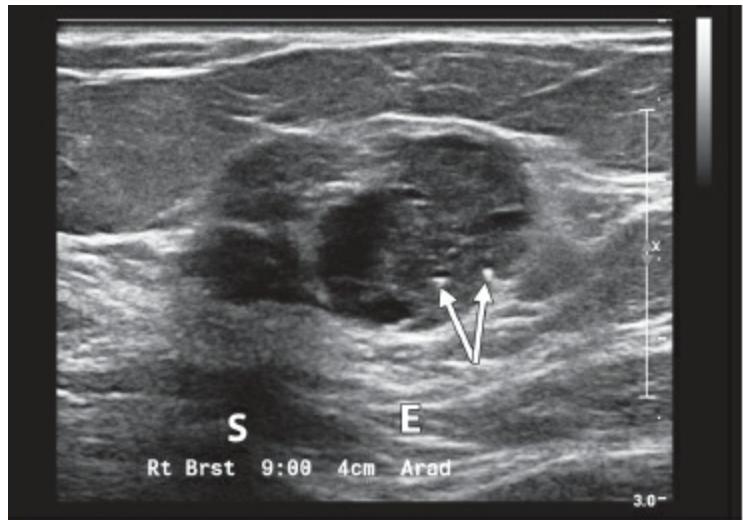


A

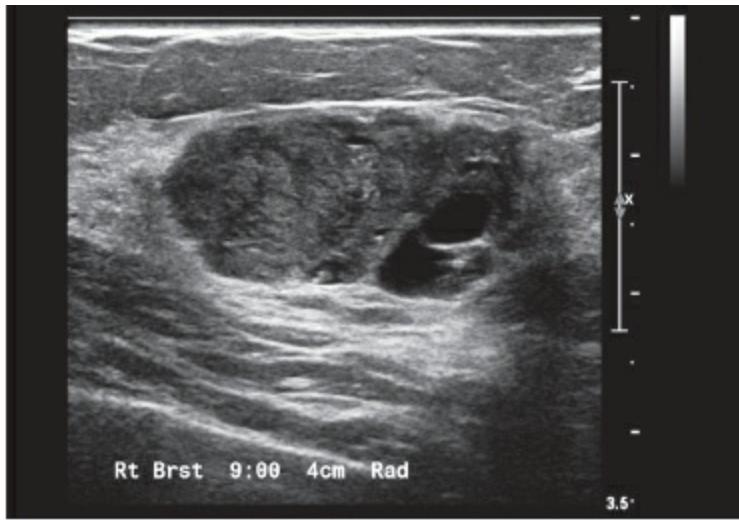


B

Figure 86 — POSTERIOR FEATURES: COMBINED PATTERN. Partial shadowing combined with no posterior features. The mass is hypoechoic and irregular in shape (a), with an indistinct margin. Histopathology: invasive ductal carcinoma.



A



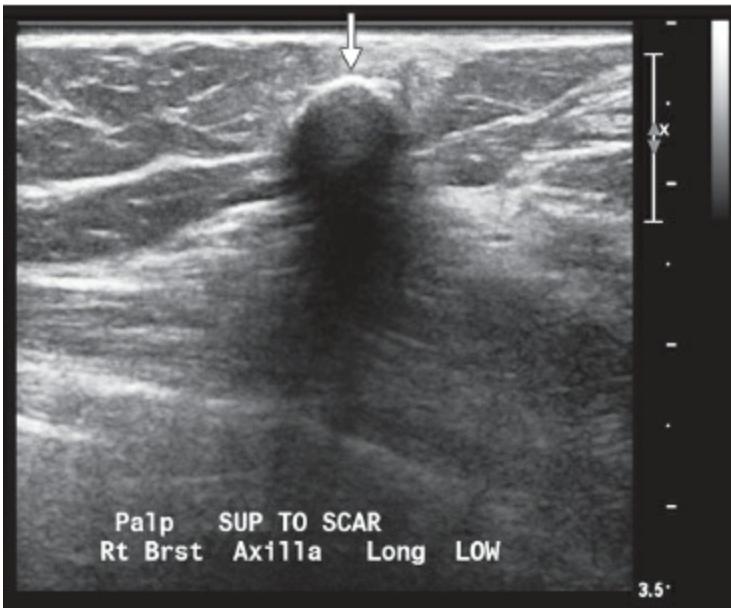
B

Figure 87 — POSTERIOR FEATURES: COMBINED PATTERN. Shadowing (S) and enhancement (E) are shown in (a), the antiradial view of this palpable, oval, circumscribed, complex cystic and solid mass, containing calcifications (arrows), in a 49-year-old woman. The long axis view (b), in which the mass is imaged radially, shadowing is less conspicuous than enhancement. Angle of insonation and compression force of the probe against the tissue can also affect depiction of posterior features. Histopathology of core biopsy specimens: fibroepithelial lesion.

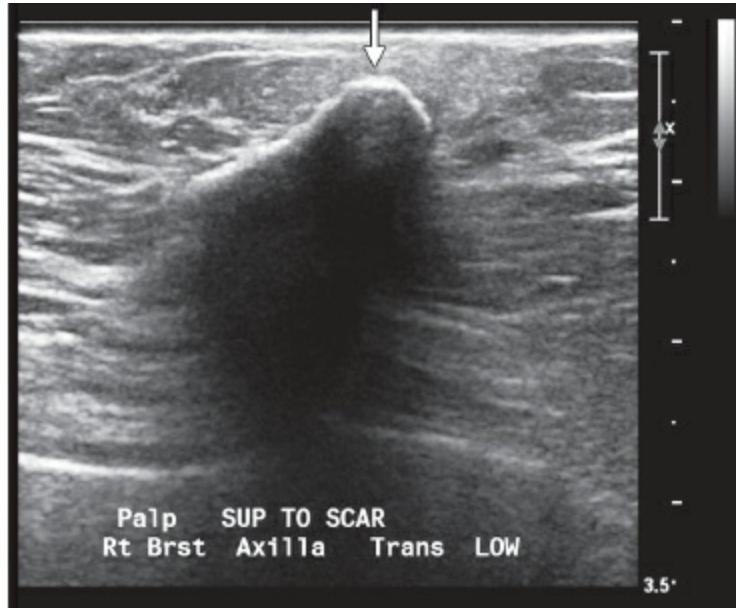
C. CALCIFICATIONS

Calcifications have been poorly characterized with US compared with mammography, but they can be recognized as echogenic foci, particularly when in a mass. High-frequency, high-resolution transducers in current use can depict intraductal calcifications well, particularly if they are superficial, and groups of microcalcifications concentrated in fibroglandular tissue can be recognized and biopsied with US guidance.

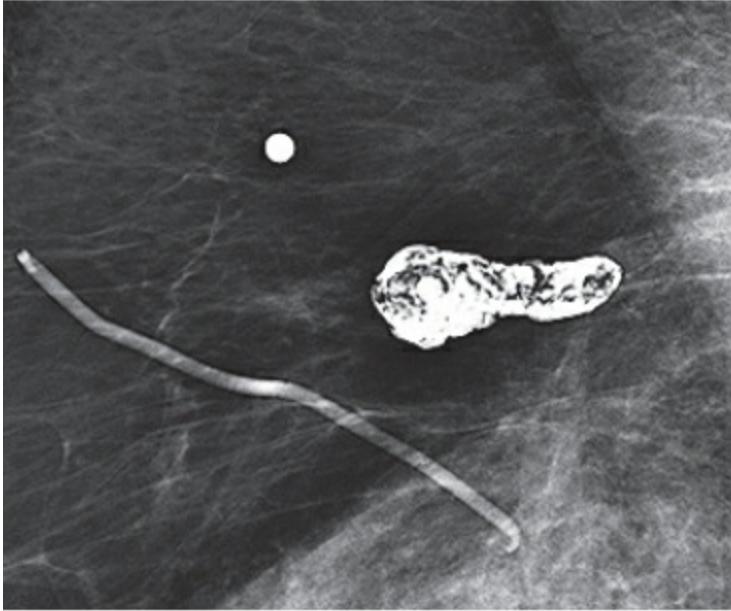
The microcalcifications seen at mammography do not occupy enough of the acoustic beam to attenuate it, and they may be seen as echogenic flecks that do not cause shadowing and are sometimes indistinguishable from noise. Aggregates of microcalcifications and large calcifications may attenuate the acoustic beam and cause shadowing.



A



B



C

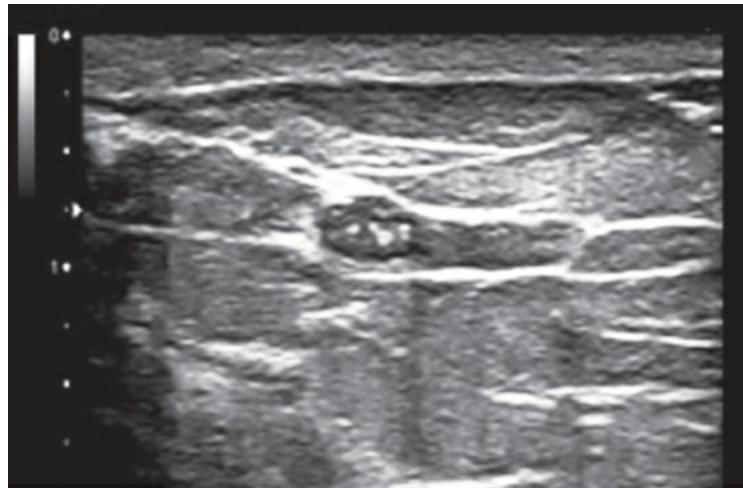
Figure 88 —CALCIFICATIONS. Dystrophic CALCIFICATION forming at the biopsy site in a 61-year-old woman who, 5 years earlier, underwent lumpectomy and radiation therapy for invasive and intraductal carcinoma, grade 1. The anterior crescent of the calcification (*a* and *b*, arrow) correlates with the shape of the rim of the characteristically benign dystrophic calcification seen at mammography in the axillary tail of the breast (*c*).

C. CALCIFICATIONS

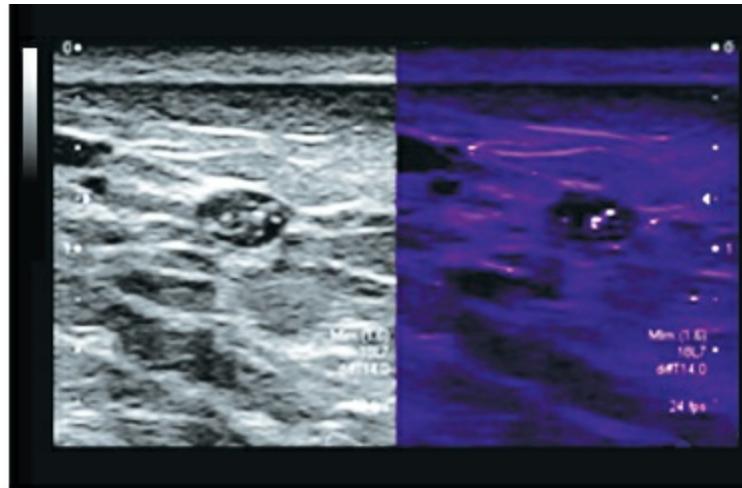
1. CALCIFICATIONS IN A MASS

Calcifications embedded in a mass may be well depicted at US, but their morphology will not be as readily discernible as at mammography. These small hyperechoic foci will

be more conspicuous in a hypoechoic mass than within a volume of fibroglandular tissue. Unless mammographic microcalcifications are grouped very closely together or are individually coarse, they will not attenuate the US beam.



A



B

Figure 89 — CALCIFICATIONS IN A MASS. Located in a fatty breast, this calcified fibroadenoma is seen to contain CALCIFICATIONS of varying size within it. These calcifications are too small to attenuate the beam, so they do not cause shadowing (*a* and *b*). On the right side of the split-screen image (*b*), the calcifications are depicted with a calcification-enhancing algorithm, but the gray-scale images show the calcific particles more clearly.



A



B

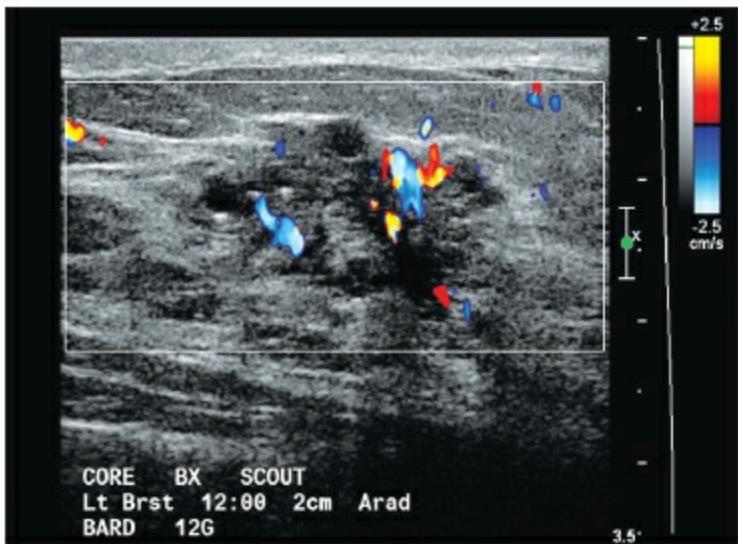


Figure 90 — CALCIFICATIONS IN A MASS. Two orthogonal views (*a* and *b*) of an irregular, complex, cystic and solid mass with an indistinct margin, which contains CALCIFICATIONS. The color Doppler image (*c*) shows the distribution of vessels within the mass. Core biopsy histopathology: sclerosing adenosis and radial scar, not upgraded at excision.

C

C. CALCIFICATIONS

2. CALCIFICATIONS OUTSIDE OF A MASS

At US, calcifications situated in fat or fibroglandular tissue are less conspicuous than when present within a mass. Small echogenic flecks grouped in tissue may sometimes be identified because they have patterns different from those of acoustic speckle and transversely sectioned Cooper ligaments or pectoral muscle fascicles. Because they occupy too small a portion of the acoustic beam, individual calcifications that are not coarse will not shadow. If calcifications are sufficiently numerous for a pattern to be discerned, they may be perceived as grouped in the area of tissue being examined with US.

When small calcifications within or outside a mass are seen well enough to target, US may be used to provide imaging guidance for percutaneous biopsy, preferably using a vacuum-assisted biopsy device. Specimen radiography should always be obtained to verify sampling of the targeted calcifications. A marker clip should be placed at the biopsy site, and its location demonstrated on postbiopsy craniocaudal and 90° lateral mammographic images.

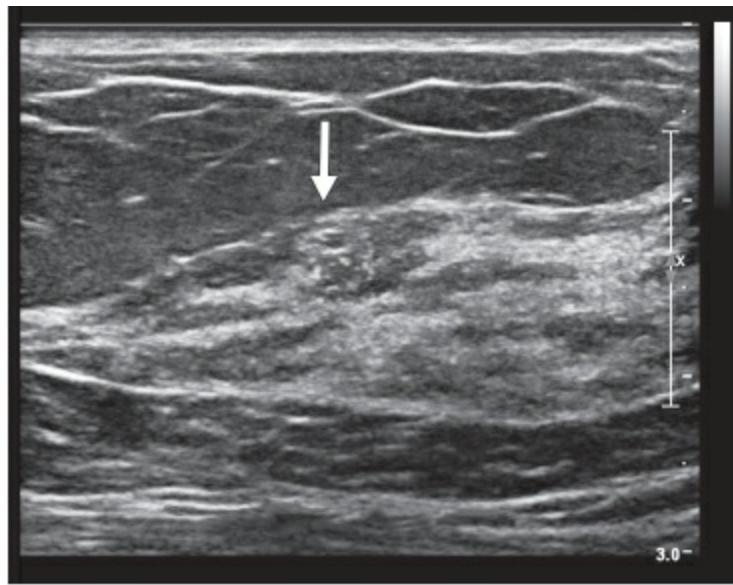
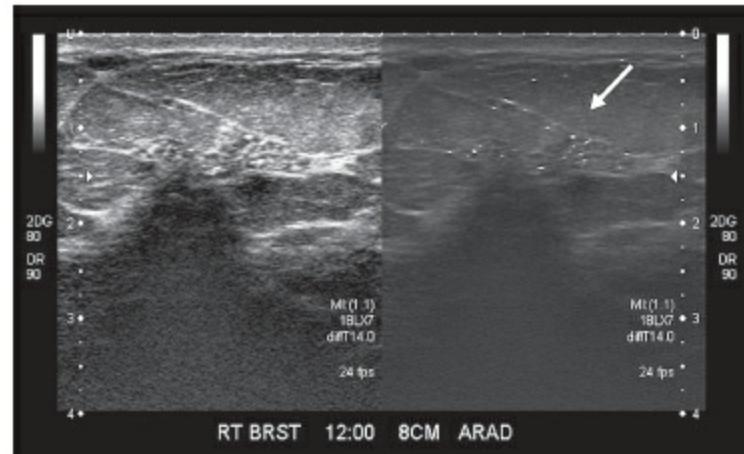


Figure 91 — CALCIFICATIONS OUTSIDE OF A MASS. US imaging was performed to look for a mass in which mammographically detected CALCIFICATIONS might be embedded. In this 53-year-old patient, no mass is seen within the dense fibroglandular tissue surrounding the calcifications (arrow). Assessment at mammography was suspicious (category 4B), but depiction of some of the calcifications at US enabled sonographically guided percutaneous biopsy. Concordant histopathology: extensive adenosis.



A

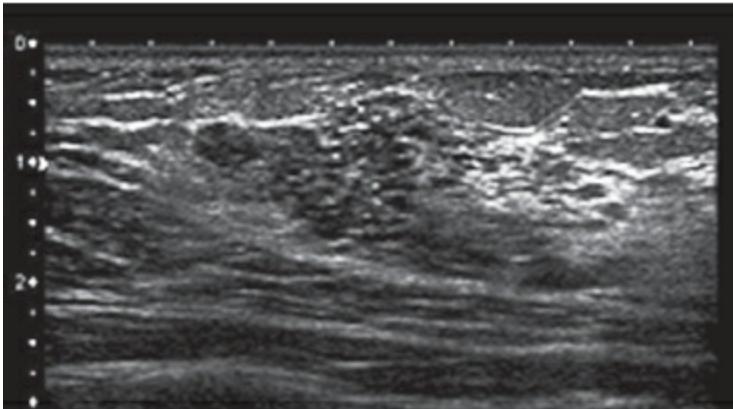


B

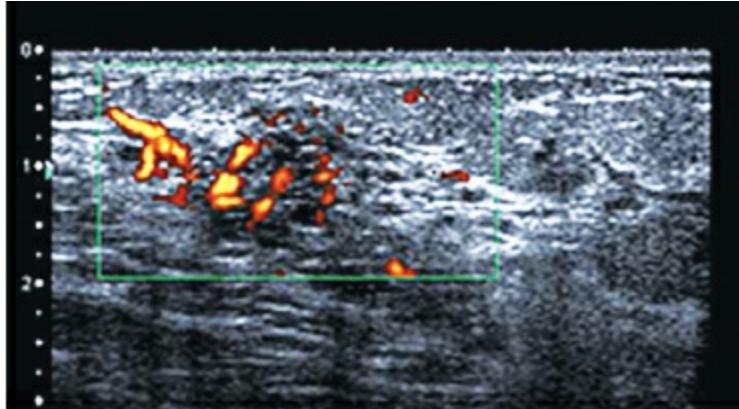
Figure 92 — CALCIFICATIONS OUTSIDE OF A MASS. A 33-year-old woman with palpable thickening of the right breast. Mammography (not shown) demonstrated fine pleomorphic calcifications in linear distribution. Calcifications are seen within the fibroglandular zone of the radial US image (a, arrow). In the split image sonogram of the same area, antiradial view (b), the linear distribution of these calcifications are shown using a special calcification depiction algorithm (arrow). Although US was not able to depict calcification morphology or extent nearly as well as mammography, the visibility of some of the mammographically demonstrated calcifications did enable sonographically guided percutaneous biopsy. Histopathology: DCIS with microinvasion, grade 3.

C. CALCIFICATIONS

3. INTRADUCTAL CALCIFICATIONS



A



B

Figure 93 — INTRADUCTAL CALCIFICATIONS. Echogenic flecks within tiny round dark areas are calcifications within ducts (a). Doppler US (b) shows vascularity within the region containing the dilated ducts and calcifications. Calcifications within ducts should be considered suspicious.

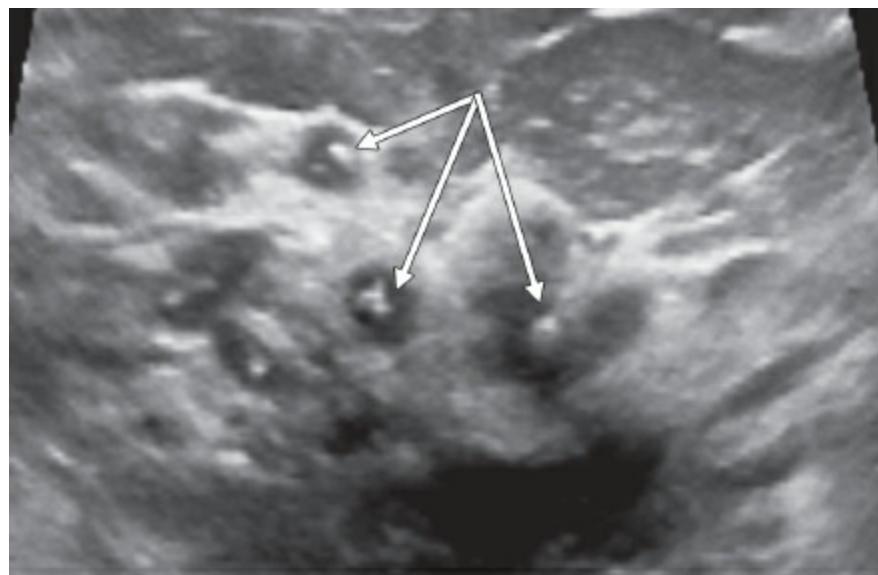


Figure 94 — INTRADUCTAL CALCIFICATIONS. The extensive intraductal component of this invasive ductal carcinoma is manifested by the several calcifications (arrows) within ducts depicted superior to the hypoechoic irregular mass. This coronal plane depiction enabled by volumetric acquisition (3-D) enhances the conspicuity of the INTRADUCTAL CALCIFICATIONS, as well as architectural distortion.

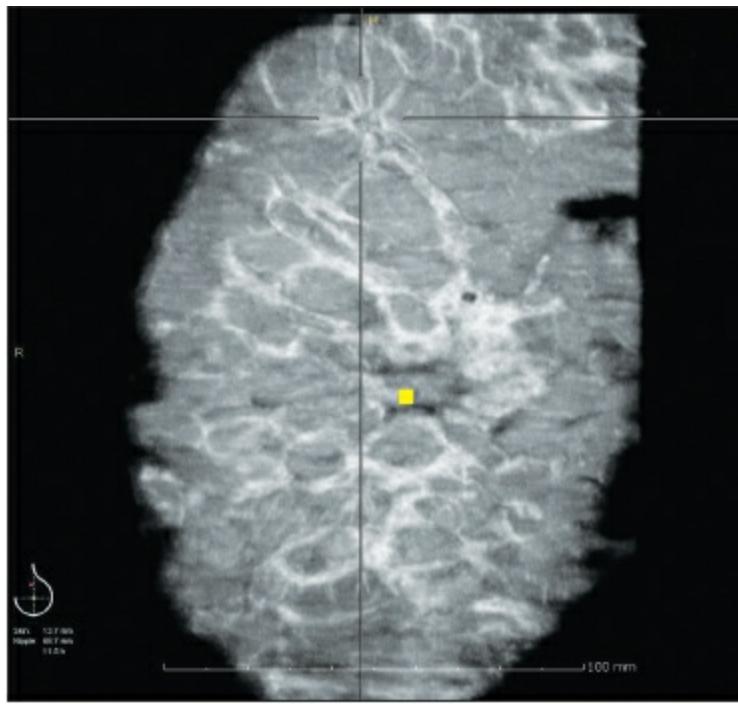
D. ASSOCIATED FEATURES

Effects of a mass on its surroundings are: architectural distortion that may be manifested by compression of the tissue around the mass, obliteration of the tissue planes by an infiltrating lesion, straightening or thickening of Cooper ligaments, aberrations of ductal patterns, and an echogenic rim. These findings in the mammography lexicon are included in "architectural distortion." For MRI, they may categorized as non-mass features. Findings of breast edema and skin thickening may be present, caused by inflammatory carcinoma, radiation therapy, mastitis, or a systemic process such as congestive heart

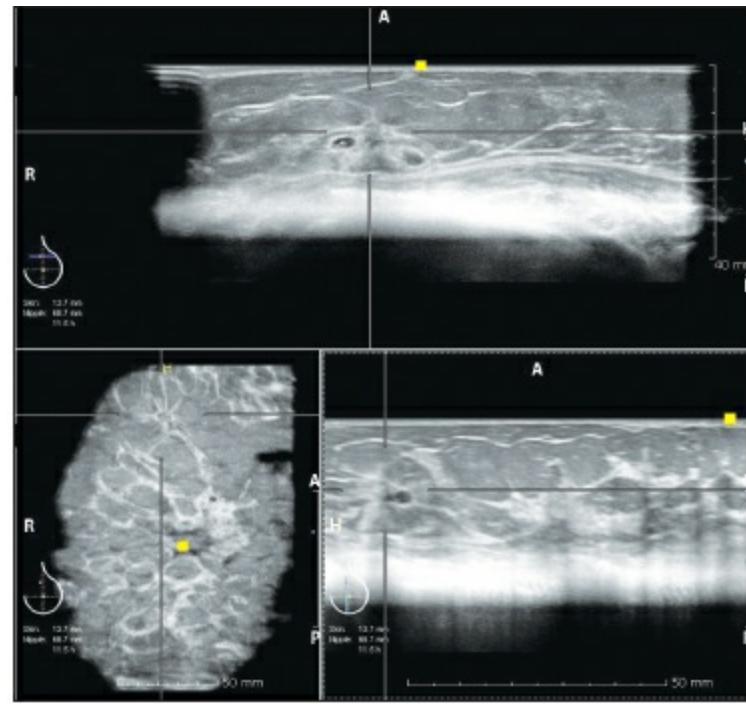
failure. Color and power Doppler vascular findings of an abnormality and tissue stiffness characteristics are also associated features.

D. ASSOCIATED FEATURES

1. ARCHITECTURAL DISTORTION



A



B

Figure 95 — ARCHITECTURAL DISTORTION. Automated US, whole breast coronal reconstruction (a), shows crosshairs defining small hypoechoic mass at 11:00 in the left breast with spicules radiating around it. Top image (b) is from the volumetric acquisition (transverse), crosshairs correlating the small mass with its appearance on the other views, coronal on lower left and sagittal on lower right image, to provide 3-D depiction. Tissue composition is fatty, and black hole at the upper right edge of the coronal view is due to lack of contact of the transducer with the skin. Histopathology: invasive ductal carcinoma, grade 2.

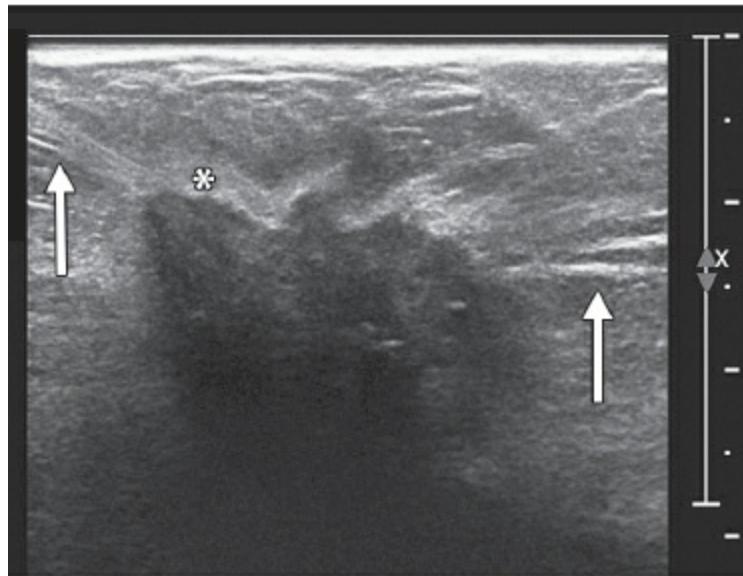


Lt Brst 10:00 5cm Arad

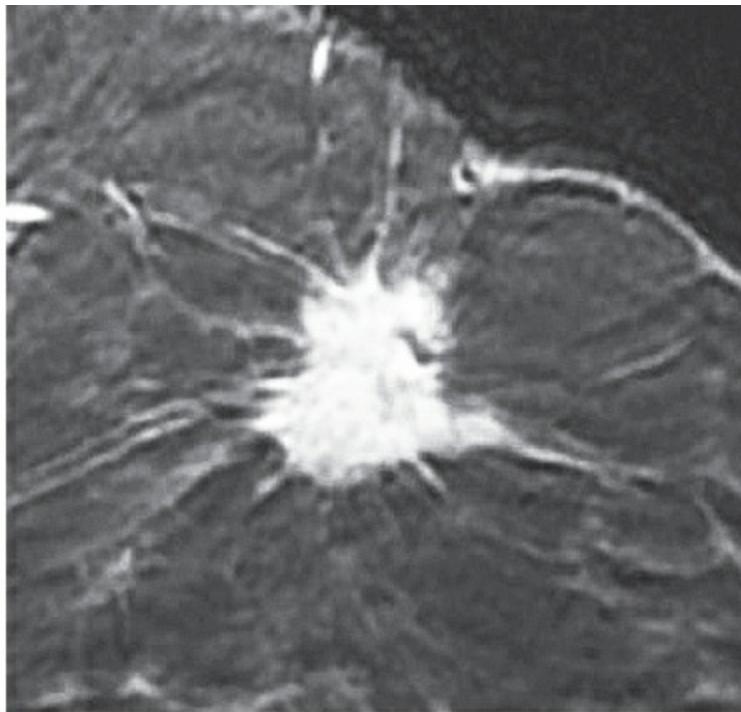


Lt Brst 10:00 5cm Rad

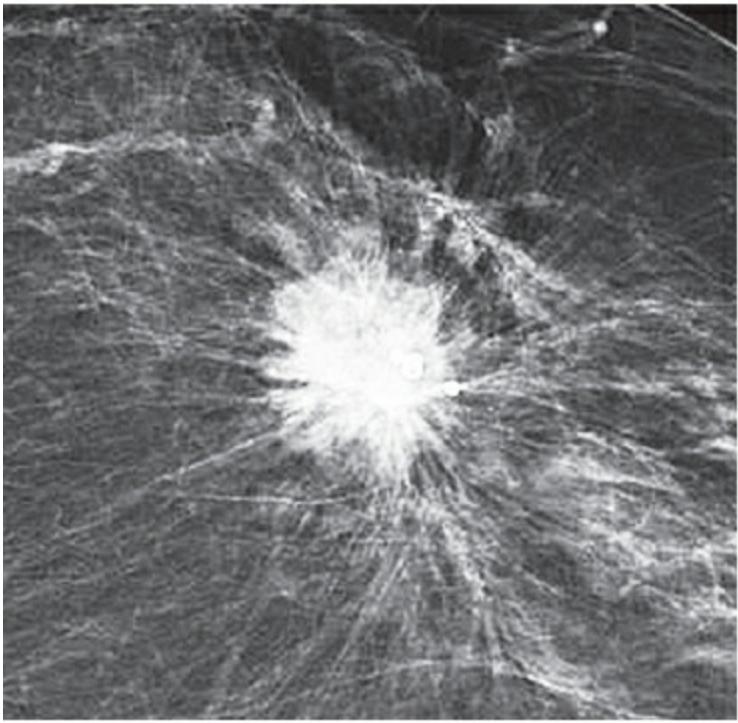
Figure 96 — ARCHITECTURAL DISTORTION. In a 56-year-old woman with pain, swelling, and redness of the left upper inner quadrant, a hypoechoic mass is seen within the fibroglandular tissue extending into the fat anterior to it, distorting the ducts within the adjacent fibroglandular tissue. Clinical considerations were mastitis and inflammatory carcinoma. Core biopsy histopathology: acute mastitis. Etiology of the acute mastitis is uncertain, but there was no history of skin abrasion, spider bite, trauma, nipple ring, or interventional procedure.



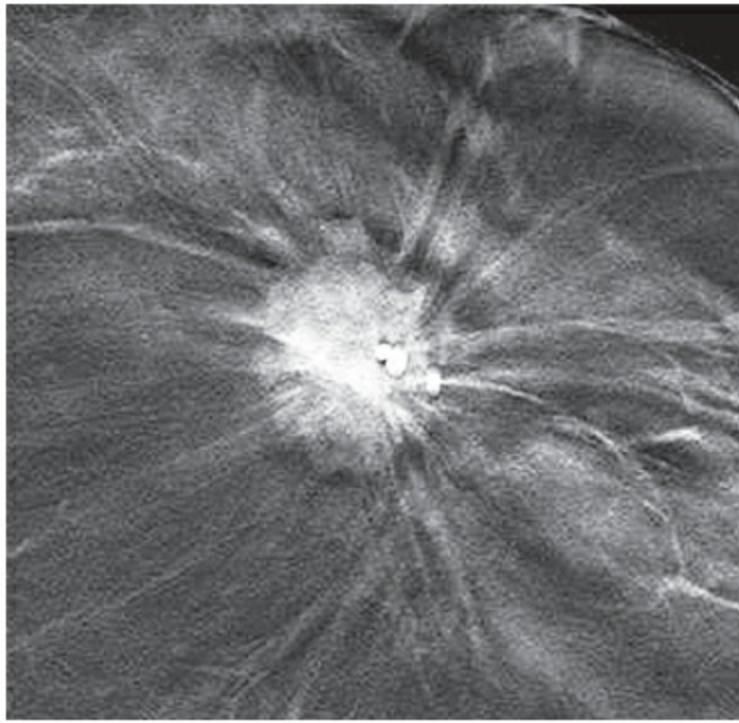
A



B



C



D

Figure 97 — ARCHITECTURAL DISTORTION. US image (a) of a mass in a 60-year-old woman demonstrates an irregular shape, spiculated margin, echogenic rim (asterisk), orientation parallel to the skin, with posterior shadowing. Manifestation of ARCHITECTURAL DISTORTION is that Cooper ligaments are straight (a, arrows) versus their normal arc shape. The postcontrast sagittal MRI (b), and craniocaudal 2-D digital (c) and tomosynthesis (d) views all show the features of a spiculated mass with associated architectural distortion. Histopathology: invasive ductal and lobular carcinoma, grade 2.

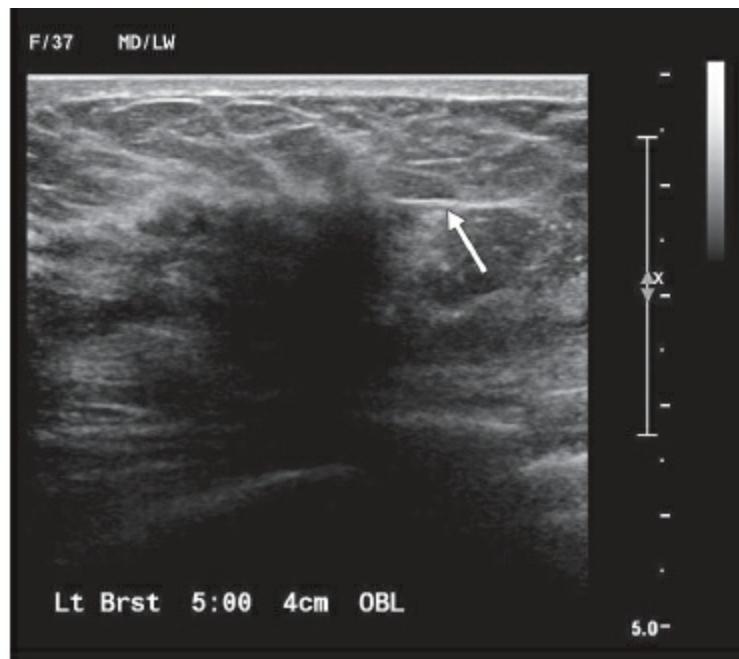
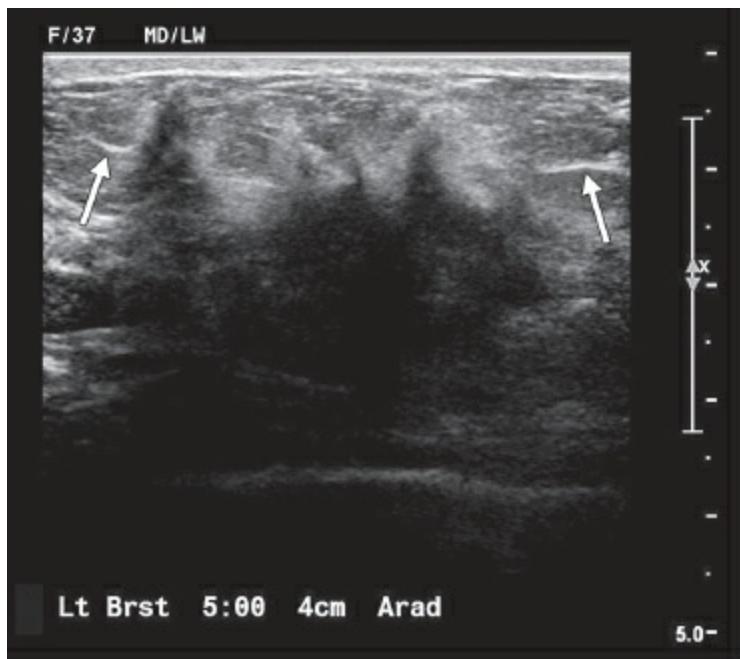
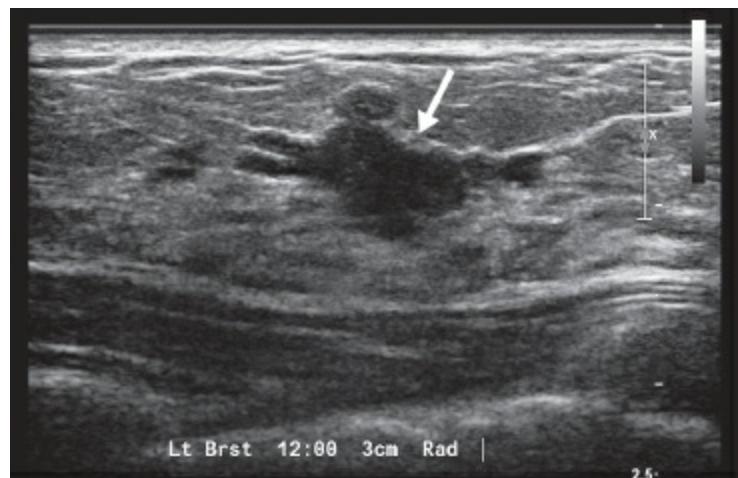


Figure 98 — ARCHITECTURAL DISTORTION. All of the findings of ARCHITECTURAL DISTORTION as an associated feature are present in this invasive lobular carcinoma, grade 2. Orthogonal US views show the tumor crossing the tissue planes, infiltrating the fat anterior to it, and straightening and shortening the nearby Cooper ligaments (arrows). Orientation of the mass, similar to that of many invasive lobular carcinomas, is parallel to the skin, with angular protrusion and echogenic rim extending into the overlying fibroglandular tissue and fat planes. The appearance of this case is similar to that of Figure 97, a combined invasive ductal and lobular carcinoma.

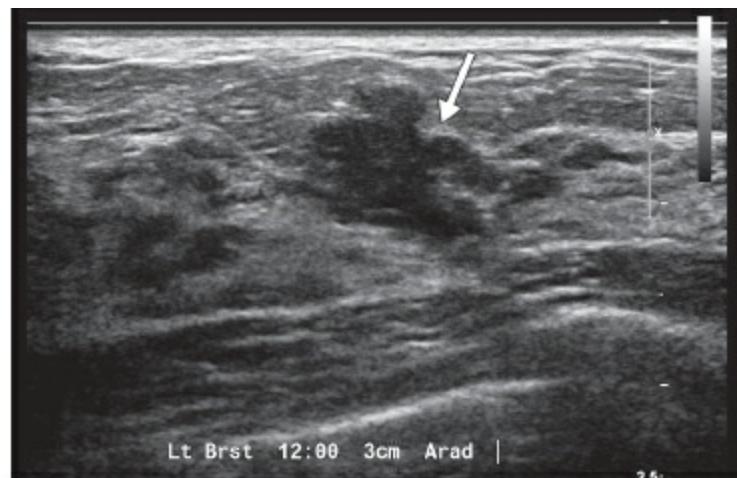
D. ASSOCIATED FEATURES

2. DUCT CHANGES

Ducts normally arborize in a smooth, regular, stepwise fashion, becoming progressively narrower in caliber from the base of the nipple distally into the parenchyma. Abnormal duct changes are manifested by the cystic dilatation of a duct or ducts involving irregularities in caliber and/or arborization, extension of duct(s) to or from a malignant mass, or the presence of an intraductal mass, thrombus, or detritus.



A



B

Figure 99 — DUCT CHANGES. A 34-year-old woman with nipple discharge. Radial (a) and antiradial (b) views of the left breast at 12 o'clock, 3 cm posterior to the nipple show DUCT CHANGES characterized by irregular cystic dilatation of duct segments (arrows). Histopathology: intraductal papillomas, no atypia.

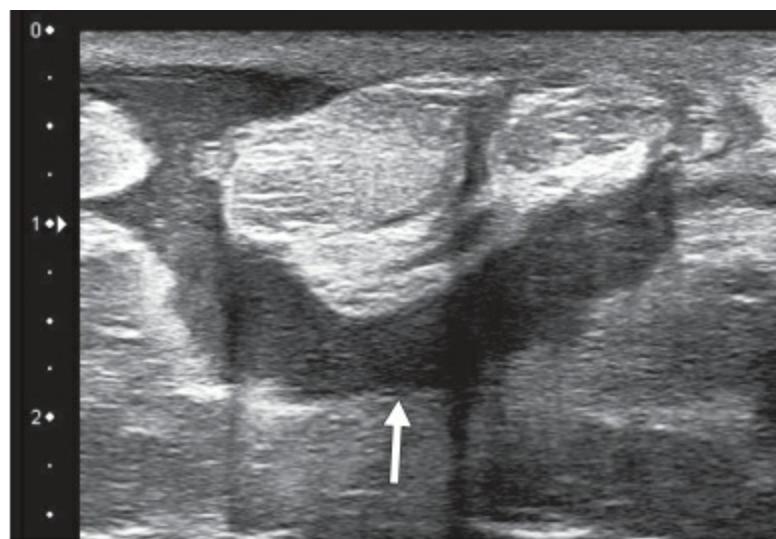
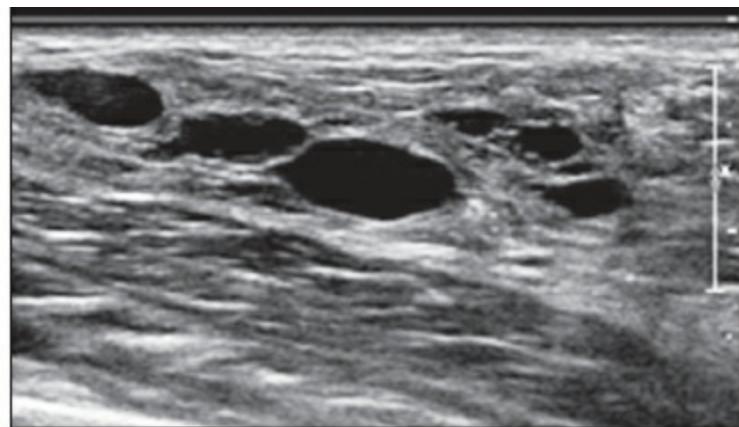
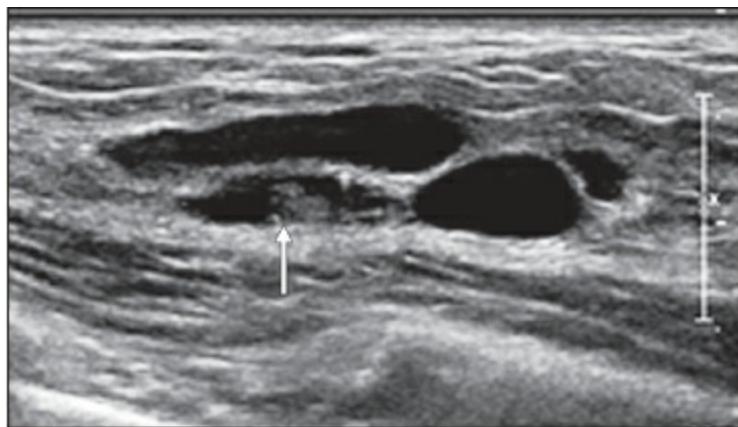


Figure 100 — DUCT CHANGES. A 19-year-old patient, whose nipple ring had been removed a month earlier, had purulent discharge from her left nipple with DUCT CHANGES characterized by irregular dilatation of a single duct (arrow). Pus was aspirated from this duct, and then successful treatment with antibiotics was provided.



Figure 101 — DUCT CHANGES. A 64-year-old patient was noted to have a solitary dilated duct at screening mammography. US was performed, showing anechoic fluid within a smoothly dilated duct. Previous outside-facility mammograms dating back a decade were obtained, showing the dilated duct to be stable. Assessment was benign (category 2).



A

B

Figure 102 — DUCT CHANGES. Baseline screening mammography in a 35-year-old woman with strong family history of breast cancer showed several dilated ducts in one breast (not shown). The patient requested supplementary US screening when she learned she had dense breasts. Dilated ducts (*a* and *b*) again were seen, with some echogenic intraductal material (arrow). Assessment was suspicious and US-guided biopsy was performed, with histopathologic diagnosis of mucocele-like lesion (MLL). At excision, ductal carcinoma in situ and atypical ductal hyperplasia were found.

D. ASSOCIATED FEATURES

3. SKIN CHANGES

a. Skin Thickening

Skin thickening may be focal or diffuse, and is defined as being > 2 mm. However, in the periareolar area and inframammary folds, normal skin thickness may be up to 4 mm.

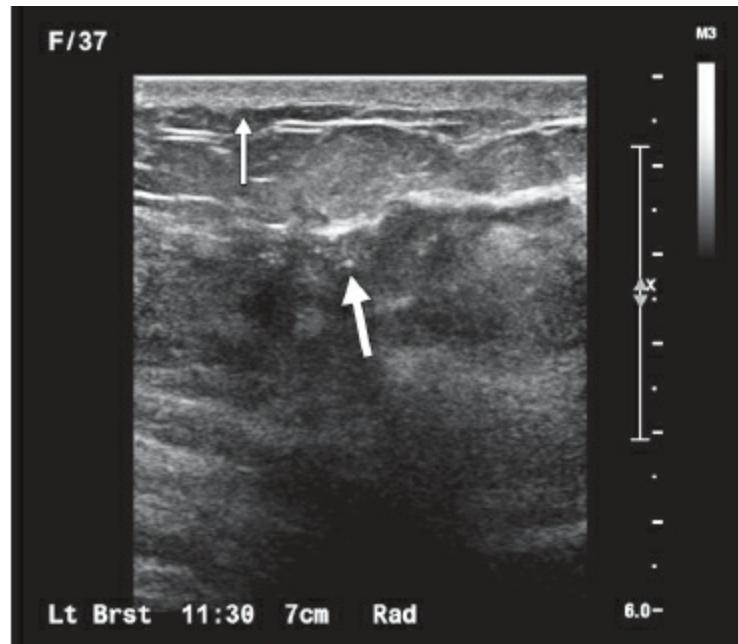


Figure 103 — SKIN CHANGES: SKIN THICKENING. Sonogram of the upper central breast shows the skin to be 5 mm thick (*thin arrow*). Large underlying mass has irregular shape, margin that is not circumscribed, and parallel orientation with posterior shadowing. Echogenic flecks (*thick arrow*) grouped in the anterior aspect of the mass are calcifications. Assessment is highly suggestive of malignancy (category 5). Histopathology: invasive and intraductal carcinoma with lymphovascular invasion.

D. ASSOCIATED FEATURES

3. SKIN CHANGES

b. Skin Retraction

The skin surface is concave or ill-defined and appears pulled in.

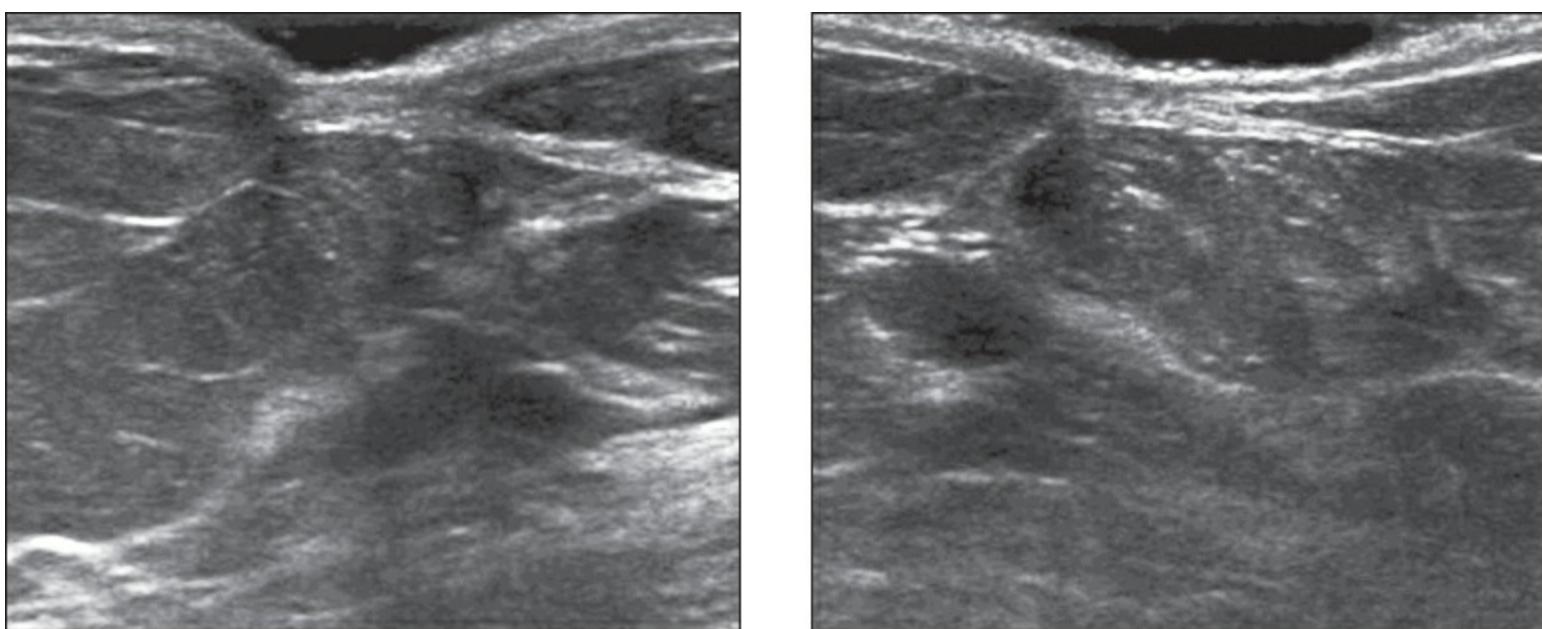


Figure 104 — SKIN CHANGES: SKIN RETRACTION and SKIN THICKENING. Focal SKIN RETRACTION and SKIN THICKENING at the incision site for a benign surgical biopsy performed many years earlier.

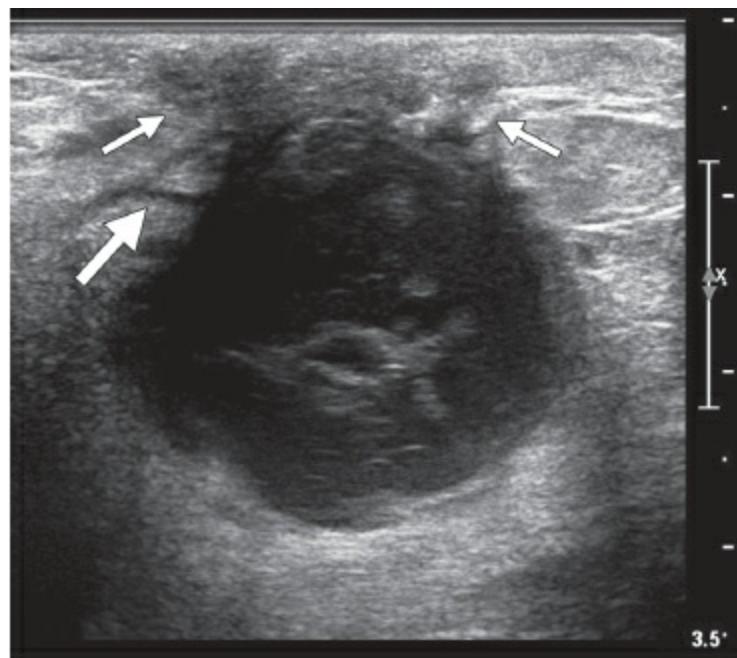


Figure 105 — SKIN CHANGES: SKIN RETRACTION and SKIN THICKENING. Hypoechoic skin immediately above an abscess shows V-shaped RETRACTION and THICKENING (thin arrows). The underlying round inflammatory mass is partially circumscribed, partially spiculated (thick arrow).

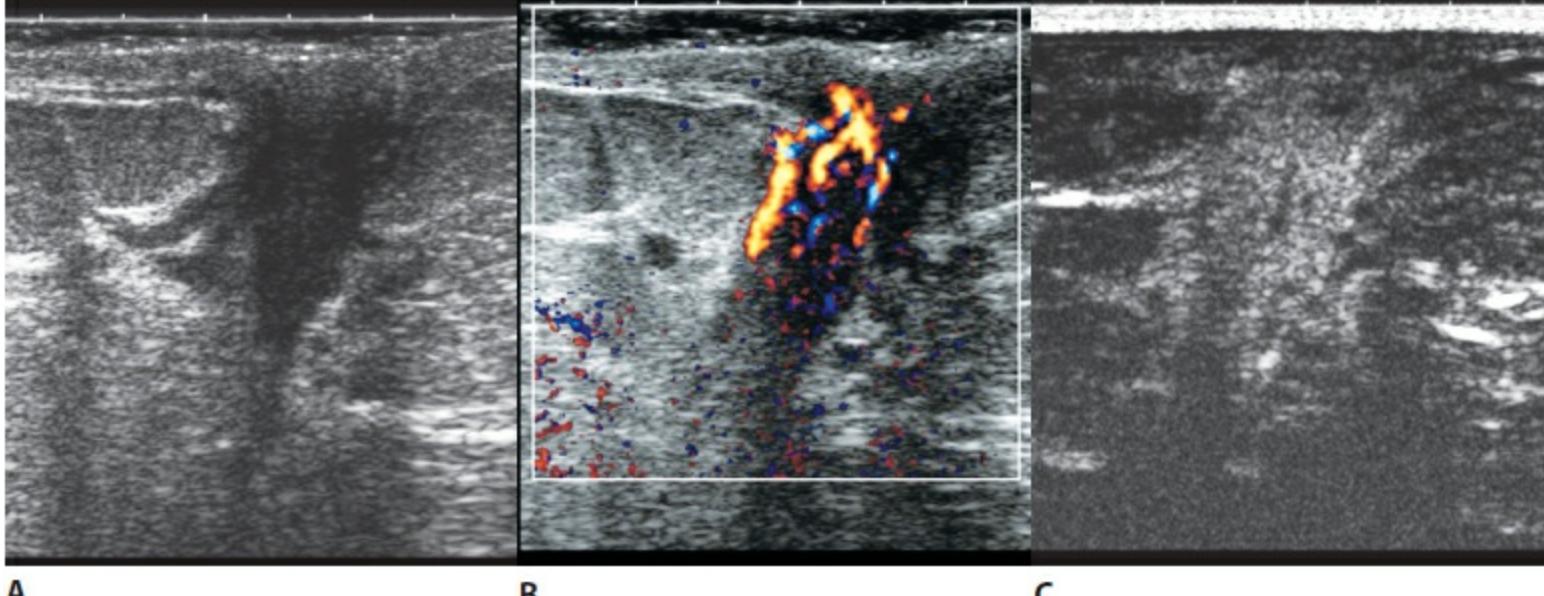
**A****B****C**

Figure 106 — SKIN CHANGES: SKIN RETRACTION and SKIN THICKENING. There is SKIN RETRACTION and SKIN THICKENING above a small hypoechoic invasive ductal carcinoma as seen on a gray scale image (a), as well as with color Doppler (b) that shows hypervascularity of the tumor, and perfusion imaging (c) after US contrast medium injection, at which the tumor appears hyperechoic.

D. ASSOCIATED FEATURES

4. EDEMA

Edema is indicated by increased echogenicity of the surrounding tissue and reticulation (angular network of hypoechoic lines representing either dilated lymphatics or interstitial fluid). Pronounced skin thickening and edema are often companion findings in inflammatory breast cancer, mastitis, and systemic disorders such as congestive heart failure.

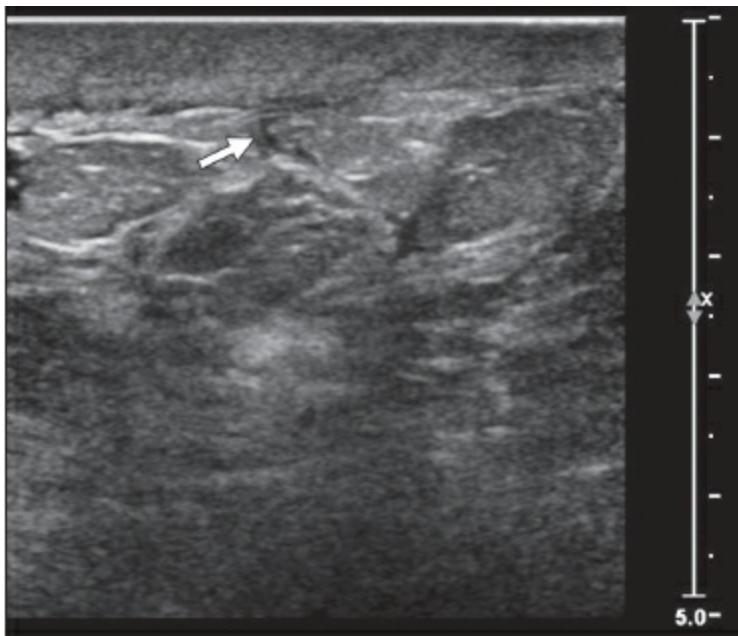
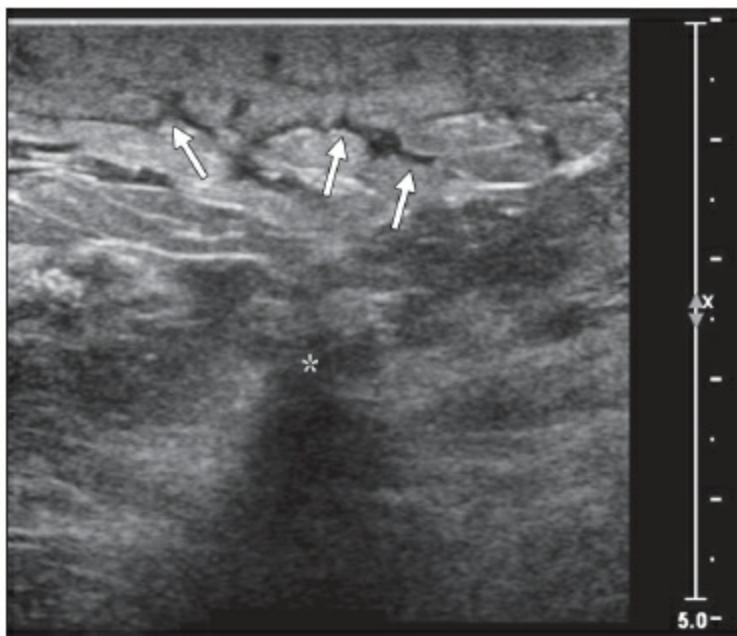
**A****B**

Figure 107 — EDEMA. Visible in inflammatory breast carcinoma. Increased echogenicity of surrounding tissue and a reticulated network of irregular hypoechoic lines (*a* and *b*, arrows) signifies EDEMA, in this case associated with inflammatory breast cancer. Skin thickening also is present. A hypoechoic, irregular mass with posterior shadowing is also seen (*b*, asterisk).



Figure 108 — EDEMA. Inflammatory carcinoma with dilated lymphatics or interstitial fluid collections in a reticulated pattern in the subcutaneous fat indicate the presence of EDEMA.

D. ASSOCIATED FEATURES

5. VASCULARITY

To describe a mass or other lesion as hypovascular or hypervascular, one must reference a contralateral normal area or unaffected site in the same breast as the basis

for comparison. No vascular pattern is specific for any particular diagnosis. Both power and color Doppler are highly dependent on technical factors, and it is important not to use vascularity as the only diagnostic feature in interpretation. Malignant lesions may not be hypervascular, while some benign lesions, such as papillomas and inflammatory processes, may be highly vascular.

a. Absent

Cysts are the most common avascular lesions. Some solid masses also have little or no vascularity. However, technical factors such as sensitivity settings for color Doppler (pulse repetition frequency should be set for low flow) may suppress the display of vascularity, falsely making a lesion appear avascular. Additionally, vigorous compression may occlude small vessels; so when scanning with color or power Doppler, little or no pressure should be applied.

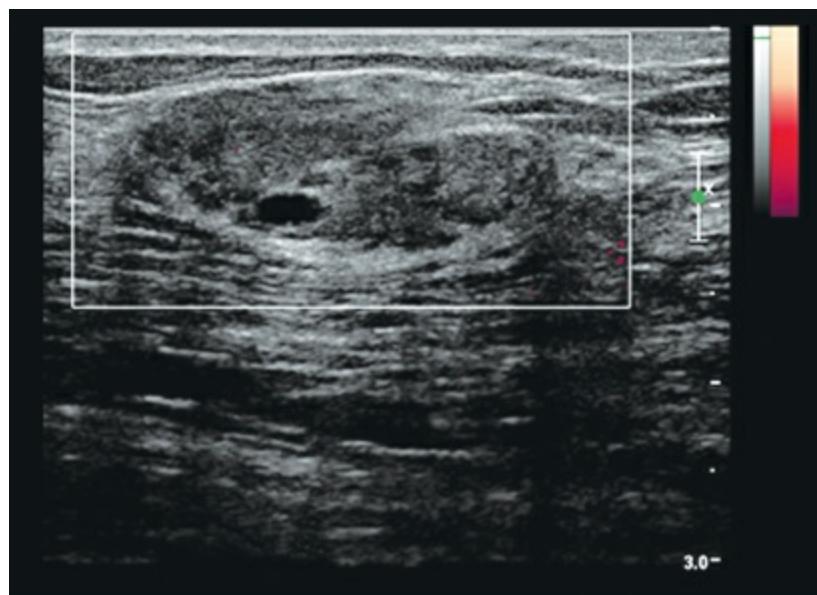


Figure 109 — VASCULARITY: ABSENT. This benign-appearing solid, circumscribed, oval mass of heterogeneous echogenicity, containing small cysts, is avascular. It had increased in size over time and biopsy was advised. The absence of vascularity does not change the morphologic analysis of the mass or its assessment. Histopathology: pseudoangiomatous stromal hyperplasia (PASH).

D. ASSOCIATED FEATURES

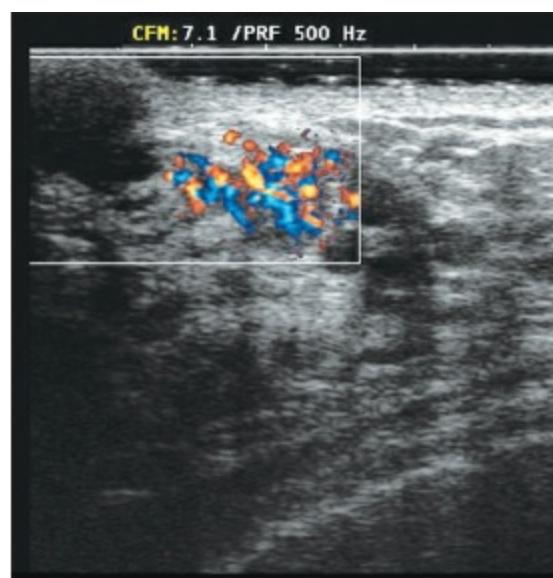
5. VASCULARITY

b. Internal Vascularity

Blood vessels are present within the mass. Vessels may penetrate the margin of the mass, or display an orderly or disorderly pattern within the mass. Abnormal flow patterns also may be found in breast tissue without the presence of a mass.

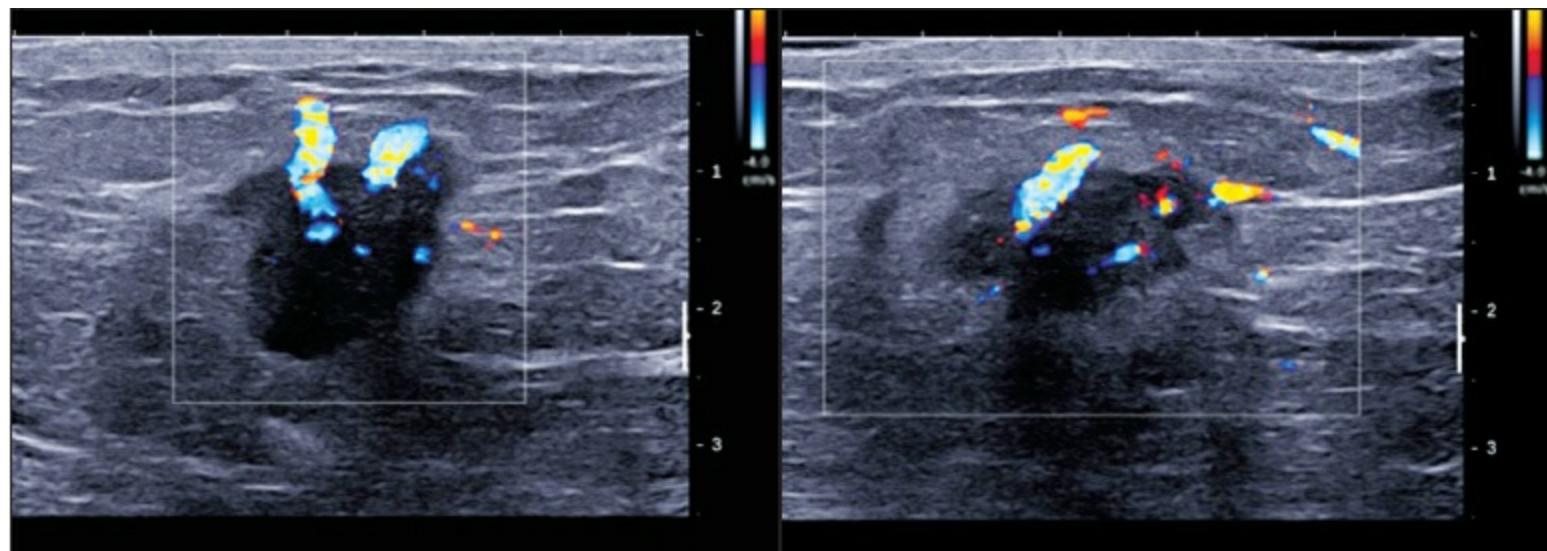


A



B

Figure 110 — VASCULARITY: INTERNAL VASCULARITY. Conventional US (a) shows a markedly dilated duct (arrows) distended with echogenic material extending towards the nipple at the upper left corner of the image frame. Color flow image (b), without compression and with correct pulse repetition frequency (PRF) parameters, confirms a solid intraductal mass that shows an increased and markedly abnormal vascular pattern. Histopathology: invasive and intraductal carcinoma.



A

B

Figure 111 — VASCULARITY: INTERNAL VASCULARITY. Vessels from outside the mass penetrate its margin to supply the tumor (a and b). Histopathology: invasive ductal carcinoma, grade 3.

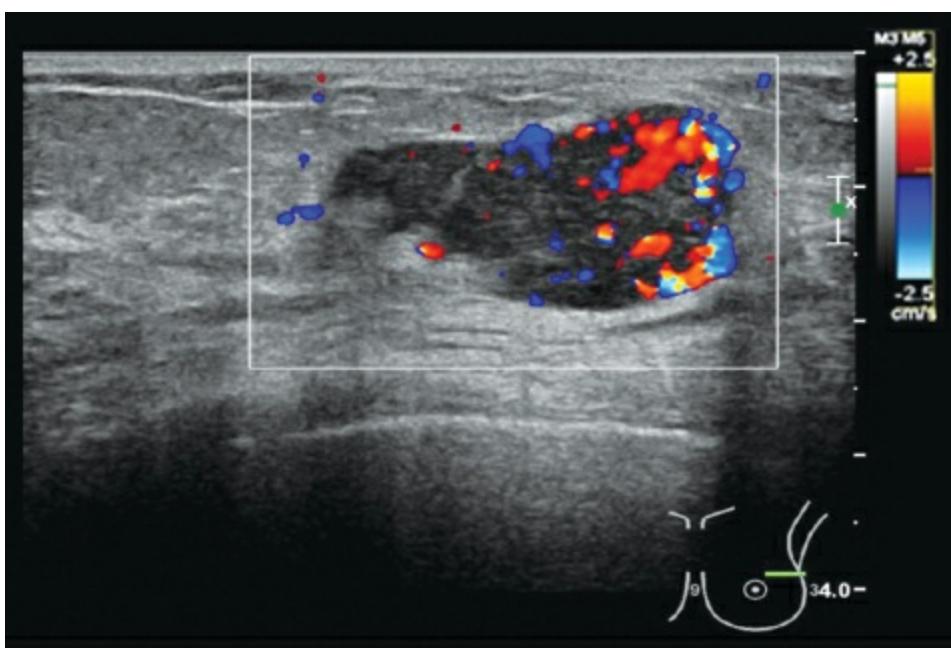


Figure 112 — VASCULARITY: INTERNAL VASCULARITY. The vessels of this invasive ductal carcinoma, grade 3, have a chaotic and disorderly branching pattern.

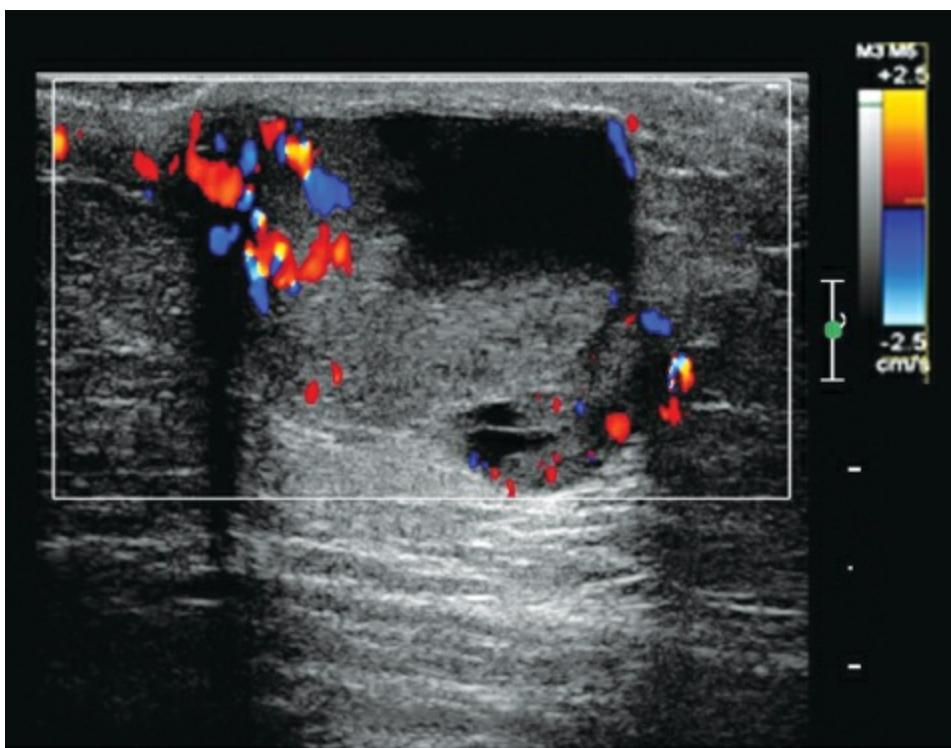
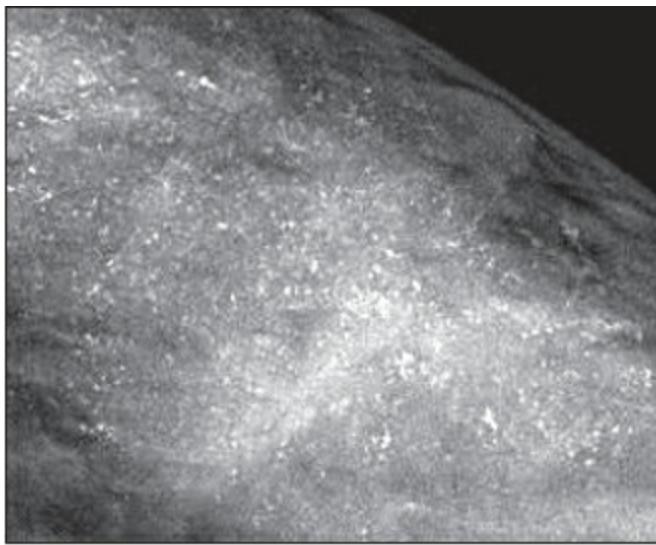
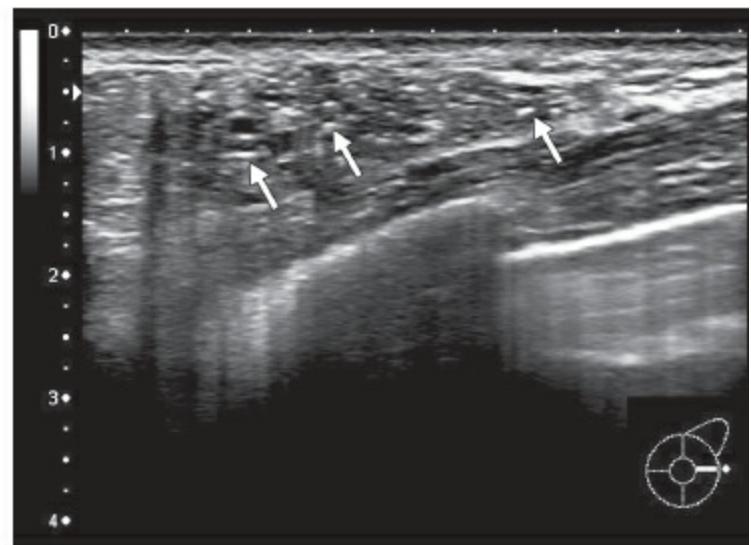


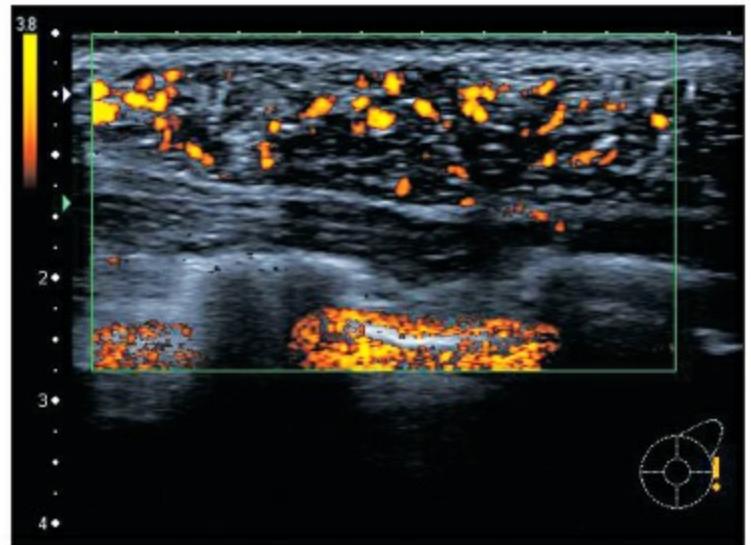
Figure 113 — VASCULARITY: INTERNAL VASCULARITY. Vessels in a disorderly pattern penetrate the margin of the lesion and are grouped within the solid portion of this complex cystic and solid mass in a 57-year-old man. Presence of vessels within the hypoechoic component helps differentiate this solid portion of the mass from detritus or clot in the dependent portion of what might have been considered a complicated cyst. Histopathology: intracystic papillary carcinoma.



A



B



C

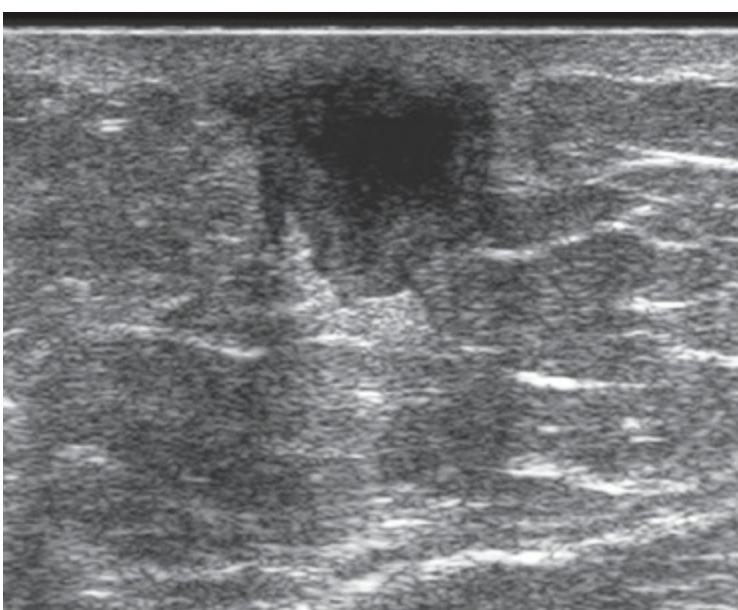
Figure 114 — VASCULARITY: INTERNAL VASCULARITY.
Calcifications in extensive ductal carcinoma in situ at mammography (a), at B-mode image (b, arrows). Increased flow is present in the area of involvement on power Doppler (c).

D. ASSOCIATED FEATURES

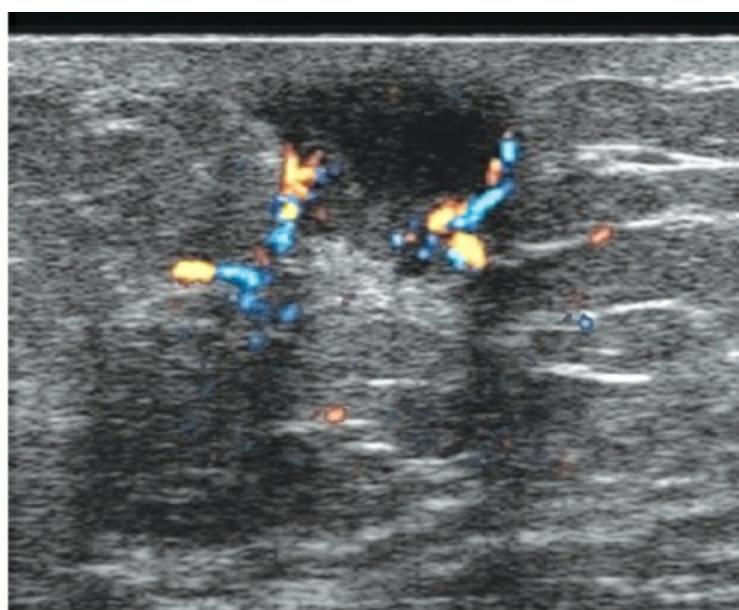
5. VASCULARITY

c. Vessels in Rim

The blood vessels may be marginal, forming part or all of a rim around a mass.



A



B

Figure 115 — VASCULARITY: VESSELS IN RIM. Retroareolar abscess in a man. B-mode image of irregularly shaped, complex cystic and solid mass (a). Color flow image (b) shows VESSELS IN RIM and in adjacent tissue.

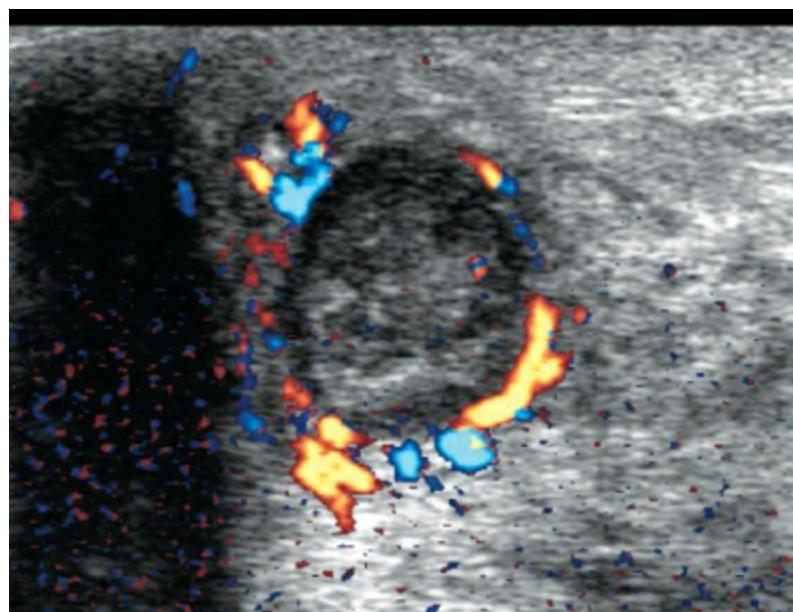


Figure 116 — VASCULARITY: VESSELS IN RIM. Circumscribed 6 mm mass with rim and peripheral vascularity. Diagnosis: abscess.

D. ASSOCIATED FEATURES

6. ELASTICITY ASSESSMENT

Stiffness as a feature of masses and surrounding tissue may be considered along with their much more important morphologic characteristics. This feature may be elicited either by manual compression of the mass ("strain") or by introduced ultrasonic energy into a mass ("shear wave"). Cancers and surrounding tissue are expected to be hard, and benign lesions are expected to be softer; although, as with all other sonographic criteria, there is overlap. Determination of the predictive value of various

measurements of tissue stiffness is an area of current research for both strain and shear-wave elastographic methods. The FDA recently approved m/s and kPa as a unit of measure of lesion stiffness for shear-wave elastography. As research continues, some of the BI-RADS® descriptors listed in this section may be validated, others rejected, and new descriptors identified. Standardization of the color scale needs to occur to help prevent misinterpretation. Descriptors that are applicable to all methods and all systems are SOFT, INTERMEDIATE, and HARD.

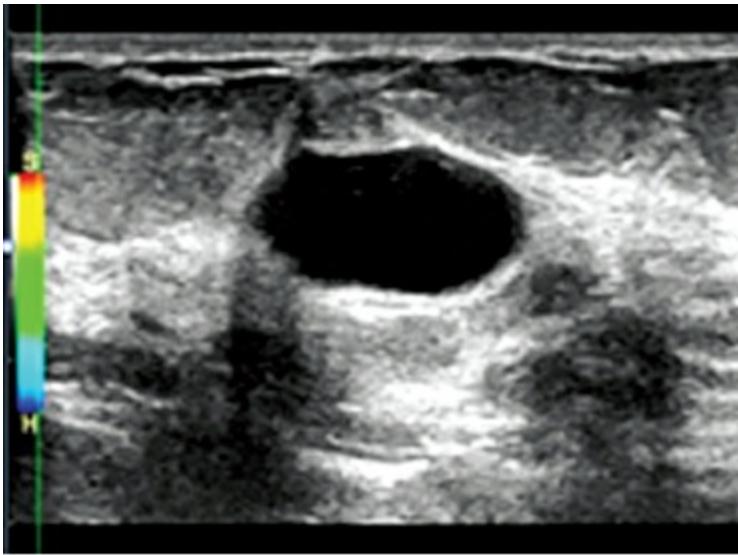
It must be emphasized that the ultrasonic criteria of shape, margin, and echogenicity are far more predictive for malignancy than hardness or softness, and elastography evaluation should not override the more predictive morphologic features of malignancy for patient management. Elastography has been included in the lexicon because it is available as a feature on many modern US units, and it is important to establish the names and definitions of descriptors for elasticity assessment. Inclusion should not be misinterpreted as an endorsement of the clinical validity of elasticity assessment.

D. ASSOCIATED FEATURES

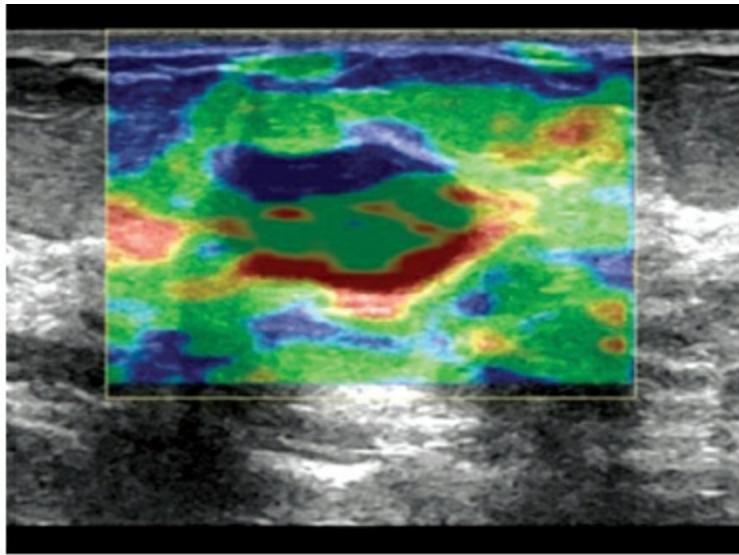
6. ELASTICITY ASSESSMENT

a. Soft

Until color coding is standardized, always check the color or black-and-white scale for the labeling of soft and hard. While blue is frequently used to symbolize soft, some equipment manufacturers use red or another color as their default setting for soft. When a gray scale is used, white most often indicates soft.



A



B

Figure 117 — ELASTICITY ASSESSMENT: SOFT. Simple cyst: B-mode image (a) shows four criteria for a simple cyst: anechoogenicity, oval shape, circumscribed margin, and posterior enhancement. The strain elastogram (b) shows the trilaminar appearance of a simple cyst, displayed by some US systems. In this color scale, red represents soft and blue represents hard.

D. ASSOCIATED FEATURES

6. ELASTICITY ASSESSMENT

b. Intermediate

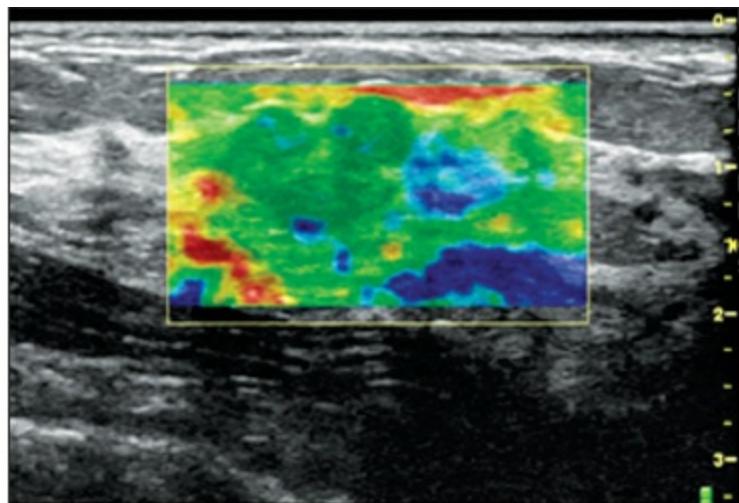
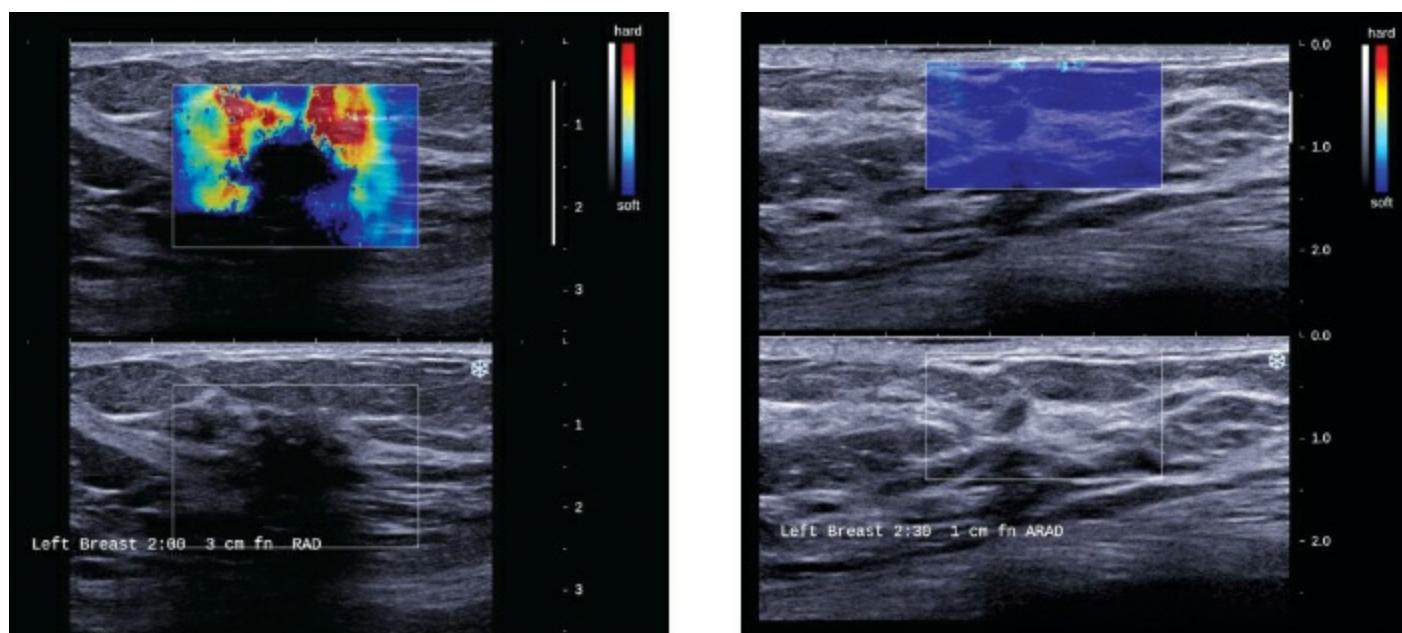


Figure 118 — ELASTICITY ASSESSMENT: INTERMEDIATE. Lobulated fibroadenoma with heterogeneous echogenicity; intermediate pattern on strain elastography. In this color scale, red represents soft and blue represents hard. Because of variability in labeling hard and soft, it is always important to refer to the color scale (left image) of each system.

D. ASSOCIATED FEATURES

6. ELASTICITY ASSESSMENT

c. Hard



A

B

Figure 119 — ELASTICITY ASSESSMENT: HARD (red depicted as hard and blue as soft).
Invasive lobular carcinoma in two sites in left breast, the larger is HARD (a) and the smaller is soft (b). Both cancers have suspicious morphologic features on the gray scale sonograms displayed below the elastograms. The two cancers also were assessed as suspicious at both mammography and MRI (not shown). Take-home message: do not let a soft elastogram supersede morphologic analysis, especially when the imaging features on two or three different modalities suggest a suspicious assessment.

E. SPECIAL CASES

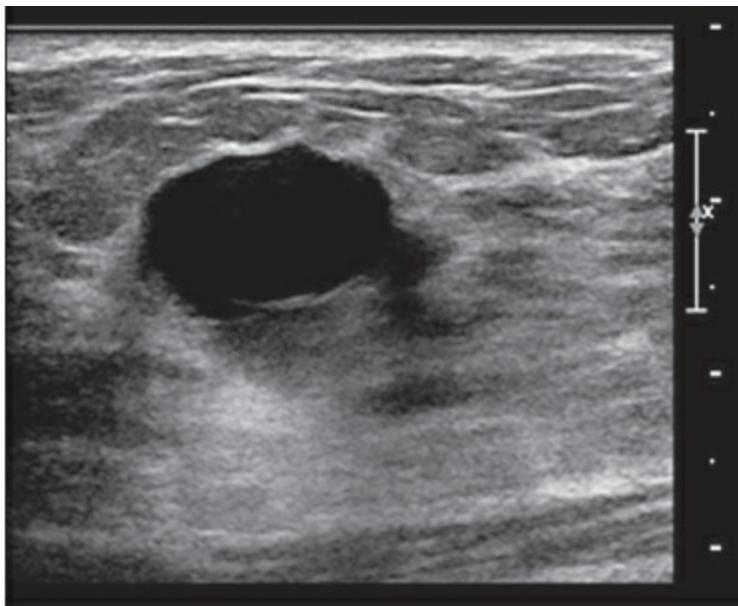
Special cases are those with a unique diagnosis or findings.

1. SIMPLE CYST

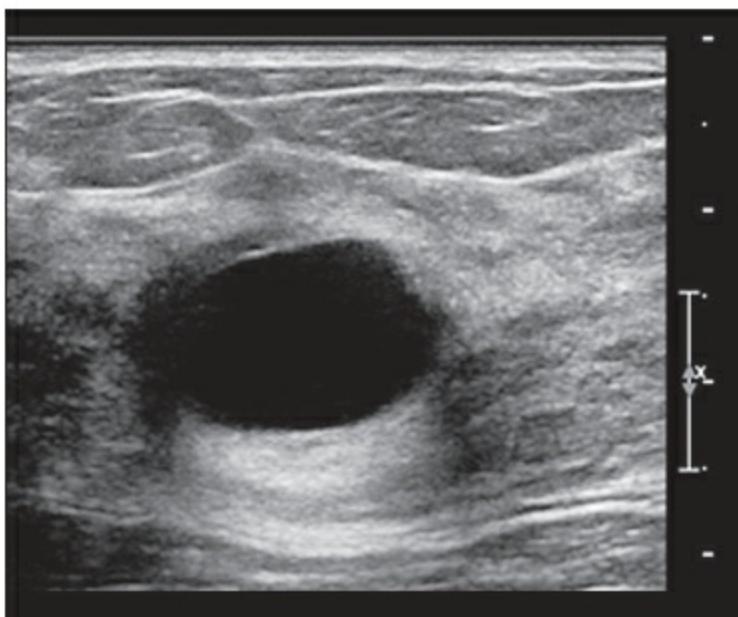
The diagnosis and management of cystic breast lesions are addressed in detail in the Guidance chapter. A simple cyst has four features: it is circumscribed, round or oval, anechoic, and shows posterior enhancement. When all four features are depicted, this establishes the diagnosis of simple cyst, a characteristically benign finding.



A



B



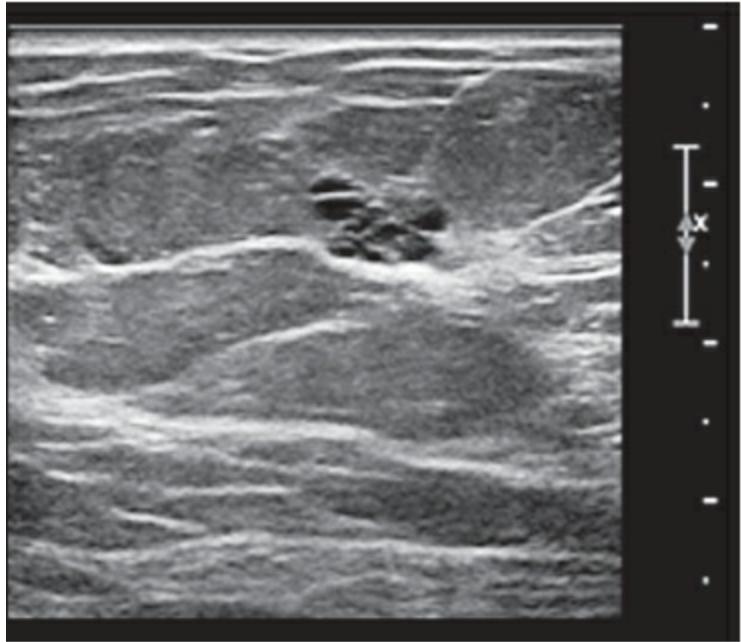
C

Figure 120 — SPECIAL CASES: SIMPLE CYST. Radial image (a) shows anechoic, circumscribed masses, one superficially located with respect to the other, with the antiradial image of the more superficial one (b) and that of the deeper one (c). When masses are grouped as these cysts are, all will not be in the same plane and margins may not be sharp. For similar masses in proximity, measurement of the depth from the skin to the anterior aspect of the mass can help differentiate.

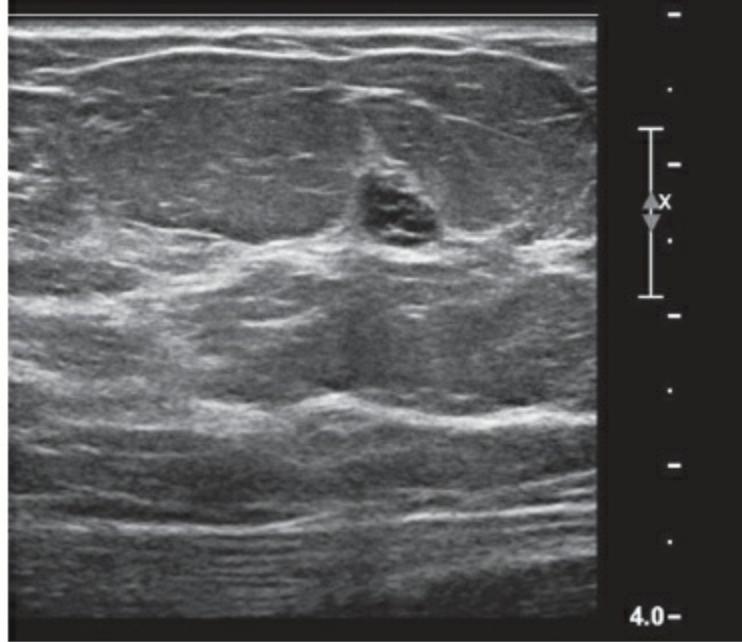
E. SPECIAL CASES

2. CLUSTERED MICROCYSTS

The lesion consists of a cluster of anechoic masses, individually < 2–3 mm, with thin (< 0.5 mm) intervening septations and **no discrete solid** component. While margins may reflect microlobulation due to individual small cysts, the margin should not be indistinct. Tissue diagnoses associated with clustered microcysts include fibrocystic change and apocrine metaplasia.



A



B

Figure 121 — CLUSTERED MICROCYSTS. Note the grouping of tiny cysts (CLUSTERED MICROCYSTS) shown on radial (a) and antiradial views (b). No solid component is present in any of the tiny cysts. If not palpable, an assessment of probably benign (category 3) or, especially if stable, benign (category 2) may be appropriate.

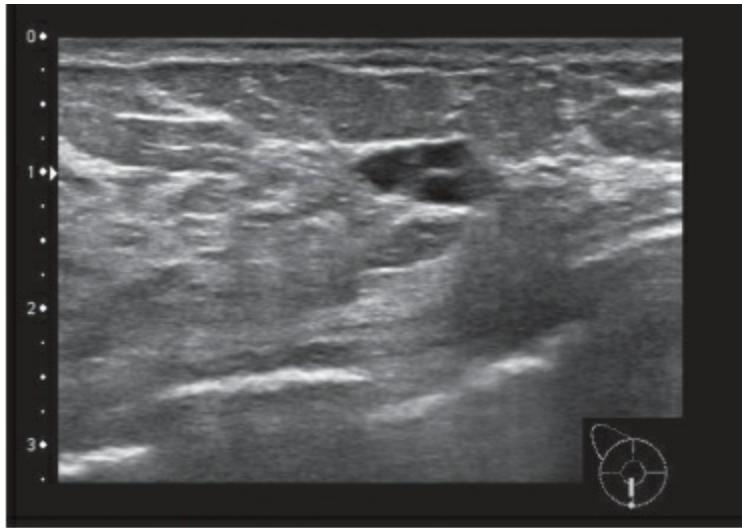
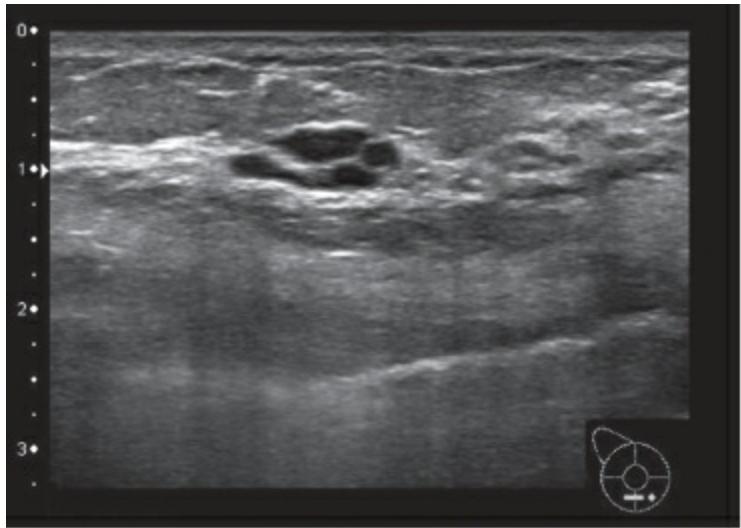
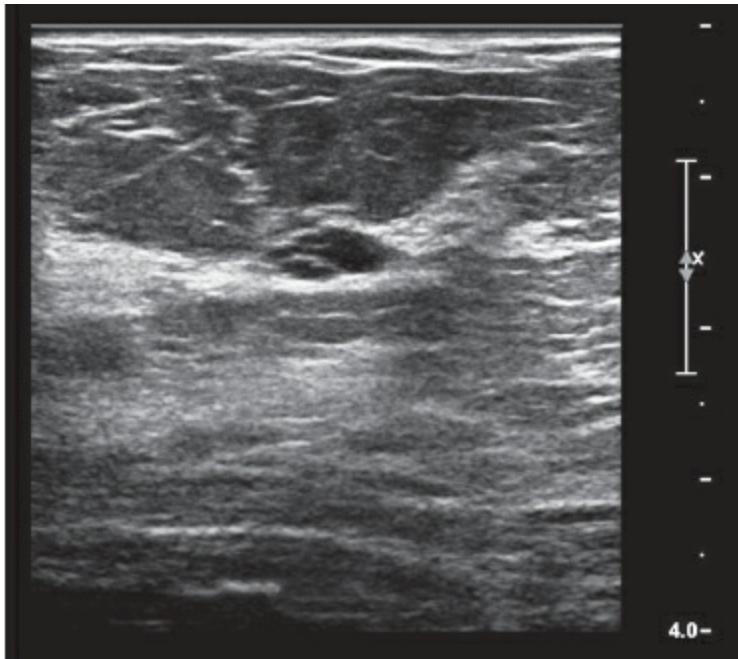
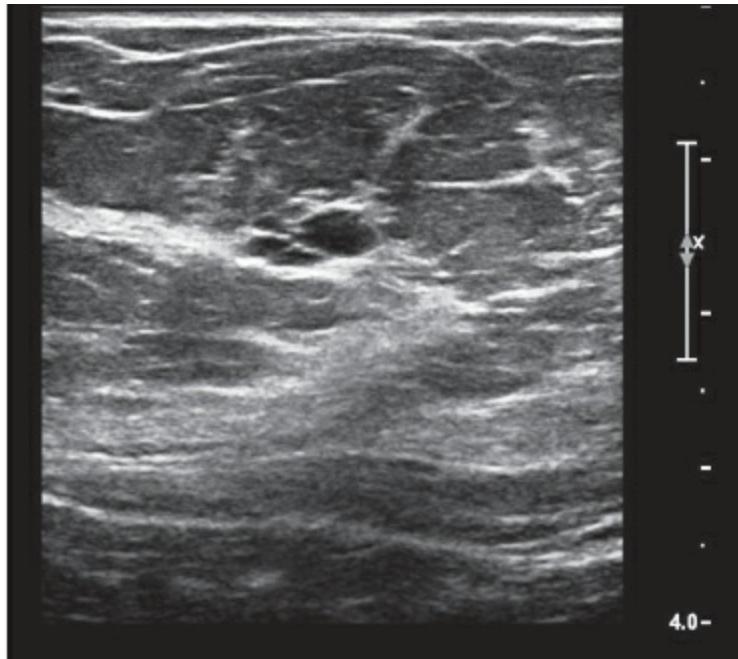


Figure 122 — CLUSTERED MICROCYSTS. Elongation and distortion of the lobule by a grouping of distended acini. CLUSTERED MICROCYSTS are often assessed as probably benign (category 3) or benign (category 2). The presence of an indistinct margin or a discrete solid component should prompt a BI-RADS® 4 assessment and recommendation for biopsy, particularly if the mass is new or in a post-menopausal patient.



A



B

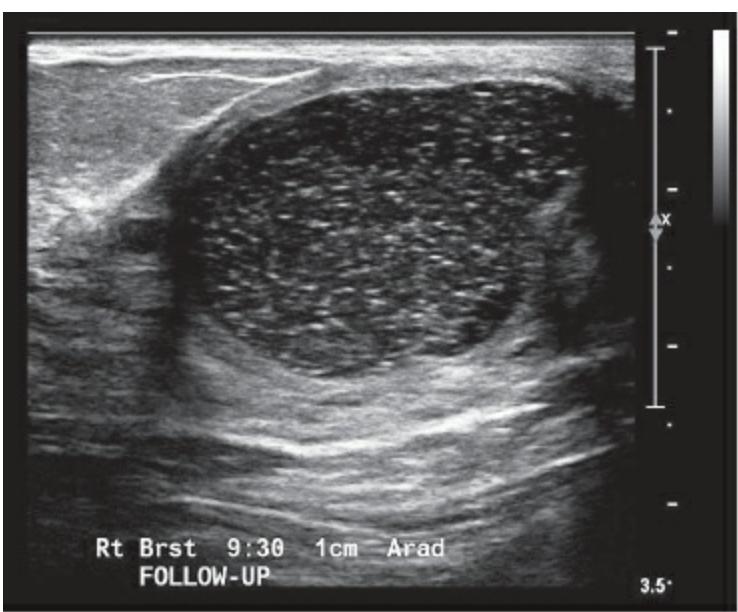
Figure 123 — CLUSTERED MICROCYSTS. This 44-year-old woman who had multiple bilateral simple and complicated cysts (not shown), also has a grouping of CLUSTERED MICROCYSTS found incidentally (*orthogonal views, a and b*) during supplementary US screening. Assessment was benign (category 2), given the multiplicity and bilaterality of these findings.

E. SPECIAL CASES

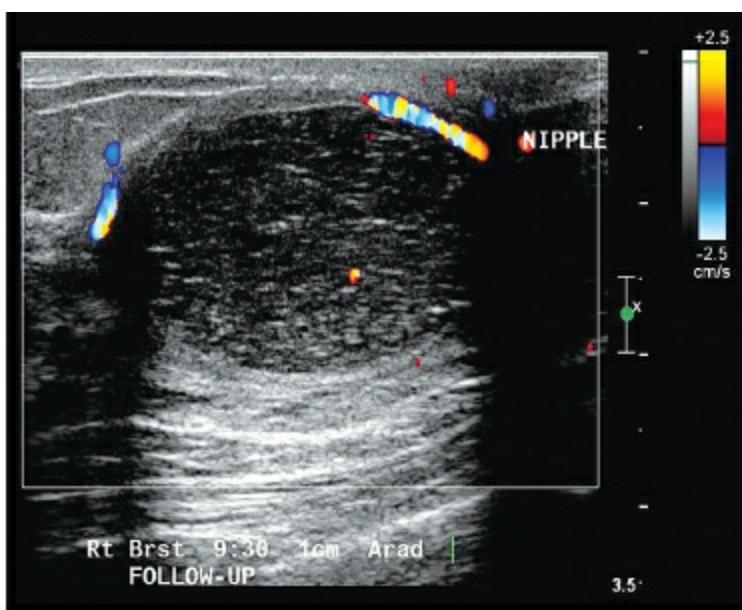
3. COMPLICATED CYST

These are cysts that contain debris, often manifest as homogeneous, low-level echoes, without a discrete solid component, and with an imperceptible wall. At real-time scanning, these echoes may have a layered appearance that may shift slowly with changes in the patient's position. A complicated cyst also may contain echogenic foci that appear to scintillate as they shift in position.

Note: The presence of a discrete solid component (including solid mural nodules) should cause what otherwise might be considered a complicated cyst to be described as a “complex cystic and solid” mass. In the past, “complicated” and “complex cystic and solid” masses were confused, because this important distinction was not respected in the reporting.



A



B

Figure 124 — COMPLICATED CYST. A 56-year-old woman with palpable mass just lateral to the nipple. This COMPLICATED CYST fulfills all of the sonographic criteria that define a simple cyst except that it contains low-level echoes throughout (a). Note the visible rim vascularity (b).

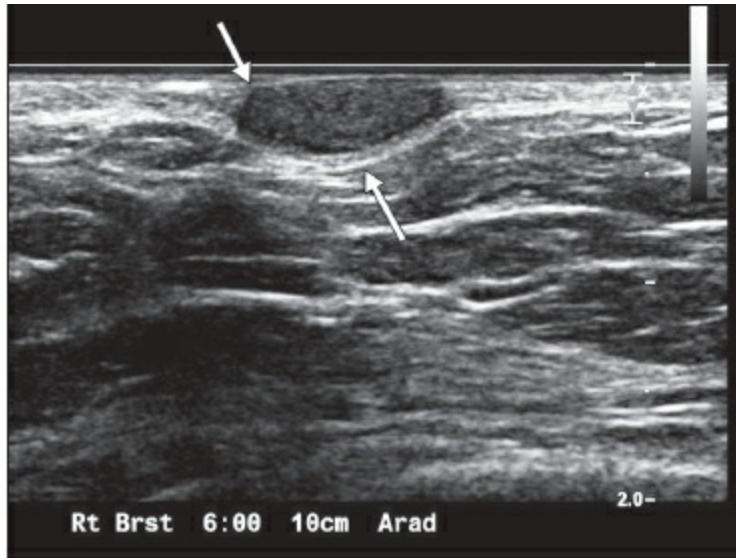
E. SPECIAL CASES

4. MASS IN OR ON SKIN

These benign masses are usually clinically apparent and include sebaceous or epidermal inclusion cysts, keloids, moles, pimples, neurofibromas, and accessory nipples. Rarely, a mass in the skin is found to be a metastasis, particularly in the setting of a mastectomy scar; but then, clinical information about the primary tumor should be available to guide image interpretation. It is important to recognize the interface between skin and parenchyma and to establish that the mass is at least partially within the two thin echogenic bands of skin.



A



B

Figure 125 — MASS IN OR ON SKIN. Sebaceous cyst has formed between the two layers of skin (*a* and *b*, orthogonal views). The skin layers enclosing the mass are best seen on (*b*, arrows). With use of a gel offset or offset pad, a stalk can sometimes be seen through which the fatty contents of a sebaceous cyst are occasionally extruded.

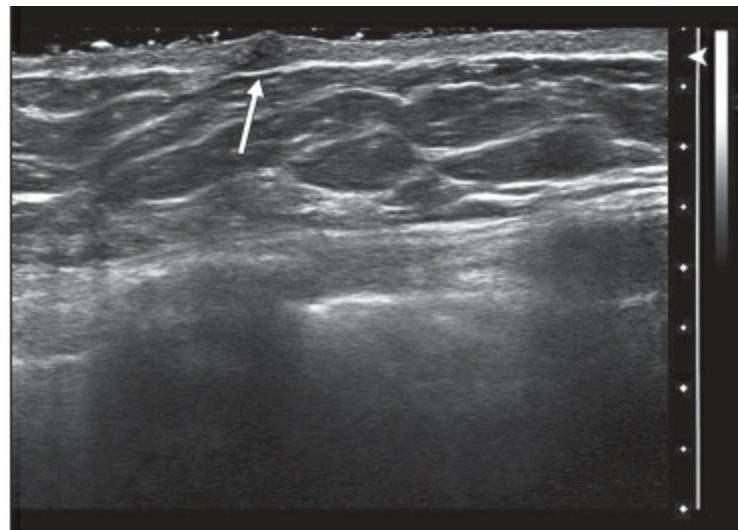


Figure 126 — MASS IN OR ON SKIN. An accessory nipple (arrow) may form along each of the embryonic milk lines that extend from axilla to groin.

E. SPECIAL CASES

5. FOREIGN BODY INCLUDING IMPLANTS

Foreign bodies include marker clips, coils, wires, catheter sleeves, injected or leaked silicone, metal or glass related to trauma, and implants. History is usually helpful in establishing the presence and nature of foreign matter within the patient. Silicone within the parenchyma has a characteristic “snowstorm” appearance at US, depicted as echogenic noise, which propagates posterior to the mass and obscures deep structures. Extravasated silicone or silicone gel bleed can travel through lymphatics and lodge in lymph nodes, which then exhibit similar characteristics.

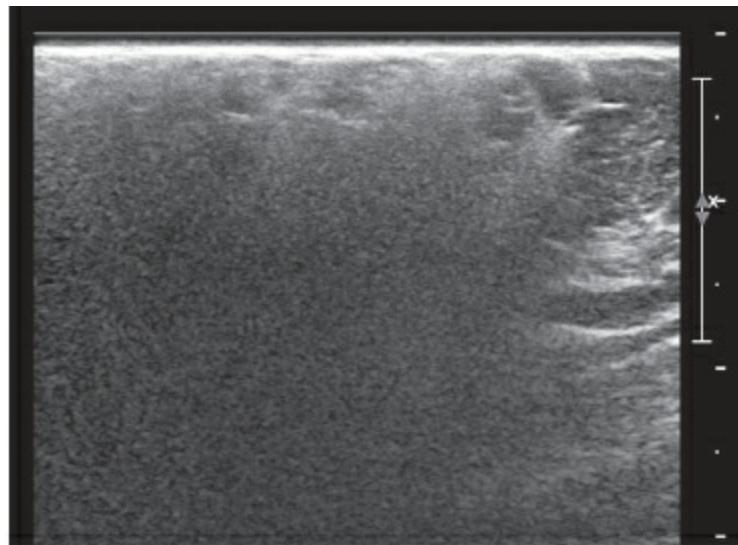


Figure 127 — FOREIGN BODY INCLUDING IMPLANTS. A 39-year-old patient who had injections of free silicone into her breasts at the age of 20. She began feeling masses in her breasts 1 year later but does not think they have changed. US shows marked attenuation of sound, as well as a "snowstorm" pattern or echogenic noise.

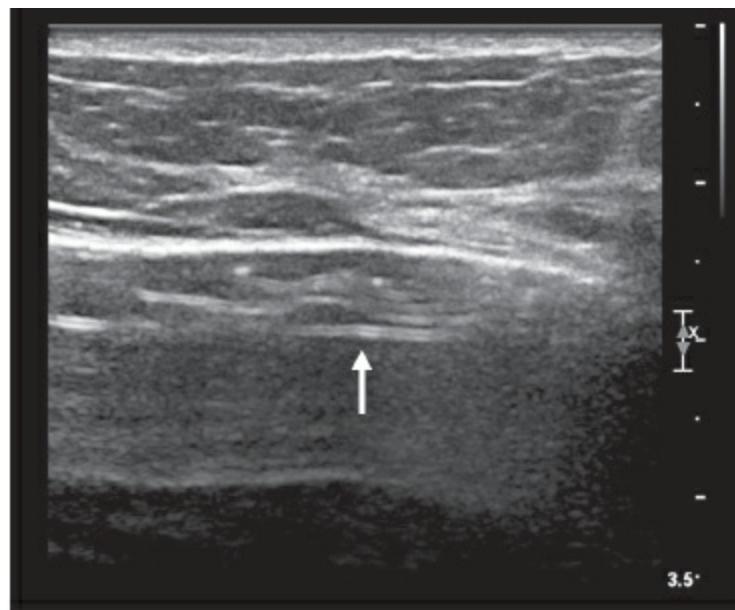


Figure 128 — FOREIGN BODY INCLUDING IMPLANTS. This 55-year-old woman had retroglandular silicone implants placed 30 years earlier. On radial US, performed to assess a parenchymal abnormality (not included), collapsed layers of the silicone implant shell were noted (the "stepladder sign"), indicative of intracapsular rupture (arrow). This is a benign finding, BI-RADS® category 2, but should be included in the report.

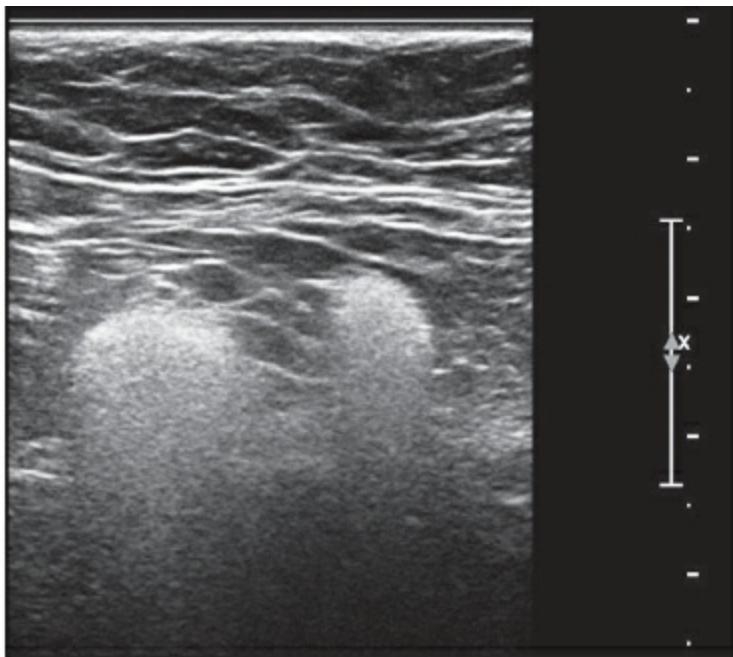


Figure 129 — FOREIGN BODY INCLUDING IMPLANTS. Silicone uptake in lymph nodes within the pectoral muscle. Given the pertinent clinical history of previous placement of a silicone implant, no interventional procedure is necessary to establish the diagnosis of extracapsular silicone.

E. SPECIAL CASES

6. LYMPH NODES — INTRAMAMMARY

These are circumscribed oval masses that often are reniform and contain hilar fat. Lymph nodes exist throughout the breast, but they are most commonly seen in the upper outer quadrant (especially the axillary tail) because they normally are larger the closer they are located to the axilla. The usual size of normal intramammary lymph nodes ranges from 3 to 4 mm up to approximately 1 cm. Whether present within the breast or axilla, lymph nodes have a distinctive appearance, with a hypoechoic cortex and echogenic fatty hilus.

When the typical features of an intramammary lymph node are depicted, the finding may be considered to be characteristically benign.

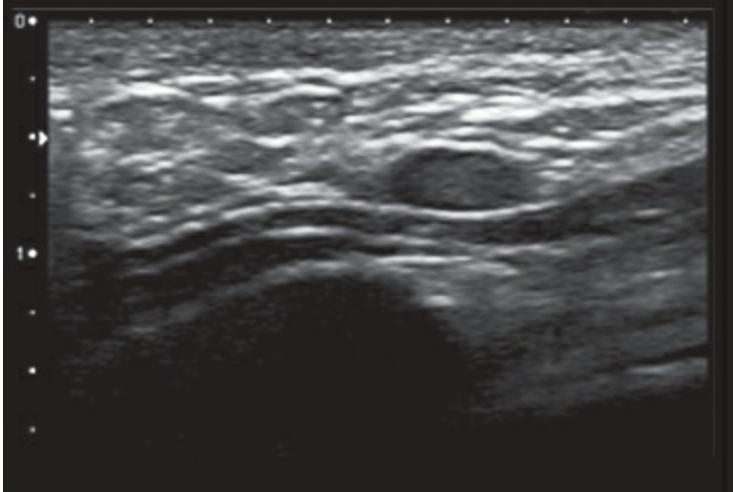
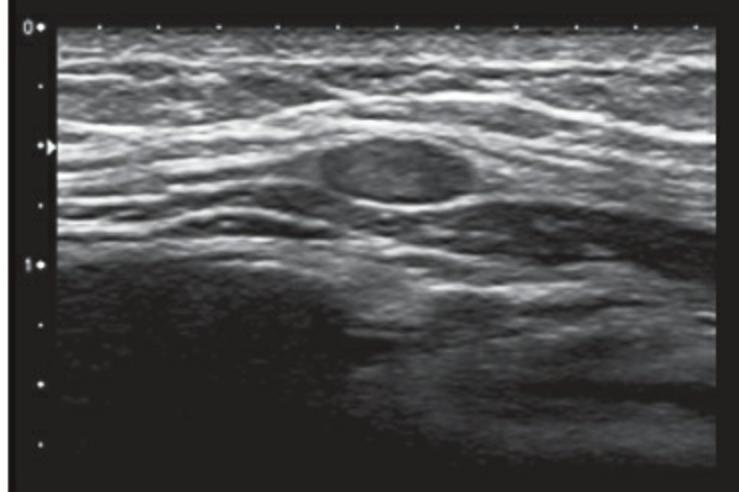
**A****B**

Figure 130 — LYMPH NODES — INTRAMAMMARY. Small, enhancing, oval mass on MR thought to be an INTRAMAMMARY LYMPH NODE is confirmed on MRI-directed US examination. The hypoechoic cortex and echogenic hilus are identifiable on orthogonal views (*a* and *b*).

E. SPECIAL CASES

7. LYMPH NODES — AXILLARY

Enlarged axillary lymph nodes may warrant comment, clinical correlation, and additional evaluation, especially if they are new or considerably larger or rounder when compared to previous examination. Although there is no specific agreed-upon measurement, a normal axillary lymph node may be up to 2 cm in its longest dimension and contain hyperechoic fatty hilar areas. Lymph nodes much larger than 2 cm may be normal when a very thin cortical rim is seen around a massive collection of hilar fat. A lymph node with no fatty hilum or with a compressed fatty hilum may be abnormal, whereas depiction of a cortical bulge or cortical area of altered echogenicity suggests the presence of metastasis. However, there is no specific sonographic feature that reliably distinguishes a nodal metastasis from a benign reactive node. Because of individual variability in the size and number of axillary lymph nodes, assessment of side-to-side symmetry may be helpful.

Following is an outline of the parameters that may be used to characterize a lymph node at US:

- a. Size
- b. Shape
 - i. Oval
 - ii. Round
 - iii. Irregular

c. Cortical thickening

i. Uniform, concentric: be wary of oblique angle of insonation as the explanation for cortical thickening, both concentric and focal. Real-time scanning should help distinguish true cortical thickening.

ii. Focal

d. Margin

i. Circumscribed

ii. Not circumscribed

e. Hilar compression or displacement

Note that the presence of fat in a nodal hilus does not exclude metastatic involvement; the hilar fat may be compressed and displaced by the metastasis. Replacement of a node by tumor may be gradual and best detected by interval change. However, images of normal-appearing lymph nodes in an axilla rarely are recorded at US (because they are characteristically benign), so it may not be possible to assess for interval sonographic change. On the other hand, increasing nodal size at mammography may be a cause for concern and underlie a recommendation for biopsy. In this case, it is important to measure the node in the same, or similar, projection on the current and previous mammograms.

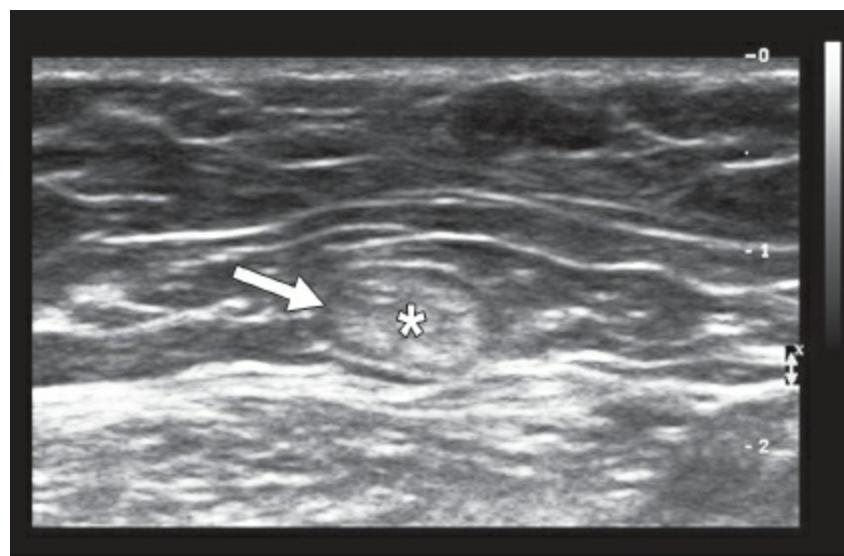


Figure 131 — LYMPH NODES — AXILLARY. Small, benign AXILLARY LYMPH NODE with very thin cortex (arrow) and large area of hilar fat (asterisk).

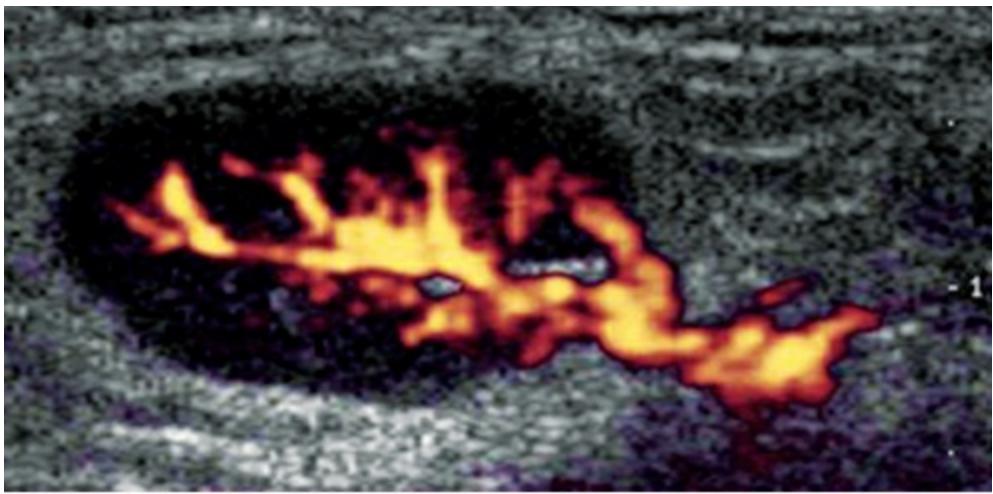
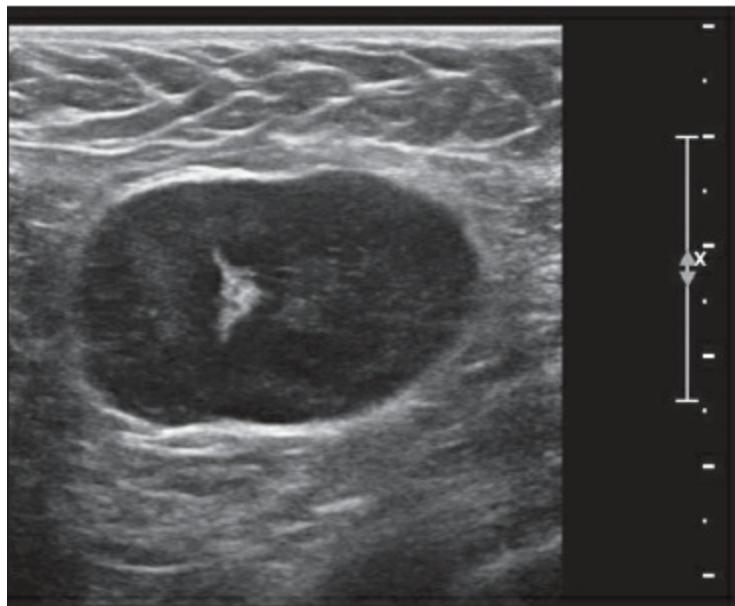
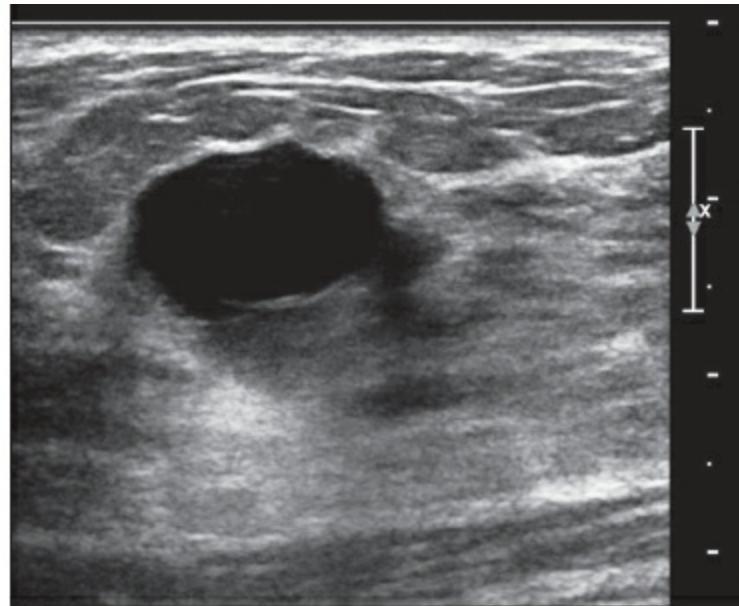


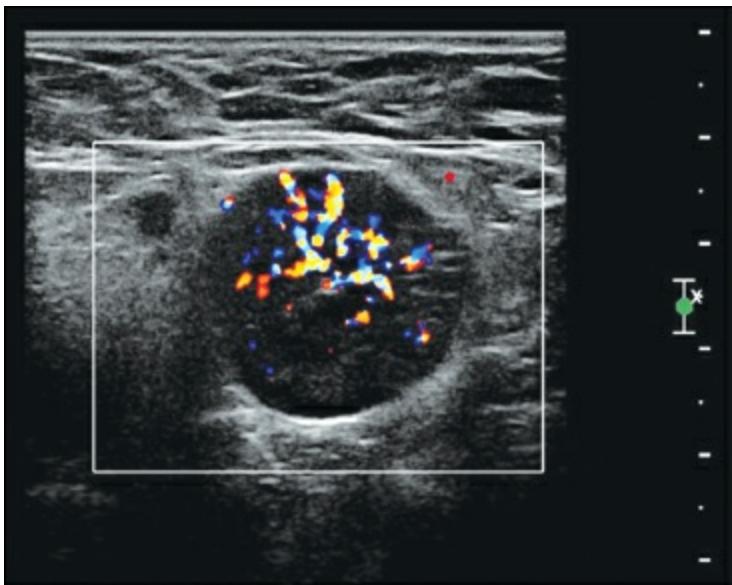
Figure 132 — LYMPH NODES — AXILLARY. Exuberant blood supply to a benign, reactive AXILLARY LYMPH NODE is shown on this power Doppler image. Blood vessels are depicted entering the nodal hilus and arborizing into the cortex.



A



B



C

Figure 133 — LYMPH NODES — AXILLARY. Orthogonal US views of an AXILLARY LYMPH NODE (a and b) with very thick cortex and compression of hilar fat, due to metastasis from ipsilateral invasive ductal carcinoma, grade 3, in a 42-year-old woman. Cortical vascularity is shown on color Doppler image (c).

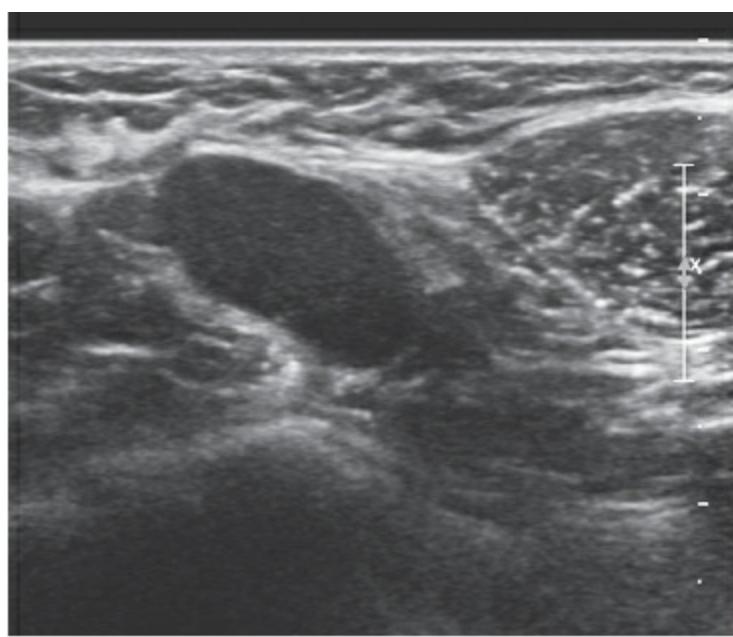


Figure 134 — LYMPH NODES — AXILLARY. AXILLARY LYMPH NODE completely replaced by metastasis from invasive ductal carcinoma. No hilar fat remains. The reniform shape and normal size of the node are retained.

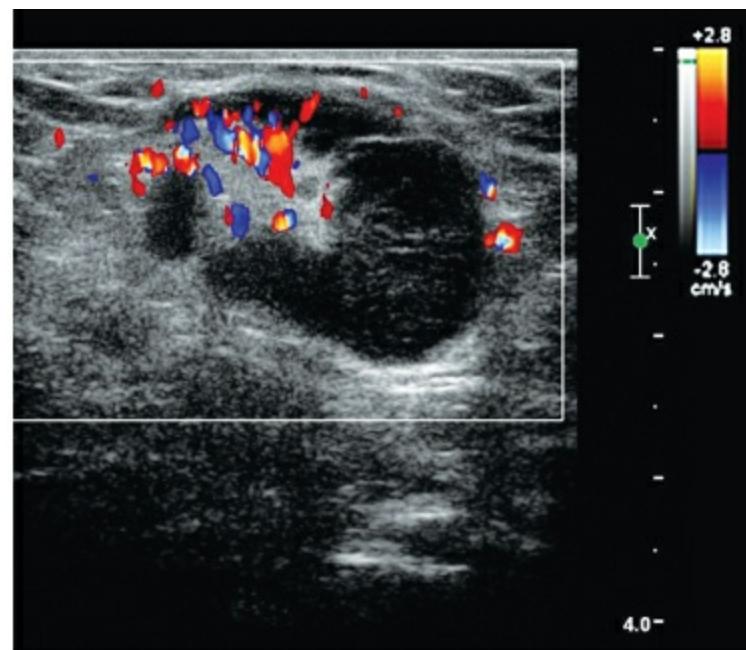
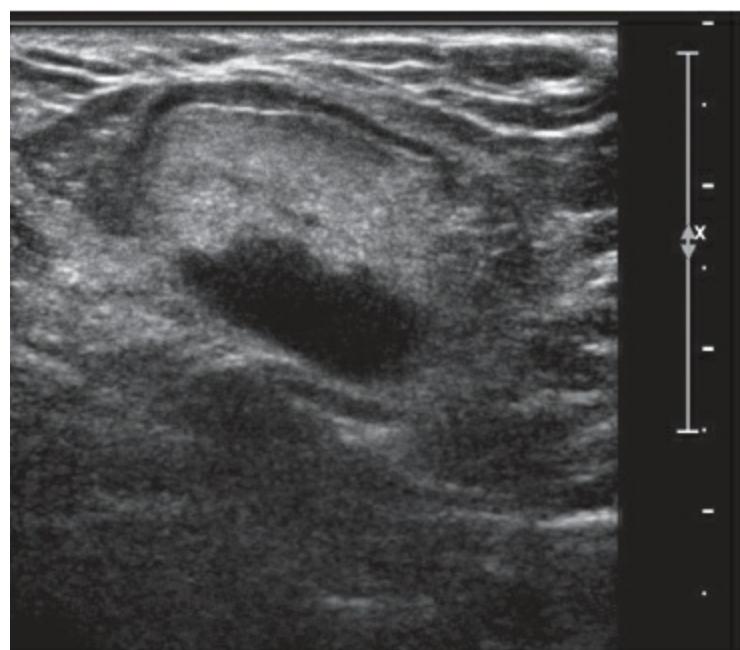


Figure 135 — LYMPH NODES — AXILLARY. Metastatic involvement of this LYMPH NODE (a) B-mode; (b) color Doppler, showing eccentric focal cortical thickening with a large area of hilar fat compressed by the cortical metastasis. The focal metastasis shows decreased echogenicity, and vascularity is absent (b).

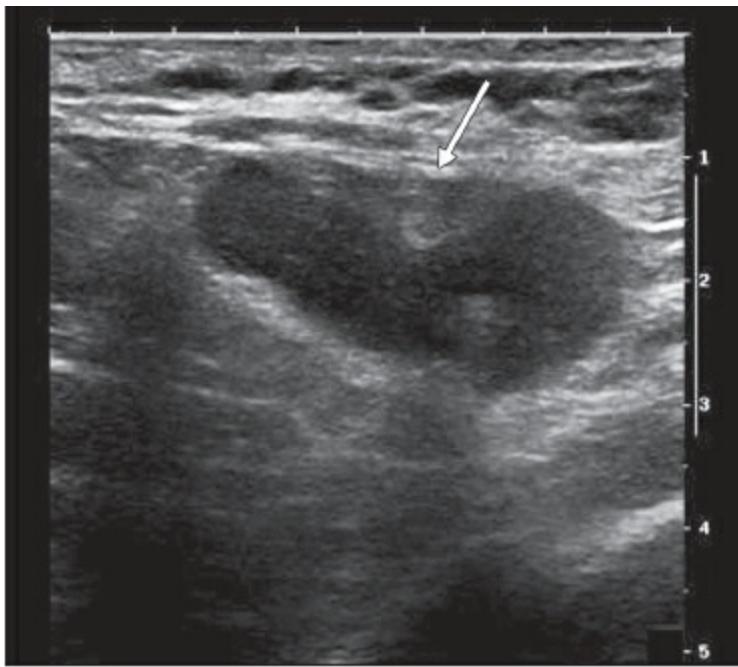
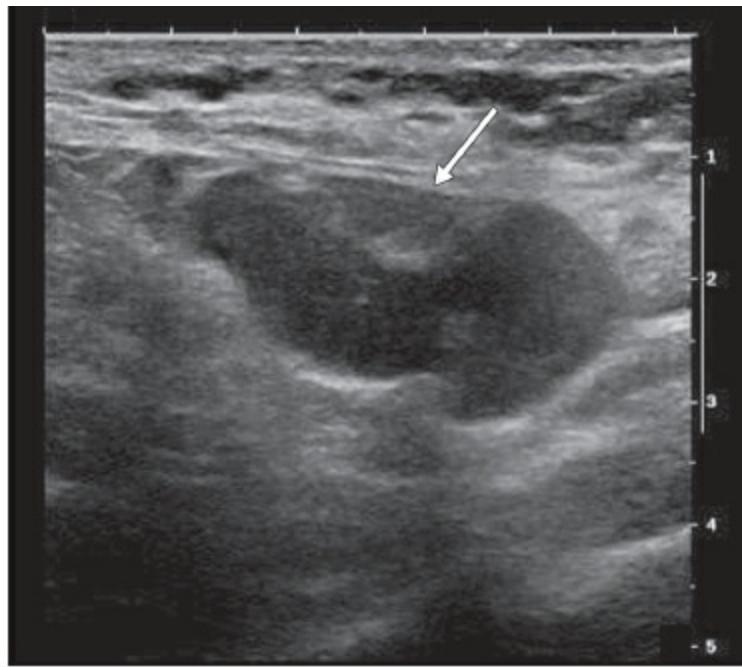
**A****B**

Figure 136 — LYMPH NODES — AXILLARY. Two US views (*a* and *b*) of this AXILLARY LYMPH NODE metastasis in a woman with invasive ductal carcinoma show thickened cortex at the periphery of the node, except anteriorly where a remnant of hilar fat is visible (arrows).

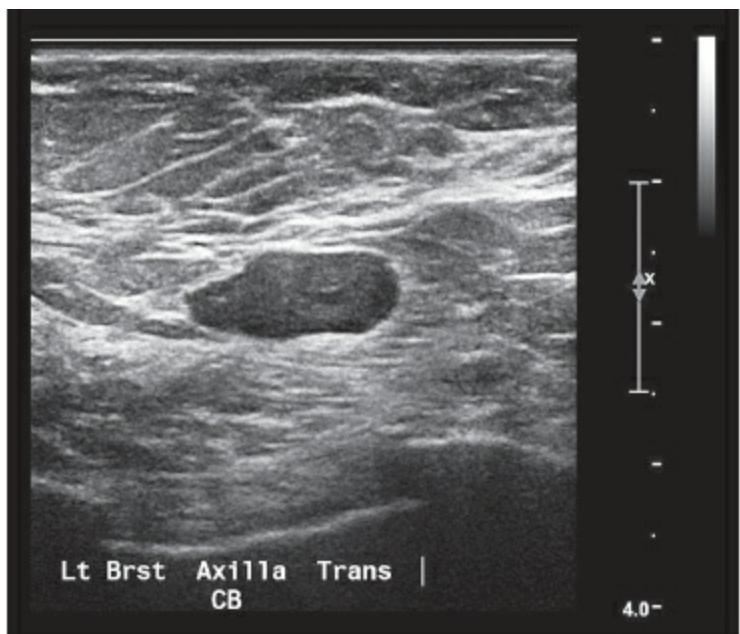
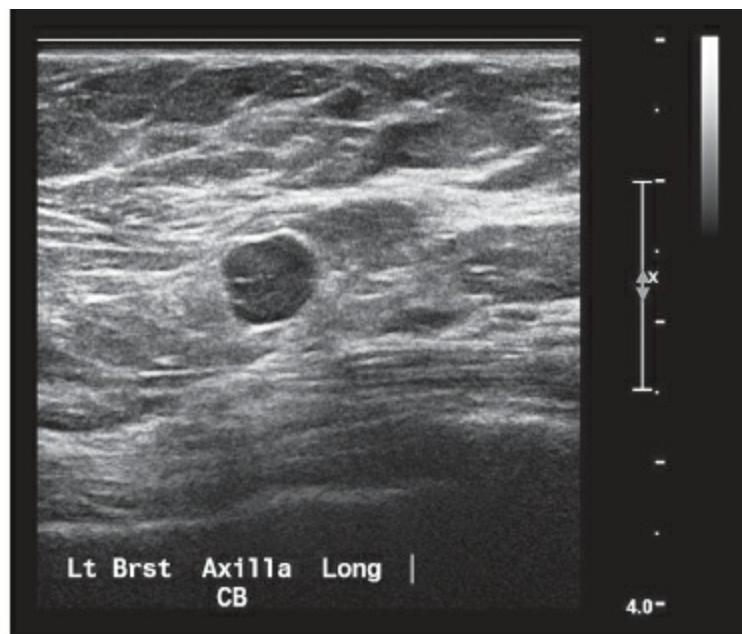
**A****B**

Figure 137 — LYMPH NODES — AXILLARY. A 43-year-old woman with newly diagnosed invasive ductal carcinoma, grade 2, and ductal carcinoma in situ, grade 3. Core biopsy of this AXILLARY LYMPH NODE confirmed metastatic involvement. Note the absence of hilar fat and nonreniform shape. This lymph node could be mistaken for a benign-appearing mass, such as a fibroadenoma, in the axillary tail.

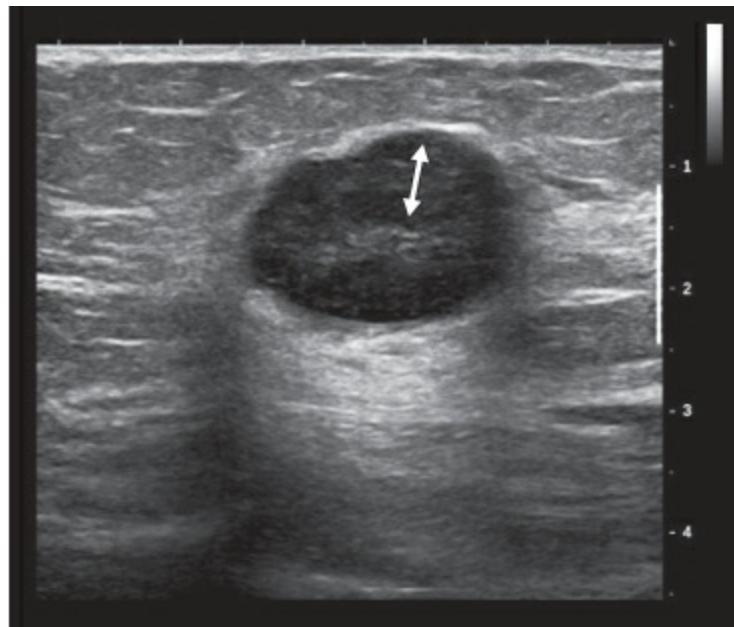


Figure 138 — LYMPH NODES — AXILLARY. Hilar fat is compressed by metastatic involvement of the markedly thickened cortex (*double arrow*). Core biopsy histopathology of AXILLARY LYMPH NODE: totally replaced by invasive ductal carcinoma, grade 3.

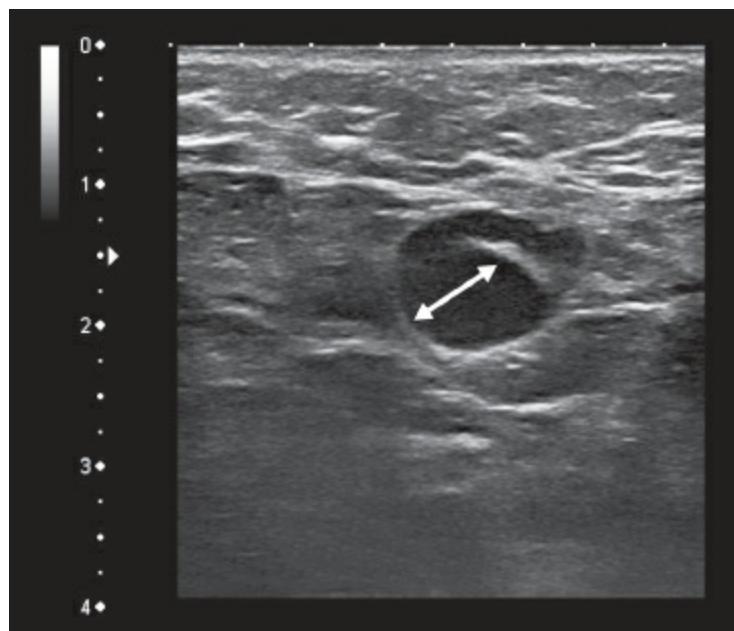
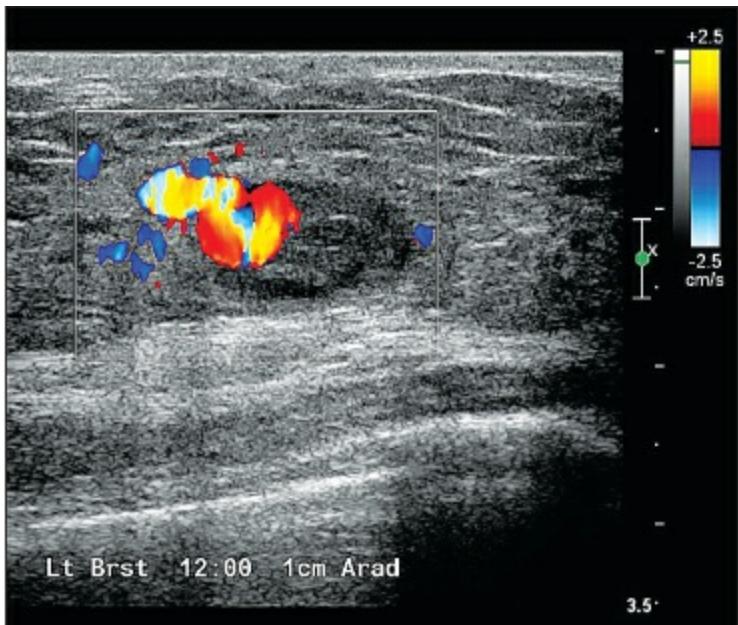


Figure 139 — LYMPH NODES — AXILLARY. There is marked cortical thickening of the posterior aspect of this AXILLARY LYMPH NODE (*double arrow*), with compression of the more anterior hilar fat into a thin crescent. Histopathology: metastasis from invasive ductal carcinoma, grade 3.

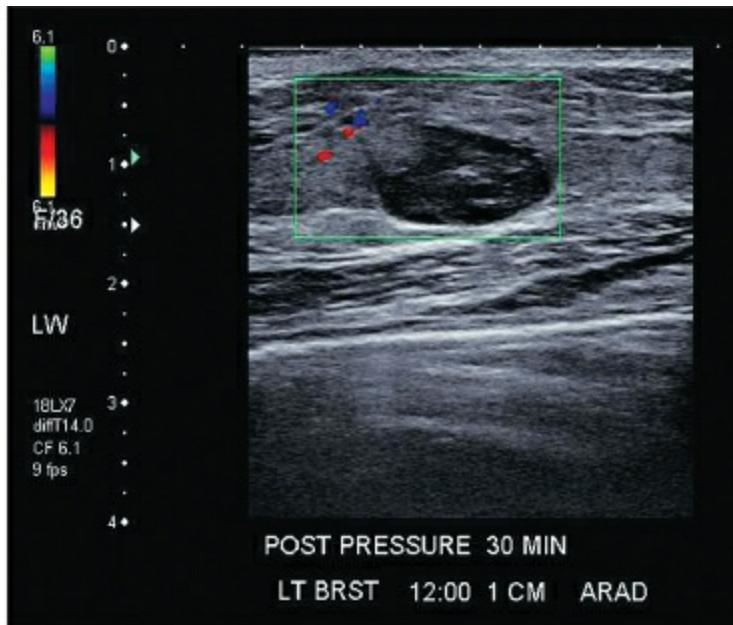
E. SPECIAL CASES

8. VASCULAR ABNORMALITIES

a. AVMs (Arteriovenous Malformations/Pseudoaneurysms)



A



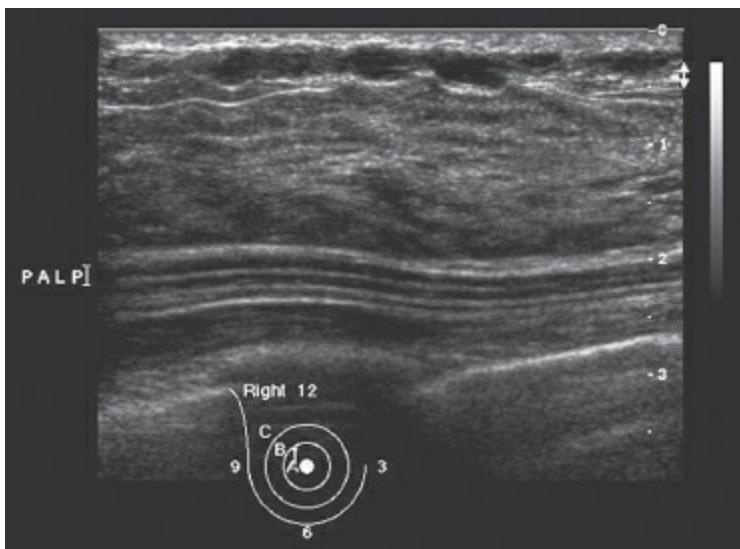
B

Figure 140 — VASCULAR ABNORMALITIES: AVMs (ARTERIOVENOUS MALFORMATIONS/ PSEUDOANEURYSMS). A rare complication, this pseudoaneurysm developed after a stereotactically-guided vacuum-assisted biopsy of microcalcifications (a). After 30 minutes of direct compression over the site, thrombosis was successful (b). The patient had no further problems.

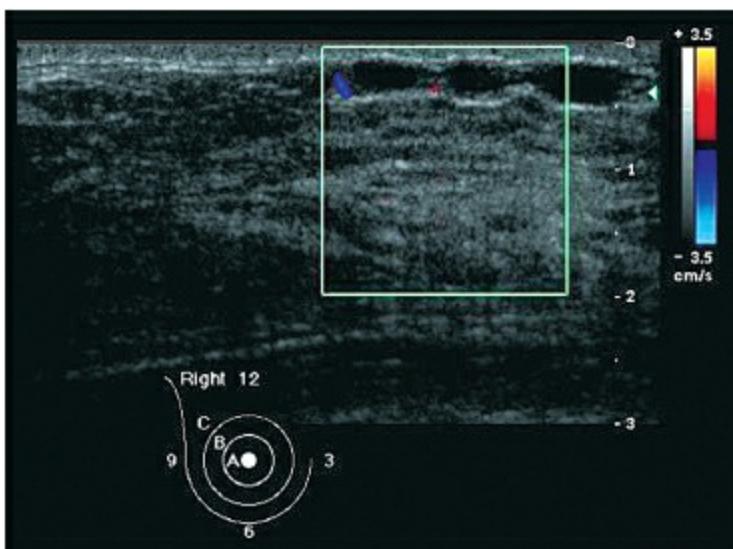
E. SPECIAL CASES

8. VASCULAR ABNORMALITIES

b. Mondor Disease



A



B

Figure 141 — VASCULAR ABNORMALITIES: MONDOR DISEASE. This 23-year-old woman developed a painful cord in the right axillary tail. The cause was a thrombosed superficial lateral thoracic vein, seen in long axis just beneath the skin (a). Color Doppler image (b) showing essentially no vascular flow within the vein confirms the diagnosis. MONDOR DISEASE is self-limited and does not require anticoagulation.

E. SPECIAL CASES

9. POSTSURGICAL FLUID COLLECTION

(For implants, see *Special Cases, item 5: Foreign Body*). The only postsurgical sonographic findings that are characteristically benign involve fluid collections, especially postoperative seroma (entirely cystic, however, at times, also containing retained blood products that are mobile on real-time evaluation). Most other postsurgical findings, especially those involving scar tissue, usually display suspicious sonographic findings, such as posterior shadowing, hypoechoicity, an irregular and occasionally spiculated lateral margin, and architectural distortion. To avoid unnecessary biopsy, interpretation of breast imaging studies of the treated breast should be made with reference to clinical history of previous surgery, with a skin scar apparent by visual inspection at the location of the sonographic findings or a linear scar marker placed on the skin at the site of incision with a mammographic view tangential to the scar marker that correlated with US findings. The histopathology of the tumor, marginal status at the time of excision, and history of radiation therapy and chemotherapy should also be taken into account when imaging findings are interpreted. Comparison with previous studies is crucial for accuracy in follow-up.

Postsurgical scars commonly evolve over time, usually contracting as they develop marginal irregularity and spiculation; these interval changes are observed much more commonly at mammography than at US because postsurgical mammography is performed much more frequently than US. The common postsurgical changes of edema and skin thickening, which tend to decrease in extent and severity over time, are depicted equally well at mammography and US, and in this context are considered to be benign. The remaining postsurgical changes that are visible at US are more accurately assessed at mammography. This includes almost all cases of fat necrosis, because the oil cyst is characteristically benign at mammography (but not at US), whether solitary or multiple, whether calcified or noncalcified. Hence, when fat necrosis is suspected at US, and when other more suspicious sonographic features are displayed that potentially represent fat necrosis, the next step before rendering a final assessment should be correlation with a concurrent mammography examination that likely will justify a benign (category 2) assessment that cannot be made at US.

E. SPECIAL CASES

9. POSTSURGICAL FLUID COLLECTION

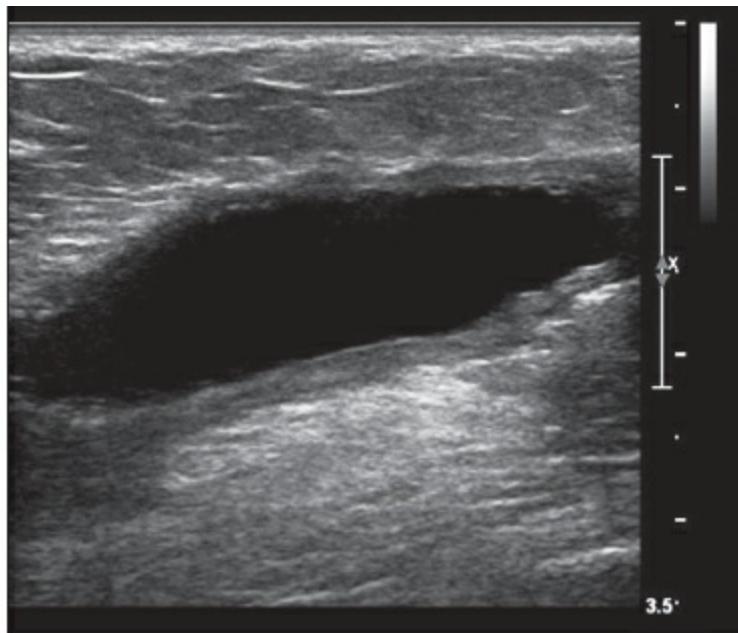
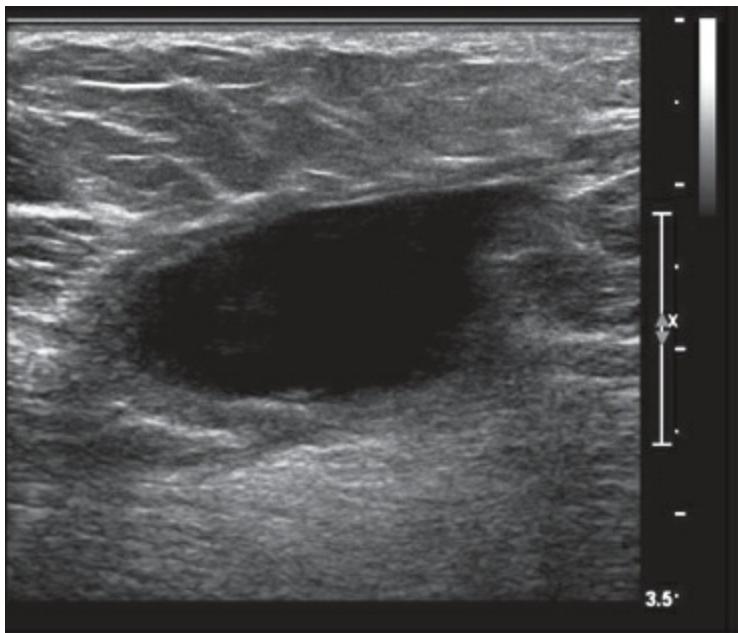
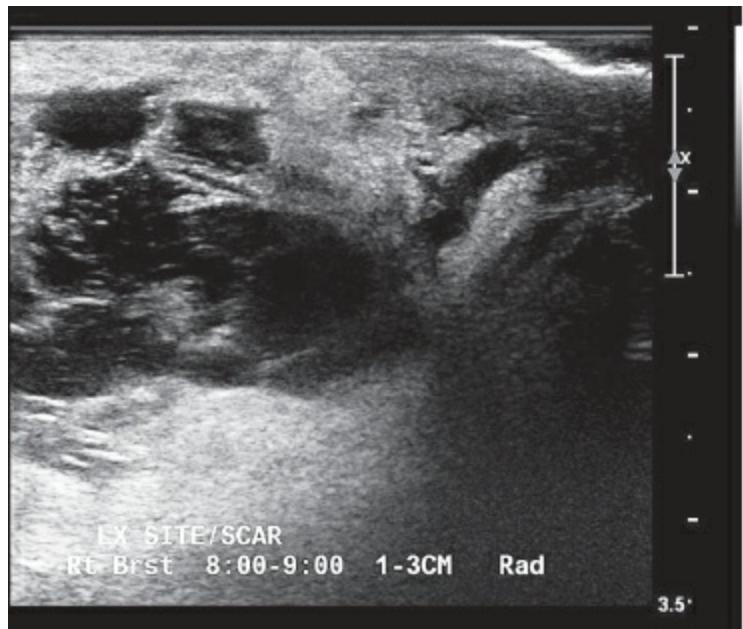
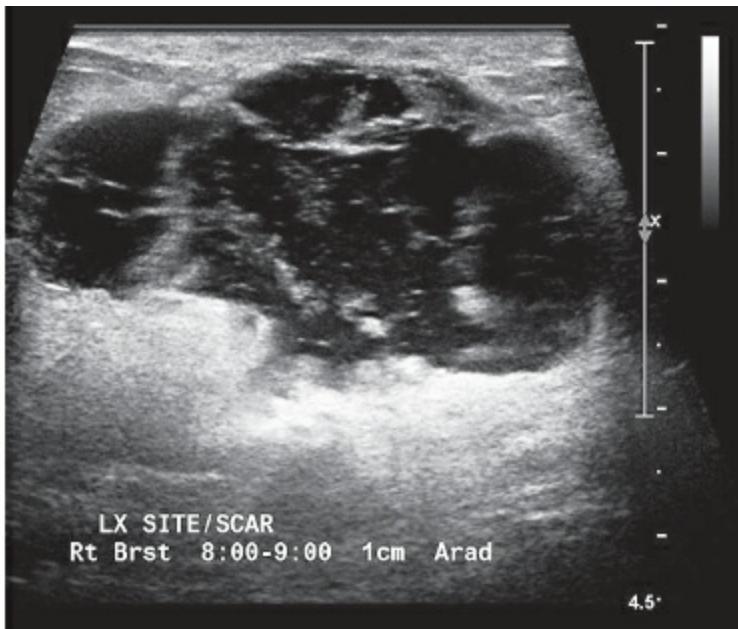


Figure 142 — POSTSURGICAL FLUID COLLECTION. Six months after lumpectomy and radiation therapy for invasive and intraductal carcinoma, grade 2, baseline post-treatment imaging of a 79-year-old woman shows elliptical FLUID COLLECTION on orthogonal US views. The thickened wall of the seroma on the US images is of no significance.



A

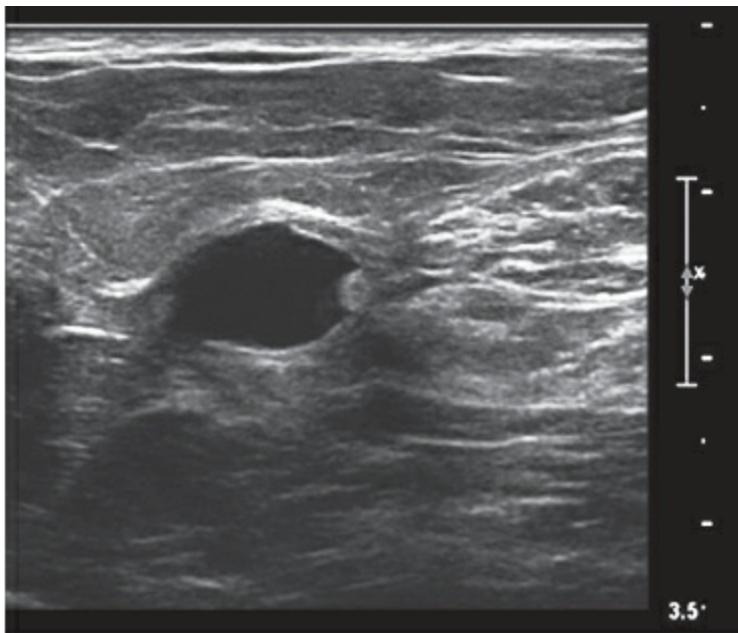


B

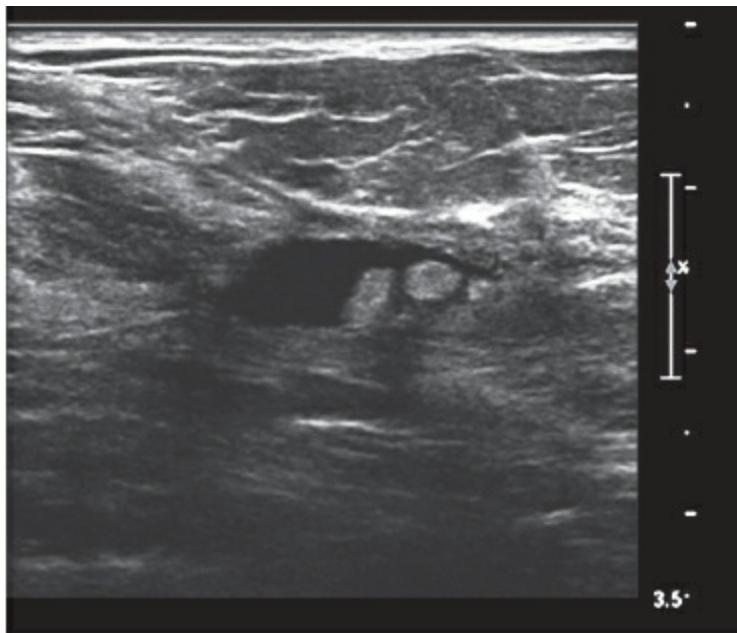
Figure 143 — POSTSURGICAL FLUID COLLECTION. Postoperative FLUID COLLECTION in a 66-year-old woman who had surgical excision of an invasive ductal carcinoma, grade 3, with 10 mm margins. Ductal carcinoma in situ, however, was present within 1 mm of the anterior, posterior, and lateral margins. Four weeks after surgery, rectangular and trapezoidal images (a and b respectively) show a large postoperative fluid collection, the septa and areas of hyperechogenicity reflecting maturing blood products in a serosanguinous collection, for which no intervention was necessary. Assessment is benign (category 2), based on clinical information that this collection developed following surgical excision.

E. SPECIAL CASES

10. FAT NECROSIS



A



B

Figure 144 — FAT NECROSIS. Early FAT NECROSIS in postoperative fluid collection is manifested by an oil cyst and architectural distortion (a and b) with three echogenic lipid nodules seen within the cyst (b).

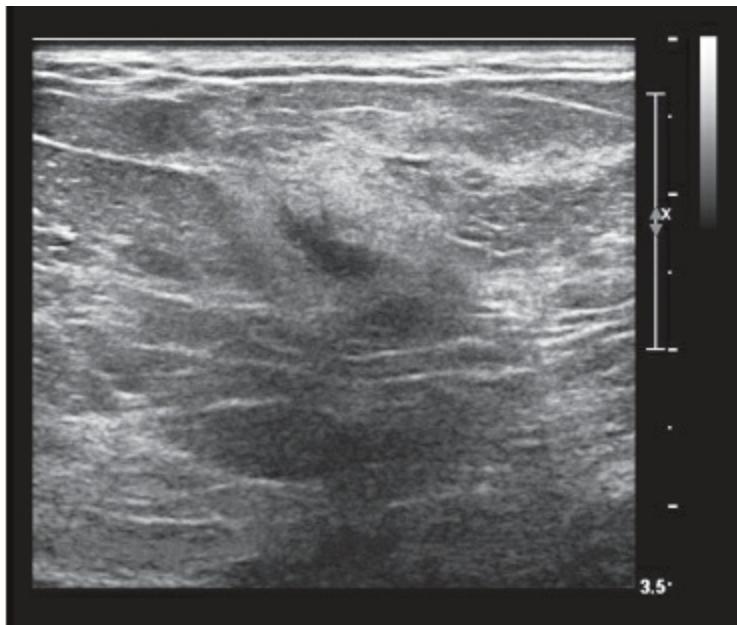
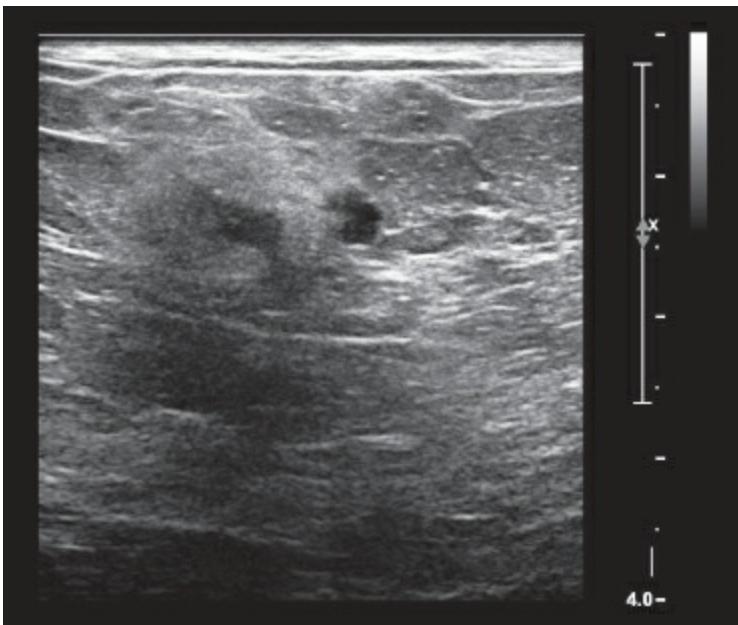
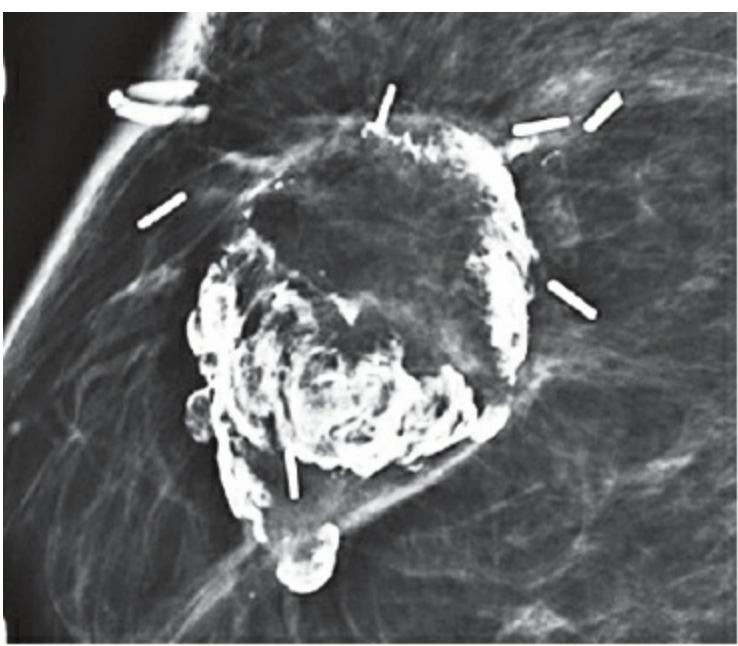
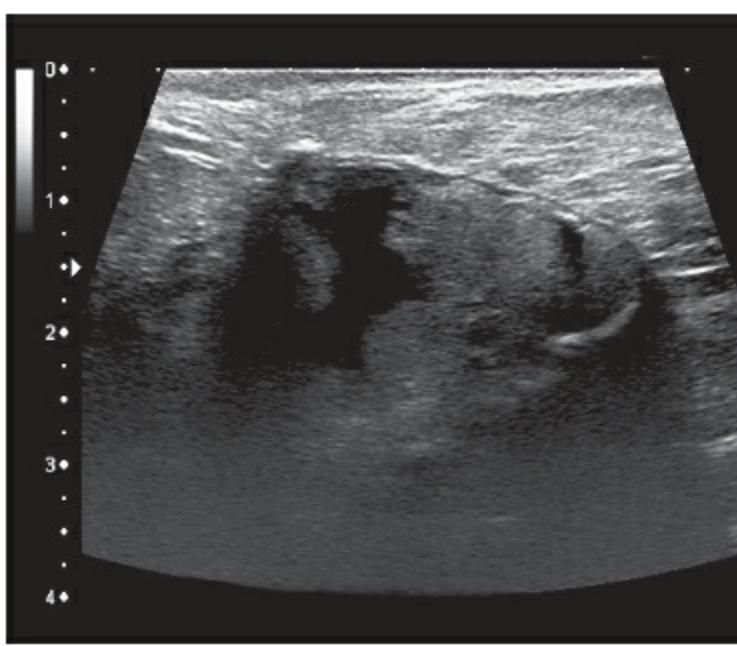


Figure 145 — FAT NECROSIS. FAT NECROSIS developing in an area of a breast hematoma is observed in this 62-year-old woman whose breast remained ecchymotic 1 month after an automobile accident with airbag injury to her right breast. BI-RADS® assessment was 3, probably benign, and when she returned 6 months later, physical, mammographic, and US findings had resolved (not shown).



A



B

Figure 146 — FAT NECROSIS. Five years earlier, this 77-year-old patient had undergone lumpectomy for invasive carcinoma, grade 1, with placement of a balloon catheter for partial breast irradiation. Follow-up imaging showed no sign of recurrence on tangential mammographic spot-compression view. The rim calcification surrounding the oil cyst of FAT NECROSIS at mammography (characteristically benign) (a) caused posterior shadowing at US (b), as well as the V-shaped incision at the skin.

III. Reporting System

A. REPORT ORGANIZATION

The report should be concise and organized using a structure such as that provided in [Table 2](#). Assessments and management recommendations are discussed in item B of this chapter on the reporting system, as well as in the Guidance chapter and in answer to some specific questions among the Frequently Asked Questions.

The indication for examination, relevant clinical history, and pertinent risk factor information should be clearly stated. If the study is performed for follow-up of a specific mass or area of concern, this should be described. The dates of any comparison examinations should be specified. As detailed in the General Considerations section on [Labeling and Measurement](#), when a specific sonographic finding is documented by recording a complete set of images, the longest horizontal dimension should be reported first, followed by the vertical measurement, and the orthogonal horizontal dimension last. Multiple simple cysts or a combination of multiple simple and complicated cysts need not be reported individually. If any lesions have been biopsied previously, this should be noted together with the prior biopsy results, if known. Correlation of any clinical, mammographic, and MRI findings with the sonographic findings should be specifically stated in the report. For diagnostic evaluations involving US characterization of mammographic abnormalities or confirmation of a mass suspected but not delineated mammographically, a single report integrating the two modalities will clearly communicate a final assessment based on the highest likelihood of malignancy and appropriate management recommendations.

Table 2. Report Organization

Report Structure
1. Indication for examination
2. Statement of scope and technique of breast US examination
3. Succinct description of the overall breast composition (screening only)
4. Clear description of any important findings
5. Comparison to previous examination(s), including correlation with physical, mammography, or MRI findings
6. Composite reports
7. Assessment
8. Management

Consistent use of BI-RADS® descriptors for US, as for mammography and MRI, helps in lesion assessment and clarifies communication with physicians and patients. Also,

structured, software-based reporting should be based on BI-RADS® terminology.

For coding and reimbursement, consider the advisability of splitting the report combining the findings of two or more concurrently performed imaging modalities or procedures into specific sections or paragraphs, one for each type of examination. However, a single assessment and recommendation for patient management should reflect integration of the findings from all of the imaging studies. Note that an assessment based on specific findings needing most urgent attention will have the greatest clinical utility.

1. INDICATION FOR EXAMINATION

The reason for performing the examination should be stated briefly at the beginning of the report. The most common indications for breast US are confirmation and characterization of a palpable mass or mammographic or MRI abnormality, guidance of interventional procedures, and as the initial imaging technique for young, pregnant, or lactating patients. Additional applications are listed in the [ACR Practice Guideline for the Performance of the Breast Ultrasound Examination](#) and include the extent of disease evaluation supplementing mammography in high-risk women who are not candidates for breast MRI or who have no easy access to MRI, and in breast imaging practices that provide the service, supplementary whole-breast screening in order to increase cancer detection in asymptomatic women with mammographically dense breasts.

2. STATEMENT OF SCOPE AND TECHNIQUE OF BREAST US EXAMINATION

The scope of examination and technique used should be stated, for example, whether the examination was directed or targeted to a specific location, or whether it was performed for supplementary screening. It is important, since US is a real-time examination, to indicate who performed the examination (sonographer, sonographer and physician, physician alone) or whether an automated whole-breast scanning system was used. If a lesion was evaluated with color or power Doppler or with strain or shear-wave elastography, observations relevant to the interpretation should be reported.

In certain situations, it may be beneficial to describe the position of the patient during the examination (e.g., "The breasts were imaged in both supine and lateral decubitus position." or "The patient was imaged in seated position, the position in which she feels the left breast thickening best.").

Automated whole breast scanners that acquire in 3-D are available for clinical use and can be formatted in three planes. These scanners depict the entire breast in coronal, transverse, and sagittal planes, with the coronal view similar to the coronal MRI view. Reporting of these studies continue to evolve, but where possible the interpretation

structure outlined in [Table 2](#) and the reporting procedures described earlier in this section should be followed.

3. SUCCINCT DESCRIPTION OF THE OVERALL BREAST COMPOSITION (screening only)

Tissue composition patterns can be estimated more easily in the large FOVs of automated US scans but can also be discerned in the small FOV of a handheld US scan. The three US descriptors for tissue composition described earlier in the US lexicon, "homogeneous background echotexture-fat," "homogeneous background echotexture-fibroglandular," and "heterogeneous background echotexture" ([Table 3](#)) correspond loosely to the four density descriptors of mammography and the four fibroglandular tissue descriptors of MRI. At US, breast tissue composition is determined by echogenicity. Subcutaneous fat, the tissue relative to which echogenicity is compared, is medium gray and darker than fibroglandular tissue, which is light gray. Heterogeneous breasts show an admixture of hypoechoic and more echogenic areas. Careful real-time scanning will help differentiate a small hypoechoic area of normal tissue from a mass.

Table 3. Breast Tissue

Tissue Composition
a. Homogeneous background echotexture-fat
b. Homogeneous background echotexture-fibroglandular
c. Heterogeneous background echotexture

4. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

The description of important findings should be made, in order of clinical relevance, using lexicon terminology, and should include:

- a. Characterization of a mass using the morphological descriptors of shape, margin, and orientation. Note should be made of the lesion's effect on the surrounding tissue, such as architectural distortion. Feature categories, such as posterior features and echogenicity, and techniques, such as color or power Doppler and elastography, may contribute information to the analysis, but only pertinent positives need to be described. Recognition of special case findings, such as simple and complicated cysts, clustered microcysts, intramammary lymph nodes, and foreign bodies, should simplify interpretation. In reporting screening examinations in asymptomatic women, as in mammography, characteristically benign findings may be reported (assessment category 2), but it is not obligatory, and the appropriate assessment would then be negative (assessment category 1).
- b. For important findings, lesion size should be given in at least two dimensions; three dimensions are preferable, especially if the volume of a mass is compared with one or

more previous examinations. It is not necessary to report the measurements of every small simple cyst, and if numerous cysts are present, especially in both breasts; location and measurements of the largest cyst in each breast will suffice.

If a mass is measured, images should be recorded with and without calipers. Marginal characteristics are one of the most important criteria to be applied in assessing the likelihood of malignancy of a mass, and, particularly with small masses, caliper markings may obscure the margin, hindering analysis.

c. Location of the lesion(s) should be indicated using a consistent and reproducible system, such as clock-face location and distance from the nipple. When more than one mass or abnormality is located in the same scan frame or in the same locale, measurement of the distance from the skin to the center of the mass or its anterior aspect may help to differentiate one lesion from another. This measurement may be particularly useful when one mass is singled out for biopsy and others are depicted in the field.

There may be variability within breast imaging practices, and members of a group practice should agree upon a consistent policy for documenting lesion location on subsequent examinations. In some practices, for all examinations that follow the initial US study, the lesion location annotation will be repeated without change. Other breast imagers may report a different location to signify the same lesion but indicate in their reports that the lesion is now seen at another clock-face position and distance from the nipple (these differences are often related to positioning and technique). A more complete discussion of this common scenario is provided in the [Frequently Asked Questions](#).

d. As at mammography, multiple bilateral circumscribed masses usually are assessed as benign (category 2) unless one mass has different imaging features than all the others. In the unusual circumstance in which the interpreting physician chooses to describe multiple benign-appearing masses individually within the US report, the masses should be listed by breast, by location within the breast, and by size. The reader of the report will be less confused, and, if surveillance is suggested as management, the performer of the subsequent examination will appreciate a list rather than verbose text. For bilateral findings, describe all the findings in each breast in a separate paragraph.

5. COMPARISON TO PREVIOUS EXAMINATION(S), INCLUDING CORRELATION WITH PHYSICAL, MAMMOGRAPHY, OR MRI FINDINGS

Breast US should be correlated with physical findings, mammography, MRI, or other imaging studies, if performed. If no statement of comparison is included in the US report, it will be assumed that no comparison was made. Note that some report templates include a “comparison” heading, in which the word “none” (if appropriate)

may be entered.

When correlating US findings with those seen at mammography and/or MRI, the operator performing handheld scanning should correlate the size and location of lesions and match the type and arrangement of tissues surrounding the lesion in order to reduce the likelihood of misregistration (identifying a different lesion or lesions at different imaging modalities). In doing this, allowance for positional changes should be made going from upright with mammography and prone with MRI to supine or supine-oblique with US. If it is determined that a sonographic finding corresponds to a palpable abnormality, or to a mammographic or MRI finding, this should be stated explicitly in the US report. If the US finding is new or has no correlate, this should also be stated in the report.

If the US examination was performed as part of a surveillance protocol to assess a previously identified finding, or if the finding was reported on a previous examination, the current report should describe any changes. An increase of 20% or more in the longest dimension of a probably benign solid mass within 6 months may prompt biopsy.¹ An increase of only 1–2 mm in lesion size may be related to differences in scanning technique or patient positioning.

6. COMPOSITE REPORTS

When more than one type of examination is performed concurrently (on the same day), it is preferable that the examinations be reported together. The findings for each examination should be described in separate paragraphs with an overall assessment and management recommendations for the combined examinations. In general, when the assessments for two examinations differ, the overall assessment (and concordant management recommendations) should reflect the more abnormal of the individual assessments (whatever management is expected to come first, supplemented by likelihood of malignancy), according to the following hierarchy of increasing abnormality: category 1, 2, 3, 6, 0, 4, 5 ([Table 4](#)).

Exceptions to this rule occur when the characteristically benign features of a given imaging finding on one examination supersede the less specifically benign features of the same finding on the other examination. An example is that of a partially circumscribed, noncalcified mass at mammography, superseded by simple cyst at US.

Table 4. Abnormality Hierarchy

BI-RADS Assessment Category	Degree of Abnormality
1	Lowest
2	
3	
6	
0	
4	
5	Highest

7. ASSESSMENT

The report should conclude with a concise summary of pertinent US findings with a final assessment using BI-RADS® US categories 1–6 and the phrases associated with them. If report of a US examination is integrated with that of a concurrently performed mammography examination, the combined final assessment should reflect the highest likelihood of malignancy assessed at the two examinations. Clear and consistent communication is a goal that can be achieved for breast US by using the same assessment categories and similar wording described in the BI-RADS® Mammography section.

In some cases, the interpreting physician may render an incomplete assessment (category 0) in order to request additional examination(s), such as mammography, comparison with previous but currently unavailable examinations, or additional physician-performed real-time scanning after either a sonographer-produced, real-time or automated whole-breast screening US examination.

8. MANAGEMENT

Management recommendations should be included in every report. Clear recommendations should be made as to the next course of action. Recommendations may include routine age-appropriate screening, surveillance imaging for a probably benign mass, annual follow-up after percutaneous or surgical biopsy, and clinical management. If an imaging-guided interventional procedure is recommended, the type of imaging for the procedure might also be suggested, for example, stereotactic, US, or MRI guidance.

B. ASSESSMENT CATEGORIES

Table 5. Concordance Between BI-RADS® Assessment Categories and Management Recommendations.

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete — Need Additional Imaging Evaluation	Recall for additional imaging	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance	> 0% but ≤ 2% likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
Category 4A: <i>Low suspicion</i> for malignancy		> 2% to ≤ 10% likelihood of malignancy
Category 4B: <i>Moderate suspicion</i> for malignancy		> 10% to ≤ 50% likelihood of malignancy
Category 4C: <i>High suspicion</i> for malignancy		> 50% to < 95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

a. Assessment Is Incomplete

Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Images for Comparison

There is a finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. In this context, additional imaging evaluation includes the recording of (nonstandard) US images to supplement the standard images recorded for a screening examination. Note that this does not include repeat real-time scanning by the interpreting physician and/or colleague as long as additional images are not recorded. This respects the unique real-time nature of US and does not penalize its use. (For further information please refer to the [Follow-Up and Outcome Monitoring section](#).)

Under certain circumstances, assessment category 0 may be used in a diagnostic US report, such as when equipment or personnel are not immediately available to perform a needed concurrent diagnostic mammography examination, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. Category 0 should **not** be used for diagnostic breast imaging findings that warrant further evaluation with MRI. Rather, the interpreting physician should issue a final assessment in a report that is made before the MRI examination is performed.

In most circumstances and when feasible, if a screening US examination is not assessed as negative or benign, the current examination should be compared to prior examination(s), if any exist. The interpreting physician should use judgment on how vigorously to attempt obtaining prior examinations, given the likelihood of success of such an endeavor and the likelihood that comparison will affect the final assessment. In this context, it is important to note that comparison to previous examination(s) may be irrelevant when a finding is inherently suspicious for malignancy.

Category 0 should be used for prior image comparison only when such comparison is **required** to make a final assessment. When category 0 is used in the context of awaiting prior examinations for comparison, there should be in place a tracking system guaranteeing with 100% reliability that a final assessment will be made within 30 days (preferably sooner), even if prior examinations do not become available. Some breast imaging practices may reasonably choose never to use category 0 in the context of awaiting prior examinations simply because they do not have a 100% reliable tracking system. If an US examination is assessed as category 0 in the context of awaiting prior examinations and then the prior examinations do become available, an addendum to the initial US report should be issued, including a revised assessment. For auditing purposes, the revised assessment should replace the initial assessment.

A need for previous studies to determine appropriate management might also temporarily defer a final assessment.

b. Assessment Is Complete — Final Categories

Category 1: Negative

There is nothing to comment on. This is a normal examination.

Category 2: Benign

As with category 1, this is a “normal” assessment, but here the interpreter chooses to describe a benign finding in the US report. For example, the interpreter may choose to describe one or more simple cysts, intramammary lymph nodes, postsurgical fluid collections, breast implants, or complicated cysts/probable fibroadenomas that are unchanged for at least 2 or 3 years, while still concluding that there is no sonographic evidence of malignancy. On the other hand, the interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1).

Note that both category 1 and category 2 assessments indicate that there is no sonographic evidence of malignancy. Both should be followed by the management recommendation for routine age-appropriate screening. The difference is that category 2 should be used when describing one or more specific benign sonographic

findings in the report, whereas category 1 should be used when no such findings are described (even if such findings are present).

Category 3: Probably Benign ([Guidance chapter](#).)

Assessment category 3, probably benign, is **not** an indeterminate category for use simply when the radiologist is unsure whether to render a benign (BI-RADS® category 2) or suspicious (BI-RADS® category 4) assessment, but one that is reserved for specific imaging findings known to have > 0% but ≤ 2% likelihood of malignancy. **For US, there is robust evidence that a solid mass with a circumscribed margin, oval shape, and parallel orientation (most commonly fibroadenoma), and an isolated complicated cyst have a likelihood of malignancy in the defined (≤ 2%) probably benign range, for which short-interval (6-month) follow-up sonography and then periodic sonographic surveillance may represent appropriate management.**^{2, 3, 4} **Similar data have been reported for clustered microcysts, but these data are less strong because they involve many fewer cases.**² The use of assessment category 3 for sonographic findings other than these three should be considered only if the radiologist has personal experience to justify a watchful-waiting approach, preferably involving observation of a sufficient number of cases of an additional sonographic finding to suggest a likelihood of malignancy within the defined (≤ 2%) probably benign range.

This edition of the BI-RADS® Atlas also emphasizes the recommendation that a category 3 assessment should not be made at screening; rather, this should be done only after completion of a full diagnostic breast imaging examination. This recommendation is appropriate for screening mammography, for which batch interpretation usually is utilized, because in this setting there is no opportunity to complete the diagnostic workup before interpreting the screening examination. However, screening US almost always is interpreted online, so a full diagnostic examination also is completed while the patient remains in the breast imaging facility, and a single breast imaging report may be issued that combines the findings of both screening and diagnostic components of the examination. Hence, there is no purpose in recommending against category 3 assessment at screening US because the diagnostic workup would be completed simultaneously. This issue is discussed in more detail in [Frequently Asked Question #2 for US in the Follow-up and Outcome Monitoring section](#)). Note that for auditing purposes, the screening component of a category 3-assessed screening US examination will be audit-positive, not only because additional nonstandard (diagnostic) images will be recorded but also because a category 3 assessment at screening is defined as being audit-positive.

For category 3 assessments, the initial short-term follow-up interval is usually 6 months, involving the breast(s) containing the probably benign finding(s). Assuming stability at this 6-month examination, a category 3 assessment again is rendered with a management recommendation for a second short-interval follow-up examination in 6 months. Again assuming stability at this second short-interval follow-up, the

examination is once more assessed as category 3, but now the recommended follow-up interval usually is lengthened to 1 year due the already-observed 12-month stability. Note that although the 1-year follow-up coincides with the routine screening interval in the United States, a category 3 assessment is rendered, to indicate that the period of imaging surveillance is still underway. As with surveillance using mammography, after 2–3 years of stability, the final assessment category should be changed to benign (BI-RADS® category 2). A benign evaluation may also be rendered before completion of category 3 analysis if, in the opinion of the interpreter , the finding has no chance of malignancy and is thus a category 2.

Category 4: Suspicious

This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy. The ceiling for category 3 assessment is a 2% likelihood of malignancy, and the floor for category 5 assessment is 95%, so category 4 assessments cover the wide range of likelihood of malignancy in between. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this category. By subdividing category 4 into 4A, 4B, and 4C, as recommended in and using the cut points indicated in the Guidance chapter, it is hoped that patients and referring clinicians will more readily make informed decisions on the ultimate course of action. An example of separating the BI-RADS® assessment category from the management recommendation (new to fifth edition — see Follow-up and Outcome Monitoring section) occurs when a simple cyst, correctly assessed as BI-RADS® 2, undergoes cyst aspiration for pain control.

Category 5: Highly Suggestive of Malignancy

These assessments carry a very high probability ($\geq 95\%$) of malignancy. This category initially was established to involve lesions for which 1-stage surgical treatment could be considered without preliminary biopsy in an era when preoperative wire localization was the primary breast interventional procedure. Nowadays, given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery rarely if ever is performed. Rather, current oncologic management almost always involves tissue diagnosis of malignancy via percutaneous tissue sampling to facilitate treatment options, such as when sentinel node imaging is included in surgical management or when neoadjuvant chemotherapy is administered prior to surgery. Therefore, the current rationale for using a category 5 assessment is to identify lesions for which any nonmalignant percutaneous tissue diagnosis is considered discordant, resulting in the recommendation for repeat (usually vacuum-assisted or surgical) biopsy. Also note that whereas the fourth edition simply indicated that “appropriate action should be taken” as management for category 5 assessments, the fifth edition provides the more directed management recommendation that “biopsy should be performed in the absence of clinical contraindication.” This new text unequivocally specifies tissue

diagnosis as the interpreting physician's management recommendation for category 5 assessments, appropriately and effectively transferring the burden of establishing a contraindication to this recommendation to the referring clinician.

Category 6: Known Biopsy-Proven Malignancy

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy but prior to surgical excision), in which there are no abnormalities other than the known cancer that might need additional evaluation.

C. WORDING THE REPORT

When performed concurrently, breast US examinations are sometimes reported separately from mammography examinations and sometimes reported as part of a combined examination. In both situations, the current examination should be compared to prior examination(s) when appropriate. The indication for examination, such as screening or diagnostic (targeted), should be stated. The report should be organized with a brief description of the composition of the breast (screening only) and any pertinent findings, followed by the assessment and management recommendations. ***Any verbal discussions between the interpreting physician and the referring clinician or patient should be documented in the original report or in an addendum to the report.***

The report should be succinct, using terminology from the latest approved lexicon without embellishment. Definitions of lexicon terms for mammographic findings should not appear in the report narrative. Following the impression section and the (concordant) management recommendation section of the report, both the assessment category number and text for the assessment category should be stated. Other aspects of the report should comply with the [ACR Practice Guideline for Communication of Diagnostic Imaging Findings](#).⁵

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IV. GUIDANCE

Many substantive changes were incorporated into the US section of this edition of the BI-RADS® Atlas to improve its clinical utility and supply a unified base for research involving breast imaging. This chapter expands on these changes as they appear in each part of the US section and provides more complete explanations for the changes. ***What follows is intended for guidance and is not meant to imply required standards of practice.***

It is important to review the beginning text of the [Follow-up and Outcome Monitoring section](#) and its [Frequently Asked Questions](#) to fully understand how auditing definitions will affect the outcomes (performance metrics) for screening examinations as well as the benchmarks that are derived from these outcomes.

A. BREAST ULTRASOUND LEXICON

Since the 2003 edition of BI-RADS® was published, the practice of breast imaging has evolved further into a more clinically oriented subspecialty of diagnostic radiology. Multimodality imaging and interventions offer options to the breast imager in designing a workup for many different diagnostic scenarios. In addition, limited for decades to mammography and physical examination, screening approaches have broadened, with supplements to mammography utilizing MRI and/or US. Interventional procedures guided by all imaging techniques are in common use, and diagnoses are rarely made through more costly and invasive open surgical procedures. Percutaneous imaging-guided core and vacuum-assisted biopsies provide most of the diagnoses, with relatively few facilities performing fine-needle aspiration cytology and even fewer open surgical procedures. In recognition of these changes, several new sections have been added to this edition of BI-RADS® for US.

Detailed knowledge of normal anatomy is important in interpreting images of all organ systems, and in all imaging modalities, more of the normal breast anatomy is routinely being documented. In the mammography and MRI sections of this edition of the BI-RADS® Atlas, description of the variable balance of fat and fibroglandular tissue in normal breasts has been updated and discussed in detail. The material under the heading Background Echotexture in the 2003 edition of BI-RADS® for US has been expanded and

the heading renamed Tissue Composition. Here we include examples of the observed spectrum of breast patterns, with wide differences in the fat-to-fibroglandular balance seen in the normal breast. Unlike mammography, one need not state the breast composition in diagnostic breast US reports. However, especially for US examinations in which the admixture of fat and fibroglandular tissue produces numerous acoustic interfaces and areas of artifactual shadowing, US may be more difficult to interpret. In these cases, at the discretion of the interpreting physician, it may be appropriate to include a statement that the breast composition is heterogeneous, which may lower the sensitivity of sonography. Although there are no data that document changes in the sensitivity of US for breasts of different tissue composition, clinical experience suggests that this may be true. Further study of this issue is encouraged in order to yield reproducible, clinically relevant data. It is strongly recommended that future research utilize the descriptors of breast tissue composition newly established in this edition of the BI-RADS® Atlas.

There are physiological changes that occur throughout life, reflective of hormonal shifts. Young nursing mothers concerned about abscesses may come for evaluation of a red, tender area, and with US being the preferred initial imaging examination, it is important for the breast imager to recognize the parenchymal findings of mastitis as distinct from the appearance of normal fibroglandular tissue stimulated by the hormones supporting lactation. Examples of involutional changes after lactation and menopause and the appearances of gynecomastia also have been added.

Sonographic correlates to mammographic breast density appear under the Tissue Composition heading, obtained with both conventional high-resolution linear transducers as well as wider FOV probes used in automated US systems. The multiplanar reconstructions provided by these automated systems also make comparisons with MRI examinations more intuitive. The larger FOV also facilitates cross-modality recognition of the various types of breast tissue composition, but correlation with mammography and MRI is also possible with commonly used small FOV US (5 cm in its greatest dimension).

In the past, many breast imagers avoided sonographic imaging of the male breast over concerns that one of several normal appearances of gynecomastia has features characteristics of carcinoma and might result in unnecessary biopsy. However, many men present with tender, palpable areas behind the nipple. Mammography in most instances is definitive, but the expectation that palpable areas will be evaluated with US both in women and men has led to greater use of US for men. We have included gynecomastia (which resembles the developing breasts of adolescent girls) in Tissue Composition, and the benign and malignant abnormalities found in male breasts are included within the appropriate descriptors of the lexicon.

With careful attention to proper scanning technique and use of widely accepted interpretive criteria, handheld US may be as reproducible and consistent as any other breast imaging technology¹. New material on image quality includes descriptions of

transducer selection and proper positioning. Fields of view, focal zone settings, gray scale gain, and contrast should be appropriately adjusted for each patient. Ergonomics of scanning should be respected, and the appropriate table height, insonation angles, and comfortable grasp of the probe housing should be chosen. Annotation recommendations are provided, and examples are shown of how and how not to measure masses. We include examples of scans whose image quality is poor for various reasons and recommendations for how they could be improved.

Nearly all of the cases selected to exemplify feature categories and their descriptors are shown in orthogonal views to emphasize that real-time scanning completely through a lesion in perpendicular planes ensures that the mass has been seen in its entirety. Focal zone settings should be appropriately placed and clearly indicated on the images, so they are included in the illustrations that we provide. Because it also is important to evaluate the skin (normally 2 mm thick, except in the periareolar area and inframammary fold where it may be thicker), our illustrations include the skin. Gel offsets are used for the most superficial findings to keep skin lesions within the appropriate focal zone.

Techniques are available on most US systems to reduce artifacts. For example, spatial compounding reduces speckle (or noise) and smoothes the image. Spatial compounding has been available on most systems for many years, and most handheld scanning is currently done in a spatial compounding mode.

Tissue harmonic imaging, which enhances contrast, is also available. It sharpens the margin of a mass and is said to “clean out” low-level echoes from cysts. However, care must be taken not to heighten contrast so much that a poorly differentiated invasive cancer is called a cyst. Breast US should display the numerous available shades of gray in order to depict the several individual anatomic components of breast tissue (i.e., skin, fat, connective tissue, fibroglandular tissue, and ducts).

Several refinements have been made to the terminology used for assessment and management. In previous editions of the BI-RADS® Atlas, management recommendations were included in the text used to describe several of the assessment categories. In this edition, we have removed the management recommendations from this text in order to provide more flexibility for several specific clinical scenarios for which a seemingly discordant management recommendation might be appropriate for a given assessment. However, except for these few scenarios, the management recommendation should be fully concordant with the assessment. Assessment-management concordance is a hallmark of appropriate interpretation. Deviating from this concordance invites confusion with the potential for producing incorrect treatment. Although relatively uncommon, many clinical scenarios in which the appropriate management recommendation may appear to be discordant with the proper BI-RADS® assessment category are described in detail in the Mammography section, and the reader is referred there for a complete discussion. The few such scenarios that are specifically pertinent to breast US are discussed among the frequently asked questions (FAQs) provided in this

chapter.

Although there is no statutory requirement to use BI-RADS® final assessment phrases in the reports of breast US examinations, as there is for mammography under FDA's Mammography Quality Standards, Final Rule,² using the same terminology as mammography is strongly encouraged. As discussed under the heading Report Organization, if both mammography and breast US are performed concurrently, results of the two modalities should be provided in an integrated report containing a single combined assessment and management recommendation(s), with the most abnormal finding, or the finding that requires the most immediate attention, taking precedence.

For the vast majority of examinations, the BI-RADS® assessment reported for US should prompt the same standard recommendations that apply to mammography ([Table 5](#)). As in mammography, the subdivision of assessment category 4 (suspicious) is optional, although recommended. This is designed to communicate to pathologists and referring physicians the relative level of suspicion of the imaging findings, to facilitate improved patient care.

The Subcommittee on BI-RADS® Ultrasound has also made several changes in the feature analysis parts of the lexicon:

- Although there are several descriptors used when the margin of a mass is not circumscribed, the key distinction is whether the margin is circumscribed or not. In future research studies involving BI-RADS® — US terminology, investigators are encouraged to report results at the circumscribed/not circumscribed level. Additional analyses utilizing the subcategories of not circumscribed margin (indistinct, angular, microlobulated, and spiculated) may also be reported.
- Lesion boundary is no longer a major feature category (shape and margin remain major feature categories). Since the presence of an echogenic transition zone (echogenic rim historically, "echogenic halo") may be seen with malignancies and abscesses, its presence should be noted. Additionally, because the absence of an echogenic transition zone is quite common and now considered to be of no diagnostic significance, the term "abrupt interface" has been dropped.
- Simple and complicated cysts are included among the Special Cases. Because confusion may persist on the distinction between "complicated cysts" and masses with complex echotexture, we have refined the terminology to clarify these entities. Specifically, a complicated cyst represents a cyst with debris, indicating that this is a finding highly likely to be benign. The debris is usually unspecified, possibly proteinaceous or cellular, sometimes containing blood or pus. The echoes visible within a complicated cyst should be homogeneously low-level echoes throughout, with no mural nodules, thick septa, thick walls, or any other suggestion of a solid component. Complex cystic and solid masses include those with a thick wall, thick septations, intracystic or mural mass,

and predominantly solid masses with cystic spaces. On real-time evaluation, these echoes may be seen to be mobile if the complicated cysts are large enough. Also, if the contents of complicated cysts are very thick, mobility may not be elicited. Therefore, the only difference between a complicated cyst and a simple cyst should be the presence of internal, mobile echoes. The margin of a cyst, simple or complicated, should be circumscribed, with no echogenic rim present. Complicated cysts may also display fluid-fluid levels (with a straight or sigmoidal separation). What previously was called a "complex mass" should now be described as a "**complex cystic and solid mass**" to indicate the mass contains a solid component. Such lesions usually are assessed as suspicious (category 4), accompanied by a recommendation for biopsy.³

- Two other descriptors, architectural distortion and duct changes, are now listed as Associated Features. This was done because such findings may be associated with a breast mass, or may stand alone as Findings when no other abnormality is present. Cooper ligament changes are a manifestation of architectural distortion; this is now listed as a subset of architectural distortion. We emphasize that architectural distortion is an important feature that influences BI-RADS® assessments. Many breast masses are found within the zone of fibroglandular tissue or at a fat-fibroglandular junction. If the mass blurs a tissue plane between fat and fibroglandular tissue or if the mass produces distortion of the ducts, these findings may be termed architectural distortion.
- Vascularity within an anechoic mass suggests that the mass is solid, possibly a primary breast cancer or metastatic lymph node. Although reporting the presence of vascularity can be helpful, its absence cannot be used to establish an anechoic or hypoechoic mass as a cyst. However, absence of flow may support the diagnosis of cyst if the mass has the features of a circumscribed margin, has an oval shape, and is anechoic. This is why vascularity, as a supportive rather than primary feature, is now listed among Associated Features.

Since most new US equipment has tissue stiffness assessment capability, elastography, whether strain or shear wave, may be used (optionally) in characterizing masses and surrounding tissue. Research is underway to determine the role of elastographic findings, if any, in lesion assessment and recommendations for management. In this edition of BI-RADS® we provide terminology for elastographic findings not to signify endorsement of this developing technology, but rather, to provide the framework for future research involving outcomes analysis. Although there are many methods to assess tissue stiffness, nearly all use a color scale or spectrum and some form of quantitation. (Quantitation is used widely outside the United States). The FDA recently approved m/s and kPa as a unit of measure of lesion stiffness for shear-wave elastography. Because there is variability among systems manufacturers in color or black and white labeling conventions, to avoid confusion, we recommend that color displays of stiffness be standardized. Most systems display blue as soft and red as hard. Black and white labeling would be more appropriate to aid color-blind breast imagers.

- Special Cases are those with pathognomonic appearances. A simple cyst is one such lesion, and the criteria for this designation are an anechoic, circumscribed, oval or round mass with an imperceptible wall, and posterior enhancement. Occasionally, simple cysts < 8 mm may be difficult to characterize, particularly when located deep in the breast.^{4, 5} Use of tissue harmonic imaging may reduce artifactual internal echoes within cysts, although great care and caution are required not to tune out true echoes from potential solid masses. Posterior features such as enhancement may be subtle but are usually discernible with small cysts even when multiple off-angle beams are used to generate the image (i.e., spatial compounding) and when small cysts are located adjacent to pectoral muscle.
- We have added the description of implants to Special Cases. Recognition of normal and abnormal implant appearances with US is encouraged, and, when imaged, should be reported.⁶ Features of the postsurgical breast are also described in Special Cases with examples.

B. PROBABLY BENIGN (CATEGORY 3) ASSESSMENTS

It is well known that for mammography several specific findings have been validated by robust literature as being probably benign, with a likelihood of malignancy > 0% but ≤ 2%, hence appropriate for category 3 assessment and a recommendation for surveillance imaging.^{7, 8, 9, 10} Several specific findings that may be appropriate for probably benign assessment at US are proposed in this edition of the BI-RADS® Atlas. The literature supporting our proposals is not as robust as exists for mammography, and in some cases it is so sparse as to involve only expert opinion rather than data from prospective clinical studies. For all findings assessed as probably benign at US, the surveillance protocol should be identical to that used for mammographically characterized lesions, involving follow-up examinations at 6, 12, and 24 months, with the option to extend the surveillance period to 36 months.

- 1) Circumscribed, oval, solid masses, parallel to the skin in orientation, hypoechoic to fat with no posterior features or minimal posterior enhancement. There is robust evidence that these lesions, most of which represent fibroadenomas, have a ≤ 2% likelihood of malignancy.¹¹ However, the literature for circumscribed, oval, solid masses that are palpable is strong only for women younger than age 40, who comprise the majority of studied cases and among whom the prior probability of malignancy is low.^{12, 13} If there is interval decrease in the size of a mass under surveillance as a probably benign finding, the mass should be assessed as benign (category 2), and if such a mass completely resolves, a negative (category 1) assessment is appropriate. An increase in diameter of more than 20% in 6 months¹⁴ or other suspicious change should prompt assessment as suspicious (category 4), with recommendation for biopsy. As with multiple bilateral mostly circumscribed masses at mammography,¹⁵ with at least three

overall and one in each breast, such findings seen only at US may be assessed as benign, with a recommendation for routine screening. Note that because US is tomographic, with each captured image representing a thin slice, the margin should be documented as completely circumscribed. Real-time evaluation will allow a more accurate and efficient evaluation.

- 2) Isolated, complicated cyst with uniform low-level echoes. The likelihood of malignancy has been shown to be 4/1,244 (0.3%).^{16, 17, 18, 19, 20} Across three series, 12% of masses thought to be complicated cysts proved to be solid, with 2/64 (3.1%) of these solid masses proving malignant.^{17, 19, 20} This represents robust evidence that the likelihood of malignancy for an isolated complicated cyst is > 0% but ≤ 2%, hence appropriate for category 3 assessment at US. As is the case for multiple bilateral mostly circumscribed masses at mammography, multiple bilateral complicated cysts (at least three overall and one in each breast) seen only at US may be assessed as benign, with a recommendation for routine follow-up.
- 3) Microlobulated or oval masses composed entirely of clustered microcysts. These findings may be assessed as benign (category 2) when clearly composed of simple cysts. However, imaging surveillance may be appropriate for smaller or deeper clustered microcysts, for which there is reduced diagnostic certainty, with one malignancy (0.5%) reported among 216 such masses across multiple centers.^{3, 17, 19, 20, 21, 22} The relatively small number of cases studied limits precision in estimating the likelihood of malignancy to be ≤ 2%; the data would be more convincing if at least 500 cases were studied.
- 4) A hyperechoic mass with central hypoechoic to anechoic components and surrounding edema is consistent with but not diagnostic of fat necrosis. There are very sparse published data indicating the likelihood of malignancy for this combination of sonographic findings, so the decision to assess such findings as probably benign (category 3) would be based only on expert opinion. However, whether or not a history of trauma or prior surgery is elicited, the preferred approach is to correlate these sonographic finding(s) with those visible at mammography, because 1) if a mass representing fat necrosis is depicted at US, it also should be visible at mammography as an oil cyst, and 2) fat necrosis presenting as oil cyst(s) has a characteristically benign mammographic appearance, whether or not rim calcification is depicted. Therefore, virtually all such cases will confidently be assessed as benign (category 2).
- 5) While refraction shadowing at the edges of fat lobules is often easily recognized as non-pathologic, posterior shadowing seen in two projections may pose problems. Careful real-time scanning may exclude the presence of an associated mass; one should be able to dismiss the shadowing as artifact if it changes in appearance on the different views, with an increase or decrease in transducer pressure on the skin, and with alterations of the angle of insonation. What should be done if a confident benign

assessment cannot be rendered? There are no published data indicating the likelihood of malignancy for this sonographic scenario, so the decision to assess as probably benign (category 3) would be based only on expert opinion. However, it is important to realize that category 3 assessments should not be rendered because the interpreting physician is unsure whether to assess as benign (category 2) or suspicious (category 4); in this situation, it would be prudent to render a suspicious (category 4) assessment.

- 6) Architectural distortion thought to be due to postsurgical scar. The patient's clinical history may be helpful in this situation, and a track may be evident sonographically that can be followed to focally thickened skin at the site of incision. However, there are very sparse published data indicating the likelihood of malignancy for sonographic findings thought to be due to postsurgical scarring, so the decision to assess as probably benign (category 3) would be based only on expert opinion. Furthermore, such an assessment would be inadvisable without first correlating the sonographic findings with those visible at mammography. A previous breast biopsy for benign disease rarely complicates or alters the interpretation at mammography.²³

In summary, among the six specific sonographic findings proposed as being appropriate for assessment as probably benign (category 3) at US, there is strong evidence supporting the first two (circumscribed, oval, solid, parallel-oriented mass and complicated cyst), less strong evidence supporting the third (clustered microcysts), and only expert opinion supporting the rest. Individual interpreting physicians should be cautious about adopting an interpretive approach to recommend surveillance imaging based only on expert opinion, unless the physician has personal experience to justify a watchful-waiting approach, preferably involving observation of a sufficient number of cases to suggest a likelihood of malignancy within the defined ($\leq 2\%$) probably-benign range. Alternatively, one should consider waiting for publication of more robust data. Further clinical studies for the latter four proposed sets of sonographic findings, involving at least 500 cases for each proposed set, should be undertaken to demonstrate whether the likelihood of malignancy for any of the findings is in the defined ($\leq 2\%$) probably-benign range and, when appropriate, the frequency with which concurrent mammography will permit a benign (category 2) assessment instead.

C. FREQUENTLY ASKED QUESTIONS

1. Which type of breast imaging examination should I recommend for my patients?

When in doubt, refer to the ACR Appropriateness Criteria® (<http://www.acr.org/Quality-Safety/Appropriateness-Criteria/Diagnostic/Breast-Imaging>). The ACR Appropriateness Criteria® provides recommendations for both screening and diagnostic breast imaging procedures.

2. A woman in her 20s consulted a gynecologist, who discovered a palpable breast mass; the

woman thinks that the mass has been palpable for a long time, but the gynecologist insists on imaging, which shows probable fibroadenoma. What should the assessment be? Is biopsy always necessary?

This scenario often presents a dilemma for the breast imager. Using feature analysis, a mass that is oval, circumscribed, solid, and oriented parallel to the skin is very likely to be benign and most commonly a fibroadenoma. Especially for a woman in her 20s, palpability of the mass will not appreciably affect the very low likelihood of malignancy. The correct assessment in this scenario would be probably benign (category 3), recommend surveillance imaging, unless the woman prefers biopsy or even excision if the mass is cyclically painful. However, even if the woman declines surveillance imaging and a biopsy is done for this category 3 lesion, the probably benign assessment should **not** change.

3. A woman undergoes breast US examination to evaluate spontaneous bloody nipple discharge, and I see a mass within a duct. How do I describe this using the BI-RADS® lexicon?

In such a case, the location of the mass is intraductal, in addition to a specified clock-face position and distance from the nipple. Most intraductal masses are papillomas, and a vascular stalk may be evident on color or power Doppler while scanning along the length of the duct from the nipple to the periphery. Stating the length of the duct segment that contains the mass or debris, size and intraductal location of such masses, presence of vascularity, clock-face position, and distance from the nipple is the most important information to convey, together with whether or not these masses are felt to explain the patient's symptoms (if any). Most of these masses require biopsy. The risk of malignancy in one series of intraductal masses (involving 79 associated with nipple discharge) was 8%, but the subset of cases with bloody nipple discharge was not stated.²⁴ Other considerations include clot or detritus, ductal carcinoma in situ (DCIS) with or without an invasive component, and intracystic papillary carcinoma (encapsulated papillary carcinoma). Some irregular masses will show intraductal extension, with the latter often representing a DCIS component to an otherwise mostly invasive malignancy; in such cases, this is an associated feature of the main mass which itself should be more fully described by its shape, margins, orientation, posterior features, and echo pattern.

If no abnormality is identified in scanning over the length of the duct segment as it approaches the nipple, consider attempting a ductogram (galactogram), which may show peripheral abnormalities more effectively than US.

4. A 52-year-old woman with a family history of unilateral breast cancer (mother diagnosed at the age of 67) presents with a large, painful breast mass. Her mammograms show no abnormalities other than a 4 cm circumscribed mass, characterized at US as a simple cyst. For relief of her symptoms, she requests aspiration. What assessment and management

recommendations should be provided in the breast imaging report?

The breast imaging report for her concurrent mammography and US examinations should provide a benign (category 2) assessment, audit negative. This is because the combination of mammographic and sonographic findings is characteristically benign (simple cyst). A management recommendation of routine screening mammography in 1 year (concordant with the benign imaging findings) should be provided. Note that the requested cyst aspiration is for therapeutic rather than diagnostic purposes. This case illustrates one of several assessment-management discordance scenarios, in which assessment should match the imaging findings, not the planned management.

5. When a woman is recalled from screening for an asymmetry, and spot-compression or spot-compression magnification views show no persistent abnormality, is it necessary to perform US?

It is neither necessary nor appropriate to perform US in this scenario, because diagnostic mammographic evaluation has proved that the asymmetry identified at screening was a summation artifact (superimposition of normal breast structures) — this, of course, assumes that the spot-compression/spot-compression magnification views were of diagnostic image quality, with the area of concern centered in the spot-compression paddle. Because there are no imaging findings at diagnostic mammography, this examination should be assessed as negative (category 1) with a recommendation for routine screening mammography in 1 year. The above described scenario is quite common. An asymmetry is a noncalcified finding seen on only one standard mammographic view, and approximately 80% of asymmetries are found to represent summation artifacts.²⁵

Had this scenario been slightly different, with spot-compression or spot-compression magnification views depicting a focal asymmetry (non-mass lesion visible on two different mammographic projections) as the only imaging finding, then it would indeed be appropriate to perform US targeted at the mammographic lesion. In most such cases, US examination will not affect subsequent management, identifying either normal-appearing fibroglandular tissue as correlate to the focal asymmetry or no sonographic finding at all. Such cases would be assessed as probably benign (category 3) unless prior mammograms demonstrated at least 2–3 years of stability resulting in a benign (category 2) assessment. However, the value of US in this scenario is that in a few cases it will depict a suspicious finding instead, leading to biopsy and often a cancer diagnosis that would otherwise have been deferred.

6. In reporting the findings of a US examination, how many sonographic descriptors of a mass should be used to support its assessment? Is it acceptable to simply report that the mass has benign characteristics?

There is no specific number of descriptors that must be used, but the three feature

categories whose descriptors are applicable to characterizing a mass as benign are margin, shape, and orientation, all of which should be used to completely characterize the mass. Within these feature categories, the descriptors that justify a benign assessment are a circumscribed margin, oval shape (this now includes the term macrolobulated), and parallel orientation. If any other sonographic descriptor within these three feature categories is applicable to the mass, such as indistinct margin, irregular shape, or not parallel orientation, the mass should be assessed as suspicious rather than as benign.

Reports should be clear and concise, and too many adjectives may detract from the message, but the referring clinician or the next radiologist who views the sonograms may appreciate knowing the criteria used to justify a benign assessment. **Note that these descriptors need not be repeated in the assessment that is provided at the end of the sonographic report.**

7. How should lesion location be reported on follow-up sonograms of a mass?

A 42-year-old woman was found to have a circumscribed mass at baseline mammography. At diagnostic mammography and US, the mass was assessed as probably benign and its location at US was recorded as right breast, 10 o'clock, 5 cm posterior to the nipple. She returned for a 6-month follow-up US, and the sonographer told the interpreting physician that the mass was located at 11:00 in the right breast 6 cm posterior to the nipple but that she had labeled her images of the mass exactly as they had been annotated on the previous US examination. The technologist asked the physician if what she had done was correct.

One could argue that there should be precise agreement concerning the location of a sonographic finding on successive surveillance examinations, for the sake of consistency. However, due to minor differences in both patient positioning and angles of insonation that are inherent in real-time scanning with a handheld transducer, it may be difficult to precisely duplicate the scanning conditions of a previous examination. As a result, the apparent clock-face location and distance from the nipple of a mass may vary slightly between examinations. The key here is to determine that the mass depicted on both examinations is one and the same. This is accomplished by real-time scanning not only at but also adjacent to the expected location of the targeted mass, to ensure that the currently visible mass is the only such finding in the area. Once this has been confirmed, a full set of diagnostic images should be recorded, with the images labeled either precisely as on the previous examination or as actually located on the current examination. If the current actual location is used in labeling, and if there is a slight difference between this location and the location labeled previously, the report could state, "The right breast mass seen previously at 10:00 position, 5 cm posterior to the nipple is the same mass seen on today's exam in the right breast at 11:00 position, 6 cm posterior to the nipple, the minor difference being due to variability in patient positioning." Thus, there will be no confusion concerning the slight differences in

lesion location described in the successive US reports.

8. US revealed a large axillary mass in a patient with known metastatic melanoma. Previously, this mass had been biopsied and shown to represent an axillary lymph node with metastatic melanoma. Except for the axillary mass, US examination revealed no abnormalities in the breast. What is the appropriate assessment for this examination?

The appropriate assessment is benign (category 2). An assessment of known biopsy-proven malignancy (category 6) would not be appropriate, as this assessment is used for known breast cancers (defined in the BI-RADS® Atlas as being either invasive breast carcinoma or ductal carcinoma in situ). Note that other malignancies (lymphoma, leukemia, sarcoma, metastasis, etc.), even when present in the breast or axilla, are not considered to be breast cancer. To avoid confusion concerning a benign assessment despite the presence of a non-breast malignancy, the report should contain an added sentence explaining the situation. In this case, the report could indicate that the axillary mass represents biopsy-proven metastatic melanoma, but that there is no sonographic evidence of breast cancer.

Had this scenario been slightly different, with a sonographic depiction of not only the axillary mass but also a mostly circumscribed but slightly indistinct solid mass within the breast, then the appropriate assessment would be suspicious (category 4). The reason is that although this in-breast lesion could represent another melanoma metastasis, it also could be a primary breast carcinoma, such that biopsy is needed to make the distinction.

9. Should assessment category 0 be applied to breast US examinations?

In general, assessment category 0 should not be assigned to **diagnostic** breast US examinations. This is because a full diagnostic breast imaging examination (involving both US and mammography, if both are needed) should be completed before the patient leaves the breast imaging facility. Rarely, if for either equipment or personnel issues, completion of the diagnostic US examination can not be completed or the patient decides to leave before completion of her workup, a category 0 may be given. In this scenario, if the diagnostic US examination is the one performed first, it should be assessed as incomplete (category 0), and the patient will be asked to return to complete her examination. When the patient returns and her examination is completed, the initial category 0 assessment is replaced by a final assessment.

However, assessment category 0 indeed is appropriate for **screening** breast US examinations. Like screening mammography, for which a small set of standard images is routinely obtained, a similar small set of standard images is routinely obtained at screening US. When additional images are recorded to further evaluate a screening-detected mammographic or sonographic finding, the screening examination is assessed as incomplete (category 0), and the additional images then constitute the

subsequent diagnostic examination, regardless of whether the patient needs to be recalled on a different day or the additional images are obtained only a few minutes afterwards.

Note that in scenarios in which both screening and diagnostic components of an examination are performed one after the other, it may be awkward to report the two examinations separately. A single report may be issued instead, containing a combined assessment that reflects the (more completely evaluated) findings at diagnostic examination. However, the screening and diagnostic components of such a combined examination must be audited separately, audit-positive for the screening examination (effectively reflecting a category 0 assessment), and either audit-positive or audit-negative for the diagnostic examination depending on the final assessment that is rendered.

10. For bilateral screening US performed either by the technologist or the physician with no abnormality identified, what images should I record?

Although no standard has been set for documenting a negative screening US examination, what was done in ACRIN 6666²⁶ has served well in many breast imaging practices that now offer screening US: in addition to demographics (patient's name, unique identifier, date of birth or age, facility name, and location), record one image in one plane (ordinarily radial) for each quadrant, at the same distance posterior to the nipple (4 cm for an average breast), and record one image of the retroareolar region just behind the nipple. The axilla could be scanned as well, but this was not required in the ACRIN 6666 protocol, nor was there a requirement to record a representative negative image. The standard set of five images per breast was recorded at the completion of real-time scanning, given that no abnormalities were suspected or observed.

11. Should I avoid using breast US for male patients with clinical findings because gynecomastia may be misinterpreted as malignancy?

No, US is indicated for evaluation of most palpable abnormalities, regardless of the patient's gender. Men with palpable masses located far from the nipple would be referred for US on completion of mammography. Gynecomastia itself is frequently palpable and tender, with mammography most commonly being definitive in confirming the diagnosis. If US is performed, however, gynecomastia may also be recognized (please see the discussion of anatomy in the lexicon).

As we do in mammography and in imaging other paired organs, it is important to keep the principle of symmetry in mind. If there is doubt about whether US shows a physiologic change (such as gynecomastia) or an abnormality that requires biopsy, scan the contralateral retroareolar area for a similar but usually smaller area (in this case, of gynecomastia). Palpable masses at sites away from the nipple, usually in fatty areas of

the male breast, can be completely characterized using mammographic feature analysis, with the role of US limited to providing imaging guidance for biopsy, if palpation-guided biopsy is not performed.

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APPENDIX

ACR BI-RADS® — Ultrasound Lexicon Classification Form

For each of the following categories, select the term that best describes the dominant lesion feature. Whenever possible, definitions and descriptions used in BI-RADS® for mammography should be applied to ultrasound.

BREAST TISSUE

A. Tissue composition (screening only): Heterogeneous background echotexture of the breast may affect the sensitivity of breast sonograms for lesion detection. (select one)

- 1. a. Homogeneous background echotexture — fat
- 2. b. Homogeneous background echotexture — fibroglandular
- 3. c. Heterogeneous background echotexture

FINDINGS

B. Masses: A mass is three dimensional and occupies space. In 2-D US, it should be seen in two different planes; with volumetric acquisitions, in three planes.

1. Shape (select one)	<input type="checkbox"/> a. Oval	Elliptical or egg-shaped (may include two or three undulations, i.e. gently lobulated or macrolobulated)
	<input type="checkbox"/> b. Round	Spherical, ball-shaped, circular, or globular
	<input type="checkbox"/> c. Irregular	Neither round nor oval
2. Orientation (select one)	<input type="checkbox"/> a. Parallel	Long axis of lesion parallels the skin line (wider than tall or horizontal)
	<input type="checkbox"/> b. Not parallel	Long axis not oriented along the skin line (taller than wide or vertical) — includes round
3. Margin (select all that apply)	<input type="checkbox"/> a. Circumscribed	Entire margin is well defined or sharp, with an abrupt transition between the lesion and surrounding tissue
	<input type="checkbox"/> b. Not circumscribed	The mass has one or more of the following features: indistinct, angular, microlobulated, or spiculated in any portion of the margin
	<input type="checkbox"/> i. Indistinct	No clear demarcation between a mass and the surrounding tissue anywhere on the margin
	<input type="checkbox"/> ii. Angular	Some or all of the margin has sharp corners, often forming acute angles
	<input type="checkbox"/> iii. Microlobulated	Margin is characterized by short-cycle undulations
	<input type="checkbox"/> iv. Spiculated	Margin is characterized by sharp lines radiating from the mass
4. Echo pattern (select one)	<input type="checkbox"/> a. Anechoic	Without internal echoes
	<input type="checkbox"/> b. Hyperechoic	Having increased echogenicity relative to fat or equal to fibroglandular tissue
	<input type="checkbox"/> c. Complex cystic and solid	Contains both anechoic (cystic or fluid) and echogenic (solid) components
	<input type="checkbox"/> d. Hypoechoic	Defined relative to subcutaneous fat; less echogenic than fat; characterized by low-level echoes throughout (e.g., complicated cysts or fibroadenomas)
	<input type="checkbox"/> e. Isoechoic	Having the same echogenicity as subcutaneous fat
	<input type="checkbox"/> f. Heterogeneous	A mixture of echogenic patterns within a solid mass

5. Posterior features <i>(select one)</i>	<input type="checkbox"/> a. No posterior features	No shadowing or enhancement deep to the mass
	<input type="checkbox"/> b. Enhancement	Appears as a column that is more echogenic (whiter) deep to the mass
	<input type="checkbox"/> c. Shadowing	The area posterior to the mass appears darker; (refractive edge shadowing is of no significance)
	<input type="checkbox"/> d. Combined pattern	More than one pattern of posterior attenuation, both shadowing and enhancement
C. Calcifications: Calcifications are poorly characterized with US but can be recognized as echogenic foci, particularly when in a mass. <i>(if present, select all that apply)</i>		
<input type="checkbox"/> 1. Calcifications in a mass		Small hyperechoic foci will be more conspicuous in a hypoechoic mass than within a volume of fibroglandular tissue (unless grouped very closely or individually coarse, they will not attenuate the US beam)
<input type="checkbox"/> 2. Calcifications outside of a mass		Calcifications situated in fat or fibroglandular tissue are less conspicuous than when present within a mass
<input type="checkbox"/> 3. Intraductal calcifications		
D. Associated features <i>(select all that apply)</i>		
<input type="checkbox"/> 1. Architectural distortion		
<input type="checkbox"/> 2. Duct changes		Manifested by cystic dilation of a duct or ducts involving irregularities in caliber and/or arborization, extension of duct(s) to or from a malignant mass, or the presence of an intraductal mass, thrombus, or detritus
3. Skin changes <i>(select all that apply)</i>	<input type="checkbox"/> a. Skin thickening	May be focal or diffuse, > 2 mm in thickness (in the periareolar area and inframammary folds up to 4 mm)
	<input type="checkbox"/> b. Skin retraction	Skin surface is concave or ill-defined, and appears pulled in
<input type="checkbox"/> 4. Edema		Increased echogenicity of surrounding tissue and reticulated (angular network of hypoechoic lines)
5. Vascularity <i>(select one)</i>		Must reference a contralateral normal area or unaffected site in the same breast as the basis for comparison
	<input type="checkbox"/> a. Absent	
	<input type="checkbox"/> b. Internal vascularity	Blood vessels present within the mass
	<input type="checkbox"/> c. Vessels in rim	Blood vessels may be marginal, occupying part or all of the rim of the mass
6. Elasticity assessment <i>(select one)</i>		Stiffness as a feature of malignant masses may be considered along with their much more important morphologic characteristics
	<input type="checkbox"/> a. Soft	
	<input type="checkbox"/> b. Intermediate	
	<input type="checkbox"/> c. Hard	

E. Special cases: These are cases with a unique diagnosis or finding. (select all that apply)

<input type="checkbox"/> 1. Simple cyst		Circumscribed, round or oval, anechoic, shows posterior enhancement
<input type="checkbox"/> 2. Clustered microcysts		A cluster of anechoic masses, each < 2-3 mm in diameter with thin (< 0.5 mm) intervening septations and no discrete solid component
<input type="checkbox"/> 3. Complicated cyst		Cysts that contain debris; characterized by homogeneous, low-level internal echoes without a discrete solid component, and with an imperceptible wall: may have layered appearance which may shift slowly with changes in the patient's position; may also contain echogenic foci that appear to scintillate as they shift
<input type="checkbox"/> 4. Mass in or on skin		These masses are clinically apparent and may include sebaceous or epidermal inclusion cysts, keloids, moles, pimples, neurofibromas, and accessory nipples
<input type="checkbox"/> 5. Foreign body including implants		May include marker clips, coils, wires, catheter sleeves, injected or leaked silicone, metal or glass related to trauma, and implants
<input type="checkbox"/> 6. Lymph nodes — intramammary		Circumscribed, oval masses with hypoechoic cortices and echogenic fatty hilae, often reniform and containing hilar fat; most commonly seen in the upper outer quadrant (especially the axillary tail); usually 3 mm to 1 cm
<input type="checkbox"/> 7. Lymph nodes — axillary		
8. Vascular abnormalities <i>(select one)</i>	<input type="checkbox"/> a. AVMs (arteriovenous malformations/pseudoaneurysms)	
	<input type="checkbox"/> b. Mondor disease	
<input type="checkbox"/> 9. Postsurgical fluid collection		
<input type="checkbox"/> 10. Fat necrosis		

ASSESSMENT CATEGORIES (select one)		
Incomplete Assessment	Management	Likelihood of Cancer
<input type="checkbox"/> Category 0: Incomplete — Need Additional Imaging Evaluation	Recall for additional imaging	N/A
Final Assessment	Management	Likelihood of Cancer
<input type="checkbox"/> Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance	> 0% but ≤ 2% likelihood of malignancy
<input type="checkbox"/> Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
<input type="checkbox"/> Category 4A: Low suspicion for malignancy		> 2% to ≤ 10% likelihood of malignancy
<input type="checkbox"/> Category 4B: Moderate suspicion for malignancy		> 10% to ≤ 50% likelihood of malignancy
<input type="checkbox"/> Category 4C: High suspicion for malignancy		> 50% to < 95% likelihood of malignancy
<input type="checkbox"/> Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
<input type="checkbox"/> Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

This US lexicon classification form is for data collection and does not constitute a written US report.



ACR BI-RADS®

Magnetic Resonance Imaging

2013

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PREFACE

The 2013 edition of BI-RADS®—MRI is an extension of the previous edition and is part of the BI-RADS® Atlas, which also includes lexicons for mammography and breast ultrasound (US). Because there are three separate lexicons often describing similar features with different modalities, one of the goals for this edition has been to provide consistency and concordance of terms among all three as often as possible. If the same descriptor can be used for the same feature on mammography or MRI, the committee has strived to provide a single term. Illustrations are included for each feature described. The original breast MRI lexicon included a section on definitions and illustrations of each morphologic feature, technical aspects of acquiring breast MRI examinations, and illustrations of dynamic curve data. The objective of that lexicon was to standardize the language used in breast MRI reporting, in an effort to aid clinicians in understanding the results of the breast MRI tests for subsequent patient management and to aid scientific research by enabling investigators to compare studies based on similar breast MRI terminology.¹

Since then, the field of breast MRI has grown and advanced significantly, with numerous changes in terminology. Understandably, certain terms have been added or deleted as better terms have been identified. Additionally, concepts such as background parenchymal enhancement have been proposed and included. Terminology has been clarified, and sections have been added on monitoring, quality, auditing, and guidance. A section, "Non-Enhancing Findings," has been added. A section on implant description and assessment is new.

There are currently no FDA regulations mandating auditing of a breast MRI practice. The American College of Radiology (ACR), however, mandates an auditing program for breast MRI accreditation (<http://www.acr.org/Quality-Safety/Accreditation/BreastMRI>), and auditing individual radiologist outcomes is helpful for practice improvement. In this edition, auditing procedures for mammography, US, and MRI are all described in a new chapter titled "[Follow-Up and Outcome Monitoring](#)". To facilitate cross-modality comparison, whenever practical, auditing procedures are identical for each of the breast imaging modalities represented in the atlas.

Reaching a consensus in describing architectural features and/or kinetic data is important so that data from breast MRI studies can be evaluated to support the evaluation or applicability of any one technique. Additionally, consistent reporting with concordant recommendations will facilitate communication of findings and results to referring physicians, as well as improve auditing practices. Guidance for auditing breast MRI is provided in the new section on [Follow-up and Outcome Monitoring](#).

The 2003 edition of the ACR BI-RADS®— MRI was the final product of development and testing by an international group of MRI experts. In the 2013 edition, we continue to include information from international members whose use of different imaging protocols and imaging with different parameters, equipment, and contrast provide valuable perspective. A broad range of images has been selected to illustrate the variety of protocols. Each of the features depicted in the ACR BI-RADS®— MRI lexicon is described by a legend below the illustration. Many images show more than one feature, but the main illustrated feature will appear in capital letters (such as “SPICULATED, rim-enhancing, irregular mass”). Whenever possible, the pathology of the illustrated finding will be included.

The ACR BI-RADS®— MRI lexicon is arranged for use in everyday practice. Regular use of the lexicon should make it possible to issue meaningful, unambiguous breast MRI reports. The committee expects this document to change with advances in morphologic and dynamic imaging techniques, so we welcome comments and/or suggestions, and request that they be addressed in writing to the ACR. However, prior to submitting comments or suggestions, please visit the ACR BI-RADS® website at <http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/BIRADSFAQs.pdf>, which displays committee-approved responses to suggestions already submitted.

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INTRODUCTION

IMPLEMENTING THE ACR BI-RADS® — MRI LEXICON IN CLINICAL PRACTICE

Breast MRI is a developing field, and it is expected that technical advances will enable faster temporal acquisitions and higher spatial resolution, easier acquisition of physiologic images, and new types of image display. As of its publication, the BI-RADS® – MRI lexicon reflects current technology; however, it is intended to be a living document that will be continually updated as new sequences and imaging techniques develop.

The ACR BI-RADS® — MRI is divided into five sections with an additional appendix.

SECTION I: Clinical Information and Acquisition Parameters

SECTION II: Breast Imaging Lexicon – MRI

SECTION III: Reporting System

SECTION IV: Implant Assessment

SECTION V: Guidance

APPENDIX: ACR BI-RADS® — MRI Lexicon Classification Form

The following are brief summaries of each section.

I. Clinical Information and Acquisition Parameters

Pertinent clinical history allows a more complete interpretation. The reason for the examination should be documented. Acquisition parameters must be described and should adhere to ACR guidelines.

II. Breast Imaging Lexicon — MRI

The terminology of breast MRI has evolved, and the descriptive terms that follow are the terms and definitions that have been recommended by the ACR Subcommittee on BI-RADS® MRI. It is believed that these terms provide a fairly complete categorization of lesions, but if lexicon users would like to recommend a significant substantive change, they may submit a proposed change to the ACR Subcommittee on BI-RADS® MRI for review. If the change is accepted by the subcommittee, it will be included in subsequent updates.

The subcommittee emphasizes that images should be viewed with the understanding that breast MRI slices are parts of 3-dimensional objects. Multiplanar reconstructions and 3-D images are appropriate for review.

While the majority of illustrations within this publication show imaging-based morphology characteristics, the subcommittee recognizes that kinetic information can be important. Kinetic data may provide additional information regarding the nature of the lesion and may be helpful in determining the appropriate management of the patient.

III. Reporting System

The reporting system is designed to provide an organized approach to image interpretation and reporting.

IV. Implant Assessment

The goal of MRI implant examination is to determine whether the implant is intact or ruptured, and if ruptured, whether the rupture is intracapsular or extracapsular.

V. Guidance

Because there will always be areas of uncertainty and questions that cannot be anticipated in advance of events, this section of the atlas offers guidance on topics not specifically addressed in the text that may be or have been encountered in practice. The Guidance chapter also describes the changes from the previous edition of the atlas along with the rationale for the changes. As with all of BI-RADS®, the Guidance chapter is designed to be dynamic and will rely on everyone working in the field to refresh and augment its content by contributing their questions and observations to the committee for discussion.

APPENDIX

The appendix contains a form for easily noting the findings of an MRI examination with the appropriate BI-RADS® terminology in a simple checklist. This form also contains the BI-RADS® assessment categories.

REFERENCES

1. Ikeda DM, Hylton NM, Kinkel K et al. [Development, standardization, and testing of a lexicon for reporting contrast-enhanced breast magnetic resonance imaging studies](#). *J Magn Reson Imaging* 2001 Jun;13(6):889–95.

REVISIONS

I. CLINICAL INFORMATION AND ACQUISITION PARAMETERS

A. CLINICAL HISTORY

There are important clinical elements that can influence breast MRI interpretation, and the study should be viewed with a goal of answering the clinical question. The clinical question or clinical problems, such as breast lump, nipple discharge, thickening, or other patient symptoms should be reported. Next, any history of biopsy or surgery, the biopsy date, and pathology results should be reported. Other factors, such as exogenous hormone replacement therapy, phase of menstrual cycle, antihormonal therapy, and radiation therapy should be reported if they affect assessment of a particular case. Risk factors for breast cancer, including family history, should be listed for high-risk screening.

B. COMPARISON TO PREVIOUS EXAMINATIONS

Imaging findings on older breast MRI examinations may indicate if a finding is stable, new, changing, or not included, providing important information that could influence patient management. As with other imaging studies, the presence of stable lesions favors a benign process. Information from breast imaging studies other than MRI is important for comparison, particularly if a finding in another imaging modality prompted the MRI examination. The date and type of the prior imaging study should be reported.

C. ACQUISITION REPORTING RECOMMENDATIONS

Because magnet field strength, breast coil specifications, pulse sequences, and other parameters vary considerably, there is no single method for performing contrast-enhanced breast MRI. However, regardless of the method, only dedicated breast coils should be used. Pulse sequence parameters that should be reported include the type of pulse sequence technique, T1 or T2 weighting, and whether fat-suppression is used. Information about anatomic referencing should include whether the right, left, or both breasts were scanned, scan orientation and plane, and other pertinent pulse sequence features (<http://www.acr.org/~media/ACR/Documents/Accreditation/BreastMRI/Requirements.pdf>).

Parameters of the contrast injection method should be reported. These should include

the contrast agent used, dose, and mode of administration. Use of an injector is recommended. Dynamic scan parameters should be reported, including the number of postcontrast acquisitions and the time interval between consecutive scans.

If image postprocessing was performed, the type of postprocessing should be noted. This includes, where appropriate, image subtraction, use of maximum-intensity-projection or surface-rendered images, type of kinetic analysis, or other techniques.

The severity of image artifacts resulting from motion, presence of metallic clips, or fat-suppression failure should be noted in the report. It is also important that any problems associated with contrast injection be noted, as well as patient motion, which may cause spurious results on dynamic scans done without motion correction.

In general, most aspects of the imaging technique will remain the same for most breast MRI examinations and standard wording can be used in the report.

D. MRI LEXICON

The breast MRI lexicon group was initially organized in 1999 under the guidance of Debra M. Ikeda, MD and Nola M. Hylton, PhD. Even though the original lexicon was written in the early days of breast MRI with somewhat limited experience, the definitions and descriptions contained in their work have stood the test of time, and the document is still very robust. Many of the terms and descriptions have allowed radiologists to define and describe findings on breast MRI. Over the past 10 years, even with the current wealth of experience, the first lexicon is still accurate. However, it is now apparent that in most breast MRI examinations, the presence of background parenchymal enhancement (BPE) of the normal breast tissue requires a separate description. Although it was recognized that BPE existed, the descriptions of background enhancement were initially included under the NON-MASS-LIKE ENHANCEMENT heading. These descriptions have now been retired.

1. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

a. Level

As MRI is performed with intravenous contrast, fibroglandular breast parenchyma may demonstrate contrast enhancement. BPE can be described as minimal, mild, moderate, or marked. BPE refers to the normal enhancement of the patient's fibroglandular tissue, and assessment occurs on the first postcontrast image at approximately 90 seconds (as cancer detection is performed at this time point). At later time points, BPE usually demonstrates progressive enhancement indicating increasing intensity, and may also occupy a greater volume of fibroglandular parenchyma on delayed imaging. In general, BPE demonstrates progressive enhancement over time; however, significant and fast enhancement can occur on

the first postcontrast image despite rapid imaging techniques.

BPE can occur regardless of the menstrual cycle or menopausal status of the patient. BPE is not necessarily directly related to the amount of fibroglandular parenchyma present. Patients with extremely dense breasts may demonstrate little or no BPE, whereas patients with scattered fibroglandular tissue may demonstrate marked BPE. BPE is evaluated with respect to the amount of fibroglandular tissue, not the entire volume of the breast. Nevertheless, most of the time, younger patients with dense breasts are more likely to demonstrate BPE.

BPE on MRI was initially thought to be similar to density on mammography insofar as it could potentially obscure suspicious, possibly malignant, enhancing lesions by decreasing conspicuity. However, this has not been observed in practice, as cancers appear to be detected regardless of BPE. Several studies have shown that increased BPE may result in an increase in call-backs, but the cancer detection rate is not decreased. A description of BPE should be included in the breast MRI report.

In general, BPE is more prominent in the luteal phase of the cycle if the patient is pre-menopausal. Therefore, for elective examinations, (e.g., high-risk screening), every effort should be made to schedule the patient early in her cycle to minimize the issue of background enhancement. Despite scheduling the patient at the optimal time of her cycle, enhancement may still occur, and the BPE terms should be applied. Women in whom cancer has been diagnosed and MRI is performed for staging (e.g., diagnostic) should be imaged with MRI regardless of the timing of the menstrual cycle or menstrual status.

We recognize that other patterns of BPE have been described that require future studies to justify inclusion among the descriptors of BPE.

b. Symmetric Versus Asymmetric Enhancement

Symmetric enhancement describes mirror-image enhancement and is suggestive of benign BPE. Preferential enhancement of breast parenchyma occurs depending on the localization of the blood supply. For example, preferential enhancement in the upper outer quadrant is commonly seen as well as along the inferior aspect of the breast (formerly described as sheets of enhancement).

Asymmetric enhancement is a further modifier of non-mass-like enhancement, describing enhancement that is more prominent in one breast than in the other on bilateral scans. Asymmetric enhancement may be due to benign as well as malignant causes.

2. FOCUS

A focus is a unique punctate enhancing dot usually < 5 mm, which is nonspecific, is too

small to be characterized morphologically, and has no corresponding finding on the precontrast scan. A focus can commonly be seen but should be evaluated in the clinical context. Multiple foci representing a pattern of background parenchymal enhancement are tiny dots of enhancement that are widely separated by intervening normal breast parenchyma that does not enhance; as stated previously, this should be considered to represent a pattern of BPE rather than multiple discrete foci of enhancement.

Although the lexicon has defined two descriptors, "focus" and "mass," which have defined features, in clinical practice one will observe that there actually is a continuum between these two descriptors, with some findings displaying intermediate features. When such an intermediate finding is encountered, the interpreting physician should first decide whether to evaluate the finding as a focus or a mass.

A focus may be benign or malignant. When evaluating a focus, the following features often indicate malignancy: unique and distinct from the BPE, no fatty hilum, washout kinetics, and significantly increased or new from the prior examination. Features of a focus that favor a benign process are: not unique compared to the BPE, bright on bright-fluid imaging, possible fatty hilum, persistent kinetics, and stable when compared to the prior examination or seen on a baseline examination.

As MRI techniques improve, fewer lesions will be described as foci, and instead be classified as masses.

3. MASSES

A mass is a 3-D, space-occupying structure with convex-outward contour. It may or may not displace or otherwise affect the surrounding normal breast tissue. Morphologic analysis is best performed with high spatial resolution techniques allowing mass shape and margin evaluation so that suspicious features can be differentiated from benign-appearing features. With high spatial resolution, the margin, internal architecture, and pattern of enhancement may be readily characterized. Findings should be viewed on pre- and postcontrast scans, and on other pertinent sequences (e.g., T2-weighted images to evaluate for cysts). In addition, in appropriate cases, 3-D reconstructions may be especially helpful in evaluating abnormal lesions.

a. Mass Shape/Margin

Mass shape and margin are used to distinguish benign from malignant breast disease. The mass shape may be oval (includes lobulated), round, or irregular. A mass margin may be circumscribed or not circumscribed (irregular, spiculated). If a mass has both irregular shape and margin, the MRI report should state that there is "a mass of irregular shape and margin" rather than stating there is an "irregular irregular mass." Although there are exceptions, in general, circumscribed masses are

suggestive of benign lesions, and not circumscribed masses are suspicious for carcinoma. Margin analysis depends on spatial resolution because a not circumscribed margin may appear relatively circumscribed on low spatial resolution scans. Compared to mammography, some small carcinomas can appear circumscribed on even high spatial resolution MRI studies. In general, mammography has extremely high spatial resolution that may not be matched with the current magnets in clinical use today. Margin and shape analysis should be performed on the first postcontrast image to avoid washout or progressive enhancement of the surrounding breast tissue.

Margin analysis on delayed imaging may be useful, as it has been observed on delayed imaging that mass margin may blur. The term "indistinct" margin has been suggested as a descriptor to address this situation and should be considered as a term under consideration. There are insufficient data at this time to include "indistinct" as a margin descriptor. We await robust data to validate any newer terms.

b. Internal Mass Enhancement Characteristics

Masses can contain homogeneous or heterogeneous enhancement. Homogeneous enhancement is confluent and uniform. Heterogeneous enhancement is nonuniform, with areas of variable signal intensity. Special mass enhancement patterns include rim enhancement and dark internal septations.

Homogeneous enhancement is suggestive of a benign process; however, as described previously, spatial resolution may limit the evaluation of small lesions. Small cancers can exhibit homogeneous enhancement. Heterogeneous enhancement is more characteristic of malignant lesions, especially if rim enhancement is present.

Non-enhancing, dark, internal septations are suggestive of fibroadenoma if other morphologic and kinetic characteristics also support this diagnosis. Non-enhancing dark internal septations are not pathognomonic of benignity, insofar as overlap with malignant lesions has been described. Non-enhancing masses with benign morphology are nearly always benign.

Rim enhancement of a solid mass is a suspicious finding. Cysts can enhance peripherally but are usually bright on bright-fluid sequences, confirming their cystic nature. Fat necrosis may exhibit rim enhancement with central low signal, lower than that of the surrounding fat. It may often be recognized based on the patient's history, mammographic findings, and verified central fat content on non-fat-suppressed images. The low signal of fat necrosis has been described as a "black hole." Both cyst and fat necrosis should be recognized as causes of a false-positive interpretation when characterizing rim-enhancing lesions, which are typically thought to represent cancers.

4. NON-MASS ENHANCEMENT (NME)

If the enhancement is neither a focus nor a mass, then it is classified as a non-mass enhancement. NME is the enhancement of an area that is not a mass and may extend over small or large regions, and whose internal enhancement characteristics can be described as a pattern discrete from the normal surrounding breast parenchyma.

a. Distribution

NME is classified according to the distribution of the enhancement, described as a focal area, linear, segmental, regional, multiple regions, or diffuse.

A focal area of abnormal enhancement encompasses a confined area of the breast, less than a breast quadrant and within a single duct system.

Linear enhancement is enhancement in a line, which corresponds to a single duct. This distribution is suspicious for carcinoma.

Segmental refers to enhancement that is triangular or cone shaped with the apex at the nipple and duct(s) and their branches. This distribution is suspicious for carcinoma.

Regional enhancement encompasses a broader area than a single duct system, may be geographic, and lacks convex-outward contour. This distribution spans at least a quadrant.

Multiple regions describe enhancement over at least two broad areas, separated by normal tissue or fat.

Diffuse enhancement describes widely scattered and evenly distributed, similar-appearing enhancement throughout the breast fibroglandular tissue.

Regional, multiple regions, and diffuse enhancement are more characteristic of benign disease, such as proliferative changes, although multicentric carcinoma may have this appearance.

b. Internal Enhancement Patterns

Focal areas, linear, segmental, regional, multiple regions, or diffuse enhancement can be further described as homogeneous, heterogeneous, clumped, or clustered ring enhancement. Clumped enhancement refers to an aggregate of enhancing foci in a cobblestone pattern that may be occasionally confluent. Clumped enhancement is suggestive of malignancy. We await data with respect to clustered ring enhancement.

5. KINETIC CURVE ASSESSMENT

Abnormal enhancement is defined as enhancement of higher signal intensity compared to the surrounding normal background parenchymal enhancement on a contrast-enhanced scan. Findings of abnormal enhancement should be evaluated on the first high-resolution, postcontrast scan when the enhancement in abnormal tissue is most intense and separable from the normal BPE.

Standard kinetic techniques are dynamic measurements in which the uptake and washout of contrast in tissues is monitored for a period of time following contrast injection. The rate of contrast media uptake and washout depends on perfusion, capillary permeability, blood volume, contrast media distribution volume, and other aspects of local anatomy and physiology. Tumors are frequently characterized by dense, highly permeable vasculature and relatively rapid blood flow, combined with a high degree of microheterogeneity. As a result, tumors tend to enhance more rapidly and more strongly than normal tissue following contrast media injection. Therefore, kinetic information can assist in the diagnosis of breast tumors and in the discrimination of benign and malignant lesions.

a. Kinetic Analysis

Analysis of the signal intensity on a pixel-by-pixel basis depicts the lesion enhancement rate over time. The kinetic information is typically expressed as a time intensity curve (TIC). Permeable tissues with good perfusion exhibit a rapid rise in contrast followed by evidence of washout seen at 4–5 minutes after a bolus injection. TICs can be manually calculated by placing a region-of-interest (ROI) of at least three pixels on the most suspicious region of enhancement within a lesion and documenting the change in signal intensity following contrast injection for 5–10 minutes. Currently, automated CAD systems often are used to calculate kinetic information, generating both color maps as well as graphs.

b. Advanced Kinetic Imaging/Parametric Imaging

Computer-aided analysis tools make it possible to depict kinetic parameters pixel-by-pixel as a parametric image, describing the variation in blood flow within a lesion and throughout the entire breast(s). Enhancement thresholds can be set by the radiologist when using these tools so that the parametric image will reflect all tissues enhancing above a designated threshold, usually set between a 50% and a 100% increase in signal intensity. The delayed phase of enhancement can then be color coded for ease of interpretation. Permeable tissues with good perfusion exhibit a rapid rise in contrast followed by evidence of washout, usually seen 4–5 minutes after a bolus injection. Many benign lesions follow a persistent type of curve, and many malignant lesions exhibit a washout curve; however, there is considerable overlap between benign and malignant lesions.

The signal intensity (SI) increase is measured relative to the baseline/background signal-intensity value and is not a quantitative measure of contrast media concentration or lesion perfusion (see below).

$$[(\text{SI}_{\text{post}} - \text{SI}_{\text{pre}})/\text{SI}_{\text{pre}}] \times 100\%$$

SI_{pre} = baseline signal intensity and SI_{post} = signal intensity after contrast injection

The accuracy of diagnosis based on signal-intensity curves depends on a predictable delivery of contrast agent using a bolus technique and a dose administered according to patient body weight.

While analysis of TICs is the most common method of analyzing kinetic MRI data, there are some weaknesses. Enhancement depends not only on contrast media concentration but also on other parameters, such as the native T1 (the tissue T1 before contrast injection) and instrumental parameters, such as flip angle and the type of RF pulse used for excitation. In addition, there is typically no correction for the arterial input function. Therefore, the maximum enhancement and the measured rates of contrast media uptake and washout depend not only on the intrinsic characteristics of local vasculature but also on systemic parameters, such as injected dose and cardiac output, as well as instrumental parameters. Quantitative methods that correct for these sources of variability are discussed below. Despite these potential sources of error, semi-quantitative analysis of TICs has been demonstrated to provide a very high sensitivity to breast cancer, combined with good specificity.

c. Use of TIC for diagnosis

Three general curve types are described, relying less on the absolute value of enhancement than on the shape of the enhancement curve. Most analysis is performed with CAD programs that create color maps that assign color based on kinetic features. There is currently a lack of a color mapping standard among vendors, therefore all the colored kinetic illustrations are accompanied by annotations of what the colors signify. As a generalization, malignancies enhance fast in the initial phase and wash out in the delayed phase. However, there is overlap in kinetics that is seen with both benign and malignant lesions, and one should not rely on color alone when assessing a lesion on MRI.

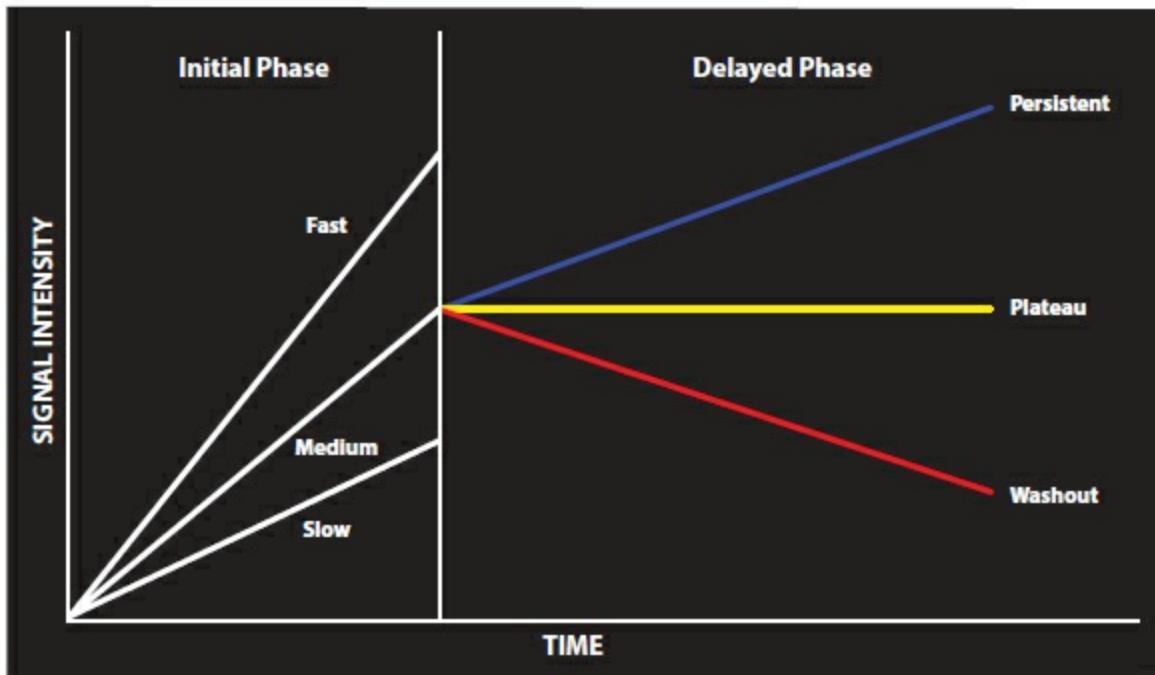
If a manual graph is generated, typically one or more ROIs are selected within a lesion, and the region with the most enhancing pixels should be reported.

TICs can be divided into three main shapes reflecting the initial enhancement phase and the delayed enhancement phase. The initial-phase enhancement pattern reflects enhancement within the first 2 minutes after injection or until peak enhancement is reached, and the delayed-phase enhancement pattern occurs after

2 minutes or after the peak enhancement is reached and is usually used to describe the curve shape.

The initial phase of enhancement is determined by comparing intensity in the first image acquired postcontrast to intensity in the precontrast image. An intensity increase of < 50% is classified as “slow,” 50%–100% is classified as “medium,” and >100% enhancement is classified as “fast.”

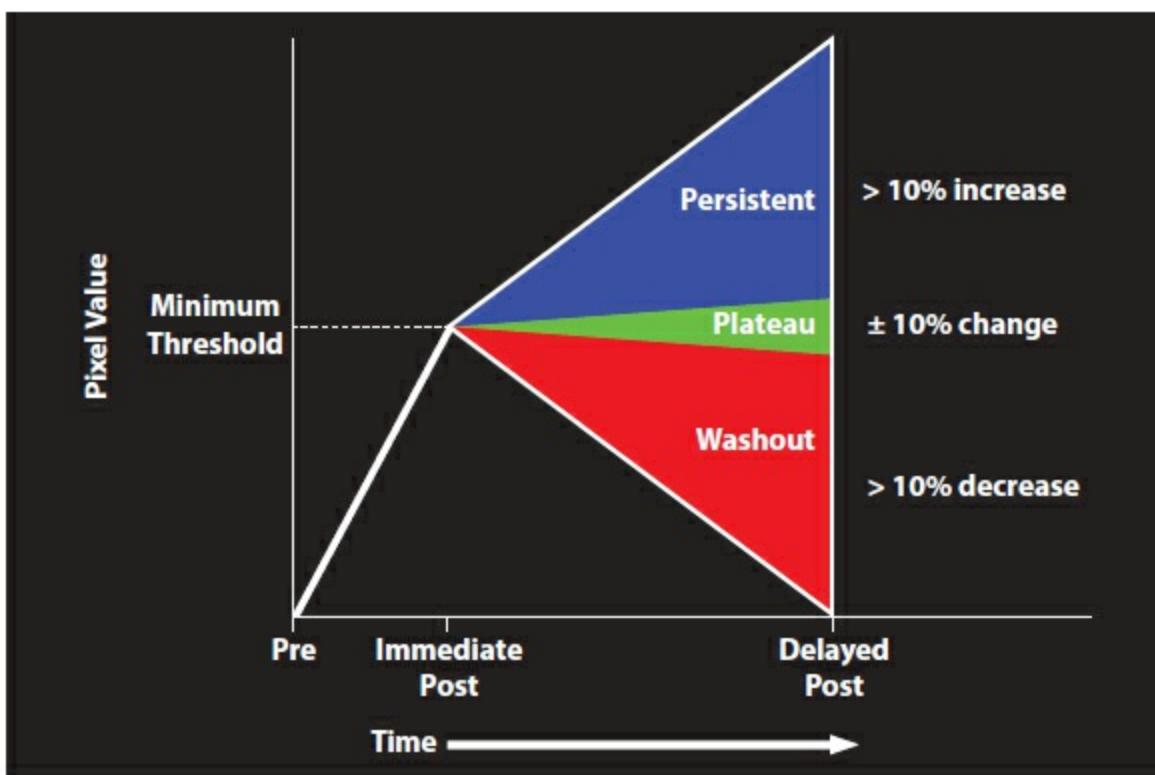
Chart 1. Kinetic Analysis



Delayed phase in this example has been coded as blue for persistent, yellow for plateau, and red for washout.

Delayed-phase enhancement is divided into three main categories: “Persistent” curves show continuously increasing enhancement throughout the delayed phase. “Plateau” curves remain constant in their signal intensity once peak enhancement is reached, usually after 2–3 minutes. “Washout” curves show decreasing signal intensity after peak enhancement is reached. In general, for the delayed phase, persistent is $\geq 10\%$ of the initial enhancement; plateau is equal to the initial enhancement; and washout is $\leq 10\%$ of the initial enhancement. However, there is overlap between the kinetic curves that depict malignant and benign lesions. As a general rule, many benign lesions follow “Persistent” curves, and many malignant lesions follow “Washout” curves. A “Plateau” curve can be seen with both benign and malignant lesions. The kinetic definition of enhancements is continuously evolving, and what we present here are representative guidelines.

Chart 2. Delayed Phase Analysis



Color coding is performed of the delayed phase on a pixel-by-pixel analysis. If a pixel's signal intensity increases (persistent) or decreases (washout) by $> 10\%$, different colors are assigned to the pixels. If the signal intensity does not change more than 10% (plateau) in either direction, then it is coded a different color. Delayed phase in this example has been coded as blue for persistent, green for plateau, and red for washout.

Morphologically benign-appearing lesions may benefit most from enhancement kinetics because enhancement kinetic data may influence the decision to biopsy a benign-appearing mass. On the other hand, suspicious morphologic features should prompt biopsy in appropriate clinical settings regardless of kinetic analysis. It should be emphasized that kinetic analysis is one aspect of interpretation, and management should not be based solely on kinetic features.

The semi-quantitative methods described above are commonly used in routine clinical practice. However, there are also established quantitative parameters that are closely related to tissue properties and are relatively independent of imaging acquisition methods. The most popular method for calculating these parameters depends on use of a two-compartment model or more complicated models to describe contrast media uptake and washout from tissue. If the contrast media concentration as a function of time and the arterial input function can be accurately estimated, equations derived from these models can be used to fit the data and, thus, extract quantitative parameters that are directly related to tissue perfusion/capillary permeability and other physiologic and anatomic features.

The most frequently used parameters include:

K_{trans}: Dependent on perfusion and capillary permeability as well as contrast media

distribution volume. A high value of K_{trans} ($> 0.25 \text{ min}^{-1}$) is associated with malignancy, but benign lesions such as fibroadenoma can also exhibit high K_{trans} .

k_{ep} : Reflects perfusion and capillary permeability. A high k_{ep} ($> 1.0 \text{ min}^{-1}$) is associated with malignant lesions. k_{ep} is particularly useful in cases where data are acquired with high temporal resolution.

v_e : Contrast media distribution volume. This parameter is sensitive to cell density and changes in cell membrane integrity.

v_b : When relatively high signal-to-noise ratio is available, blood volume can be calculated using an extended two-compartment model. High blood volume is an indicator of aggressive cancer.

AUC: The “area-under-the-curve” of contrast media concentration versus time is related to perfusion and capillary permeability.

AIF: For cases in which a local “arterial input function” can be measured, parameters associated with the AIF (e.g., delay and dispersion) can reflect important aspects of tumor anatomy and physiology, particularly interstitial pressure.

In principle, accurate calculation of these parameters allows quantitative characterization of hemodynamics, but the required calculations are subject to both systematic and random error. There is as yet no consensus that one or more quantitative methods should be used clinically.

6. DIFFUSION WEIGHTED IMAGING (DWI)

There is growing evidence that the specificity of breast MRI could be improved by advanced techniques such as DWI and magnetic resonance spectroscopy (MRS).^{1,2} DWI and MRS may be used for several clinical applications, such as monitoring the response to cancer therapies and improving the accuracy of lesion diagnosis (distinguish malignant versus benign lesions, reduce the number of unnecessary breast biopsies). At the time of this writing, however, both of these techniques remain in the research realm and are considered investigational.

DWI is a technique involving the exchange of water molecules (diffusion) between the breast tissue compartments. Diffusion rates vary between normal and pathologic tissue. DWI is quantified by a calculation called apparent diffusion coefficient (ADC) mapping, a calculated measure of water diffusion through the breast tissue. Previous studies have shown that ADC values vary between malignant and benign breast tissue,

but overlap exists as benign breast changes can mimic malignancies. Further complicating ADC evaluation, ADC values of the human breast are notoriously complicated to normalize. Despite these limitations, DWI has potential to become a useful tool and we await robust clinical data.

7. MAGNETIC RESONANCE SPECTROSCOPY (MRS)

MRS may be performed during an MRI examination to obtain information about the chemical content of breast lesions. Initial MRS studies of breast cancer show promising results, and a growing number of research groups are incorporating the technique analyzing hydrogen atoms (¹H) into their breast MRI protocols.

¹H-MRS analysis relies on the fact that a resonance from choline-containing compounds (tCho) is commonly present in malignant lesions but not in benign or normal tissues. Studies performed ex vivo have identified the numerous different choline compounds giving rise to the tCho resonance at a chemical shift of 3.2 ppm. In vivo, however, these are difficult to separate; therefore, the simplified approach is to treat the 3.2 ppm as a single resonance.

Studies have shown that the choline peak is elevated in cancer. The precise mechanism that produces an elevated choline is unknown. One theory is that elevated choline is an indicator of increased cellular proliferation because the largest component contributing to the choline peak from neoplastic tissue is phosphocholine (a membrane precursor). Therefore, increased choline in neoplastic tissues may be a reflection of increased membrane turnover by replicating cells.

Despite having incomplete knowledge of the mechanism, several groups have successfully shown that choline can be used as an indicator of malignancy with clinical 1.5T and higher field scanners.³ Some groups have also shown that the choline peak decreases or disappears in response to chemotherapy treatment.⁴ The results of these studies are encouraging, and with continued technical development and improvements in the case of clinical implementation, it seems possible that MRS may become a useful tool in detecting and managing breast cancer.

8. FINAL OVERALL ASSESSMENT

The breast MRI report should include a concise description of the important findings and final impression describing the radiologist's assessment of all imaging and clinical data. As taken from the BI-RADS® mammography lexicon, following the impressions, a final assessment category must be reported. The assessment categories include:

Category 0: Incomplete — Need Additional Imaging Evaluation

Category 1: Negative

Category 2: Benign

Category 3: Probably Benign

Category 4: Suspicious

Category 5: Highly Suggestive of Malignancy

Category 6: Known Biopsy-Proven Malignancy

If the findings are straightforward and the same for both breasts, a combined single final overall assessment may be reported. However, if there are multiple findings in each breast, separate, final, overall assessments should be reported for each breast.

In the event that multiple imaging studies are combined into a single breast imaging report, the final assessment should reflect the overall recommendation.

Implant studies should not be assigned a final assessment.

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1. Bartella L, Morris EA, Dershaw DD, et al. [Proton MR spectroscopy with choline peak as malignancy marker improves positive predictive value for breast cancer diagnosis: preliminary study](#). *Radiology* 2006;239:686–92.
2. Partridge SC, DeMartini WB, Kurland BF, Eby PR, White SW, Lehman CD. [Quantitative diffusion-weighted imaging as an adjunct to conventional breast MRI for improved positive predictive value](#). *AJR* 2009;193:1716–22.
3. Meisamy S, Bolan PJ, Baker EJ, et al. [Neoadjuvant chemotherapy of locally advanced breast cancer: predicting response with in vivo ¹H MR spectroscopy — a pilot study at 4T](#). *Radiology* 2004;233:424–31.
4. Tozaki M, Sakamoto W, Oyama Y, Maruyama K, Fukuma E. [Predicting pathological response to neoadjuvant chemotherapy in breast cancer with quantitative ¹H MR spectroscopy using the external standard method](#). *J Magn Reson Imaging* 2010;31:895–902.

II. BREAST IMAGING LEXICON – MRI

Table 1. BI-RADS® Breast MRI Lexicon Overview

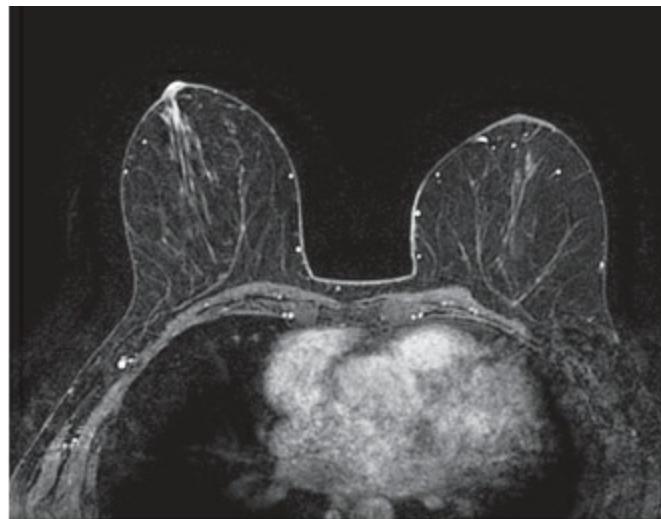
Breast Tissue	Terms	
A. Amount of fibroglandular tissue (FGT)	1. a. Almost entirely fat 2. b. Scattered fibroglandular tissue 3. c. Heterogeneous fibroglandular tissue 4. d. Extreme fibroglandular tissue	
B. Background parenchymal enhancement (BPE)	1. Level	a. Minimal b. Mild c. Moderate d. Marked
	2. Symmetric or asymmetric	a. Symmetric b. Asymmetric
Findings	Terms	
C. Focus		
D. Masses	1. Shape	a. Oval b. Round c. Irregular
	2. Margin	a. Circumscribed b. Not circumscribed i. Irregular ii. Spiculated
	3. Internal enhancement characteristics	a. Homogeneous b. Heterogeneous c. Rim enhancement d. Dark internal septations
E. Non-mass enhancement (NME)	1. Distribution	a. Focal b. Linear c. Segmental d. Regional e. Multiple regions f. Diffuse
	2. Internal enhancement patterns	a. Homogeneous b. Heterogeneous c. Clumped d. Clustered ring
F. Intramammary lymph node		
G. Skin lesion		
H. Non-enhancing findings	1. Ductal precontrast high signal on T1W 2. Cyst 3. Postoperative collections (hematoma/seroma) 4. Post-therapy skin thickening and trabecular thickening 5. Non-enhancing mass 6. Architectural distortion 7. Signal void from foreign bodies, clips, etc.	
I. Associated features	1. Nipple retraction 2. Nipple invasion 3. Skin retraction 4. Skin thickening 5. Skin invasion a. Direct invasion b. Inflammatory cancer 6. Axillary adenopathy	

	7. Pectoralis muscle invasion	
	8. Chest wall invasion	
	9. Architectural distortion	
J. Fat containing lesions	1. Lymph nodes	a. Normal b. Abnormal
	2. Fat necrosis	
	3. Hamartoma	
	4. Postoperative seroma/hematoma with fat	
K. Location of lesion	1. Location 2. Depth	
L. Kinetic curve assessment Signal intensity (SI)/time curve description	1. Initial phase	a. Slow b. Medium c. Fast
	2. Delayed phase	a. Persistent b. Plateau c. Washout
M. Implants	1. Implant material and lumen type	a. Saline b. Silicone i. Intact ii. Ruptured c. Other implant material d. Lumen type
	2. Implant location	a. Retroglandular b. Retropectoral
	3. Abnormal implant contour	a. Focal bulge
	4. Intracapsular silicone findings	a. Radial folds b. Subcapsular line c. Keyhole sign (teardrop, noose) d. Linguine sign
	5. Extracapsular silicone	a. Breast b. Lymph nodes
	6. Water droplets	
	7. Peri-implant fluid	

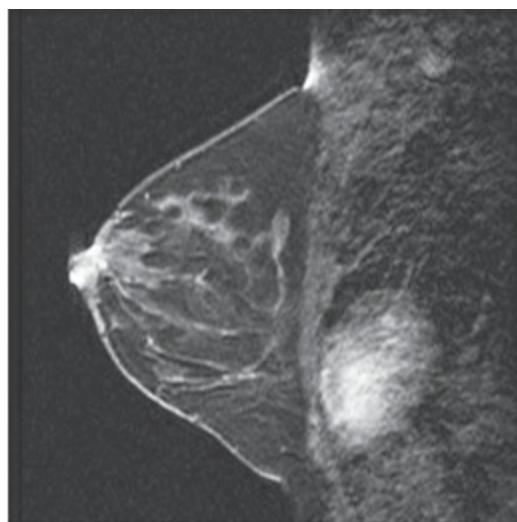
A. AMOUNT OF FIBROGLANDULAR TISSUE (FGT)

FGT is assessed on fat-saturated T1W imaging or non-fat-saturated T1W imaging.

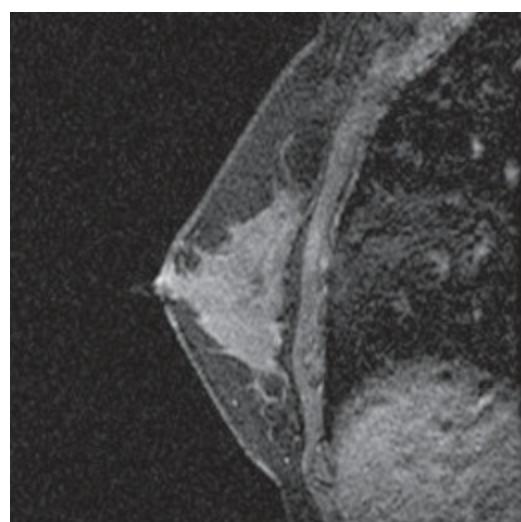
1. a. ALMOST ENTIRELY FAT
2. b. SCATTERED FIBROGLANDULAR TISSUE
3. c. HETEROGENEOUS FIBROGLANDULAR TISSUE
4. d. EXTREME FIBROGLANDULAR TISSUE



**Figure 1 – AMOUNT OF FIBROGLANDULAR TISSUE:
ALMOST ENTIRELY FAT.** Fat-suppressed T1W image.



**Figure 2 – AMOUNT OF FIBROGLANDULAR
TISSUE: SCATTERED FIBROGLANDULAR
TISSUE.** Fat-suppressed T1W image.



**Figure 3 – AMOUNT OF FIBROGLANDULAR
TISSUE: HETEROGENEOUS FIBROGLANDULAR
TISSUE.** Fat-suppressed T1W image.



Figure 4 – AMOUNT OF FIBROGLANDULAR TISSUE: EXTREME FIBROGLANDULAR TISSUE.
Fat-suppressed T1W image.

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

1. LEVEL

a. Minimal

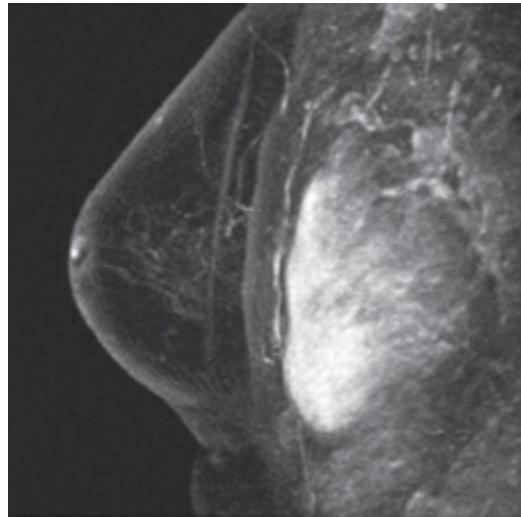


Figure 5 – LEVEL: MINIMAL BPE. Subtraction maximum intensity projection (MIP) Fat-suppressed postcontrast T1W image.

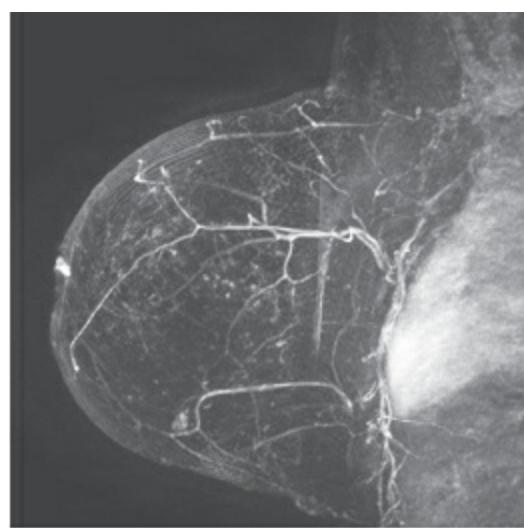


Figure 6 – LEVEL: MINIMAL BPE. Subtraction MIP. Fat-suppressed postcontrast T1W image.

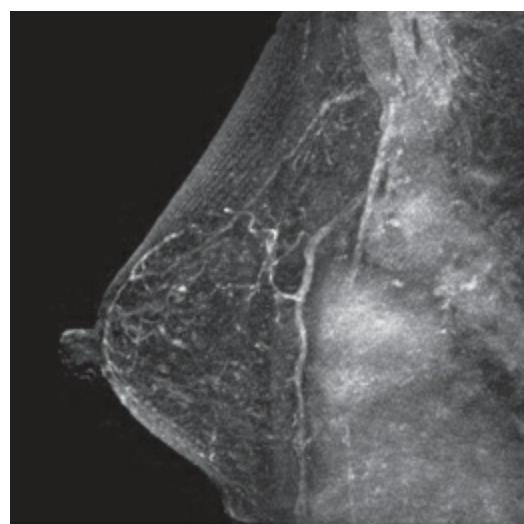


Figure 7 – LEVEL: MINIMAL BPE. Subtraction MIP. Fat-suppressed postcontrast T1W image.



Figure 8 – LEVEL: MINIMAL BPE. Fat-suppressed postcontrast T1W image. Note clip artifact inferiorly (arrow).

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

1. LEVEL

b. Mild

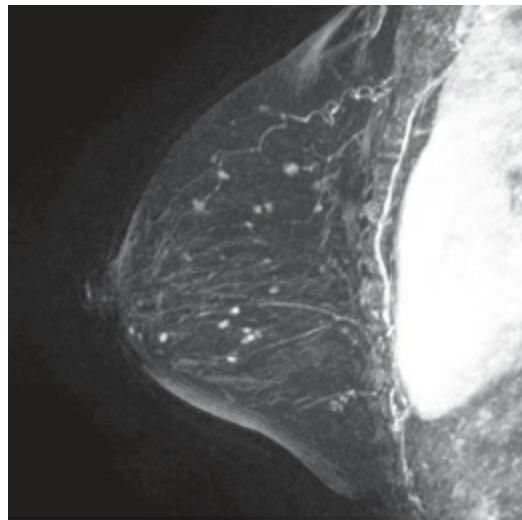


Figure 9 – LEVEL: MILD BPE. Subtraction MIP. Fat-suppressed postcontrast T1W image.

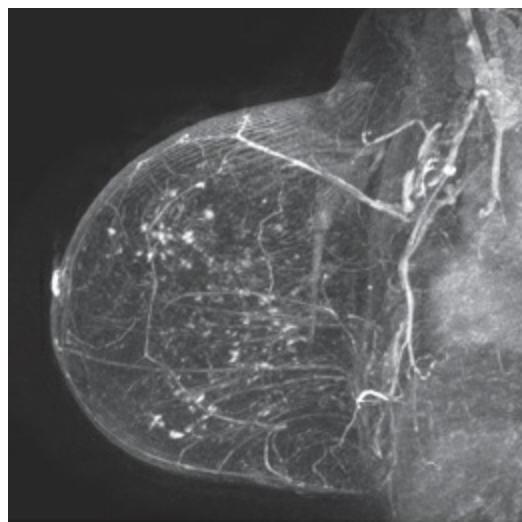


Figure 10 – LEVEL: MILD BPE. Subtraction MIP image. Fat-suppressed postcontrast T1W image.

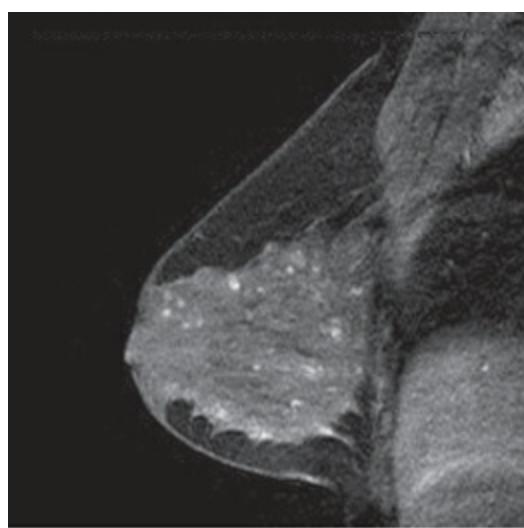


Figure 11 – LEVEL: MILD BPE. First fat-suppressed postcontrast T1W image.

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

1. LEVEL

c. Moderate

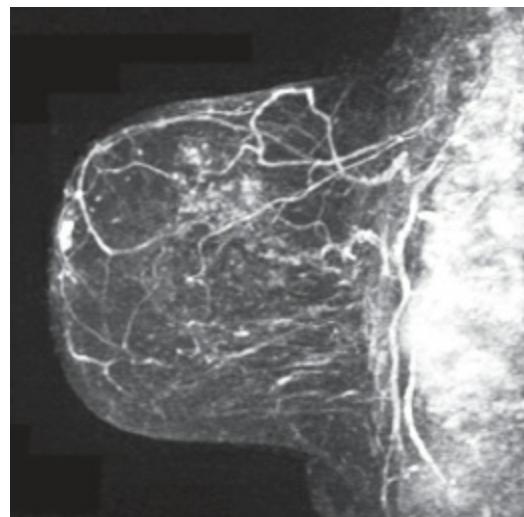


Figure 12 – LEVEL: MODERATE BPE.
Subtraction MIP. Fat-suppressed postcontrast T1W image.

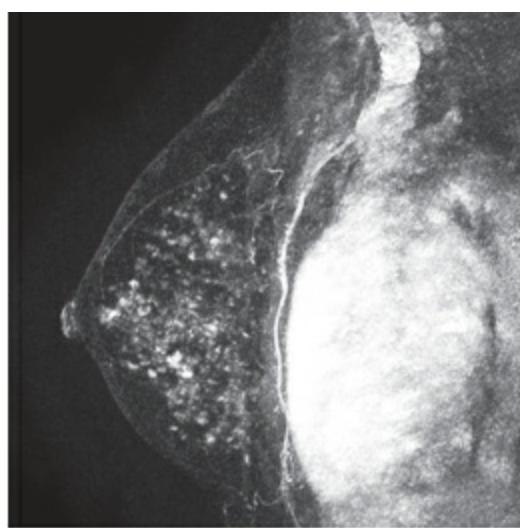


Figure 13 – LEVEL: MODERATE BPE.
Subtraction MIP. Fat-suppressed postcontrast T1W image.

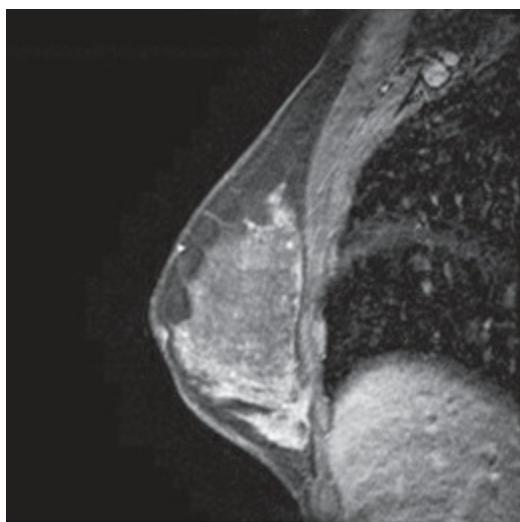


Figure 14 – LEVEL: MODERATE BPE. First fat-suppressed postcontrast T1W image.

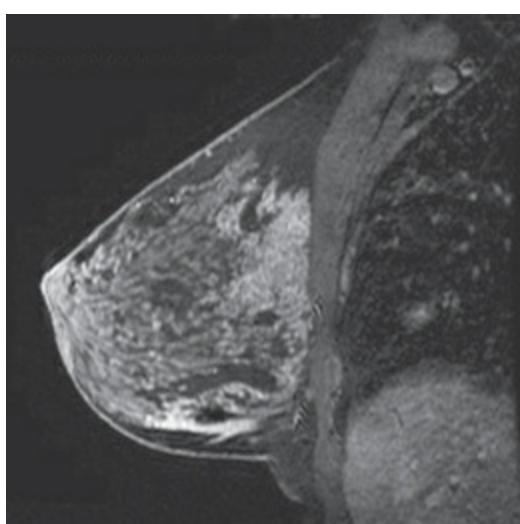


Figure 15 – LEVEL: MODERATE BPE. First fat-suppressed postcontrast T1W image.

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

1. LEVEL

d. Marked

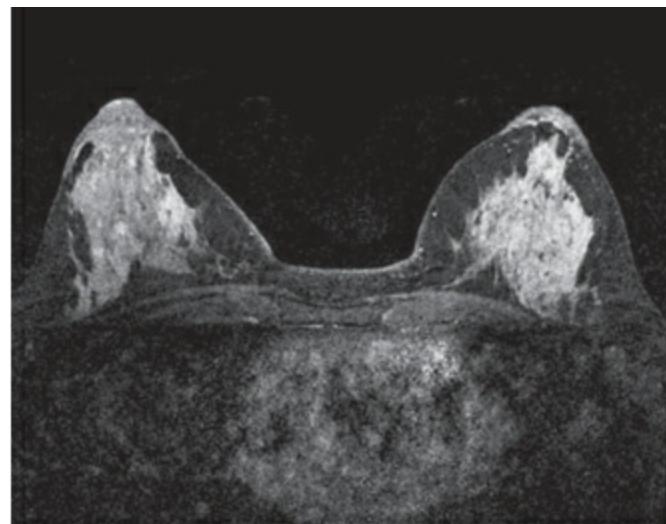


Figure 16 – LEVEL: MARKED BPE. Fat-suppressed postcontrast T1W image.

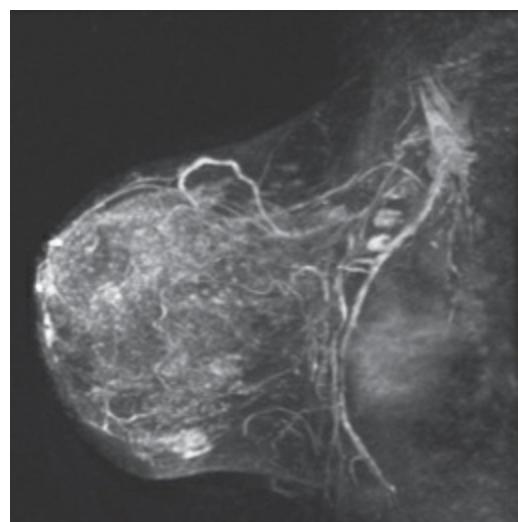


Figure 17 – LEVEL: MARKED BPE. Subtraction MIP postcontrast T1W image.

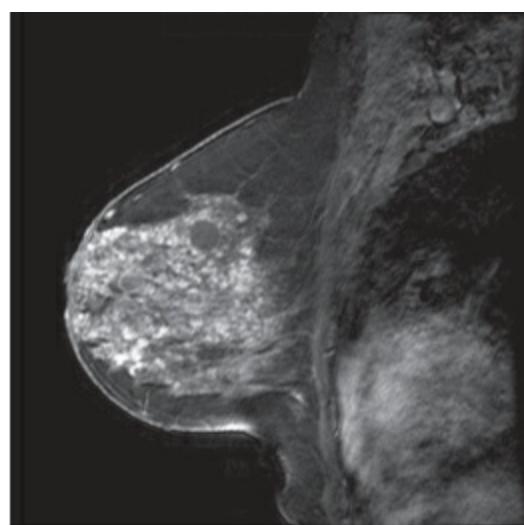


Figure 18 – LEVEL: MARKED BPE. First fat-suppressed postcontrast T1W image.

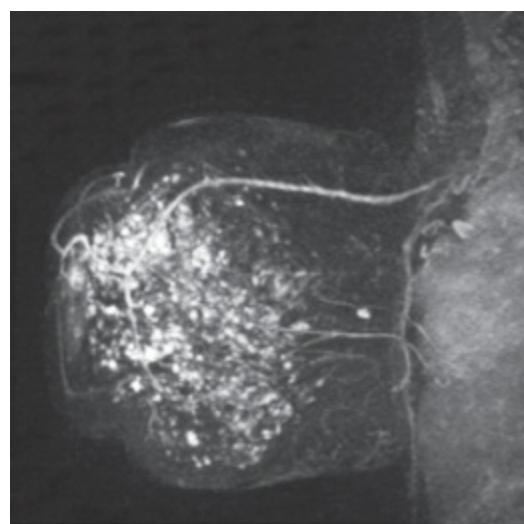


Figure 19 – LEVEL: MARKED BPE. Subtraction MIP. Postcontrast T1W image.

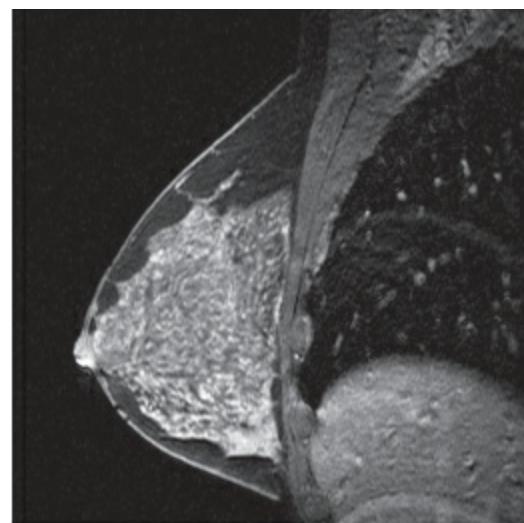


Figure 20 – LEVEL: MARKED BPE. First fat-suppressed postcontrast T1W image.

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

2. SYMMETRIC OR ASYMMETRIC

Report if bilateral scans are done.

a. Symmetric

Symmetric denotes enhancement in both breasts. Mirror-image patterns of symmetric BPE are likely related to the vascular supply of the breast. For example, early preferential enhancement may occur in the upper outer quadrants and along the inferior aspect of the breast (previously described as sheets of enhancement).

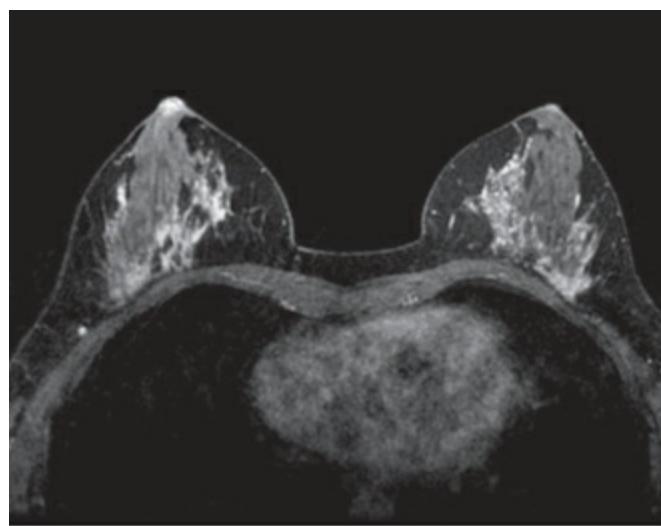


Figure 21 – SYMMETRIC OR ASYMMETRIC: SYMMETRIC.
Moderate BPE. Fat-suppressed postcontrast T1W image.

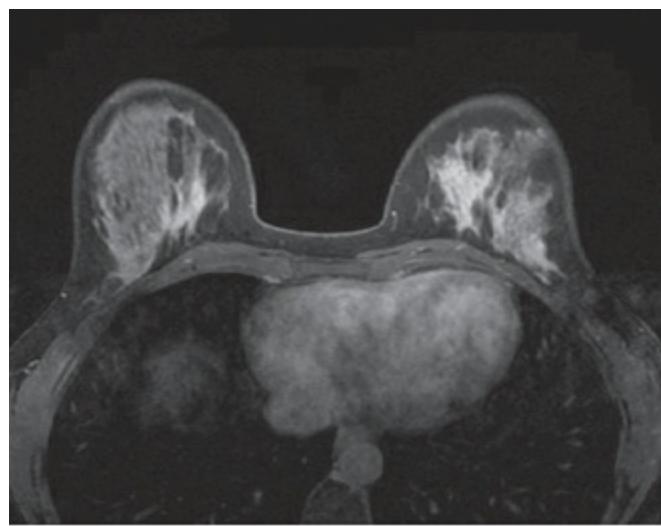


Figure 22 – SYMMETRIC OR ASYMMETRIC: SYMMETRIC.
Moderate BPE. Fat-suppressed postcontrast T1W image.

B. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

2. SYMMETRIC OR ASYMMETRIC

b. Asymmetric

Asymmetric denotes more enhancement in one breast than in the other — this can be seen after radiation therapy, when the radiated breast has less BPE than the nonradiated breast. Asymmetric enhancement should be evaluated carefully as it may represent a pathologic process.

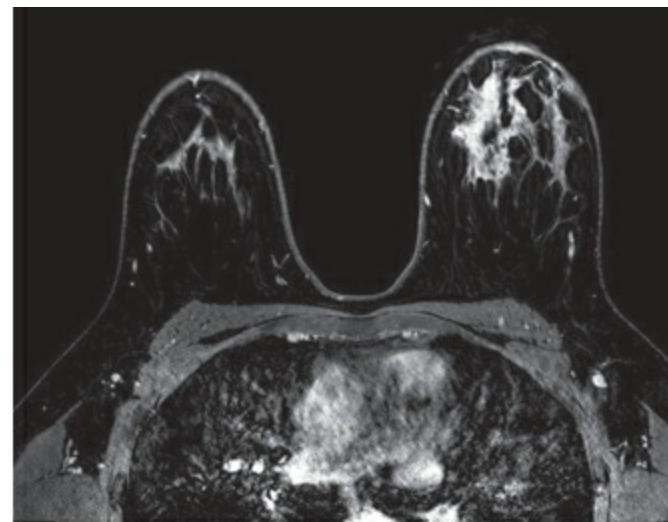


Figure 23 – SYMMETRIC OR ASYMMETRIC: ASYMMETRIC.
Mastitis in the left breast causing increased enhancement.
Fat-suppressed postcontrast T1W image.

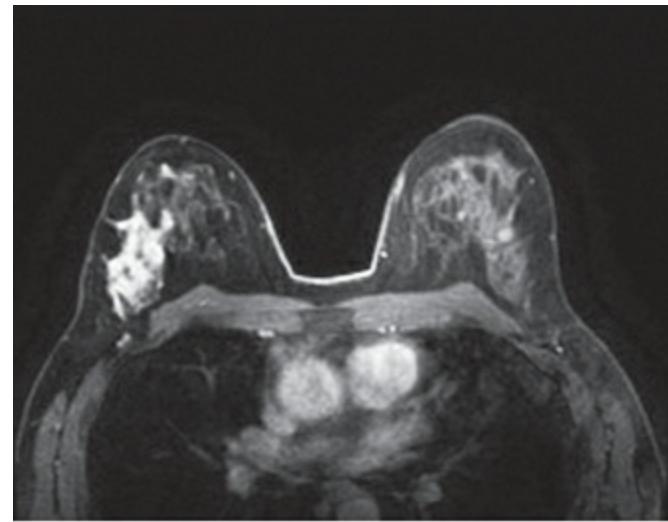


Figure 24 – SYMMETRIC OR ASYMMETRIC: ASYMMETRIC.
Increased enhancement in the lateral right breast. Fat-suppressed postcontrast T1W image. Pathology: ductal carcinoma in situ (DCIS).

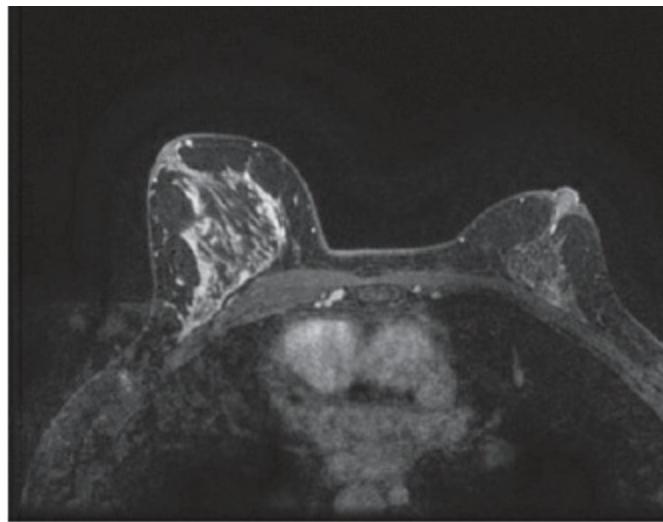


Figure 25 – SYMMETRIC OR ASYMMETRIC: ASYMMETRIC.
Moderate BPE right breast. Minimal BPE left breast status post-breast-conservation therapy and radiation therapy.
Fat-suppressed postcontrast T1W image.

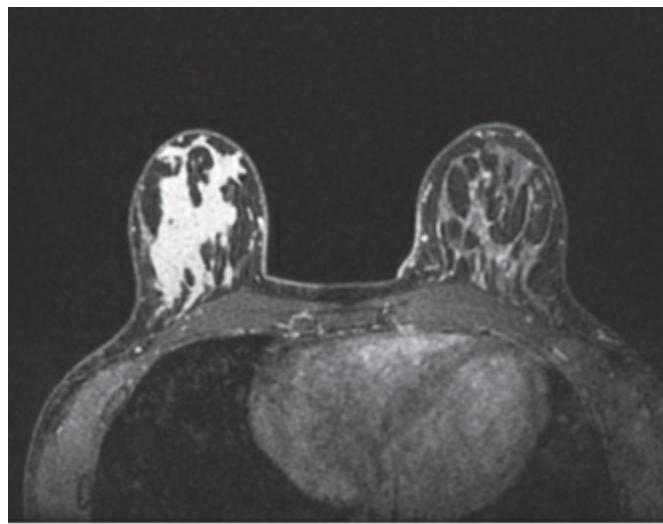


Figure 26 – SYMMETRIC OR ASYMMETRIC: ASYMMETRIC.
Regional enhancement in the right breast. Extensive lobular carcinoma in situ (LCIS) and invasive lobular carcinoma. Fat-suppressed postcontrast T1W image.

C. FOCUS

A focus is a dot of enhancement so small that it cannot be otherwise characterized; its shape and margin cannot be seen clearly enough to be described. A focus does not clearly represent a space-occupying lesion or mass and is unique from the surrounding background parenchymal enhancement. In general, foci are a few millimeters in size; however, applying strict size criteria is discouraged, since cancers < 5 mm may be identified in the breast on MR imaging. Multiple foci (i.e., not unique) can be separated widely in the breast by normal fibroglandular tissue or fat and usually represent a pattern of background parenchymal enhancement.

The following features make a focus more likely to be benign:

- high signal on bright-fluid imaging
- fatty hilum
- persistent kinetics
- stable since the prior examination

The following features make a focus more suspicious:

- not bright on T2W imaging
- no fatty hilum
- washout kinetics
- increase in size since the prior exam or new since the prior exam

If a focus has an irregular shape, a margin that is not circumscribed, or internal enhancement characteristics, then the finding should be described as a mass.

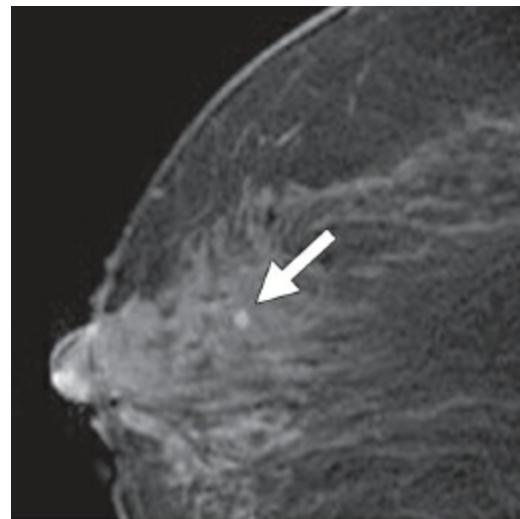


Figure 27 – FOCUS (arrow). Fat-suppressed first postcontrast T1W image. Stable from prior exams. No pathology.

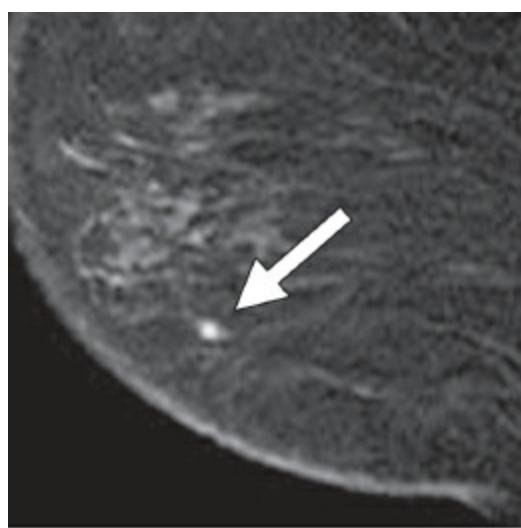


Figure 28 – FOCUS (arrow). Fat-suppressed first postcontrast T1W Image. Stable from prior exams. No pathology.



Figure 29 – FOCUS. Anterior to lumpectomy site (arrow). Fat-suppressed first postcontrast T1W image. MR vacuum biopsy yielded atypical duct hyperplasia (ADH). Surgery yielded ductal carcinoma in situ.

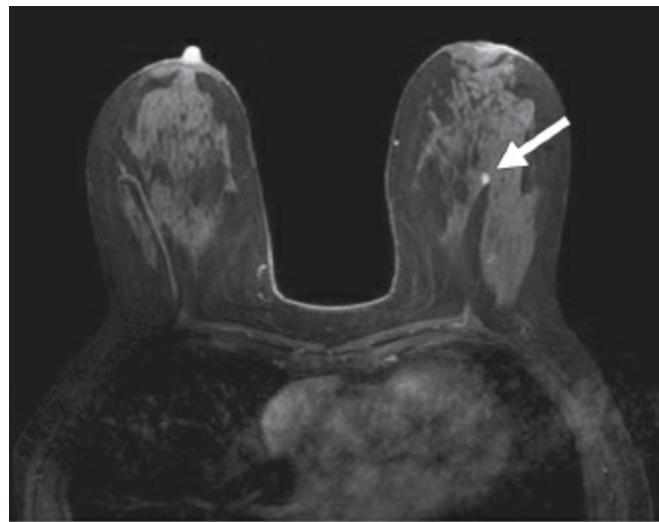


Figure 30 – FOCUS. Solitary FOCUS. Fat-suppressed first postcontrast T1W image. Pathology: lobular carcinoma in situ (arrow).

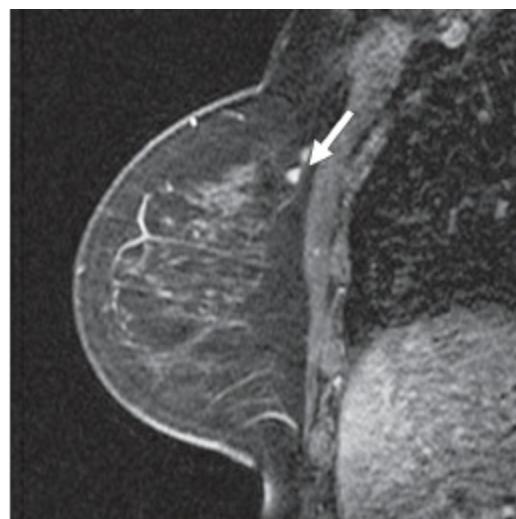


Figure 31 – FOCUS (arrow). Fat-suppressed first postcontrast T1W image.

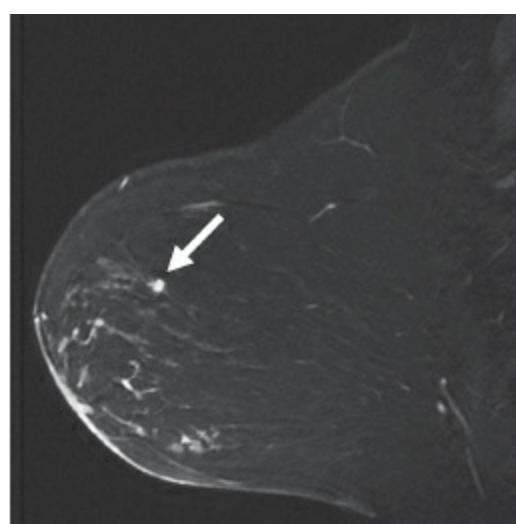


Figure 32 – FOCUS (arrow). Fat-suppressed first postcontrast T1W image.

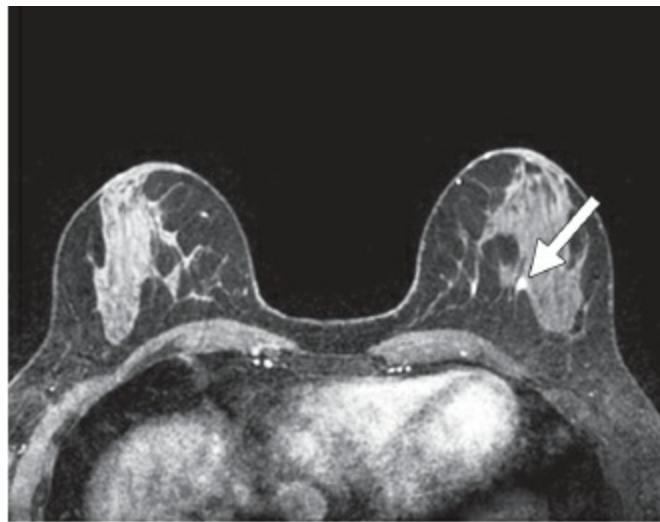


Figure 33 – FOCUS. Left breast (arrow). Fat-suppressed first postcontrast T1W image.

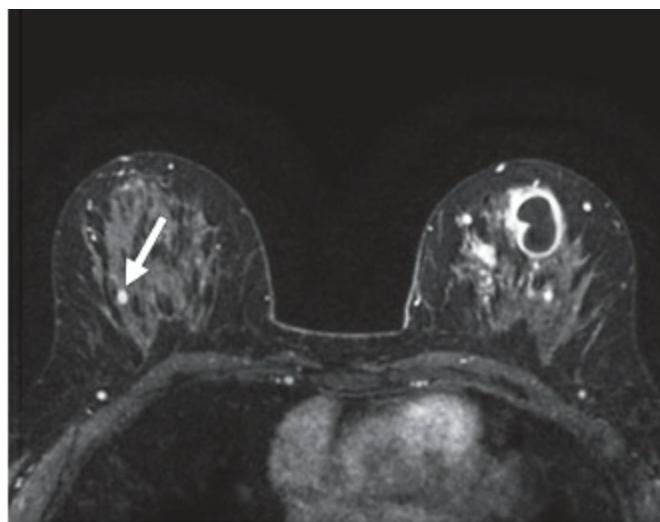


Figure 34 – FOCUS. Right breast (arrow). Note multicentric carcinoma in the contralateral left breast. Fat-suppressed first postcontrast T1W image.

Bright-fluid imaging can help in the evaluation of a focus. Benign lesions are generally very high in signal intensity (cyst-like).

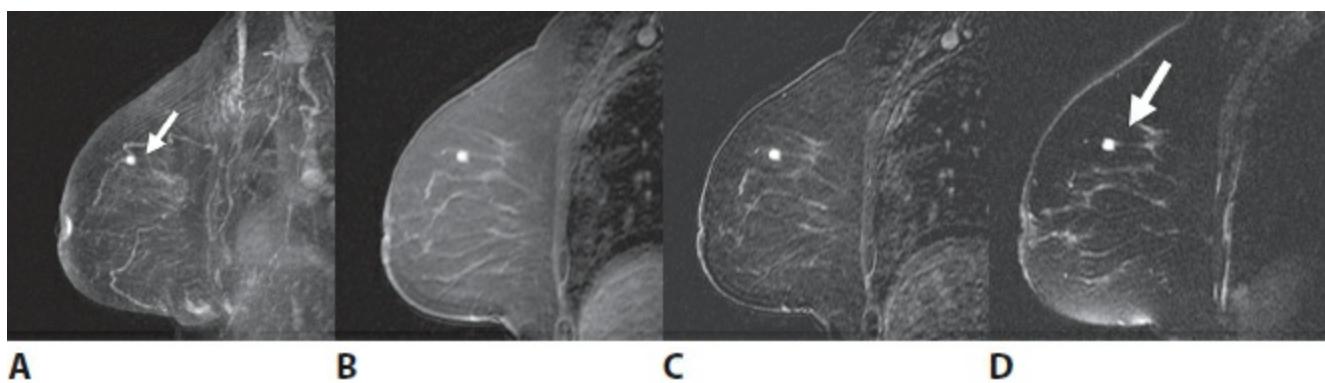


Figure 35 – FOCUS. Corresponded to lymph node on targeted US (thin arrow). Note extremely high signal on T2W image (thick arrow). MIP (a); T1W imaging postcontrast (b); subtraction (c); T2W imaging (d).

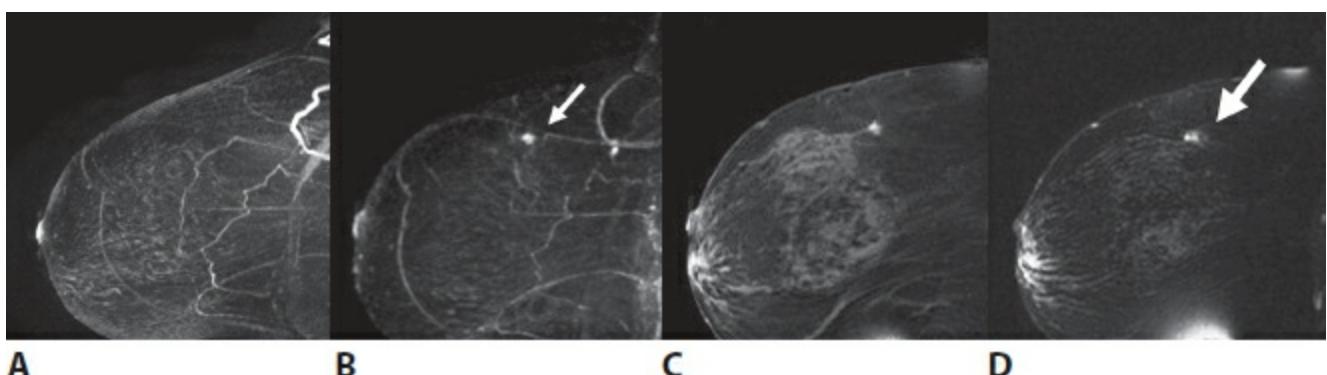


Figure 36 – FOCUS (arrow). This is a new finding increasing suspicion. Also note only slightly high signal intensity of invasive cancer (not cyst-like) on T2W imaging (thick arrow), adding to lesion suspicion. Prior 1-year MIP (a); T1W imaging (b); subtraction (c); T2W imaging (d).

D. MASSES

A mass is 3-D and occupies space. It has a convex-outward contour and is usually oval, round, or irregular in shape.

1. SHAPE

a. Oval (includes lobulated)

Oval describes a mass that is elliptical or egg-shaped (may include two or three undulations).

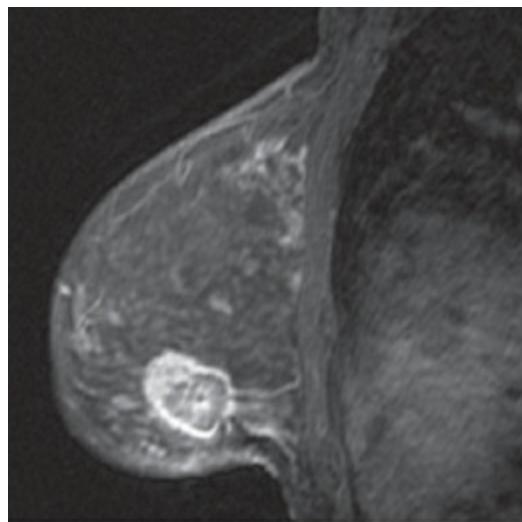


Figure 37 – SHAPE: OVAL. Rim-enhancing mass. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

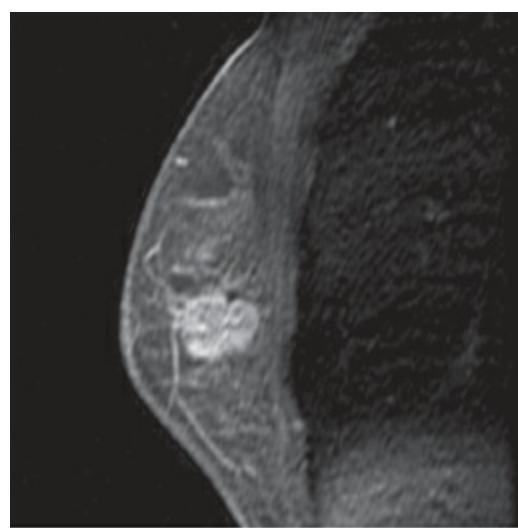


Figure 38 – SHAPE: OVAL. Rim-enhancing mass. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

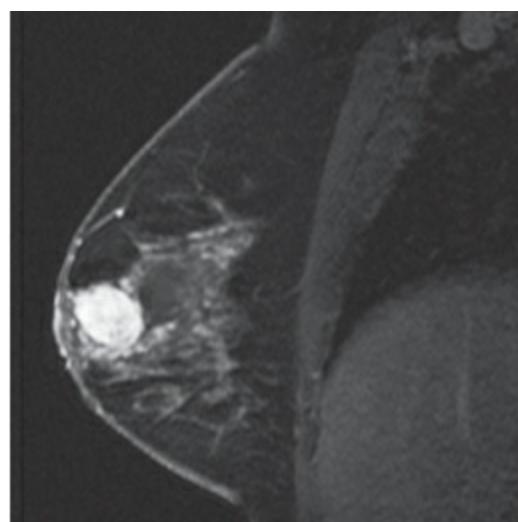


Figure 39 – SHAPE: OVAL. Mass with heterogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: phyllodes tumor.

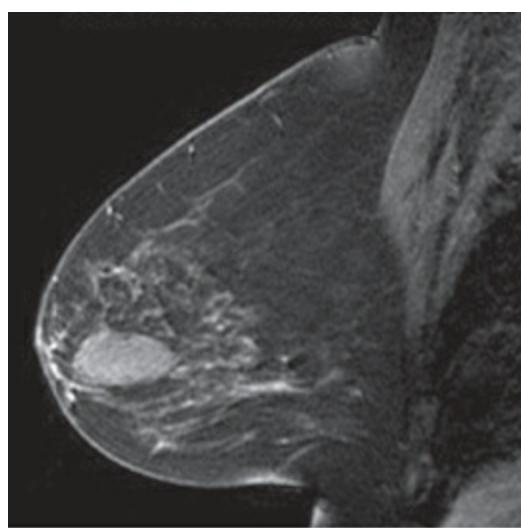


Figure 40 – SHAPE: OVAL. Mass with homogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: fibroadenoma.

D. MASSES

1. SHAPE

b. Round

Round describes a mass that is spherical, ball-shaped, circular, or globular in shape.

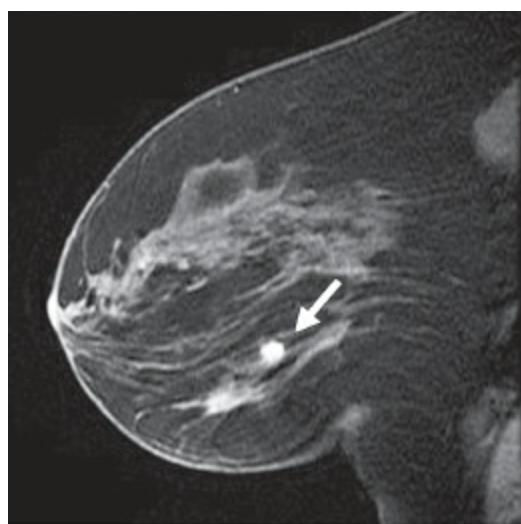


Figure 41 – SHAPE: ROUND. Not circumscribed mass (arrow) with heterogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

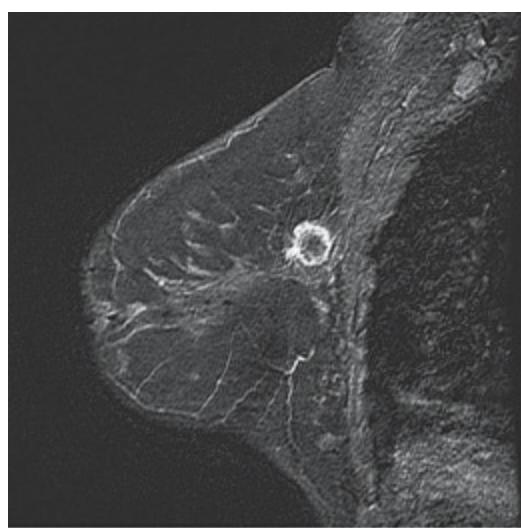


Figure 42 – SHAPE: ROUND. Not circumscribed mass with rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: metaplastic squamous carcinoma.

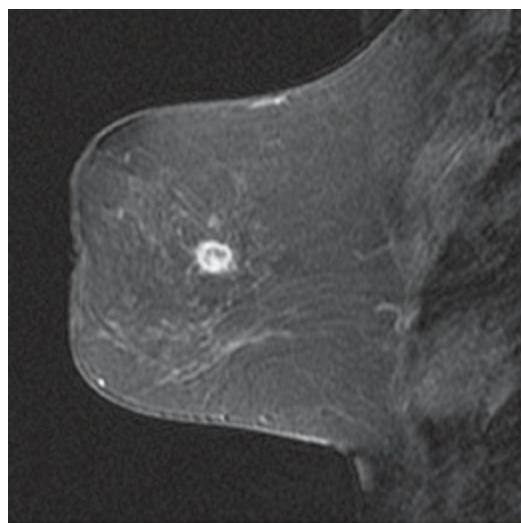


Figure 43 – SHAPE: ROUND. Not circumscribed mass with rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: metaplastic squamous carcinoma.

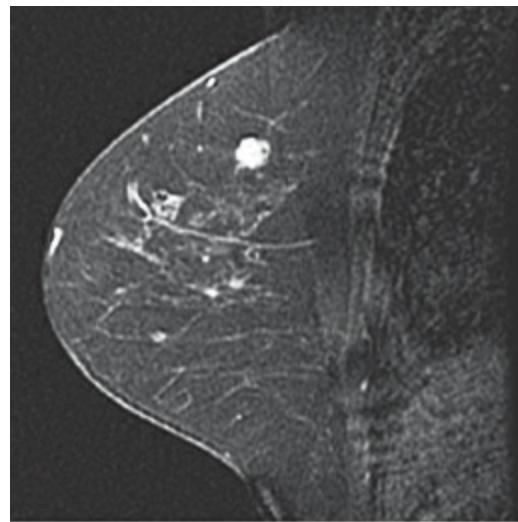


Figure 44 – SHAPE: ROUND. Not circumscribed mass with heterogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: fibroadenoma.

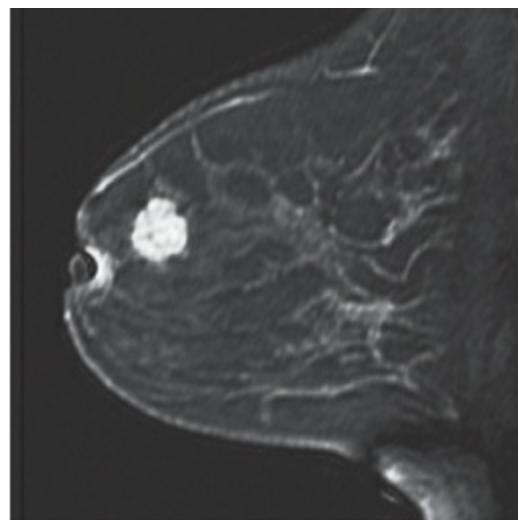


Figure 45 – SHAPE: ROUND. Not circumscribed mass with heterogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

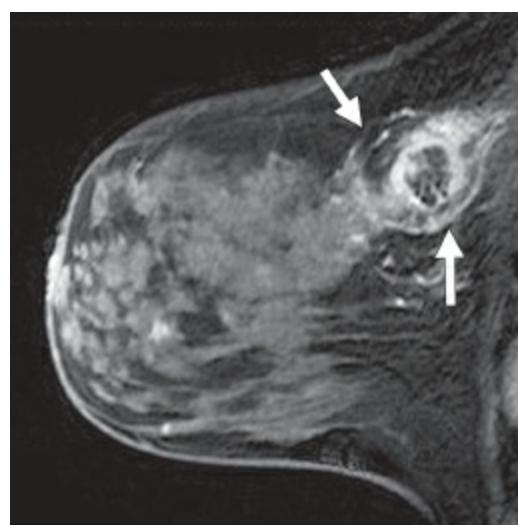


Figure 46 – SHAPE: ROUND. Circumscribed mass with rim and heterogeneous enhancement (*arrows*). Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

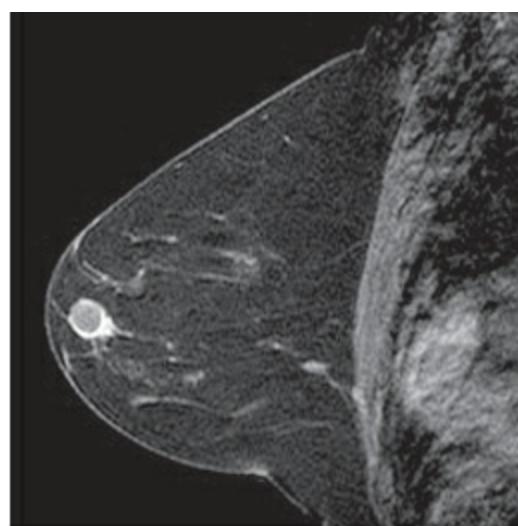


Figure 47 – SHAPE: ROUND. Not circumscribed mass with heterogeneous enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

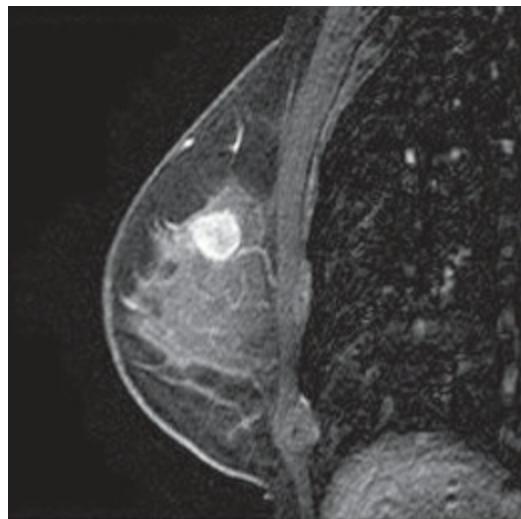


Figure 48 – SHAPE: ROUND. Not circumscribed mass with rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

D. MASSES

1. SHAPE

c. Irregular

The lesion's shape is neither round nor oval. For MRI, use of this descriptor usually implies a suspicious finding.

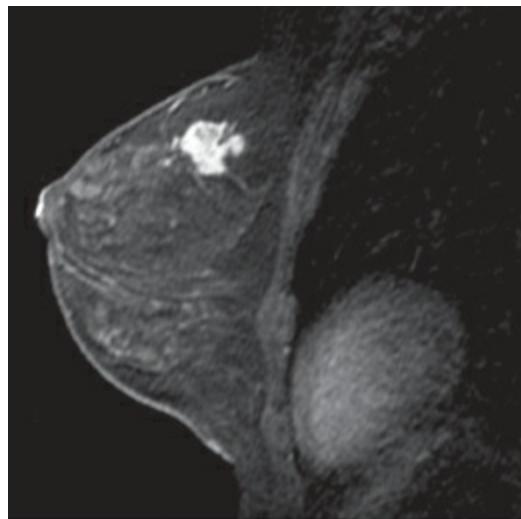


Figure 49 – SHAPE: IRREGULAR. Not circumscribed mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

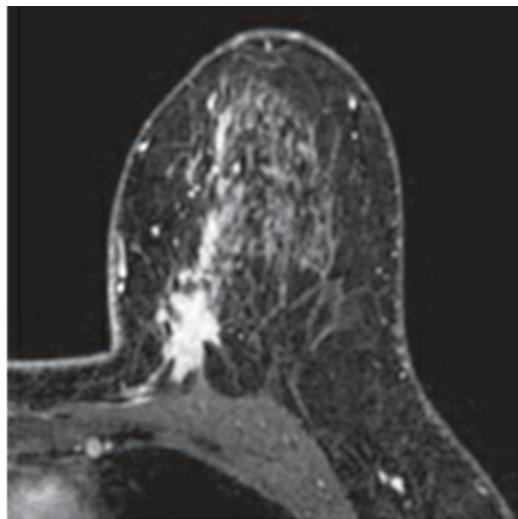


Figure 50 – SHAPE: IRREGULAR. Not circumscribed mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma. Note tenting of the pectoralis muscle but no invasion. Note linear clumped non-mass enhancement anterior to the mass representing DCIS.

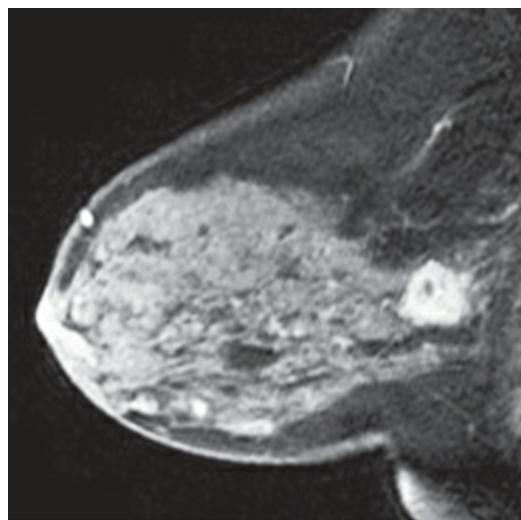


Figure 51 – SHAPE: IRREGULAR. Not circumscribed mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

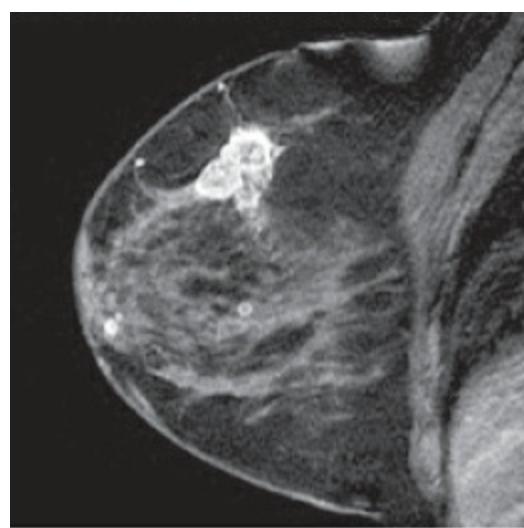


Figure 52 -SHAPE: IRREGULAR. Not circumscribed mass with rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

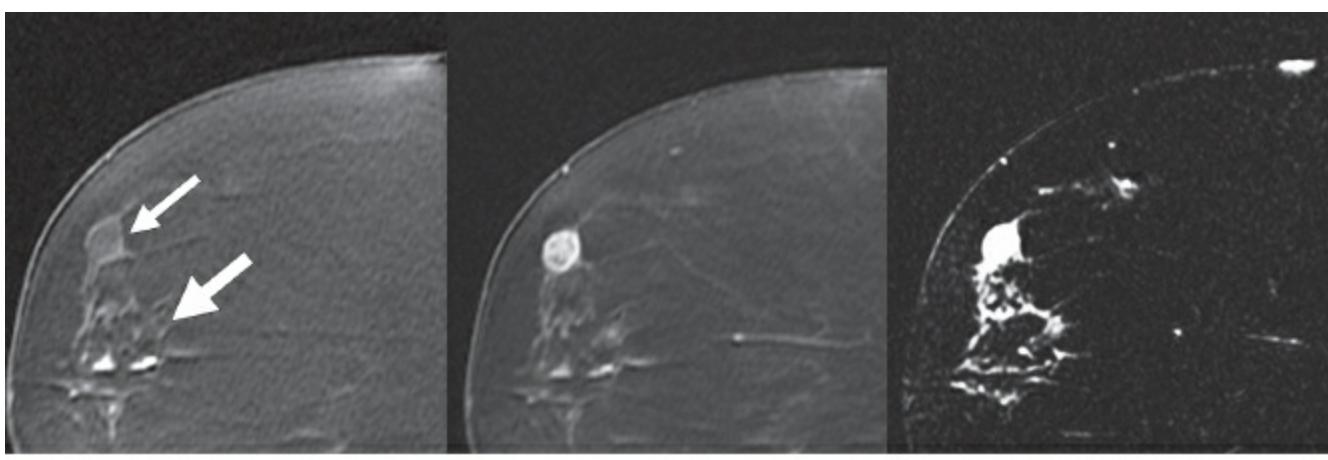
D. MASSES

2. MARGIN

The margin is the edge or border of the lesion. The descriptors of margin, like the descriptors of shape, are important predictors of whether a mass is benign or malignant. The descriptor for margin modifies the shape of the mass and characterizes the mass border with the surrounding breast tissue. The margin may be described as circumscribed or not circumscribed.

a. Circumscribed (historically, smooth)

The margin is sharply demarcated with an abrupt transition between the lesion and the surrounding tissue. For MRI, the entire margin must be well defined for a mass to qualify as “circumscribed”. A mass for which any portion of the margin is not circumscribed should be classified on the basis of the latter (the more suspicious finding).



A **B** **C**

Figure 53 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass. Fibroadenoma (*thin arrow*). Fat-suppressed precontrast T1W image (*a*). Note high signal in ducts (*thick arrow*). Fat-suppressed postcontrast T1W image (*b*) demonstrates rim enhancement. T2W image (*c*).

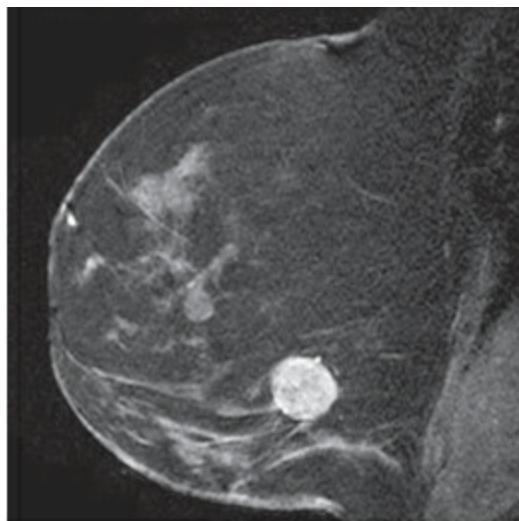


Figure 54 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

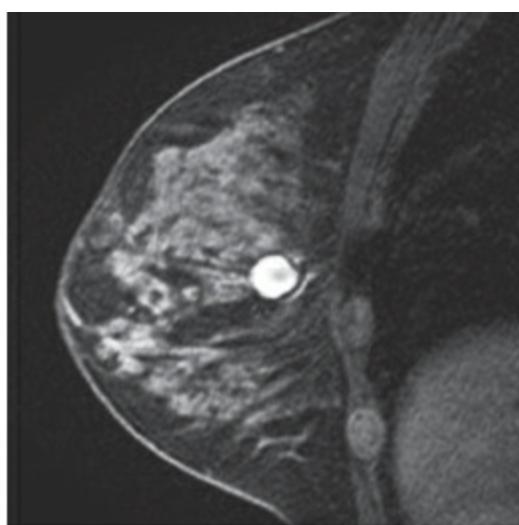


Figure 55 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass. Fat-suppressed precontrast T1W image. No enhancement was noted on the postcontrast images. Post-biopsy hematoma.

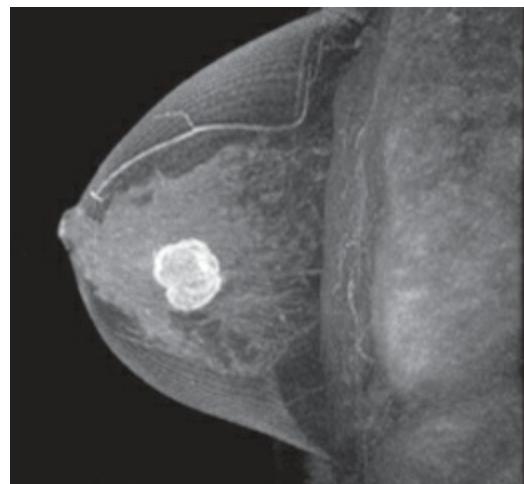


Figure 56 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass with rim enhancement. Fat-suppressed first postcontrast T1W MIP image. Pathology: invasive ductal carcinoma.

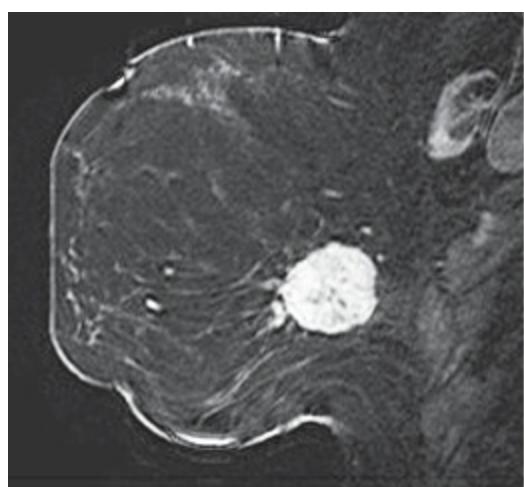


Figure 57 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass. Fat-suppressed precontrast T1W image. No enhancement was noted on the postcontrast images. Postbiopsy hematoma.

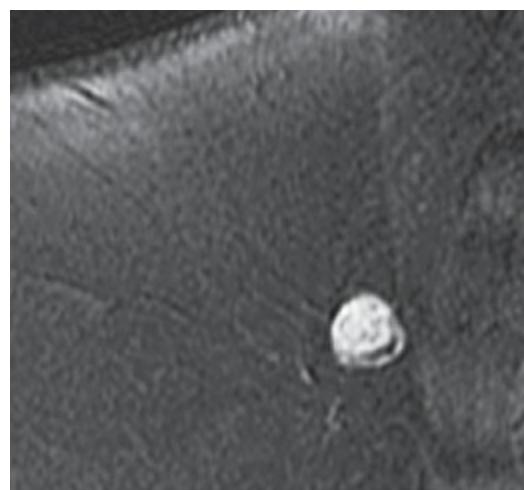


Figure 58 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass with rim enhancement. Fat-suppressed first postcontrast T1W MIP image. Pathology: invasive ductal carcinoma.

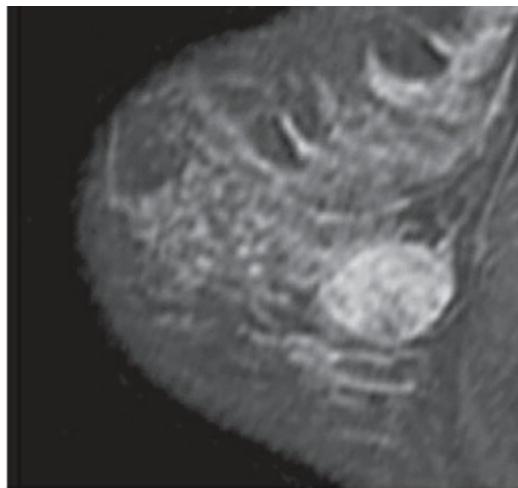


Figure 59 – MARGIN: CIRCUMSCRIBED. Round, CIRCUMSCRIBED mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

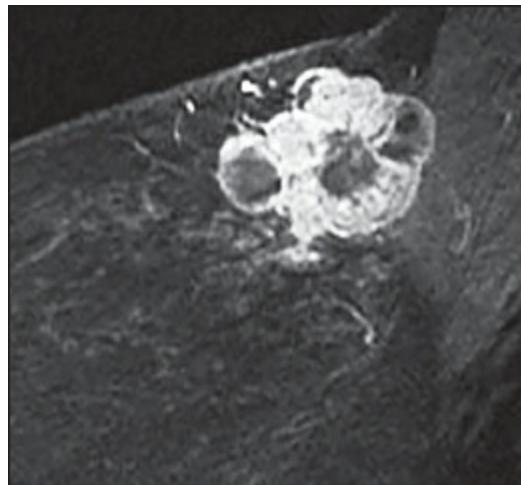


Figure 60 – MARGIN: CIRCUMSCRIBED. Oval, macrolobulated, CIRCUMSCRIBED mass with heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

D. MASSES

2. MARGIN

b. Not Circumscribed

i. Irregular

The margin is composed of edges that are either uneven or jagged but not spiculated (see below). Use of this descriptor implies a suspicious finding.

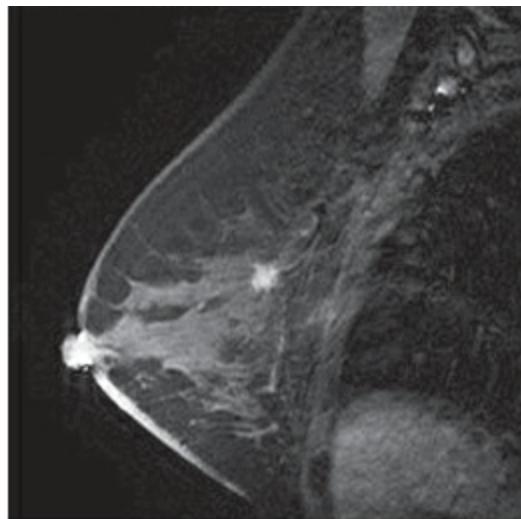


Figure 61 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

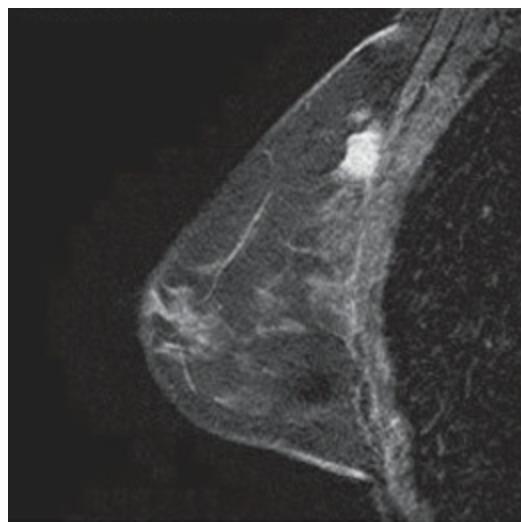


Figure 62 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Oval mass with IRREGULAR margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

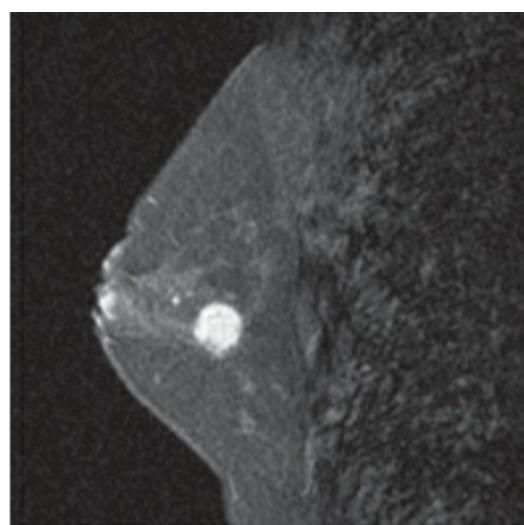


Figure 63 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

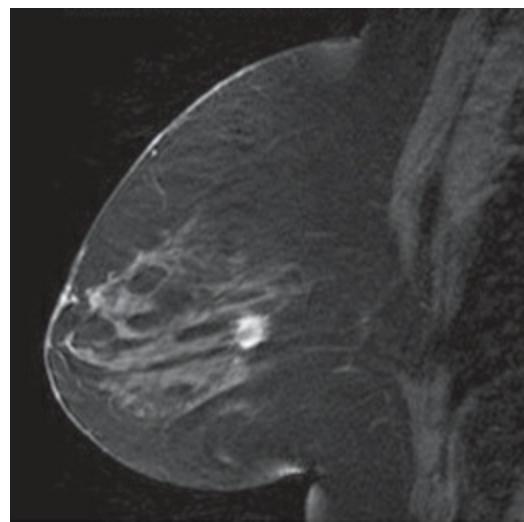


Figure 64 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

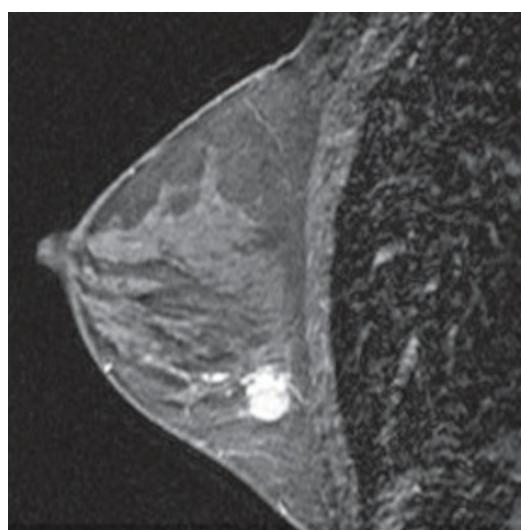


Figure 65 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

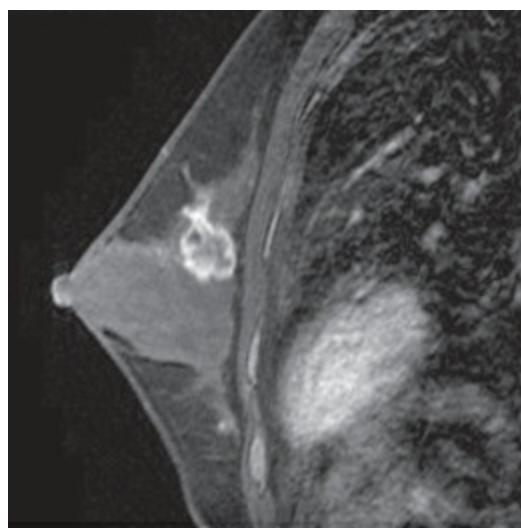


Figure 66 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

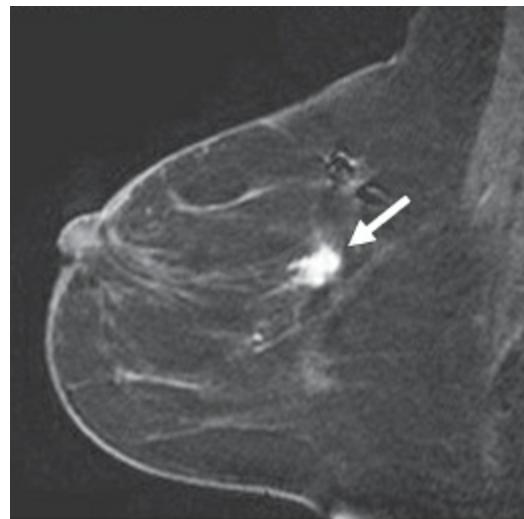


Figure 67 – MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Round mass with IRREGULAR margin and rim enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

D. MASSES

2. MARGIN

b. Not Circumscribed

ii. Spiculated

The margin is characterized by lines radiating from the mass. Use of this descriptor implies a suspicious finding.

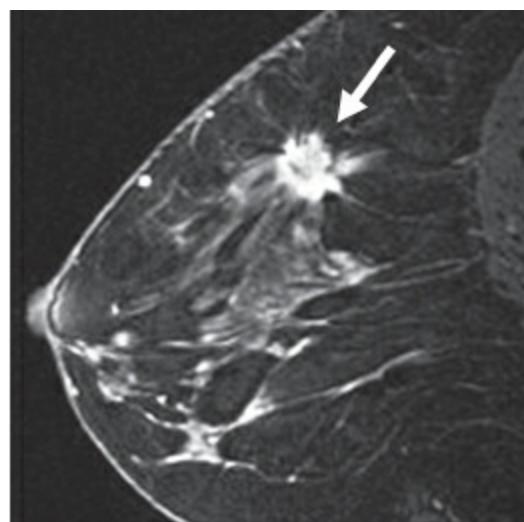


Figure 68 – MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Irregular mass with SPICULATED margin and heterogeneous internal enhancement (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive lobular carcinoma.

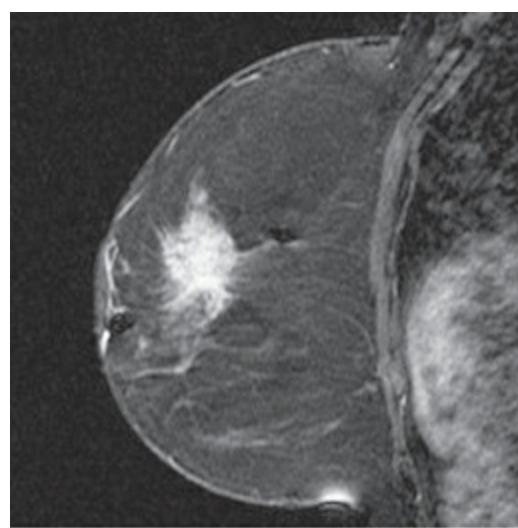


Figure 69 – MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Irregular mass with SPICULATED margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive lobular carcinoma.

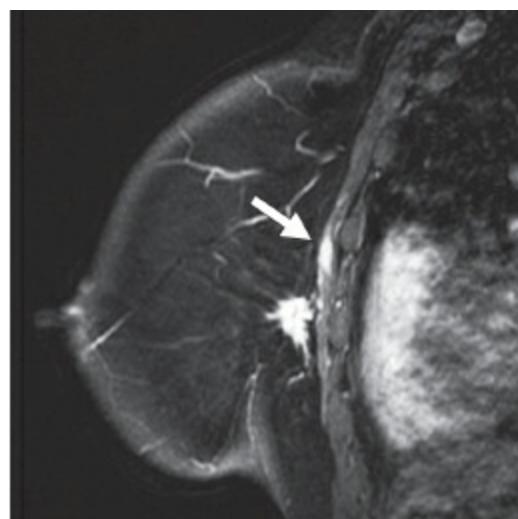


Figure 70 – MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Irregular mass with SPICULATED margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma. Note abnormal enhancement in the pectoralis muscle (*arrow*) proven to be carcinoma.

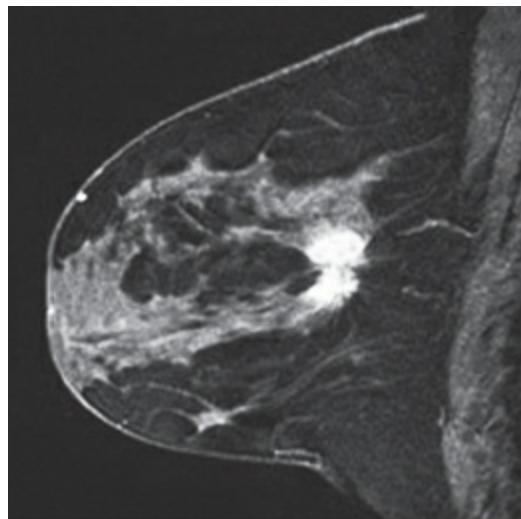


Figure 71 – MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Irregular mass with SPICULATED margin and heterogeneous internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

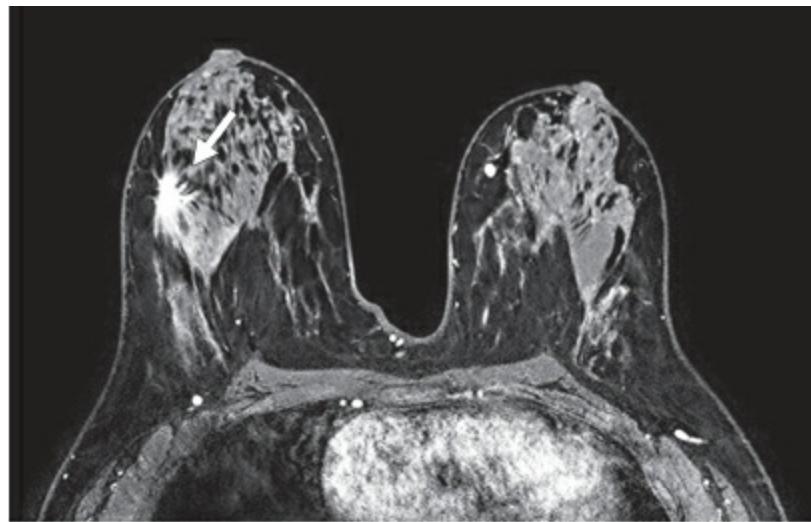


Figure 72 – MARGIN: NOT CIRCUMSCRIBED, SPICULATED. Oval mass with SPICULATED margin (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

Internal enhancement describes the enhancement pattern within the abnormally enhancing structure.

a. Homogeneous

There is confluent uniform enhancement of the mass.

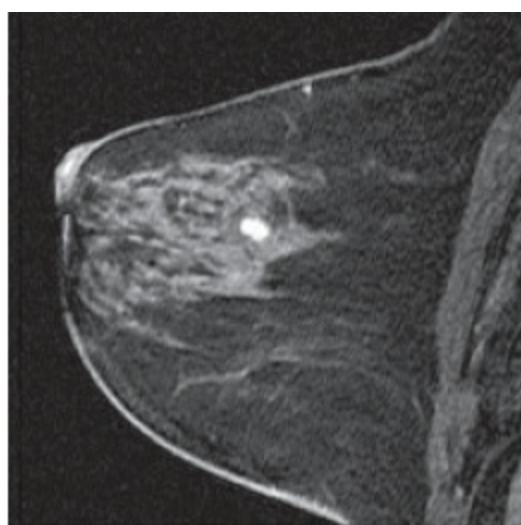


Figure 73 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: fibroadenoma.

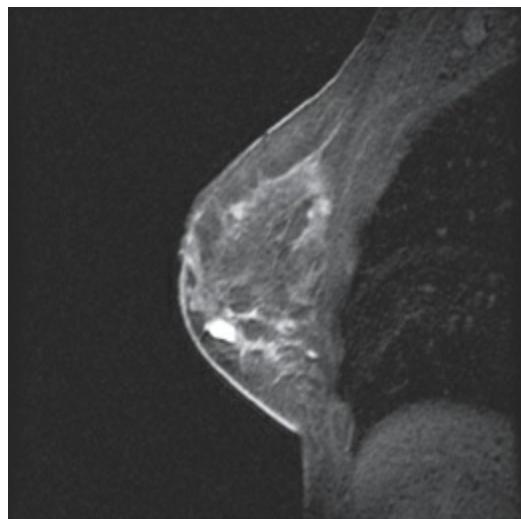


Figure 74 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: fibroadenoma.

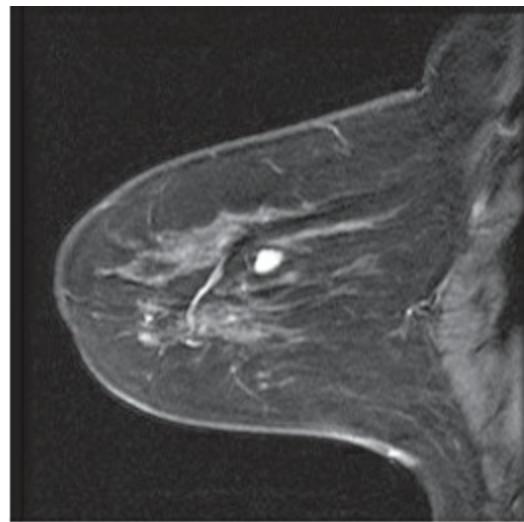


Figure 75 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: invasive ductal carcinoma.

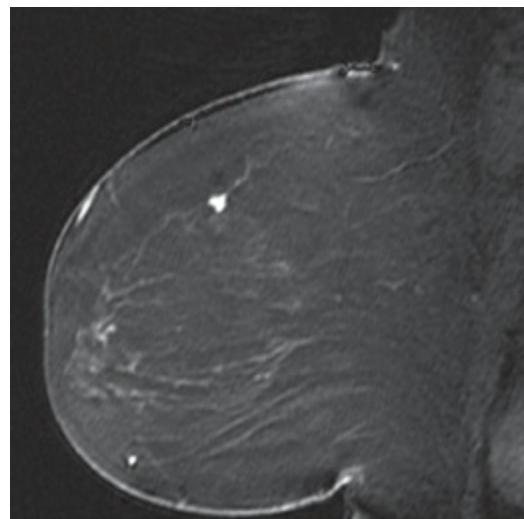


Figure 76 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: invasive ductal carcinoma.

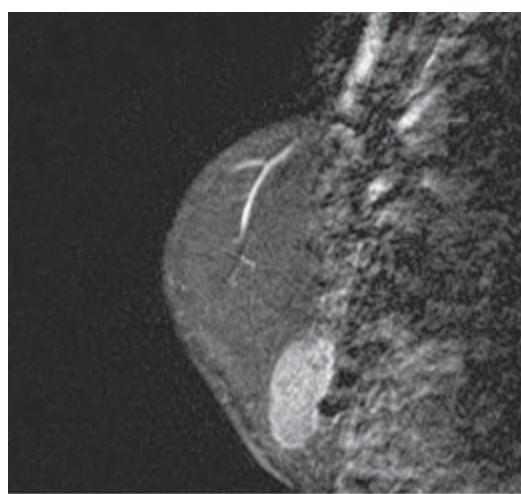


Figure 77 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: desmoid tumor.

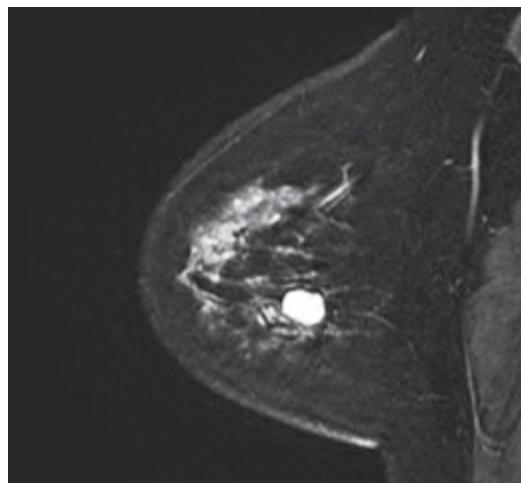


Figure 78 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval,
circumscribed, HOMOGENEOUS mass. Fat-
suppressed first postcontrast T1W image.
Pathology: invasive ductal carcinoma.

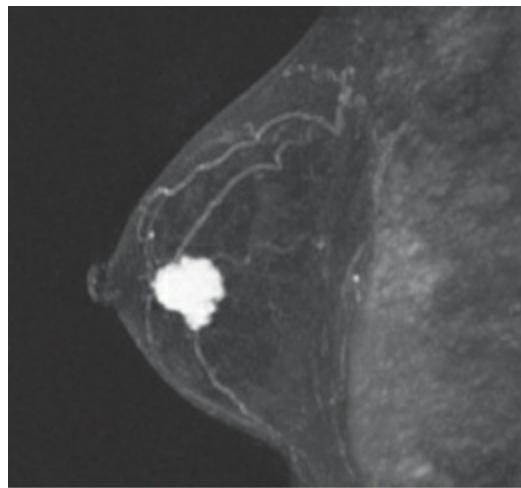


Figure 79 – INTERNAL ENHANCEMENT CHARACTERISTICS: HOMOGENEOUS.
Round, irregular, HOMOGENEOUS mass. Fat-suppressed first postcontrast T1W image.
Pathology: atypical vascular lesion.

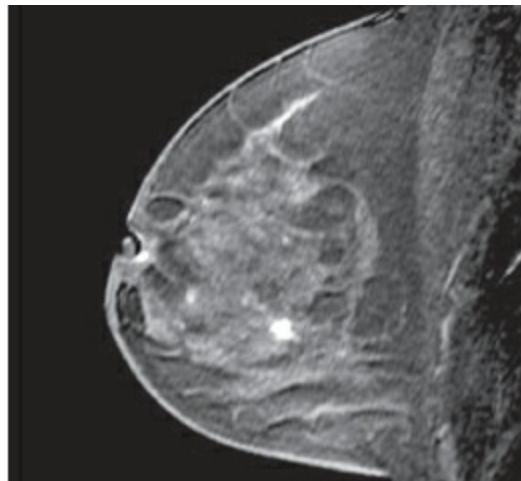


Figure 80 – INTERNAL ENHANCEMENT CHARACTERISTICS: HOMOGENEOUS.
Round, irregular, HOMOGENEOUS mass. Fat-suppressed first postcontrast T1W image.
Pathology: invasive ductal carcinoma.

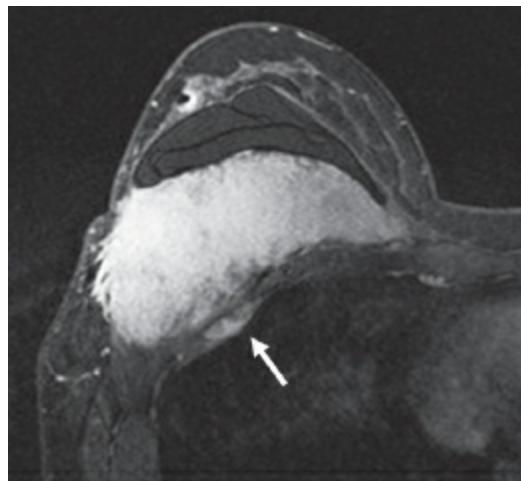


Figure 81 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Oval, circumscribed, HOMOGENEOUS mass. Fat-suppressed first postcontrast T1W image. Pathology: extra-abdominal desmoid tumor. Note involvement of the chest wall (arrow).



Figure 82 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HOMOGENEOUS. Round, HOMOGENEOUS mass. Fat-suppressed first postcontrast T1W image. Pathology: fibroadenoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

b. Heterogeneous

There is nonuniform enhancement with variable signal intensity.

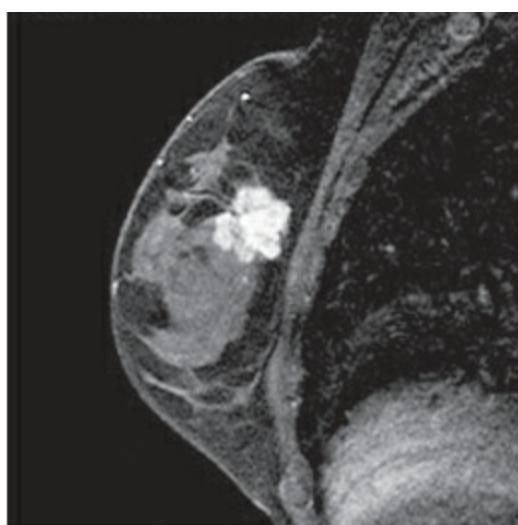


Figure 83 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS. Not circumscribed mass with HETEROGENEOUS internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

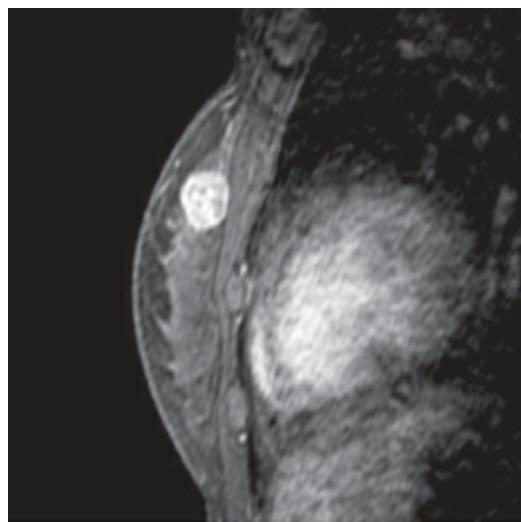


Figure 84 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS. Round, circumscribed mass with HETEROGENEOUS internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

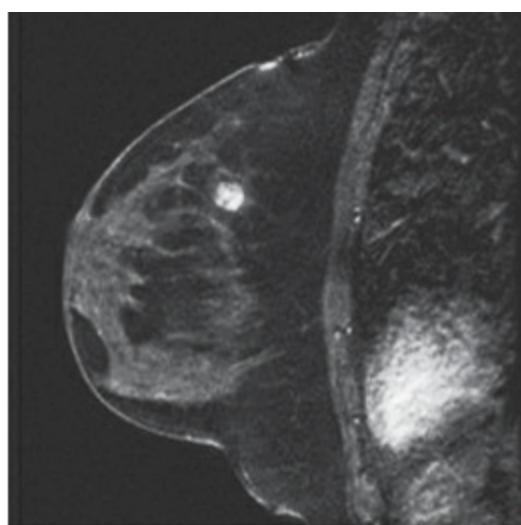


Figure 85 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS.
Round mass with HETEROGENEOUS
internal enhancement. Fat-suppressed first
postcontrast T1W image. Pathology: lobular
carcinoma in situ.

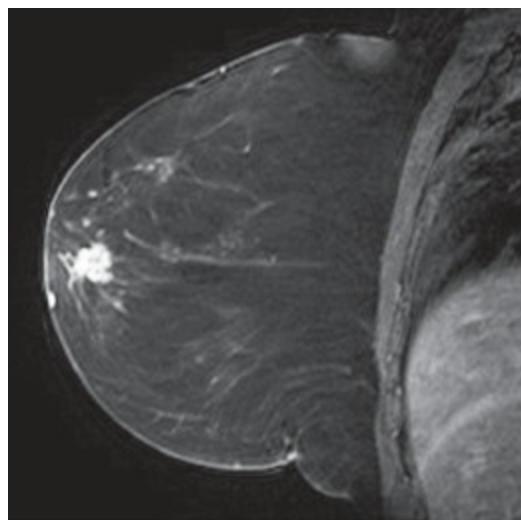


Figure 86 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS.
Irregular mass with HETEROGENEOUS
internal enhancement. Fat-suppressed first
postcontrast T1W image. Pathology: invasive
ductal carcinoma.

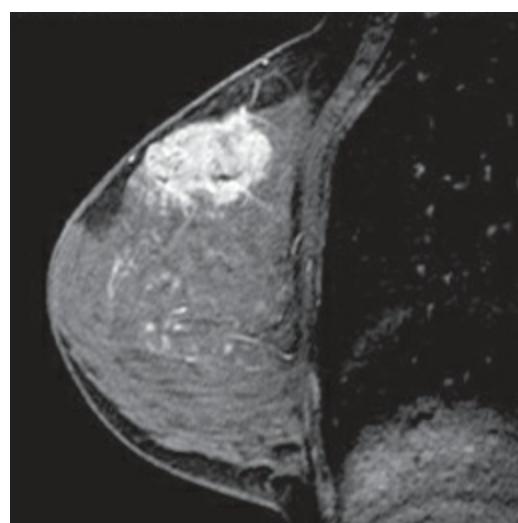


Figure 87 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS.
Oval, irregular mass with HETEROGENEOUS
internal enhancement. Fat-suppressed first
postcontrast T1W image. Pathology: invasive
ductal carcinoma.

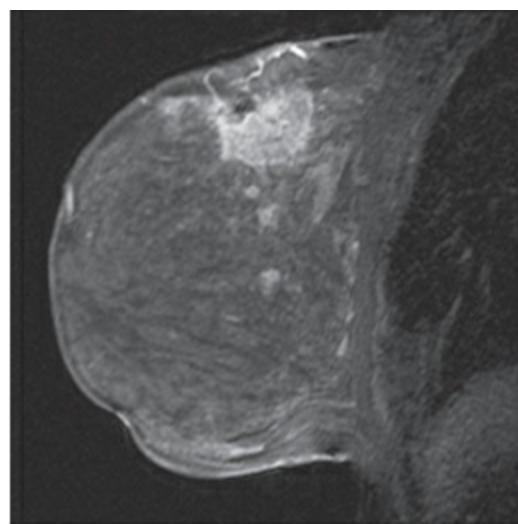


Figure 88 – INTERNAL ENHANCEMENT
CHARACTERISTICS: HETEROGENEOUS.
Oval, irregular mass with HETEROGENEOUS
enhancement. Fat-suppressed first postcontrast
T1W image. Pathology: invasive ductal
carcinoma.



Figure 89 – INTERNAL ENHANCEMENT CHARACTERISTICS: HETEROGENEOUS.
HETEROGENEOUSLY enhancing mass with irregular shape and margin. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

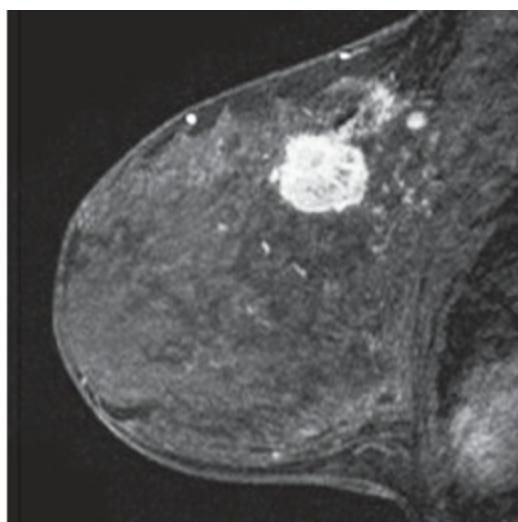
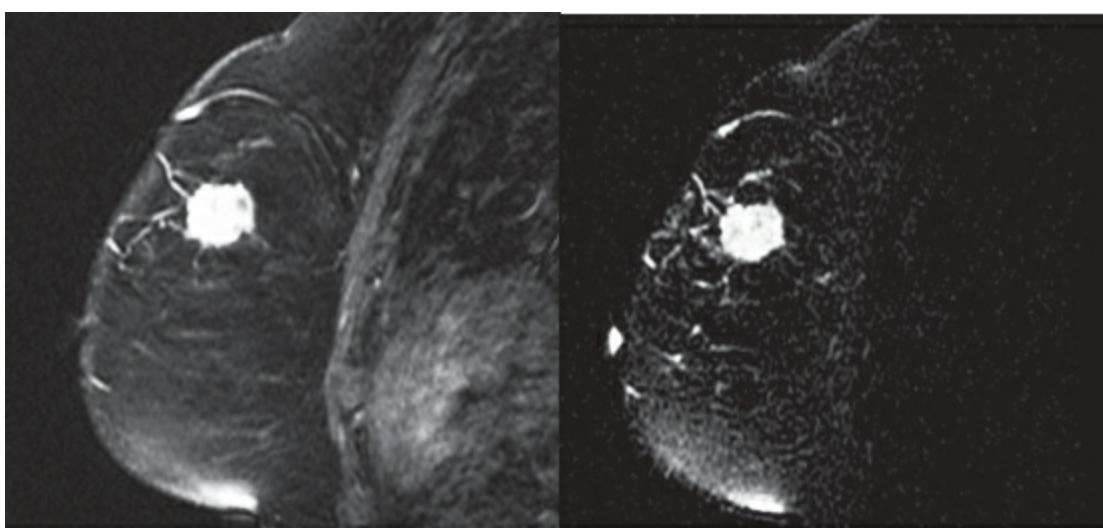


Figure 90 – INTERNAL ENHANCEMENT CHARACTERISTICS: HETEROGENEOUS.
Round, not circumscribed mass with HETEROGENEOUS internal enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.



A

B

Figure 91 – INTERNAL ENHANCEMENT CHARACTERISTICS: HETEROGENEOUS. Round, irregular marginated mass with HETEROGENEOUS internal enhancement. Fat-suppressed first postcontrast T1W image (*a*) demonstrates a round irregular mass with heterogeneous internal enhancement. T2W image (*b*) demonstrates heterogeneous high signal. Pathology: invasive ductal carcinoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

c. Rim Enhancement

Enhancement is more pronounced at the periphery of the mass.

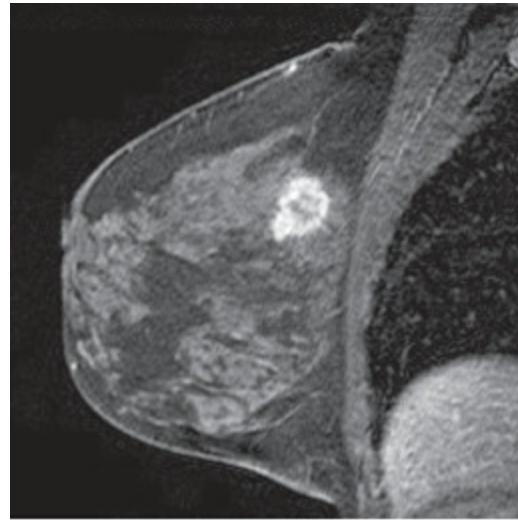


Figure 92 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT. Irregular, spiculated mass with RIM ENHANCEMENT. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

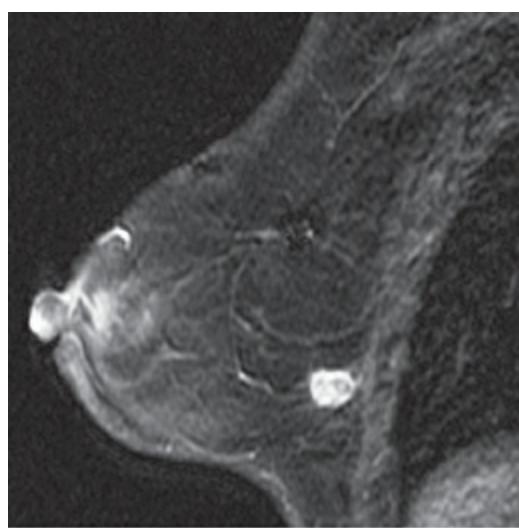


Figure 93 – INTERNAL ENHANCEMENT
CHARACTERISTICS: RIM ENHANCEMENT.
Round, circumscribed mass with RIM
ENHANCEMENT. Fat-suppressed first
postcontrast T1W image. Pathology: invasive
ductal carcinoma.

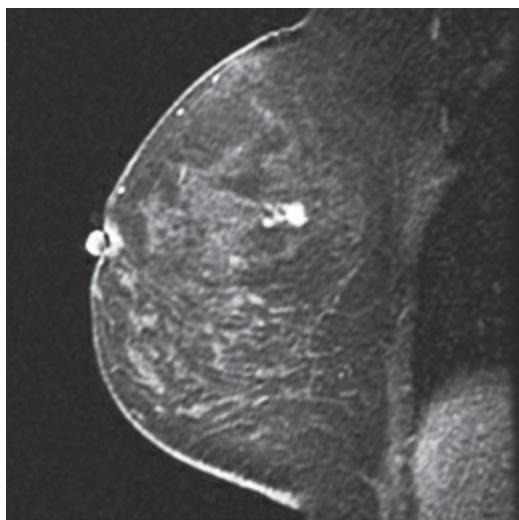


Figure 94 – INTERNAL ENHANCEMENT
CHARACTERISTICS: RIM ENHANCEMENT.
Round, not circumscribed mass with RIM
ENHANCEMENT and associated non-
mass enhancement. Fat-suppressed first
postcontrast T1W image. Pathology: ductal
carcinoma in situ and 3 mm invasive ductal
carcinoma.

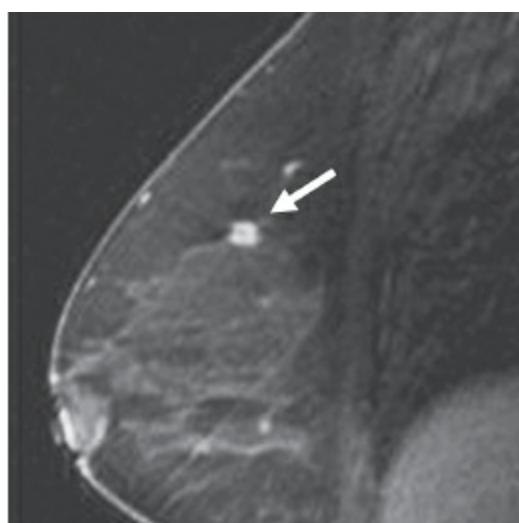


Figure 95 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT.
Round, not circumscribed mass with RIM ENHANCEMENT (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

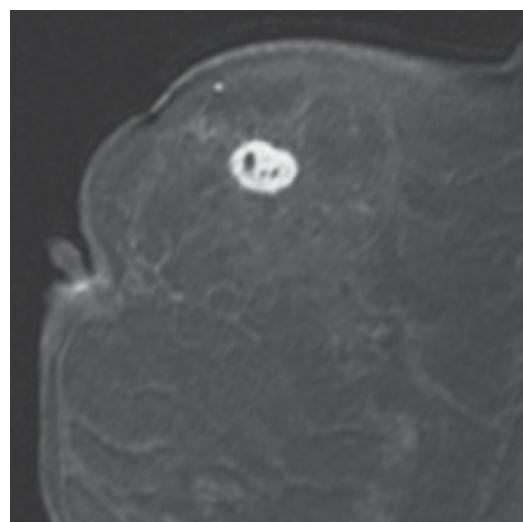


Figure 96 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT. Oval, circumscribed mass with RIM ENHANCEMENT. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.



Figure 97 – INTERNAL ENHANCEMENT
CHARACTERISTICS: RIM ENHANCEMENT.
Round, circumscribed mass with with
RIM ENHANCEMENT (anterior arrow) and
oval, irregular mass (posterior arrow)
with heterogeneous enhancement. Fat-suppressed
first postcontrast T1W image. Pathology:
multifocal invasive ductal carcinoma.

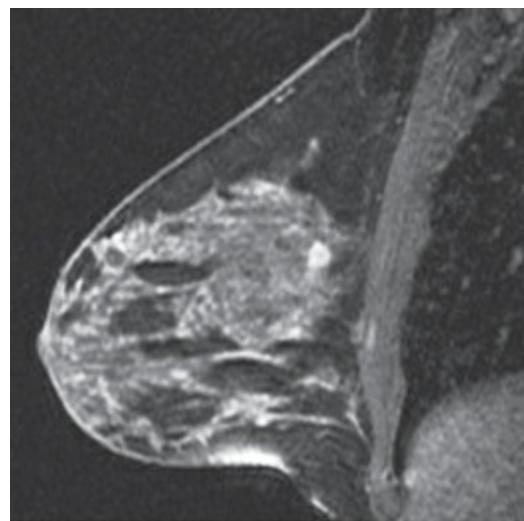


Figure 98 – INTERNAL ENHANCEMENT
CHARACTERISTICS: RIM ENHANCEMENT.
Round, irregular mass with RIM
ENHANCEMENT. Fat-suppressed first
postcontrast T1W image. Pathology: invasive
ductal carcinoma.

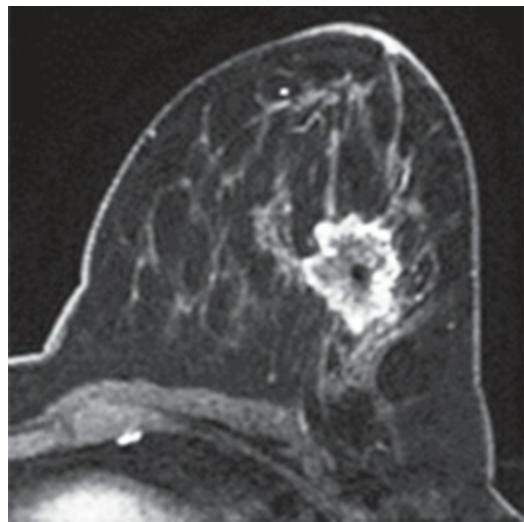


Figure 99 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT.
Oval, not circumscribed mass with RIM ENHANCEMENT. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

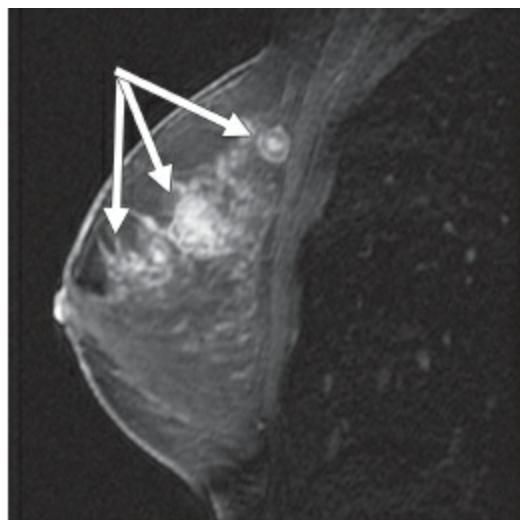


Figure 100 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT.
Round, circumscribed mass with RIM ENHANCEMENT (superior arrow).
Two additional irregular masses with heterogeneous enhancement are also seen (mid and inferior arrows). Fat-suppressed first postcontrast T1W image. Pathology: multicentric invasive ductal carcinoma.

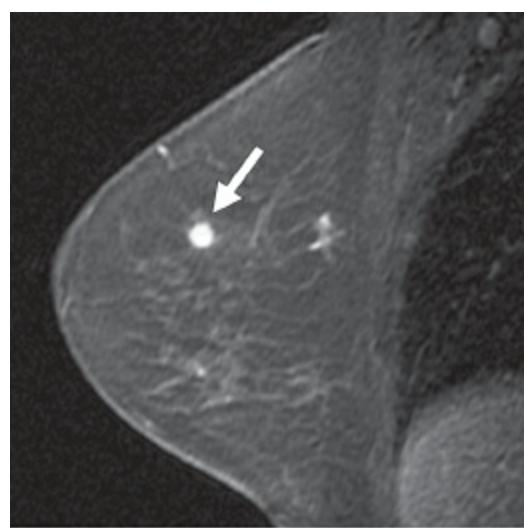


Figure 101 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT.
Round, circumscribed mass with RIM ENHANCEMENT (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive lobular carcinoma.

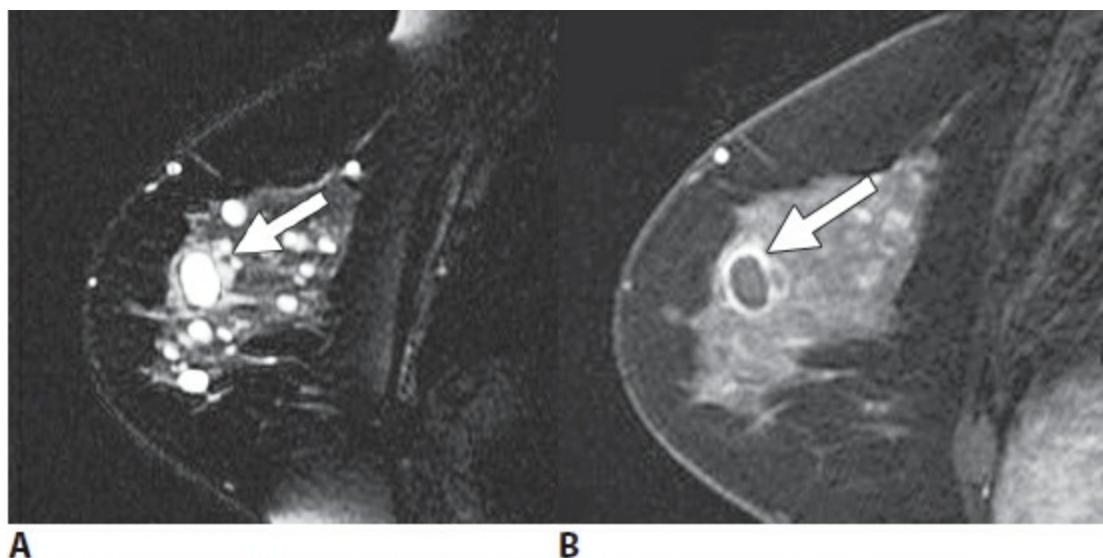
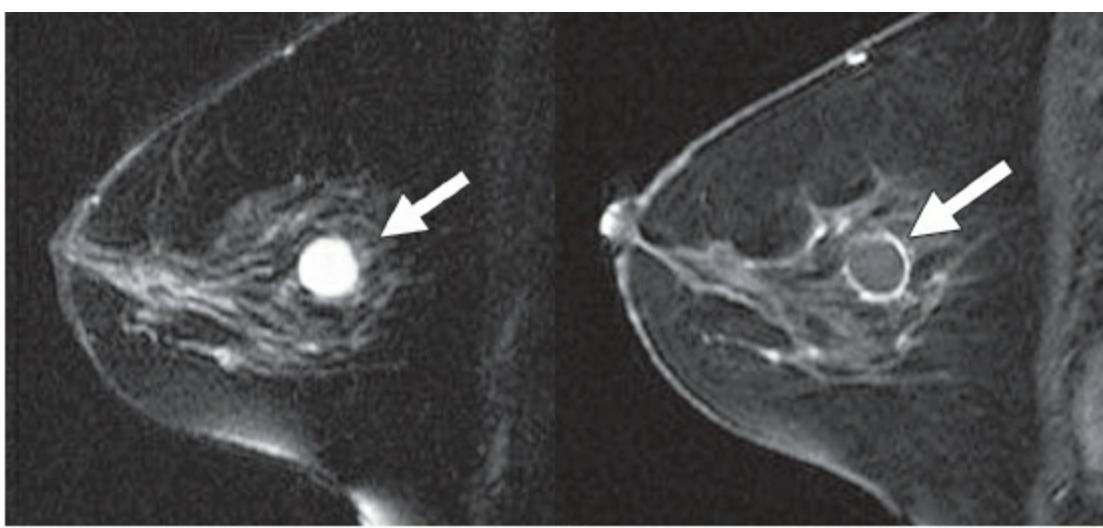
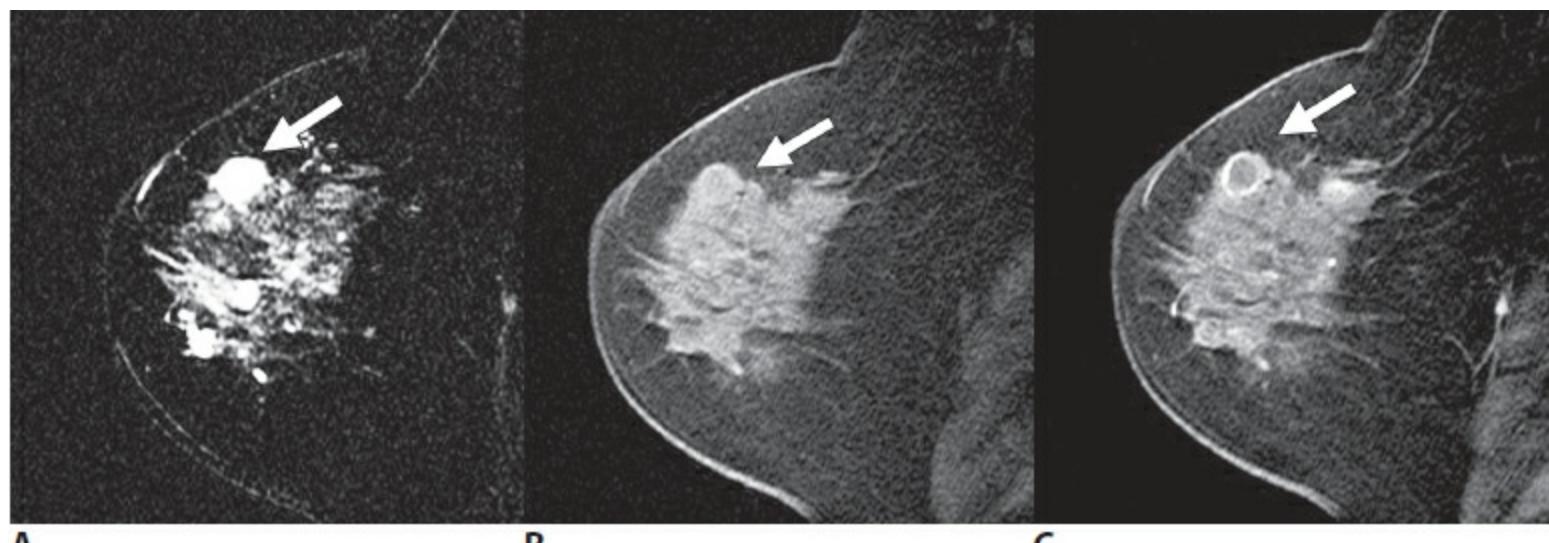


Figure 102 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT. Oval, circumscribed mass (arrow) with RIM ENHANCEMENT. T2W bright fluid is compatible with inflammatory cyst. Fat-suppressed T2W image (a). Fat-suppressed postcontrast T1W image (b).



A **B**

Figure 103 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT. Round, circumscribed mass with RIM ENHANCEMENT (arrow). T2W bright fluid is compatible with inflammatory cyst. Fat-suppressed T2W image (a). Fat-suppressed post-contrast T1W image (b).



A **B** **C**

Figure 104 – INTERNAL ENHANCEMENT CHARACTERISTICS: RIM ENHANCEMENT. Round, circumscribed mass (arrow) with RIM ENHANCEMENT. T2W bright fluid is compatible with inflammatory cyst. Fat-suppressed T2W image (a). Fat-suppressed precontrast T1W image (b). Fat-suppressed postcontrast T1W image (c).

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

d. Dark Internal Septations

These are dark, non-enhancing lines within a mass. Non-enhancing dark internal septations are suggestive of fibroadenomas, if the other morphologic and kinetic characteristics support benignity.



Figure 105 – INTERNAL ENHANCEMENT
CHARACTERISTICS: DARK INTERNAL
SEPTATIONS. Oval, circumscribed,
homogeneously enhancing mass with
DARK INTERNAL SEPTATIONS (arrow). First
fat-suppressed postcontrast T1W image.
Pathology: fibroadenoma.

E. NON-MASS ENHANCEMENT (NME)

Non-mass enhancement is used to describe an area that is neither a mass nor a focus. This includes enhancement patterns that may extend over small or large regions and in which internal enhancing characteristics are discrete from the normal surrounding background parenchymal enhancement. NME may have areas or spots of normal fibroglandular tissue or fat between the abnormally enhancing components.

1. DISTRIBUTION

a. Focal

Focal describes enhancement in a confined area in which internal enhancement may be characterized as a non-mass internal enhancement pattern. Part of the definition of focal is that it occupies less than a breast quadrant volume and has fat or normal glandular tissue interspersed between the abnormally enhancing components (exception: focal homogeneous enhancement).

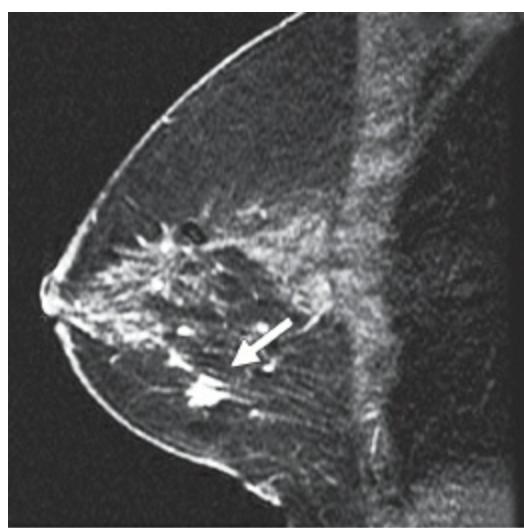


Figure 106 – DISTRIBUTION: FOCAL. FOCAL
clumped, non-mass enhancement (*arrow*).
Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ.

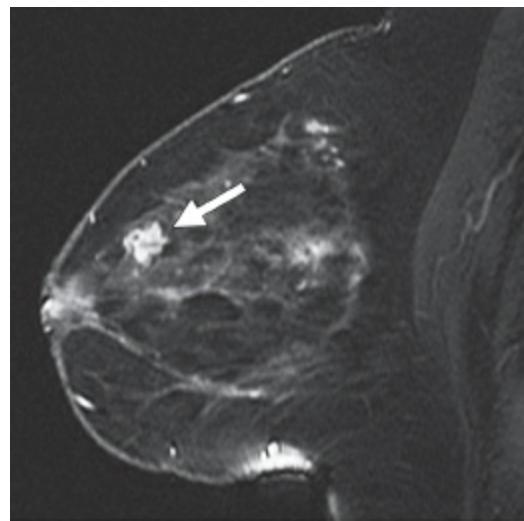


Figure 107 – DISTRIBUTION: FOCAL. FOCAL
clumped, non-mass enhancement (*arrow*).
Fat-suppressed first postcontrast T1W image.
Pathology: atypical duct hyperplasia.



Figure 108 – DISTRIBUTION: FOCAL. FOCAL
clumped, non-mass enhancement (arrow).
Fat-suppressed first postcontrast T1W image.
Pathology: atypical duct hyperplasia.

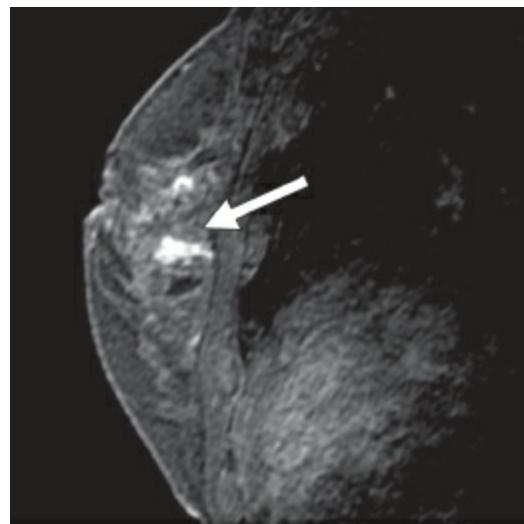


Figure 109 – DISTRIBUTION: FOCAL. FOCAL
clumped, non-mass enhancement (arrow).
Fat-suppressed first postcontrast T1W image.
Pathology: papillomatosis.

E. NON-MASS ENHANCEMENT (NME)

1. DISTRIBUTION

b. Linear

Linear describes enhancement arrayed in a line (not necessarily a straight line) or a line that branches. This distribution may elevate suspicion for malignancy because it suggests enhancement within or around a duct.

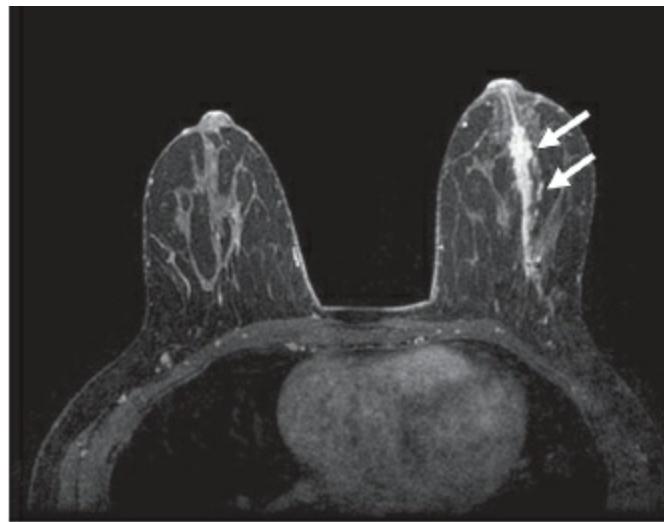


Figure 110 – DISTRIBUTION: LINEAR. LINEAR non-mass enhancement (*arrows*) extending from a postoperative collection toward the nipple. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

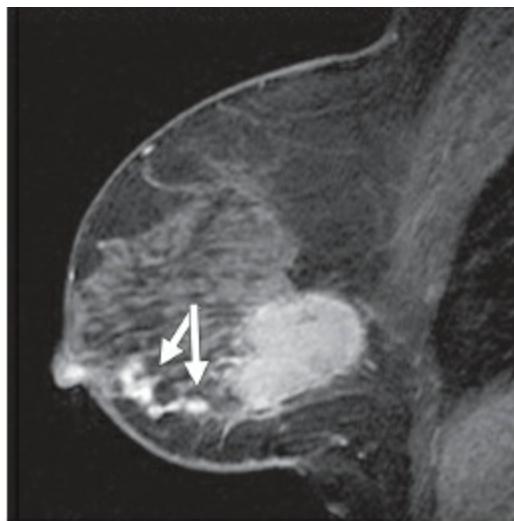


Figure 111 – DISTRIBUTION: LINEAR. LINEAR, clumped non-mass enhancement (*arrows*) extending from a postoperative collection toward the nipple. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

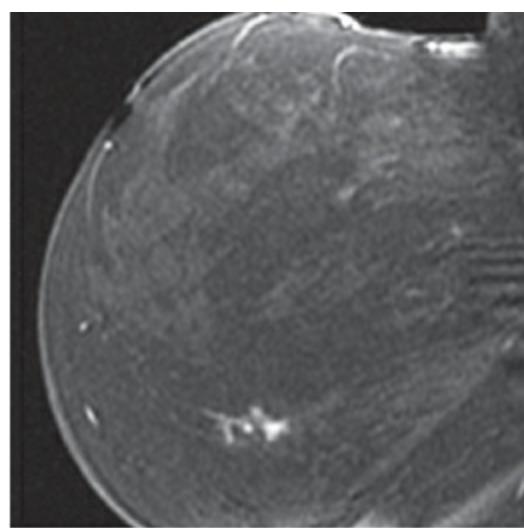


Figure 112 – DISTRIBUTION: LINEAR. LINEAR non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

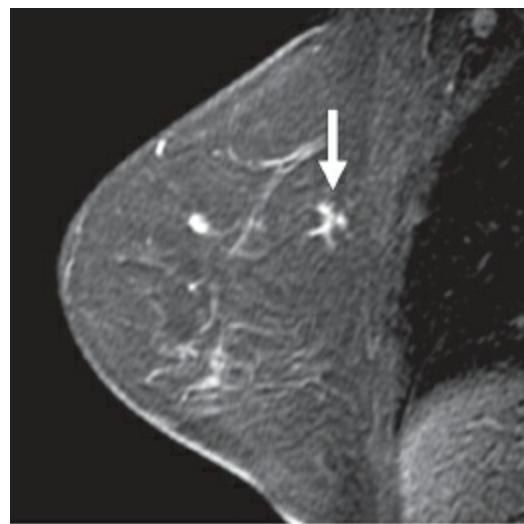


Figure 113 – DISTRIBUTION: LINEAR. LINEAR (arrow) non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

E. NON-MASS ENHANCEMENT (NME)

1. DISTRIBUTION

c. Segmental

Segmental describes enhancement that is triangular or cone shaped with the apex at the nipple. Segmental distribution is of concern because it suggests enhancement within or around a duct or ducts and their branches, raising the possibility of extensive or multifocal breast cancer in a lobe or segment of the breast.

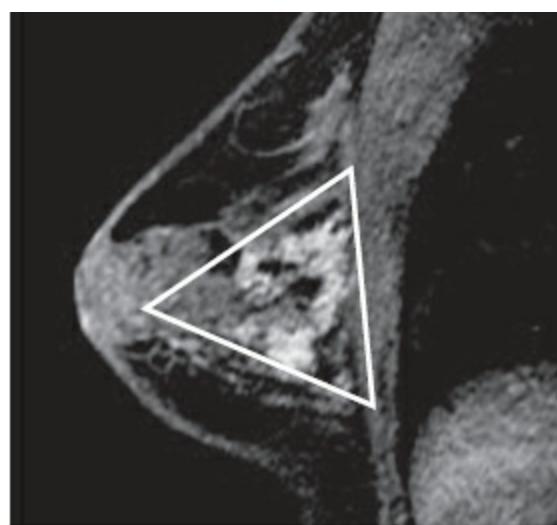


Figure 114 – DISTRIBUTION: SEGMENTAL.
SEGMENTAL, non-mass enhancement. Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ.

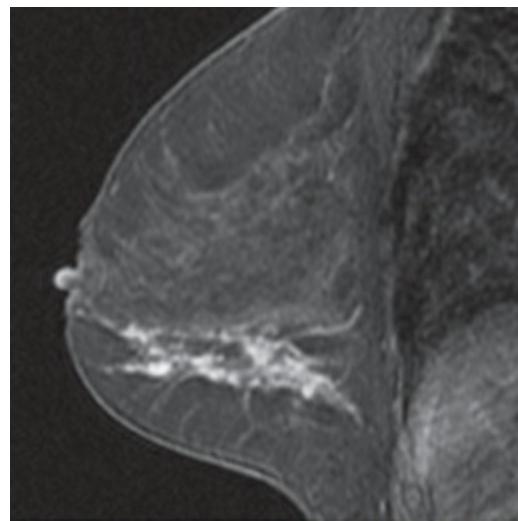


Figure 115 – DISTRIBUTION: SEGMENTAL.
SEGMENTAL non-mass enhancement. Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ.

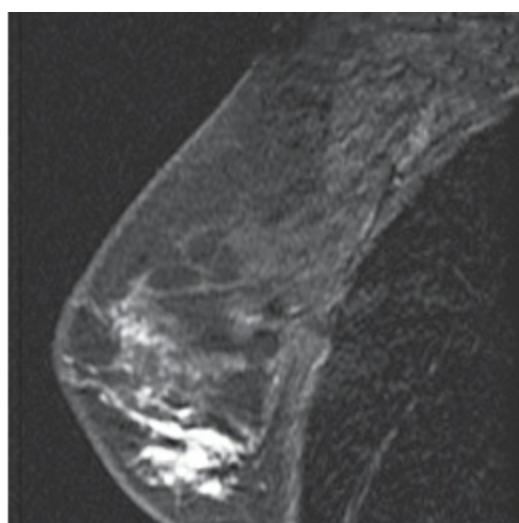


Figure 116 – DISTRIBUTION: SEGMENTAL.
SEGMENTAL, non-mass enhancement. Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ and invasive ductal carcinoma.

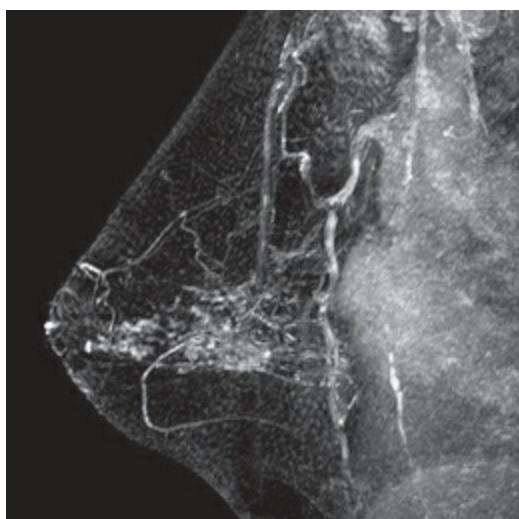


Figure 117 – DISTRIBUTION: SEGMENTAL.
Subtraction MIP SEGMENTAL, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

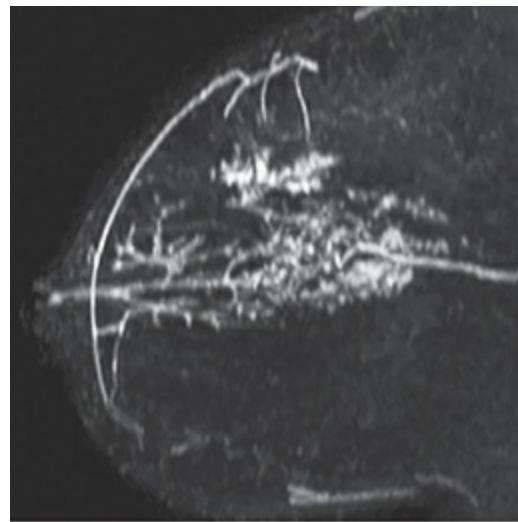


Figure 118 – DISTRIBUTION: SEGMENTAL.
SEGMENTAL, non-mass enhancement. Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ.

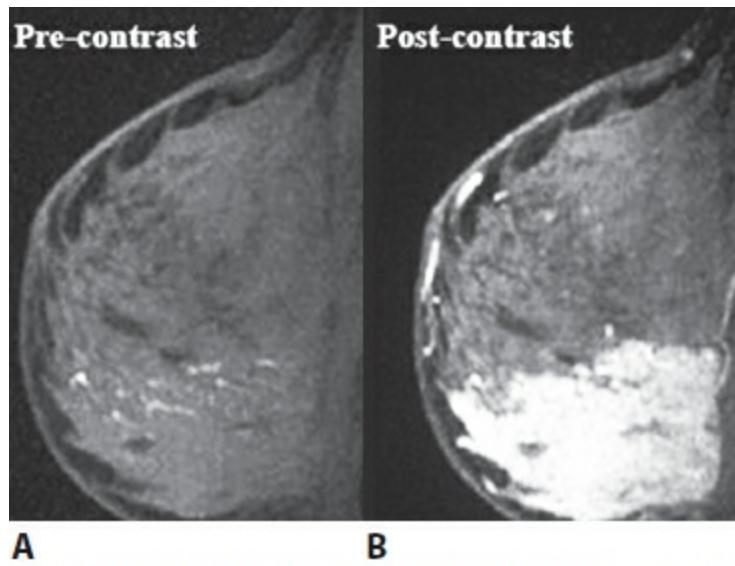


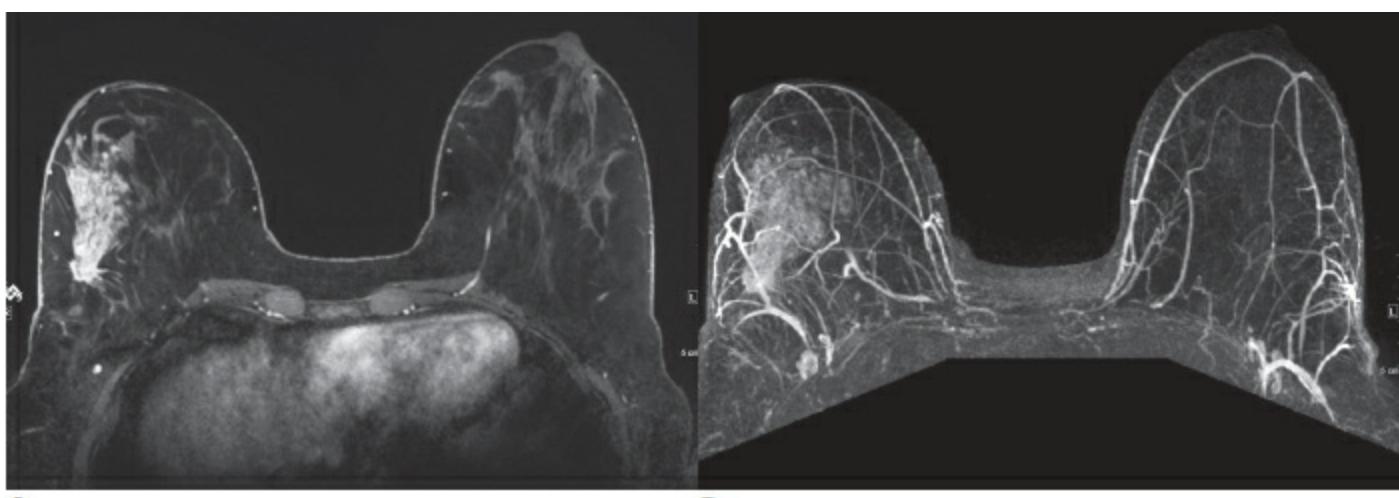
Figure 119 – DISTRIBUTION: SEGMENTAL. SEGMENTAL, non-mass enhancement. Fat-suppressed precontrast T1W image (a). Fat-suppressed postcontrast T1W image (b). Pathology: DCIS.

E. NON-MASS ENHANCEMENT (NME)

1. DISTRIBUTION

d. Regional

Regional describes enhancement that encompasses more than a single duct system. This descriptor is used for enhancement that occupies a large portion of breast tissue, at least a quadrant.



A

B

Figure 120 – DISTRIBUTION: REGIONAL. REGIONAL, non-mass enhancement. Axial fat-suppressed postcontrast T1W image (a). Subtraction MIP (b). Pathology: invasive carcinoma and DCIS.

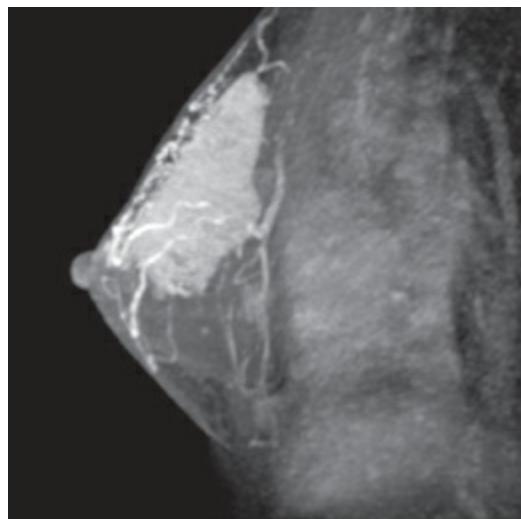


Figure 121 – DISTRIBUTION: REGIONAL.
MIP REGIONAL, non-mass enhancement.
Fat-suppressed T1W MIP. Pathology: ductal
carcinoma in situ and invasive ductal
carcinoma.

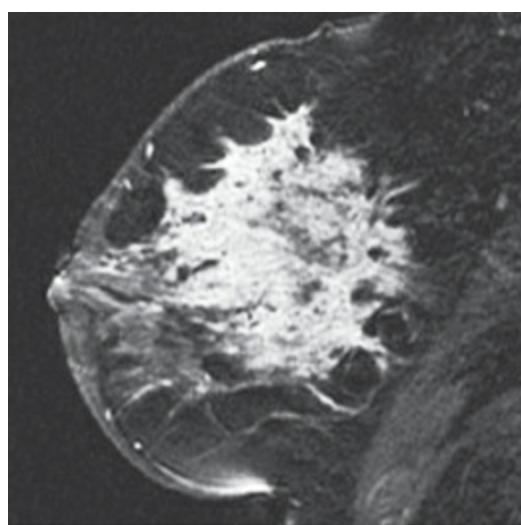
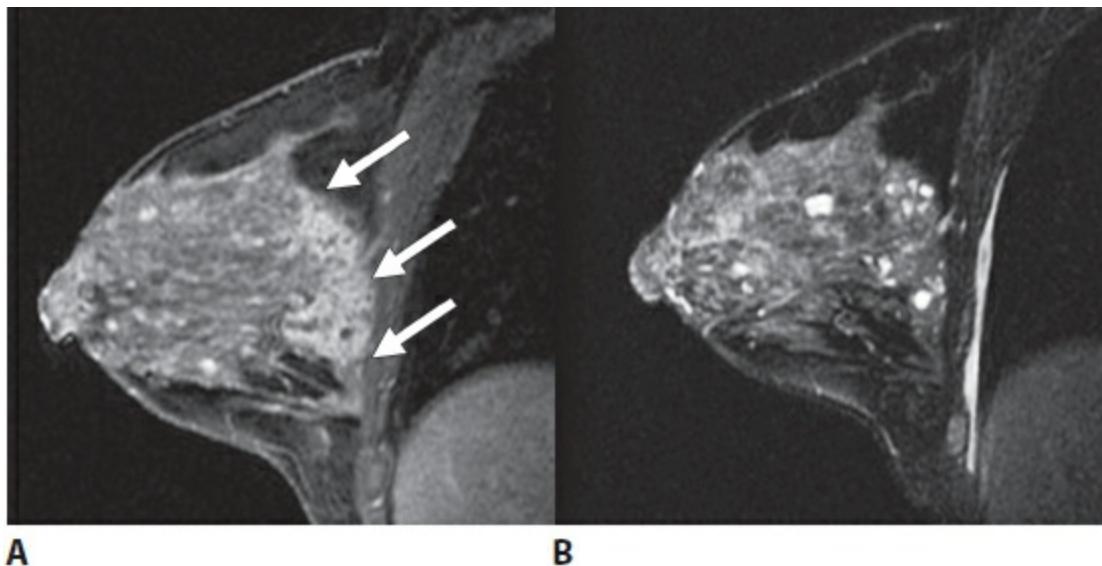


Figure 122 – DISTRIBUTION: REGIONAL.
REGIONAL enhancement as opposed to large mass. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.



A **B**

Figure 123 – DISTRIBUTION: REGIONAL. REGIONAL, non-mass enhancement (arrows). Pathology: fibrocystic changes. Fat-suppressed first postcontrast T1W image (a). T2W image demonstrates multiple cysts (b).

E. NON-MASS ENHANCEMENT (NME)

1. DISTRIBUTION

e. Multiple Regions

“Multiple regions” describes enhancement in at least two large volumes of tissue, not conforming to a ductal distribution and separated by normal tissue; it involves many areas of geographic enhancement and is patchy in appearance.

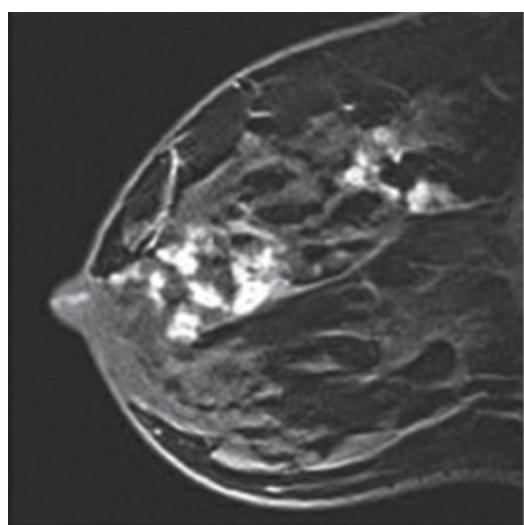


Figure 124 – DISTRIBUTION: MULTIPLE REGIONS. MULTIPLE REGIONS, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

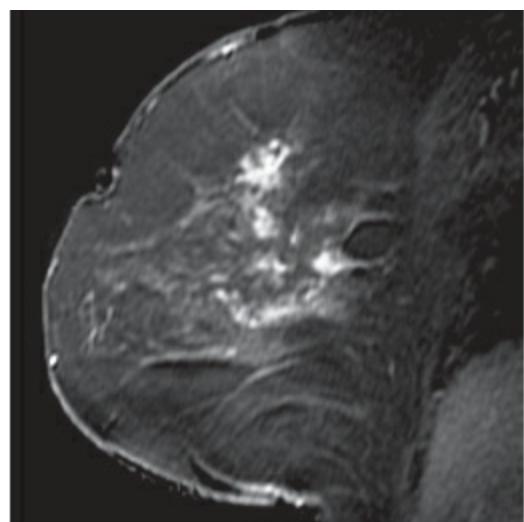


Figure 125 – DISTRIBUTION: MULTIPLE REGIONS. MULTIPLE REGIONS, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

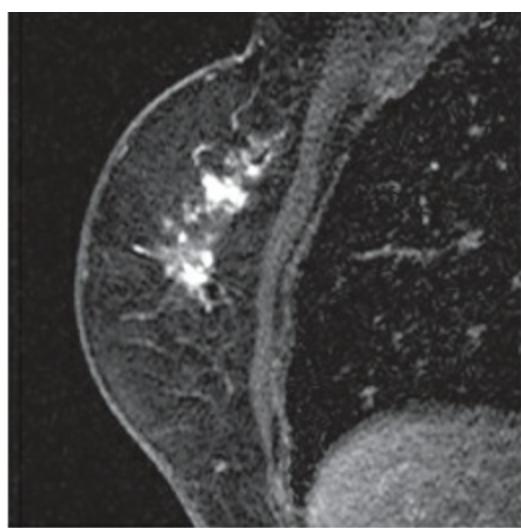


Figure 126 – DISTRIBUTION: MULTIPLE REGIONS. MULTIPLE REGIONS, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT (NME)

1. DISTRIBUTION

f. Diffuse

Diffuse describes enhancement distributed randomly throughout the breast.

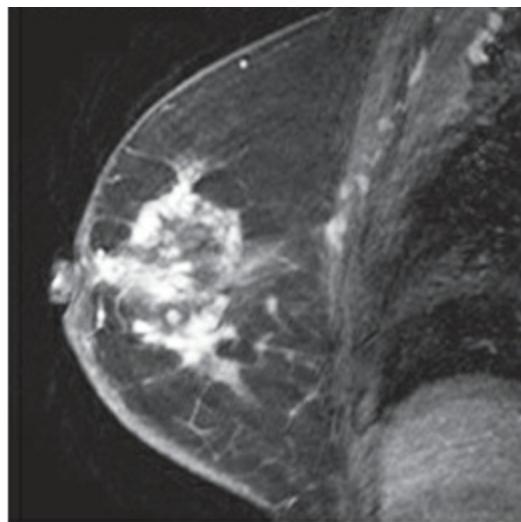


Figure 127 – DISTRIBUTION: DIFFUSE. Non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

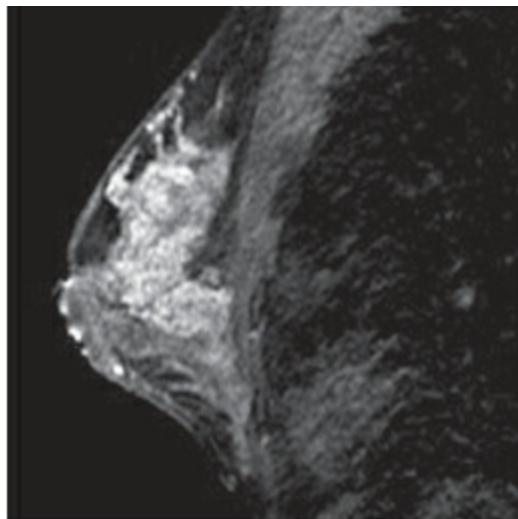


Figure 128 – DISTRIBUTION: DIFFUSE. Non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

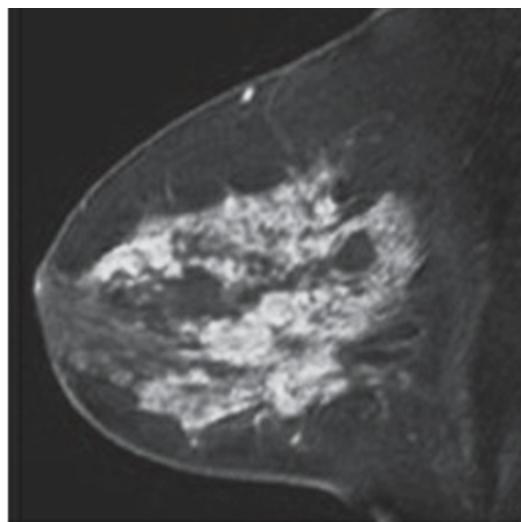


Figure 129 – DISTRIBUTION: DIFFUSE. Non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT (NME)

2. INTERNAL ENHANCEMENT PATTERNS

a. Homogeneous

Homogeneous describes a confluent, uniform enhancement.

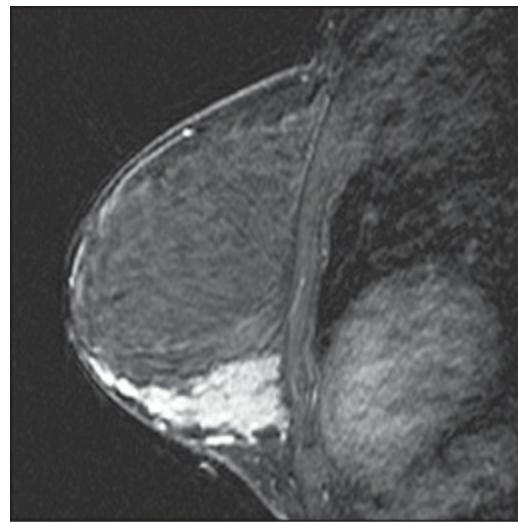


Figure 130 – INTERNAL ENHANCEMENT
PATTERNS: HOMOGENEOUS. Invasive ductal carcinoma HOMOGENEOUS, segmental, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: sclerosing adenosis.



Figure 131 – INTERNAL ENHANCEMENT
PATTERNS: HOMOGENEOUS. Invasive ductal carcinoma HOMOGENEOUS, segmental, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ and invasive ductal carcinoma.

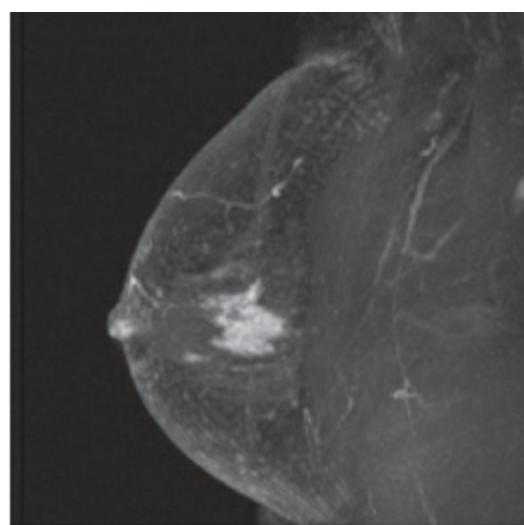


Figure 132 – INTERNAL ENHANCEMENT PATTERNS: HOMOGENEOUS. HOMOGENEOUS, focal, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

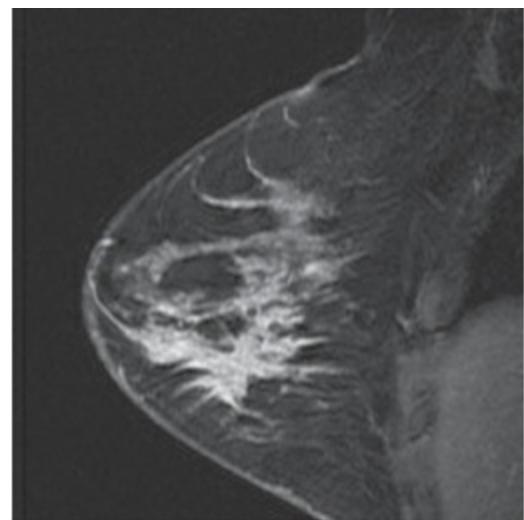


Figure 133 – INTERNAL ENHANCEMENT PATTERNS: HOMOGENEOUS. HOMOGENEOUS, regional, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT (NME)

2. INTERNAL ENHANCEMENT PATTERNS

b. Heterogeneous

Heterogeneous describes a nonuniform enhancement in a random pattern, separated by areas of normal breast parenchyma or fat.

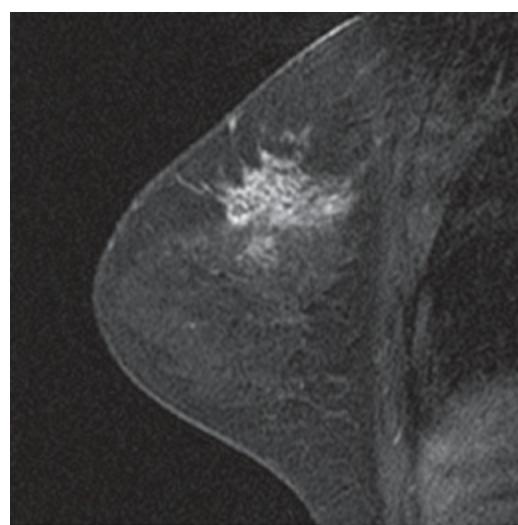


Figure 134 – INTERNAL ENHANCEMENT PATTERNS: HETEROGENEOUS.
HETEROGENEOUS, non-mass enhancement.
Fat-suppressed first postcontrast T1W image.
Pathology: ductal carcinoma in situ.

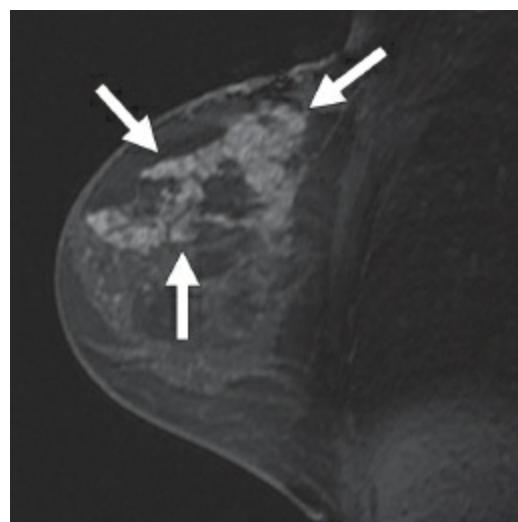


Figure 135 –INTERNAL ENHANCEMENT PATTERNS: HETEROGENEOUS.
HETEROGENEOUS, non-mass enhancement (arrows). Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

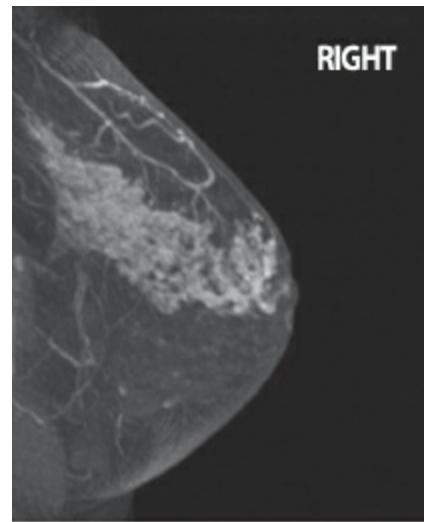


Figure 136 – INTERNAL ENHANCEMENT PATTERNS: HETEROGENEOUS. HETEROGENEOUS, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ and invasive ductal carcinoma.

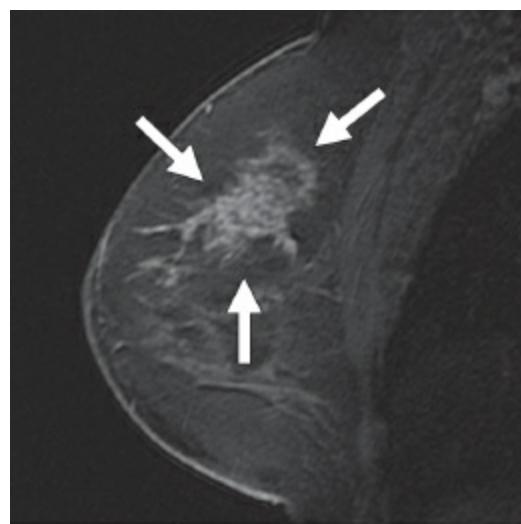


Figure 137 – INTERNAL ENHANCEMENT PATTERNS: HETEROGENEOUS. HETEROGENEOUS, non-mass enhancement (arrows). Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

E. NON-MASS ENHANCEMENT (NME)

2. INTERNAL ENHANCEMENT PATTERNS

c. Clumped

Clumped describes a cobblestone enhancement of varying shapes and sizes with occasional confluent areas; this pattern may look like grapes if in a focal area, or it may look beaded or like a string of pearls if in a line. Use of this descriptor implies

suspicion and the need for tissue sampling.

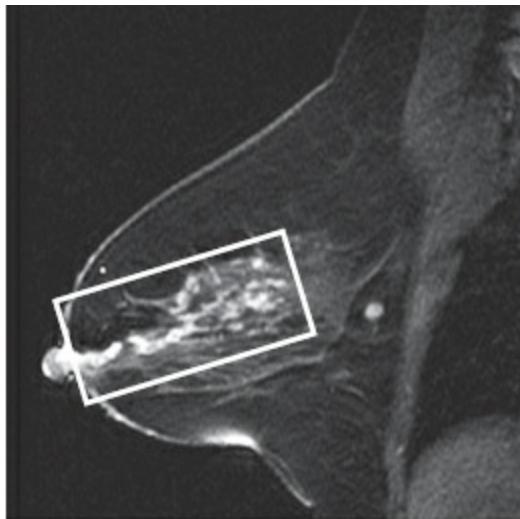


Figure 138 – INTERNAL ENHANCEMENT
PATTERNS: CLUMPED. CLUMPED, linear
(rectangle). Fat-suppressed first postcontrast
T1W image. Pathology: ductal carcinoma
in situ.

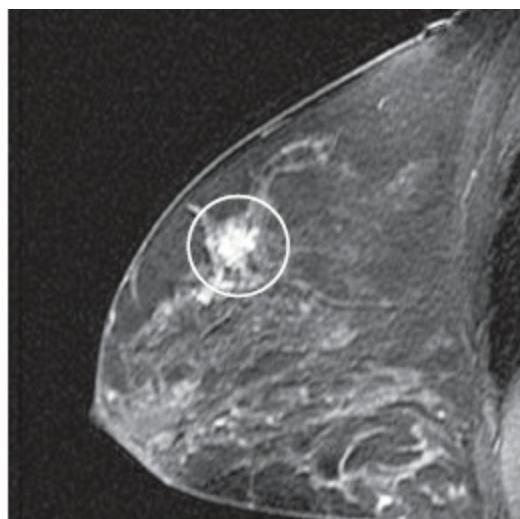


Figure 139 – INTERNAL ENHANCEMENT
PATTERNS: CLUMPED. CLUMPED, focal, non-
mass enhancement (circle). Fat-suppressed
first postcontrast T1W image. Pathology:
ductal carcinoma in situ.

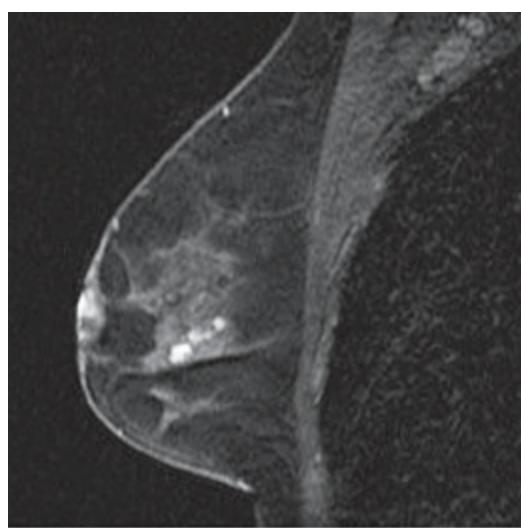


Figure 140 – INTERNAL ENHANCEMENT
PATTERNS: CLUMPED. CLUMPED, linear, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

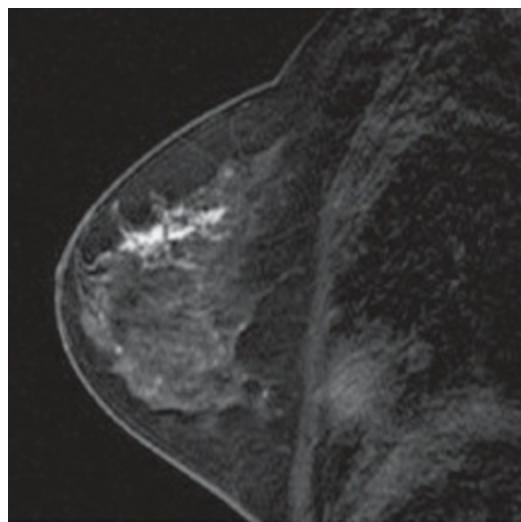


Figure 141 – INTERNAL ENHANCEMENT
PATTERNS: CLUMPED. CLUMPED, linear, non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

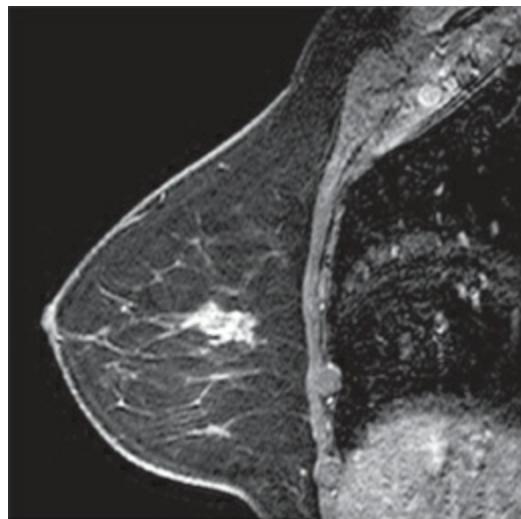


Figure 142 – INTERNAL ENHANCEMENT PATTERNS: CLUMPED. Focal CLUMPED non-mass enhancement. Fat-suppressed postcontrast T1W image. Pathology: focal fibrocystic change.

E. NON-MASS ENHANCEMENT (NME)

2. INTERNAL ENHANCEMENT PATTERNS

d. Clustered Ring

Clustered ring describes thin rings of enhancement clustered together around the ducts. Enhancement in the periductal stroma, best seen on high-resolution images, implies a suspicious finding.

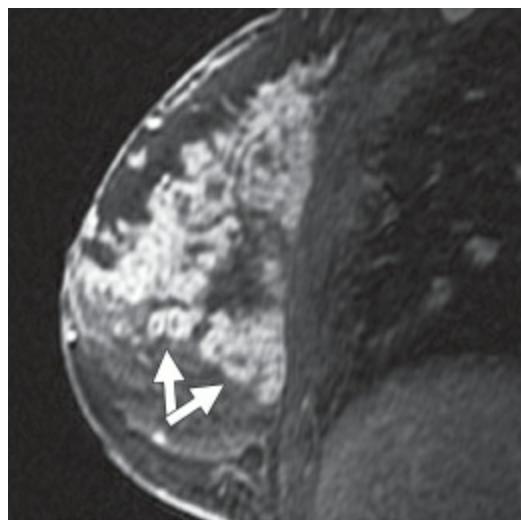


Figure 143 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (arrows), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

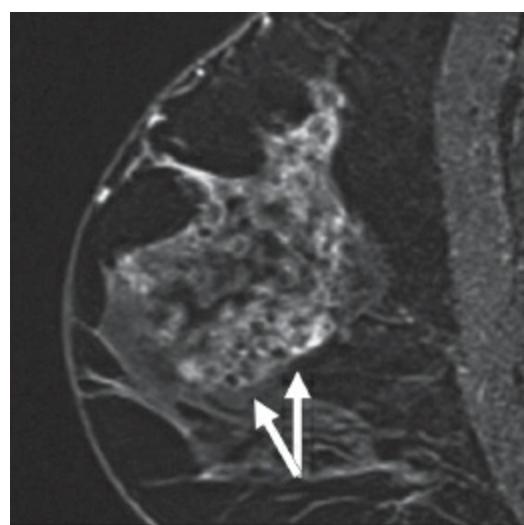


Figure 144 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (*arrows*), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

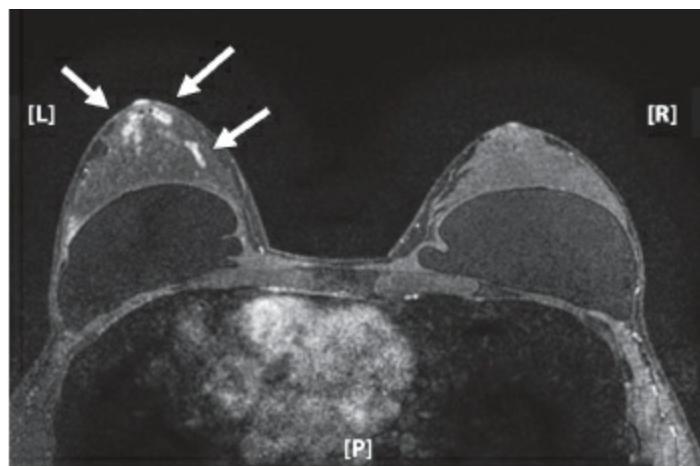


Figure 145 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING, non-mass enhancement (*arrows*) in the left breast. First postcontrast fat-suppressed T1W image. Pathology: duct ectasia.

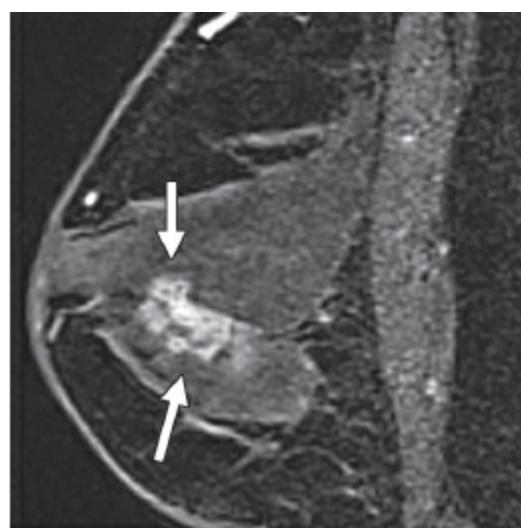


Figure 146 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (arrows), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

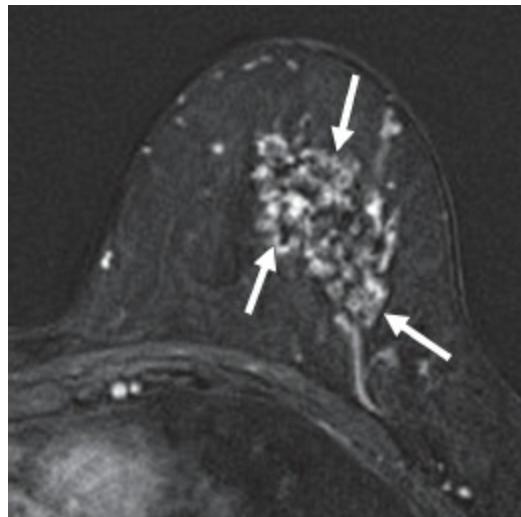


Figure 147 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (arrows), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

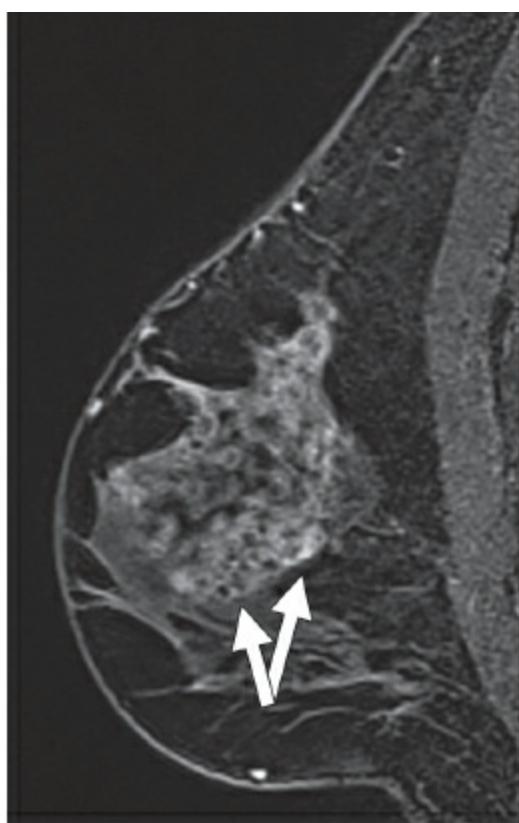


Figure 148 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (*arrows*), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

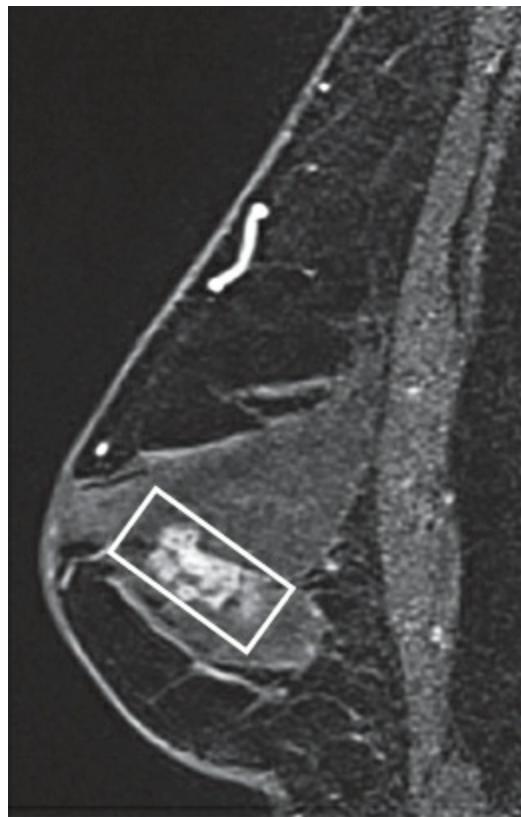


Figure 149 –INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING (rectangle), non-mass enhancement. Fat-suppressed first postcontrast T1W image. Pathology: ductal carcinoma in situ.

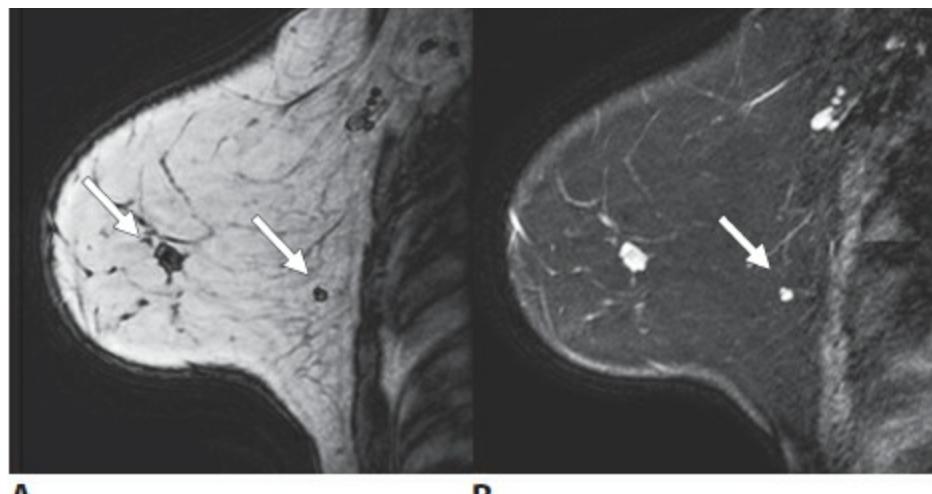


Figure 150 – INTERNAL ENHANCEMENT PATTERNS: CLUSTERED RING. CLUSTERED RING, non-mass enhancement (arrows). Fat-suppressed first postcontrast T1W image. Pathology: fibrocystic changes.

F. INTRAMAMMARY LYMPH NODE

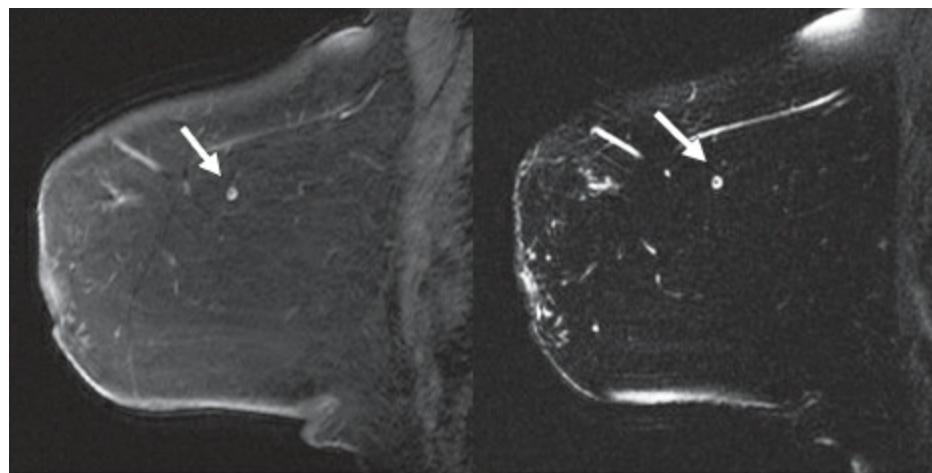
These are circumscribed, homogeneously enhancing masses that are reniform and have hilar fat. They are generally 1 cm or smaller in size. They may be larger than 1 cm and

characterized as normal when fat replacement is pronounced. They frequently occur in the lateral and usually upper portions of the breast closer to the axilla, although they may occur anywhere in the breast. They are usually seen adjacent to a vein, because the lymphatic drainage of the breast parallels the venous drainage.



A **B**

Figure 151 – INTRAMAMMARY LYMPH NODE (arrows). Non-fat-suppressed T1W precontrast image (a). Fat-suppressed T1W postcontrast image (b).



A **B**

Figure 152 – INTRAMAMMARY LYMPH NODE (arrow). Fat-suppressed T1W postcontrast image (a). Fat-suppressed T2W image (b).

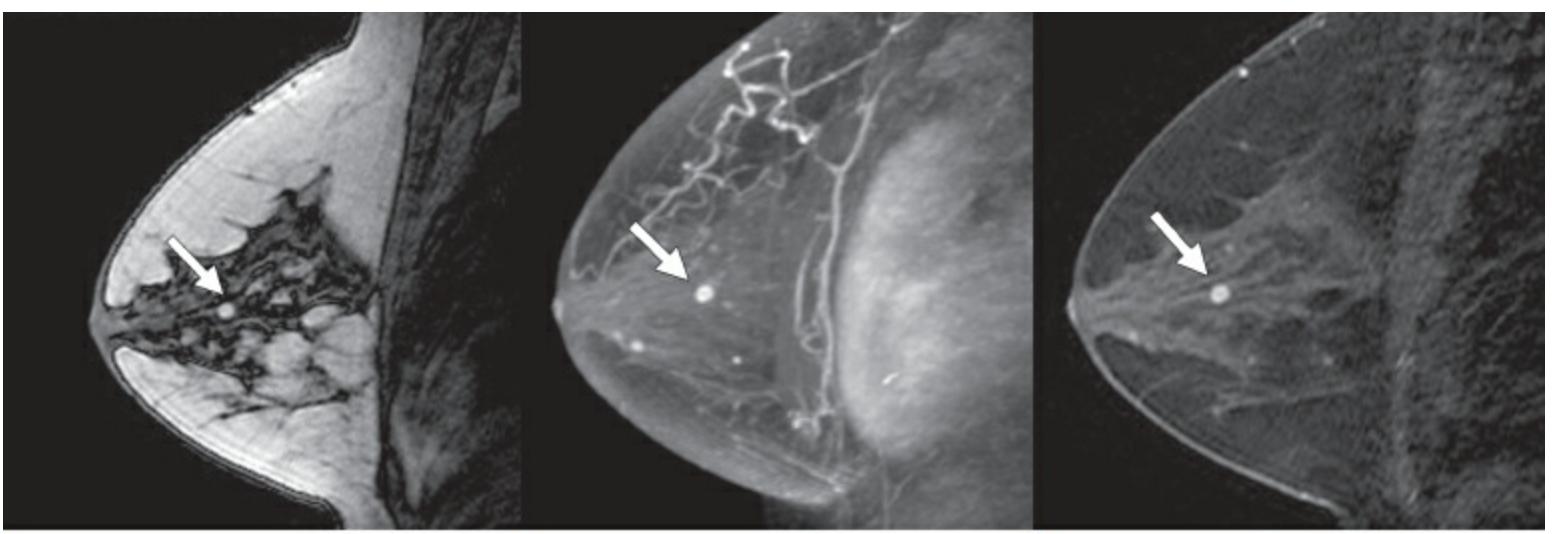
**A****B****C**

Figure 153 – INTRAMAMMARY LYMPH NODE (arrow). Non-fat-suppressed precontrast T1W image (a). First postcontrast T1W MIP image (b). Fat-suppressed T1W postcontrast image (c).

G. SKIN LESION

These are benign enhancing lesions of the skin. Keloids, sebaceous cysts, and areas of dermatitis may enhance.

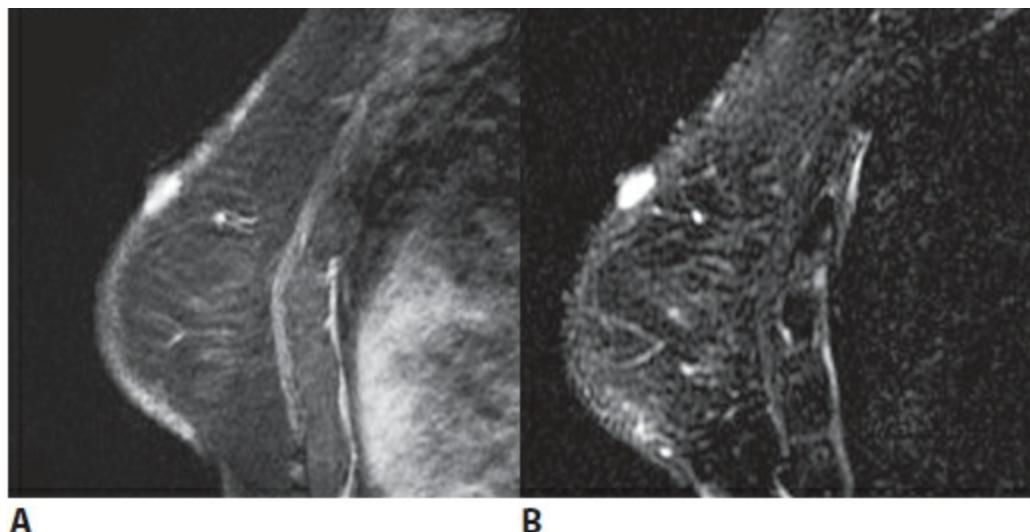
**A****B**

Figure 154 – SKIN LESION. Sebaceous cyst. Fat-suppressed postcontrast T1W image (a). T2W image (b).



Figure 155 – SKIN LESION. Postreduction mammoplasty. Enhancement along the surgical incisions in the periareolar (*thin arrows*) and inframammary locations (*thick arrows*). Fat-suppressed postcontrast T1W image.

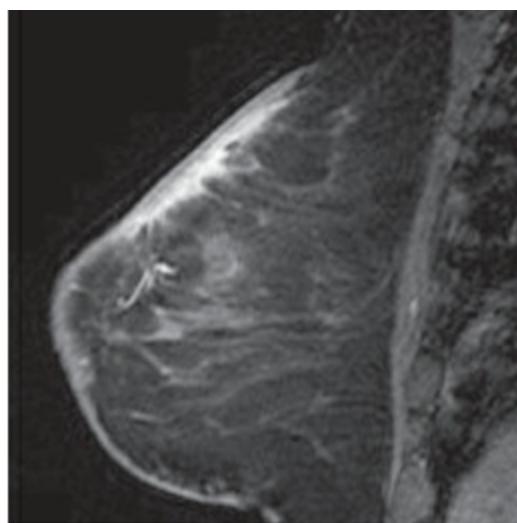


Figure 156 – SKIN LESION. Radiation mastitis. Note enhancement of the skin and associated skin thickening. Fat-suppressed postcontrast T1W image.

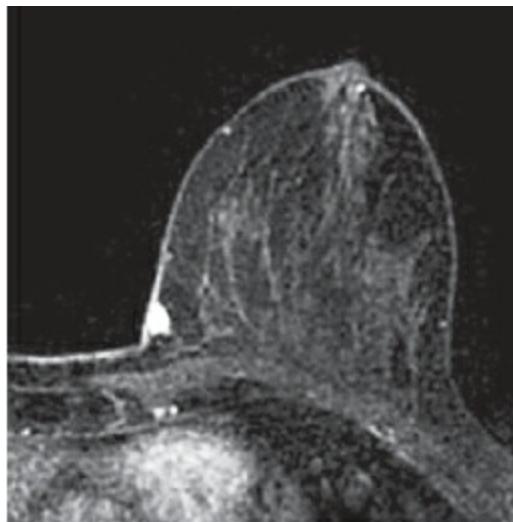


Figure 157 – SKIN LESION. Sebaceous cyst.
Fat-suppressed postcontrast T1W image.

H. NON-ENHANCING FINDINGS

1. DUCTAL PRECONTRAST HIGH SIGNAL ON T1W

Bright signal in ducts before contrast enhancement on T1-weighted images is a characteristically benign finding.

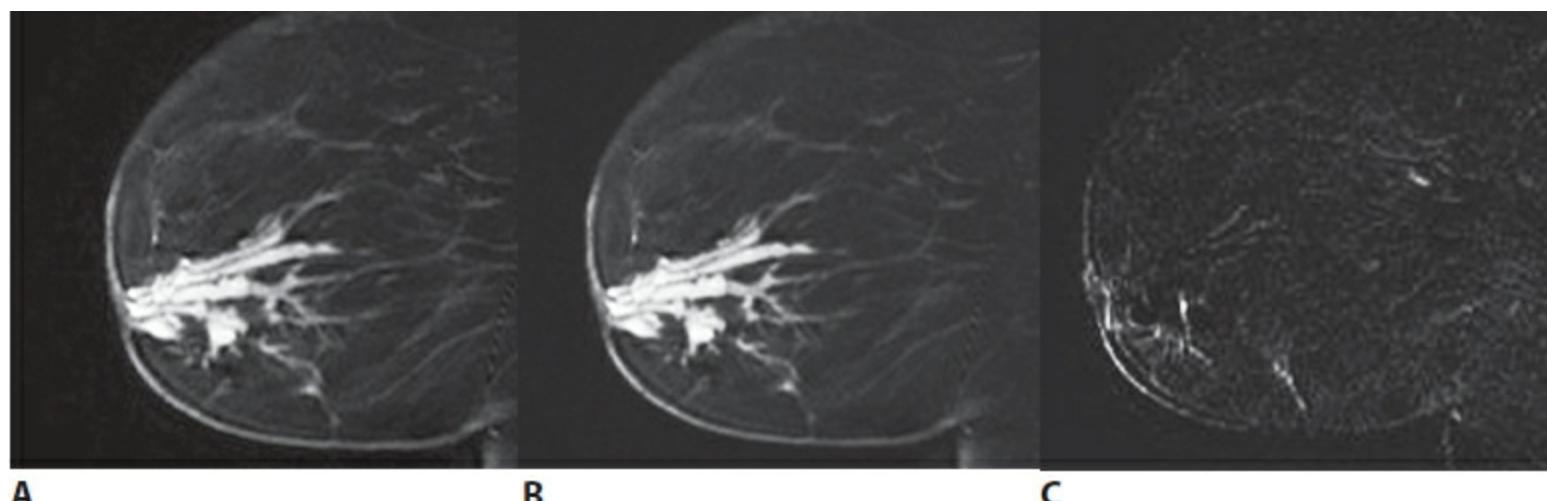
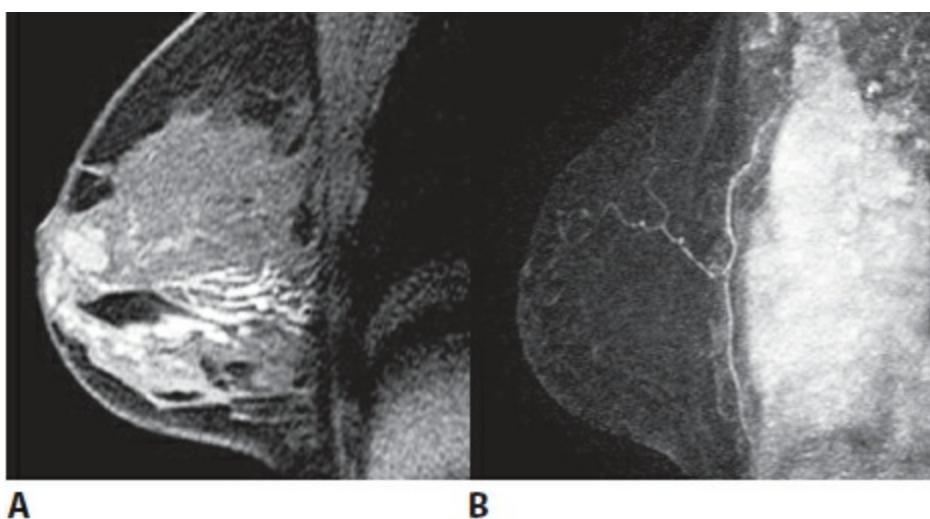


Figure 158 – DUCTAL PRECONTRAST HIGH SIGNAL ON T1W. Duct ectasia. High signal fluid/debris in the ducts is present. There is no enhancement. Fat-suppressed T1W precontrast image (a). Fat-suppressed T1W postcontrast image (b). Subtraction (c).



A **B**

Figure 159 – DUCTAL PRECONTRAST HIGH SIGNAL ON T1W. Duct ectasia. Fat-suppressed T1W precontrast image (a). Subtraction MIP (b). No enhancement.



Figure 160 – DUCTAL PRECONTRAST HIGH SIGNAL on T1W. Fat-suppressed postcontrast T1W image. Pathology: duct ectasia

H. NON-ENHANCING FINDINGS

2. CYST

A cyst usually is a circumscribed, round or oval, fluid-filled mass with an imperceptible wall. Signal characteristics are usually bright on T2W images, although benign cysts may have variable signal characteristics. Cysts are characteristically benign if no enhancing solid elements are detected. Occasionally, the wall of a cyst can enhance; this is also a benign finding if thin and uniform.

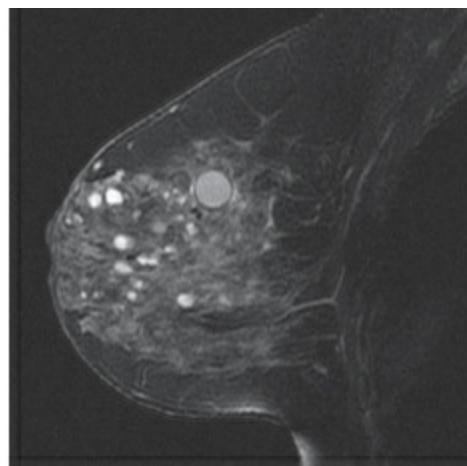
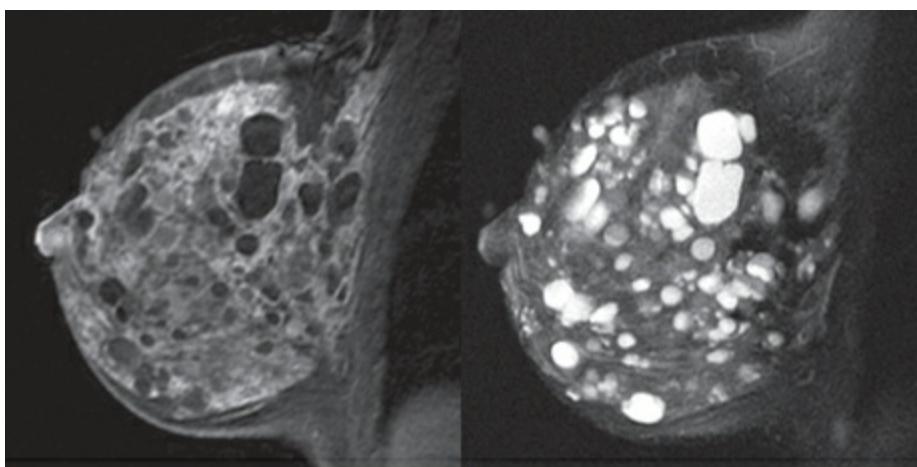


Figure 161 – CYST. Numerous CYSTS of varying signal intensities. Fat-suppressed T2W image.



A **B**
Figure 162 – CYST. Numerous CYSTS. Fat-suppressed third postcontrast T1W image (a). T2W image demonstrates numerous cysts (b).

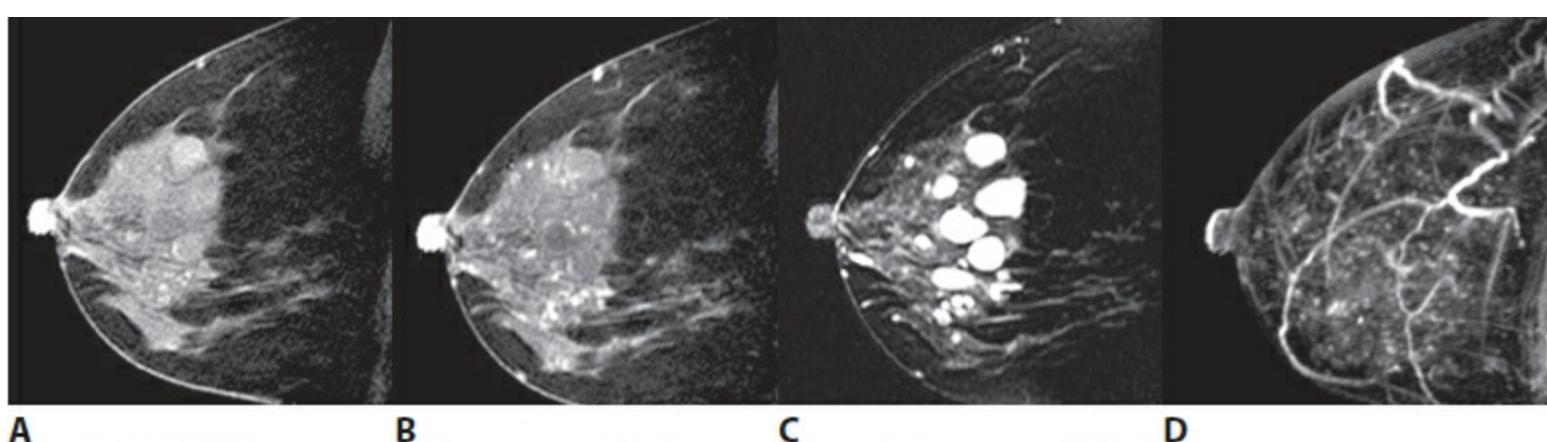


Figure 163 – CYST. Numerous CYSTS. Fat-suppressed T1W precontrast image (a). Fat-suppressed T1W postcontrast image (b). Fat-suppressed T2W image (c). Subtraction MIP demonstrates moderate BPE (d).

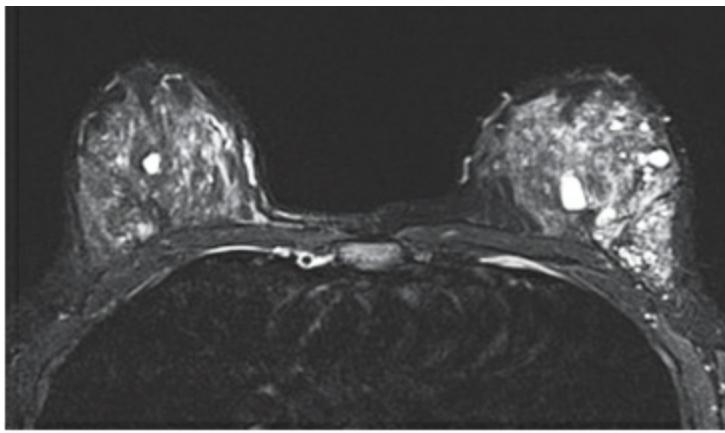


Figure 164 – CYST. Numerous bilateral CYSTS. Short inversion time inversion recovery (STIR) image.

H. NON-ENHANCING FINDINGS

3. POSTOPERATIVE COLLECTIONS (HEMATOMA/SEROMA)

Postoperative collections may be simple or complicated. The collections may contain bright signal on T1W imaging due to blood products. A fat-fluid layer may be present. Postoperative collections will usually demonstrate thin peripheral enhancement around the cavity, a characteristically benign finding.

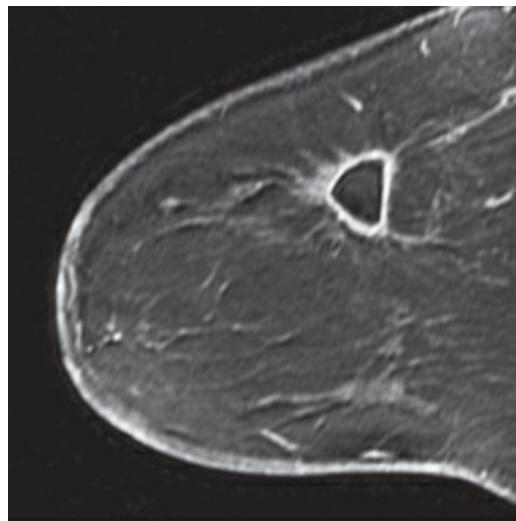


Figure 165 – POSTOPERATIVE COLLECTIONS (HEMATOMA/SEROMA). POSTOPERATIVE COLLECTIONS following breast surgery with central low signal compatible with fat necrosis and benign postoperative changes. Fat-suppressed first postcontrast T1W image. Note normal thin rim enhancement around the area of fat necrosis.

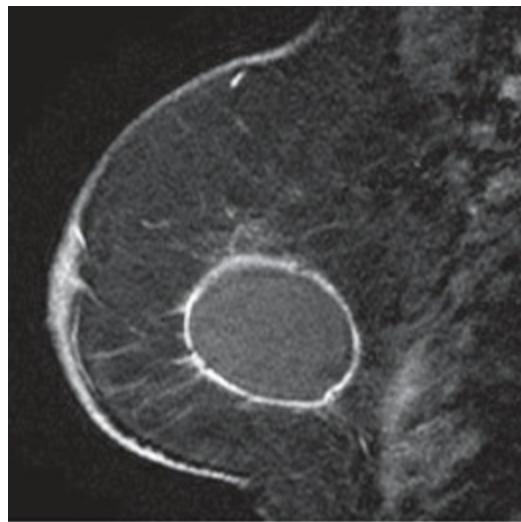
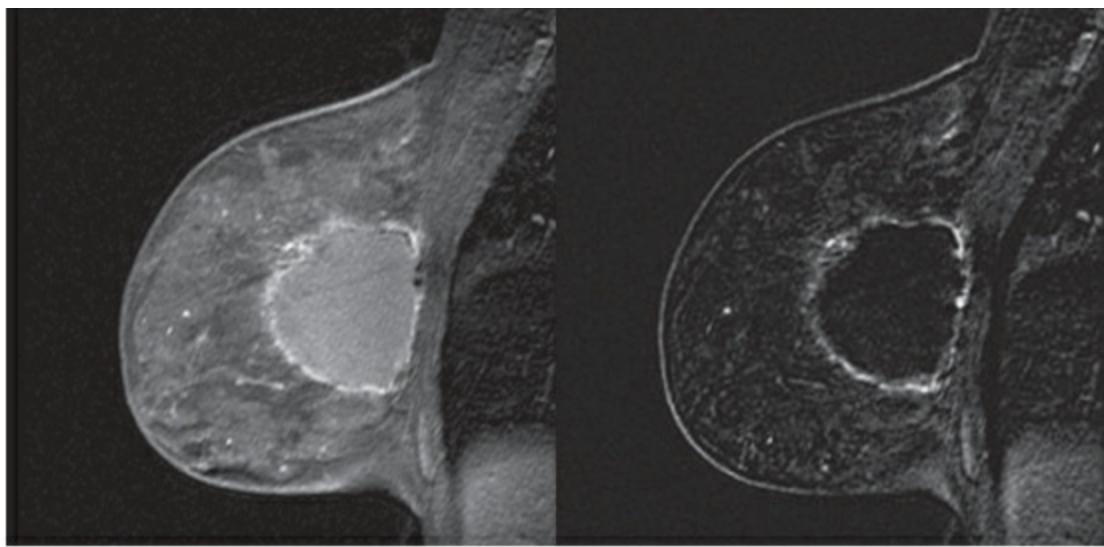


Figure 166 – POSTOPERATIVE COLLECTIONS (HEMATOMA/SEROMA). POSTOPERATIVE COLLECTIONS following breast conserving surgery 1 year ago. Fat-suppressed first postcontrast T1W image. Thin rim enhancement around the postoperative bed is a normal finding and may persist for several years.



A **B**

Figure 167 – POSTOPERATIVE COLLECTIONS (HEMATOMA/SEROMA). POSTOPERATIVE COLLECTIONS following breast conservation surgery 1 year ago. Fat-suppressed first postcontrast T1W image (a). Subtraction (b).

H. NON-ENHANCING FINDINGS

4. POST-THERAPY SKIN THICKENING AND TRABECULAR THICKENING

Trabecular thickening with associated skin thickening may be seen following surgery and/or radiation therapy.

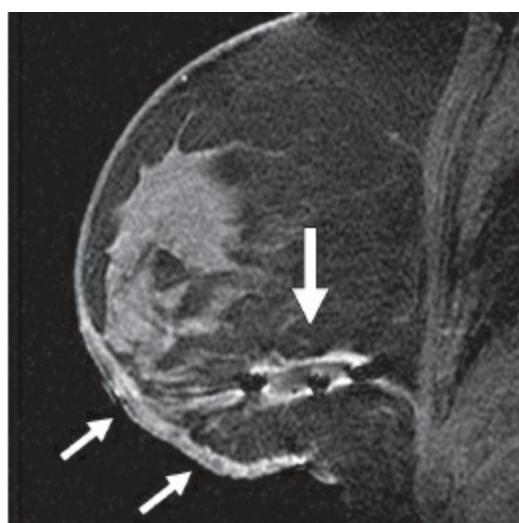


Figure 168 – POST-THERAPY SKIN THICKENING AND TRABECULAR THICKENING.
Post-lumpectomy SKIN THICKENING (*thin arrows*). Note postoperative collection in lower breast (*thick arrow*). Fat-suppressed first postcontrast T1W image.

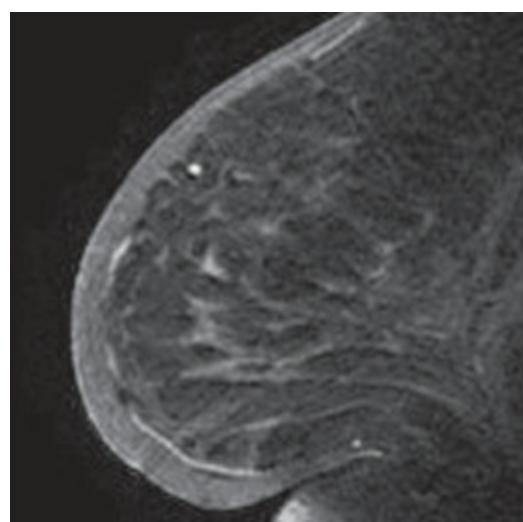


Figure 169 – POST-THERAPY SKIN THICKENING AND TRABECULAR THICKENING.
Diffuse post-radiation SKIN THICKENING without enhancement. Note inferior skin fold indicating difficulty in positioning this patient. Fat-suppressed first postcontrast T1W image.

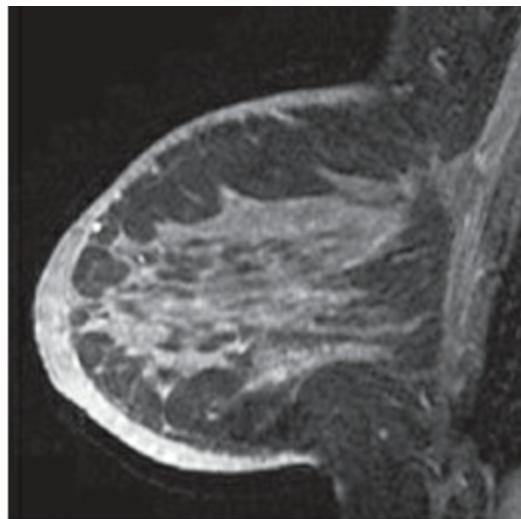


Figure 170 – POST-THERAPY SKIN THICKENING AND TRABECULAR THICKENING.
Post-radiation SKIN THICKENING. Fat-suppressed first postcontrast T1W image.

H. NON-ENHANCING FINDINGS

5. NON-ENHANCING MASS

Non-enhancing solid masses are usually identified on the precontrast images and do not demonstrate enhancement. Subtraction imaging confirms the presence of no enhancement. Other sequences (such as bright-fluid imaging) may identify the mass due to signal characteristics that differentiate it from the surrounding tissue. These non-enhancing masses are solid lesions and differentiated from cysts as they do not contain fluid.

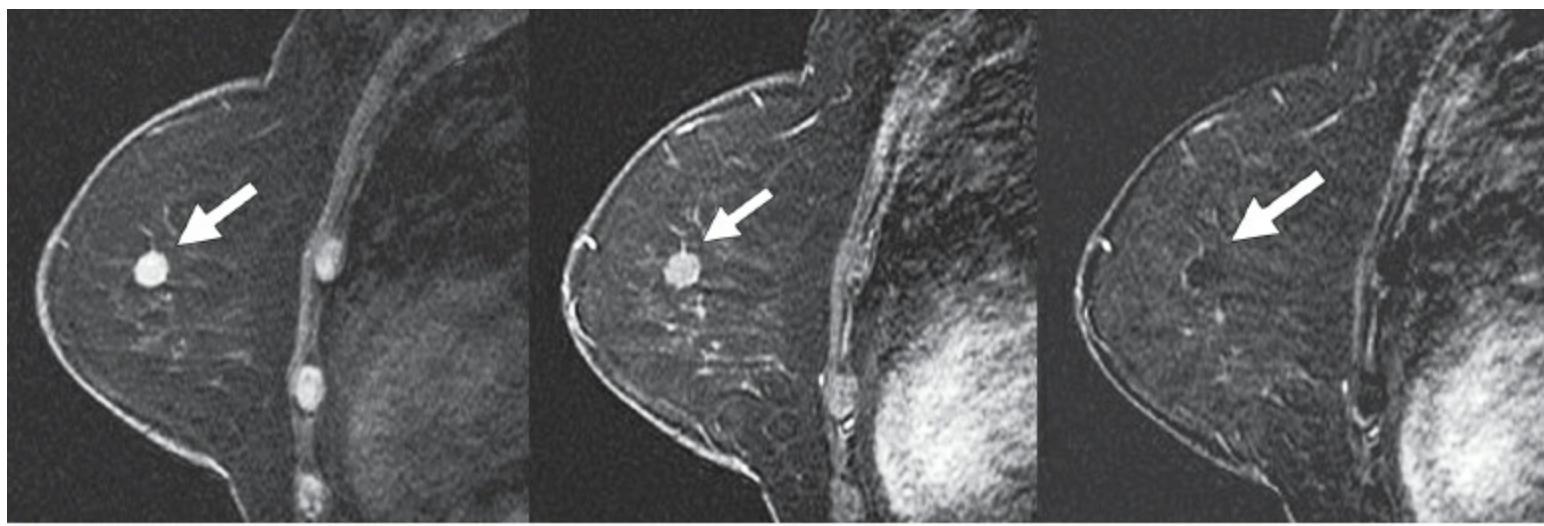


Figure 171 – NON-ENHANCING MASS. Round circumscribed NON-ENHANCING mass (arrows). Fat-suppressed precontrast T1W image (a). Fat-suppressed postcontrast T1W image (b). Subtraction T1W image (c). Pathology: Fibroadenoma.

H. NON-ENHANCING FINDINGS

6. ARCHITECTURAL DISTORTION

The parenchyma is distorted with no definite mass visible. For MRI, this includes focal retraction and distortion of the parenchyma.

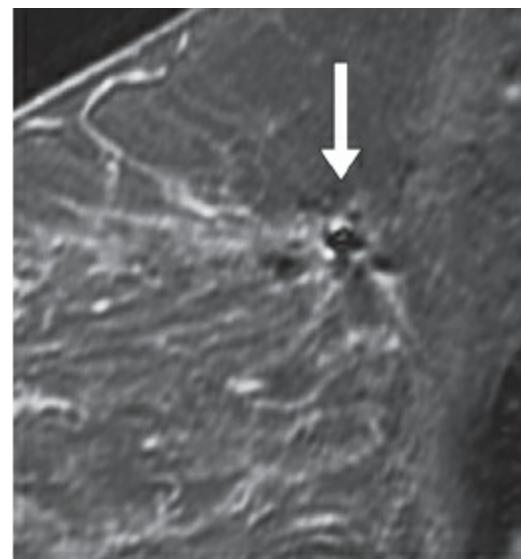


Figure 172 – ARCHITECTURAL DISTORTION.
Following surgery for breast cancer. Note signal void from surgical clips (arrow). Fat-suppressed first postcontrast T1W image.

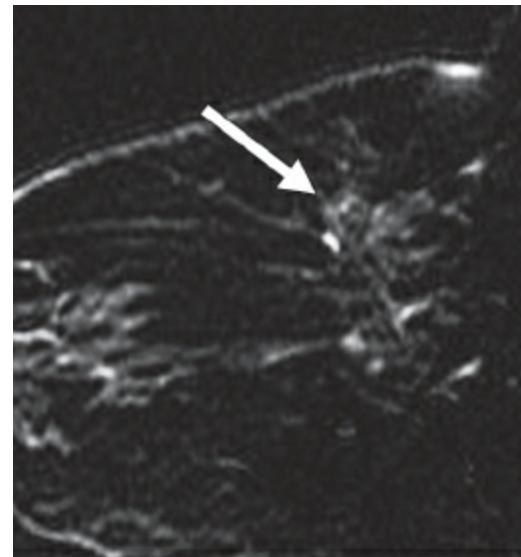


Figure 173 – ARCHITECTURAL DISTORTION (arrow). Following benign breast biopsy. Fat-suppressed first postcontrast T1W image.

H. NON-ENHANCING FINDINGS

7. SIGNAL VOID FROM FOREIGN BODIES, CLIPS, ETC.

There is an absence of signal due to an artifact.

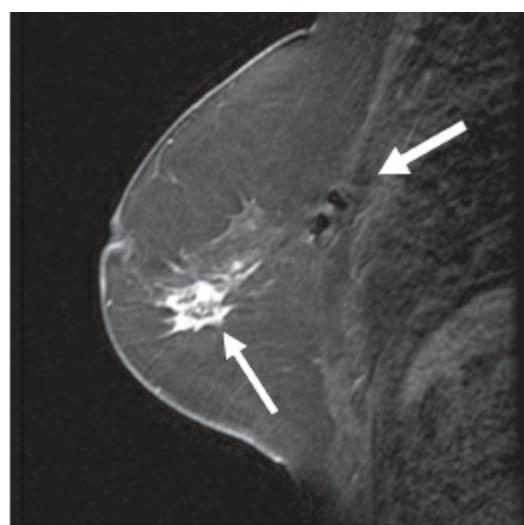


Figure 174 – SIGNAL VOID FROM FOREIGN BODIES, CLIPS, ETC. Surgical clips. Remote history of breast conserving therapy (*thick arrow marks lumpectomy site and signal void*). Note mass (*thin arrow*) anterior to lumpectomy site, biopsy-proven recurrence. Fat-suppressed first postcontrast T1W image.

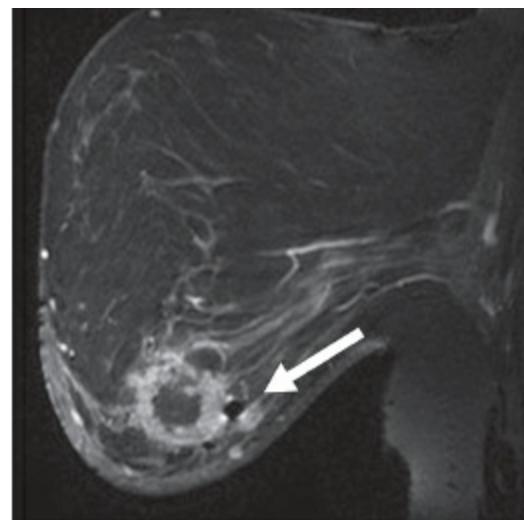


Figure 175 – SIGNAL VOID FROM FOREIGN BODIES, CLIPS, ETC. Biopsy marker placed following percutaneous biopsy (*arrow*). Fat-suppressed first postcontrast T1W image. Pathology: triple negative invasive ductal carcinoma.

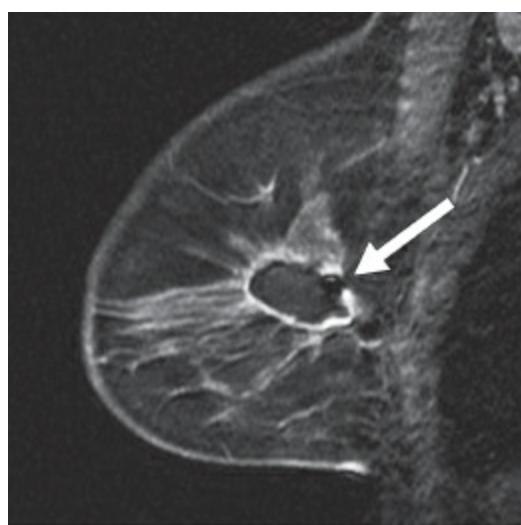


Figure 176 – SIGNAL VOID FROM FOREIGN BODIES, CLIPS, ETC. Signal void from surgical clip (arrow) following recent breast conserving surgery. Clip is at the periphery of post-operative collection. Fat-suppressed first postcontrast T1W image.

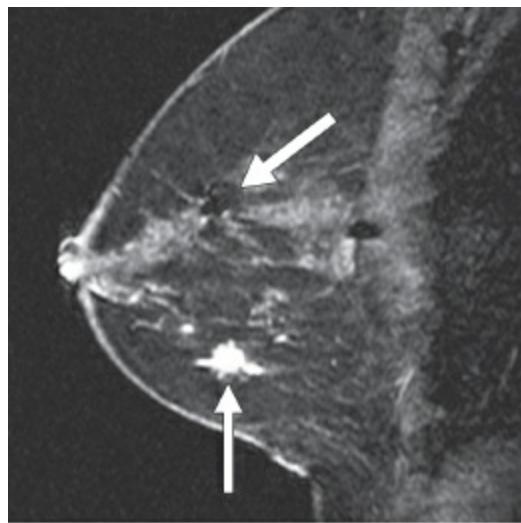


Figure 177 – SIGNAL VOID FROM FOREIGN BODIES, CLIPS, ETC. Signal void from surgical clip (thick arrow) at surgical site from prior lumpectomy. Irregular mass (thin arrow) represents recurrence. Fat-suppressed first postcontrast T1W image.

I. ASSOCIATED FEATURES

Associated feature are used with other findings of abnormal enhancement or may stand alone as findings when no other abnormality is present. Associated features may increase suspicion for breast cancer if detected with other findings and are particularly important if they influence surgical management or breast cancer staging.

1. NIPPLE RETRACTION

The nipple is pulled in. This should not be confused with nipple inversion, which is often bilateral. In the absence of any suspicious findings and when stable for a long period of time, nipple retraction is not a sign of malignancy. If it is new, suspicion for underlying malignancy is increased.

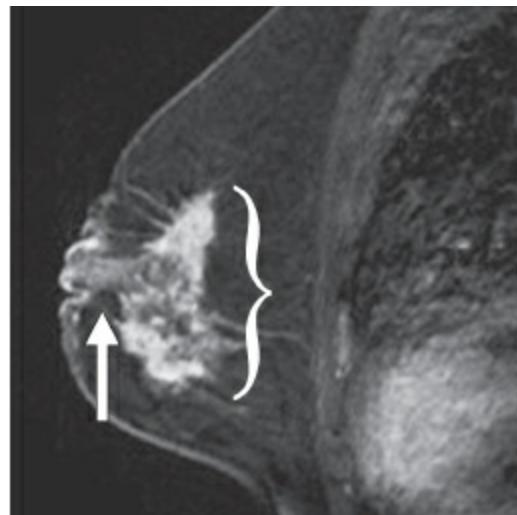


Figure 178 – NIPPLE RETRACTION. (arrow). Regional, heterogeneous enhancement with architectural distortion (brace). Fat-suppressed first postcontrast T1W image.

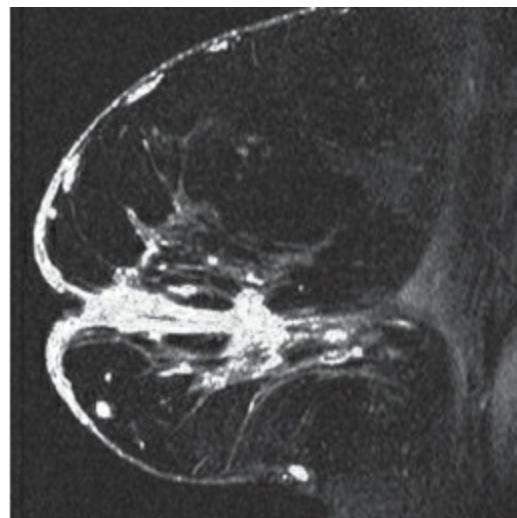


Figure 179 – NIPPLE RETRACTION. Secondary to underlying carcinoma. Fat-suppressed first postcontrast T1W image.

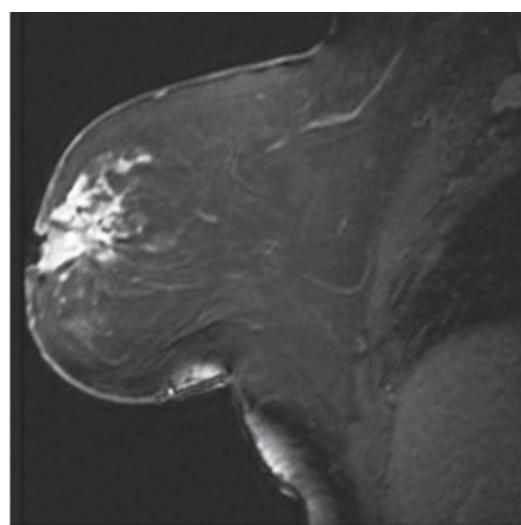


Figure 180 – NIPPLE RETRACTION.
Secondary to a spiculated mass. Pathology:
Invasive ductal carcinoma. Fat-suppressed
postcontrast T1W image.

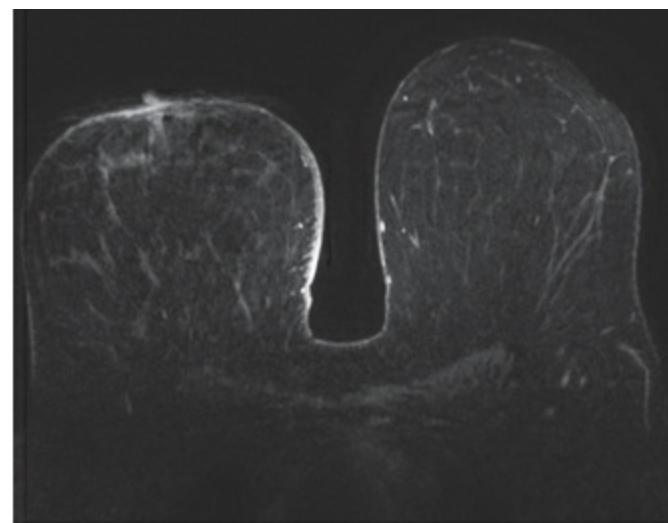


Figure 181 – NIPPLE RETRACTION. Secondary to post-operative changes from prior lumpectomy. Note skin thickening from prior radiation therapy. Fat-suppressed postcontrast T1W image.

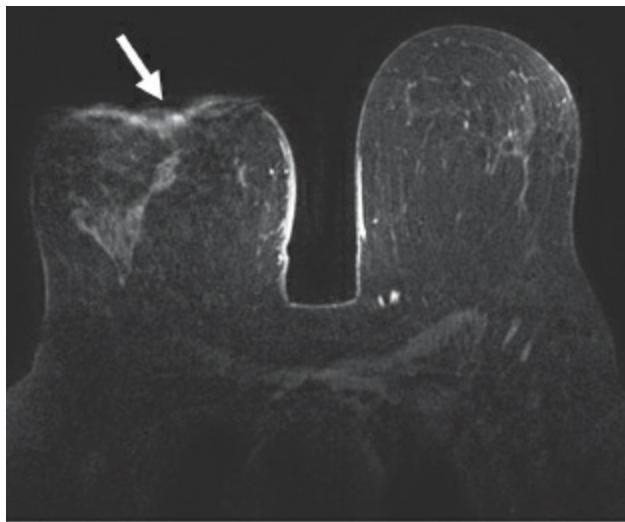


Figure 182 – NIPPLE RETRACTION (arrow). From prior breast surgery. Fat-suppressed postcontrast T1W image.

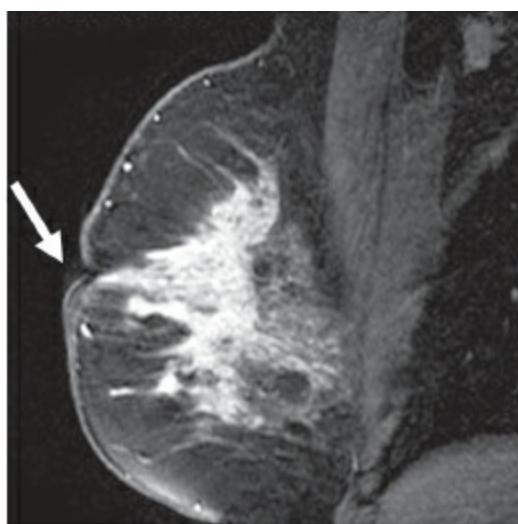


Figure 183 – NIPPLE RETRACTION. Secondary to underlying invasive lobular carcinoma (arrow). Fat-suppressed first postcontrast T1W image.

I. ASSOCIATED FEATURES

2. NIPPLE INVASION

The tumor directly invades and is contiguous with the nipple.

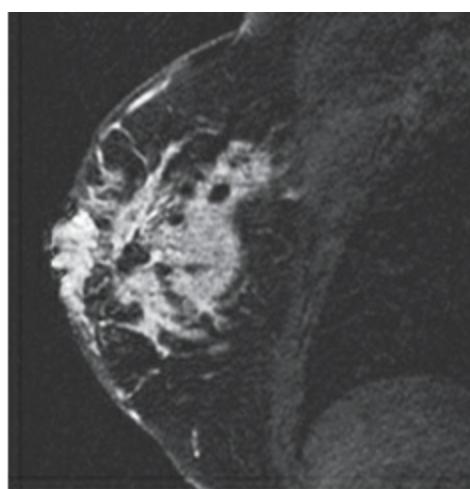


Figure 184 – NIPPLE INVASION. Fat-suppressed first postcontrast T1W image.

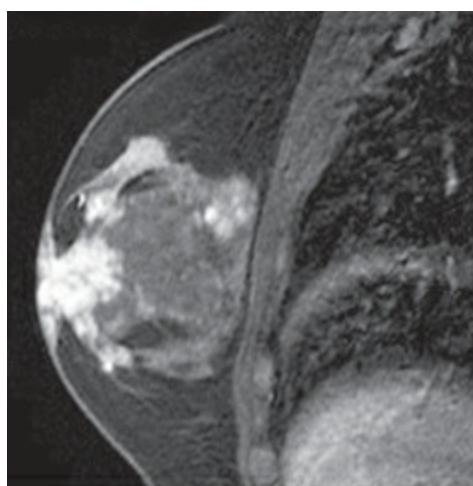


Figure 185 – NIPPLE INVASION. Fat-suppressed first postcontrast T1W image.

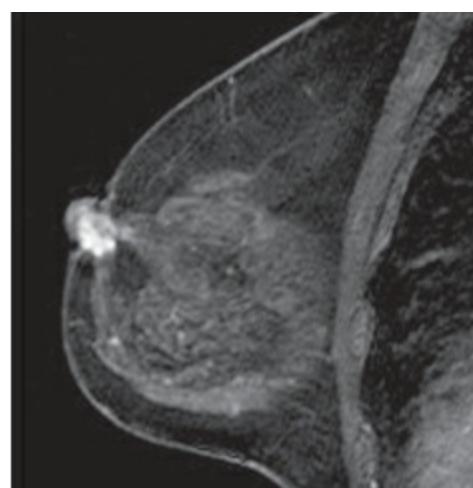


Figure 186 – NIPPLE INVASION. Fat-suppressed first postcontrast T1W image.

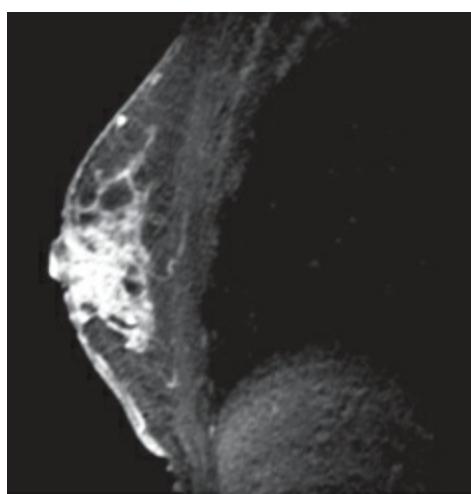


Figure 187 – NIPPLE INVASION. Fat-suppressed first postcontrast T1W image.

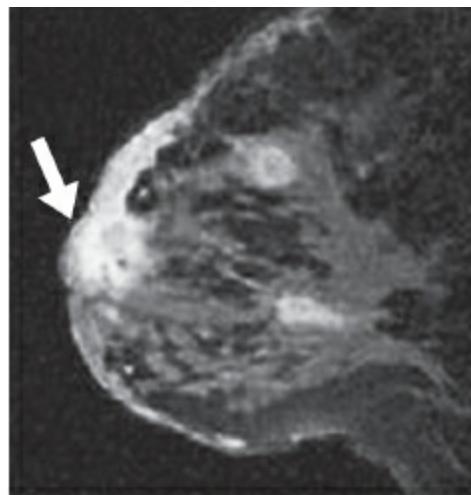


Figure 188 – NIPPLE INVASION (arrow). Fat-suppressed first postcontrast T1W image.

I. ASSOCIATED FEATURES

3. SKIN RETRACTION

The skin is pulled in abnormally.

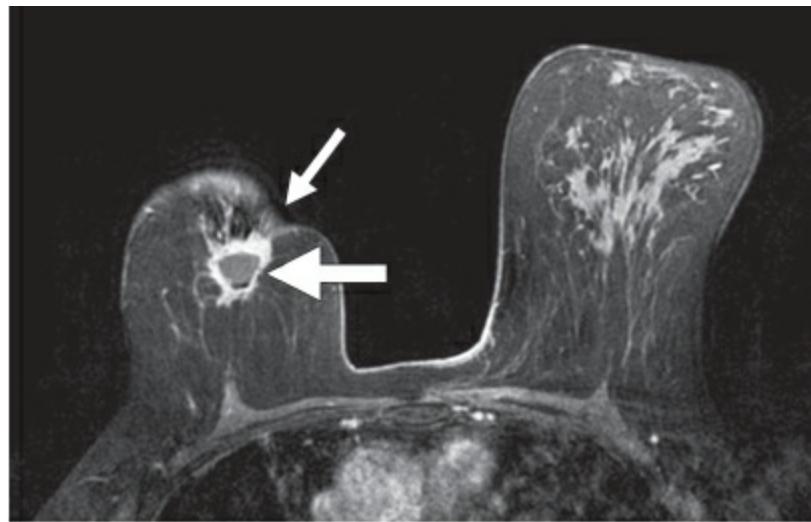


Figure 189 – SKIN RETRACTION. SKIN RETRACTION (*thin arrow*) secondary to prior breast cancer surgery over 1 year ago. Note normal appearing postoperative collection with a fat-fluid layer (*thick arrow*).

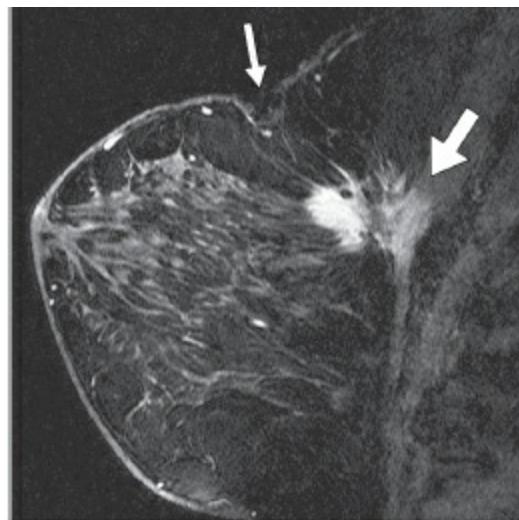


Figure 190 – SKIN RETRACTION. Invasive ductal carcinoma causing SKIN RETRACTION (*thin arrow*). Note pectoralis muscle invasion (*thick arrow*). Fat-suppressed first postcontrast T1W image.

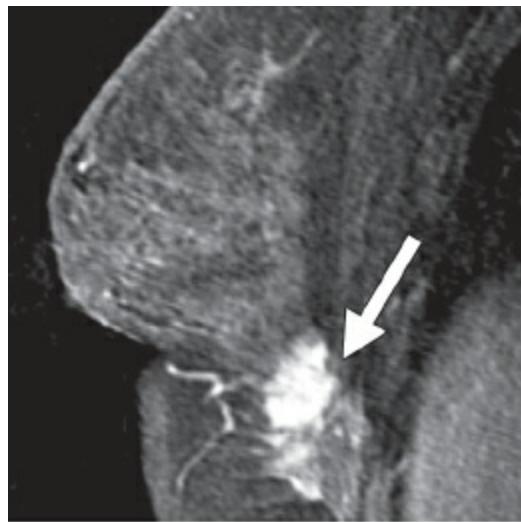


Figure 191 – SKIN RETRACTION. Invasive ductal carcinoma causing SKIN RETRACTION. Note chest wall invasion (arrow). Fat-suppressed first postcontrast T1W image.

I. ASSOCIATED FEATURES

4. SKIN THICKENING

Skin thickening may be focal or diffuse, and is defined as being greater than 2 mm in thickness. Without associated enhancement, skin thickening is usually related to post-treatment changes (surgery and radiation therapy).

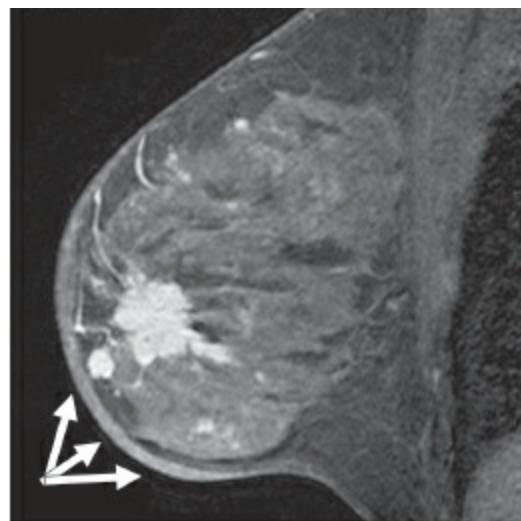


Figure 192 – SKIN THICKENING. Focal SKIN THICKENING (arrows), secondary lymphedema from malignant adenopathy (not pictured). Fat-suppressed first postcontrast T1W image. Note multifocal carcinoma.

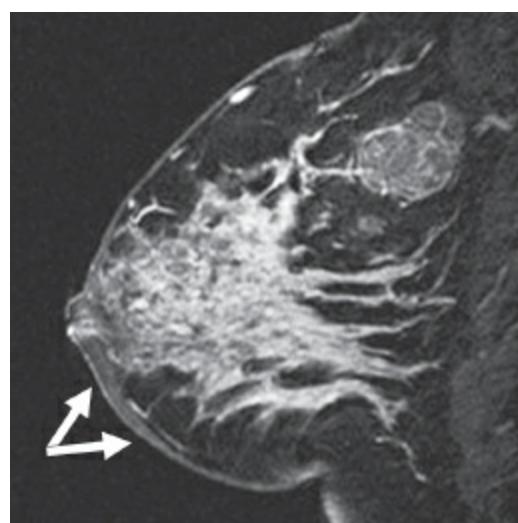


Figure 193 – SKIN THICKENING. Focal SKIN THICKENING (arrows), secondary lymphatic obstruction from malignant axillary adenopathy. Note diffuse enhancement compatible with locally advanced breast carcinoma. Fat-suppressed first postcontrast T1W image.

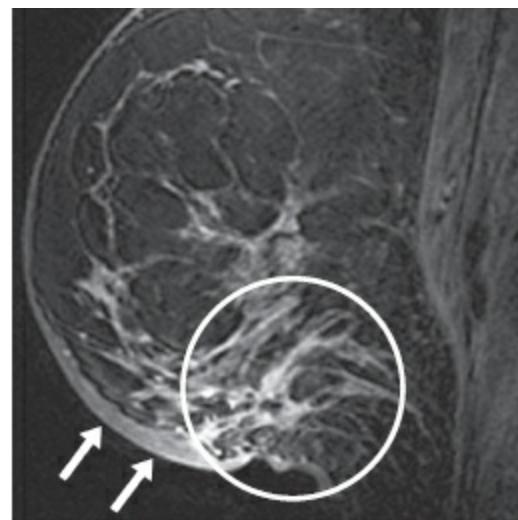


Figure 194 – SKIN THICKENING. Focal SKIN THICKENING (arrows) due to postoperative changes. Fat-suppressed first postcontrast T1W image. Note adjacent postsurgical changes (circle).

I. ASSOCIATED FEATURES

5. SKIN INVASION

There is abnormal enhancement within the skin, which is thickened.

a. Direct Invasion

The skin enhances where the tumor directly invades.

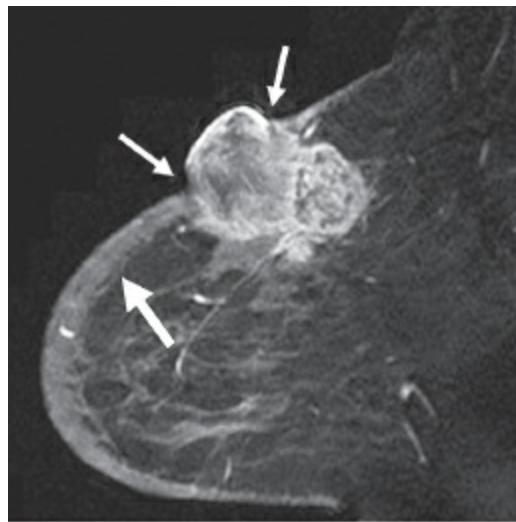


Figure 195 – SKIN INVASION: DIRECT INVASION (thin arrows). Note anterior skin is thickened due to lymphedema [not enhancing] (thick arrow]. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

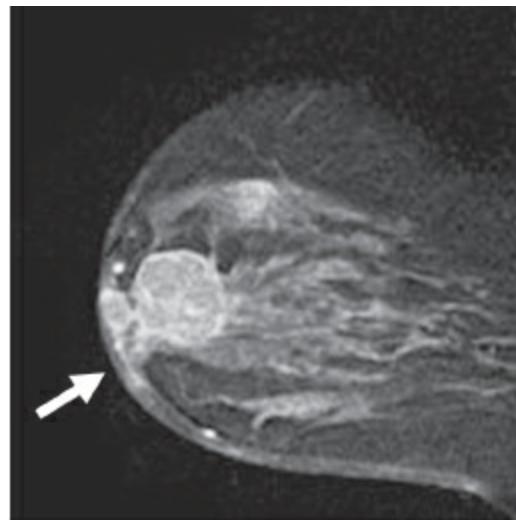


Figure 196 – SKIN INVASION: DIRECT INVASION (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

I. ASSOCIATED FEATURES

5. SKIN INVASION

b. Inflammatory Cancer

Enhancement of the skin can be diffuse or focal depending on the extent of invasion of dermal lymphatics.

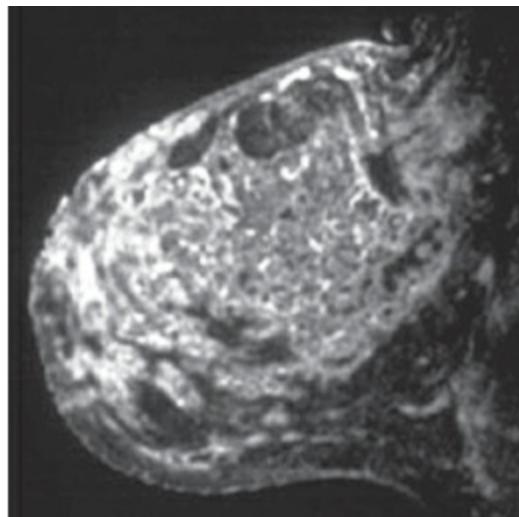


Figure 197 – SKIN INVASION: INFLAMMATORY CANCER. Diffuse skin thickening and enhancement. Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

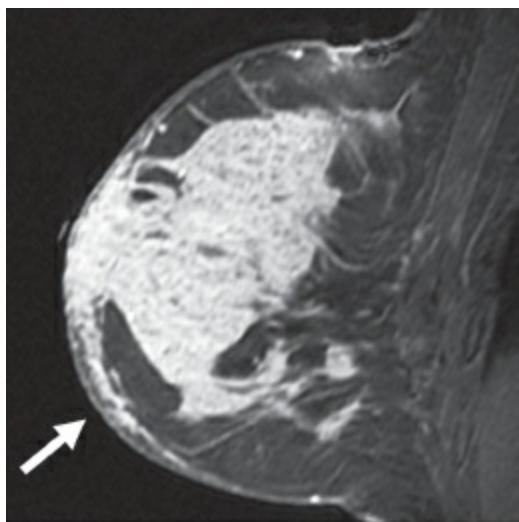


Figure 198 – SKIN INVASION: INFLAMMATORY CANCER. Diffuse skin thickening and enhancement (arrow). Fat-suppressed first postcontrast T1W image. Pathology: invasive ductal carcinoma.

I. ASSOCIATED FEATURES

6. AXILLARY ADENOPATHY

Enlarged axillary lymph nodes may warrant comment, clinical correlation, and additional evaluation, especially if they are new or considerably larger or rounder when compared with the previous examination. On MRI, loss of the fatty hilum and heterogeneous enhancement is a suspicious finding. A review of the patient's medical history may elucidate the cause for axillary adenopathy, averting a recommendation for additional evaluation. A margin that is not circumscribed may indicate extranodal extension. When one or more large axillary nodes are substantially composed of fat,

this is a normal variant.

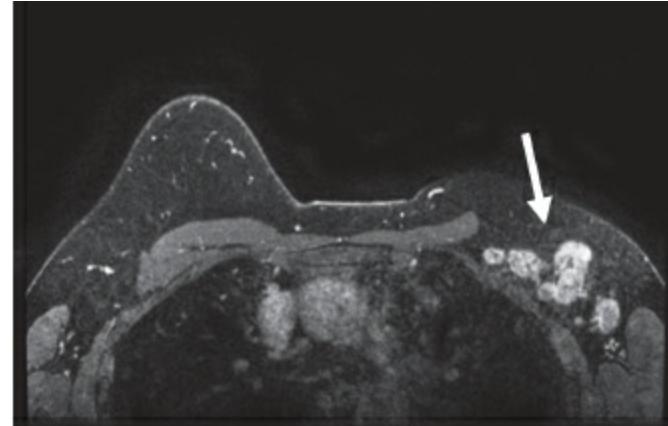


Figure 199 – AXILLARY ADENOPATHY. Malignant AXILLARY ADENOPATHY (arrow). Note Poland Syndrome. Fat-suppressed first postcontrast T1W image. Primary tumor not imaged.

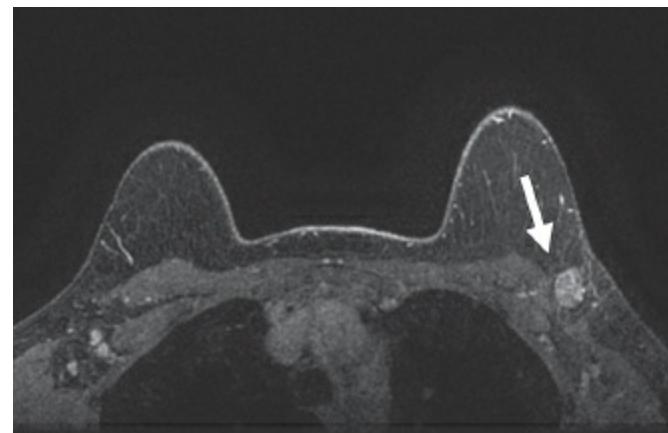


Figure 200 – AXILLARY ADENOPATHY. Malignant AXILLARY ADENOPATHY (arrow). Fat-suppressed first postcontrast T1W image. Primary tumor not imaged.

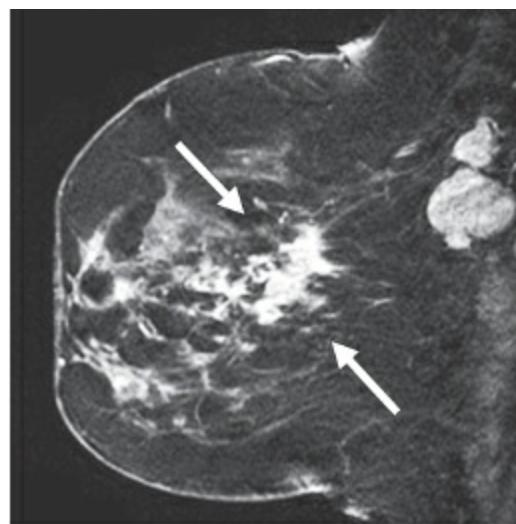


Figure 201 – AXILLARY ADENOPATHY. Malignant AXILLARY ADENOPATHY secondary to metastatic, breast carcinoma (arrows).

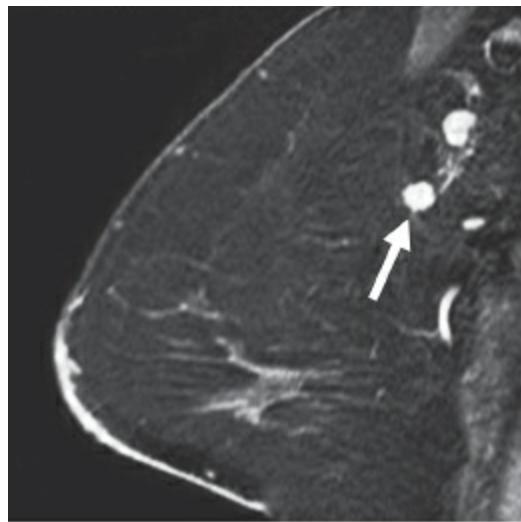


Figure 202 – AXILLARY ADENOPATHY.
Malignant AXILLARY ADENOPATHY. Note not circumscribed margin (arrow).

I. ASSOCIATED FEATURES

7. PECTORALIS MUSCLE INVASION

There is abnormal enhancement extending into the adjacent pectoralis muscle.

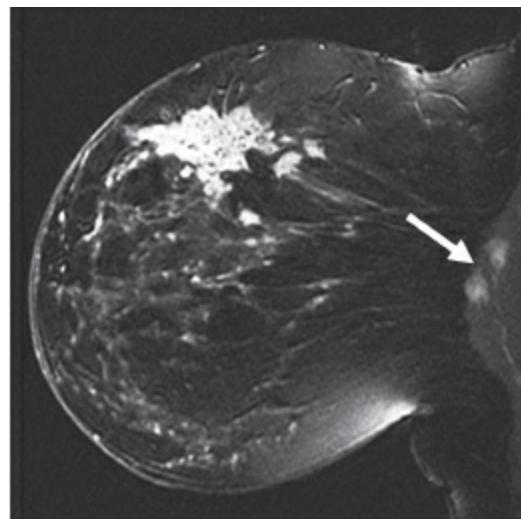


Figure 203 – PECTORALIS MUSCLE INVASION.
Large breast cancer with abnormal masses in the underlying pectoralis muscle (arrow).
PECTORALIS MUSCLE INVASION. Fat-suppressed first postcontrast T1W image.

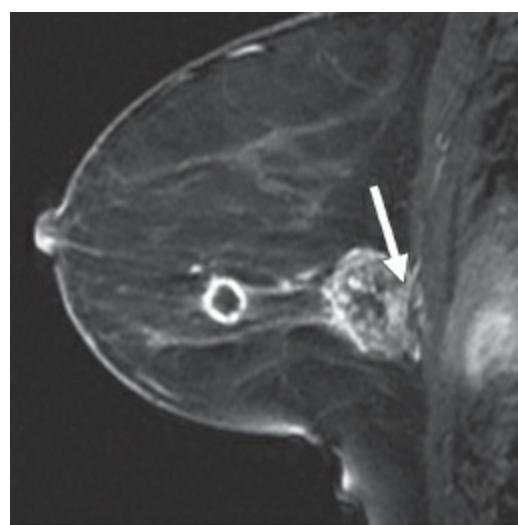


Figure 204 – PECTORALIS MUSCLE INVASION.
Note enhancement in the pectoralis muscle
(arrow). First fat-suppressed postcontrast T1W
image.

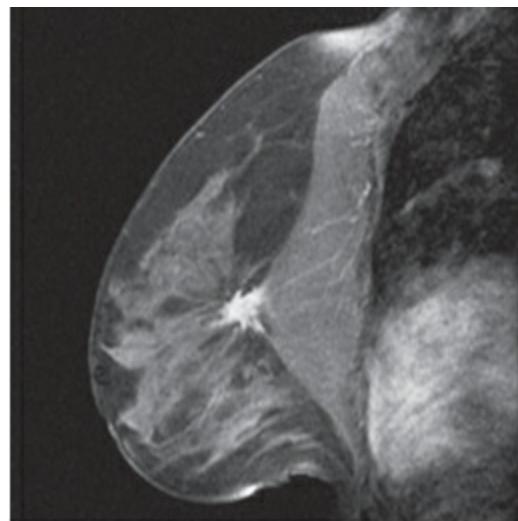


Figure 205 – PECTORALIS MUSCLE INVASION.
Spiculated mass with enhancement in
the underlying muscle compatible with
PECTORALIS MUSCLE INVASION. Fat-
suppressed postcontrast T1W image.
Pathology: fibromatosis.

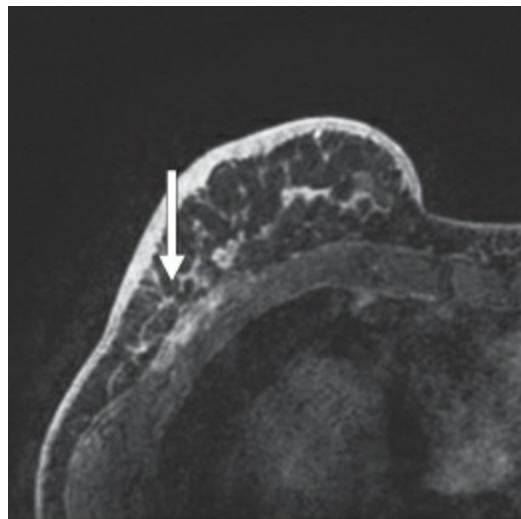


Figure 206 – PECTORALIS MUSCLE INVASION.
Inflammatory breast carcinoma with
PECTORALIS MUSCLE INVASION (arrow)
and skin thickening with enhancement.
Pathology: invasive ductal carcinoma. Fat-
suppressed postcontrast T1W image.

I. ASSOCIATED FEATURES

8. CHEST WALL INVASION

There is abnormal enhancement extending into the ribs or intercostal spaces (behind the pectoralis muscle).

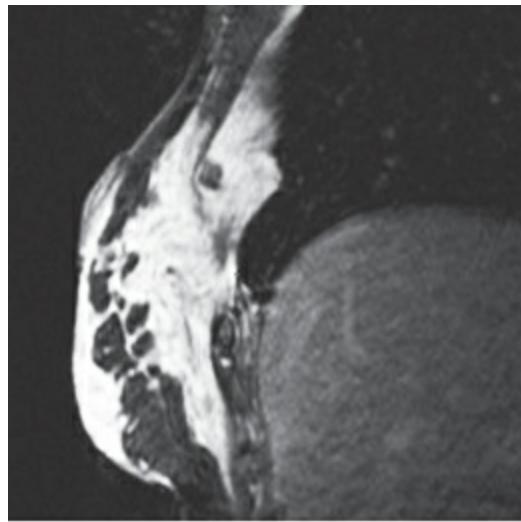


Figure 207 – CHEST WALL INVASION. Fat-
suppressed first postcontrast T1W image.

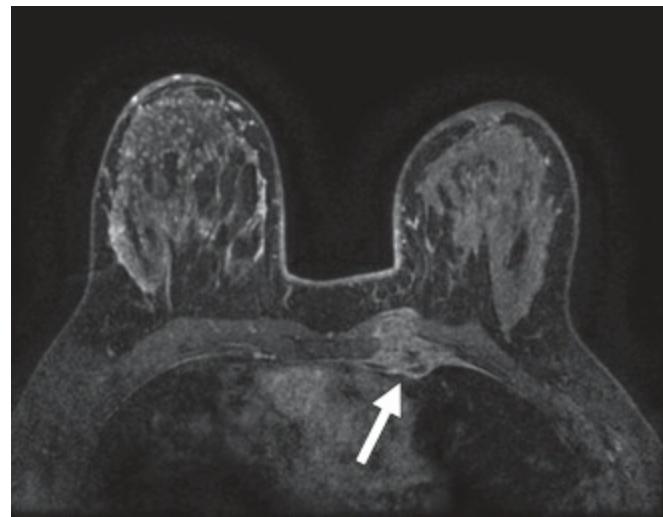


Figure 208 – CHEST WALL INVASION (arrow). Fat-suppressed first postcontrast T1W image.

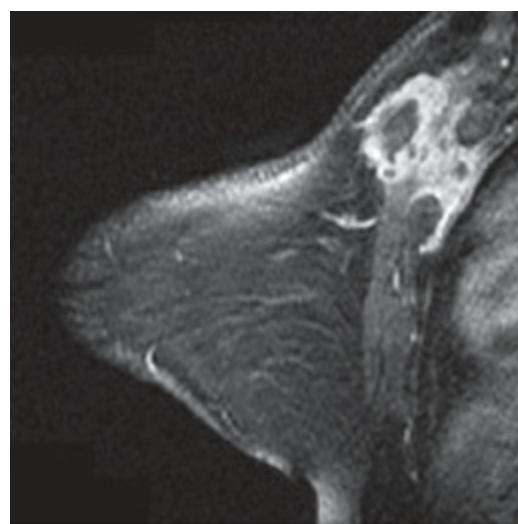


Figure 209 – CHEST WALL INVASION. Fat-suppressed first postcontrast T1W image.

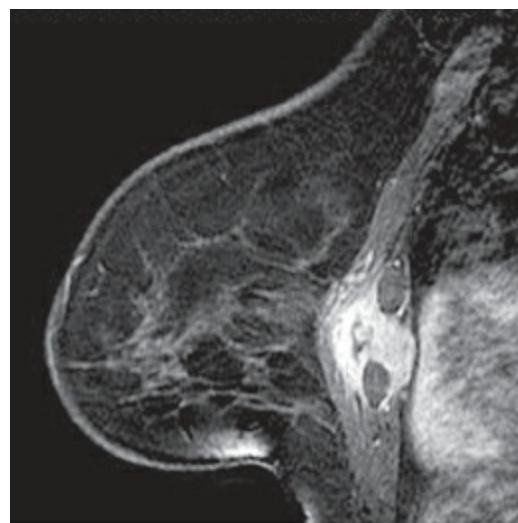


Figure 210 – CHEST WALL INVASION. Fat-suppressed first postcontrast T1W image.

I. ASSOCIATED FEATURES

9. ARCHITECTURAL DISTORTION

As an associated feature, architectural distortion may be used in conjunction with another finding to indicate that the parenchyma is distorted or retracted adjacent to the finding.

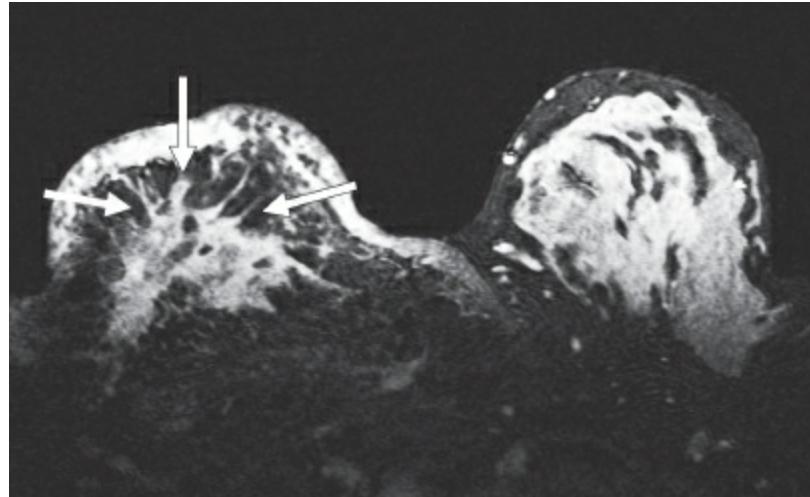


Figure 211 – ARCHITECTURAL DISTORTION. Large spiculated mass with associated ARCHITECTURAL DISTORTION (arrows) of the right breast. Fat-suppressed postcontrast T1W image. Note marked BPE in the contralateral breast due to lactation. Note overlying skin thickening and enhancement compatible with inflammatory carcinoma.

J. FAT-CONTAINING LESIONS

1. LYMPH NODES

a. Normal

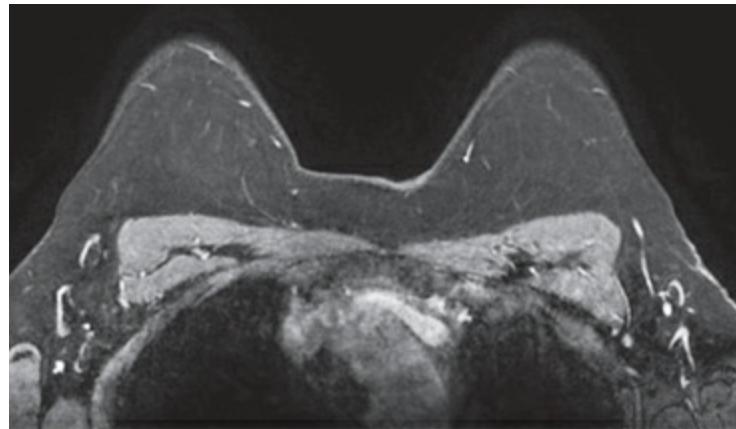


Figure 212 – LYMPH NODES: NORMAL. Axillary LYMPH NODES. Fat-suppressed postcontrast T1W image.

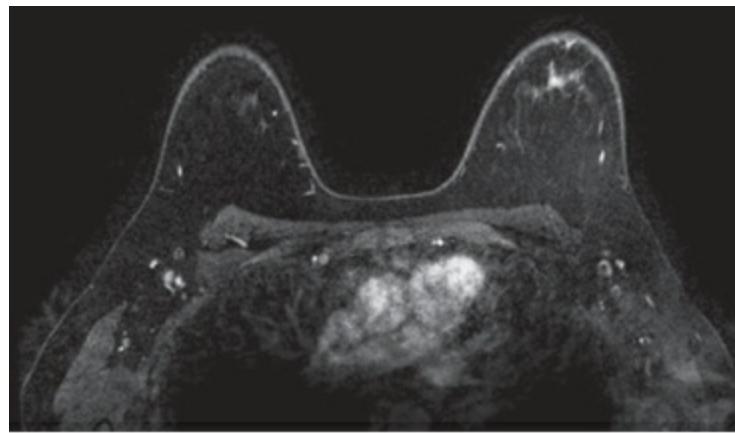


Figure 213 – LYMPH NODES: NORMAL. Axillary LYMPH NODES. Fat-suppressed postcontrast T1W image.

J. FAT-CONTAINING LESIONS

1. LYMPH NODES

b. Abnormal

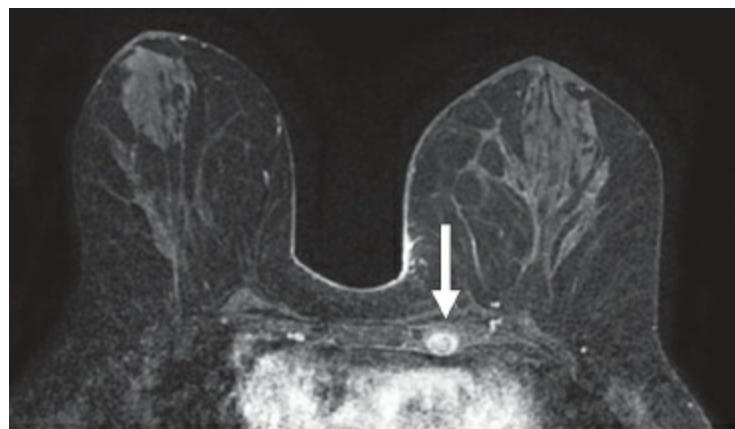


Figure 214 – LYMPH NODES: ABNORMAL. Internal mammary LYMPH NODE (arrow) compatible with metastatic disease. Fat-suppressed postcontrast T1W image.

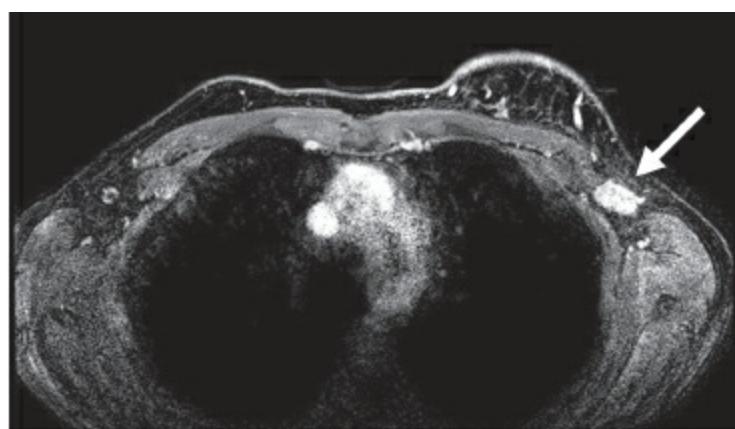


Figure 215 – LYMPH NODES: ABNORMAL. LYMPH NODES (arrow) in the left axilla compatible with metastatic disease. Fat-suppressed postcontrast T1W image.

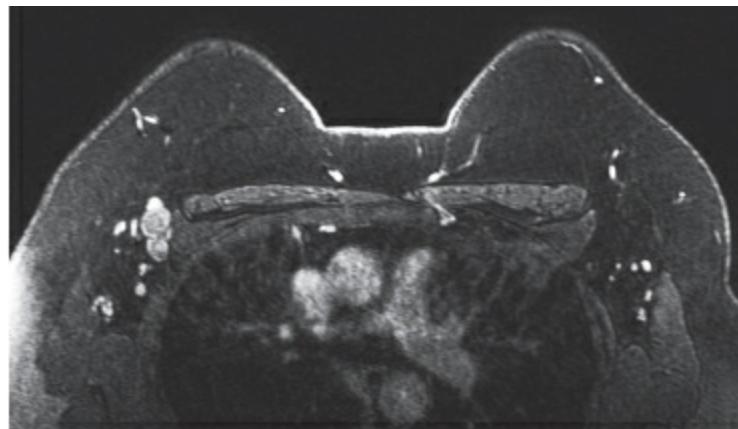


Figure 216 – LYMPH NODES: ABNORMAL. LYMPH NODES in the right axilla compatible with metastatic disease. Fat-suppressed postcontrast T1W image.

J. FAT-CONTAINING LESIONS

2. FAT NECROSIS

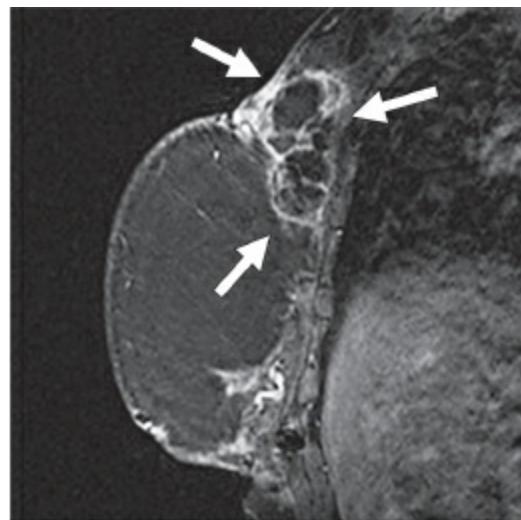


Figure 217 – FAT NECROSIS. Rim-enhancing masses in the superior aspect of a transverse rectus abdominis myocutaneous (TRAM) flap (arrow). Central fat noted on nonfat suppressed images. Findings compatible with FAT NECROSIS. First postcontrast T1W image.

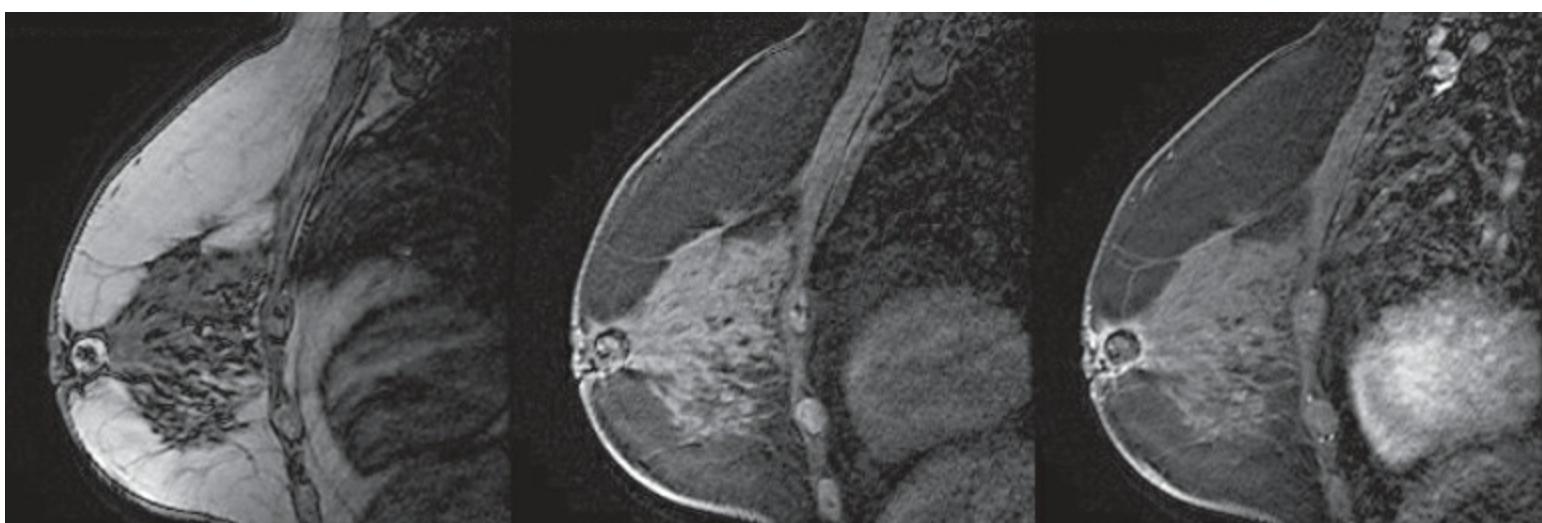


Figure 218 – FAT NECROSIS. Postbiopsy FAT NECROSIS. Collection contains fat as well as organized clot. Non-fat-suppressed T1W image (a). Fat-suppressed precontrast (b). Fat-suppressed postcontrast (c).

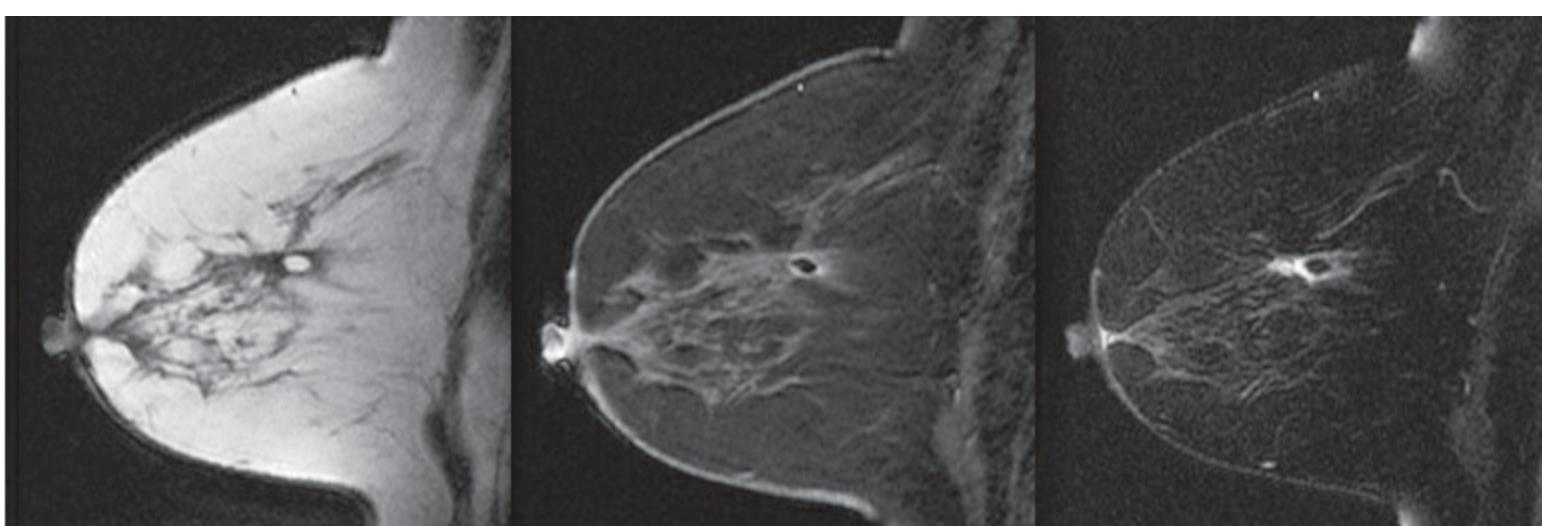


Figure 219 – FAT NECROSIS. Postbiopsy FAT NECROSIS. Note expected enhancement that can be observed in association with fat necrosis. Non-fat-suppressed T1W image (a). Fat-suppressed precontrast T1W image (b). Fat-suppressed postcontrast subtraction T1W image (c).

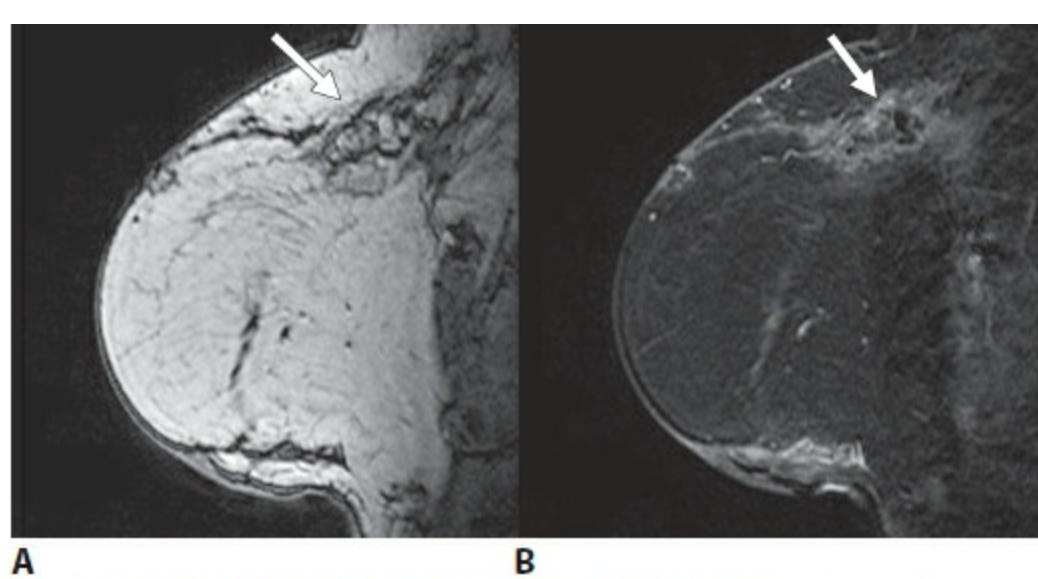
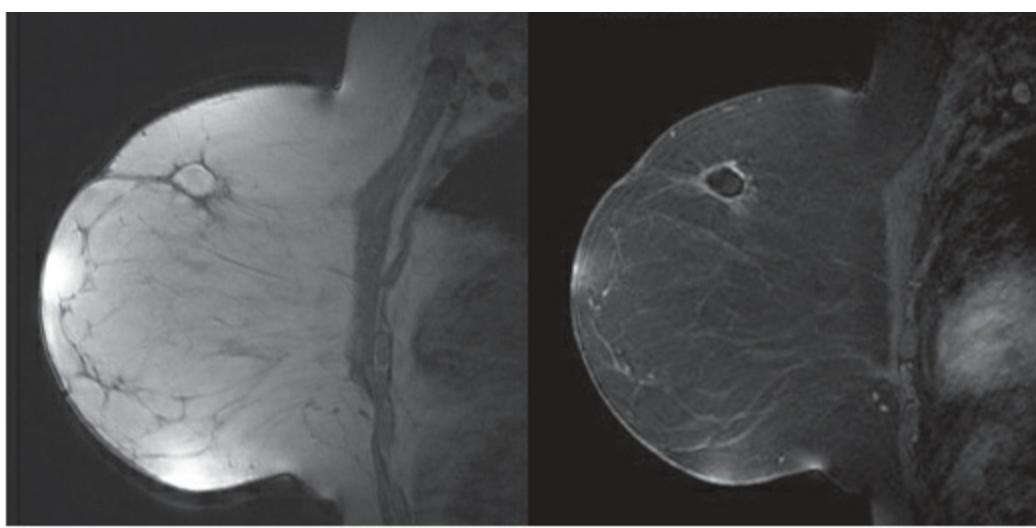


Figure 220 – FAT NECROSIS. FAT NECROSIS (arrows) in TRAM flap for breast reconstruction. Non-fat-suppressed T1W image (a). Fat-suppressed postcontrast T1W image (b).



A

B

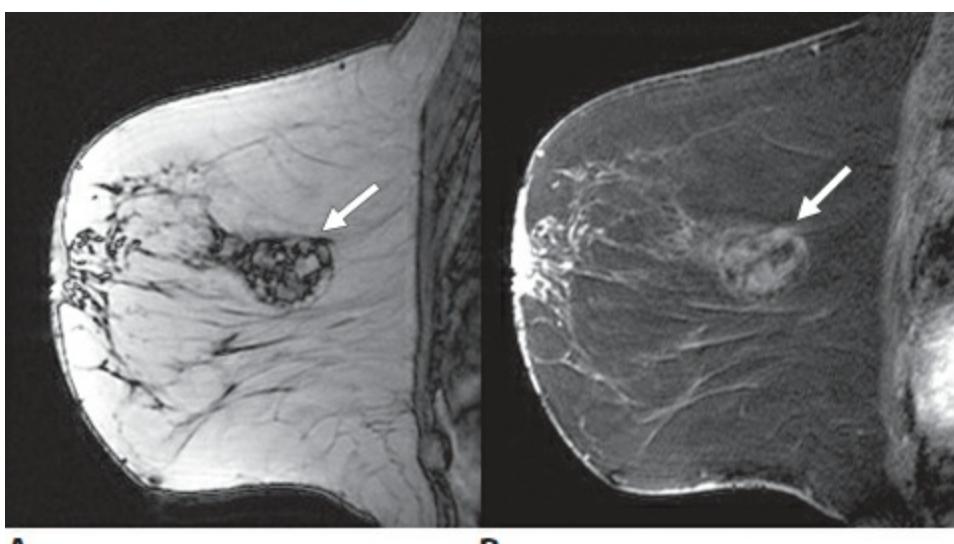
Figure 221 – FAT NECROSIS. FAT NECROSIS following benign excisional biopsy. Non-fat-suppressed T1W image (*a*). Fat-suppressed postcontrast T1W image (*b*).

J. FAT-CONTAINING LESIONS

3. HAMARTOMA



Figure 222 – HAMARTOMA (arrows). Fat-suppressed first postcontrast T1W image.



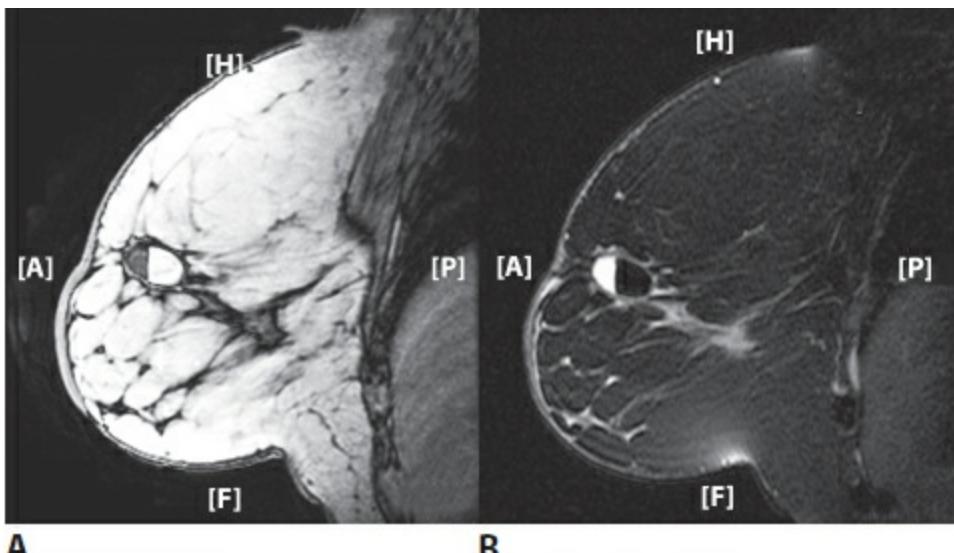
A

B

Figure 223 – HAMARTOMA (arrows). Contains fat. Non-fat-suppressed T1W image (a). Postcontrast fat-suppressed T1W image (b).

J. FAT-CONTAINING LESIONS

4. POSTOPERATIVE SEROMA/HEMATOMA WITH FAT



A

B

Figure 224 – POSTOPERATIVE SEROMA/HEMATOMA WITH FAT. Postoperative collection with fat fluid layer. Non-fat-suppressed T1W image (a). Fat-suppressed T2W image (b).

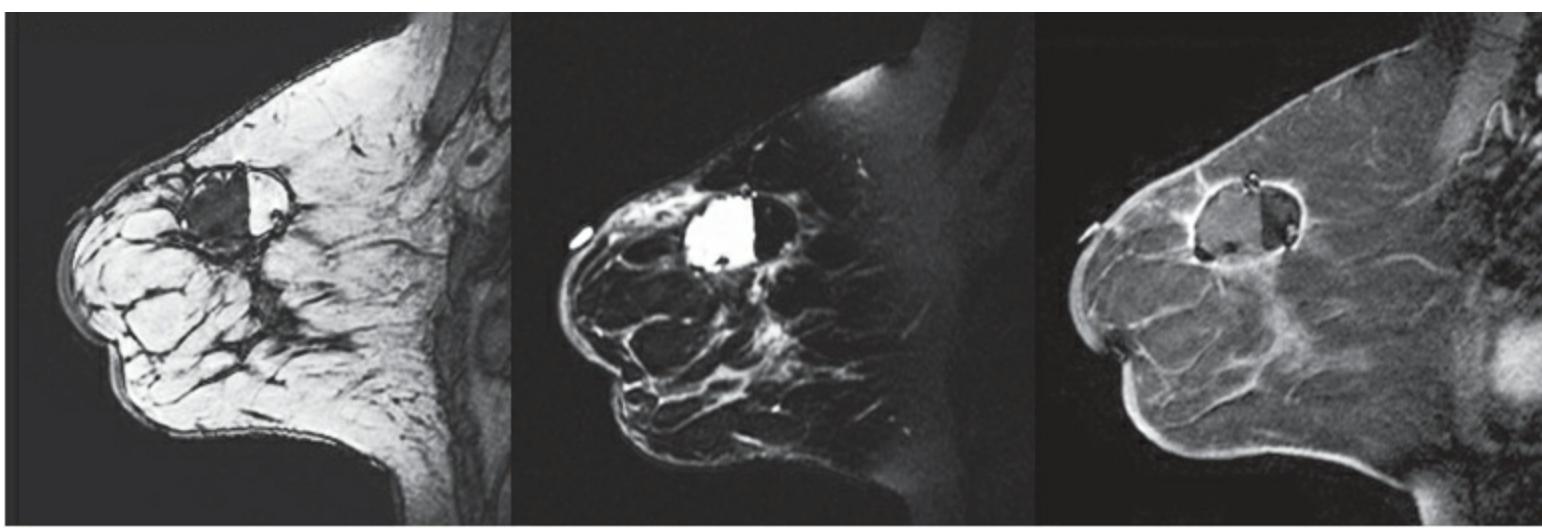
**A****B****C**

Figure 225 – POSTOPERATIVE SEROMA/HEMATOMA WITH FAT. Postoperative collection with fat fluid layer. Non-fat-suppressed T1W image (a). Fat-suppressed T2W image (b). Fat-suppressed first postcontrast T1W image (c). Note normal thin rim enhancement following recent surgery.

K. LOCATION OF LESION

An important lesion (assessed as anything other than benign) must always be triangulated so that its 3-D location within the breast is known. This usually requires it to be described using the clinical orientation extrapolated from the MRI location. The breast is viewed as the face of a clock with the patient facing the observer. Use of quadrants and clock face to describe location is recommended to reduce the likelihood of right-left confusion, as explained in detail in the [Mammography section](#). The side is given first, followed by the location and depth of the lesion. Depth is given as centimeters from the nipple, skin, or chest wall, as appropriate. Immediately beneath the nipple is the retroareolar region. (**e.g., right, upper outer quadrant, 10:00, anterior third, 3 cm from nipple**)

1. LOCATION

Describe location using right, left, or both breasts. Use clock-face position and quadrant location (described in detail in the [Mammography section](#), note that central, retroareolar, and axillary tail descriptors may be used instead of quadrant descriptors and do not require indication of clock-face location).

2. DEPTH

Indicate the depth in the breast using anterior, middle, posterior third (see [Figure 226](#)). Include the distance in centimeters from the nipple, skin, or chest wall as appropriate.

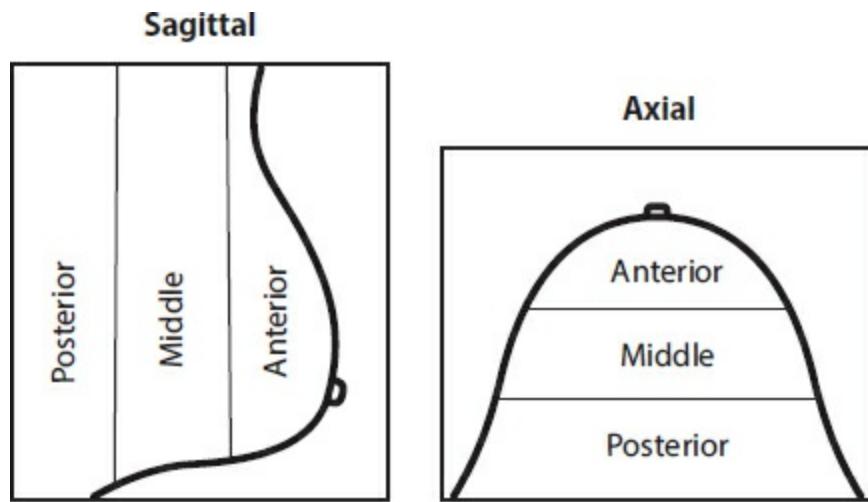


Figure 226 – Depth Diagrams

L. KINETIC CURVE ASSESSMENT

Enhancement characteristics during injection of the contrast media may be described.

HOW TO REPORT THE KINETIC CURVE — As most lesions on kinetic analysis are heterogeneous, the most suspicious feature should be reported. Kinetic analysis is assessed by using color maps (based on pixel by pixel curve analysis) and/or curves that may be generated manually or by CAD systems. The color maps demonstrate heterogeneity better than the manual curves.

SIGNAL INTENSITY (SI)/TIME CURVE DESCRIPTION

1. INITIAL PHASE

This is the enhancement pattern within the first 2 minutes or when the curve starts to change.

a. Slow —

< 50% increase in signal intensity within the first 2 minutes.

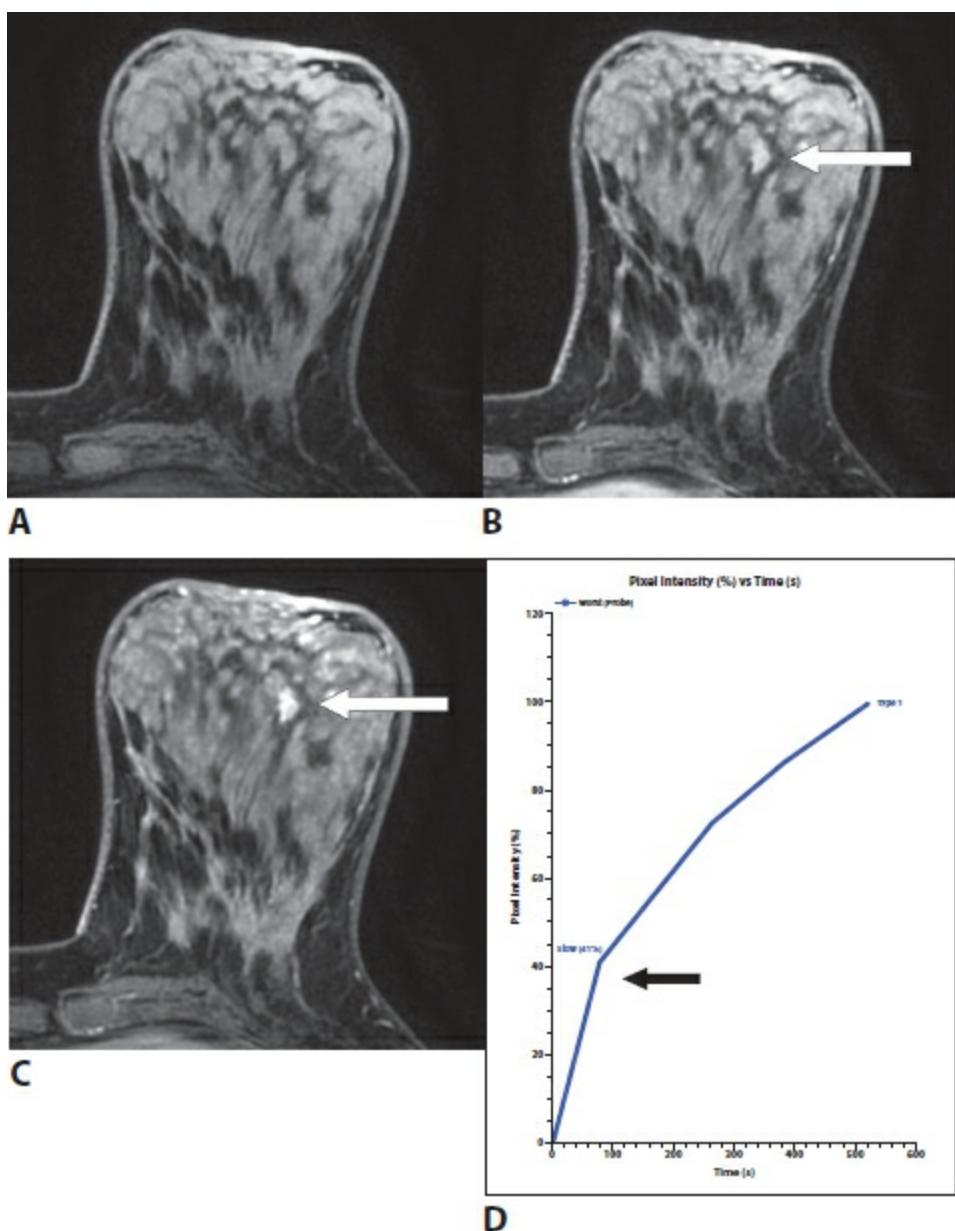


Figure 227 – INITIAL PHASE: SLOW. Left breast T1W fat-saturated precontrast axial image (a). First postcontrast (1 min) image demonstrates a slowly enhancing mass (b, arrow). Delayed postcontrast (5 min) image demonstrates progressive enhancement of the mass (c, arrow). Graph of the kinetic curve from the mass (d) confirms a SLOW initial (< 50% increase in pixel intensity within the first 2 min, arrow) and delayed persistent enhancement pattern (Type 1 curve). Pathology: pseudoangiomatous stromal hyperplasia.

L. KINETIC CURVE ASSESSMENT

SIGNAL INTENSITY (SI)/TIME CURVE DESCRIPTION

1. INITIAL PHASE

b. Medium —

50%–100% increase in signal intensity within the first 2 minutes.

c. Fast —

> 100% increase in signal intensity within the first 2 minutes.

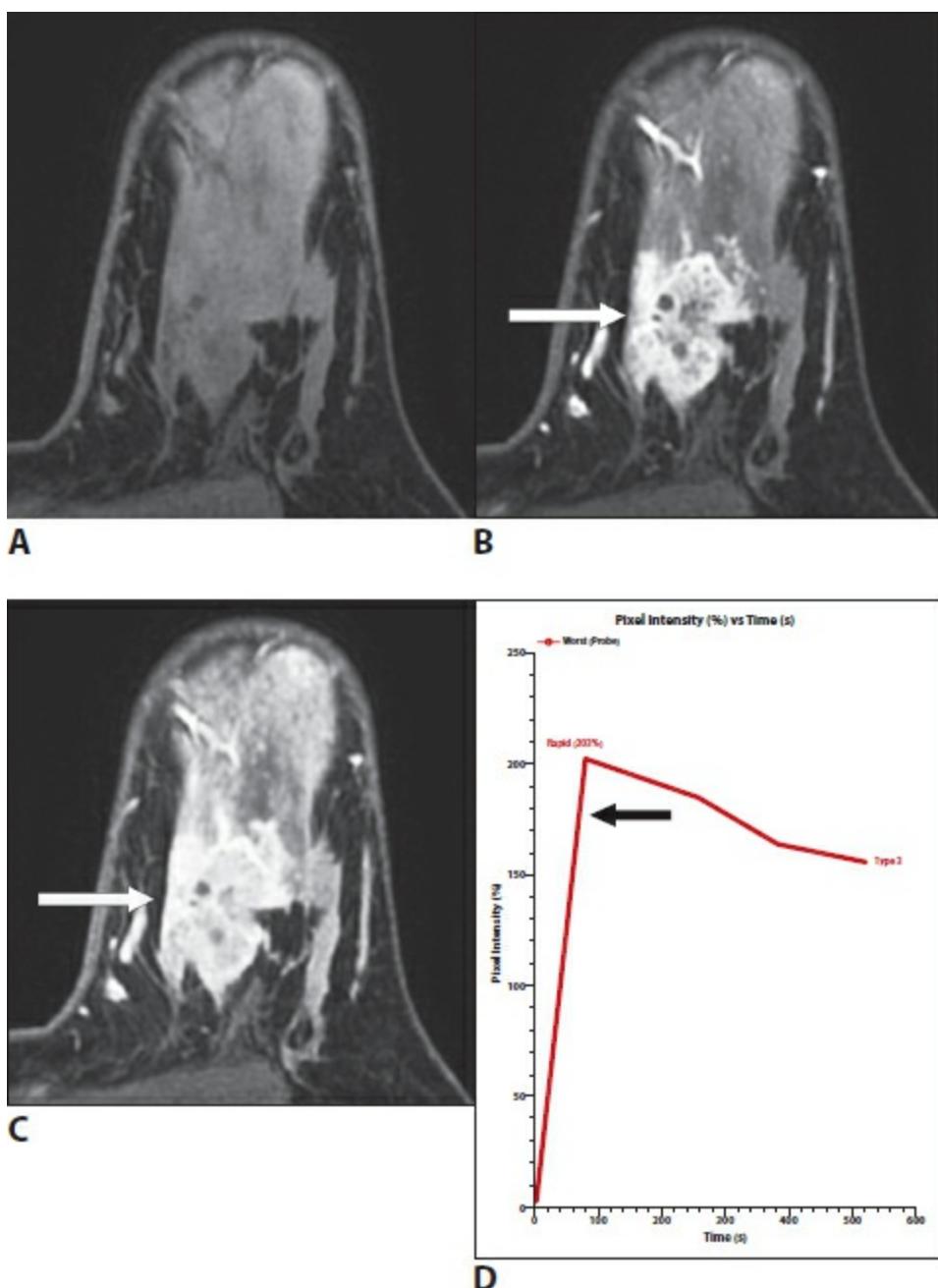


Figure 228 – INITIAL PHASE: FAST. Left breast T1W fat-saturated precontrast axial image (*a*). First postcontrast (1 min) image demonstrates a rapidly enhancing mass (*b*, arrow). Delayed post contrast (5 min) image demonstrates washout (*c*, arrow). Graph of the kinetic curve from the mass (*d*) confirms a FAST initial (> 100% increase in pixel intensity within the first 2 min, *arrow*) and a delayed washout enhancement pattern (Type 3 curve). Pathology: invasive ductal carcinoma.

L. KINETIC CURVE ASSESSMENT

SIGNAL INTENSITY (SI)/TIME CURVE DESCRIPTION

2. DELAYED PHASE

This is the enhancement pattern after 2 minutes or after the curve starts to change.

a. Persistent —

continued > 10% increase in signal over time.

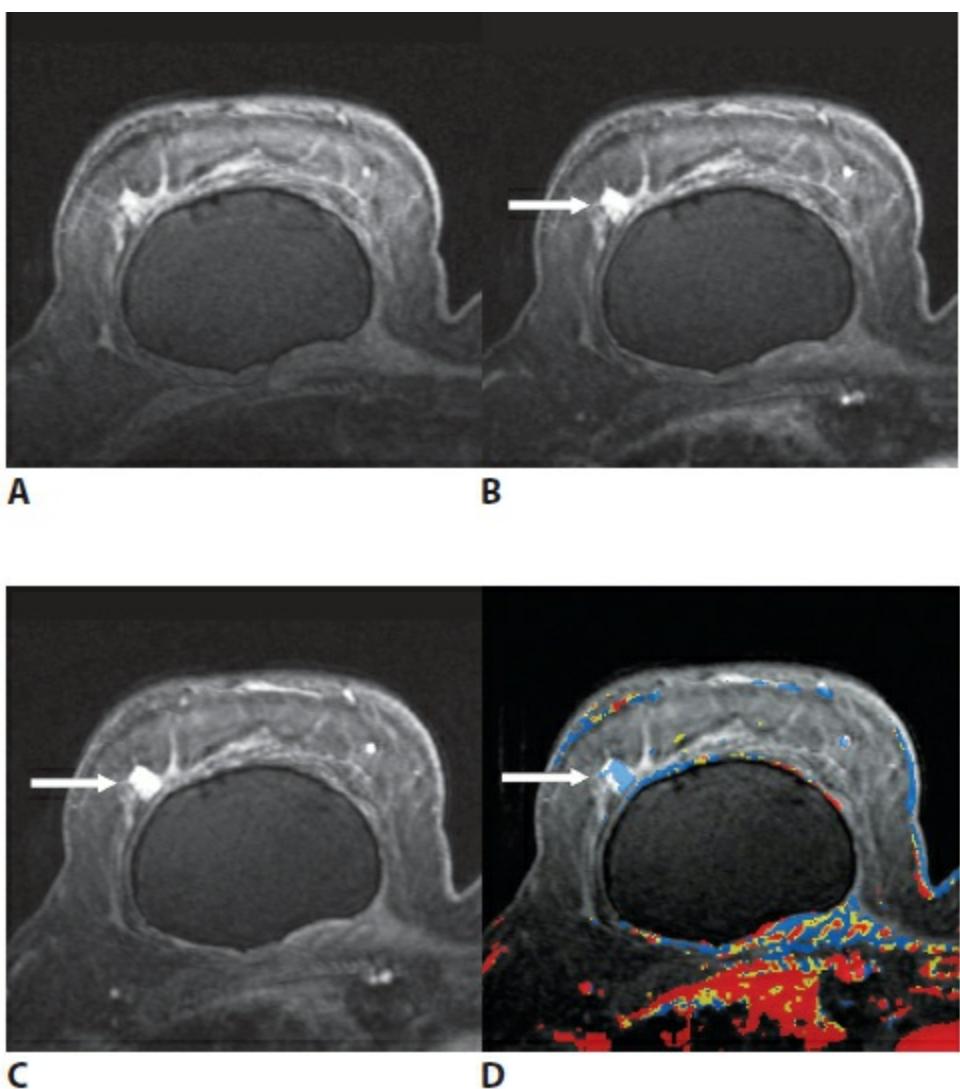


Figure 229 – DELAYED PHASE: PERSISTENT. Right breast T1W fat-saturated precontrast axial image (a). First postcontrast image demonstrates a rapidly enhancing mass (b, arrow). Delayed postcontrast image demonstrates PERSISTENT enhancement (c, arrow). Color map demonstrates the mass with a blue overlay (d, arrow) indicating PERSISTENT enhancement. Pathology: invasive ductal carcinoma.

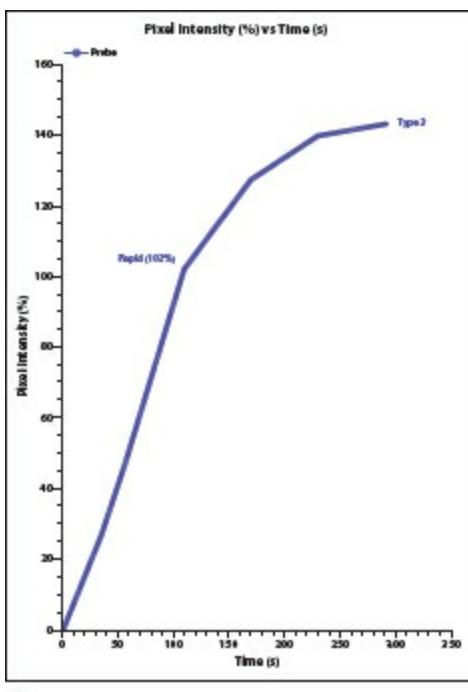
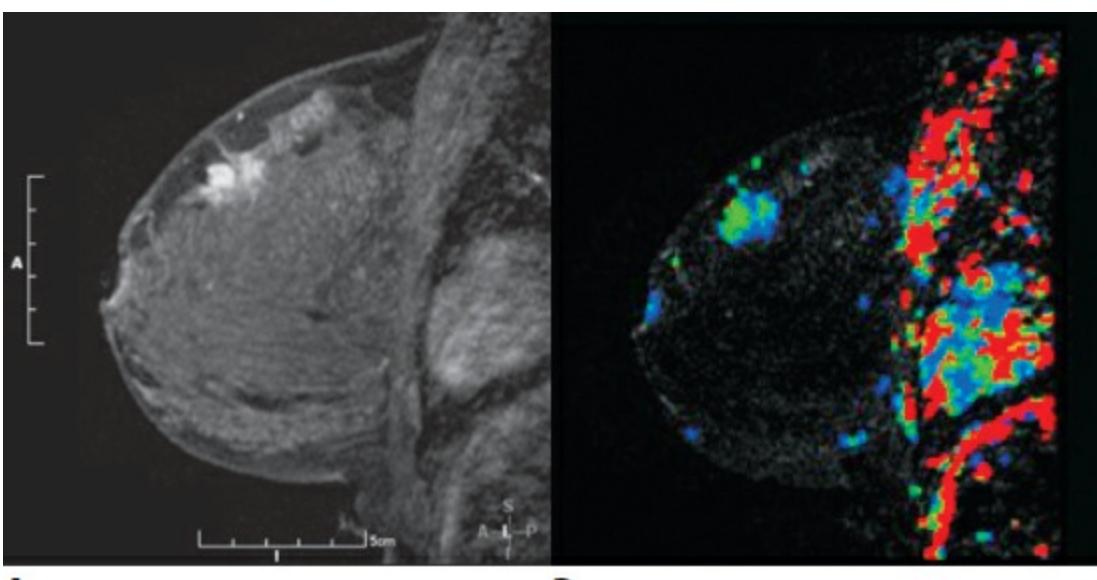


Figure 229 (continued) – DELAYED PHASE: PERSISTENT. Graph of the kinetic curve from the mass confirms a PERSISTENT enhancement pattern (e, Type 1 curve). Pathology: invasive ductal carcinoma.



A **B**
Figure 230 – DELAYED PHASE: PERSISTENT and PLATEAU. Irregular mass with PERSISTENT and PLATEAU kinetics. Morphologic features are suspicious despite benign kinetics. Fat-suppressed postcontrast T1W image (*a*). Kinetic overlay demonstrates PLATEAU and PERSISTENT kinetics (*b*). Pathology: invasive ductal carcinoma.

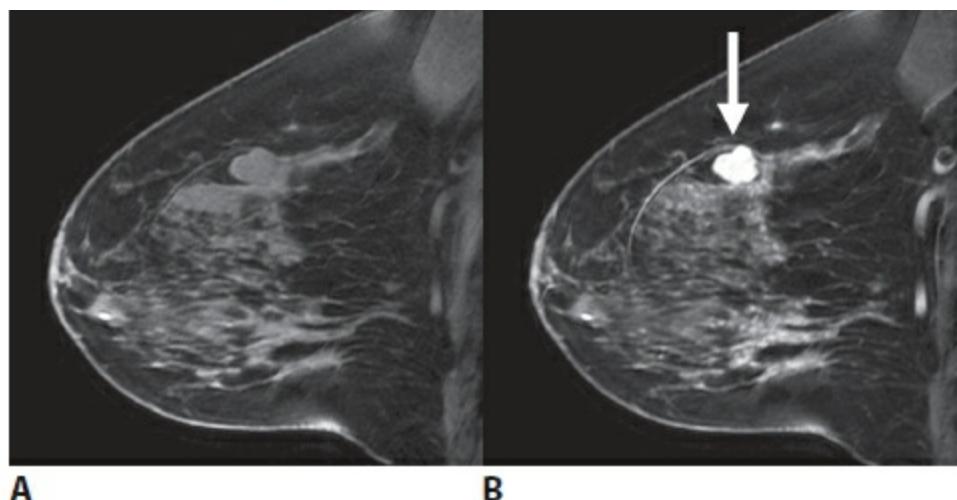
L. KINETIC CURVE ASSESSMENT

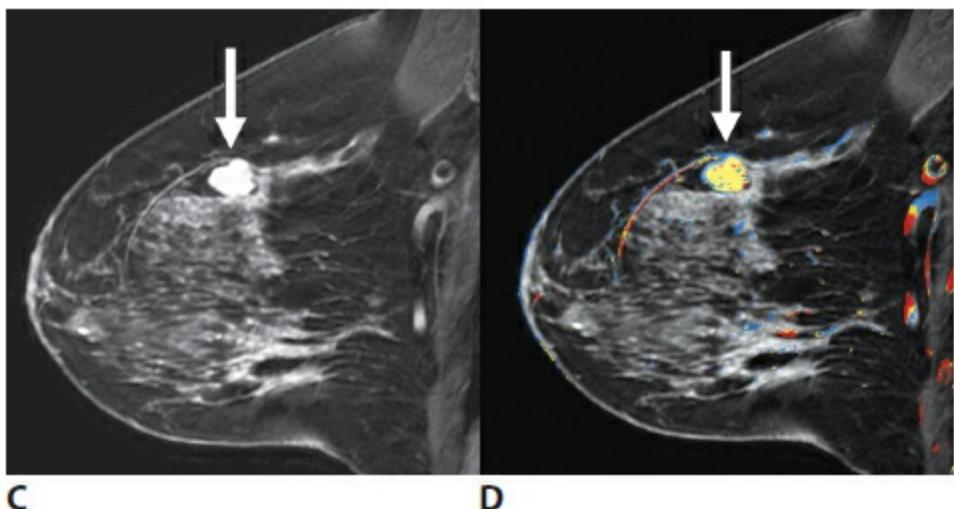
SIGNAL INTENSITY (SI)/TIME CURVE DESCRIPTION

2. DELAYED PHASE

b. Plateau —

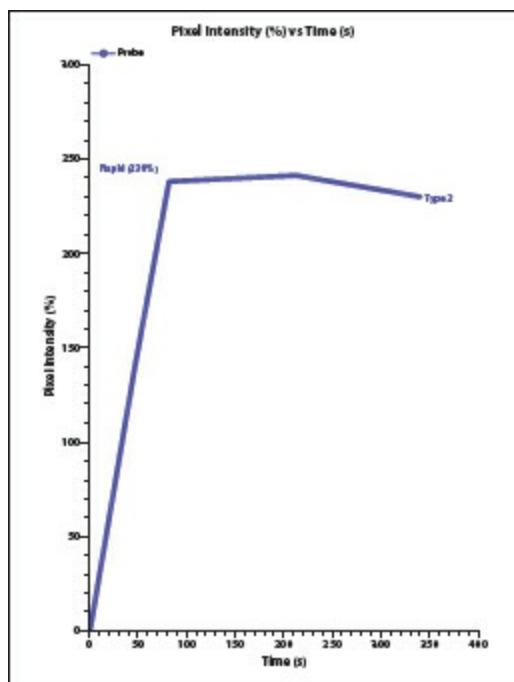
signal intensity does not change over time after its initial rise, flat.





C **D**

Figure 231 – DELAYED PHASE: PLATEAU. Right breast T1W fat-saturated precontrast sagittal image (a). First postcontrast image demonstrates a rapidly enhancing mass (b, arrow). Delayed postcontrast image demonstrates PLATEAU enhancement (c, arrow). Color map demonstrates the mass with a yellow overlay (d, arrow) indicating PLATEAU enhancement. Pathology: benign phyllodes tumor.



E

Figure 231 (continued) – DELAYED PHASE: PLATEAU. Graph of the kinetic curve from the mass confirms a PLATEAU enhancement pattern (e, Type 2 curve). Pathology: benign phyllodes tumor.

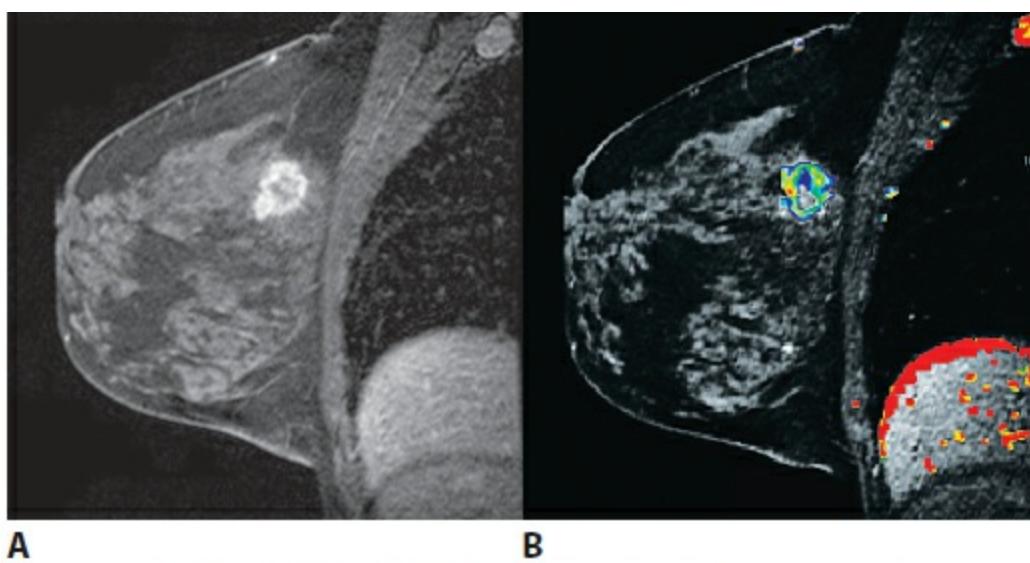


Figure 232 – DELAYED PHASE: PERSISTENT and PLATEAU. Round, irregular, rim-enhancing mass with suspicious morphology. Kinetic analysis demonstrates PERSISTENT and PLATEAU curves favoring benign process. Morphologic features the most suspicious finding. Fat-suppressed postcontrast T1W image (*a*). Delayed kinetics demonstrates a color map with predominantly PLATEAU kinetics (*b*). Pathology: invasive ductal carcinoma.

L. KINETIC CURVE ASSESSMENT

SIGNAL INTENSITY (SI)/TIME CURVE DESCRIPTION

2. DELAYED PHASE

c. Washout —

signal intensity decreases > 10% after its highest point from its initial rise. This indicates a suspicious finding.

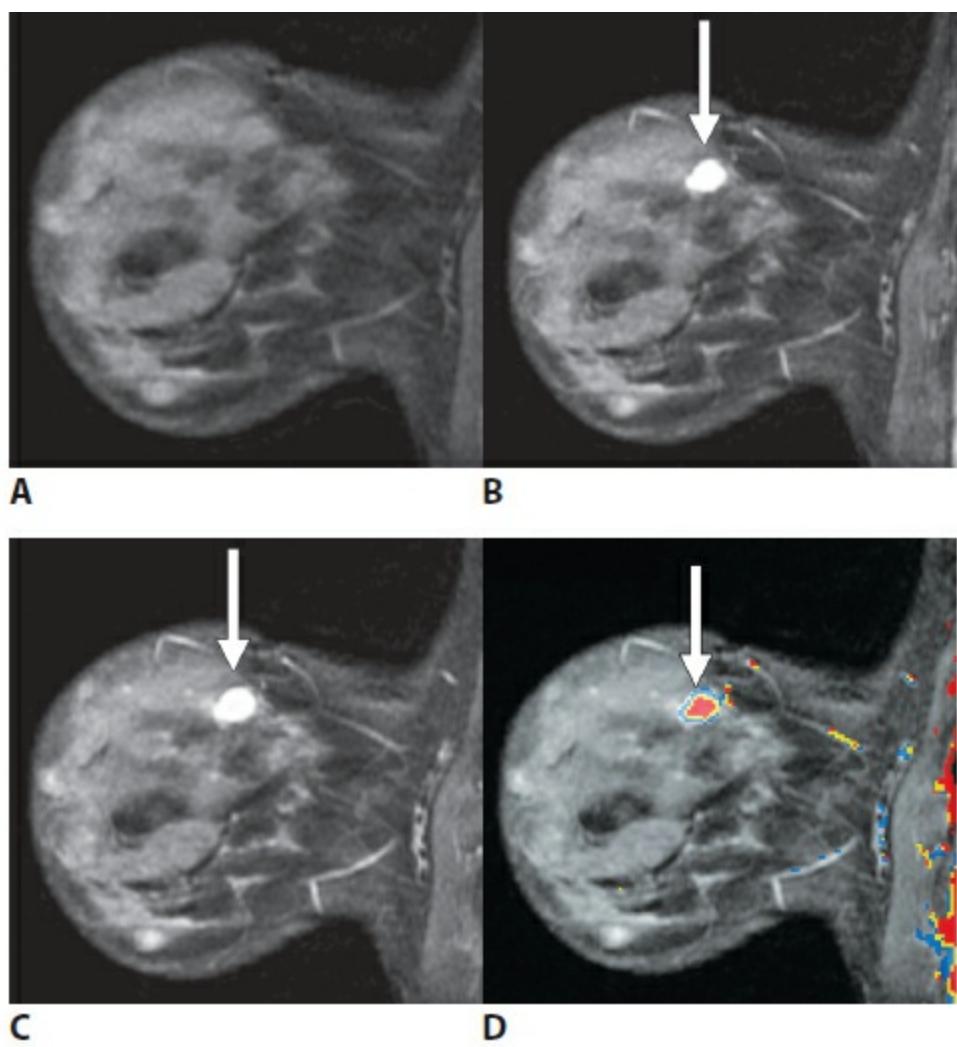


Figure 233 – DELAYED PHASE: WASHOUT. Right breast T1W fat-saturated precontrast sagittal image (a). First postcontrast image demonstrates a rapidly enhancing mass (b, arrow). Delayed postcontrast image demonstrates WASHOUT enhancement (c, arrow). Color map demonstrates the mass with a red overlay (d, arrow) indicating WASHOUT enhancement. Pathology: invasive ductal carcinoma.

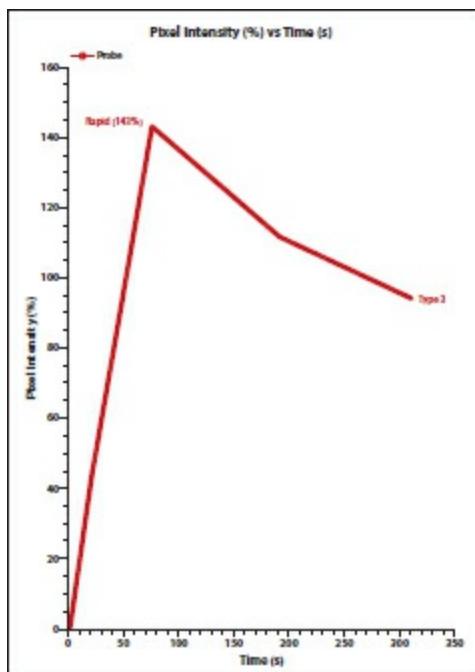


Figure 233 (continued) – DELAYED PHASE: WASHOUT. Graph of the kinetic curve from the mass confirms a WASHOUT enhancement pattern (e, Type 3 curve). Pathology: invasive ductal carcinoma.

E

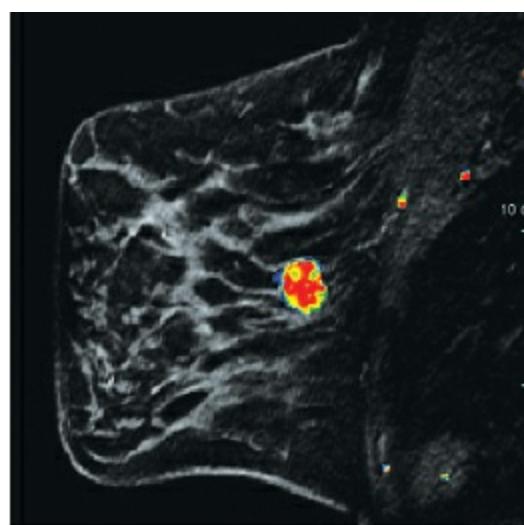
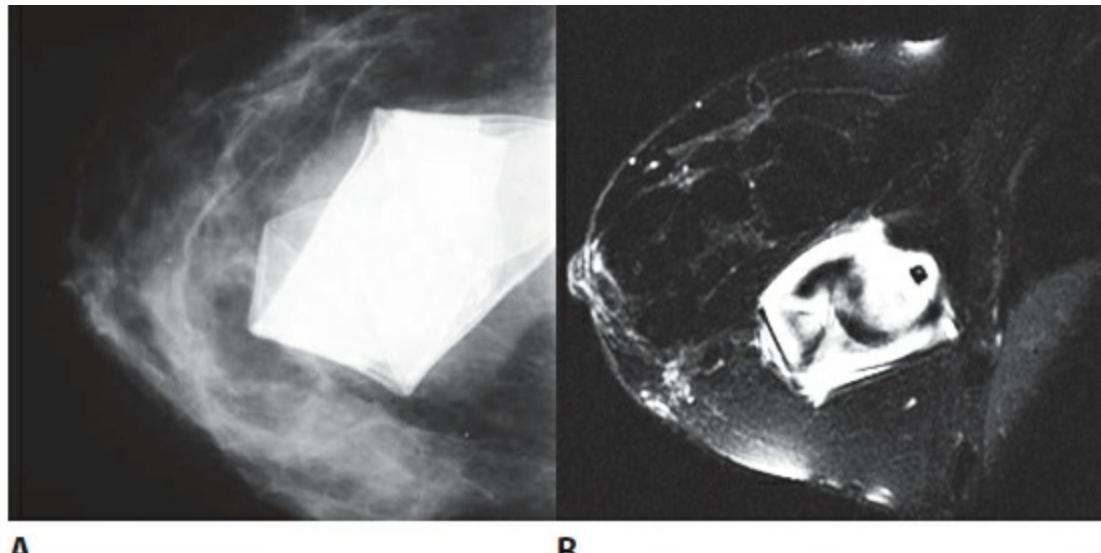


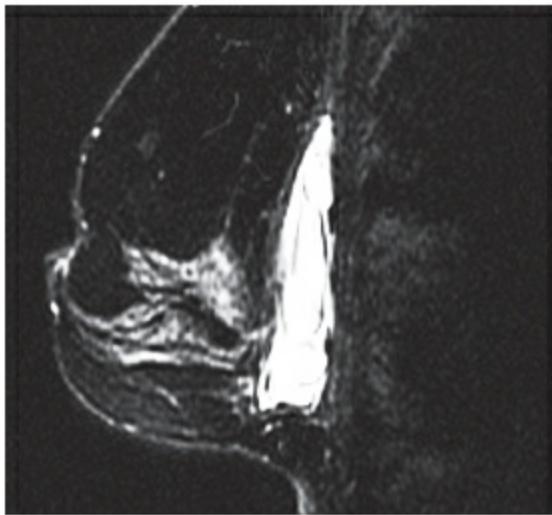
Figure 234 – DELAYED PHASE: WASHOUT.
Color map demonstrates predominant
WASHOUT on the delayed phase in an invasive
ductal carcinoma. Fat-suppressed postcontrast
T1W image.

M. IMPLANTS

1. IMPLANT MATERIAL AND LUMEN TYPE

a. Saline





C

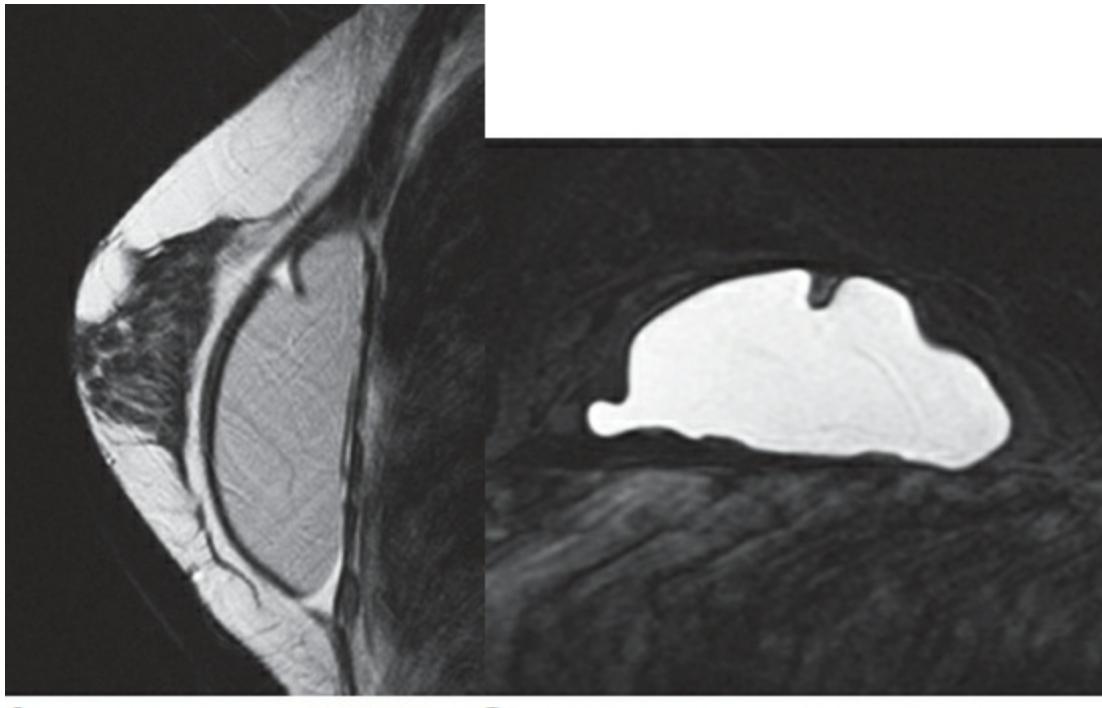
Figure 235 – IMPLANT MATERIAL AND LUMEN TYPE: SALINE. Mammogram showing collapsed implant near the chest wall (a). MRI is not needed to characterize a collapsed SALINE implant, but MRI illustrations are provided to display the appearance. Sagittal fat-suppressed T2W image showing collapsed, saline implant near the chest wall (b). Note the multiple folds in the implant. Sagittal, fat-suppressed T2W image showing the deflated implant (still containing some saline) near the chest wall (c). Fat-suppressed T2W image.

M. IMPLANTS

1. IMPLANT MATERIAL AND LUMEN TYPE

b. Silicone

i. Intact



A

B

Figure 236 – IMPLANT MATERIAL AND LUMEN TYPE: SILICONE, INTACT. Sagittal T2W image of INTACT subpectoral silicone implant (a). Axial silicone selective sequence (STIR with water suppression) where only silicone is bright showing INTACT silicone implant (b). Radial folds at the periphery should not be mistaken for rupture.

ii. Ruptured (Implant Assessment.)

c. Other Implant Materials

Alternative materials for implants might be soy oil, polypropylene, polyurethane, and sponges; this includes direct injections.

M. IMPLANTS

1. IMPLANT MATERIAL AND LUMEN TYPE

d. Lumen Type

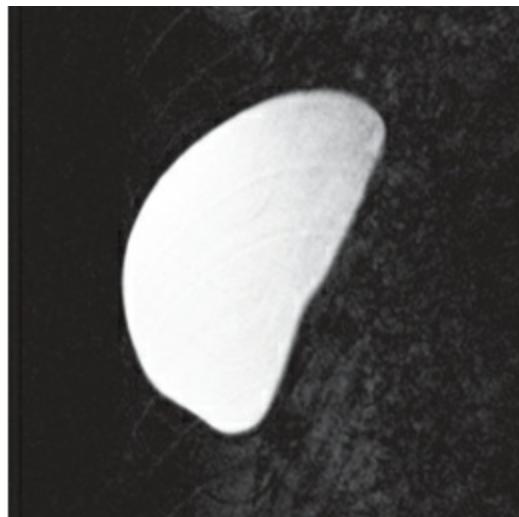


Figure 237 – IMPLANT MATERIAL AND LUMEN TYPE: LUMEN TYPE. Silicone selective sequence showing a normal intact single lumen silicone implant in the sagittal plane.

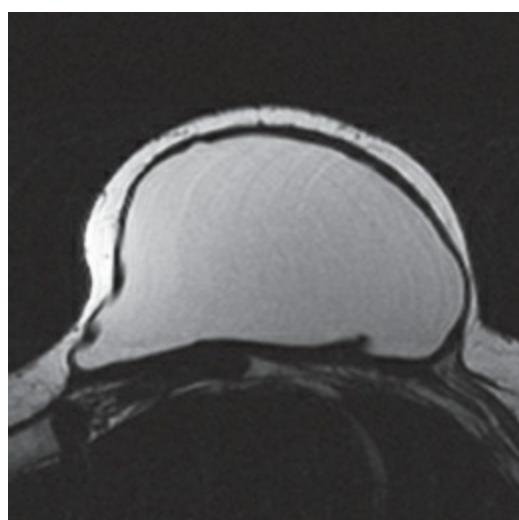


Figure 238 – IMPLANT MATERIAL AND LUMEN TYPE: LUMEN TYPE. Axial T2W image of an intact single lumen silicone implant.

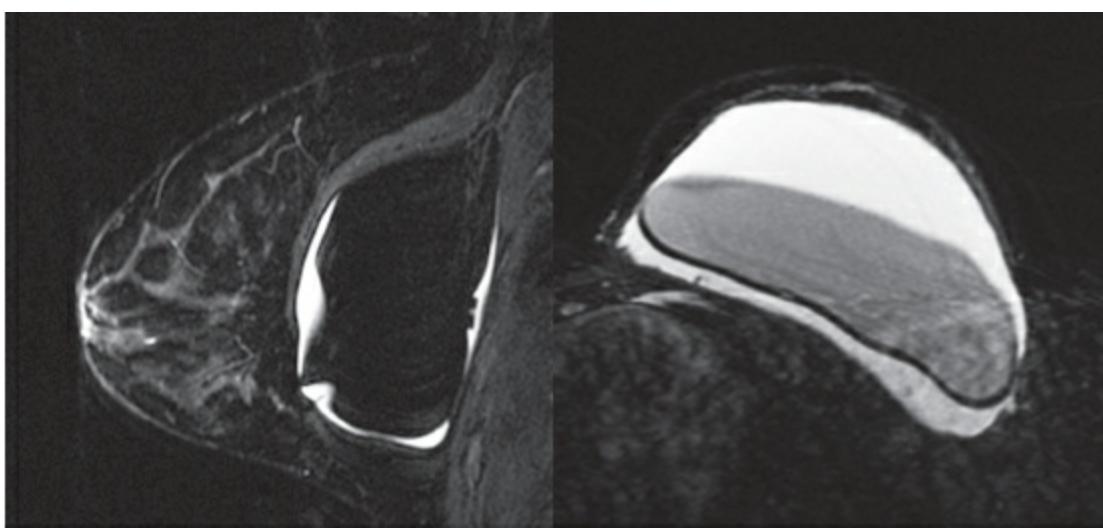
**A****B**

Figure 239 – IMPLANT MATERIAL AND LUMEN TYPE: LUMEN TYPE. Normal intact double lumen implant in the sagittal plane. T2W, fat-suppressed, sagittal image of double lumen retropectoral implant (*a*). The outer lumen is saline and the inner lumen is silicone. Both lumens are intact. Axial T2W image of an intact double lumen implant with outer saline and inner silicone lumen (*b*).

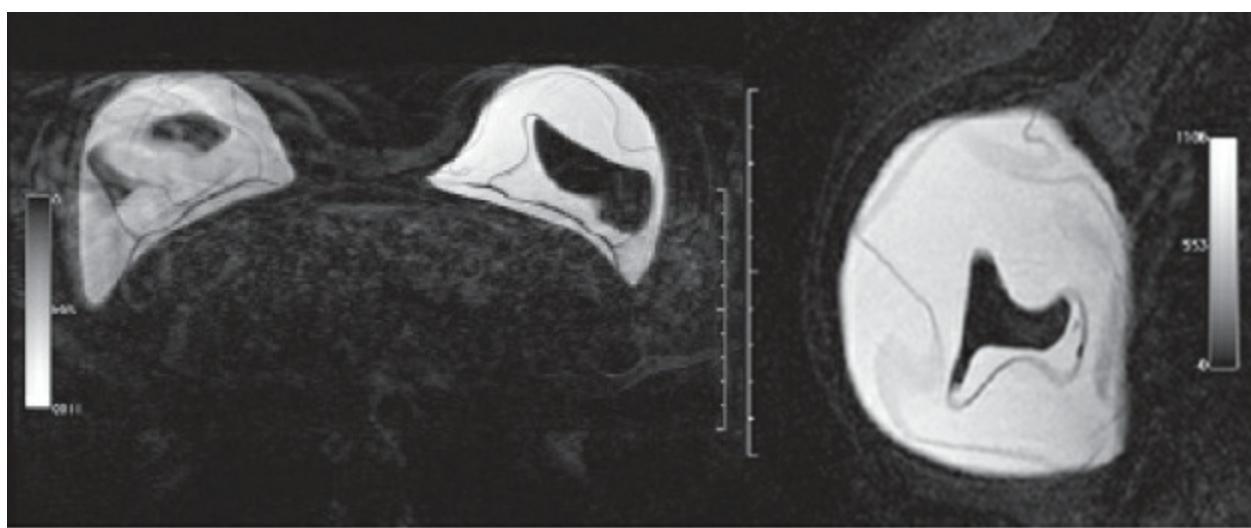
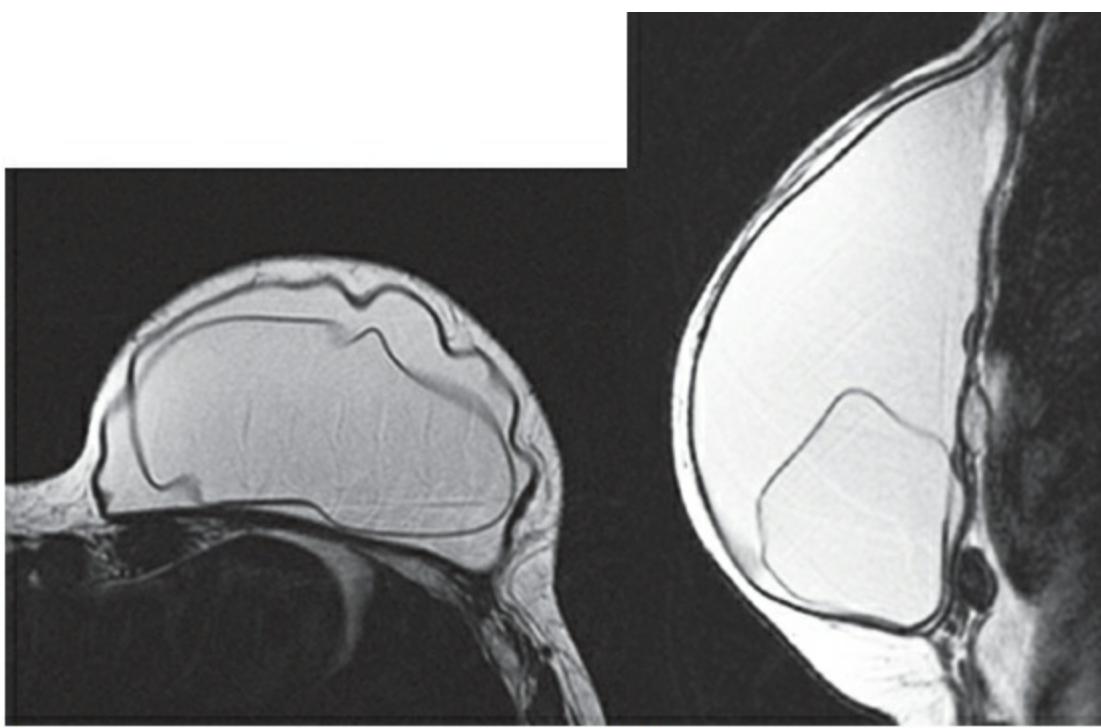
**A****B**

Figure 240 – IMPLANT MATERIAL AND LUMEN TYPE: LUMEN TYPE. Axial, silicone selective image of silicone outer, saline inner complex implant with subcapsular lines (*a*). Intracapsular rupture. Silicone selective sagittal image of silicone outer, saline inner complex implant with subcapsular lines (*b*). Intracapsular rupture.



A

B

Figure 241 – IMPLANT MATERIAL AND LUMEN TYPE: LUMEN TYPE. Axial, T2W image of double lumen implant in which both are filled with silicone (*a*). Both lumens are intact in this case. Sagittal T2W image of an intact double lumen silicone/silicone implant (*b*).

M. IMPLANTS

2. IMPLANT LOCATION

a. Retroglandular

The implant is located anterior to the pectoralis muscles.



A

B

Figure 242 – IMPLANT LOCATION: RETROGLANDULAR. Sagittal image of intact silicone implant in RETROGLANDULAR location (*a*). Normal radial fold (arrows). Axial image of intact silicone implants with radial folds in RETROGLANDULAR location (*b*). Normal RETROGLANDULAR implants axial (any type).

M. IMPLANTS

2. IMPLANT LOCATION

b. Retropectoral

The implant is located deep to the pectoralis muscles.

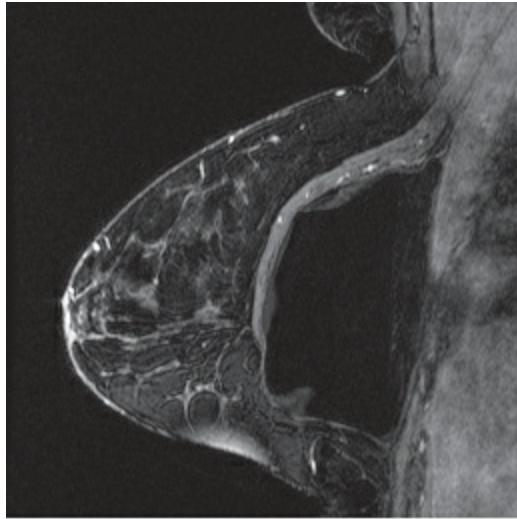


Figure 243 – IMPLANT LOCATION: RETROPECTORAL. Normal RETROPECTORAL implant on fat-suppressed T1W contrast-enhanced sagittal image in the anterior breast. Note that the silicone implant is dark on this image without a silicone-specific sequence.

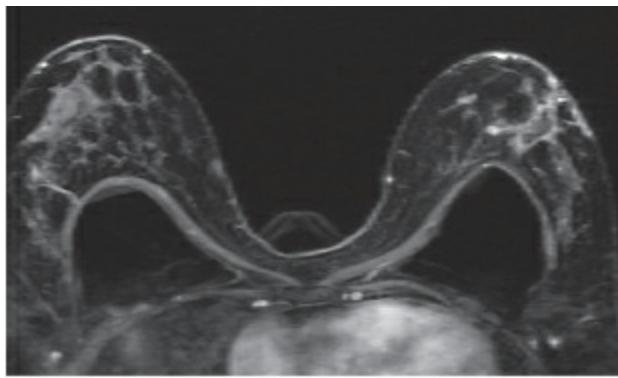


Figure 244 – IMPLANT LOCATION: RETROPECTORAL. Normal RETROPECTORAL implants on fat-suppressed T1W axial images.

M. IMPLANTS

3. ABNORMAL IMPLANT CONTOUR

a. Focal Bulge



Figure 245 – ABNORMAL IMPLANT CONTOUR: FOCAL BULGE. Axial, T1W image showing silicone implant herniated through the fibrous capsule laterally.

M. IMPLANTS

4. INTRACAPSULAR SILICONE FINDINGS

a. Radial Folds

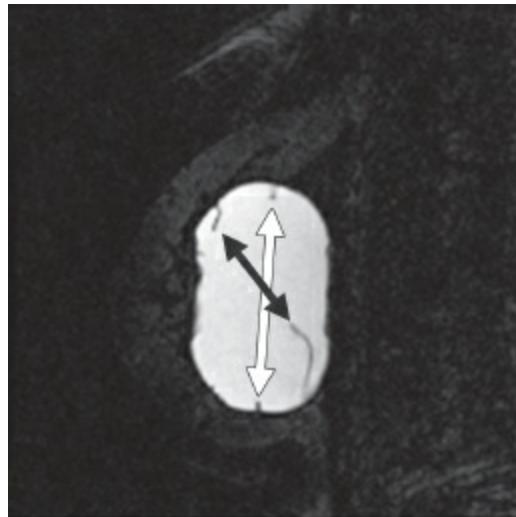


Figure 246 – INTRACAPSULAR SILICONE FINDINGS: RADIAL FOLDS. Sagittal image of an intact silicone implant showing RADIAL FOLDS (arrows).

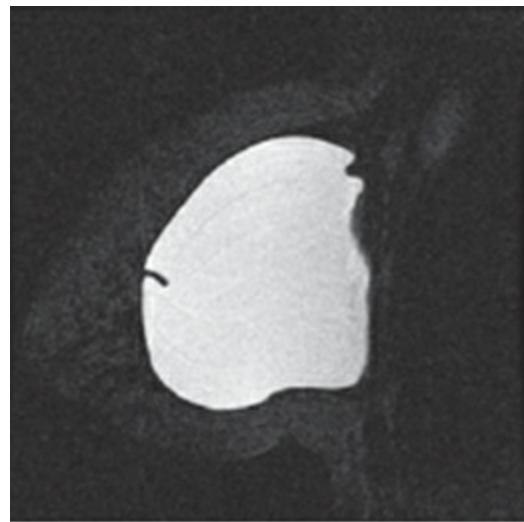


Figure 247 – INTRACAPSULAR SILICONE FINDINGS: RADIAL FOLDS. Sagittal image of an intact silicone implant showing RADIAL FOLD.

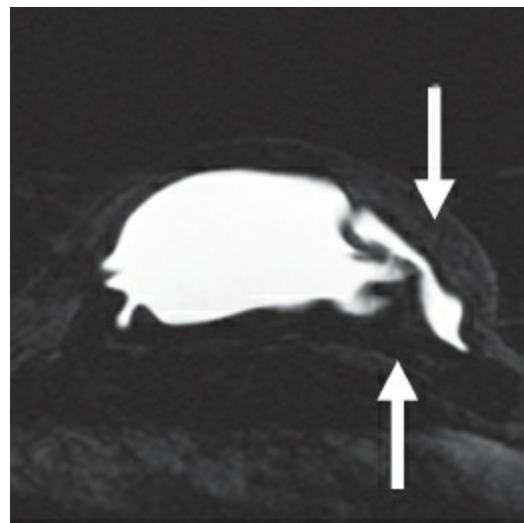


Figure 248 – INTRACAPSULAR SILICONE FINDINGS: RADIAL FOLDS. Axial silicone selective sequence showing complex RADIAL FOLDS (arrows) in an intact silicone implant.

M. IMPLANTS

4. INTRACAPSULAR SILICONE FINDINGS

b. Subcapsular Line

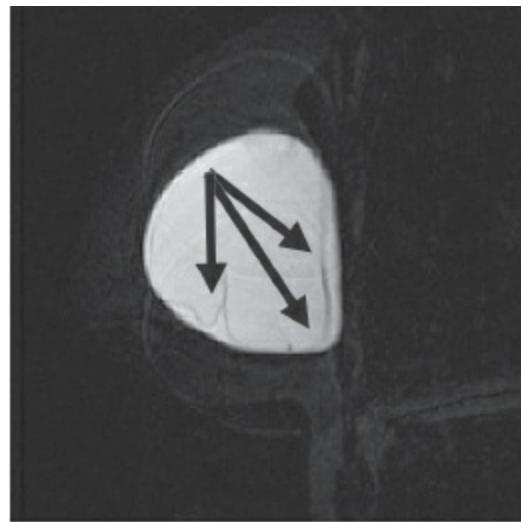


Figure 249 – INTRACAPSULAR SILICONE FINDINGS: SUBCAPSULAR LINE. Sagittal, silicone-selective image of silicone implant with intracapsular rupture showing SUBCAPSULAR LINES (*arrows*) indicating intracapsular rupture.

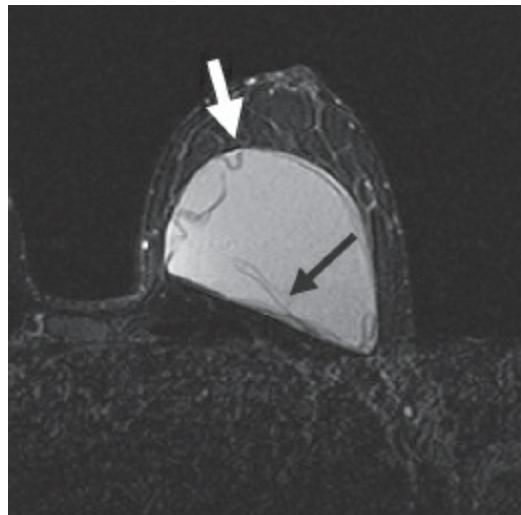


Figure 250 – INTRACAPSULAR SILICONE FINDINGS: SUBCAPSULAR LINE and KEYHOLE SIGN (TEARDROP, NOOSE). Axial, silicone-selective image of implant showing intracapsular rupture with SUBCAPSULAR LINES (*black arrow*) and KEYHOLE SIGN [TEARDROP, NOOSE] (*white arrow*) indicating silicone within and outside the collapsed implant shell.

M. IMPLANTS

4. INTRACAPSULAR SILICONE FINDINGS

c. Keyhole Sign (teardrop, noose)

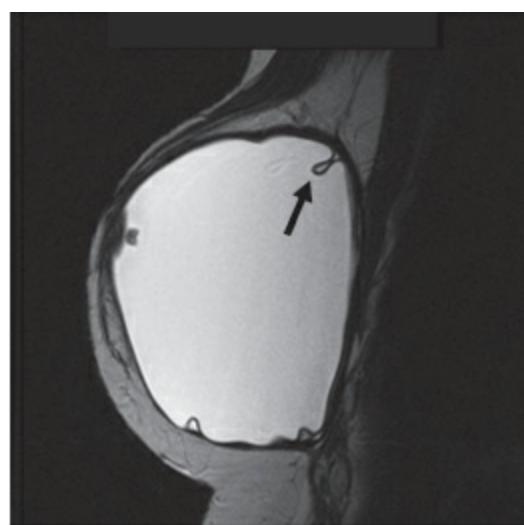


Figure 251 – INTRACAPSULAR SILICONE FINDINGS: KEYHOLE SIGN (TEARDROP, NOOSE). Sagittal image of implant with intracapsular rupture showing KEYHOLE SIGN [TEARDROP, NOOSE] (arrow). Notice that there is white silicone on the inside of the dark line.

M. IMPLANTS

4. INTRACAPSULAR SILICONE FINDINGS

d. Linguine Sign

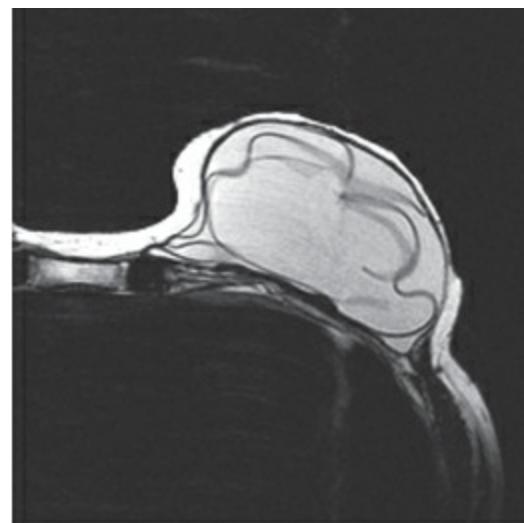


Figure 252 – INTRACAPSULAR SILICONE FINDINGS: LINGUISE SIGN. Sagittal image shows multiple lines in the implant, LINGUISE SIGNS, indicating intracapsular rupture. Non-fat-suppressed image.

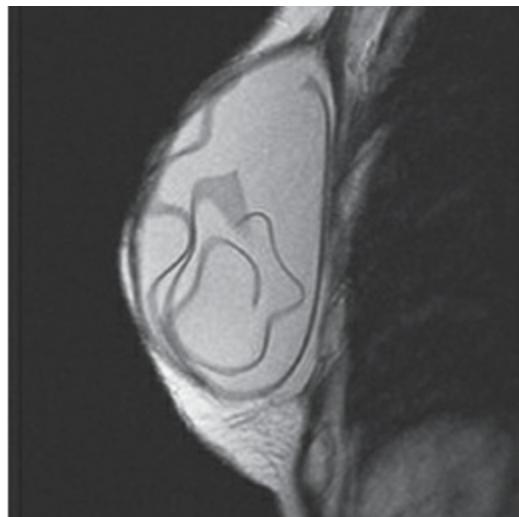


Figure 253 – INTRACAPSULAR SILICONE FINDINGS: LINGUINE SIGN. Axial image shows multiple lines in the implant, LINGUINE SIGNS, indicating intracapsular rupture. Non-fat-suppressed image.

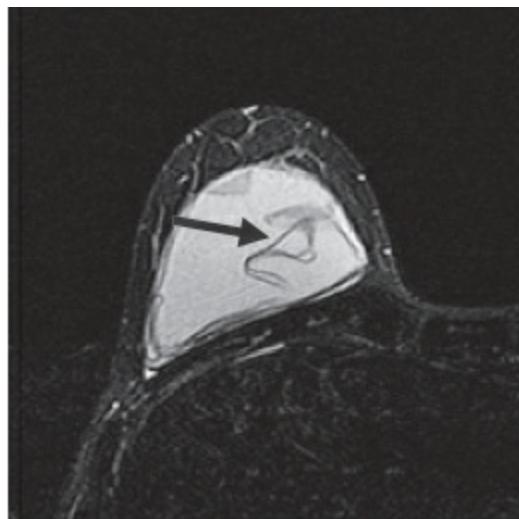


Figure 254 – INTRACAPSULAR SILICONE FINDINGS: LINGUINE SIGN. Axial image showing intracapsular rupture with LINGUINE SIGN (arrow).

M. IMPLANTS

5. EXTRACAPSULAR SILICONE

a. Breast

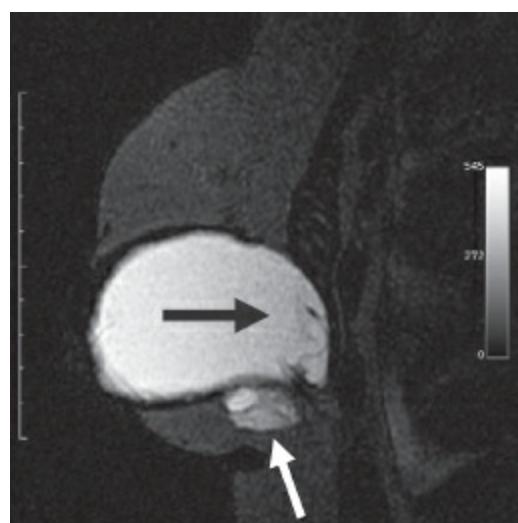


Figure 255 – EXTRACAPSULAR SILICONE: BREAST. Sagittal, silicone-specific sequence showing extracapsular rupture of a silicone implant. Note the EXTRACAPSULAR SILICONE (white arrow) and findings of intracapsular rupture [subcapsular and keyhole] (black arrow).

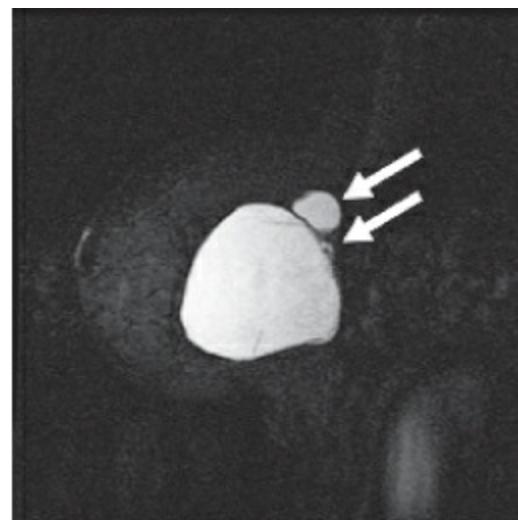


Figure 256 – EXTRACAPSULAR SILICONE: BREAST. Axial scan showing EXTRACAPSULAR SILICONE (arrows). There are also signs of intracapsular rupture, keyhole (teardrop, noose) subcapsular lines.

M. IMPLANTS

5. EXTRACAPSULAR SILICONE

b. Lymph Nodes

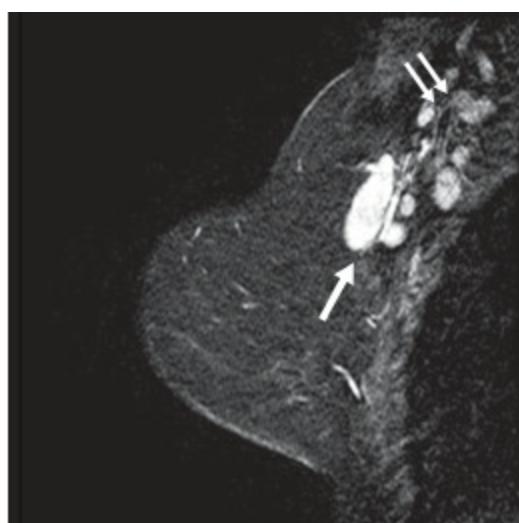


Figure 257 – EXTRACAPSULAR SILICONE: LYMPH NODES. Sagittal image showing bright EXTRACAPSULAR SILICONE (arrow) and silicone in axillary LYMPH NODES (thin arrows).

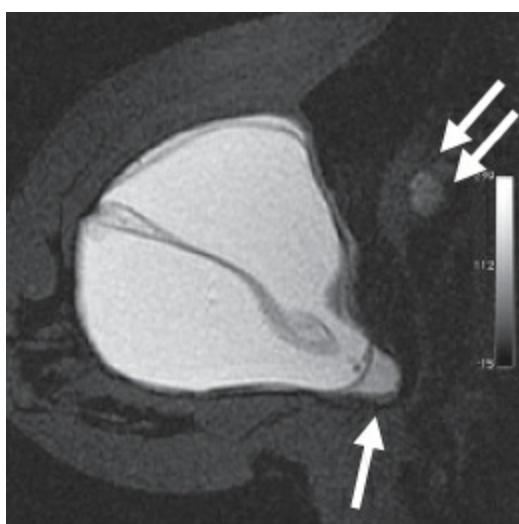
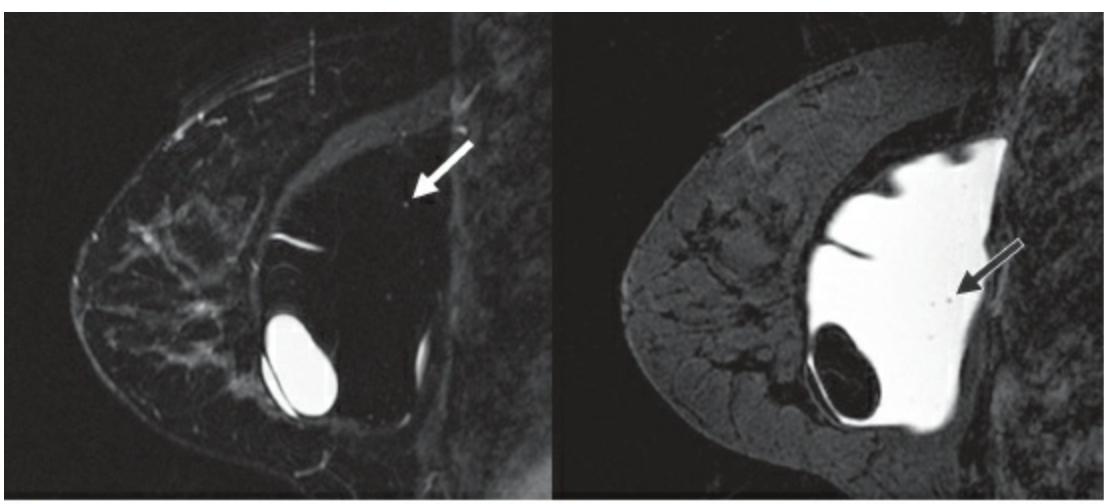


Figure 258 – EXTRACAPSULAR SILICONE: LYMPH NODES. Implant rupture with subcapsular line, keyhole (teardrop, noose) indicating rupture. There may also be EXTRACAPSULAR SILICONE (arrow) and silicone in a LYMPH NODE (two arrows).

M. IMPLANTS

6. WATER DROPLETS



A

B

Figure 259 – WATER DROPLETS. Sagittal, subglandular saline outer, silicone inner, double-lumen intact implant with incidental WATER DROPLETS (arrows). See radial fold in intact silicone component. Fat-suppressed T2W image (a). Silicone-selective sequence (b).

M. IMPLANTS

7. PERI-IMPLANT FLUID

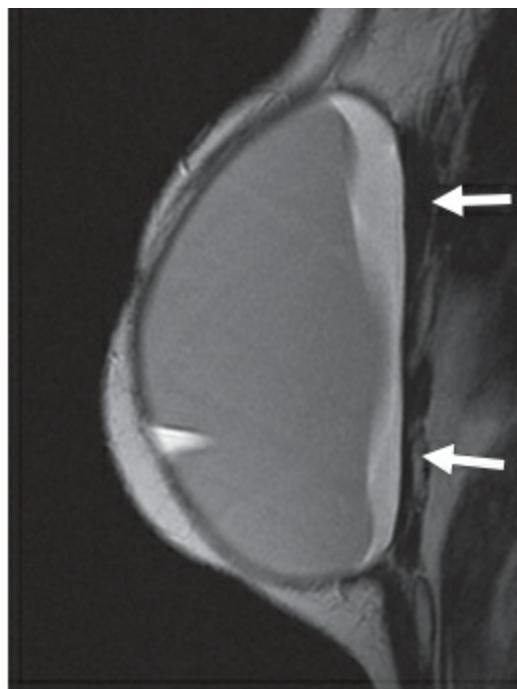


Figure 260 – PERI-IMPLANT FLUID. Sagittal, T2W image of an intact single-lumen silicone implant with surrounding fluid (arrows). This can be seen as a reaction to recent implantation but can also be an indication of bleeding or infection.



Figure 261 – PERI-IMPLANT FLUID. Sagittal, T2W image of an intact single-lumen silicone implant with a complex collection posteriorly (arrow). This is consistent with an organizing postsurgical hematoma.

III. REPORTING SYSTEM

A. REPORT ORGANIZATION

The reporting system should be concise and organized. Any pertinent clinical history that may affect scan interpretation, as well as any MRI acquisition techniques (including postprocessing information) that may affect the scan interpretation, should be described. The breast MRI report should first describe the amount of fibroglandular tissue and the background parenchymal enhancement (BPE). Abnormal enhancement (unique and separate from the BPE) is described based on morphology, distribution, and kinetics. Results from any physiologic or parametric imaging should be described. An assessment is rendered that includes the degree of concern and any recommendation(s). Benign findings need not be reported, especially if the interpreting physician is concerned that the referring clinician or patient might infer anything other than absolute confidence in benignity.

Table 2. Report Organization

Report Structure
1. Indication for examination
2. MRI technique
3. Succinct description of overall breast composition
4. Clear description of any important findings
5. Comparison to previous examination(s)
6. Assessment
7. Management

1. INDICATION FOR EXAMINATION

Provide a brief description of the indication for examination. For example, this may be high-risk screening, follow-up of a probably benign lesion, follow-up of cancer treated with neoadjuvant chemotherapy, or evaluation of the newly diagnosed cancer patient.

As background parenchymal enhancement can be affected by cyclical hormonal changes, it may be helpful to include menstrual history. If the patient is pre-menopausal, the week of the menstrual cycle may be important information to aid in interpretation. Current therapy (neoadjuvant, adjuvant, hormonal, or radiation therapy) for breast cancer treatment in the pre-or postsurgical setting may be important information and may inform exam interpretation.

The indication for examination should contain a concise description of the patient's clinical history, including:

- a. Reason for performing the exam (e.g., screening, staging, problem solving)
- b. Clinical abnormalities, including size, location, and duration
 - i. Palpable finding
 - ii. Nipple discharge
 - iii. Other pertinent clinical findings or history
- c. Previous biopsies
 - i. Biopsy type
 - ii. Biopsy location
 - iii. Benign or malignant pathology (cytology or histology)
- d. Hormonal status if applicable
 - i. Pre- or post-menopausal
 - ii. Menstrual cycle phase (second week or other) or last menstrual period
 - iii. Peripartum
 - iv. Exogenous hormone therapy, tamoxifen, aromatase inhibitors, or other hormones or medications/herbs/vitamins that might influence MRI

2. MRI TECHNIQUE

Give a detailed description of the technical factors of how the MRI examination was obtained. At a minimum, a bright-fluid sequence of both breasts should be obtained. Pre- and post-gadolinium T1-weighted images should be obtained, preferably with fat suppression, simultaneously of both breasts. Subtraction imaging may be desired as well as other processing techniques and parametric analysis. Elements of this description routinely include:

- a. Right, left, or both breasts
- b. Location of markers and their significance (scar, nipple, palpable lesion, etc.)
- c. Weighting

- i. T1 weighted
 - ii. T2 weighted
 - iii. Fat saturation
 - iv. Scan orientation and plane
 - v. Other pertinent pulse sequence features
- d. Contrast dose
- i. Name of contrast agent
 - ii. Dosage (mmol/kg) and volume (in cc)
 - iii. Injection type: bolus or infusion
 - iv. Timing (relationship of bolus injection to scan start time and scan length)
 - v. If multiple scans: number of postcontrast scans and acquisition techniques of each (how fast, how many slices, and slice thickness)
- e. Postprocessing techniques as applicable
- i. MPR/MIP
 - ii. Time/signal intensity curves
 - iii. Subtraction
 - iv. Other techniques

3. SUCCINCT DESCRIPTION OF OVERALL BREAST COMPOSITION

This should include an overall description of the breast composition, including:

- a. The amount of FGT that is present

Table 3. Breast Tissue — Fibroglandular Tissue (FGT)

Amount of Fibroglandular Tissue
a. Almost entirely fat
b. Scattered fibroglandular tissue
c. Heterogeneous fibroglandular tissue
d. Extreme fibroglandular tissue

The four categories of breast composition ([Table 3](#)) are defined by the visually estimated content of FGT within the breasts. If the breasts are not of apparently equal amounts of FGT the breast with the most FGT should be used to categorize breast composition. Although there may be considerable variation in visually estimating breast composition, categorizing based on percentages (and specifically into quartiles) is not recommended. We recognize that quantification of breast FGT volume on MRI may be feasible in the future, but we await publication of robust data before endorsing percentage recommendations. We urge the use of BI-RADS® terminology instead of numbers to classify breast FGT in order to eliminate any possible confusion with the BI-RADS® assessment categories, which are numbered.

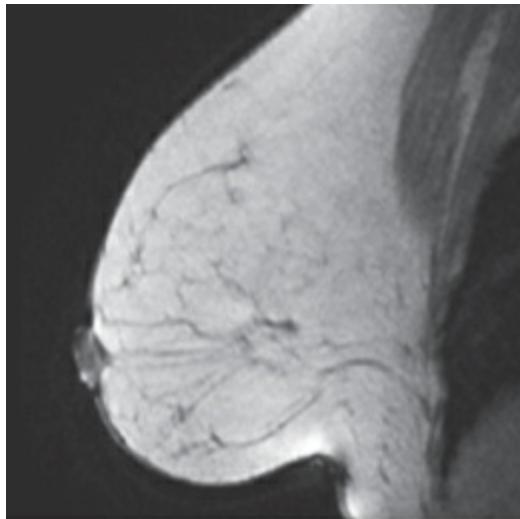


Figure 262 – Almost entirely fat.

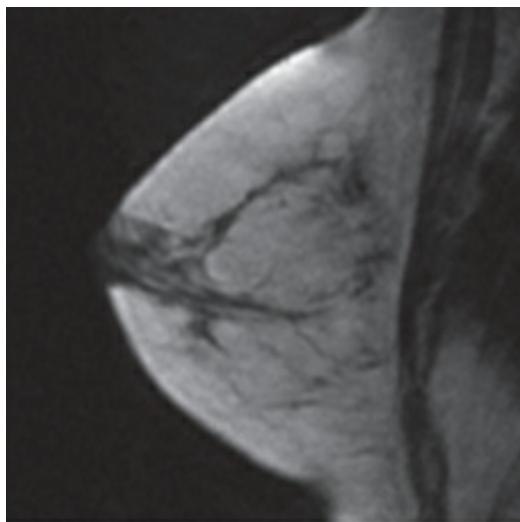


Figure 263 – Scattered fibroglandular tissue.

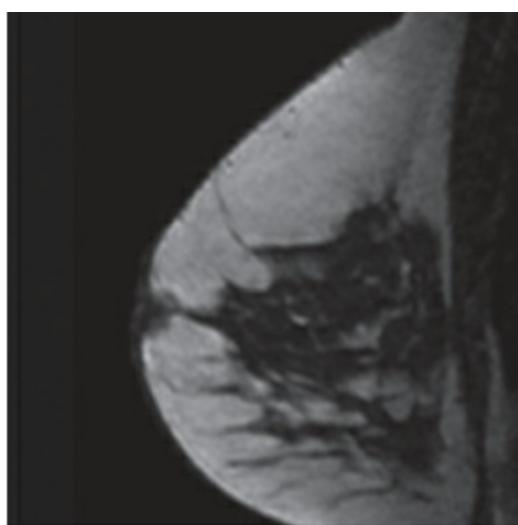


Figure 264 – Heterogeneous fibroglandular tissue.

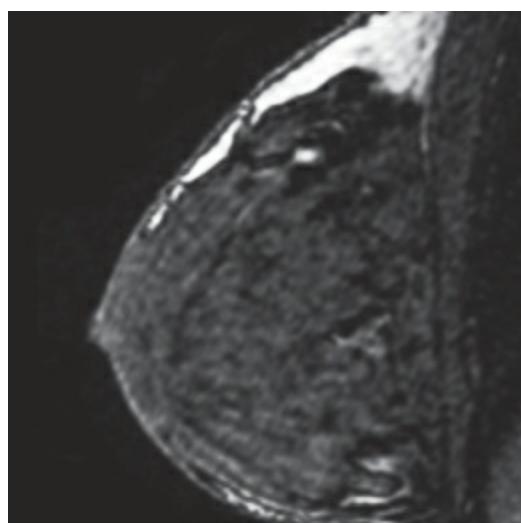


Figure 265 – Extreme fibroglandular tissue.

b. The amount of background parenchymal enhancement in the image

Table 4. Breast Tissue — Background Parenchymal Enhancement (BPE)

Background Parenchymal Enhancement
a. Minimal
b. Mild
c. Moderate
d. Marked

The four categories of BPE (Table 4) are defined by the visually estimated enhancement of the FGT of the breast(s). If the breasts are not of an apparently equal amounts of BPE, the breast with the most BPE should be used to categorize BPE. In the event that treatment has altered BPE in one or both breasts, this can be reported. Although there may be considerable variation in visually estimating BPE, categorizing based on percentages (and specifically into quartiles) is not

recommended. Quantification of BPE volume and intensity on MRI may be feasible in the future, but we await publication of robust data on that topic before endorsing percentage recommendations. We recognize that there are variations in BPE distribution and morphology. However, we defer on recommending descriptions of distribution or morphology until additional data are available. Currently, BPE refers to the volume of enhancement and the intensity of enhancement. For consistency, BPE should be included for all patients, using the categories in [Table 4](#).

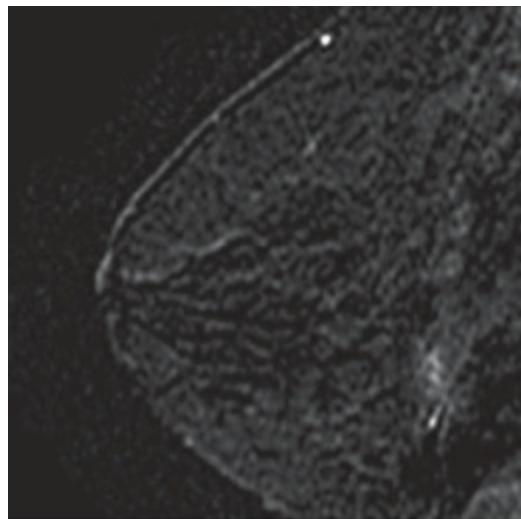


Figure 266 – Minimal.

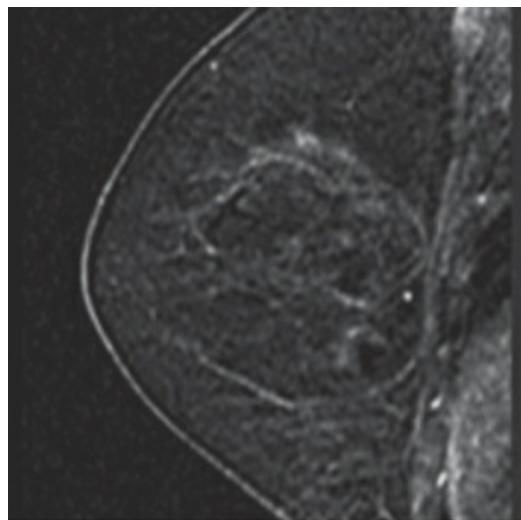


Figure 267 – Mild.

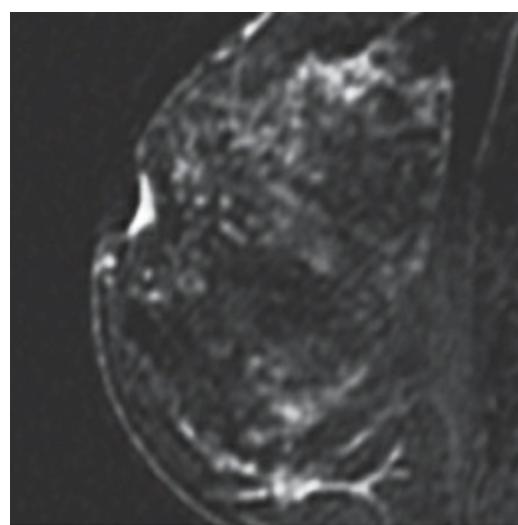


Figure 268 – Moderate.

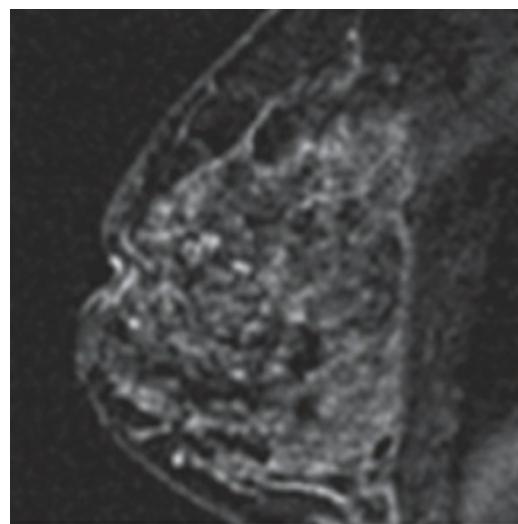


Figure 269 – Marked.

On bilateral scans, describe whether the pattern is asymmetric or symmetric, if appropriate. Asymmetric denotes more enhancement in one breast than in the other. Symmetric enhancement is mirror image.

c. Whether implants are present

If an implant is present, it should be so stated in the report. Information should include its composition (saline, silicone, or other) and the number of lumens (single or multiple).

4. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

Abnormal enhancement is unique and separate from BPE. Its description should indicate the breast in which the abnormal enhancement occurs, the lesion type, and modifiers.

The clinical location of the abnormality as extrapolated from the MRI location (based

on clock-face position and quadrant location) should be reported. It should be recognized that there may be variation in location of a clinically detected lesion (patient is upright or supine), a mammographically detected lesion (patient is upright and compressed), a sonographically detected lesion (patient is supine or supine oblique), and an MRI-detected lesion (patient is prone) based on positional differences. A more consistent measurement is the distance from the nipple. It is encouraged that distance from the nipple for a lesion be reported in order to facilitate correlation between modalities, although it should be understood that one should expect some difference in distance from the nipple among the breast imaging modalities.

For bilateral axial examinations, the breasts should be pointing up, following the cross-sectional imaging convention.

The descriptors should include:

a. Size

b. Location

i. Right or left

ii. Breast quadrant and clock-face position (or central, retroareolar, and axillary tail descriptors)

iii. Distance from nipple, skin, or chest wall in centimeters (if applicable)

Descriptors for abnormal enhancement:

c. Findings associated with abnormal enhancement include:

i. Artifacts that affect interpretation

ii. Focus: a tiny dot of enhancement that does not clearly represent a space-occupying lesion or mass and does not clearly show a mass on precontrast imaging.

iii. Masses: space-occupying lesions, usually spherical or ball-like, may displace or retract surrounding breast tissue

Descriptors — modifiers describing a mass:

(a) Shape: describes the overall morphology of the enhancement

- Oval (includes lobulated)

- Round

- Irregular

(b) Margin: describes the borders

- Circumscribed
- Not circumscribed
 - Irregular
 - Spiculated

(c) Internal enhancement characteristics

- Homogeneous
- Heterogeneous
- Rim enhancement
- Dark internal septations

iv. Non-mass enhancement (NME): modifiers describing enhancement patterns with a specific MRI pattern

(a) Distribution

- Focal
- Linear
- Segmental
- Regional
- Multiple regions
- Diffuse

(b) Internal enhancement patterns (for all other types)

- Homogeneous
- Heterogeneous
- Clumped

- Clustered ring

v. Intramammary lymph node (rarely important)

vi. Skin lesion (rarely important)

vii. Non-enhancing findings

(a) Ductal precontrast high signal on T1W

(b) Cyst

(c) Postoperative collections (hematoma/seroma)

(d) Post-therapy skin thickening and trabecular thickening

(e) Non-enhancing mass

(f) Architectural distortion

(g) Signal void from foreign bodies, clips, etc.

viii. Associated features

(a) Nipple retraction

(b) Nipple invasion

(c) Skin retraction

(d) Skin thickening

(e) Skin invasion

- Direct invasion

- Inflammatory cancer

(f) Axillary adenopathy

(g) Pectoralis muscle invasion

(h) Chest wall invasion

(i) Architectural distortion

ix. Fat-containing lesions

(a) Lymph nodes

- Normal
- Abnormal

(b) Fat necrosis

(c) Hamartoma

(d) Postoperative seroma/hematoma with fat

x. Stability: describe how the enhancement changed (if new, stable, or changed in size from previous examination)

xi. Kinetic curve assessment (if applicable)

(a) The fastest enhancing portion of the lesion or the most suspicious washout curve pattern in the lesion should be assessed

- Sample fast enhancing areas
- Sample for and report on the worst looking kinetic curve shape

(b) Signal intensity/time curve

• Initial enhancement phase – describes the enhancement pattern within the first 2 minutes or when the curve starts to change

◦ Slow

◦ Medium

◦ Fast

• Delayed phase – describes the enhancement pattern after 2 minutes or after the curve starts to change

◦ Persistent

◦ Plateau

◦ Washout

xii. Implants

(a) Implant material and lumen type

- Saline
- Silicone
 - Intact
 - Ruptured
- Other implant material (such as soy oil, polypropylene, polyurethane, and sponges; includes direct injections)
- Lumen type

(b) Implant location

- Retroglandular
- Retropectoral

(c) Abnormal implant contour

- Focal bulge

(d) Intracapsular silicone findings

- Radial folds
- Subcapsular line
- Keyhole sign (teardrop, noose)
- Linguine sign

(e) Extracapsular silicone

- Breast
- Lymph nodes

(f) Water droplets

(g) Peri-implant fluid

Also, we recognize that other techniques may be used in the evaluation of breast lesions. Newer and evolving techniques are constantly being introduced. Findings from other techniques, such as diffusion-weighted imaging or MR spectroscopy,

should be reported if clinically important.

5. COMPARISON TO PREVIOUS EXAMINATION(S)

Include a statement indicating that the current examination has been compared to previous examination(s) with specific date(s). If this is not included, it should be assumed that no comparison has been made; however, it is preferable to indicate explicitly that no comparison was made. Comparison to a previous examination may assume importance if the finding of concern requires an evaluation of change or stability. Comparison is less important when the finding has characteristically benign features. Comparison may be irrelevant if the finding is inherently suspicious for malignancy. Information in this area should include:

- a. Previous MRI — date of examination
- b. Other imaging studies (mammogram, US, nuclear medicine examination, other) and date of examination

6. ASSESSMENT

This is a description of an overall summary of MRI findings, including assessment.

Incorporating an assessment category in the overall summary of the breast MRI report is sound medical practice. All final impressions should be complete with each lesion fully categorized.

An incomplete assessment (category 0) is used when full diagnostic imaging has not been performed and should be given only when additional imaging or clinical evaluation is recommended to establish the benignity of a finding (e.g., a possible intramammary lymph node or fat necrosis at MRI may require additional mammography and/or US examination).

Interpretation is facilitated by recognizing that almost all MRI examinations may be classified into a few assessment categories, listed in the section on [Assessment Categories](#).

7. MANAGEMENT

This is a description of patient management recommendations, as appropriate.

If an incomplete assessment (category 0) is rendered, a specific suggestion for the next course of action should be given (physical examination, diagnostic mammography, targeted diagnostic US, etc.). Note that an incomplete assessment (category 0) should not be rendered when recommending targeted US in order to determine the feasibility of performing biopsy using sonographic guidance; such a scenario requires

the use of a category 4 or 5 assessment (suspicious or highly suggestive of malignancy).

If a suspicious abnormality is detected, the report should indicate that a biopsy should be performed in the absence of clinical contraindication. This means that the radiologist has sufficient concern that a biopsy is warranted; the term “clinical contraindication” indicates that there may be reasons why the patient and her physician might wish to defer the biopsy.

B. ASSESSMENT CATEGORIES

The assessment categories are based on BI-RADS® categories developed for mammography.

Table 5. Concordance Between BI-RADS® Assessment Categories and Management Recommendations.

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete — Need Additional Imaging Evaluation	Recommend additional imaging: mammogram or targeted US	N/A
Category 1: Negative	Routine breast MRI screening if cumulative lifetime risk $\geq 20\%$	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine breast MRI screening if cumulative lifetime risk $\geq 20\%$	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up	$\geq 0\%$ but $\leq 2\%$ likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	$> 2\%$ but $< 95\%$ likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	$\geq 95\%$ likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

1. ASSESSMENT IS INCOMPLETE

Category 0: Incomplete — Need Additional Imaging Evaluation

Use this for a finding that needs additional imaging evaluation. This may be used for a technically unsatisfactory scan or when more information is needed to interpret the scan. A recommendation for additional imaging evaluation might involve a repeat MRI with satisfactory technique or obtaining information with other imaging modalities (mammographic views, US, etc.). The radiologist should use judgment in how vigorously to pursue previous studies.

Every effort should be made not to use category 0. The reason for this is that almost always there is enough information on the initial breast MRI examination to provide a management recommendation. In general, the decision to biopsy or not may be made on the basis of the existing MRI study. A situation in which a final assessment of 0 may

be helpful is when a finding on MRI is suspicious, but demonstration that the finding is characteristically benign on an additional study would avert biopsy. For example, if a small mass is suspicious on MRI but there is a possibility that it may represent a benign finding, such as an intramammary lymph node, then a category 0 assessment may be made, with the recommendation for targeted US (that might demonstrate characteristically benign features) to possibly avert biopsy. Another example would be a suspicious finding at MRI that may represent fat necrosis, with the recommendation for diagnostic mammography (that might demonstrate characteristically benign features) to possibly avert biopsy. If a category 0 assessment is rendered at MRI, detailed recommendations should describe the subsequent diagnostic imaging workup and the level of suspicion (pertinent in case the additional imaging does not establish benignity).

When additional studies are completed, a final assessment is rendered. If the additional studies are described in the same report, separate paragraphs indicating the pertinent findings from each imaging study will contribute to the final integrated assessment that takes all the findings into consideration.

2. ASSESSMENT IS COMPLETE — FINAL ASSESSMENT CATEGORIES

Category 1: Negative

There is nothing to comment on. This is a normal examination.

No abnormal enhancement was found; routine follow-up is advised. There is nothing to comment on. The breasts are symmetric, and no enhancing masses, architectural distortion, or suspicious areas of enhancement are present.

Category 1 includes a normal description of breast composition (amount of FGT) and the degree of BPE. It should be emphasized that BPE is a normal finding, and short-term follow-up is not necessary to assess BPE for stability.

Category 2: Benign

Like category 1, this is a normal assessment, but here the interpreter chooses to describe a benign finding in the breast MRI report. The interpreter may describe a benign finding such as: intramammary lymph node, implants, metallic foreign bodies (such as core biopsy and surgical clips), enhancing and non-enhancing fibroadenomas, cysts, old non-enhancing scars or recent scars; postoperative collections, fat-containing lesions (such as oil cysts, lipomas, galactoceles, and hamartomas). On the other hand, the interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1). Both category 1 and 2 assessments indicate that there is no evidence of malignancy. The difference is that category 2 should be used when describing one or more specific benign MRI findings

in the report, whereas category 1 should be used when no such findings are described (even if such findings are present).

The committee supports a directive for annual follow-up MRI and mammography after either a category 1 or 2 screening MRI assessment, in line with established guidelines for high-risk screening.

Category 3: Probably Benign

A finding assessed using this category should have a $\leq 2\%$ likelihood of malignancy, but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding. A probably benign finding is not expected to change over the suggested period of imaging surveillance, but the interpreting physician prefers to establish stability of the finding before recommending management limited to routine breast screening.

Although data are becoming available that shed light on the efficacy of short-interval follow-up for selected MRI findings, at the present time, such management recommendations are based on limited data. The use of a probably benign (category 3) assessment is reserved for specific findings that are separate from the BPE and are very likely benign. The use of a category 3 assessment has been intuitive in the past; however, there are several studies.^{1, 2, 3} that specifically address rates of malignancy and, to a very limited extent, types of lesions. Although these studies examined different populations of patients, several of them were able to demonstrate a $\leq 2\%$ malignancy rate, demonstrating the feasibility of using category 3 assessments at MRI. However, none of the studies provided PPVs for specific types of lesions, ***so the use of category 3 assessment at MRI remains intuitive for radiologists who lack extensive (audited) personal experience with any given specific type of lesion.*** Currently, this is an evolving area that needs the support of robust data before an unqualified endorsement is made to use category 3 assessments at MRI.

As at mammography, if a probably benign finding is smaller or less prominent (i.e., less contrast enhancement) on follow-up examination, the finding should be assessed as benign (category 2), eliminating the need for continued surveillance imaging. When a finding that otherwise meets probably benign imaging criteria is either new or has increased in size, extent, or conspicuity, then a recommendation for biopsy would be prudent and a recommendation for follow-up should not be rendered.

BPE, a benign finding on nearly all MRI examinations, should not be the reason for a probably benign assessment. However, if findings cannot be ascribed to normal variation of BPE and there is a question about whether observed enhancement could be transient and related to the hormonal status of the patient, then a probably benign (category 3) assessment with a recommendation to return for very-short-interval follow-up (2–3 months) may be appropriate.

Because a benign hormonal enhancement can vary from cycle to cycle, a category 3 assessment may be used for the menstruating patient who was scanned in a suboptimal phase of her cycle; a follow-up MRI examination should be scheduled for the optimal (week 2) phase of her cycle. Additionally, a category 3 assessment may be used for the post-menopausal patient who is on hormone replacement therapy (HRT) and in whom probable hormonal enhancement is observed. Stopping HRT for several weeks and repeating the scan may be warranted in this scenario. It should be emphasized that unexplained areas of enhancement that are demonstrated to be due to HRT are uncommon. As with mammography, if the finding is smaller or less prominent (i.e., less contrast enhancement) at follow-up examination, the finding is benign.

Recommendations will likely undergo future modifications as more data accrue regarding the validity of using category 3 assessments at MRI, the follow-up interval required, and the type of findings that should be followed.

Follow-up of Foci

Foci are defined as small dots of enhancement that are unique and stand out from the BPE. They are too small to be accurately assessed with respect to margin or internal enhancement. Indeed, if margin or internal enhancement can be assessed, the finding should be considered a small mass and not a focus. New foci or foci that have increased in size should be viewed with suspicion and carefully evaluated.

Correlation with bright-fluid imaging (T2W imaging or STIR imaging) can be helpful in the evaluation of a focus. If a correlate is uniformly very high in signal intensity or if cyst-like features are identified, the focus may be assessed as benign. (Most of these foci represent lymph nodes or small myxomatous fibroadenomas.) However, if the focus does not have a very high signal correlate on bright-fluid imaging, then the focus may or may not be benign. These foci may be followed or biopsied. In certain cases (if the finding is new or increased in size) the focus always should be biopsied. Note that malignant foci may be brighter than the surrounding FGT, although they do not usually appear cyst-like.

Follow-up of Masses

Masses that enhance and are identified on an initial MRI examination should undergo assessment based on morphology and kinetics. It has been documented that occasionally malignancy may demonstrate benign-appearing MRI features, such as an oval or round shape with a circumscribed margin and homogeneous internal enhancement. Therefore, in a scenario in which the stability of the finding is unknown, periodic surveillance imaging may be appropriate, depending on various factors that affect the prior probability of malignancy (age, cancer risk, etc.) as well as the patient's willingness to accept surveillance imaging as an alternative to biopsy,

given less than robust data that support a watchful waiting approach. If surveillance imaging is undertaken, an increase in size of the mass should prompt immediate biopsy.

Follow-up of NME

NME that is unique and separate from the overall background enhancement should undergo assessment based on morphology and kinetics. Bright-fluid imaging sequences can be helpful in these instances to demonstrate any associated cysts, which may support a diagnosis of focal fibrocystic change and a benign (category 2) assessment. However, limited data on linear, clumped, and segmental enhancement indicate that these findings should not be followed, as the malignancy rate appears to be greater than 2%.⁴ At this time, the literature is not sufficiently robust to endorse the use of a category 3 assessment for NME.

Timing of Follow-up

Final assessment category 3 is best used for a unique focal finding and managed with an initial short-interval follow-up (6 months) examination followed by additional examinations until long-term (2- or 3-year) stability is demonstrated. For category 3 assessments, the initial short-term follow-up interval is usually 6 months, involving the breast(s) containing the probably benign finding(s). Assuming stability at this 6-month examination, a category 3 assessment again will be rendered with a management recommendation for a second short-interval follow-up examination in 6 months, but now involving both breasts if the opposite breast will be due for routine annual screening. Again assuming stability at this second short-interval follow up, the examination is once more assessed as category 3, but now the recommended follow-up interval usually is lengthened to 1 year due to the already-observed 12-month stability. The recommended 2- or 3-year follow-up in these cases is: 6 months, 6 months, 1 year, and, optionally, 1 more year to establish stability. After 2 to 3 years of stability, the finding should be assessed as benign (category 2). It should be emphasized that this approach is borrowed from mammography. While the vast majority of probably benign findings are managed with follow-up, there may be occasions in which biopsies are done instead (patient preference or overriding clinical concern). As with any interpretive examination, a less experienced reader may conclude that a finding such as benign BPE, for example, should be classified as category 3. A more experienced reader may recognize this as normal or benign at 6 or 12 months and classify it as category 1 or 2. With a properly worded report, the assessment category may then be changed to one that the current reader feels is appropriate, even though long-term stability has not been demonstrated.

It is imperative that surveillance imaging does not alter the stage at diagnosis or prognosis of the few patients with malignancies who are given category 3 assessments. Because this has not yet been demonstrated for MRI, as it has been for

mammography, careful auditing of the use of category 3 assessments is necessary, and publication of outcomes data is strongly recommended. Although the data are not robust, it appears the \leq 2% malignancy rate already demonstrated at mammographic follow-up also may be achieved at MRI. Several recent publications have demonstrated that focal lesions assigned to category 3 had a \leq 2% malignancy rate, albeit without use of specific BI-RADS® MRI descriptors for the lesions included in the studies.^{5, 6, 7} Publication of outcomes data for specific category 3 lesions, using BI-RADS® MRI, is strongly recommended. It should be noted that a \leq 2% malignancy rate may be difficult to achieve due to the high-risk population that usually is studied by MRI (higher than average prior probability of cancer).

A desirable goal for the frequency of making category 3 assessments at MRI is less than 10%. Over time, this rate should decrease to the point that a mature program should demonstrate a rate much closer to the approximately 1%–2% rate currently achieved at mammography, especially as the availability of previous examination(s) increases. A decrease in the frequency of category 3 assessments and false-positive outcomes has been demonstrated in the breast MRI literature as experience is gained.

Category 4: Suspicious

This category is reserved for findings that do not have the classic appearance of malignancy but are sufficiently suspicious to justify a recommendation for biopsy. The ceiling for a category 3 assessment is a 2% likelihood of malignancy and the floor for a category 5 assessment is 95%, so category 4 assessments cover the wide range of likelihood of malignancy in between. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this assessment category. In breast MRI, assessment category 4 is not currently divided into subcategories 4A, 4B, and 4C.

Category 4 is used for the majority of findings prompting breast intervention, which can be performed by percutaneous biopsy, by US or stereotactic guidance, or by MRI guidance for lesions not visible at either US or mammography. As cysts rarely pose a problem in interpretation at MRI, diagnostic aspiration is not commonly performed. In many patients with a suspicious abnormality at MRI, targeted US will identify a corresponding abnormality so that US-guided biopsy can be performed. US-guided biopsies are faster, more comfortable for the patient, and more cost effective than MRI-guided biopsies. There are no established guidelines on who should undergo targeted US. However, in general, patients with masses larger than 5 mm should be examined by targeted US if the MR appearance is suspicious. Areas of NME may be evident on US as well, thus bringing the radiologist's judgment into play. Factors that may limit visibility at US include fatty breasts, extremely complex breasts with multiple cysts, very large breasts, and very deep lesions. If there is any question about

whether a presumed sonographic correlate actually is the same as the suspicious MRI lesion, MR-guided biopsy is advised.

Category 5: Highly Suggestive of Malignancy

These assessments carry a very high probability ($\geq 95\%$) of malignancy. This category initially was established to include lesions for which 1-stage surgical treatment was considered without preliminary biopsy, in an era when preoperative wire localization was the primary breast interventional procedure. Nowadays, given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery rarely if ever is performed. Rather, current oncologic management almost always involves tissue diagnosis of malignancy via percutaneous tissue sampling. This facilitates treatment options, such as when sentinel node biopsy is included in surgical management or when neoadjuvant chemotherapy is administered prior to surgery. Therefore, the current rationale for using category 5 assessment is to identify lesions for which any nonmalignant percutaneous tissue diagnosis is considered discordant, resulting in a recommendation for repeat (usually surgical) biopsy.

No single MRI descriptor is sufficiently predictive of malignancy to produce the $\geq 95\%$ probability required for a category 5 assessment. Just as in mammography and US, an appropriate combination of suspicious findings is needed to justify a category 5 assessment at MRI. It is recommended that category 5 assessments be audited separately to verify a $\geq 95\%$ PPV, thereby validating that the assessment is not being overused.

Category 6: Known Biopsy-Proven Malignancy

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy) but prior to surgical excision, in which there are no abnormalities other than the known cancer that might need additional evaluation. That is, a cancer diagnosis has already been established, a lesion is depicted at MRI, and this lesion corresponds to the previously biopsied cancer.

A category 6 is not appropriate following successful lumpectomy or mastectomy (margin of resection free of tumor). The rationale for establishing category 6 is exclusion of these cases from auditing, because additional malignancy is frequently found such that auditing these cases would inappropriately skew overall outcomes. In the event that the breast with known cancer has a separate suspicious MRI finding that requires biopsy for diagnosis, the appropriate category 4 or 5 assessment should be rendered, and this would be the overall assessment because it leads to more prompt intervention.

C. WORDING THE REPORT

The current examination should be compared to prior examinations when appropriate. The indication for examination, such as screening or diagnostic, should be stated. The report should be organized with a brief description of the composition of the breast and any pertinent findings, followed by the assessment and management recommendations. All discussions between the interpreting physician and the referring clinician or patient should be documented in the original report or in an addendum to the report.

The report should be succinct, using terminology from the approved lexicon without embellishment. Do not use definitions of the lexicon terms in the report narrative; use only the descriptors themselves. Following the impression section and the (concordant) management recommendations section of the report, the terminology for the assessment category should be stated, as well as its category number. Other aspects of the report data should comply with the [ACR Practice Guideline for Communication: Diagnostic Radiology](#).

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IV. IMPLANT ASSESSMENT

Silicone breast implants were introduced in 1962, and in the United States are used for

both augmentation (80%) and reconstruction (20%). Breast implants most commonly have a single lumen, but they may contain double lumens or even multiple lumens. The implants usually contain either silicone gel or saline, although other implant materials exist.¹ Various types of silicone were also used, such as those resulting in recall of a specific silicone-filled implant, the Poly Implant Prothese (PIP).² Breast implants are usually placed either anterior to the pectoralis muscle behind the breast glandular tissue (retroglandular) or posterior the pectoralis muscle (retropectoral).

In 1992, the FDA restricted silicone implant use only to breast cancer reconstruction because of a possible association between connective tissue disease, breast cancer, and silicone implant rupture. A U.S. district court order established a National Science Panel to investigate whether an association between silicone breast implants and connective tissue disease existed. The resulting report by Tugwell, et al concluded that there is no scientific evidence of a relationship between connective tissue disease, breast cancer, and silicone breast implants.^{3, 4} The FDA reapproved silicone breast implants for cosmesis in 2008.

The MRI implant examination goal is to determine whether the implant is ruptured, and, if so, whether the rupture is intracapsular or extracapsular. This was first described by Gorczyca, et al in 1992.⁵ Both axial and sagittal planes should be imaged, because implant rupture seen on only one plane may represent an implant fold; a rupture should be confirmed in a second plane.⁶ Imaging should also include both water- and silicone-specific sequences, as both are necessary for diagnosis and may be obtained with a variety of techniques.^{7, 8, 9, 10}

The human body forms a fibrous capsule around breast implants, and usually the fibrous capsule is not seen on the breast MRI around an intact implant. The intact implant contour is usually smooth. However, even intact implants may bulge abnormally due to fibrous capsular contraction,¹¹ which can cause a focal bulge in the implant contour. In these cases, the fibrous capsule is intact and the implant is intact, and there are no signs of implant rupture within the implant itself on the MRI.

When a silicone implant ruptures, it is either contained by the fibrous capsule forming around the implant (intracapsular rupture) or extrudes beyond the fibrous capsule into the breast tissue (extracapsular rupture). With extracapsular rupture, there should also be signs of intracapsular implant rupture on the MRI. The only case in which there is extracapsular silicone with intact implants is when there has been a prior rupture with residual silicone remaining in the breast.

To distinguish between a focal bulge in an intact implant versus extruded silicone from an extracapsular rupture, a focal bulge will have signs of an intact implant on MRI. The extracapsular rupture should have findings of intracapsular rupture inside the implant on MRI, and the extruded silicone should show a dark line between the extruded

silicone glob and the implant.

Intracapsular silicone implant findings provide clues to whether the implant is intact or ruptured. Intact silicone implants normally have folds, called radial folds, in the implant envelope. Radial folds are dark lines that extend from the implant periphery into the silicone lumen, representing the folds in the intact implant envelope. In the intact implant, the end of the radial fold has a dark ball. In the ruptured implant, the end of the fold has a white ball called "keyhole," "teardrop," or "noose."

In an intracapsular silicone implant rupture, the implant envelope ruptures, but the fibrous capsule remains intact and contains the silicone away from the breast tissue. The collapsing ruptured implant envelope falls into the space held by the fibrous capsule, and silicone leaks in between the folds of the collapsing implant and into the space between the collapsing implant envelope and the fibrous capsule. The overall implant shape is maintained because the fibrous capsule still contains the silicone within. Silicone between the fibrous capsule and the collapsing implant envelope results in a subcapsular line, which is a dark line paralleling the implant edge. There is bright silicone between the subcapsular line and the implant periphery, sometimes with gentle undulations extending into the implant lumen, representing silicone between the envelope and the fibrous capsule as the collapsing implant envelope pulls away from the fibrous capsule. "Keyhole," "teardrop," and "noose" describe silicone within an implant fold, indicating rupture. The keyhole, teardrop, and noose appear as dark lines that contain white silicone inside their folds. These lines extend from the implant periphery into the silicone lumen, but unlike the normal radial fold, the lines contain a white ball at the end of the loop where it extends deepest into the implant, representing silicone in the implant envelope fold. "Linguine" describes an even further collapse of the implant envelope into the lumen and looks like a loose thread or piece of cooked linguine floating in the silicone.⁵

With an extracapsular rupture, both the implant and fibrous capsule are ruptured. The broken fibrous capsule allows silicone to leak into the surrounding breast tissues. With an extracapsular rupture, silicone is seen clearly outside the normally shaped fibrous capsule/implant contour and forms bright silicone globs adjacent to the implant, or within ducts, or within adjacent axillary lymph nodes.

Water droplets inside breast implants are seen on water-specific images; they may be normal or associated with implant rupture. Peri-implant fluid also is seen on water-specific sequences and can be normal or associated with an abnormal seroma or with infection.

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V. GUIDANCE

It is important to review the beginning text of the [Follow-up and Outcome Monitoring section](#) and its [Frequently Asked Questions](#) to fully understand how auditing definitions will affect the outcomes (performance metrics) for screening examinations as well as the benchmarks that are derived from these outcomes.

A. BREAST IMAGING LEXICON – MRI

The Breast Imaging Lexicon – MRI was modeled as much as possible on the lexicon for mammography. This chapter expands on the descriptions in the MRI BI-RADS® section and provides explanations and rationale for the terms. ***What follows is intended for guidance and is not meant to imply required standards of practice.***

1. POINTS OF CLARIFICATION

Since the publication of the 2003 edition of the BI-RADS® MRI lexicon, many previously used terms have not stood the test of time. We have eliminated some and organized the descriptors in order to be internally consistent with the mammography and US lexicons. For example, with respect to mass margin, we now use “circumscribed” and “not circumscribed.” “Lobular” shape has been eliminated in favor of “oval (includes lobulated)” and “smooth” margin has been changed to “circumscribed.” Confusion may have arisen because descriptors may be used more than once to describe different features of a mass. Specifically, the descriptor “irregular” was applied to both a mass shape and a mass margin, which could conceivably have resulted in an “irregularly shaped” mass with “irregular margins.” Because of this situation and the possibility for confusion, we recommend that the term “irregular” be used only once to describe the mass shape, and “indistinct” has been added as a term for margin analysis for lesions that are not “circumscribed.” Similarly, the terms “central enhancement,” “enhancing septations,” and “reticular/dendritic” have been removed due to underuse. “non-mass-like” enhancement has been replaced by “non-mass.”

Differentiation between a very large, irregular, heterogeneous mass and a large, heterogeneous area of regional enhancement still proves difficult, as both terms describe abnormally enhancing large volume-occupying findings. To help make a distinction, a mass should have a definable convex margin with a separable distinct edge from the surrounding glandular tissue. In general, a mass is composed of a pathologic process in a ball-like 3-D structure. On the other hand, regional enhancement is not as distinct from the surrounding elements. Regional enhancement may represent normal or pathologic changes, depending on the character of the enhancement within the region. Regional enhancement can also represent abnormal pathologic processes such as a large heterogeneously enhancing extensive breast cancer, or a wide area of regional clumped enhancement representing ductal carcinoma in situ (DCIS). Regional enhancement should not be used for BPE. However, even using these guidelines, categorization of large enhancing findings into “mass” or “regional enhancement” may still prove problematic, because one person’s large mass may be another person’s regional enhancement.

There has been confusion regarding the terms “focus,” which describes a specific tiny enhancing dot that cannot otherwise be characterized, and “focal area,” the

distribution descriptor for a small region of non-mass abnormal enhancement. A "focus" is an isolated spot of enhancement that is so small (generally < 5 mm) that no definitive morphologic descriptors can be applied to it. Characterization of a focus will depend on imaging parameters, and are so small that kinetic data may be spurious due to partial volume averaging with surrounding normal tissue. "Foci" has been eliminated as it was used to describe several such tiny dots separated widely by normal tissue and is a pattern of BPE that can be diffuse or focal.

"Focal area" of enhancement describes a small area of abnormal enhancement (larger than a "focus") that contains a specific characteristic morphologic enhancing pattern that can be distinguished from the surrounding normal tissue, has isolated spots of fat or normal glandular tissue within it (to distinguish it from a "mass"), and is larger than a "focus." In general, a focal area occupies less than a breast quadrant volume. For example, "a 1 cm focal area of clumped enhancement near the chest wall" might be used to describe a small region of DCIS, whereas "a 1 cm focal area of heterogeneous NME" might describe a small region of fibrocystic change.

Other questions arose regarding the terms "linear," "ductal," and "segmental." Because "ductal" enhancement is linear by definition, there was confusion over the differentiation of these terms. Since "ductal" describes a pathological finding and not a radiographic finding, the term "linear" is favored to describe enhancement in a line whether or not it is suspected to be in a duct. Before the concept of background enhancement, "sheets" of linear enhancement were described (which likely related to variations in BPE); therefore, these terms were historically used to differentiate between the two. "Linear" enhancement describes abnormal enhancement in a linear distribution, may have a smooth or irregular margin, and in general is pointing toward the nipple, possibly representing enhancement in breast ducts. "Linear" enhancement may be identified on images with enough high spatial resolution to define and separate individual ducts, particularly at high resolution with high-field systems (see "clustered ring enhancement").

"Segmental" enhancement is enhancement in a cone or triangular area with its apex pointing at the nipple. "Segmental" enhancement may be seen more frequently on thicker sections, but the same process might show individual "linear" enhancement if the spatial resolution were high enough. Both "linear" and "segmental" enhancement most likely represent enhancement in ductal structures; however, the morphologic appearance of the ductal system on MRI depends on spatial resolution as well as the orientation of the viewing plane. As resolution has increased, enhancement of the periductal stroma has been noted and described as "clustered ring enhancement."

2. AMOUNT OF FIBROGLANDULAR TISSUE (FGT)

MRI is unique in that 3-D volumetric data can be acquired from the image, and separation of fat and fibroglandular parenchyma is performed relatively easily. There

are no data comparing mammographic density (breast composition) to MRI assessment of the amount of FGT. Density is a term that should be applied only to mammography. The amount of fibroglandular tissue should be described as:

ALMOST ENTIRELY FATTY

SCATTERED FIBROGLANDULAR TISSUE

HETEROGENEOUS FIBROGLANDULAR TISSUE

EXTREME FIBROGLANDULAR TISSUE

As in the 2013 Edition of BI-RADS® — Mammography, the amount of fibroglandular parenchyma is not described using percentages. Unlike mammography, in which noncalcified breast lesions may be obscured by dense tissue, breast MRI is able to easily reveal an enhancing suspicious lesion independent of breast composition. Therefore, the amount of fibroglandular parenchyma does not adversely impact lesion detectability.

3. BACKGROUND PARENCHYMAL ENHANCEMENT (BPE)

As MRI is performed with intravenous contrast, the fibroglandular breast parenchyma can demonstrate contrast enhancement. BPE refers to the normal enhancement of the patient's FGT on the first postcontrast image. BPE refers to both the volume of enhancement as well as the intensity of enhancement, and an evaluation of background enhancement should take both into consideration.

The background enhancement is described as:

MINIMAL

MILD

MODERATE

MARKED

Although these categories are roughly quartiles, assigning strict percentages to indicate the degree of enhancement is likely artificial, difficult to assess without automation, and should be avoided. In general, BPE is bilateral symmetric; however, the enhancement pattern can also be focal and asymmetric, particularly if the patient has undergone treatment for breast cancer with radiation change, which can decrease background enhancement globally in the treated breast. The description of BPE can be modified by describing the findings as:

SYMMETRIC

ASYMMETRIC

In general, BPE may not be evenly distributed throughout the entire breast. Due to preferential blood supply, there is the probability of greater enhancement in the upper outer quadrant of the breast and along the inferior aspect of the breast (formerly described as "sheet-like" enhancement). BPE may be more prominent in the luteal phase of the cycle if the patient is pre-menopausal. Therefore, for elective examinations (e.g., high-risk screening), effort should be made to schedule the patient in the second week of her cycle (days 7–14) to minimize the issue of background enhancement. Despite scheduling the patient at the optimal time of her cycle, BPE will still occur and the BPE terms should be applied. Women in whom cancer has been diagnosed and MRI is performed for staging (i.e., diagnostic) should be imaged with MRI, regardless of the timing of the menstrual cycle or menstrual status.

The pattern of BPE can be variable from patient to patient, although in general, the pattern of BPE for an individual is fairly constant. It is still uncertain what the patterns of enhancement mean; therefore, description beyond the recommended descriptors is optional. There is some evidence that BPE may indicate a level of risk for the development of breast cancer, as therapeutic measures such as anti-estrogen therapy can decrease the level of BPE. BPE, however, does not appear to affect the ability to detect breast cancer.

BPE can occur regardless of the menstrual cycle or menopausal status of the patient. BPE may not be directly related to the amount of fibroglandular parenchyma present. Patients with extremely dense breasts at mammography may demonstrate little or no BPE, whereas patients with mildly dense breasts may demonstrate marked BPE. Nevertheless, most of the time, younger patients with dense breasts are more likely to demonstrate BPE.

In general, BPE is progressive over time; however, significant and fast enhancement can occur on the first postcontrast image despite fast imaging techniques. BPE on MRI is unique to a patient as is breast density at mammography. A description of BPE should be included in the breast MRI report.

Patterns of BPE are under investigation, as there is wide variation in the appearance from woman to woman. BPE may present as multiple areas of enhancement, either uniformly scattered or more concentrated in one area, in a pattern previously described as "stippled" enhancement. What used to be called stippled enhancement now is recognized to be a pattern of BPE; this is usually diffuse and symmetric, but it may present as a more discrete finding instead (particularly in an area where cysts are found), suggesting focal fibrocystic disease.

4. FOCUS

A focus is a unique, punctate, enhancing dot usually < 5 mm that is nonspecific, is too small to be characterized morphologically, and has no corresponding finding on the precontrast scan. A focus can commonly be seen but should be evaluated in the clinical context. Multiple foci representing a pattern of BPE are tiny dots of enhancement that are widely separated by intervening normal breast parenchyma that does not enhance; as stated previously, this should be considered to represent a pattern of BPE rather than multiple discrete foci of enhancement.

Although the lexicon designates two descriptors, “focus” and “mass,” which have defined features, in clinical practice one will observe that there is actually a continuum between these two descriptors, with some findings displaying intermediate features. When such an intermediate finding is encountered, the interpreting physician should first decide whether to evaluate the finding as a focus or a mass.

A focus may be benign or malignant. When evaluating a focus, the following features often indicate malignancy: unique and distinct from the BPE, no fatty hilum, washout kinetics, and significantly increased or new from the prior examination. Features of a focus that favor a benign process are: not unique compared to the BPE, bright on bright-fluid imaging, possible fatty hilum, persistent kinetics, and stable when compared to the prior examination or seen on a baseline examination.

As MRI techniques improve, fewer lesions will be described as foci, instead being classified as masses.

5. MASS ENHANCEMENT

A mass is an area of enhancement with an epicenter and convex borders, existing as a 3-D structure. The committee decided not to assign a size requirement, recognizing that suspicious masses can be of all sizes. In general, as the mass size increases so does the likelihood of malignancy.

Mass descriptors for shape and margin have been adopted from the mammography BI-RADS® lexicon. In general, as with mammography, circumscribed, oval or round masses are seen more with benign lesions, whereas irregular, spiculated masses are more likely to be malignant. Care should be taken with respect to morphology as round, circumscribed masses on MRI represent cancer more frequently than at mammography. There are several possible explanations for the presence of morphologically benign lesions representing cancer on MRI. First, with current techniques and field strength, MRI does not have the spatial resolution of mammography, so that margin analysis internal enhancement may suffer. Second, the cancers with benign morphology on MRI are usually small — smaller than we may be used to detecting on mammography. As with most imaging techniques, the ability to

resolve margin depends on the size of the lesion. Kinetic evaluation is important when considering these morphologically benign-appearing lesions. As with other imaging techniques, the worst feature of the lesion under evaluation should be used to determine the need for biopsy.

A mass has internal enhancement that can be characterized. In general, homogeneous enhancement and non-enhancing internal septations indicate a possible benign process. While it is definitely possible to see classic appearances of certain lesions, morphologic overlap can occur between benign and malignant lesions, and if there is any doubt, biopsy should be performed. The committee recognizes that when masses become large and ill-defined they may be described as regional enhancement.

Mass analysis may benefit from bright-fluid sequences, (i.e., T2W or STIR) in addition to the postcontrast sequences obtained. In general, benign mass lesions may be increased in signal relative to fibroglandular parenchyma on bright-fluid imaging, particularly cysts, lymph nodes, and fibroadenomas. Cancers may or may not exhibit increased signal on bright-fluid imaging. Cancer can be heterogeneously high in signal on bright-fluid imaging if the tumors are necrotic, cellular, or mucinous. Mucinous carcinoma and liposarcoma classically demonstrate very high signal on bright-fluid sequences; however, there are usually other suspicious features, such as irregular shape or not circumscribed margins, which warrant biopsy.

6. NON-MASS ENHANCEMENT

In the 2003 edition of the BI-RADS® Lexicon — MRI, NME was used to describe BPE as well as areas that are still considered to be NME. With greater experience and understanding of BPE, some terms have been removed, and the NME descriptors have been refined. NME describes enhancement in a pattern that does not have convex borders and may have intervening fat or normal FGT contained within the extent of the enhancement.

Clumped enhancement refers to enhancement that has the appearance of cobblestones where there are small aggregates of enhancement that are variable in size and morphology. The term clumped refers to enhancement in a focal, linear or linear-branching, segmental, or regional distribution. The term “clumped” on MRI is similar to the term “pleomorphic” on mammography as it indicates enhancement in varying shapes and sizes. As ductal carcinoma in situ (DCIS) may present with this morphologic pattern, a description of clumped usually indicates a need for biopsy. The diagnosis of DCIS is usually made solely on lesion morphology, as many times the kinetic appearance does not meet the minimal threshold, and the time intensity curves are not typical for malignancy.

7. NON-ENHANCING FINDINGS

Non-enhancing findings seen on the precontrast or bright-fluid images are benign. Examples include cysts, duct ectasia, and some fibroadenomas and postoperative collections. Assessment of the absence of enhancement is best made on the subtraction image. Follow-up or biopsy of areas of non-enhancement are not necessary unless there are suspicious findings on another imaging modality, such as mammography or US.

B. REPORT ORGANIZATION

The report should be succinct and should use the latest lexicon terms. The report should include an INDICATION FOR EXAMINATION (or clinical statement), a DESCRIPTION OF THE MRI TECHNIQUE used, brief description of FGT and BPE of the breast, any pertinent FINDINGS, a COMPARISON TO PREVIOUS EXAMINATION(S), an ASSESSMENT, and MANAGEMENT recommendations. For pre-menopausal patients, a record of the stage of the menstrual cycle is helpful. For patients who are post-menopausal, the presence of exogenous estrogen and/or progesterone is similarly helpful. For patients who have undergone breast conserving therapy, the documentation of hormonal therapy (aromatase inhibitors or selective estrogen receptor modulators) and radiation therapy may also be in the interpretation of the examination.

When describing findings, it is helpful to describe the series number as well as the image number so that the finding can be easily retrieved. Documentation of communication of suspicious findings to the referring clinician is recommended. Unlike other areas of diagnostic breast imaging, in which the results often are communicated directly to the patient, the referring clinician usually discusses the breast MRI results with the referring physician. Any verbal discussions or written communications between the radiologist and the referring physician should be documented in the original report or in an addendum to the report.

C. ASSESSMENT CATEGORIES

The final assessment should be based on the most suspicious finding present in each breast. A separate BI-RADS® assessment for each breast should be stated after the impression text. If the interpretation is straightforward and the same for both breasts, an overall impression that includes both breasts may be used. The overall assessment should be based on the most worrisome findings present in each breast. For example, if benign findings, such as lymph nodes or cysts, are noted along with a more suspicious finding, such as a spiculated mass, the final assessment category should be 4 or 5. Similarly, if immediate additional evaluation is needed for one breast for a suspicious finding (with targeted US for example), and there is a probably benign finding in the breast as well, the final assessment code for that breast would be category 4. If a breast with a known cancer has an additional suspicious finding warranting biopsy, then the final assessment code for

that breast is category 4, not category 6.

1. CATEGORY 0

Every effort should be made not to use category 0 in reading breast MRI. However, in the event that the examination is technically unacceptable (e.g., poor fat suppression, poor positioning) and would not be sufficient for interpretation, and a meaningful report could not be issued, then a category 0 may be issued. The MRI exam has characteristics that make it unique in comparison to mammography and US. The first and most obvious difference is the use of a contrast agent. This adds the parameter of blood flow to morphology with the associated flow metrics that may be calculated. The second is the acquisition of the same number and sequences whether the exam is for screening or diagnostic. As with mammography, BI-RADS® 0 should be used only in the screening setting. In interpreting breast MRI, there is enough information on the properly performed examination to decide to biopsy or recommend short-term follow-up of a specific finding. MRI, like mammography, can give a category 0 for prior MRIs before a report is issued. If there is a reliable method to track this undictated MRI while awaiting outside MRIs, a final report with a final assessment category can be issued when prior exams are received. However, if an MRI is reported and provided with a category 0 request for prior exams, this 0 may not be changed when these exams are received. An addended report can be issued with a final BI-RADS® assessment that will close out the 0. This will not be counted in the audit as recall. This is similar to a category 0 for technical reasons.

A final assessment of 0 is helpful when a finding on MRI is suspicious but a benign corresponding finding on an additional study would prevent a biopsy. If a category 0 is given on MRI, then an explanatory note in the MRI report clarifying why this suspicious morphologic and frequently physiologic finding is not immediately given a 4 or 5 on MRI is called for. For example, if a mass is suspicious on MRI but there is a possibility that it might represent a benign finding, such as a lymph node, a targeted US that would prove the lesion is benign would prevent a biopsy. In the case of a recommendation for US following the MRI examination, the terms "MRI-directed" or "MRI-targeted" US are preferable to "second-look" US, as it is not always certain that a "first-look" US has been performed. Another example in which category 0 would be useful is for a finding on MRI that is most likely fat necrosis but for which the reader would like to confirm and correlate the findings to a mammogram that is not available.

When additional studies are compared or completed, a final MRI assessment is rendered, replacing the category 0 assessment. If the additional studies can be reported in the same report, separate paragraphs indicating the pertinent findings from each imaging study can contribute to the final integrated assessment that takes into consideration the findings of all imaging studies.

2. CATEGORY 1

This is a normal examination. A description of the FGT and BPE should be included.

3. CATEGORY 2

Benign findings are described in the report. Benign findings include intramammary lymph nodes, cysts, duct ectasia, postoperative collections, fat necrosis, scar, and masses, such as fibroadenomas, assessed as benign by morphology/kinetics or prior biopsy.

4. CATEGORY 3

We recognize that there are few data in defining types of lesions that can be followed. There are reports¹ that support short-term follow-up of 1) a new unique focus that is separate from the BPE but has benign morphologic and kinetic features, and 2) a mass on an initial examination with benign morphologic and kinetic features. However, it must be stressed that the depth of scientific validation for this approach in mammography is currently not present for MRI. There are data to suggest that BPE should not be followed;² therefore, BPE is inappropriate for follow-up. Asymmetric non-mass enhancement should be characterized as either benign or malignant and given a final assessment; it should not be recommended for surveillance imaging since even less data are present for this finding than for masses to provide a category 3 assessment.

5. CATEGORY 4

Category 4 is used for the vast majority of findings prompting breast interventional procedures, ranging from diagnostic aspiration of complicated cysts to biopsy of fine linear and branching calcifications. According to BI-RADS® definitions expressed in terms of likelihood of malignancy, the cut points between category 3 versus category 4 assessments and category 4 versus category 5 assessments are 2% and 95%, respectively. Many institutions, on an individual basis, have subdivided category 4 to account for the vast range of lesions subjected to interventional procedures and the corresponding broad range of likelihood of malignancy. This allows a more meaningful practice audit, is useful in research involving receiver-operating characteristic (ROC) curve analysis, and is an aid for clinicians and pathologists.

Lesions that are appropriate to place in this category are 1) suspicious non-mass enhancement such as clumped, linear, or segmental, 2) irregular, heterogeneous, or rim enhancing masses, and 3) foci with any suspicious morphology or kinetics. Specifically, a new focus with any suspicious feature warrants further evaluation by biopsy.

Suspicious findings on MRI warranting biopsy (category 4) can be evaluated by targeted US. In general, masses are more likely to be seen on US than non-mass lesions.

Biopsy of the finding should be performed with the modality that best illustrates the finding. If a correlate to the MRI finding can be reliably found on ultrasound, US biopsy may be preferable as it is usually more ubiquitous and costs less than MR biopsy. Follow-up after both US and MRI biopsy is recommended, as missed lesions have been reported. Regarding the timing of follow up, it has been recommended that 6-month follow-up MRI be performed for all concordant nonspecific benign pathology to ensure adequate sampling of the lesion. Some authors have suggested a single noncontrast T1W image following US biopsy for a suspicious lesion to ensure adequate and accurate sampling.

6. CATEGORY 5

Category 5 (Highly Suggestive of Malignancy) was established at a time when most nonpalpable breast lesions underwent preoperative wire localization prior to surgical excision. Category 5 assessments were used for those lesions that had such characteristic features of cancer that 1-stage surgical treatment might be performed immediately following frozen-section histological confirmation of malignancy. Today, breast cancer diagnosis for imaging-detected lesions almost always involves percutaneous tissue sampling, so the current rationale for using a category 5 assessment is to identify lesions for which any nonmalignant percutaneous tissue diagnosis is considered discordant, resulting in the recommendation for repeat (usually surgical) biopsy.

The likelihood of malignancy for category 5 assessments is $\geq 95\%$, so use of this assessment category is reserved for classic examples of malignancy. Note that there is no single MRI feature that is associated with a likelihood of malignancy of $\geq 95\%$. Just as for mammography and breast US examinations, it takes a combination of suspicious MRI findings to justify a category 5 assessment.

7. CATEGORY 6

This assessment category was added to the fourth edition of BI-RADS® for use in the special circumstance when breast imaging is performed after a tissue diagnosis of malignancy but prior to complete surgical excision. Unlike the more common situations when BI-RADS® categories 4 and 5 are used, a category 6 assessment will not usually be associated with a recommendation for tissue diagnosis of the target lesion because biopsy already has established the presence of malignancy. Category 6 is the appropriate assessment, prior to complete surgical excision, for staging examinations of previously biopsied findings already shown to be malignant, after an attempted complete removal of the target lesion by percutaneous core biopsy, and for the monitoring of response to neoadjuvant chemotherapy.

However, there are other scenarios in which patients with known biopsy-proven malignancy have breast imaging examinations. For example, the use of category 6 is

not appropriate for breast imaging examinations performed following surgical excision of a malignancy (lumpectomy). In this clinical setting, tissue diagnosis will not be performed unless breast imaging demonstrates residual or new suspicious findings. Therefore, if a post-lumpectomy examination demonstrates surgical scarring but no visible residual malignancy, the appropriate assessment is benign (BI-RADS® category 2). On the other hand, if there are, for example, residual suspicious lesions, the appropriate assessment is category 4 or 5.

There is one other potentially confusing situation involving the use of assessment category 6. This occurs when, prior to complete surgical excision of a biopsy-proven malignancy, breast imaging demonstrates one or more possibly suspicious findings other than the known cancer. Because subsequent management should first evaluate the as yet undetermined finding(s), involving additional imaging, imaging-guided tissue diagnosis, or both, it must be made clear that besides the known malignancy there is at least one more finding requiring specific prompt action. The single overall assessment should be based on the most immediate action needed. If a finding or findings are identified for which tissue diagnosis is recommended, then a category 4 or 5 assessment should be rendered. If, at additional imaging for finding(s) other than the known malignancy, it is determined that tissue diagnosis is not appropriate, then a category 6 assessment should be rendered accompanied by the recommendation that subsequent management now should be directed to the cancer. As for any examination in which there is more than one finding, the management section of the report may include a second sentence that describes the appropriate management for the finding(s) not covered by the overall assessment.

Note that, as described in the auditing chapter, examinations with a category 6 assessment should not be included in breast imaging audits. Because the diagnosis of malignancy already has been established, inclusion of these cases would skew the data for many performance parameters, confounding the interpretation of audit results.

Known biopsy-proven cancers are described. If there are any additional suspicious findings that warrant biopsy, these should be described. When reporting the final assessment, a recommendation of biopsy (BI-RADS® 4 or 5) supersedes a BI-RADS® category 6 assessment.

D. FREQUENTLY ASKED QUESTIONS

1. Do the FDA mammography regulations require that BI-RADS® categories be assigned to MR examinations?

No, the FDA mammography regulations do not apply to MRI; however, the ACR does recommend using BI-RADS® final assessment codes for MR examinations.

2. A patient's breast MRI exam resulted in a BI-RADS® category 2 assessment (Benign); her mammography exam resulted in a BI-RADS® category 4 assessment (Suspicious). The patient has a previous history of malignancy following lumpectomy, and her physician believes that the area needs a biopsy. If the mammography report disagrees with the breast MRI exam, is it appropriate to recommend a biopsy in the impression of the breast MRI report based on the positive mammogram?

Yes, you may include a recommendation for biopsy in your breast MRI report in a separate sentence after having rendered a benign assessment, explaining that a biopsy is recommended based on suspicious mammographic findings. If your reporting system has a combined module that includes all three breast imaging modalities (mammography, US, and MRI), appropriate letters will be sent to clinicians and patients based on the most serious BI-RADS® category (in this case category 4). Also, as a general rule, imaging studies should not be used to contradict a biopsy from another breast imaging study.

3. A screening mammography examination received an incomplete assessment (BI-RADS® category 0) due to an abnormal asymmetry. The subsequent diagnostic mammography examination is also BI-RADS® category 0. A US examination then is performed that is assessed as negative (BI-RADS® category 1). Even though the US is negative, I want to further evaluate this patient with MRI because the mammography examination was of concern. If I issue an overall final assessment for all of the procedures, how should I determine the appropriate assessment category to ensure proper care?

This question involves two nonrecommended uses of BI-RADS® category 0. First, with few uncommon exceptions, category 0 should not be used for diagnostic mammography examinations. Therefore, if diagnostic mammography is performed in conjunction with US, an overall BI-RADS® assessment category should be given (rather than a category 0 assessment for the mammography followed by a category 1 assessment for the US). The overall assessment would depend on the mammographic and sonographic findings and whether benign findings are or are not described in the diagnostic breast imaging report. Refer to the following examples.

- If no findings are described in either the mammography or US portions of the report, the appropriate overall assessment is negative (BI-RADS® category 1).
- If one or more specific benign findings are described in either the mammography or US portions of the report, the appropriate overall assessment is benign (BI-RADS® category 2).
- If diagnostic mammography depicts a focal asymmetry with no associated mass, calcifications, or architectural distortion; if there is no sonographic or palpable correlate to the mammographic finding; and if there are no prior mammography examinations available for comparison, it may be appropriate to render a probably

benign (BI-RADS® category 3) assessment.

- If diagnostic mammography indicates the presence of a suspicious abnormality despite absence of a sonographic correlate (or vice versa), the appropriate overall assessment is suspicious (BI-RADS® category 4).

Second, BI-RADS® category 0 should **not be used for diagnostic breast imaging findings that warrant further evaluation with MRI**. Rather, the radiologist should issue a final assessment for the combined diagnostic mammography and US examinations in a report that is made **before** the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations in the combined mammography/US report. This provides the following advantages:

- If the recommended MRI examination is not performed, the combined diagnostic breast imaging report will stand as issued.
- If MRI is performed as recommended, it would not be necessary to re-interpret the mammography and US examinations. A negative or benign MRI assessment would sustain a similar assessment made at diagnostic mammography and US. If the MRI examination shows more abnormal findings than those identified at mammography and US, the MRI assessment would supersede that made for mammography and US.

Also note that breast MRI is not appropriate follow-up in many situations, including:

- Instead of biopsy of a suspicious finding at mammography and/or US.
- As an alternative to short-interval follow-up of probably benign findings at mammography and/or US.
- To further evaluate findings that should be recognized as benign at mammography and/or US, such as gynecomastia or multiple bilateral partially circumscribed, partially obscured masses. Also most lymph nodes and fat necrosis may be characterized as benign at mammography and/or US.

MRI is rarely helpful in further evaluation of possible architectural distortion that is too vague to target for stereotactic or sonographic biopsy.

4. What happens if additional imaging following a BIRADS® 0 assessment does not show a benign finding?

Short-interval follow-up or biopsy would most likely be necessary. The MR interpretation should be detailed with descriptions of any and all abnormalities with the level of suspicion, so that the radiologist performing the additional imaging does not need to reinterpret the original MR examination.

5. Axillary adenopathy is seen at screening MRI with no suspicious findings in the breasts.

What should the BI-RADS® final assessment be?

In the absence of a known infectious or inflammatory cause, isolated **unilateral** axillary adenopathy should receive a suspicious (BI-RADS® category 4) assessment. Unilateral axillary adenopathy suggests occult breast carcinoma or, much less commonly, lymphoma, metastatic melanoma, ovarian cancer, or other metastatic cancer. Consequently, a careful search of the ipsilateral breast images is warranted. Bilateral axillary US may be performed to confirm that the finding is asymmetric/unilateral. Clinical evaluation for infection or inflammation in the ipsilateral breast, axilla, arm, and hand is recommended at the time of US, as mastitis, breast abscess, an infected skin lesion, and cat scratch fever are all potential sources of benign unilateral axillary adenopathy. If a benign cause is elucidated, a benign (BI-RADS® category 2) assessment would be appropriate. In the absence of a known infectious or inflammatory source, a suspicious (BI-RADS® category 4) assessment would be appropriate, with the intent to biopsy after further evaluation and review of the clinical history. It is then appropriate to proceed with US-guided fine-needle aspiration (FNA) or core biopsy, and it may be advisable to perform ipsilateral whole-breast US at that visit to search for an occult primary breast carcinoma.

Bilateral axillary adenopathy would be assessed as benign (BI-RADS® category 2) in some situations and as suspicious (BI-RADS® category 4) in others. Bilateral axillary adenopathy is frequently reactive/infectious in origin, such as with inflammatory conditions (sarcoidosis, systemic lupus erythematosis, psoriasis, etc.) and HIV. In such situations, the appropriate assessment is benign (BI-RADS® category 2). Patients with known lymphoma or leukemia may also have bilateral axillary adenopathy. In this situation, the BI-RADS® assessment should be based on findings in the breasts themselves, but the report also should indicate the presence of adenopathy and the known underlying disease. For example, a report might indicate a negative or benign assessment, followed by “with bilateral axillary adenopathy presumed due to known lymphoma.” It may be helpful to have an assistant contact the referring health care provider to clarify whether there is such a history before issuing a final report. If there is no known explanation for bilateral adenopathy, and particularly if it is new, then it may be a sign of lymphoma-leukemia, and a suspicious (BI-RADS® category 4) assessment is warranted, with a recommendation for US-guided FNA or core biopsy. Note that ideally, biopsy specimens should be kept in saline or RPMI 1640 if lymphoma is suspected, to facilitate fluorescence-activated cell sorting.

6. What assessment category should be used for a breast MRI exam for implant integrity (i.e., one that demonstrates intact or ruptured implants)? Should such exams be audited as TP, FP, TN, or FN?

Implant assessments should not be assigned a BI-RADS® assessment category. They do not include imaging of breast tissue.

REFERENCES

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2. Hambly NM, Liberman L, Dershaw DD, Brennan SB, Morris EA. *Background parenchymal enhancement on baseline screening breast MRI: impact on biopsy rate and short-term follow-up*. AJR 2011;196:218-24.

APPENDIX

ACR BI-RADS® — MRI Lexicon Classification Form

For each of the following categories, select the term that best describes the dominant lesion feature.
Whenever possible, definitions used in BI-RADS® for mammography should be applied to MRI of the breast.

BREAST TISSUE

A. Amount of Fibroglandular Tissue (FGT): Assessed on fat-saturated T1W imaging or non-fat-saturated T1W imaging.
(select one)

- 1. a. Almost entirely fat
- 2. b. Scattered fibroglandular tissue
- 3. c. Heterogeneous fibroglandular tissue
- 4. d. Extreme fibroglandular tissue

B. Background Parenchymal Enhancement (BPE): Refers to the normal enhancement of fibroglandular tissue, occurs on the first postcontrast image at approximately 90 seconds.

1. Level (select one)	<input type="checkbox"/> a. Minimal	
	<input type="checkbox"/> b. Mild	
	<input type="checkbox"/> c. Moderate	
	<input type="checkbox"/> d. Marked	
2. Symmetric or asymmetric (report for bilateral scans)	<input type="checkbox"/> a. Symmetric	Enhancement in both breasts
	<input type="checkbox"/> b. Asymmetric	More enhancement in one breast than the other

FINDINGS

C. Focus: Dot of enhancement so small (< 5 mm) it cannot be otherwise characterized (if only finding, go to Section E)

D. Masses: 3-D, space-occupying lesion, convex-outward contour

1. Shape (select one)	<input type="checkbox"/> a. Oval (includes lobulated)	Elliptical or egg-shaped (may include two or three undulations)
	<input type="checkbox"/> b. Round	Spherical, ball-shaped, circular, or globular
	<input type="checkbox"/> c. Irregular	Neither oval nor round
2. Margin (select one)	<input type="checkbox"/> a. Circumscribed	Entire margin is sharply demarcated with abrupt transition between the lesion and surrounding tissue
	<input type="checkbox"/> b. Not circumscribed	
	<input type="checkbox"/> i. Irregular	Uneven or jagged edges (but not spiculated)
	<input type="checkbox"/> ii. Spiculated	Characterized by lines radiating from the mass
3. Internal enhancement characteristics (select one)	<input type="checkbox"/> a. Homogeneous	Confluent uniform enhancement
	<input type="checkbox"/> b. Heterogeneous	Nonuniform enhancement with variable signal intensity
	<input type="checkbox"/> c. Rim enhancement	Enhancement more pronounced at the periphery of mass
	<input type="checkbox"/> d. Dark internal septations	Dark non-enhancing lines within a mass

E. Non-mass Enhancement (NME): In an area that is neither a mass nor a focus

1. Distribution <i>(select one)</i>	<input type="checkbox"/> a. Focal	In a confined area, less than a breast quadrant volume with fat or normal glandular tissue interspersed between the abnormally enhancing components (exception: focal homogeneous enhancement)
	<input type="checkbox"/> b. Linear	Enhancement arrayed in a line (not necessarily a straight line) or a line that branches
	<input type="checkbox"/> c. Segmental	Triangular or cone-shaped region of enhancement, apex at the nipple
	<input type="checkbox"/> d. Regional	Enhancement that encompasses more than a single duct system
	<input type="checkbox"/> e. Multiple regions	Enhancement in at least two large volumes of tissue not conforming to a ductal distribution and separated by normal tissue, multiple geographic areas, patchy in appearance
	<input type="checkbox"/> f. Diffuse	Enhancement distributed randomly throughout the breast
2. Internal enhancement patterns <i>(select one)</i>	<input type="checkbox"/> a. Homogeneous	Confluent uniform enhancement
	<input type="checkbox"/> b. Heterogeneous	Nonuniform enhancement in a random pattern, separated by normal breast parenchyma or fat
	<input type="checkbox"/> c. Clumped	Cobblestone enhancement of varying shapes and sizes with occasional confluent areas
	<input type="checkbox"/> d. Clustered ring	Thin rings of enhancement clustered together around ducts

F. **Intramammary lymph node:** Circumscribed, homogeneously enhancing masses, reniform, with hilar fat (generally ≤ 1cm)

G. **Skin lesion:** Benign, enhancing lesions of the skin

H. Non-enhancing findings (select all that apply)

<input type="checkbox"/> 1. Ductal precontrast high signal on T1W	Bright signal in ducts before contrast enhancement on T1W images
<input type="checkbox"/> 2. Cyst	Circumscribed, round or oval, fluid-filled mass with an imperceptible wall; usually bright on T2W images
<input type="checkbox"/> 3. Postoperative collections (hematoma/seroma)	May be simple or complicated; may contain bright signal on T1W images; usually demonstrate thin peripheral enhancement around the cavity
<input type="checkbox"/> 4. Post-therapy skin thickening and trabecular thickening	May be seen following surgery and/or radiation therapy
<input type="checkbox"/> 5. Non-enhancing mass	Usually identified on precontrast images; usually solid lesions, do not use this descriptor for cysts
<input type="checkbox"/> 6. Architectural distortion	This includes focal retraction and distortion of the parenchyma with no definite mass visible
<input type="checkbox"/> 7. Signal void from foreign bodies, clips, etc.	Absence of signal due to an artifact

I. Associated features (select all that apply)

<input type="checkbox"/> 1. Nipple retraction	Nipple is pulled in; do not confuse with nipple inversion
<input type="checkbox"/> 2. Nipple invasion	Tumor directly invades and is contiguous with the nipple
<input type="checkbox"/> 3. Skin retraction	The skin is pulled in abnormally
<input type="checkbox"/> 4. Skin thickening	May be focal or diffuse, > 2 mm in thickness
5. Skin invasion	Abnormal enhancement within the skin, which is thickened
	<input type="checkbox"/> a. Direct invasion <input type="checkbox"/> b. Inflammatory cancer
<input type="checkbox"/> 6. Axillary adenopathy	Enlarged lymph nodes may warrant comment, clinical correlation, and additional evaluation especially if new or considerably larger or rounder compared to previous examination
<input type="checkbox"/> 7. Pectoralis muscle invasion	Abnormal enhancement extending into the adjacent pectoralis muscle
<input type="checkbox"/> 8. Chest wall invasion	Abnormal enhancement extending into the ribs or intercostal spaces (behind the pectoralis muscle)
<input type="checkbox"/> 9. Architectural distortion	As an associated feature, may be used in conjunction with another finding to indicate distortion or retraction of parenchyma adjacent to the other finding

J. Fat containing lesions (select all that apply)

1. Lymph nodes	<input type="checkbox"/> a. Normal <input type="checkbox"/> b. Abnormal
<input type="checkbox"/> 2. Fat necrosis	
<input type="checkbox"/> 3. Hamartoma	
<input type="checkbox"/> 4. Postoperative seroma/hematoma with fat	

K. Location of lesion: An important lesion (assessed as anything other than benign) must always be triangulated so that its 3-D location within the breast is known

<input type="checkbox"/> 1. Location		Describe: right, left, or both breasts Use: quadrant location (upper outer, upper inner, lower outer, lower inner) and clock-face position, or Use: retroareolar, central, and axillary tail preceded by right, left, or both breasts
<input type="checkbox"/> 2. Depth		Indicate depth (anterior, middle, posterior third); include centimeters from the nipple, skin, or chest wall, as appropriate

L. Kinetic curve assessment: Enhancement characteristics during injection of contrast media
Signal intensity (SI)/time curve description

1. Initial phase (select one)		Enhancement pattern within the first 2 minutes or when curve starts to change
	<input type="checkbox"/> a. Slow	< 50% increase in signal intensity within the first 2 minutes
	<input type="checkbox"/> b. Medium	50% – 100% increase in signal intensity within the first 2 minutes
	<input type="checkbox"/> c. Fast	> 100% increase in signal intensity within the first 2 minutes
2. Delayed phase (select all that apply)		Enhancement pattern after 2 minutes or after curve starts to change
	<input type="checkbox"/> a. Persistent	Continued > 10% increase in signal over time
	<input type="checkbox"/> b. Plateau	Signal intensity does not change over time after its initial rise, flat
	<input type="checkbox"/> c. Washout	Signal intensity decreases > 10% after its highest point from its initial rise

M. Implants

1. Implant material and lumen type (select one)	<input type="checkbox"/> a. Saline	
	<input type="checkbox"/> b. Silicone	
	<input type="checkbox"/> i. Intact	
	<input type="checkbox"/> ii. Ruptured	
	<input type="checkbox"/> c. Other implant material	Such as soy oil, polypropylene, polyurethane, and sponges; includes direct injections
	<input type="checkbox"/> d. Lumen type	
2. Implant location (select one)	<input type="checkbox"/> a. Retroglandular	Anterior to the pectoralis muscles
	<input type="checkbox"/> b. Retropectoral	Deep to the pectoralis muscles
3. Abnormal implant contour	<input type="checkbox"/> a. Focal bulge	
4. Intracapsular silicone findings (select all that apply)	<input type="checkbox"/> a. Radial folds	
	<input type="checkbox"/> b. Subcapsular line	
	<input type="checkbox"/> c. Keyhole sign (teardrop, noose)	
	<input type="checkbox"/> d. Linguine sign	
5. Extracapsular silicone (select one)	<input type="checkbox"/> a. Breast	
	<input type="checkbox"/> b. Lymph nodes	
<input type="checkbox"/> 6. Water droplets		
<input type="checkbox"/> 7. Peri-implant fluid		

ASSESSMENT CATEGORIES (select one)		
Incomplete Assessment	Management	Likelihood of Cancer
<input type="checkbox"/> Category 0: Incomplete — Need Additional Imaging Evaluation	Recommend additional imaging: mammogram or targeted US	N/A
Final Assessment		
<input type="checkbox"/> Category 1: Negative	Routine breast MRI screening if cumulative lifetime risk $\geq 20\%$	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 2: Benign	Routine breast MRI screening if cumulative lifetime risk $\geq 20\%$	Essentially 0% likelihood of malignancy
<input type="checkbox"/> Category 3: Probably Benign	Short-interval (6-month) follow-up	> 0% but $\leq 2\%$ likelihood of malignancy
<input type="checkbox"/> Category 4: Suspicious	Tissue diagnosis	> 2% but $< 95\%$ likelihood of malignancy
<input type="checkbox"/> Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	$\geq 95\%$ likelihood of malignancy
<input type="checkbox"/> Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

This MRI lexicon classification form is for data collection and does not constitute a written MRI report.



ACR BI-RADS®

Follow-up and Outcome Monitoring

2013

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PREFACE

Current regulations of the Food and Drug Administration (FDA)¹ require a minimal audit of all facilities engaged in mammography. The American College of Radiology (ACR) asserts that more complex auditing is required for a breast imaging practice and its individual interpreting physicians to determine acceptable clinical performance. The section on follow-up and outcome monitoring describes in detail how to conduct a clinically relevant audit (what data to collect and what metrics to calculate to analyze the data). Knowing how we perform will help to identify deficiencies, facilitate research, and be of practical value in reducing adverse medicolegal consequences.

In the fourth edition of the BI-RADS® Atlas, the material on follow-up and outcome monitoring was part of the Mammography section because auditing procedures for mammography had been established for many years and benchmarks using these auditing procedures were presented so that an individual mammography facility (or individual interpreting physician) might compare observed outcomes with these benchmarks. There were no standardized auditing procedures for either breast US or breast MRI, and no performance parameter benchmarks for either breast US or breast MRI had been published.

Since that time, there has been a substantial and widespread increase in the use of breast US and breast MRI for both screening and diagnostic applications, to the point where it now is practical, indeed timely, to establish auditing procedures for these modalities. Therefore, with publication of the fifth edition of BI-RADS®, we have created this new, expanded Follow-up and Outcome Monitoring section which includes auditing procedures for all three breast imaging modalities.

This section clearly defines positive and negative breast imaging examinations, how “truth” is established for each, and the role of assessment categories and management recommendations in making these determinations. For auditing purposes, positive “truth” is defined as tissue diagnosis of breast cancer within an interval after breast imaging examination equal in length to the recommended screening interval. For all of the definitions provided within this section, the recommended screening interval is assumed to be 1 year (365 days) because this is by far the most frequently recommended interval in the United States. However, the breast imaging facility that uses a 2-year (or longer) interval must substitute the appropriate interval in all the definitions, whether that facility is located in the United States or elsewhere.

Practical examples of true-positive, true-negative, false-positive, and false-negative examinations are presented and then characterized using the definitions provided in this section. Please note that a breast imaging examination assessed as BI-RADS® category 6 is not to be included in the audit process since there already is a known biopsy-proved

malignancy. Inclusion of such examinations would inappropriately skew performance parameters such as cancer detection rate and positive predictive value, thereby confounding the understanding of auditing outcomes and complicating the process of considering whether to remediate deficiencies.

This illustrated fifth edition of the BI-RADS® Atlas is designed for everyday practice and should make it possible for breast imaging facilities and individual interpreting physicians to conduct clinically relevant audits. BI-RADS® was always intended to be a dynamic and evolving document that would adapt to changes in the practice of breast imaging and be of practical use to interpreting physicians. Therefore, the Committee on BI-RADS® welcomes any comments and/or suggestions from its users and requests that these be submitted in writing or electronically to the ACR. However, prior to submitting comments or suggestions, please first visit the ACR BI-RADS® web site at [<http://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/BIRADSFAQs.pdf>], which displays committee-approved responses to suggestions already submitted

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INTRODUCTION

This chapter on the breast imaging audit describes the data to be collected and utilized to calculate important derived data, which allow each interpreting physician to assess his or her overall performance in breast imaging interpretation. If practical, auditing should be done separately for screening and diagnostic examinations. The basic principles described in this section also apply to mammography, breast ultrasound (US), and breast MRI in the appropriate setting. In addition to the basic clinically relevant audit, more complete audit data may also be collected and utilized to calculate derived data that provide other important information regarding breast imaging performance. Practical examples of everyday situations are presented and then characterized using the definitions and mathematical formulas included in this section.

Auditing must be based on a set of objective and reproducible rules, so that the outcomes data observed for all breast imaging practices are comparable. Furthermore, auditing for different breast imaging modalities should utilize the same set of rules to facilitate cross-modality comparisons, except when the unique aspects of a given modality justify a different approach.

The auditing procedures for mammography have been established for many years, and clinically representative benchmarks using these auditing procedures now have been published so that an individual mammography facility (or individual interpreting physician) may reliably compare observed outcomes with these benchmarks. Therefore, it is reasonable to base the auditing of US and MRI examinations on approaches that utilize the standards and rules for mammography, whenever practical.

At one end of a spectrum of approaches, screening mammography involves the production of a set of standard images (usually paired MLO and CC views of each breast, occasionally supplemented by exaggerated lateral CC views and anterior compression MLO views to include more breast tissue in the image field and to improve image quality, respectively), which then are evaluated by making the binary decision of recommending action before the next routine screening versus recommending no action until the next routine screening. The recommendation for, or production of, additional (diagnostic) mammographic images to further evaluate a finding depicted on the standard images provides an objective and reproducible rule that defines the “positive” screening examination, because it involves action before the next screening. In a similar manner, no further action prior to subsequent screening defines the “negative” screening examination. When a screening mammography examination is interpreted while the patient waits for her results (online interpretation), it is the production of additional images that defines a positive examination, whether or not separate screening and diagnostic reports are issued. It is crucial to understand the difference between BI-RADS® assessments used to produce

clear and unambiguous clinical reports and the performance metrics needed to ensure accurate, comparable audits. In the online example cited previously, the interpreting physician may choose not to report the screening exam separately but wait until additional images are produced to report the entire examination. If the final report then involves a benign (category 2) assessment, the screening portion of that combined assessment, ***for auditing purposes***, should be “need additional imaging evaluation” (category 0) and the diagnostic portion “benign” (category 2). Thus, this would be audit-positive for the screening portion and audit-negative for the diagnostic portion. It would be acceptable for a single report to be issued reflecting only the final benign (category 2) assessment, but it would be inappropriate and misleading for both portions of the examination to be considered audit-negative.

At the other end of the spectrum, screening breast MRI involves the production of continuous sets of images that are thin tomographic sections of the entirety of one or both breasts. The images recorded at screening usually are identical to those recorded for a diagnostic breast MRI examination. Hence, a screening examination is simultaneously a full diagnostic examination, so the definitions of positive screening and positive diagnostic examinations are the same.

Intermediate between these two modalities is screening breast US, which usually involves the real-time examination of both breasts followed by the recording of representative images that support the assessment made at real-time examination. Despite the real-time nature of screening US image interpretation, and because a representative set of images is recorded to support that interpretation, the basic standards and auditing rules applied for mammography to define negative and positive screening examinations may also be applied for screening US. At screening US, usually performed with a handheld transducer, the operator (whether the interpreting physician or an appropriately trained breast imaging sonographer) records only a small set of images that are representative of the entire breast. In the recent ACR Imaging Network trial of screening breast US, for a negative examination, this was defined as at least five images per breast, one for each quadrant and one for the retroareolar area.² This definition is also applicable to routine clinical practice for all normal (negative and benign) screening US examinations, and is recommended in this edition of BI-RADS®. When a potentially abnormal finding is identified during real-time scanning by the sonographer and/or physician or depicted in one or more of the screening images from an automated breast US unit, the decision may be made to further scan the patient to clarify the significance of this finding and/or to record one or more additional (diagnostic) images to demonstrate the complete set of sonographic features of the finding for short-term follow-up or biopsy purposes. These additional images, similar to those obtained at diagnostic breast US examination, usually involve paired images of the finding with perpendicular transducer orientation, often with and without caliper measurements and sometimes using additional sonographic techniques such as Doppler, compound, harmonic, and elastographic imaging. Thus, identical to screening mammography, the production of additional (diagnostic) images to further evaluate a

finding depicted on the standard images provides an objective and reproducible rule that defines the positive screening US examination, because this involves action before next screening. As with online interpretation of a positive screening mammography examination, this pertains whether or not separate screening and diagnostic reports are issued or whether the time between the screening and diagnostic examination is minutes or weeks. Note that if a given breast US facility defines a different number of standard screening images per breast, as described in the facility's policy and procedures manual, the benchmark data derived for screening US utilizing the recommended BI-RADS® definition may not be applicable.

The definition of a positive screening US examination also applies to the automated screening breast US examination for which the patient is recalled for additional diagnostic breast imaging examination(s) to further evaluate a potentially abnormal finding depicted on screening images and, as such, is functionally similar to batch interpretation of a screening mammography examination for which the patient is recalled for additional diagnostic breast imaging.

Note that central to the auditing definitions of positive screening for screening mammography and screening US is whether additional diagnostic images are recorded to further evaluate a finding depicted on screening images. This accomplishes objectivity and reproducibility (and overcomes subjectivity) by basing the auditing rule on something that does not require judgment, which for screening breast US is readily determined by requiring the imaging report to contain a description of whether only standard or standard plus additional (diagnostic) images were recorded. Auditing will be greatly facilitated if screening breast US reports were created using a computerized reporting system, which would prospectively capture data on whether additional images were recorded.

In summary, the fifth edition of BI-RADS® establishes objective and reproducible approaches to auditing breast imaging examinations for all three major breast imaging modalities, approaches that are internally consistent and permit more meaningful cross-modality comparison of outcomes data. It is expected that such cross-comparisons will become increasingly important as the newer modalities of breast US and breast MRI become more widely used.

To ensure that audit data are protected as peer-review information, interpreting physicians should consult applicable state law and regulations.

REVISIONS

I. GLOSSARY OF STATISTICAL TERMS

Following is a glossary of statistical terms that are used for the basic and comprehensive audit of a breast imaging practice, both of which are described in detail following the glossary:

1. **Screening examination (mammography, breast US, breast MRI)** — An examination performed on an asymptomatic woman to detect early, clinically unsuspected breast cancer. Screening involves the binary decision of recommending action before the next routine screening versus recommending no action until the next routine screening.
2. **Diagnostic examination** — The unique aspects of screening mammography, breast US, and breast MRI examinations result in some differences in the how the definition of a “diagnostic examination” is applied to each of the three imaging modalities:
 - a. **Mammography** — These diagnostic examinations may be performed for various reasons, most commonly including:
 - i. *Patient has **clinical signs or symptoms** that may suggest breast cancer, or the patient has a recent diagnosis of breast cancer.*
 - ii. *Further mammographic evaluation of a patient has been requested because of an abnormal screening mammography examination, breast US, or breast MRI examination.*
 - iii. *Further mammographic evaluation of the patient has been performed online to assess a finding at a screening mammography examination, while the patient remains in the breast imaging facility (paragraph 4a).* Remember that, as indicated previously, for auditing purposes the screening component of the examination should be audited as positive (effectively, a category 0 assessment), and a final BI-RADS® assessment should be rendered based on the additional (diagnostic) images. Also note that the mammography report may describe only the final (diagnostic) assessment for clarity and clinical utility, even though the examination will be audited separately as screening and diagnostic components.
 - iv. *Patient is undergoing periodic mammographic surveillance for a finding previously assessed at mammography as probably benign.* After a demonstration of long-term (2-year or 3-year) stability or at the interpreter’s discretion during the surveillance period, when a benign (category 2) assessment is rendered, the patient then may be returned to screening.
 - v. *Short-interval follow-up for a cancer patient recently treated with breast conservation therapy.* Once again, at the interpreter’s discretion, after the period of short-interval follow-up

is complete, the patient then may be returned to screening.

(Other types of special screening examinations, such as those performed on asymptomatic women with a personal history of breast cancer or benign breast biopsy, and those performed on asymptomatic women with breast augmentation, are often performed as diagnostic examinations, but for **audit purposes** should be included in the **screening group**.)

b. **Breast US** — These diagnostic examinations may be performed for various reasons, including:

- i. *The patient has **clinical signs or symptoms** that may suggest breast cancer, or the patient has a recent diagnosis of breast cancer.*
- ii. *Further US evaluation of the patient has been requested because of abnormal screening or diagnostic mammography, screening breast US, or breast MRI examination.*
- iii. *Further US evaluation of the patient has been performed to assess a finding at a screening US examination, while the patient remains in the breast imaging facility ([paragraph 4b](#)).*
- iv. *The patient is undergoing periodic breast US surveillance for a finding previously assessed at US as probably benign. After demonstration of long-term (2-year or 3-year) stability or at the interpreter's discretion during the surveillance period, when a benign (category 2) assessment is rendered, the patient then may be returned to screening.*
- v. *Short-interval follow-up of a breast cancer patient recently treated with neoadjuvant chemotherapy or breast conservation therapy.*

(Breast US examinations performed on asymptomatic women with a personal history of breast cancer and on asymptomatic women with breast augmentation may be performed as diagnostic examinations, but for **audit purposes** should be included in the **screening group**.)

c. **Breast MRI** — These diagnostic examinations may be performed for various reasons, including:

- i. *The patient has **clinical signs or symptoms** that may suggest breast cancer, or the patient has a recent diagnosis of breast cancer.*
- ii. *Further MRI evaluation of the patient has been requested because of an abnormal screening or diagnostic mammography or breast US examination.*
- iii. *The patient is undergoing periodic breast MRI surveillance for a finding previously assessed at MRI as probably benign. After demonstration of long-term (2-year or 3-year) stability or at the interpreter's discretion during the surveillance period, when a benign (category 2)*

assessment is rendered, the patient then may be returned to screening.

- iv. *Short-interval follow-up after a concordantly benign result at MRI-guided biopsy.*
- v. *Short-interval follow-up of a breast cancer patient recently treated with neoadjuvant chemotherapy or breast conservation therapy.*

(Breast MRI examinations performed on asymptomatic women with a personal history of breast cancer and on asymptomatic women with breast augmentation may be performed as diagnostic examinations, but for ***audit purposes*** should be included in the ***screening group***.)

Table 1. Diagnostic Examinations – Definition Summary

Mammography	Breast US	Breast MRI
Clinical signs or symptoms that may suggest breast cancer or recent diagnosis of breast cancer	Clinical signs or symptoms that may suggest breast cancer or recent diagnosis of breast cancer	Clinical signs or symptoms that may suggest breast cancer or recent diagnosis of breast cancer
Requested because of abnormal screening mammography, breast US, or breast MRI examination	Requested because of abnormal screening mammography, screening breast US, or breast MRI examination	Requested because of abnormal screening mammography or breast US examination
To obtain additional images to assess a finding at screening mammography examination while patient remains in breast imaging facility	To obtain additional images to assess a finding at screening breast US examination while patient remains in breast imaging facility	
Periodic mammographic surveillance for finding previously assessed at mammography as probably benign	Periodic breast US surveillance for finding previously assessed at breast US as probably benign	Periodic breast MRI surveillance for finding previously assessed at breast MRI as probably benign, or following concordant benign result at MRI-guided biopsy
Short-interval follow-up for cancer patient recently treated with breast conservation therapy	Short-interval follow-up for cancer patient recently treated with neoadjuvant chemotherapy or breast conservation therapy	Short-interval follow-up for cancer patient recently treated with neoadjuvant chemotherapy or breast conservation therapy

3. Tissue diagnosis — This is a pathologic diagnosis rendered after any type of interventional procedure (fine-needle aspiration cytology, core biopsy, incisional biopsy, excisional biopsy). A tissue diagnosis is considered to be concordant if the cytological or histological diagnosis rendered by the pathologist is consistent with the imaging findings of the biopsied lesion. A tissue diagnosis is considered to be discordant if the cytological or histological diagnosis rendered by the pathologist is not consistent with the imaging findings of the biopsied lesion. Examples of discordant tissue diagnoses include histological diagnosis of fibroadenoma for a spiculated mass containing fine linear calcifications, and histological diagnosis of benign fibrofatty breast tissue for a circumscribed oval mass. Also included in the definition of tissue diagnosis is ***diagnostic cyst aspiration***, performed in order to confirm the suspected

diagnosis of cyst for cases in which mammographic and sonographic findings are not characteristically benign, with aspiration of cyst fluid accompanied by disappearance of the mass making it unnecessary to obtain a pathologic diagnosis. Note that ***therapeutic cyst aspiration*** is not included in the definition of tissue diagnosis. Such an aspiration, performed for characteristically benign cysts in order to provide symptomatic relief of focal pain or tenderness or to relieve patient anxiety, is not defined as tissue diagnosis because the interventional procedure is not recommended for diagnostic purposes.

4. Positive screening examination — This is a screening examination for which additional diagnostic imaging is recommended prior to the next routine screening examination; for which additional diagnostic imaging is performed to further evaluate a screening-detected finding whether or not the patient remains in the breast imaging facility (whether or not separate screening and diagnostic reports are issued); or for which tissue diagnosis is recommended. The unique aspects of screening mammography, breast US, and breast MRI examinations are taken into account in the following paragraphs that describe positive screening examinations.

a. Mammography — For screening mammography, this usually involves an examination for which recall is recommended (BI-RADS® category 0), or for which additional diagnostic breast imaging is performed to further evaluate a screening-detected finding while the patient remains in the breast imaging facility (online interpretation). Much less frequently (use discouraged), a positive screening mammography examination is one for which tissue diagnosis or short-term follow-up is recommended (BI-RADS® categories 4 and 5 or BI-RADS® category 3, respectively). Note that this definition of a positive screening examination is different from that used in the *MQSA Final Rule*¹, for which “positive” examinations are limited to those for which tissue diagnosis is recommended. A meaningful audit of screening examinations requires that the recommendation for recall imaging (BI-RADS® category 0) also be considered positive, and this includes screening examinations that are converted to diagnostic examinations when interpreted online because the additional imaging performed as part of the combined examination is, from an auditing perspective, the functional equivalent to recall for additional imaging on a different day. Also note that BI-RADS® category 3 assessments should not be used for screening mammography examinations; rather, these assessments should be used only after appropriate imaging workup of screening-detected findings. However, if contrary to recommended practice, a screening examination actually is assessed as BI-RADS® category 3 with the recommendation for short-interval follow-up imaging, then this is considered a positive screening examination because additional imaging is recommended before the next routine screening.

b. Breast US — For screening breast US, this usually involves an examination for which additional diagnostic breast US is performed to further evaluate a potentially abnormal screening-US-detected finding while the patient remains in the breast imaging facility.

As such, from an auditing perspective, this is functionally similar to online interpretation of a positive screening mammography examination, because images are recorded in addition to those obtained for the standard normal screening examination (these additional images usually involve paired images with perpendicular transducer orientation, often with and without caliper measurements of the finding, sometimes also using additional sonographic techniques such as Doppler, compound, harmonic, and elastographic imaging). Note that this definition of a positive screening US examination applies to all examinations performed with a handheld transducer, whether the operator is the interpreting physician or an appropriately trained breast imaging sonographer. As with online interpretation of a positive screening mammography examination, it is the recording of additional (diagnostic) images that causes the screening US examination to be considered positive ***for auditing purposes***, whether or not separate screening and diagnostic reports are issued. As an example, if a sonographer or physician performs a screening examination, and additional images are recorded in addition to the routine screening images described in the facility's policy and procedure manual, this will be audited as a positive screening examination. However, if only routine screening images are recorded and a negative or benign assessment is rendered, this will be audited as a negative screening examination because the recorded images were judged sufficient for documentation. Note that even though only routine screening images were recorded, a single image of one or more benign findings may indeed be sufficient, given that the finding(s) were fully evaluated at real-time scanning and that characteristically benign findings do not require comparison at subsequent US examination. The definition of a positive screening US examination also applies to the automated screening breast US examination for which the patient is recalled for additional diagnostic breast imaging examination(s) to further evaluate a potentially abnormal finding, and as such, is, from an auditing perspective, functionally similar to batch interpretation of a screening mammography examination for which the patient is recalled for additional diagnostic breast imaging. Also note that if any type of screening US examination is assessed as BI-RADS® category 3 with a recommendation for short-interval follow-up imaging (a full set of diagnostic images usually is recorded for probably benign findings because comparison with these several recorded images will be important at subsequent surveillance US examinations), this is considered a positive screening examination not only because of the additional (diagnostic) images recorded but also because additional imaging is recommended before the next routine screening.

- c. **Breast MRI** — Breast MRI is different from mammography and breast US because there usually is no difference in the images recorded for a screening or a diagnostic breast MRI examination; hence, a screening examination is simultaneously a full diagnostic examination. Therefore, a positive screening breast MRI examination will often directly recommend tissue diagnosis (BI-RADS® categories 4 and 5). Although experience is limited, a meaningful audit of breast MRI screening examinations requires that the rare recommendation for additional imaging (BI-RADS® category 0) also be considered

positive. BI-RADS® category 3 assessments may be used for breast MRI screening examinations, which are different from mammography and US for the same reason discussed earlier in this paragraph. However, if a breast MRI screening examination is assessed as BI-RADS® category 3 with a recommendation for short-interval follow-up, then this is considered a positive screening examination because additional imaging is recommended before the next routine screening.

5. Positive diagnostic examination (mammography, breast US, breast MRI) — This is a diagnostic examination for which tissue diagnosis is recommended (BI-RADS® categories 4 and 5).

6. Negative diagnostic examination (mammography, breast US, breast MRI) — This is a diagnostic examination for which tissue diagnosis is not recommended, that is, an examination assessed as negative, benign, or probably benign (BI-RADS® category 1, 2, or 3 respectively). Note that a category 3 assessment is considered negative at diagnostic breast imaging (because tissue diagnosis is not recommended), whereas a category 3 assessment is considered positive at screening breast imaging (because it is associated with the recommendation for additional imaging before the next routine screening examination).

7. Cancer — This is tissue diagnosis of either ductal carcinoma in situ (DCIS) or any type of primary (not metastatic) invasive breast carcinoma. For auditing purposes, positive truth is defined as a tissue diagnosis of cancer within an interval after breast imaging examination equal in length to the recommended screening interval. *In the definitions listed later in this section (true-positive, true-negative, etc.), as well as in the subsequent examples, the recommended screening interval is assumed to be 1 year (365 days) because this is by far the most frequently recommended interval in the United States. One should substitute a 2-year (or longer) interval in these definitions, if appropriate.*

Note that for diagnostic examinations performed as recall imaging (following BI-RADS® category 0 assessment at screening), the interval to cancer diagnosis begins on the date of the screening examination. For diagnostic examinations performed for other indications, the interval to cancer diagnosis begins on the date of the diagnostic examination.

8. True-Positive (TP) — There is tissue diagnosis of cancer within 1 year after a positive examination. Remember that BI-RADS® category 3 assessments made at screening are considered to be positive examinations.

9. True-Negative (TN) — There is no known tissue diagnosis of cancer within 1 year of a negative examination (BI-RADS® categories 1 or 2 for screening; BI-RADS® categories 1, 2, or 3 for diagnostic).

10. False-Negative (FN) — There is tissue diagnosis of cancer within 1 year of a negative

examination (BI-RADS® category 1 or 2 for screening, BI-RADS® category 1, 2, or 3 for diagnostic).

11. False-Positive (FP) — There are three separate definitions:

- a. **FP₁:** No known tissue diagnosis of cancer within 1 year of a positive screening examination. Remember that this includes BI-RADS® category 3 assessments made at screening.
- b. **FP₂:** No known tissue diagnosis of cancer within 1 year after recommendation for tissue diagnosis or surgical consultation on the basis of a positive examination (BI-RADS® category 4 or 5).
- c. **FP₃:** Concordant benign tissue diagnosis (or discordant benign tissue diagnosis and no known tissue diagnosis of cancer) within 1 year after recommendation for tissue diagnosis on the basis of a positive examination (BI-RADS® category 4 or 5).

Note: TP + TN + FP + FN = Total number of examinations.

This note refers to terms 9, 10, 11, and 12.

12. Positive Predictive Value (PPV) — There are three separate definitions:

- a. **PPV₁ (abnormal findings at screening):** The percentage of all positive screening examinations (usually BI-RADS® categories 0, 3, 4, and 5) that result in a tissue diagnosis of cancer within 1 year. A screening assessment of BI-RADS® category 4 or 5 is rare (use discouraged) for mammography, but is possible. This also includes BI-RADS® category 3 assessments made at screening. Because a positive screening examination at breast MRI almost always will involve a BI-RADS® category 4 or 5 assessment, the PPV₁ for MRI screening will be essentially the same as PPV₂.

$$\text{PPV}_1 = \text{TP}/(\text{number of positive screening examinations})$$

OR

$$\text{PPV}_1 = \text{TP}/(\text{TP} + \text{FP}_1) \text{ (see 11a for the definition of FP}_1\text{)}$$

- b. **PPV₂ (biopsy recommended):** The percentage of all diagnostic (or rarely, screening) examinations recommended for tissue diagnosis or surgical consultation (BI-RADS® categories 4 and 5) that result in a tissue diagnosis of cancer within 1 year.

$$\text{PPV}_2 = \text{TP}/(\text{number of screening or diagnostic examinations recommended for tissue diagnosis})$$

OR

$$\mathbf{PPV}_2 = \text{TP}/(\text{TP} + \text{FP}_2) \text{ (see 11b for the definition of } \text{FP}_2\text{)}$$

Note that PPV_2 is a metric designed to evaluate diagnostic imaging examinations. However, some published studies of **mammography screening** outcomes also report PPV_2 data. In the screening context, PPV_2 (or screening PPV_2) is based on a variant of the definition of FP_2 , in which the positive examination includes the rare screening examination at which tissue diagnosis is recommended (BI-RADS® categories 4 and 5), as well as the screening examination at which recall examination is recommended (BI-RADS® category 0), followed by a diagnostic examination at which tissue diagnosis is recommended for the same lesion (BI-RADS® categories 4 and 5). Therefore, screening PPV_2 is meant to indicate the downstream outcomes of tissue diagnoses that result from positive screening examinations, even if the recommendation for tissue diagnosis is made at the diagnostic imaging examination by a different interpreting physician than the screening interpreter who recommended only recall imaging. As such, screening PPV_2 is more pertinent as a measure of screening practice in general than as a direct measure of the performance of the interpreting physician who interpreted the screening examination.

- c. **PPV₃ (biopsy performed):** The percentage of all known biopsies done as a result of positive diagnostic examinations (BI-RADS® categories 4 and 5) that resulted in a tissue diagnosis of cancer within 1 year. PPV_3 is also known as the Biopsy Yield of Malignancy or the Positive Biopsy Rate (PBR).

$$\mathbf{PPV}_3 = \text{TP}/(\text{number of biopsies})$$

OR

$$\mathbf{PPV}_3 = \text{TP}/(\text{TP} + \text{FP}_3) \text{ (see 11c for the definition of } \text{FP}_3\text{)}$$

Note that although PPV_3 is a metric designed to evaluate diagnostic imaging examinations, it also is occasionally used for mammography screening examinations, using similar definitions and for similar purposes as the use of PPV_2 at screening (see 12b).

13. **Sensitivity** — The probability of interpreting an examination as positive when cancer exists. This is measured as the number of positive examinations for which there is a tissue diagnosis of cancer within 1 year of imaging examination, divided by all cancers present in the population examined in the same time period.

$$\mathbf{Sensitivity} = \text{TP}/(\text{TP} + \text{FN}) \text{ [FN comprises cancer cases missed at imaging]}$$

14. Specificity — The probability of interpreting an examination as negative when cancer does not exist. This is measured as the number of negative examinations for which there is no tissue diagnosis of cancer within 1 year of examination, divided by all examinations for which there is no tissue diagnosis of cancer within the same time period.

$$\text{Specificity} = \text{TN}/(\text{TN} + \text{FP})$$

15. Cancer Detection Rate — The number of cancers detected at imaging per 1000 patients examined.

- a. This metric is of value when calculated only for screening examinations, or when calculated separately for screening and diagnostic examinations.
- b. This may also be calculated separately for “prevalent” cancers (those found at first-time screening examination) and for “incident” cancers (those found at subsequent screening examination performed at or close to the recommended screening interval).

16. Abnormal Interpretation Rate — The percentage of examinations interpreted as positive. For screening, positive examinations usually involve BI-RADS® category 0 assessments for mammography and (for auditing purposes) breast US, but BI-RADS® categories 4 and 5 assessments for breast MRI. This also includes BI-RADS® category 3 assessments made at screening for all imaging modalities. For diagnostic imaging, positive examinations involve BI-RADS® category 4 and 5 assessments.

$$\text{Abnormal Interpretation Rate} = (\text{positive examinations}) / (\text{all examinations})$$

Note that many scientific publications describing screening mammography correctly assert that **Recall Rate** is equivalent to the Abnormal Interpretation Rate, and include BI-RADS® category 4 or 5 assessments in addition to BI-RADS® category 0 assessments for this calculation. This is done because BI-RADS® category 4 or 5 assessments at screening require prompt additional imaging evaluation to assess for the extent of disease and to plan for imaging-guided biopsy in addition to tissue diagnosis for virtually all of the few screening examinations that are given BI-RADS® category 4 or 5 assessments. Calculation of a recall rate is meaningful for screening mammography only if it actually represents the Abnormal Interpretation Rate, that is, only if **all** positive screening examinations are counted, not just those examinations recommended for recall. BI-RADS® category 0, 4, and 5 assessments should be counted as well as any category 3 assessments made at screening when calculating the abnormal interpretation (recall) rate at screening.

Figure 1. References for Biopsy Results — Screening and Diagnostic

BIOPSY RESULTS			
SCREENING		Positive (tissue diagnosis of cancer within 1 year)	Negative (concordant benign tissue diagnosis, or no tissue diagnosis of cancer within 1 year)
	Breast imaging positive (BI-RADS® categories 0, 3, 4, 5) ^a	TP	FP
	Breast imaging negative (BI-RADS® categories 1, 2)	FN	TN

$$\text{Sensitivity} = \text{TP}/(\text{TP} + \text{FN})$$

BIOPSY RESULTS

DIAGNOSTIC		Positive (tissue diagnosis of cancer within 1 year)	Negative (concordant benign tissue diagnosis, or no tissue diagnosis of cancer within 1 year)
	Breast imaging positive (BI-RADS® categories 4,5) ^a	TP	FP
	Breast imaging negative (BI-RADS® categories 1, 2, 3)	FN	TN

$$\text{Sensitivity} = \text{TP}/(\text{TP} + \text{FN})$$

$$\text{Specificity} = \text{TN}/(\text{TN} + \text{FP})$$

$$\text{PPV} = \text{TP}/(\text{TP} + \text{FP})$$

^aFor mammography — usually involves category 0 assessments but also includes rare category 4 or 5 assessments (use discouraged). For breast US — effectively involves category 0 assessments. For breast MRI — usually involves category 4 or 5 assessments; includes all category 3 assessments made at screening for mammography, US, and MRI.

II. THE BASIC CLINICALLY RELEVANT AUDIT

Certain minimum raw data should be collected and utilized to calculate important derived data that allow each interpreting physician to assess his or her overall performance in breast imaging interpretation. Only two of the raw data parameters (and none of the derived data calculations) are now required under the MQSA, and this applies only to mammography, so even a basic audit involves much more data collection and analysis than what is currently required by federal regulations.¹

Table 2. The Basic Clinically Relevant Audit

A. Data to Be Collected

1. Modality or modalities.
2. Dates of audit period and total number of examinations in that period.
3. Number of screening examinations; number of diagnostic examinations (separate audit statistics should be maintained for each).
4. Number of recommendations for additional imaging evaluation (recalls) (ACR BI-RADS® category 0 — "Need Additional Imaging Evaluation").
5. Number of recommendations for short-interval follow-up (ACR BI-RADS® category 3 — "Probably Benign").
6. Number of recommendations for tissue diagnosis (ACR BI-RADS® category 4 — "Suspicious" and category 5 — "Highly Suggestive of Malignancy").
7. Tissue diagnosis results: malignant or benign, for all ACR BI-RADS® category 0, 3, 4 and 5 assessments (ACR suggests that you keep separate data for fine-needle aspiration/core biopsy cases and for surgical biopsy cases). MQSA Final Rule requires that an attempt is made to collect tissue diagnosis results for those mammography examinations for which tissue diagnosis is recommended.²
8. Cancer staging: histologic type, invasive cancer size, nodal status, and tumor grade.
9. MQSA Final Rule also requires analysis of any *known* false-negative mammography examinations by attempting to obtain surgical and/or pathology results and by review of negative mammography examinations.²

B. Derived Data to Be Calculated

1. True-positives (TP)
2. False-positives (FP_1 , FP_2 , FP_3)
3. Positive predictive value (PPV_1 , PPV_2 , PPV_3)
 - a. In a screening/diagnostic facility, PPV may be obtained in one or more of three ways:
 1. PPV_1 — based on positive cases at screening examination, which includes recommendation for anything other than routine screening (BI-RADS® categories 0, 3, 4, 5)

- 2. PPV_2 — based on recommendation for tissue diagnosis (BI-RADS® categories 4, 5)
- 3. PPV_3 — based on results of biopsies actually performed (otherwise known as biopsy yield of malignancy or positive biopsy rate [PBR])
 - b. If screening exclusively, obtain in only one way:
 - 1. PPV_1 — based on “positive” cases at screening examination, which includes recommendation for anything other than routine screening (BI-RADS® categories 0, 3, 4, 5)
 - 4. Cancer detection rate
 - 5. Percentage of invasive cancers that are node-negative
 - 6. Percentage of cancers that are “minimal” (minimal cancer is defined as invasive cancer ≤ 1 cm, or ductal carcinoma in situ [DCIS] of any size)
 - 7. Percentage of cancers that are stage 0 or 1
 - 8. Abnormal interpretation (recall) rate for screening examinations

Collection of these data requires proper coding of the data elements for efficient retrieval, often requiring considerable effort. However, once collected and calculated, these data allow clinically relevant measurement of one’s practice outcomes by providing quantifiable evidence in pursuit of the three major goals of breast cancer screening:

1. Find a high percentage of the cancers that exist in a screening population (measurement: cancer detection rate).
2. Find these cancers within an acceptable range of recommendation for additional imaging and recommendation for tissue diagnosis, in an effort to minimize cost and morbidity (measurement: abnormal interpretation [recall] rate, positive predictive values).
3. Find a high percentage of small, node-negative, early-stage cancers, which are more likely to be curable (measurement: percentages of node-negative, minimal, and stage 0 + 1 cancers).

Auditing data are more clinically useful if the outcomes observed for a given breast imaging facility or for an individual interpreting physician are compared with standard performance parameters that have been designated as acceptable. To this end, for mammography the numbers obtained for each of the data elements in [Table 1](#) may be compared to:

1. Benchmarks reported by the Breast Cancer Surveillance Consortium (BCSC), derived from very large numbers of screening and diagnostic mammography examinations that are likely to be representative of practice in the United States ([Tables 3](#) and [6](#)).

2. Recommendations derived by a panel of expert breast imaging interpreting physicians, based on critical analysis of scientific data published in the peer-reviewed literature (including BCSC data), as well as extensive personal experience ([Table 7](#)).

3. Outcomes reported from the ACR National Mammography Database (<https://nrdr.acr.org/Portal/NMD/Main/page.aspx>).

Selected performance outcomes for screening US have been reported in single-institution and multi-institution studies. The auditing definitions in most of these studies differ, at least somewhat, from those established in this edition of BI-RADS®. Since it is expected that all future auditing for screening US will be conducted using BI-RADS® definitions and approaches, only those already published data that follow BI-RADS® practice are cited herein as benchmark data.

MRI benchmarks should generally be in the range of those established for mammography. These have been accepted as appropriate for a screening program in terms of patient tolerance of biopsies and cost benefit. Supporting data are provided for screening breast MRI examination ([Table 5](#)).

Table 3. Analysis of Medical Audit Data: BCSC Mammography Screening Benchmarks^a

Cancer detection rate (per 1,000 examinations)	4.7
Median size of invasive cancers (in mm)	14.0
Percentage node-negative of invasive cancers	77.3%
Percentage minimal cancer ^b	52.6%
Percentage stage 0 or 1 cancer	74.8%
Abnormal interpretation (recall) rate	10.6%
PPV ₁ (abnormal interpretation)	4.4%
PPV ₂ (recommendation for tissue diagnosis)	25.4%
PPV ₃ (biopsy performed)	31.0%
Sensitivity (if measurable) ^c	79.0%
Specificity (if measurable) ^c	89.8%

^aOriginal article describes methodology in detail.³ BCSC data are updated periodically and reported at <http://breastscreening.cancer.gov/data/benchmarks/screening/>. Updated data are presented in this table, comprising 4,032,556 screening mammography examinations, 1996-2005, collected from 152 mammography facilities and 803 interpreting physicians that serve a geographically and ethnically representative sample of the United States population. Average data are presented here, but the source material also includes data on ranges and percentiles of performance.

^bMinimal cancer is invasive cancer ≤ 1 cm or ductal carcinoma in situ.

^cSensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

Table 4. Analysis of Medical Audit Data: Breast US Screening Benchmarks^a

Cancer detection rate (per 1,000 examinations)	3.7
Median size of invasive cancers (in mm)	10.0
Percentage node-negative of invasive cancers	96%
Percentage minimal cancer	TBD ^b
Percentage stage 0 or 1 cancer	TBD ^b
Abnormal interpretation (recall) rate	TBD ^b
PPV1 (abnormal interpretation)	TBD ^b
PPV2 (recommendation for tissue diagnosis)	TBD ^b
PPV3 (biopsy performed)	7.4%
Sensitivity (if measurable) ^c	TBD ^b
Specificity (if measurable) ^c	TBD ^b

^aOriginal article describes methodology in detail, but involves women with substantially elevated risk for breast cancer.⁴ If available, data are presented for incidence rather than prevalence screening to parallel the great majority of service screening in clinical practice. Furthermore, because these data are derived from skilled US screening practices involved in the conduct of a research study, they are different from the BCSC data displayed in Table 3 (derived from service screening among practices that serve a geographically and ethnically representative sample of the United States population). Therefore, the US data displayed in this table may be more an indication of expert-practice outcomes than community-practice outcomes in high-risk women rather than women whose only risk factor is dense breasts.

^bTBD (to be determined) – No definitive data exist for these items, especially for women whose only risk factor is dense breasts.

^cSensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

There are insufficient rigorous data at this time to address benchmarks for diagnostic breast MRI and US examination.

Table 5. Analysis of Medical Audit Data: Breast MRI Screening Benchmarks^a

Cancer detection rate (per 1,000 examinations)	20-30
Median size of invasive cancers (in mm)	TBD ^b
Percentage node-negative of invasive cancers	>80%
Percentage minimal cancer ^c	>50%
Percentage stage 0 or 1 cancer	TBD ^b
PPV ₂ (recommendation for tissue diagnosis)	15%
PPV ₃ (biopsy performed)	20-50%
Sensitivity (if measurable) ^d	>80%
Specificity (if measurable) ^d	85-90%

^a Analysis of five prospective screening MRI trials of women with hereditary predisposition for breast cancer.⁵⁻⁹ Because these data are derived from skilled screening MRI practices involved in the conduct of research studies, they are different from the BCSC data displayed in Table 3 (derived from service screening among practices that serve a geographically and ethnically representative sample of the United States population). Therefore, the MRI data displayed in this table may be more an indication of expert-practice outcomes than community-practice outcomes.

^b TBD = to be determined.

^c Minimal cancer is invasive cancer ≤ 1 cm or ductal carcinoma in situ.

^d Sensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

There are insufficient rigorous data at this time to address benchmarks for diagnostic breast MRI and US examination.

Table 6. Analysis of Medical Audit Data: BCSC Diagnostic Mammography Benchmarks^a

	Palpable ^b	All Examinations
Cancer detection rate (per 1,000 examinations)	57.7	30.0
Median size of invasive cancers (in mm)	21.8	17.0
Percentage node-negative of invasive cancers	56.5%	68.2%
Percentage minimal cancer ^c	15.2%	39.8%
Percentage stage 0 or 1 cancer	37.0%	60.7%
Abnormal interpretation (recall) rate	13.3%	9.6%
PPV ₂ (recommendation for tissue diagnosis)	43.7%	31.2%
PPV ₃ (biopsy performed)	49.1%	35.9%
Sensitivity (if measurable) ^d	87.8%	83.1%
Specificity (if measurable) ^d	92.2%	93.2%

^a Original article describes methodology in detail.¹⁰ BCSC data are updated periodically and reported at <http://breastscreening.cancer.gov/data/benchmarks/diagnostic/>. Updated data are presented in this table, comprising 401,572 diagnostic mammography examinations, 1996-2005, collected from 153 mammography facilities and 741 interpreting physicians that serve a geographically and ethnically representative sample of the United States population. Average data are presented here, but the source material also includes data on ranges and percentiles of performance.

^b Patients undergoing diagnostic mammography performed to evaluate palpable lumps have a higher probability of having breast cancer than all patients undergoing diagnostic mammography. This accounts for the differences in observed outcomes.

^c Minimal cancer is invasive cancer \leq 1 cm, or ductal carcinoma in situ.

^d Sensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

Table 7. Analysis of Medical Audit Data: Acceptable Ranges of Screening Mammography Performance^a

Cancer detection rate (per 1,000 examinations)	≥ 2.5
Abnormal interpretation (recall) rate	5%-12%
PPV ₁ (abnormal interpretation)	3%-8%
PPV ₂ (recommendation for tissue diagnosis)	20%-40%
Sensitivity (if measurable) ^b	≥ 75%
Specificity (if measurable) ^b	88%-95%

^aOriginal article describes methodology in detail.¹¹ Performance ranges were determined given the assumption that outcome for a metric outside any of the stated ranges would prompt review of individual interpreting physicians in the context of outcomes for all the other metrics and the specific practice setting, and that if appropriate, consideration be given for additional training.

^b Sensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

Table 8. Analysis of Medical Audit Data: Acceptable Ranges of Diagnostic Mammography Performance^a

	Workup of Abnormal Screening	Palpable Lump
Cancer detection rate (per 1,000 examinations)	≥ 20	≥ 40
Abnormal interpretation rate	8%-25%	10%-25%
PPV ₂ (recommendation for tissue diagnosis)	15%-40%	25%-50%
PPV ₃ (biopsy performed)	20%-45%	30%-55%
Sensitivity (if measurable) ^b	≥ 80%	≥ 85%
Specificity (if measurable)	80%-95%	83%-95%

^a Original article describes methodology in detail.¹² Performance ranges were determined given the assumption that outcome for a metric outside any of the stated ranges would prompt review of individual interpreting physicians in the context of outcomes for all the other metrics and the specific practice setting, and that if appropriate, consideration be given for additional training.

^b Sensitivity and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

The following issues should be carefully considered when conducting a breast imaging audit:

A clinically useful audit includes calculation of several rather than only one or two metrics, the more the better. Furthermore, evaluation of the interpretive performance of a breast imaging facility or of an individual interpreting physician should not be based on only one or two metrics, but rather on the combination of metrics described for the basic clinically relevant audit (or for the more complete audit as outlined in the next portion of this section).

FDA regulations¹ specify that a facility's first audit analysis be **initiated** (end date of audit period established) no later than 12 months after the date the facility becomes certified. This audit analysis must be **completed** within an additional 12 months. The additional 12 months are needed for performance of diagnostic procedures (including biopsies), for collection of outcomes data, and to allow **sufficient time for determination of cancer status**. Therefore, an audit conducted at the end of 2012 would involve examinations performed during calendar year 2011. Subsequent audit analyses must be conducted at least once every 12 months, also involving the additional 12 months to produce meaningful audit outcomes. Data are typically collected and analyzed for 12-month periods. However, due to the random variation in the comparatively small number of cases collected in any individual practice audit (especially with regard to cancers detected at screening) and the

demographic differences in patient populations served by individual practices, comparison with benchmark data may be less meaningful than assessing the trend of one's own performance over time or assessing this trend in comparison to that of other members of the same practice. Moreover, for low-volume practices, and especially for individual interpreting physicians who work in low-volume practices, some metrics will lack precision because the number of cancers is small. An acceptable workaround, after the first-year audit is established, is to perform annual audits involving the most recent 2, 3, or 4 years rather than just the most recent year. For example, an audit analysis conducted at the end of 2013 may include data from 2010, 2011, and 2012; the following audit analysis at the end of 2014 would include data from 2011, 2012, and 2013, etc.

Whether data are being collected for the basic clinically relevant audit or for the more complete audit as outlined in the next portion of this section, separate audit statistics should be maintained for screening and diagnostic examinations, as all of the audit outcomes are significantly different for screening and diagnostic examinations.^{3, 9, 13} However, some breast imaging practices may find it impractical or impossible to segregate screening from diagnostic examinations during an audit. In this situation, expected outcomes will vary depending on the relative frequencies of screening and diagnostic examinations. If one is able to estimate this case mix, simple mathematical modeling may be applied to combined screening/diagnostic audit data to derive suggested overall benchmark data.¹⁴

Whether data are being collected for the basic clinically relevant audit, or for the more complete audit as outlined in the next portion of this section, all audit data should be monitored for each interpreting physician and in the aggregate for the entire breast imaging facility.

Tissue diagnosis data for fine-needle aspiration cytology/core biopsy may be collected separately from surgical biopsy data, but should be included with surgical biopsy data for statistical calculations. Only biopsies performed for diagnostic purposes (benign versus malignant) should be counted, not surgical excisions performed to completely remove known cancer. Refer to Frequently Asked (Questions #7 and #8) later in this section for discussion of how to audit high-risk lesions.

Sensitivity and specificity are frequently reported in publications of research studies and centrally organized government-funded screening programs. This is done in part because the data are readily available, and because the combination of data on sensitivity and specificity facilitate receiver operating characteristic (ROC) analysis, a widely used approach to assess the important trade-offs between cancer detection (true positive) and false-positive outcomes. However, almost all breast imaging facilities in the United States cannot reliably calculate sensitivity and specificity because they are unable to acquire sufficiently accurate data on false-negative and true-negative examinations (unless they have access to linkage of audit data with the breast cancer data in a regional tumor registry or in the tumor registry of a large organization that serves a captive, nonmobile patient population).

Nevertheless, all breast imaging facilities may collect useful data on detected cancers (invasive cancer size, lymph node status, cancer stage), permitting successful evaluation of the same trade-offs that are assessed by ROC analysis. This alternative approach has the added benefit that tumor metrics may be more clinically relevant than sensitivity and specificity, because invasive cancer size, lymph node status, and cancer stage actually are used in planning cancer treatment. Furthermore, high sensitivity does not necessarily imply improved outcome. In this regard, note that sensitivity is consistently observed to be higher for mammography screening at 2-year intervals than at yearly intervals (presumably because most of the cancers depicted at biennial versus annual screening are larger and therefore easier to identify), whereas invasive cancer size, lymph node status, and cancer stage indicate a less favorable prognosis for mammography screening at 2-year intervals than at yearly intervals (presumably because many of the annually detected cancers are detected 1 year earlier).

Also, the potential for under-ascertainment of true-positive examinations exists. Although the MQSA Final Rule requires that an attempt is made to obtain tissue diagnosis results for those mammography examinations for which tissue diagnosis is recommended, it may not be practical for some mammography facilities to identify as many cancers among positive examinations as are identified at facilities that participate in the BCSC (audit data from BCSC facilities are routinely linked with the breast cancer data in a regional tumor registry). Therefore, those BCSC benchmarks, listed previously in Tables 3 and 6), that are dependent on cancer ascertainment, especially cancer detection rate, will likely exceed the performance that is measured at a given mammography facility. The potential for under-ascertainment of true-positive examinations is higher for US and MRI because the FDA regulations¹ do not apply to these examinations, so that breast imaging facilities are not compelled to attempt to obtain tissue diagnosis results for MRI and US examinations for which tissue diagnosis is recommended.

Breast imaging practices that record only overall BI-RADS® assessments for diagnostic mammography/US examinations performed concurrently should expect outcomes that are different from published benchmarks, which involve the performance of diagnostic mammography alone. Currently there are no published benchmarks for overall mammography/US examinations performed concurrently. By recording separate assessments for the mammography and US components as well as the overall assessment, one may derive outcomes for each component examination as well as for the overall combined) examination. The same statements in this paragraph also apply to overall BI-RADS® assessments made for other combinations of diagnostic breast imaging examinations performed concurrently (mammography/MRI and US/MRI and mammography/US/MRI).

III. THE MORE COMPLETE AUDIT

Although the basic clinically relevant audit provides nearly all the data needed to assess one's performance in interpreting breast imaging examinations, certain additional audit data may also be collected and utilized to calculate derived data that provide further important information regarding breast imaging performance. The following comprise the data for such a comprehensive audit:

Table 9. The More Complete Audit: Data to Be Collected

1. Modality or modalities.
2. Dates of audit period and total number of examinations in that period (usually a 12-month period).
3. Risk factors:
 - Patient's age at the time of the examination.
 - Breast and ovarian cancer history: personal or family (especially premenopausal breast cancer in first-degree relative — mother, sister, or daughter).
 - Previous biopsy-proven hyperplasia with cellular atypia, or lobular carcinoma in situ (LCIS).
 - Hormone replacement therapy.
 - Breast density as estimated at mammography.
4. Number and type of examination: screening (asymptomatic), diagnostic (evaluation of clinical symptoms or signs suggesting the possibility of breast cancer, evaluation of screening-detected findings, short-interval follow-up examinations).^a
5. First-time examination or not.
6. Number of recommendations for:
 - Additional imaging evaluation (recall) (BI-RADS® category 0 = "Need Additional Imaging Evaluation").
 - Routine (usually annual) screening (BI-RADS® category 1 = "Negative" and category 2 = "Benign").
 - Short-interval follow-up (BI-RADS® category 3 = "Probably Benign").
 - Tissue diagnosis (BI-RADS® category 4 = "Suspicious" and category 5 = "Highly Suggestive of Malignancy").
7. Tissue diagnosis results: malignant or benign, for all ACR BI-RADS® category 0, 3, 4 and 5 assessments (keep separate data for fine-needle aspiration, core biopsy and surgical biopsy cases). MQSA Final Rule requires that an attempt is made to collect tissue diagnosis results only for mammography examinations for which tissue diagnosis is recommended.²

8. Cancer data:
 - Imaging findings: mass, calcifications, other signs of malignancy (including architectural distortion and the several types of asymmetry), no signs of malignancy.
 - Palpable or nonpalpable at time of imaging examination.
 - **Cancer staging: histologic type, invasive cancer size, nodal status, and tumor grade.**
9. MQSA Final Rule also requires analysis of any **known false-negative mammography examinations by attempting to obtain surgical and/or pathology results and by review of negative mammography examinations.**²

Note: **Bolded** items indicate data included in the basic clinically relevant mammography audit.

^aSeparate audit statistics should be maintained for screening examinations and for each of the subtypes of diagnostic examinations.^{3,9,13}

Table 10. The More Complete Audit: Derived Data to Be Calculated

1. **True-positives, false-positives (three sub-definitions: FP_1 , FP_2 , FP_3), true-negatives (if measurable)^a, and false-negatives (if measurable).**^a
2. **Positive predictive value**
 - a. **In a screening/diagnostic facility, PPV may be obtained in one or more of three ways:**
 - **PPV₁** — based on positive cases at screening examination, which includes recommendation for anything other than routine screening (BI-RADS® categories 0, 3, 4, 5).
 - **PPV₂** — based on recommendation for tissue diagnosis (BI-RADS® category 4, 5) — separately for screening and the subtypes of diagnostic examinations.
 - **PPV₃** — based on results of biopsies actually performed (otherwise known as **biopsy yield of malignancy or positive biopsy rate [PBR]**) — separately for screening and the subtypes of diagnostic examinations.
 - b. **If screening exclusively, obtain in only one way:**
 - **PPV₁** — based on positive cases at screening examination, which includes recommendation for anything other than routine screening (BI-RADS® categories 0, 3, 4, 5).

3. Cancer detection rate
 - **Cancer detection rate for screening and diagnostic examinations**
 - Prevalent and incident cancer detection rates for screening examinations
 - Cancer detection rate for the several types of diagnostic examinations
 - Cancer detection rates within various age groups
4. Percentage of cancers that are nonpalpable — separately for screening and the several types of diagnostic examinations
5. **Percentage of invasive cancers that are node-negative** — separately for screening and the subtypes of diagnostic examinations
6. **Percentage of cancers that are “minimal” (minimal cancer is defined as node-negative invasive cancer ≤ 1 cm, or ductal carcinoma in situ [DCIS] of any size)** — separately for screening and the subtypes of diagnostic examinations
7. **Percentage of cancers that are stage 0 or I** — separately for screening and the subtypes of diagnostic examinations
8. **Abnormal interpretation (recall) rate for screening examinations**
9. Abnormal interpretation rate for the subtypes of diagnostic examinations
10. Sensitivity (if measurable)^a
11. Specificity (if measurable)^a

Note: **Bolded** items indicate data included in the basic clinically relevant mammography audit.

^a True-negatives, false-negatives, sensitivity, and specificity are measured with reasonable accuracy only if outcomes data are linked to breast cancer data in a regional tumor registry.

IV. EXAMPLES OF HOW TO CLASSIFY EXAMINATIONS AS TRUE-POSITIVE, TRUE-NEGATIVE, FALSE-POSITIVE, AND FALSE-NEGATIVE

Remember, at screening examination, BI-RADS® categories 0, 4, and 5 are positive assessments, whereas BI-RADS® categories 1 and 2 are negative assessments. When online interpretation is made for screening mammography or screening breast US and additional diagnostic image(s) are recorded, the screening component of the examination ***is audited as positive (the same as recall for additional imaging, BI-RADS® category 0), whether or not separate screening and diagnostic reports are issued.*** BI-RADS® category 3 assessments made at screening also are considered to be positive assessments. The rationale behind these definitions of positive and negative is that the interpretation of screening examinations involves the binary decision of recommending additional imaging prior to next routine screening (positive) versus recommending no additional imaging until next routine screening (negative). At diagnostic examination, BI-RADS® categories 4 and 5 are positive assessments, whereas BI-RADS® categories 1, 2, and 3 are negative assessments, based on the definition that a positive diagnostic examination is one for which tissue diagnosis is recommended. True or false outcomes depend on whether there is a tissue diagnosis of breast cancer within 1 year of the breast imaging examination (1 year is stated here and in all subsequent examples because this is by far the most frequently recommended screening interval in the United States; if a longer screening interval is recommended, the length of that interval should be substituted for 1 year both here and in all subsequent examples).

A. BI-RADS® Assessment Concordant with Management Recommendation

1. A woman has a screening examination that is read as negative or benign and no breast cancer is diagnosed within 1 year of the examination. The interpretation is negative, and because no cancer is diagnosed within 1 year, the examination is classified as ***true-negative (TN).***
2. A woman has a screening examination and is recalled for additional imaging evaluation of a finding (BI-RADS® category 0). The diagnostic breast imaging examination is read as suspicious (BI-RADS® category 4) with a recommendation for tissue diagnosis, a biopsy is performed, and the tissue diagnosis is malignant. Both the screening and diagnostic interpretations are positive, and because cancer is diagnosed

within 1 year, both examinations are classified as **true-positive (TP)**.

3. A woman has a screening examination and is recalled for additional imaging evaluation of a finding (BI-RADS® category 0). The diagnostic examination leads to a biopsy. The biopsy is concordantly benign, and breast cancer is not diagnosed within 1 year of the screening examination. The screening interpretation is positive (BI-RADS® category 0). The diagnostic interpretation also is positive (BI-RADS® category 4 or 5). Both the screening and diagnostic examinations are classified as **false-positive (FP)** because no breast cancer is diagnosed within 1 year.
4. A woman has a screening examination for which a benign calcified fibroadenoma is described (BI-RADS® category 2). A palpable mass develops within 1 year of examination, is biopsied, and is found to be malignant. The screening interpretation is negative. However, because malignancy is diagnosed within 1 year, the examination is classified as **false-negative (FN)**.
5. An asymptomatic woman has a diagnostic breast imaging examination following recall (BI-RADS® category 0) for a noncalcified circumscribed mass identified at screening. Diagnostic mammography and targeted breast US examination show the mass to be consistent with but not diagnostic of a benign cyst. The diagnostic examination is assessed as suspicious (BI-RADS® category 4), and a diagnostic cyst aspiration is recommended. At US-guided cyst aspiration, cyst fluid is obtained and the mass is no longer visible at post-aspiration imaging. The cyst fluid is discarded. No breast cancer is diagnosed within 1 year. The screening interpretation is positive (BI-RADS® category 0). The diagnostic interpretation also is positive (BI-RADS® category 4), and tissue diagnosis is recommended. Both the screening and diagnostic mammogram and US are classified as **false-positive (FP)** because no breast cancer is diagnosed within 1 year. Note that diagnostic cyst aspiration, performed for the purpose of confirming the suspected diagnosis of cyst for cases in which mammographic and sonographic findings are not characteristically benign, is considered to represent a tissue diagnosis despite the absence of a pathology diagnosis.
6. A woman with recent-onset focal unilateral breast pain has a diagnostic breast imaging examination. Diagnostic mammography and targeted breast US examination show a characteristically benign mass at the symptomatic site, diagnostic of a benign cyst. The diagnostic examination is assessed as benign (BI-RADS® category 2) and routine mammography screening is recommended, but therapeutic cyst aspiration also is recommended to provide symptomatic relief. At US-guided cyst aspiration, cyst fluid is obtained and the mass is no longer visible at post-aspiration imaging. The cyst fluid is discarded. No breast cancer is diagnosed within 1 year. The diagnostic interpretation is negative (BI-RADS® category 2). The diagnostic examination is classified as **true-negative (TN)** because no breast cancer is diagnosed within the year. Note that therapeutic cyst aspiration, performed for characteristically benign cysts in order to provide symptomatic relief of focal pain or tenderness, is not considered to represent a tissue

diagnosis because the interventional procedure is not recommended for diagnostic purposes.

7. A woman has a diagnostic breast imaging examination because of a clinically suspicious lesion. This examination is assessed as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging. The area of clinical suspicion is biopsied within 1 year and is found to be malignant. The initial diagnostic interpretation is negative (BI-RADS® category 3). Because malignancy is diagnosed within 1 year, this examination is classified as **false-negative (FN)**. Note that most of the scientific literature that justifies mammographic surveillance for probably benign findings excludes palpable lesions.
8. A woman has a screening examination and is recalled for additional imaging evaluation of a finding (BI-RADS® category 0). The diagnostic breast imaging examination is read as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging. At 6 months, the second diagnostic examination shows a change, and tissue diagnosis is recommended (BI-RADS® category 4). Malignancy is found. The screening interpretation is positive (BI-RADS® category 0). The first diagnostic interpretation is negative (BI-RADS® category 3). The second (6-month) diagnostic interpretation is positive (BI-RADS® category 4). Breast cancer indeed is diagnosed within 1 year of all three examinations. Thus, the **screening** examination is classified as **true-positive (TP)**, the **first diagnostic** examination is classified as **false-negative (FN)**, and the **second diagnostic** examination is classified as **true-positive (TP)**.
9. A woman has a screening examination and is recalled for additional imaging evaluation of a finding (BI-RADS® category 0). The diagnostic breast imaging examination is read as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging. At 6 months, the second diagnostic examination shows a change, and tissue diagnosis is recommended (BI-RADS® category 4). A biopsy is done, is concordantly benign, and no breast cancer is found within 1 year of the follow-up examination. Thus, the screening interpretation is positive, the first diagnostic interpretation is negative, and the second (6-month) diagnostic interpretation is positive. Because no breast cancer is found within 1 year of any of the examinations, the **screening** interpretation is classified as **false-positive (FP)**, the **first diagnostic** interpretation is classified as **true-negative (TN)**, and the **second diagnostic** interpretation is classified as **false-positive (FP)**.
10. A woman has a screening examination and is recalled for additional imaging evaluation of a finding (BI-RADS® category 0). The diagnostic breast imaging examination is performed a few days later and is read as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging. At 6 months, the second diagnostic examination shows no change, and again is read as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging. The woman returns for her next examination 7 months later, at which time a

change is seen, tissue diagnosis is recommended (BI-RADS® category 4), and malignancy is found. Thus, the screening interpretation is positive, the first diagnostic interpretation is negative, the second (6-month) diagnostic examination is negative and the last (13-month) interpretation is positive. Because no breast cancer is found within 1 year of the ***screening*** examination and the ***first diagnostic*** examination, these are classified as ***false-positive (FP)*** and ***true-negative (TN)***, respectively. Because breast cancer indeed is diagnosed within 1 year of the ***second*** (6-month) examination and the ***last*** (13-month) examination, these are classified as ***false-negative (FN)*** and ***true-positive (TP)***, respectively.

11. A woman has a mammography screening examination that is assessed as probably benign (BI-RADS® category 3) with a recommendation for short-interval follow-up imaging, despite the guidance provided in BI-RADS® recommending not to use category 3 assessments at mammography screening. At 6 months, diagnostic breast imaging examination shows the finding to be characteristically benign, resulting in a BI-RADS® category 2 assessment. No breast cancer is diagnosed during the next year. The screening assessment is positive (additional imaging recommended prior to next routine screening) and the diagnostic assessment is negative. Because no cancer is diagnosed within 1 year, the ***screening*** examination is classified as ***false-positive (FP)*** and the ***diagnostic*** examination is classified as ***true-negative (TN)***. Note that proper classification of BI-RADS® category 3 screening assessments as positive interpretations causes these cases to be counted in the calculation of the abnormal interpretation (recall) rate, so radiologists should not rationalize their use of assessment category 3 at screening by the false premise that recall rate will be lowered. Actually, in the clinical scenario illustrated here, the only effect of using a BI-RADS® category 3 assessment at screening is to delay by 6 months the diagnostic breast imaging examination that results in a definitively benign diagnosis, thereby prolonging the period of uncertainty and the patient's anxiety.

12. A woman has a mammography screening examination at a facility in which the examination is interpreted before the woman leaves the premises, so that additional imaging can be performed immediately if needed. A noncalcified asymmetry is seen in one breast, only on the craniocaudal view. The interpreting radiologist obtains a second craniocaudal view to clarify the significance of this asymmetry. The examination is then interpreted as negative because the asymmetry (judged to represent a summation artifact) is not visible on the repeat craniocaudal view. No breast cancer is found within 1 year of examination. This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a negative (BI-RADS® category 1) assessment. Thus, the ***screening*** component of this examination should be classified as ***false-positive (FP)*** and the ***diagnostic*** component of the examination should be classified as ***true-negative (TN)***. Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to

a diagnostic examination to clarify a mammographic finding identified on standard screening views, this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered.

13. A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A focal area of posterior acoustic shadowing is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify the significance of this finding, and records one or more images to demonstrate that the focal area of shadowing is not reproducible. The completed examination is then interpreted as negative because the initially depicted finding is judged to be an artifact rather than a true abnormality. No breast cancer is found within 1 year of examination. This single examination in effect represents a positive screening examination (BI-RADS® category 0) for which the woman was recalled for additional diagnostic imaging that resulted in a negative (BI-RADS® category 1) assessment. Thus, the **screening** component of this examination should be classified as **false-positive (FP)** and the **diagnostic** component of the examination should be classified as **true-negative (TN)**. Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and a positive or negative diagnostic interpretation depending on the final assessment that is rendered. Also note that in the provided scenario, had the interpreting physician determined at repeat scanning that the initially depicted finding was an artifact without documenting this by recording one or more additional images, the completed **screening** examination would have contained only standard images, been assessed as negative (BI-RADS® category 1), and therefore been audited as **true-negative (TN)**. Also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding; however, this exposure might be mitigated by adding a sentence to the screening report indicating that the depicted finding is considered to be an artifact because it could not be reproduced at subsequent rescanning (no additional images recorded).

14. A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A mass that may be a simple cyst is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify the significance of this finding, and records one or more images to demonstrate that the mass indeed is a simple cyst. The cyst is described in the screening report, and the completed examination is assessed as benign. No breast cancer is found within 1 year

of examination. This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a benign (BI-RADS® category 2) assessment. Thus, the **screening** component of this examination should be classified as **false-positive (FP)** and the **diagnostic** component of the examination should be classified as **true-negative (TN)**. Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered. Note that if the interpreting physician in the provided scenario had determined at repeat scanning that the initially depicted finding was characteristically benign without documenting this by recording one or more additional images, the completed **screening** examination would have contained only standard images, been assessed as benign (BI-RADS® category 2), and therefore been audited as **true-negative (TN)**. Also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding; however, this exposure might be mitigated by adding a sentence to the screening report indicating that the depicted finding is considered to be characteristically benign at subsequent rescanning (no additional images recorded).

15. A woman has a breast US screening examination using a hand-held transducer, so that additional imaging can be performed immediately if needed. A mass that is characteristic of a simple cyst is visible on one of the standard images recorded by the breast sonographer as part of the screening examination. The interpreting physician decides to further scan the patient to verify the presence of a simple cyst, verifies at real-time scanning that the mass indeed is a simple cyst, but does not record any additional images. The cyst is described in the screening report, and the completed examination is assessed as benign. No breast cancer is found within 1 year of examination. Because no additional (diagnostic) images were recorded, the examination is audited purely as a screening examination that resulted in a benign (BI-RADS® category 2) assessment, classified as **true-negative (TN)**. Note that whenever a screening US examination is interpreted before a woman leaves the premises, but the examination is not converted to a diagnostic examination by the recording of additional images (even though rescanning is performed to clarify a sonographic finding identified on a standard screening view), the examination is audited purely as a screening examination. Also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding; however, in the case of a finding correctly assessed as benign (BI-RADS® category 2), the likelihood of malignancy is essentially zero. Furthermore, note that in routine clinical practice, the

presence of one or more characteristically benign findings does not require full documentation by diagnostic imaging because 1) the likelihood of malignancy is essentially zero, and 2) the fully documented appearance of the finding(s) will not be needed for future comparison, because a) if the finding(s) again appear characteristically benign at a subsequent examination, interval change in size would be irrelevant, and b) if the finding(s) do not appear characteristically benign, biopsy would be recommended. Finally, note that even though characteristically benign finding(s) are depicted on standard screening view(s) in an asymptomatic woman, the interpreting physician may reasonably decide not to describe the finding(s) in the breast imaging report, instead rendering a negative (BI-RADS® category 1) assessment.

16. A woman has a screening examination showing no gross abnormalities but that is assessed as incomplete (BI-RADS® category 0), need comparison with prior studies. The previous examinations are obtained 2 weeks later, confirming no abnormalities in either breast, and an addendum is issued with a negative (BI-RADS® category 1) assessment and recommendation for routine screening in 1 year. The negative screening interpretation supersedes (replaces) the positive assessment made because of the recommendation for comparison with prior studies. If no cancer is diagnosed within 1 year, the examination is classified as **true-negative (TN)**. Note that in this scenario, the second interpretation replaces the initial interpretation, which effectively was deferred until prior examinations were available for comparison.

17. A woman has a screening examination showing no gross abnormalities but that is assessed as incomplete (BI-RADS® category 0), need comparison with prior studies. The previous examinations are obtained 2 weeks later, demonstrating interval appearance of a focal asymmetry (developing asymmetry) in one breast that was not apparent until its interval appearance was recognized. An addendum is issued, repeating the BI-RADS® category 0 assessment but now with a recommendation for additional imaging evaluation. The subsequent diagnostic imaging examination is assessed as suspicious (BI-RADS® category 4) with a recommendation for tissue diagnosis, a biopsy is performed, and the tissue diagnosis is malignant. The positive screening interpretation recommending additional imaging evaluation supersedes (replaces) the positive assessment that was made because of the recommendation for comparison with prior studies. The diagnostic interpretation also is positive. Because cancer is diagnosed within 1 year, both the **screening and diagnostic** examinations are classified as **true-positive (TP)**. Note that in this scenario, even though both screening interpretations were positive, the second interpretation replaces the initial interpretation, which effectively was deferred until prior examinations were available for comparison.

18. A woman has a screening examination showing no gross abnormalities but that is assessed as incomplete (BI-RADS® category 0), need comparison with prior studies. The previous examinations are not obtained within 30 days and an addendum is issued, repeating the BI-RADS® category 0 assessment but now with a recommendation for additional imaging evaluation. The subsequent diagnostic imaging examination is

assessed as negative (BI-RADS® category 1) with a recommendation for routine screening. Breast cancer is not diagnosed within 1 year of examination. The positive screening interpretation recommending additional imaging evaluation supersedes (replaces) the positive assessment that was made because of the recommendation for comparison with prior studies. The diagnostic interpretation is negative. Because cancer is not diagnosed within 1 year, the **screening** examination is classified as **false-positive (FP)** and the **diagnostic** examination is classified as **true-negative (TN)**. Note that in this scenario, the second positive screening interpretation replaces the initial interpretation, which effectively was deferred until prior examinations were found to be unavailable for comparison. Also note, as indicated by this example and the two preceding examples, that one should **never** audit an incomplete assessment (BI-RADS® category 0), need comparison with prior studies. Each of these assessments is superseded, either by an addendum assessment based on comparison with prior examination(s) or by an addendum assessment made within 30 days if no prior examinations become available for comparison.

19. A woman has a mammography screening examination showing no gross abnormalities but that is assessed as incomplete (BI-RADS® category 0) with the recommendation for additional imaging because of substantial motion blur on both oblique-view mammograms. When the woman returns for additional imaging, repeat oblique views are obtained, no abnormalities are identified in either breast, and an addendum is issued with a negative (BI-RADS® category 1) assessment and recommendation for routine screening in 1 year. The negative screening interpretation supersedes (replaces) the positive assessment made as a technical recall. Because no cancer is diagnosed within 1 year, the examination is classified as **true-negative (TN)**. Note that in this scenario, the second interpretation replaces the initial interpretation, which effectively was deferred until technically adequate images were obtained. Also note that the approach to auditing the technical recall examination is similar to the auditing approach used for the incomplete assessment (BI-RADS® category 0), need comparison with prior studies.

20. A woman presents with a palpable mass in the left breast. The diagnostic breast imaging examination is read as suspicious for the (contralateral) right breast with a recommendation for tissue diagnosis. Both the palpable mass and the breast imaging lesion are biopsied. The palpable mass is found to be benign, and the breast imaging lesion is found to be malignant. The diagnostic interpretation is positive (BI-RADS® category 4) and because malignancy indeed is diagnosed within 1 year on the side of breast imaging abnormality, the diagnostic examination is classified as **true-positive (TP)**.

21. A woman presents with a palpable mass in the left breast. The diagnostic mammography examination is read as suspicious for the (contralateral) right breast with a recommendation for tissue diagnosis. The palpable mass is biopsied and is found to be malignant. The mammographic lesion is biopsied, is found to be concordantly

benign, and no breast cancer is diagnosed in this breast within 1 year of examination. The diagnostic interpretation is positive (BI-RADS® category 4) for the breast in which no breast cancer is found within 1 year of examination, and the interpretation also is negative (BI-RADS® category 1) for the breast in which breast cancer indeed is diagnosed within 1 year. Thus the diagnostic interpretation is classified as **false-positive (FP)** for the **right** breast and as **false-negative (FN)** for the **left** breast. Note that the MQSA Final Rule requires only a single overall assessment for both breasts for all mammography examinations.² So for most mammography facilities, which would not capture separate-breast assessments, this examination would be classified as **true-positive (TP)** because the overall positive interpretation would appear to match the subsequent cancer diagnosis, even though the cancer diagnosis applies to the breast contralateral to the breast with the suspicious mammographic finding. However, the FDA has approved an alternative standard for the reporting of assessments, which under certain circumstances allows a mammography facility to report separate assessments for each breast rather than a combined assessment for both breasts (<http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/regulations/ucm259285.htm>). Thus, mammography facilities that choose to report separate-breast assessments under the alternative FDA standard would record more clinically meaningful although less favorable outcomes data.

22. A woman has a mammography examination showing a finding that is assessed as suspicious (BI-RADS® category 4) and then found to be benign at biopsy, but an unsuspected cancer is diagnosed elsewhere in the same breast within 1 year. All mammography facilities, including those that capture separate-breast assessment data, would classify such an examination as **true-positive (TP)** because the positive (BI-RADS® category 4) assessment for that breast would appear to match the subsequent cancer diagnosis, even though interpretation of the suspicious but benign finding actually was **false-positive (FP)** and interpretation of the unrecognized cancer actually was **false-negative (FN)**. The FDA does not allow abnormality-level assessments to replace a breast-level assessment in the mammography report. However, if a mammography facility chooses to collect abnormality-level data anyway, the resultant audit outcomes would be more clinically meaningful, albeit less favorable.

B. BI-RADS® Assessment Does Not Match Management Recommendation

All of the previous clinical scenarios assume that the BI-RADS® assessment category is concordant with the accompanying management recommendation in the breast imaging report. That is, category 1 and 2 assessments accompany recommendations for routine screening, category 3 assessments accompany recommendations for imaging surveillance, category 0 assessments accompany recommendations for additional imaging, and category 4 and 5 assessments accompany recommendations for tissue diagnosis. However, just as radiologists occasionally do not follow BI-RADS® guidance by

making category 3 assessments at mammography screening, so do they occasionally render (nonrecommended) discordant breast imaging reports, in which the BI-RADS® assessment category does not match the accompanying management recommendation. There are numerous discordant combinations of assessment category and management recommendation. Two of these are described below to illustrate how to make proper assessments so as to avoid such discordances.

1. A woman has a baseline screening examination assessed as probably benign (BI-RADS® category 3) with a management recommendation for routine screening, because the interpreting radiologist does not want to produce undue patient anxiety for an imaging finding that is so likely benign that repeat imaging can wait until 1 year from now. For auditing purposes, this incorrectly assessed examination is classified as a negative screening examination because no additional imaging is recommended until the next screening. However, in this scenario, the proper assessment would have been benign (BI-RADS® category 2), which would have been concordant with the recommendation for routine screening. Remember that if the interpreting radiologist had assessed the screening examination as probably benign (BI-RADS® category 3) with a suggested management of short-interval follow-up (which is not a recommended practice), for auditing purposes, this would be classified as a positive screening examination because additional imaging was recommended before next routine screening.
2. A woman has a baseline mammography screening examination assessed as benign (BI-RADS® category 2) with a management recommendation for short-interval follow-up imaging in 6 months because of the interpretive uncertainty produced by the availability of only the two standard-projection mammographic views for a finding judged to be very likely benign. For auditing purposes, this incorrectly assessed examination is classified as a positive screening examination because additional imaging is recommended before the next screening. In this scenario, the proper and concordant assessment would have been incomplete (BI-RADS® category 0), recommend additional imaging evaluation, which likely would have permitted a more confident and prompt (diagnostic) category 2 assessment and management recommendation of routine screening. Note that at screening, recall for additional imaging is recommended in order to complete a full diagnostic imaging workup before deciding to recommend short-interval follow-up imaging.

V. AREAS OF CONFUSION IN THE DATA COLLECTION PROCESS

A. Double Reading

Which reader gets credit for interpreted cases?

For the facility-wide audit, the most practical approach is the simplest: count each examination once, based on the final assessment after double reading is completed. However, in attributing assessments to the individual radiologists who participate in double reading, the method of assigning responsibility should depend on the type of double reading used.

1. If the first radiologist performs thorough interpretations and the second radiologist performs “quick reads” with knowledge of the interpretations made by the first radiologist, looking only to change negative assessments to positive (or alternatively, to change positive assessments to negative), the first radiologist will assume responsibility for all examinations based on his or her individual assessments, but the second radiologist will assume separate responsibility only for those examinations for which he or she changes the final assessment.
2. If the two radiologists interpret examinations independently and consensus is determined by predefined rules (for example, an examination is given a positive final assessment if either radiologist makes a positive individual assessment, or, alternatively, an examination is given a positive final assessment only if both radiologists make positive individual assessments), then each radiologist will assume separate responsibility for examinations based on his/her individual assessments.
3. If the two radiologists interpret examinations independently but then arrive at consensus by re-reviewing examinations and coming to a joint decision, then each radiologist will assume separate responsibility for examinations based on the final assessment after double reading is completed.
4. If the two radiologists interpret examinations together (simultaneously), then each radiologist will assume separate responsibility for examinations based on the joint assessment that they make.
5. If the two radiologists interpret examinations independently but consensus is made by a third radiologist, then all three radiologists will assume separate responsibility for examinations, the first two readers based on their individual assessments and the

consensus reader based on the final assessment that he or she makes.

Note that for all previous examples, the assignment of responsibility relates only to the performance of individual radiologists at audit (for quality assurance purposes), not in the clinical-care context that may have medicolegal consequences. The mammography facility that utilizes double reading may choose to adopt different approaches in deciding which radiologist(s) to name on double-read mammography reports.

B. The “Screening” Versus the “Diagnostic Workup” Radiologist

If two different radiologists in a mammography facility interpret the screening and diagnostic examinations for the same patient, who gets credit for finding a cancer when it is correctly identified?

The answer to this question is analogous to that provided in the previous discussion concerning double reading. When two different radiologists interpret one or more examinations for the same patient, each radiologist should assume separate responsibility for the examination(s) that he or she interprets. If a screening and a diagnostic examination are each interpreted as positive, and there is a subsequent diagnosis of breast cancer within 1 year, then both the screening and diagnostic examinations are classified as true-positive (TP), and each radiologist gets credit for his or her interpretation.

C. Cancer Identified at Routine Screening Examination with Cancer Diagnosis LESS THAN 1 YEAR After the Previous Negative Screening Examination

Is the person who missed the cancer on the previous negative examination charged with a FN, or is the person who detected the cancer at the “early” second screening examination credited with a TP?

Because the first screening examination was interpreted as negative but breast cancer was diagnosed within 1 year, this examination is classified as FN. Because the second screening examination was read as positive and breast cancer was diagnosed shortly thereafter, this examination is classified as TP.

For purposes of the audits of the two individual radiologists, each will assume responsibility for his or her individual assessment, the first radiologist for a FN interpretation, and the second radiologist for a TP interpretation.

It may appear to be unfair that the first radiologist is assigned a FN outcome when the only reason for this outcome is that the woman returned for screening sufficiently early that a breast cancer diagnosis was made less than 1 year after her previous examination. However, for auditing to produce meaningful overall results, consistent and uniformly applied rules must be utilized. Therefore, subjectivity must be eliminated from the process of determining outcomes, such as allowing one to decide whether what appears to be a FN outcome is actually the result of early subsequent screening (one then would

need to examine the previous screening examination in retrospect to decide whether it should or should not have been interpreted as negative).

There are two reasons why this scenario is encountered infrequently. First, true or false outcomes depend on whether there is a **tissue diagnosis** of breast cancer within 1 year of examination. It often takes several days to weeks after the detection of an abnormality at early subsequent screening until a tissue diagnosis of breast cancer is actually obtained, thus allowing the 1-year anniversary of the previous screening examination to be passed. Second, insurance reimbursement often is denied when a woman undergoes screening substantially less than 1 year after her most recent screening examination, so that most breast imaging facilities establish a policy that discourages or prevents the scheduling of early screening examinations.

D. The Group of Examinations Assessed as Probably Benign (BI-RADS® Category 3) with a Recommendation for Short-Interval Follow-up and Surveillance Imaging

Should they be audited separately?

If these data are available, as in the more complete audit ([Table 9](#)) then initial category 3 assessments may be evaluated separately from routine screening examinations and from diagnostic examinations performed to evaluate clinical problems. Indeed, it would be of value to establish how frequently those examinations assessed as probably benign do continue to demonstrate benign findings. If too many (i.e., > 2%) of these cases are found subsequently to represent breast cancer, this would indicate incorrect assessment of truly suspicious findings as being probably benign. Such an outcome would be identified only through a separate “category 3 audit.” This would permit appropriate action to be taken by the radiologist(s) involved to modify the interpretive criteria being used to assess lesions as probably benign.

E. The Group of Examinations Assessed as Known Biopsy-Proven Malignancy (BI-RADS® Category 6)

Should they be audited separately?

It is not necessary to audit mammograms assessed as BI-RADS® category 6 separately. A typical example would involve a woman with known breast cancer (proved at recent core biopsy, not yet excised) who has a diagnostic examination to assess response of the tumor to neoadjuvant chemotherapy (BI-RADS® category 6). All such interpretations should **not** be audited. There are two reasons. First, these examinations are performed to evaluate response to pre-excision treatment, not to evaluate for the presence or absence of malignancy. As such, the purpose of performing these examinations falls outside the scope of a breast imaging audit. Second, it is not appropriate to include mammograms assessed as BI-RADS® category 6 in the audit. The likelihood that breast cancer will be

diagnosed within 1 year of examination is extremely high. Inclusion of such examinations among the other (large majority of) diagnostic examinations would inappropriately skew the overall audit results for a mammography facility and for the individual radiologist interpreter, thus rendering selected outcomes (cancer detection rate, PPV₂, PPV₃, sensitivity, etc.) very difficult to assess.

VI. FREQUENTLY ASKED QUESTIONS CONCERNING BREAST IMAGING AUDITS

A. All Breast Imaging Modalities

1. According to the BI-RADS® Atlas, category 0 assessments at screening are considered positive for auditing purposes. Does this apply to examinations for which comparison with prior examination(s) is recommended or to examinations assessed as incomplete due to technical deficiency?

As discussed in Section IV, examples #16, #17, and #18, when an incomplete (BI-RADS® category 0) screening assessment is rendered with the recommendation to await prior examination(s) for comparison, interpretation of the current examination actually is being deferred until informed by the imaging data provided by the previous examination(s). When such an interpretation ultimately is completed (either when previous examination[s] become available for comparison, or within 30 days if no comparison examination[s] become available), the initial category 0 assessment is **replaced** either by a final (category 1–5) assessment or by a category 0 assessment that recommends additional imaging. Hence, category 0 assessments that are made awaiting prior examination(s) for comparison are not included in audits at all (therefore considered neither positive nor negative), because these assessments always are replaced by something else. This same answer also applies to “technical repeat” or “technical recall” examinations. Such examinations, assessed as incomplete (BI-RADS® category 0) due to technical deficiency in image quality, also are not included in audits because they are replaced by examinations of acceptable image quality (for mammography, batch-interpreted screening examinations with poor breast positioning, inadequate breast compression, motion blur, improper exposure, etc.; for breast US, screening examinations with improper setting of focal zone, field-of-view, gray scale gain, etc.; and for breast MRI, examinations with poor breast positioning, inadequate or absent contrast injection, and image artifacts resulting from patient motion, fat-suppression failure, etc.).

2. The BI-RADS® Atlas does not indicate whether to consider category 0 assessments at diagnostic imaging as positive or negative for auditing purposes. How should these examinations be audited?

It is important to understand that an incomplete (BI-RADS® category 0) assessment should be made only rarely at diagnostic imaging, because such an examination is monitored in real time by the radiologist so that imaging is sufficiently complete to render a final (category 1–5) assessment. However, unusual extenuating

circumstances may prevent completion of a diagnostic examination, such as when imaging equipment or technologist personnel are not immediately available, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. This situation is analogous to the screening examination assessed as incomplete (BI-RADS® category 0) awaiting prior examination(s) for comparison. Interpretation of the current (in this case, diagnostic) examination is deferred until it is completed, at which time the initial category 0 assessment is **replaced** by a final (category 1–5) assessment. Hence, category 0 assessments at diagnostic imaging are not included in audits at all (therefore considered neither positive nor negative) because these assessments always are replaced by final assessments.

3. When a diagnostic breast imaging examination is completed for a woman who has been recalled after screening examination, should an addendum be made to the screening report changing the assessment from BI-RADS® category 0 to whatever final assessment is made on the basis of the diagnostic imaging examination?

No, the assessment at screening has not changed. For purposes of auditing, this screening assessment is considered positive (action before the next routine screening), and the clinical outcome will determine whether this assessment is TP (cancer diagnosis within 1 year of screening) or FP (no cancer diagnosis within 1 year of screening). If screening assessments were amended to reflect the final assessments made after diagnostic imaging examination, auditing of screening outcomes would not be meaningful.

4. Is it necessary for a breast imaging facility to separate the medical audit into screening and diagnostic components?

FDA regulations¹ do not require auditing at the level of complexity described in parts of this section, including separate auditing of screening and diagnostic examinations. However, periodic auditing is sound medical practice and the best way for a breast imaging practice and its individual radiologists to determine acceptable clinical performance. The ACR strongly recommends that screening and diagnostic examinations be audited separately because the outcomes of these two types of examination differ significantly.^{3, 9, 13} For practices that are unable to segregate examinations by screening versus diagnostic indication, mathematical models have been developed to provide guidance on how to evaluate combined audit data.¹⁴

5. Published benchmarks for PPV₂ and PPV₃ are similar. Which one is the more accurate indicator of interpretive performance?

PPV₂ and PPV₃ are performance measures that relate primarily to diagnostic mammography examination. PPV₂ involves the positive predictive value calculation (percentage of positive examinations that are TP) based on the number of

examinations for which tissue diagnosis is recommended, whereas PPV₃ involves the same calculation based on the number of examinations for which tissue diagnosis actually is performed. Because performed biopsies are more likely to yield a cancer diagnosis than biopsies not performed, one would expect the value of PPV₃ to be somewhat higher than that of PPV₂, and this is what is observed in almost all breast imaging audits. PPV₃ is the more accurate indicator of cancer status because biopsy results may be obtained in virtually all cases. Furthermore, the data collected for the PPV₃ calculation are the same as what is required by the FDA regulations¹. However, the advantage of the PPV₂ calculation is that it relates directly to the performance of the interpreting radiologist (involving all examinations for which tissue diagnosis is recommended), whereas the interpreting radiologist has little if any control in selecting the subset of PPV₂ cases that qualify for the PPV₃ calculation (biopsies actually performed). Therefore, although PPV₃ is the more accurate indicator of cancer status, PPV₂ is the more accurate indicator of interpretive performance.

6. Why is it important to use several (rather than just one or two) performance metrics in conducting a breast imaging audit?

A breast imaging audit is clinically relevant to the extent that it provides meaningful indicators of interpretive performance. It stands to reason that the more data collected and analyzed, the more comprehensive an understanding one may derive about underlying interpretive performance. Analysis of performance based on a single metric is of little value. For example, what useful information can one deduce from the recall rate alone? One can deduce simply that a given percentage of screened women are recommended for additional imaging evaluation, but nothing about how frequently biopsy is recommended, the likelihood of cancer when biopsy is recommended, the frequency of cancer detection, or whether detected cancers are clinically occult or early in stage (hence favorable in prognosis). A similar, very limited amount of information may be derived from any other single performance metric or pair of metrics. Instead, the data collected in and derived from the basic clinically relevant audit, as described in [Table 2](#) should provide sufficient insight into the interpretive performance of a breast imaging practice and its individual radiologists. The more complete audit described in [Tables 9](#) and [10](#) should provide an even more comprehensive understanding of performance.

7. When doing medical audits, are the pathology-proven high-risk lesions described in the BI-RADS® Atlas (lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia, peripheral duct papillomas, phyllodes tumor) considered “truth positive” in categorizing examinations as TP or FP?

No, these are considered **negative** pathology results. Note that some cases of pleomorphic lobular carcinoma in situ (LCIS) may be treated as breast cancer.

However, to maintain consistency in auditing, a uniform definition of cancer is required (no exceptions permitted), so this definition does not include the diagnosis of pleomorphic LCIS. **Nor, by the way, does the definition of cancer include malignant phyllodes tumor, breast sarcoma, metastasis, lymphoma, leukemia, etc. These are malignancies that occur within the breast but are not breast cancer.**

8. A patient has a diagnostic examination assessed as suspicious (BI-RADS® category 4) with a management recommendation for tissue diagnosis. Within the next month, she then has a core biopsy showing atypical ductal hyperplasia (ADH), followed 1 week later by an excisional biopsy showing ductal carcinoma in situ and invasive ductal carcinoma. Should the diagnostic examination be classified as both FP (for the ADH) and TP (for the cancer)?

In this scenario, the diagnostic examination was interpreted as positive (BI-RADS® category 4 with a management recommendation for tissue diagnosis). Because there is a tissue diagnosis of cancer within the next year, the examination is classified as TP. Note that the examination would still be classified as TP even if there were many biopsies within the next year and only one of them yielded a cancer diagnosis.

B. Mammography

1. Isn't it internally inconsistent to consider BI-RADS® category 3 assessments positive at screening but negative at diagnostic imaging?

No, this actually is internally consistent. The binary management decision at screening involves recommending action before the next routine screening (positive) versus recommending no action until the next routine screening (negative), whereas the management decision pertinent to diagnostic imaging involves recommending tissue diagnosis (positive) versus anything other than tissue diagnosis (negative). Also remember that, as stated previously, BI-RADS® category 3 assessments are not recommended for use at screening.

2. Does MQSA require auditing of BI-RADS® category 0 assessments?

No, FDA regulations¹ specify that mammography facilities "collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician." The FDA considers mammograms with a final assessment of suspicious (BI-RADS® category 4) or highly suggestive of malignancy (BI-RADS® category 5) to be positive, not category 0 assessments. However, the ACR asserts that a meaningful audit of screening examinations requires that a management recommendation for additional imaging evaluation (BI-RADS® category 0) also be considered positive, and that facilities should collect and review outcome data on category 0 screening examinations.

3. We always do a postprocedure mammography examination after an imaging-guided biopsy. We bill for the mammography examination separately from the biopsy procedure and use the FDA's final assessment of "Post Procedure Mammograms for Marker Placement." However, because this final assessment is not included in the BI-RADS® Atlas, the software vendor for our breast imaging reporting system has not provided this option in their medical audit software. Consequently, we cannot include these examinations in our annual breast imaging audit. Do you have any suggestions for how we can include these examinations?

These mammography examinations are performed to assess for successful treatment (proper marker-clip placement) rather than for the presence or absence of malignancy. Therefore, it is not appropriate to include these examinations in the breast imaging audit.

4. We have several mobile mammography units, each accredited and certified as a separate facility. FDA regulations require that each facility has a separate mammography medical outcomes audit. May we combine the mammography medical outcomes audits for these facilities and units?

Yes, the FDA has approved an alternative standard (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm135407.htm>) allowing mobile unit operators to combine mammography medical outcomes audits under certain conditions. In situations where multiple mobile mammography facilities are under the same ownership, they may be treated collectively as a single facility for the purposes of meeting FDA audit requirements, if all of the following conditions are met.

Each facility must consist of a single mobile mammography unit.

- The same entity or group administers the operation of all of the included mobile facilities.
- The same lead interpreting physician has the responsibility for assuring that all of the included mobile facilities meet FDA requirements.
- The same group of radiologists interprets all of the images from all of the included mobile facilities.
- All of the included mobile facilities provide services to the same patient population.

5. The following discussion also appears previously as item #12 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-

Negative.” It is duplicated here because the topic is specific to mammography, and because questions are frequently asked about how to audit in this clinical scenario.

A woman has a mammography screening examination at a facility in which the examination is interpreted before the woman leaves the premises, so that additional imaging can be performed immediately if needed. A noncalcified asymmetry is seen in one breast, only on the craniocaudal view. The interpreting radiologist obtains a second craniocaudal view to clarify the significance of this asymmetry. The examination is then interpreted as negative because the asymmetry (judged to represent a summation artifact) is not visible on the repeat craniocaudal view. No breast cancer is found within 1 year of examination. How should this scenario be classified?

This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a negative (BI-RADS® category 1) assessment. Thus the screening component of this examination should be classified as false-positive (FP) and the diagnostic component of the examination should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a mammographic finding identified on standard screening views, this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered.

C. Ultrasound

1. In most practices, a completed screening breast US examination contains the same images as a full diagnostic US examination. Why are screening breast US examinations audited using an approach similar to that for mammography rather than breast MRI, for which a screening examination is considered to be equivalent to a full diagnostic examination?

As explained in the Introduction to the Follow-up and Outcome Monitoring section, auditing must be based on objective and reproducible rules. Furthermore, auditing for all breast imaging modalities should utilize the same rules to facilitate cross-modality comparisons, except when the unique aspects of a given modality justify a different approach. Auditing procedures for mammography have been established for many years and clinically representative benchmarks using these auditing procedures have been published, so that an individual mammography facility (or individual interpreting physician) may reliably compare observed outcomes with these benchmarks. Only now, with publication of the fifth edition of BI-RADS®, are auditing procedures being established for breast US and breast MRI examinations. And now is the appropriate time to establish these procedures because the use of US and MRI for both screening and diagnostic breast imaging has become widespread. It

is not only reasonable but also highly desirable to base the auditing of US and MRI examinations on the procedures used for mammography, whenever practical. In defining positive screening examinations, mammography auditing utilizes the objective and reproducible rule of whether one or more additional images is recorded to further characterize a finding depicted on standard screening images, in so doing, taking into account the scenario of online interpretation. This rule also may be applied to US auditing because, contrary to what is stated in the question, additional (nonstandard) images are recorded to further characterize findings on some but not all screening breast US examinations. Indeed, each breast imaging facility should indicate in its policy and procedure manual what standard images should be recorded for normal (BI-RADS® category 1 or 2) screening examinations. Furthermore, the screening breast US report should indicate whether standard or standard plus additional (diagnostic) images were recorded. This will allow for objective and reproducible auditing, especially if screening breast US reports are created using a computerized reporting system, which would prospectively capture data on whether additional images were recorded, hence permitting auditing of additional-image examinations as screening-positive and diagnostic-positive/negative depending on the final assessment rendered. The mammography auditing rule defining positive screening examinations (whether one or more additional images is recorded to further characterize a finding depicted on standard screening images) does not apply to screening breast MRI examinations because there usually is no difference in the standard images recorded for a screening and diagnostic breast MRI examination; hence, a screening examination is simultaneously a full diagnostic examination. As a result of this difference, the outcome parameters of recall rate and PPV₁ do not apply to the auditing of screening breast MRI examinations, as they do to both screening mammography and screening breast US.

2. I do not understand why BI-RADS® assessment category 3 is not recommended at screening for mammography but there is no mention of this for US. Why this difference in recommendations?

BI-RADS® assessment category 3 is not recommended at screening for mammography because a full diagnostic breast imaging workup should be completed before rendering a category 3 assessment. In most breast imaging practices, mammography screening examinations are interpreted in batches (after women have left the breast imaging center), so there is no opportunity to complete the diagnostic workup before interpreting the screening examination. However, for almost all breast imaging practices, US screening currently is interpreted online, while the woman remains in the breast imaging center. If an abnormal finding is identified at screening (whether on one or more images recorded by the breast sonographer or as seen during real-time scanning by the interpreting physician), additional nonstandard images (perpendicular images of the finding without and

with caliper measurements) will be recorded that supplement the screening examination with a simultaneous diagnostic examination. Hence, there would be no purpose in recommending against category 3 assessments at US screening because the diagnostic imaging workup would be completed simultaneously. Note that this same explanation is why there is no recommendation against using BI-RADS® assessment categories 4 or 5 at US screening. Such cases also would involve the recording of both screening and diagnostic images. Remember that for US screening examinations given a final assessment of category 3, 4, or 5, the screening component of the examination would be audited as positive while the diagnostic component of the examination would be audited as negative (if category 3) or positive (if category 4 or 5).

3. If handheld screening US is performed either by a physician or a technologist, does every potential abnormality identified at sonography need to be documented before an assessment is made?

Identification of findings ("every potential abnormality") at handheld US examination is accomplished in real time by the operator, whether this is a technologist or the interpreting physician. Then, selected images are recorded. The interpreting physician then renders an assessment in the screening US report. At times, abnormalities are being identified and documented by a non-physician, but it is the physician's ultimate responsibility to interpret the examination and render an assessment in the screening US report. The situation is straightforward if the screening examination is performed by the interpreting physician, because he or she completes interpretation in real time. Rarely, the interpreting physician may also call in a colleague for a second opinion. Thus, in the vast majority of cases, additional images need not be recorded since the characteristically benign findings may be safely dismissed after real-time scanning while those findings requiring further analysis and management can be appropriately documented. The situation is more complex if a technologist scans the breasts, depending upon the policy established in the breast imaging facility. In some facilities, the established policy is that the interpreting physician routinely rescans the patient if the technologist identifies a potential abnormality. Using this approach, the interpreting physician then decides at real-time scanning how to interpret the examination, appropriate images are recorded, and an assessment is rendered in the screening US report. In other facilities, the established policy is that the technologist records images of every potential abnormality she identifies, and then the interpreting physician decides whether these images are sufficient for rendering an assessment, hence whether rescanning is needed. The decision of whether or not to rescan, made by the interpreting physician, depends on how skilled the technologist is at detecting and recording potential abnormalities, how many images are recorded of each potential abnormality (this also is part of the established policy), how benign or suspicious each finding appears on the recorded image(s), and a variety of other factors.

The approaches described above will provide good patient care. Basic to these policies is usage of the full potential of US, which is its real time capability. Utilization of this capability may be assigned to a highly trained sonographer who is the agent of the interpreting physician in regards to detection and recording of potential findings.

4. I have been asked to do a screening ultrasound examination of both breasts. I have only handheld scanning equipment. How should I perform the examination?

There is no standard examination procedure for bilateral handheld whole-breast US, but in some research studies, such as ACRIN 6666,¹⁵ real-time, handheld sonography was performed by the interpreting physician, on a quadrant-by-quadrant basis without image capture. Transverse or antiradial scanning of a quadrant (sweeping from posterior to anterior) was most efficient, then longitudinal or radial scanning of that quadrant, concluding with scanning just posterior to the nipple. Representative images were captured: one of each quadrant in the radial plane at the same distance posterior to the nipple, 4 cm on average, with appropriate annotation of each image (for example, R breast, 10 o'clock, 4 cm FN), and last, recording of the retroareolar image. These were the images recorded when no findings were identified, and constituted the images for a negative (category 1) screening US examination. Note that ACRIN 6666 was a research study, for which there was interest in capturing fully documented (diagnostic) images of many findings that were assessed as benign at real time scanning and which probably contributed to the median examination time of 19 minutes.¹⁵ At service screening (screening in usual clinical practice), it will be much more time efficient to limit the frequency of recording fully documented images of benign-assessed findings, since these will be assessed as characteristically benign at real-time scanning and no further action is required prior to the next scheduled screening exam. For each characteristically benign finding that is described in the US report, consider recording only one representative image (instead of the standard negative image of that quadrant). Also note that it is not necessary to describe all characteristically benign findings in a screening US report. Indeed, in usual clinical practice (service screening), most interpreting physicians do not describe all characteristically benign findings at screening mammography. If a significant finding (one that will require either surveillance imaging or biopsy prior to the next scheduled screening exam) is identified during handheld scanning, return to it and record appropriate views, following the same procedure as for a diagnostic examination. This, in effect, converts the screening examination into a (recalled) diagnostic examination.

5. The following discussion also appears previously as item #13 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US and because questions are frequently asked about how to audit in this clinical scenario.

A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A focal area of posterior acoustic shadowing is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify the significance of this finding, and records one or more images to demonstrate that the focal area of shadowing is not reproducible. The completed examination is then interpreted as negative because the initially depicted finding is judged to be an artifact rather than a true abnormality. No breast cancer is found within 1 year of examination. How should this scenario be classified?

This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a negative (BI-RADS® category 1) assessment. Thus, the screening component of this examination should be classified as false-positive (FP), and the diagnostic component of the examination should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered. Also note if the interpreting physician in the provided scenario had determined at repeat scanning that the initially depicted finding was an artifact without documenting this by recording one or more additional images, the completed screening examination would have contained only standard images, been assessed as negative (BI-RADS® category 1), and therefore been audited as true-negative (TN). However, also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, although this exposure might be somewhat mitigated by adding a sentence to the screening report indicating that the depicted finding is considered to be an artifact because it could not be reproduced at subsequent rescanning (no additional images recorded).

6. The following discussion also appears previously as item #14 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US, and because questions are frequently asked about how to audit in this clinical scenario.

A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A mass that appears to be a simple cyst is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify

the significance of this finding, and records one or more images to demonstrate that the mass indeed is a simple cyst. The cyst is described in the screening report and the completed examination is assessed as benign. No breast cancer is found within 1 year of examination. How should this scenario be classified?

This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a benign (BI-RADS® category 2) assessment. Thus, the screening component of this examination should be classified as false-positive (FP), and the diagnostic component of the examination should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and a positive or negative diagnostic interpretation, depending on the final assessment that is rendered. Also note that in the provided scenario, if the interpreting physician in the provided scenario had determined at repeat scanning that the initially depicted finding was characteristically benign without documenting this by recording one or more additional images, the completed screening examination would have contained only standard images, been assessed as benign (BI-RADS® category 2), and therefore been audited as true-negative (TN). However, also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, although this exposure might be mitigated by adding a sentence to the screening report indicating that the depicted finding is considered to be characteristically benign at subsequent rescanning (no additional images recorded).

7. The following discussion also appears previously as item #15 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US and because questions are frequently asked about how to audit in this clinical scenario.

A woman has a breast US screening examination using a hand-held transducer, so that additional imaging can be performed immediately if needed. A mass that is characteristic of a simple cyst is visible on one of the standard images recorded by the breast sonographer as part of the screening examination. The interpreting physician decides to further scan the patient to verify the presence of a simple cyst, verifies at real-time scanning that the mass indeed is a simple cyst, but does not record any additional images. The cyst is described in the screening report and the completed examination is assessed as benign. No breast cancer is found within 1 year of examination. How should this scenario be classified?

Because no additional (diagnostic) images were recorded, the examination is audited purely as a screening examination that resulted in a benign (BI-RADS® category 2) assessment, classified as true-negative (TN). Note that whenever a screening US examination is interpreted before a woman leaves the premises, but the examination is not converted to a diagnostic examination by recording additional images (even though rescanning is performed to clarify a sonographic finding identified on a standard screening view), the examination is audited purely as a screening examination. Also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, but in the case of a finding correctly assessed as benign (BI-RADS® category 2), the likelihood of malignancy is essentially zero. Furthermore, note that in routine clinical practice, the presence of one or more characteristically benign findings does not require full documentation by diagnostic imaging, because 1) the likelihood of malignancy is essentially zero, and 2) the fully documented appearance of the finding(s) will not be needed for future comparison, because a) if the finding(s) again appear characteristically benign at a subsequent examination, interval change in size would be irrelevant, and b) if the finding(s) do not appear characteristically benign, biopsy would be recommended. Finally, note that even though characteristically benign finding(s) are depicted on standard screening view(s) in an asymptomatic woman, the interpreting physician may reasonably decide not to describe the finding(s) in the breast imaging report, instead rendering a negative (BI-RADS® category 1) assessment.

D. MRI

1. I do not understand why BI-RADS® assessment category 3 is not recommended at screening for mammography but accepted for MRI. Also, I see that a category 3 assessment should be considered positive, regardless of the modality. Why the differences in recommendations for use and why the similarity in how to audit category 3 assessments?

The first part of the answer is that MRI screening is unique in that the images recorded for a screening examination are usually identical to those recorded for a diagnostic examination, so that a breast MRI screening examination is simultaneously a full diagnostic examination (hence, a category 3 assessment is acceptable because, in effect, a full diagnostic examination also has been obtained). The second part of the answer is that a category 3 assessment at screening is considered positive at auditing, independent of screening modality, because the management recommendation (short-interval follow-up) is something other than routine screening in 1 year.

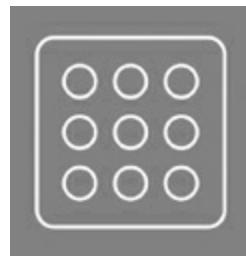
2. Why is it that the outcome parameters of recall rate and PPV, do not apply to breast MRI

screening, although they do apply to both mammography and breast US screening?

For auditing purposes, the definition of a positive screening examination is different for breast MRI than it is for both mammography and breast US. This is because mammography and breast US auditing utilize the objective and reproducible rule of whether one or more additional (diagnostic) images is recorded to further characterize a finding depicted on standard screening images. However, breast MRI is unique in that the images recorded for a screening examination are usually identical to those recorded for a diagnostic examination, so that a breast MRI screening examination is simultaneously a full diagnostic examination. The outcome parameters recall rate and PPV₁ relate only to purely screening examinations. Recall rate is meaningless for screening MRI because all patients simultaneously undergo what is effectively a diagnostic examination. Concerning PPV₁, were it to be calculated for breast MRI screening, it would be essentially the same as PPV₂.

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ACR BI-RADS®

Data Dictionary

2013

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REVISIONS

Date	Hardcopy Page(s)	Section	Description of Revisions
12/31/2013	—	—	Original issue
02/28/2014	87	Data Dictionary	“PDP - Peripheral duct papillomas” added to High Risk.
03/14/2014	75	Data Dictionary	Field Number 107, Management – Left breast. The text for Use changed to: “Required if audit data are reported at breast level, and management for the right breast is not reported.”
03/14/2014	76	Data Dictionary	Field Number 108, Management – Right breast. The text for Use changed to: “Required if audit data are reported at breast level, and management for the left breast is not reported.”
04/17/2015	10	Data Dictionary	New Field Number 8.1 added.
04/17/2015	10	Data Dictionary	New Field Number 8.2 added.
04/17/2015	29	Data Dictionary	Field Number 39, Additional imaging – modified to insert ‘Screening’ before ‘mammography and ultrasound only.’

DATA DICTIONARY ORGANIZATION

This data dictionary combines the data specifications for BI-RADS® and the National Mammography Database™ (NMD).

This section follows a format identifying the data fields, description of the field, logic for use of the field and recommended values for the field. Collection of the data will allow a facility to conduct appropriate follow-up and outcome monitoring. The data dictionary includes only those fields required for the basic and more complete medical audit, and supports the requirements for data collection found in the FDA mammography regulations. Unlike the data dictionary in the previous edition of BI-RADS®, it does not include fields specific to the Breast Cancer Surveillance Consortium.

Developers of BI-RADS® tracking systems may choose to include in such systems additional data fields that are not required for auditing purposes. Although data dictionaries that support these systems may include additional fields, they must not include specifications that conflict with the data fields listed here.

When participating in database or registry activities you must make sure that data are protected and comply with all state and federal regulations.

Dictionary Format: The information in the BI-RADS® Atlas Data Dictionary is organized according to:

Field number
Field name
NMD usage: A "Y" after "In NMD?" indicates that the field is used by the NMD.
Description
Use: Whether required or optional
Response: For example, "Select only one"
Values: Valid responses for field

Field names, descriptions, use or values modified by the user of this data dictionary must be identified as to source.

Dictionary Sections:

The dictionary contains sections for

- Audit Parameters
- Patient Demographic Data
- Physician Data
- Patient History for this Examination
- Study Data for this Examination
- Breast Tissue
- Findings
- Pathology Data

DATA DICTIONARY

Audit Parameters

1 . Start date of audit period	In NMD? N
---------------------------------------	------------------

Description: Date of the first examination to be included in the audit period

Use: Required

Response: Indicate start date of audit period.

Values: Any valid date in mm/dd/yyyy format

2 . End date of audit period	In NMD? N
-------------------------------------	------------------

Description: Date of the last examination to be included in the audit period

Use: Required

Response: Indicate end date of audit period.

Values: Any valid date in mm/dd/yyyy format

3 . Screening interval	In NMD? N
-------------------------------	------------------

Description: Length of screening interval in days

Use: Required

Response: Indicate length of screening interval in days.

Values: Any integer between 0 and 999

4 . Audit type

In NMD? N

Description: Indicates type of audit to be performed

Use: Required

Response: Select one.

Values:

- 1 Basic clinically relevant audit
- 2 More complete audit

5 . Laterality of audit data

In NMD? Y

Description: Indicates whether the audit captures separate-breast assessment data or patient-level assessment data

Use: Required

Response: Indicate whether audit data are reported at breast or patient level.

Values:

- 1 Separate-breast assessment data
- 2 Patient-level assessment data

6 . Combination examinations

In NMD? Y

Description:	Indicates whether the audit captures data for each component of combination examinations (e.g., separate assessments for mammography and ultrasound components), or for the combination examination only
Use:	Required
Response:	Indicate whether audit data are reported at component level or combination level.
Values:	
1	Component-level assessment data
2	Combination-level assessment data

7 . Category 3 screening assessment allowed

In NMD? N

Description:	Indicates whether the facility allows category 3 screening assessments
Use:	Required
Response:	Select one.
Values:	
0	No
1	Yes

8 . Category 4 or 5 screening assessment allowed

In NMD? N

Description: Indicates whether facility allows category 4 or 5 screening assessments

Use: Required

Response: Select one.

Values:

0 No

1 Yes

8.1 . Standard screening mammography imaging

In NMD? Y

Mammography only

Description: Indicates how the facility defines standard screening mammography images

Use: Required

Response: Select one.

Values: The BI-RADS® standard is in “ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography” (1 CC and 1 MLO per breast), including additional images only as needed to overcome technical deficiency or inadequate tissue coverage.

- 1 BI-RADS® standard screening mammography imaging is performed.
- 2 Mammography imaging other than BI-RADS® standard screening mammography imaging is performed.
- 3 The facility does not perform screening mammography imaging.

Ultrasound only

Description: Indicates whether the facility defines standard screening ultrasound images as defined in BI-RADS® 5th Ed.

Use: Required

Response: Select one.

Values: See BI-RADS® 5th Ed. Introduction to Follow-Up and Outcome Monitoring section (recording 1 image for each breast quadrant and the retroareolar region, hence 5 images per breast), including additional images only as needed to overcome technical deficiency

- 1 The BI-RADS®-recommended definition of recording standard screening ultrasound images is in use.
- 2 A definition of recording standard screening ultrasound images other than the BI-RADS®-recommended definition is in use.
- 3 The facility does not perform screening ultrasound imaging.

Patient Demographic Data

9 . Patient identifier

In NMD? Y

Description: Unique patient identifier within the facility

Use: Required if Social Security Number is not reported; optional otherwise

Response: Indicate patient identifier.

Values: Any value up to 50 characters in length

10 . Patient Social Security Number

In NMD? Y

Description: Patient Social Security Number

Use: Required if patient identifier is not reported; optional otherwise

Response: Indicate patient Social Security Number.

Values: Any valid Social Security Number in nnn-nn-nnnn format

11 . Patient date of birth

In NMD? Y

Description: Patient date of birth

Use: Required

Response: Indicate patient's date of birth.

Values: Any valid date in mm/dd/yyyy format

12. Patient sex

In NMD? Y

Description: Patient sex**Use:** Required**Response:** Select one.**Values:**

- 1 Male
- 2 Female
- 9 Unknown

13 . Physician identifier

In NMD? Y

Description: Unique identifier of the interpreting physician, such as the National Provider Identifier

Use: Optional

Response: Indicate one unique identifier for each interpreting physician taking responsibility for the assessment.

Values: Any value up to 10 characters in length

14 . Physician-level assessment - Left breast

In NMD? Y

Description: Assessment made by an individual physician when double reading - Left breast

Use: Required if a physician identifier is reported and the physician's assessment differs from the final assessment assigned to the examination; not applicable if a physician identifier is not reported; optional otherwise

Response: Select one.

Values:

Incomplete Assessment

Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data.

- 0 Category 0:
(Mammography only)
Incomplete - Need
additional imaging
evaluation and/or prior
mammograms for
comparison
(Ultrasound and MRI only)
Incomplete - Need
additional imaging
evaluation

Final Assessment

- | | |
|---|---|
| 1 Category 1: Negative | Essentially 0% likelihood of malignancy |
| 2 Category 2: Benign | Essentially 0% likelihood of malignancy |
| 3 Category 3: Probably benign | > 0% but \leq 2% likelihood of malignancy |
| 4 Category 4: Suspicious | > 2% but $<$ 95% likelihood of malignancy |
| 5 Category 5: Highly suggestive of malignancy | \geq 95% likelihood of malignancy |
| 6 Category 6: Known biopsy-proven malignancy | |

**15 . Physician-level assessment - Left breast - Subcategory In NMD? Y
of category 4**

Mammography and ultrasound only

Description: Subcategory of a category 4 assessment made by an individual physician when double reading - Left breast

Use: Optional if a category 4 physician-level assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | |
|--|---|
| A Category 4A: Low suspicion for malignancy | > 2% to ≤ 10% likelihood of malignancy |
| B Category 4B: Moderate suspicion for malignancy | > 10% to ≤ 50% likelihood of malignancy |
| C Category 4C: High suspicion for malignancy | > 50% to < 95% likelihood of malignancy |
-

16 . Physician-level assessment - Right breast In NMD? Y

Description: Assessment made by an individual physician when double reading - Right breast

Use: Required if a physician identifier is reported and the physician's assessment differs from the final assessment assigned to the examination; not applicable if a physician identifier is not reported; optional otherwise

Response: Select one.

Values:

- | | |
|-----------------------|---|
| Incomplete Assessment | Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data. |
|-----------------------|---|

- 0 Category 0:
(Mammography only)
Incomplete - Need
additional imaging
evaluation and/or prior
mammograms for
comparison
(Ultrasound and MRI only)
Incomplete - Need
additional imaging
evaluation

Final Assessment

1 Category 1: Negative	Essentially 0% likelihood of malignancy
2 Category 2: Benign	Essentially 0% likelihood of malignancy
3 Category 3: Probably benign	> 0% but \leq 2% likelihood of malignancy
4 Category 4: Suspicious	> 2% but < 95% likelihood of malignancy
5 Category 5: Highly suggestive of malignancy	\geq 95% likelihood of malignancy
6 Category 6: Known biopsy-proven malignancy	

**17 . Physician-level assessment - Right breast -
Subcategory of category 4**

In NMD? Y***Mammography and ultrasound only***

Description: Subcategory of a category 4 assessment made by an individual physician when double reading - Right breast

Use: Optional if a category 4 physician-level assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | | |
|---|--|--|
| A | Category 4A: Low suspicion for malignancy | > 2% to \leq 10% likelihood of malignancy |
| B | Category 4B: Moderate suspicion for malignancy | > 10% to \leq 50% likelihood of malignancy |
| C | Category 4C: High suspicion for malignancy | > 50% to < 95% likelihood of malignancy |
-

18 . Physician-level assessment - Patient level

In NMD? Y

Description: Assessment made by an individual physician when double reading - Patient level

Use: Required if a physician identifier is reported and the physician's assessment differs from the final assessment assigned to the examination; not applicable if a physician identifier is not reported; optional otherwise

Response: Select one.

Values:

- | | |
|-----------------------|---|
| Incomplete Assessment | Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data. |
|-----------------------|---|

0	Category 0: (Mammography only) Incomplete - Need additional imaging evaluation and/or prior mammograms for comparison (Ultrasound and MRI only) Incomplete - Need additional imaging evaluation	
Final Assessment		
1	Category 1: Negative	Essentially 0% likelihood of malignancy
2	Category 2: Benign	Essentially 0% likelihood of malignancy
3	Category 3: Probably benign	> 0% but \leq 2% likelihood of malignancy
4	Category 4: Suspicious	> 2% but < 95% likelihood of malignancy
5	Category 5: Highly suggestive of malignancy	\geq 95% likelihood of malignancy
6	Category 6: Known biopsy-proven malignancy	

Mammography and ultrasound only

Description: Subcategory of a category 4 assessment made by an individual physician when double reading - Patient level

Use: Optional if a category 4 physician-level assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | | |
|---|--|---|
| A | Category 4A: Low suspicion for malignancy | > 2% to ≤ 10% likelihood of malignancy |
| B | Category 4B: Moderate suspicion for malignancy | > 10% to ≤ 50% likelihood of malignancy |
| C | Category 4C: High suspicion for malignancy | > 50% to < 95% likelihood of malignancy |

Patient History for this Examination

20. First examination ever

In NMD? Y

Description: Indicates whether this is the patient's first-ever breast imaging examination, including mammograms

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

0 No

1 Yes

9 Not sure / Unknown

21. Date of previous examination

In NMD? Y

Description: Date of the patient's most recent breast imaging examination, including mammograms

Use: Required for the more complete audit if known; optional for the basic clinically relevant audit if known; not applicable otherwise

Response: Indicate date of previous examination.

Values: Any valid date in mm/dd/yyyy format

22. Time since previous examination

In NMD? Y

Description: Time interval since the patient's most recent breast imaging examination, including mammograms

Use: Required for more complete audit if this is not the patient's first-ever examination and the date of the previous examination was not reported; optional otherwise

Response: Select one.

Values:

- 1 ≤ 6 months
- 2 ≤ 1 year but > 6 months
- 3 ≤ 2 years but > 1 year
- 4 > 2 years
- 99 Not sure / Unknown

23. Personal history of breast cancer

In NMD? Y

Description: Personal history of breast cancer

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

- 0 No
- 1 Yes
- 9 Not sure / Unknown

24. Breast cancer in first-degree relative - premenopausal In NMD? Y

Description: Mother, sister, or daughter with history of premenopausal breast cancer

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

0 No

1 Yes

2 A first-degree relative has a history of breast cancer; unsure whether premenopausal or postmenopausal

9 Unsure whether any first-degree relative has a history of breast cancer

25. Breast cancer in first-degree relative - postmenopausal In NMD? Y

Description: Mother, sister, or daughter with history of postmenopausal breast cancer

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

0 No

1 Yes

2 A first-degree relative has a history of breast cancer; unsure whether premenopausal or postmenopausal

- 9 Unsure whether any first-degree relative has a history of breast cancer
-

26 . Family history of breast cancer, other than first-degree relative In NMD? Y

Description: Family history of breast cancer, other than mother, sister or daughter

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

0 No

1 Yes

9 Not sure / Unknown

27 . Personal history of ovarian cancer In NMD? Y

Description: Personal history of ovarian cancer

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

0 No

1 Yes

9 Not sure / Unknown

28 . Family history of ovarian cancer

In NMD? Y

Description: Family history of ovarian cancer**Use:** Required for the more complete audit; optional otherwise**Response:** Select one.**Values:**

0 No

1 Yes

9 Not sure / Unknown

29 . Previous biopsy-proved hyperplasia with cellular atypia In NMD? Y**Description:** Personal history of biopsy-proved hyperplasia with cellular atypia**Use:** Required for the more complete audit; optional otherwise**Response:** Select one.**Values:**

0 No

1 Yes

9 Not sure / Unknown

30 . Previous lobular carcinoma in situ (LCIS)**In NMD? Y**

Description: Personal history of lobular carcinoma in situ (LCIS)

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

- 0 No
 - 1 Yes
 - 9 Not sure / Unknown
-

31 . Hormone replacement therapy**In NMD? Y**

Description: Personal history of hormone replacement therapy

Use: Required for the more complete audit; optional otherwise

Response: Select one.

Values:

- 0 No
- 1 Yes
- 9 Not sure / Unknown

Study Data for this Examination

32 . Date of examination

In NMD? Y

Description: Date of examination

Use: Required

Response: Indicate date of examination.

Values: Any valid date in mm/dd/yyyy format

33 . Indication for examination

In NMD? Y

Description: Indication or reason for the examination

Use: Required

Response: Select one.

Values:

- 1 Screening
- 2 Diagnostic - evaluation of an abnormal finding at screening
- 3 Diagnostic - surveillance imaging for a probably benign finding or following breast conservation treatment
- 4 Diagnostic - evaluation of a breast problem - palpable abnormality
- 5 Diagnostic - evaluation of a breast problem - other
- 99 Unknown

Description: Modality or modalities used for the examination

Use: Required

Response: Select one.

Values:

1 Mammography

2 Ultrasound

3 MRI

The following terms are valid only when data for combination examinations are reported at the combination level, i.e., not at the component level.

4 Mammography / Ultrasound

5 Mammography / MRI

6 Ultrasound / MRI

7 Mammography / Ultrasound / MRI

35 . Use of computer-aided detection (CAD) - Additional views

In NMD? Y

Mammography only

Description: Indicates whether computer-aided detection was used for additional views

Use: Optional

Response: Select one.

Values:

0 No

1 Yes

36. Use of tomosynthesis

In NMD? Y

Mammography only

Description: Indicates whether tomosynthesis was used

Use: Optional

Response: Select one.

Values:

0 No

1 Yes

37. Use of computer-aided detection (CAD) - Standard views

In NMD? Y

Mammography only

Description: Indicates whether computer-aided detection was used for standard views

Use: Optional

Response: Select one.

Values:

0 No

1 Yes

Mammography only

Description: Indicates whether the image was recorded on film or digitally

Use: Optional

Response: Select one.

Values:

1 Film

2 Digital

Screening mammography and ultrasound only

Description: Indicates whether additional imaging was performed

Use: Required

Response: Select one.

Values:

1 Standard imaging only

2 Standard plus additional imaging

99 Unknown / Not applicable

40 . Breast composition - Left breast

In NMD? Y

Mammography only

Description: Visually estimated content of fibroglandular-density tissue within the breast

Use: Required if audit data are reported at breast level, and right breast composition is not reported; optional otherwise

Response: Select one.

Values:

- 1 a. The breast is almost entirely fatty.
- 2 b. There are scattered areas of fibroglandular density.
- 3 c. The breast is heterogeneously dense, which may obscure small masses.
- 4 d. The breast is extremely dense, which lowers the sensitivity of mammography.

99 Unknown

41 . Breast composition - Right breast

In NMD? Y

Mammography only

Description: Visually estimated content of fibroglandular-density tissue within the breast

Use: Required if audit data are reported at breast level, and left breast composition is not reported; optional otherwise

Response: Select one.

Values:

- 1 a. The breast is almost entirely fatty.

- 2 b. There are scattered areas of fibroglandular density.
 - 3 c. The breast is heterogeneously dense, which may obscure small masses.
 - 4 d. The breast is extremely dense, which lowers the sensitivity of mammography.
- 99 Unknown

42 . Breast composition - Patient level**In NMD? Y*****Mammography only***

- Description:** Visually estimated content of fibroglandular-density tissue within the breasts. If the breasts are not of apparently equal density, the denser breast should be used to categorize breast density.
- Use:** Required if audit data are reported at patient level; optional otherwise
- Response:** Select one.

Values:

- 1 a. The breasts are almost entirely fatty.
- 2 b. There are scattered areas of fibroglandular density.
- 3 c. The breasts are heterogeneously dense, which may obscure small masses.
- 4 d. The breasts are extremely dense, which lowers the sensitivity of mammography.

99 Unknown

Ultrasound screening only

- Description:** The background echotexture of the breast may affect the sensitivity of breast sonograms for lesion detection.
- Use:** Required if audit data are reported at breast level, and right breast tissue composition is not reported; optional otherwise
- Response:** Select one.
- Values:**
- 1 a. Homogeneous background echotexture — fat
 - 2 b. Homogeneous background echotexture — fibroglandular
 - 3 c. Heterogeneous background echotexture
 - 99 Unknown

Ultrasound screening only

- Description:** The background echotexture of the breast may affect the sensitivity of breast sonograms for lesion detection.
- Use:** Required if audit data are reported at breast level, and left breast tissue composition is not reported; optional otherwise
- Response:** Select one.
- Values:**
- 1 a. Homogeneous background echotexture — fat
 - 2 b. Homogeneous background echotexture — fibroglandular
 - 3 c. Heterogeneous background echotexture

45 . Tissue composition - Patient level

In NMD? Y

Ultrasound screening only

Description: The background echotexture of the breast may affect the sensitivity of breast sonograms for lesion detection.

Use: Required if audit data are reported at patient level; optional otherwise

Response: Select one.

Values:

- 1 a. Homogeneous background echotexture — fat
- 2 b. Homogeneous background echotexture — fibroglandular
- 3 c. Heterogeneous background echotexture

99 Unknown

46 . Amount of fibroglandular tissue (FGT) - Left breast

In NMD? Y

MRI only

Description: Assessed on fat-saturated T1W imaging or non-fat-saturated T1W imaging

Use: Required if audit data are reported at breast level, and amount of FGT in the right breast is not reported; optional otherwise

Response: Select one.

Values:

- 1 a. Almost entirely fat
- 2 b. Scattered fibroglandular tissue
- 3 c. Heterogeneous fibroglandular tissue

4 d. Extreme fibroglandular tissue

99 Unknown

47 . Amount of fibroglandular tissue (FGT) - Right breast

In NMD? Y

MRI only

Description: Assessed on fat-saturated T1W imaging or non-fat-saturated T1W imaging

Use: Required if audit data are reported at breast level, and amount of FGT in the left breast is not reported; optional otherwise

Response: Select one.

Values:

- 1 a. Almost entirely fat
- 2 b. Scattered fibroglandular tissue
- 3 c. Heterogeneous fibroglandular tissue
- 4 d. Extreme fibroglandular tissue

99 Unknown

48 . Amount of fibroglandular tissue (FGT) - Patient level

In NMD? Y

MRI only

Description: Assessed on fat-saturated T1W imaging or non-fat-saturated T1W imaging

Use: Required if audit data are reported at patient level; optional otherwise

Response: Select one.

Values:

- 1 a. Almost entirely fat
- 2 b. Scattered fibroglandular tissue

3 c. Heterogeneous fibroglandular tissue

4 d. Extreme fibroglandular tissue

99 Unknown

49 . Background parenchymal enhancement (BPE): Level - In NMD? Y
Left breast

MRI only

Description: Background parenchymal enhancement (BPE): Level - Left breast

Use: Required

Response: Select one.

Values:

1 Minimal

2 Mild

3 Moderate

4 Marked

99 Unknown

50 . Background parenchymal enhancement (BPE): Level - In NMD? Y
Right breast

MRI only

Description: Background parenchymal enhancement (BPE): Level - Right breast

Use: Required

Response: Select one.

Values:

1 Minimal

2 Mild

3 Moderate

4 Marked

99 Unknown

51. Background parenchymal enhancement (BPE): Level - In NMD? Y
Patient level

MRI only

Description: Background parenchymal enhancement (BPE): Level - Patient level

Use: Required

Response: Select one.

Values:

1 Minimal

2 Mild

3 Moderate

4 Marked

99 Unknown

52. Background parenchymal enhancement (BPE): In NMD? Y
Symmetric or asymmetric

MRI only

Description: Background parenchymal enhancement (BPE): Symmetric or asymmetric

Use: Required for bilateral scans; not applicable otherwise

Response: Select one.

Values:

1 Symmetric

2 Asymmetric

99 Unknown

53 . Focus

In NMD? N

MRI only

Description: Dot of enhancement so small (< 5 mm) it cannot be otherwise characterized

Use: Required

Response: Indicate whether the finding is present.

Values:

0 No

1 Yes

9 Not sure / Unknown

54 . Masses: Shape

In NMD? N

Description: Masses: Shape

Use: Required

Response: Select one.

Values:

1 Oval (Mammography and MRI only)

Elliptical or egg-shaped (may include 2 or 3 undulations)

Oval (Ultrasound only)

Elliptical or egg-shaped (may include 2 or 3 undulations, i.e., "gently lobulated" or "macrolobulated")

2 Round

Spherical, ball-shaped, circular, or globular

3 Irregular

Neither round nor oval

99 Not applicable

Ultrasound only

Description: Orientation is defined with reference to the skin line. Obliquely situated masses may follow a radial pattern, and their long axes will help determine classification as parallel or not parallel.

Use: Required

Response: Select one.

Values:

- | | |
|-------------------|--|
| 1 Parallel | Long axis of lesion parallels the skin line ("wider than tall" or "horizontal") |
| 2 Not parallel | Long axis not oriented along the skin line ("taller than wide" or "vertical") - includes round |
| 99 Not applicable | |

Mammography only

Description: The margin is the edge or border of the lesion.

Use: Required

Response: Select one.

Values:

- | | |
|------------------|--|
| 1 Circumscribed | At least 75% of the margin is sharply demarcated, with an abrupt transition between the lesion and surrounding tissue. |
| 2 Obscured | 25% or more of the margin is hidden by superimposed or adjacent fibroglandular tissue. |
| 3 Microlobulated | A margin characterized by short-cycle undulations |

4	Indistinct	No clear demarcation of the entire margin or any portion of it from the surrounding tissue
5	Spiculated	Margin is characterized by lines radiating from the mass.
99	Not applicable	

57 . Masses: Margin - Ultrasound

In NMD? N

Ultrasound only

Description: The margin is the edge or border of the lesion.

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | | |
|---|-----------------------------------|--|
| 1 | Circumscribed | Entire margin is well defined or sharp, with an abrupt transition between the lesion and surrounding tissue. |
| 2 | Not circumscribed: Indistinct | No clear demarcation between a mass and the surrounding tissue anywhere on the margin |
| 3 | Not circumscribed: Angular | Some or all of the margin has sharp corners, often forming acute angles |
| 4 | Not circumscribed: Microlobulated | Margin is characterized by short-cycle undulations |
| 5 | Not circumscribed: Spiculated | Margin is characterized by sharp lines radiating from the mass |

MRI only

Description: The margin is the edge or border of the lesion.

Use: Required

Response: Select one.

Values:

- | | |
|---------------------------------|--|
| 1 Circumscribed | Entire margin is sharply demarcated with abrupt transition between the lesion and surrounding tissue |
| 2 Not circumscribed: Irregular | Uneven or jagged edges (but not spiculated) |
| 3 Not circumscribed: Spiculated | Characterized by lines radiating from the mass |
| 99 Not applicable | |

Mammography only

Description: This is used to define the x-ray attenuation of the mass relative to the expected attenuation of an equal volume of normal fibroglandular breast tissue.

Use: Required

Response: Select one.

Values:

- | | |
|----------------|--|
| 1 High density | X-ray attenuation of the mass is greater than the expected attenuation of an equal volume of fibroglandular breast tissue. |
|----------------|--|

2 Equal density	X-ray attenuation of the mass is the same as the expected attenuation of an equal volume of fibroglandular breast tissue.
3 Low density	X-ray attenuation of the mass is less than the expected attenuation of an equal volume of fibroglandular breast tissue.
4 Fat-containing	Includes all masses containing fat, such as oil cyst, lipoma, or galactocele as well as mixed-density lesions such as hamartoma
99 Not applicable	

60 . Masses: Echo pattern

In NMD? N

Ultrasound only

Description: The echogenicity of most benign and malignant masses is hypoechoic compared with mammary fat. While many completely echogenic masses are benign, prospective assessment as benign is more reliable if based on margin descriptors.

Use: Required

Response: Select one.

Values:

- | | |
|----------------------------|---|
| 1 Anechoic | Without internal echoes |
| 2 Hyperechoic | Having increased echogenicity relative to fat or equal to fibroglandular tissue |
| 3 Complex cystic and solid | Mass contains both anechoic (cystic or fluid) and echogenic (solid) components. |

4	Hypoechoic	Defined relative to subcutaneous fat; characterized by low-level echoes throughout (e.g., complicated cysts or fibroadenomas)
5	Isoechoic	Having the same echogenicity as subcutaneous fat
6	Heterogeneous	A mixture of echogenic patterns within a solid mass
99	Not applicable	

61 . Masses: Posterior features

In NMD? N

Ultrasound only

Description: Posterior features represent the attenuation characteristics of a mass with respect to its acoustic transmission. Attenuation (shadowing) and enhancement are additional attributes of masses, mostly of secondary rather than primary predictive value

Use: Required

Response: Select one.

Values:

- | | | |
|----|-----------------------|--|
| 1 | No posterior features | No shadowing or enhancement deep to the mass |
| 2 | Enhancement | Appears as a column that is more echogenic (whiter) deep to the mass |
| 3 | Shadowing | The area posterior to the mass appears darker; refractive edge shadowing is of no significance |
| 4 | Combined pattern | More than one pattern of posterior attenuation, both shadowing and enhancement |
| 99 | Not applicable | |

MRI only

Description: Enhancement pattern within the abnormally enhancing structure

Use: Required

Response: Select one.

Values:

- | | | |
|----|--------------------------|---|
| 1 | Homogeneous | Confluent uniform enhancement |
| 2 | Heterogeneous | Nonuniform enhancement with variable signal intensity |
| 3 | Rim enhancement | Enhancement more pronounced at the periphery of mass |
| 4 | Dark internal septations | Dark non-enhancing lines within a mass |
| 99 | Not applicable | |

Mammography only

Description: Calcifications: Typically benign

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | | |
|---|----------|--|
| 1 | Skin | Usually lucent-centered and pathognomonic in appearance |
| 2 | Vascular | Parallel tracks or linear, tubular calcifications that are clearly associated with blood vessels |

3	Coarse or "popcorn-like"	These calcifications are classic, large (> 2 to 3 mm in greatest diameter), and produced by an involuting fibroadenoma.
4	Large rod-like	Associated with ductal ectasia, may form solid or discontinuous, smooth linear rods, usually ≥ 0.5 mm in diameter
5	Round	May vary in size and, therefore, also in opacity (when < 0.5 mm, the term "punctate" should be used)
6	Rim	Appear as calcium deposited on the surface of a sphere (usually < 1 mm in thickness when viewed on edge)
7	Dystrophic	Irregular in shape and usually > 1 mm in size; often with lucent centers
8	Milk of calcium	A manifestation of sedimented calcifications in macro- or microcysts, usually but not always grouped. Refer to lexicon classification form for complete description.
9	Suture	Typically linear or tubular in appearance; when present, knots are frequently visible

Mammography only

Description: Calcifications: Suspicious morphology

Use: Required

Response: Select one.

Values:

- | | |
|--|--|
| 1 Amorphous | So small and/or hazy in appearance that a more specific particle shape cannot be determined |
| 2 Coarse heterogeneous | Irregular, conspicuous calcifications that are generally between 0.5 mm and 1.0 mm and tend to coalesce but are smaller than dystrophic calcifications |
| 3 Fine pleomorphic | Usually more conspicuous than amorphous forms and are seen to have discrete shapes. Refer to lexicon classification form for complete description. |
| 4 Fine linear or fine-linear branching | Thin, linear, irregular calcifications, which may be discontinuous and are < 0.5 mm in caliber - occasionally, branching forms may be seen |
| 99 Not applicable | |

Mammography only

Description: Used to indicate the arrangement of calcifications in the breast

Use: Required

Response: Select one.

Values:

- | | |
|-------------------|--|
| 1 Diffuse | Distributed randomly throughout the breast |
| 2 Regional | Used for numerous calcifications that occupy a large portion of breast tissue (> 2 cm in greatest dimension), not conforming to a duct distribution - may involve most of a quadrant or even more than a single quadrant |
| 3 Grouped | Used when relatively few calcifications occupy a small portion of breast tissue. Refer to lexicon classification form for complete description. |
| 4 Linear | Calcifications arrayed in a line |
| 5 Segmental | Used when the distribution of calcifications suggests deposits in a duct or ducts and their branches |
| 99 Not applicable | |

Ultrasound only

Description: Calcifications are poorly characterized with ultrasound but can be recognized as echogenic foci, particularly when in a mass.

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | |
|------------------------------------|---|
| 1 Calcifications in a mass | Small hyperechoic foci will be more conspicuous in a hypoechoic mass than within a volume of fibroglandular tissue (unless grouped very closely or individually coarse, they will not attenuate the US beam). |
| 2 Calcifications outside of a mass | Calcifications situated in fat or fibroglandular tissue are less conspicuous than when present within a mass. |
| 3 Intraductal calcifications | |

Mammography only

Description: The parenchyma is distorted with no definite mass visible.

Use: Required

Response: Indicate whether the finding is present.

Values:

- 0 No
- 1 Yes
- 9 Not sure / Unknown

Mammography only

Description: Involve a spectrum of mammographic findings that represent unilateral deposits of fibroglandular tissue not conforming to the definition of a radiodense mass

Use: Required

Response: Select one.

Values:

1 Asymmetry

An area of fibroglandular-density tissue that is visible on only one mammographic projection, frequently representing superimposition of normal breast structures (summation artifact)

2 Global asymmetry

Judged relative to the corresponding area in the contralateral breast and represents a large amount of fibroglandular-density tissue over a substantial portion of the breast. Refer to lexicon classification form for complete description.

3 Focal asymmetry

Judged relative to the corresponding location in the contralateral breast and represents a relatively small amount of fibroglandular-density tissue over a confined portion of the breast. Refer to lexicon classification form for complete description.

4 Developing asymmetry

A focal asymmetry that is new, larger, or more conspicuous than on a previous examination

99 Not applicable

MRI only

Description: Distribution in an area that is neither a mass nor a focus

Use: Required

Response: Select one.

Values:

- | | |
|--------------------|--|
| 1 Focal | In a confined area, less than a breast quadrant volume with fat or normal glandular tissue interspersed between the abnormally enhancing components (exception: focal homogeneous enhancement) |
| 2 Linear | Enhancement arrayed in a line (not necessarily a straight line) or a line that branches |
| 3 Segmental | Triangular or cone-shaped region of enhancement, apex at the nipple |
| 4 Regional | Enhancement that encompasses more than a single duct system |
| 5 Multiple regions | Enhancement in at least two large volumes of tissue not conforming to a ductal distribution and separated by normal tissue, multiple geographic areas, patchy in appearance |
| 6 Diffuse | Enhancement distributed randomly throughout the breast |
| 99 Not applicable | |

70 . Non-mass enhancement (NME): Internal enhancement In NMD? N

MRI only

Description: Internal enhancement patterns in an area that is neither a mass nor a focus

Use: Required

Response: Select one.

Values:

- | | | |
|----|----------------|--|
| 1 | Homogeneous | Confluent uniform enhancement |
| 2 | Heterogeneous | Nonuniform enhancement in a random pattern, separated by normal breast parenchyma or fat |
| 3 | Clumped | Cobblestone enhancement, with occasional confluent areas |
| 4 | Clustered ring | Thin rings of enhancement clustered together around ducts |
| 99 | Not applicable | |

71 . Intramammary lymph nodes In NMD? N

Mammography and MRI only

Description: Mammography only: These are circumscribed masses that are reniform and have hilar fat. Refer to the lexicon classification form for a complete description.

MRI only: Circumscribed, homogenously enhancing masses, reniform, with hilar fat (generally $\leq 1\text{cm}$)

Use: Required

Response: Indicate whether the finding is present.

Values:

- | | |
|---|-----|
| 0 | No |
| 1 | Yes |

72. Skin lesion

In NMD? N

Mammography and MRI only

Description: Mammography only: Refer to the lexicon classification form for a complete description.
MRI only: Benign, enhancing lesions of the skin

Use: Required

Response: Indicate whether the finding is present.

Values:

0 No

1 Yes

9 Not sure / Unknown

73. Solitary dilated duct

In NMD? N

Mammography only

Description: This is a unilateral tubular or branching structure that likely represents a dilated or otherwise enlarged duct.

Use: Required

Response: Indicate whether the finding is present.

Values:

0 No

1 Yes

9 Not sure / Unknown

MRI only

Description: Non-enhancing findings

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | |
|--|--|
| 1 Ductal precontrast high signal on T1W | Bright signal in ducts before contrast enhancement on T1W images |
| 2 Cyst | Circumscribed, round or oval, fluid-filled mass with an imperceptible wall; usually bright on T2W images |
| 3 Postoperative collections (hematoma/seroma) | May be simple or complicated; may contain bright signal on T1W images; usually demonstrate thin peripheral enhancement around the cavity |
| 4 Post-therapy skin thickening and trabecular thickening | May be seen following surgery and/or radiation therapy |
| 5 Non-enhancing mass | Usually identified on precontrast images; usually solid lesions; do not use this descriptor for cysts. |
| 6 Architectural distortion | This includes focal retraction and distortion of the parenchyma with no definite mass visible. |
| 7 Signal void from foreign bodies, clips, etc. | Absence of signal due to an artifact |

Mammography only

Description: Used with masses, asymmetries, or calcifications, or may stand alone as findings when no other abnormality is present.

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | |
|----------------------------|---|
| 1 Skin retraction | The skin is pulled in abnormally. |
| 2 Nipple retraction | The nipple is pulled in (should not be confused with nipple inversion which is often bilateral). |
| 3 Skin thickening | May be focal or diffuse, and is defined as being > 2 mm in thickness |
| 4 Trabecular thickening | A thickening of the fibrous septa of the breast |
| 5 Axillary adenopathy | Enlarged axillary lymph nodes may warrant comment, clinical correlation and additional evaluation, especially if new or considerably larger or rounder when compared to previous examination. |
| 6 Architectural distortion | As an associated feature, architectural distortion may be used in conjunction with another finding to indicate that the parenchyma is distorted or retracted adjacent to the finding. |

As an associated feature, this may be used in conjunction with one or more other finding(s) to describe calcifications within or immediately adjacent to the finding(s) (see descriptors of calcifications, section B, Mammography section)

76. Associated features - Ultrasound**In NMD? N**

Ultrasound only**Description:** Associated features - Ultrasound**Use:** Required**Response:** Select all that apply.**Values:** 0 (No) or 1 (Yes) for each of the following:

1 Architectural distortion

Manifested by cystic dilation of a duct or ducts involving irregularities in caliber and/or arborization, extension of duct(s) to or from a malignant mass, or the presence of an intraductal mass, thrombus, or detritus

2 Duct changes

May be focal or diffuse, > 2 mm in thickness (in the periareolar area and inframammary folds up to 4 mm)

3 Skin changes: Skin thickening

Skin surface is concave or ill-defined, and appears pulled in.

4 Skin changes: Skin retraction

Increased echogenicity of surrounding tissue and reticulated (angular network of hypoechoic lines)

Select only one of the following three terms for vascularity:

- 6 Vascularity: Absent
7 Vascularity: Internal vascularity

- 8 Vascularity: Vessels in rim

Select only one of the following three terms for elasticity assessment:

- 9 Elasticity assessment: Soft
10 Elasticity assessment: Intermediate
11 Elasticity assessment: Hard

Must reference a contralateral normal area or unaffected site in the same breast as the basis for comparison

Blood vessels present within the mass

Blood vessels may be marginal, occupying part or all of a mass's rim.

Stiffness as a feature of malignant masses may be considered along with their much more important morphologic characteristics.

77. Associated features - MRI

In NMD? N

MRI only

Description: Associated features - MRI

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- 1 Nipple retraction

Nipple is pulled in; do not confuse with nipple inversion.

- 2 Nipple invasion

Tumor directly invades and is contiguous with the nipple.

- 3 Skin retraction

The skin is pulled in abnormally.

4	Skin thickening	May be focal or diffuse, > 2 mm in thickness
5	Skin invasion: Direct invasion	Abnormal enhancement within the skin, which is thickened. The skin enhances where the tumor directly invades.
6	Skin invasion: Inflammatory cancer	Abnormal enhancement within the skin, which is thickened. The enhancement may be diffuse or focal depending on the extent of invasion of dermal lymphatics.
7	Axillary adenopathy	Enlarged lymph nodes may warrant comment, clinical correlation, and additional evaluation especially if new or considerably larger or rounder compared to previous examination.
8	Pectoralis muscle invasion	Abnormal enhancement extending into the adjacent pectoralis muscle
9	Chest wall invasion	Abnormal enhancement extending into the ribs or intercostal spaces (behind the pectoralis muscle)
10	Architectural distortion	As an associated feature, may be used in conjunction with another finding to indicate distortion or retraction of parenchyma adjacent to the other finding

Ultrasound only

Description: These are cases with a unique diagnosis or finding.

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | |
|-----------------------------------|---|
| 1 Simple cyst | Circumscribed, round or oval, anechoic, shows posterior enhancement |
| 2 Clustered microcysts | A cluster of anechoic masses, each < 2–3 mm in diameter with thin (< 0.5 mm) intervening septations and no discrete solid component |
| 3 Complicated cyst | Cysts that contain debris; characterized by homogeneous, low-level internal echoes without a discrete solid component, and with an imperceptible wall. Refer to lexicon classification form for complete description. |
| 4 Mass in or on skin | These masses are clinically apparent and may include sebaceous or epidermal inclusion cysts, keloids, moles, pimples, neurofibromas, and accessory nipples |
| 5 Foreign body including implants | May include marker clips, coils, wires, catheter sleeves, injected or leaked silicone, metal or glass related to trauma, and implants |

- 6 Lymph nodes - intramammary Circumscribed, oval masses, often reniform and containing hilar fat; most commonly seen in the upper outer quadrant (especially the axillary tail); usually 3 mm to 1 cm
- 7 Lymph nodes - axillary
- Select only one of the following two terms for vascular abnormalities:
- 8 Vascular abnormalities: AVMs (arteriovenous malformations / pseudoaneurysms)
- 9 Vascular abnormalities: Mondor disease
- 10 Postsurgical fluid collection
- 11 Fat necrosis

79 . Fat-containing lesions**In NMD? N**

MRI only**Description:** Fat-containing lesions**Use:** Required**Response:** Select all that apply.**Values:** 0 (No) or 1 (Yes) for each of the following:

- 1 Lymph nodes: Normal
- 2 Lymph nodes: Abnormal
- 3 Fat necrosis
- 4 Hamartoma
- 5 Postoperative seroma / hematoma with fat

Mammography and MRI only

Description: Indicates right or left breast

Use: Required

Response: Select one.

Values:

- 1 Right
- 2 Left
- 3 Both (MRI only)

Mammography and MRI only

Description: Location of lesion: Quadrant or region. Use of both clock-face and quadrant location is encouraged.

Use: Required if clock-face location is not used; optional otherwise

Response: Select one.

Values:

- 1 Upper outer quadrant
- 2 Upper inner quadrant
- 3 Lower outer quadrant
- 4 Lower inner quadrant
- 5 Upper central
- 6 Lower central
- 7 Outer central
- 8 Inner central
- 9 Retroareolar

10 Central

11 Axillary tail

82. Location of lesion: Clock-face location

In NMD? N

Mammography and MRI only

Description: Location of lesion: Clock-face location. Use of both clock-face and quadrant location is encouraged

Use: Required if quadrant or region are not used; optional otherwise

Response: Select one.

Values: Integer between 1 and 12

83. Location of lesion: Depth

In NMD? N

Mammography and MRI only

Description: Location of lesion: Depth

Use: Required

Response: Select one. Indicate depth in the breast.

Values:

- 1 Anterior third
- 2 Middle third
- 3 Posterior third

Mammography and MRI only

Description: Location of lesion: Distance

Use: Required

Response: Mammography only: Indicate distance from the nipple in cm.
Distance of the lesion from the nipple provides a more precise indication of its depth.
MRI only: Indicate distance from the nipple, skin, or chest wall in cm.

Values: Integer between 1 and 99

MRI only

Description: Indicates origin of distance measurement

Use: Required

Response: Select one.

Values:

- 1 Nipple
- 2 Skin
- 3 Chest wall

86. Kinetic curve assessment - Signal intensity (SI) / time In NMD? N
curve description: Initial phase

MRI only

Description: Enhancement pattern within the first 2 minutes or when curve starts to change

Use: Required

Response: Select one.

Values:

- | | | |
|----|---------|--|
| 1 | Slow | < 50% increase in signal intensity within the first 2 minutes |
| 2 | Medium | 50% – 100% increase in signal intensity within the first 2 minutes |
| 3 | Fast | > 100% increase in signal intensity within the first 2 minutes |
| 99 | Unknown | |

87. Kinetic curve assessment - Signal intensity (SI) / time In NMD? N
curve description: Delayed phase

MRI only

Description: Enhancement pattern after 2 minutes or after curve starts to change

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

- | | | |
|---|------------|--|
| 1 | Persistent | Continued > 10% increase in signal over time |
| 2 | Plateau | Signal intensity does not change over time after its initial rise, flat |
| 3 | Washout | Signal intensity decreases > 10% after its highest point from its initial rise |

MRI only

Description: Implants: Implant material and lumen type

Use: Required

Response: Select one.

Values:

1 Saline

2 Silicone: Intact

3 Silicone: Ruptured

4 Other implant material

Such as soy oil, polypropylene,
polyurethane, and sponges;
includes direct injections

5 Lumen type

99 Not applicable

MRI only

Description: Implants: Implant location

Use: Required

Response: Select one.

Values:

1 Retroglandular

Anterior to the pectoralis muscles

2 Retropectoral

Deep to the pectoralis muscles

99 Not applicable

MRI only

Description: Implants: Abnormal implant contour

Use: Required

Response: Select one.

Values:

1 Focal bulge

99 Not applicable

MRI only

Description: Implants: Intracapsular silicone findings

Use: Required

Response: Select all that apply.

Values: 0 (No) or 1 (Yes) for each of the following:

1 Radial folds

2 Subcapsular line

3 Keyhole sign (teardrop, noose)

4 Linguine sign

MRI only

Description: Implants: Extracapsular silicone

Use: Required

Response: Select one.

Values:

1 Breast

2 Lymph nodes

99 Not applicable

MRI only

Description: Implants: Water droplets

Use: Required

Response: Indicate whether the finding is present.

Values:

0 No

1 Yes

9 Not sure / Unknown

MRI only

Description: Implants: Peri-implant fluid

Use: Required

Response: Indicate whether the finding is present.

Values:

0 No

1 Yes

9 Not sure / Unknown

Description: Assessment - Left breast

Use: Required if audit data are reported at breast level, and right breast assessment is not reported; optional otherwise

Response: Select one.

Values:

Incomplete Assessment

Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data.

- 0 Category 0:
(Mammography only)
Incomplete - Need additional imaging evaluation and/or prior mammograms for comparison
(Ultrasound and MRI only)
Incomplete - Need additional imaging evaluation

Final Assessment

1 Category 1: Negative	Essentially 0% likelihood of malignancy
2 Category 2: Benign	Essentially 0% likelihood of malignancy
3 Category 3: Probably benign	> 0% but \leq 2% likelihood of malignancy
4 Category 4: Suspicious	> 2% but $<$ 95% likelihood of malignancy
5 Category 5: Highly suggestive of malignancy	\geq 95% likelihood of malignancy
6 Category 6: Known biopsy-proven malignancy	

96 . Assessment - Left breast - Subcategory of category 4 In NMD? Y

Description: Assessment - Left breast - Subcategory of category 4

Use: Optional if a category 4 assessment is reported; not applicable otherwise

Response: Select one.

Values:

- A Category 4A: Low suspicion for malignancy > 2% to \leq 10% likelihood of malignancy
- B Category 4B: Moderate suspicion for malignancy > 10% to \leq 50% likelihood of malignancy
- C Category 4C: High suspicion for malignancy > 50% to $<$ 95% likelihood of malignancy

Description: Assessment - Right breast

Use: Required if audit data are reported at breast level, and left breast assessment is not reported; optional otherwise

Response: Select one.

Values:

Incomplete Assessment

- 0 Category 0:
(Mammography only)
Incomplete - Need
additional imaging
evaluation and/or prior
mammograms for
comparison
(Ultrasound and MRI only)
Incomplete - Need
additional imaging
evaluation

Do not include incomplete
assessments needing
comparison with prior studies or
technical recall examinations in
audit data.

Final Assessment

- | | |
|--|--|
| 1 Category 1: Negative | Essentially 0% likelihood of
malignancy |
| 2 Category 2: Benign | Essentially 0% likelihood of
malignancy |
| 3 Category 3: Probably benign | > 0% but ≤ 2% likelihood of
malignancy |
| 4 Category 4: Suspicious | > 2% but < 95% likelihood of
malignancy |
| 5 Category 5: Highly suggestive of
malignancy | ≥ 95% likelihood of malignancy |

6 Category 6: Known biopsy-proven malignancy

98 . Assessment - Right breast - Subcategory of category 4 In NMD? Y

Description: Assessment - Right breast - Subcategory of category 4

Use: Optional if a category 4 assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | | |
|---|--|---|
| A | Category 4A: Low suspicion for malignancy | > 2% to ≤ 10% likelihood of malignancy |
| B | Category 4B: Moderate suspicion for malignancy | > 10% to ≤ 50% likelihood of malignancy |
| C | Category 4C: High suspicion for malignancy | > 50% to < 95% likelihood of malignancy |
-

99 . Assessment - Patient level

In NMD? Y

Description: Assessment - Patient level

Use: Required if audit data are reported at patient level; optional otherwise

Response: Select one.

Values:

- | | |
|-----------------------|---|
| Incomplete Assessment | Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data. |
|-----------------------|---|

0	Category 0: (Mammography only) Incomplete - Need additional imaging evaluation and/or prior mammograms for comparison (Ultrasound and MRI only) Incomplete - Need additional imaging evaluation	
Final Assessment		
1	Category 1: Negative	Essentially 0% likelihood of malignancy
2	Category 2: Benign	Essentially 0% likelihood of malignancy
3	Category 3: Probably benign	> 0% but \leq 2% likelihood of malignancy
4	Category 4: Suspicious	> 2% but < 95% likelihood of malignancy
5	Category 5: Highly suggestive of malignancy	\geq 95% likelihood of malignancy
6	Category 6: Known biopsy-proven malignancy	

100 . Assessment - Patient level - Subcategory of category 4 In NMD? Y

Description: Assessment - Patient level - Subcategory of category 4

Use: Optional if a category 4 assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | | |
|---|---|---|
| A | Category 4A: Low suspicion for malignancy | > 2% to \leq 10% likelihood of malignancy |
|---|---|---|

B	Category 4B: Moderate suspicion for malignancy	> 10% to ≤ 50% likelihood of malignancy
C	Category 4C: High suspicion for malignancy	> 50% to < 95% likelihood of malignancy

101. Overall assessment - Left breast

In NMD? Y

Description: Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Left breast

Use: Optional

Response: Select one.

Values:

Incomplete Assessment

Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data.

- 0 Category 0: Incomplete - Need additional imaging evaluation

Final Assessment

- 1 Category 1: Negative

Essentially 0% likelihood of malignancy

- 2 Category 2: Benign

Essentially 0% likelihood of malignancy

- 3 Category 3: Probably benign

> 0% but ≤ 2% likelihood of malignancy

- 4 Category 4: Suspicious

> 2% but < 95% likelihood of malignancy

- 5 Category 5: Highly suggestive of malignancy

≥ 95% likelihood of malignancy

- 6 Category 6: Known biopsy-proven malignancy

102. Overall assessment - Left breast - Subcategory of category 4

In NMD? Y

Description: Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Left breast - Subcategory of category 4

Use: Optional if a category 4 assessment is reported; not applicable otherwise

Response: Select one.

Values:

- | | |
|--|---|
| A Category 4A: Low suspicion for malignancy | > 2% to ≤ 10% likelihood of malignancy |
| B Category 4B: Moderate suspicion for malignancy | > 10% to ≤ 50% likelihood of malignancy |
| C Category 4C: High suspicion for malignancy | > 50% to < 95% likelihood of malignancy |

103. Overall assessment - Right breast

In NMD? Y

Description: Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Right breast

Use: Optional

Response: Select one.

Values:

- | | |
|---|---|
| Incomplete Assessment | Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data. |
| 0 Category 0: Incomplete - Need additional imaging evaluation | |
| Final Assessment | |

1 Category 1: Negative	Essentially 0% likelihood of malignancy
2 Category 2: Benign	Essentially 0% likelihood of malignancy
3 Category 3: Probably benign	> 0% but ≤ 2% likelihood of malignancy
4 Category 4: Suspicious	> 2% but < 95% likelihood of malignancy
5 Category 5: Highly suggestive of malignancy	≥ 95% likelihood of malignancy
6 Category 6: Known biopsy-proven malignancy	

104 . Overall assessment - Right breast - Subcategory of category 4 In NMD? Y

Description:	Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Right breast - Subcategory of category 4
Use:	Optional if a category 4 assessment is reported; not applicable otherwise
Response:	Select one.
Values:	
A Category 4A: Low suspicion for malignancy	> 2% to ≤ 10% likelihood of malignancy
B Category 4B: Moderate suspicion for malignancy	> 10% to ≤ 50% likelihood of malignancy
C Category 4C: High suspicion for malignancy	> 50% to < 95% likelihood of malignancy

Description: Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Patient level

Use: Optional

Response: Select one.

Values:

Incomplete Assessment

Do not include incomplete assessments needing comparison with prior studies or technical recall examinations in audit data.

- 0 Category 0: Incomplete - Need additional imaging evaluation

Final Assessment

- 1 Category 1: Negative

Essentially 0% likelihood of malignancy

- 2 Category 2: Benign

Essentially 0% likelihood of malignancy

- 3 Category 3: Probably benign

> 0% but \leq 2% likelihood of malignancy

- 4 Category 4: Suspicious

> 2% but < 95% likelihood of malignancy

- 5 Category 5: Highly suggestive of malignancy

\geq 95% likelihood of malignancy

- 6 Category 6: Known biopsy-proven malignancy

106. Overall assessment - Patient level - Subcategory of category 4	In NMD?	Y
Description:	Overall assessment for combinations of diagnostic breast imaging examinations, performed concurrently (e.g., mammography / ultrasound) - Patient level - Subcategory of category 4	
Use:	Optional if a category 4 assessment is reported; not applicable otherwise	
Response:	Select one.	
Values:		
A Category 4A: Low suspicion for malignancy	> 2% to ≤ 10% likelihood of malignancy	
B Category 4B: Moderate suspicion for malignancy	> 10% to ≤ 50% likelihood of malignancy	
C Category 4C: High suspicion for malignancy	> 50% to < 95% likelihood of malignancy	
107. Management - Left breast	In NMD?	Y
Description:	Management - Left breast	
Use:	Required if audit data are reported at breast level, and management for the right breast is not reported	
Response:	Select one.	
Values:		
1 (Mammography only)	Recall for additional imaging and/or comparison with prior examination(s)	
(Ultrasound only)	Recall for additional imaging	
(MRI only)	Recommend additional imaging: Mammogram or targeted ultrasound	
2 (Mammography only)	Routine mammography screening	

(Ultrasound only)	Routine screening
(MRI only)	Routine breast MRI screening if cumulative lifetime risk $\geq 20\%$
3 (Mammography only)	Short-interval (6-month) follow-up or continued surveillance mammography
(Ultrasound only)	Short-interval (6-month) follow-up or continued surveillance
(MRI only)	Short-interval (6-month) follow-up
4 (All modalities)	Tissue diagnosis
5 (All modalities)	Surgical excision when clinically appropriate
6 (All modalities)	Other

108 . Management - Right breast
In NMD? Y

Description: Management - Right breast

Use: Required if audit data are reported at breast level, and management for the left breast is not reported

Response: Select one.

Values:

1 (Mammography only)	Recall for additional imaging and/or comparison with prior examination(s)
(Ultrasound only)	Recall for additional imaging
(MRI only)	Recommend additional imaging: Mammogram or targeted ultrasound
2 (Mammography only)	Routine mammography screening
(Ultrasound only)	Routine screening

(MRI only)	Routine breast MRI screening if cumulative lifetime risk ≥ 20%
3 (Mammography only)	Short-interval (6-month) follow-up or continued surveillance mammography
(Ultrasound only)	Short-interval (6-month) follow-up or continued surveillance
(MRI only)	Short-interval (6-month) follow-up
4 (All modalities)	Tissue diagnosis
5 (All modalities)	Surgical excision when clinically appropriate
6 (All modalities)	Other

109 . Management - Patient level

In NMD? Y

Description: Management - Patient level

Use: Required if audit data are reported at patient level; optional otherwise

Response: Select one.

Values:

1 (Mammography only)	Recall for additional imaging and/or comparison with prior examination(s)
(Ultrasound only)	Recall for additional imaging
(MRI only)	Recommend additional imaging: Mammogram or targeted ultrasound
2 (Mammography only)	Routine mammography screening
(Ultrasound only)	Routine screening
(MRI only)	Routine breast MRI screening if cumulative lifetime risk ≥ 20%

3 (Mammography only)	Short-interval (6-month) follow-up or continued surveillance mammography
(Ultrasound only)	Short-interval (6-month) follow-up or continued surveillance
(MRI only)	Short-interval (6-month) follow-up
4 (All modalities)	Tissue diagnosis
5 (All modalities)	Surgical excision when clinically appropriate
6 (All modalities)	Other

Pathology Data

110. Date of biopsy

In NMD? Y

Description: Date of biopsy

Use: Required if biopsy performed; not applicable otherwise

Response: Indicate date of biopsy.

Values: Any valid date in mm/dd/yyyy format

111. Biopsy procedure

In NMD? Y

Description: Biopsy procedure

Use: Required

Response: Select one.

Values:

- 1 Fine needle aspiration cytology
- 2 Core biopsy
- 3 Cyst aspiration - diagnostic
- 4 Incisional biopsy
- 5 Excisional biopsy
- 6 Mastectomy
- 99 Not applicable / Not available

112. Pathology code(s)

In NMD? N

Description:	May be defined by the user. Classification and malignancy type of user-defined codes must not conflict with those of BI-RADS® codes.
Use:	Required if breast cancer pathology identified; not applicable otherwise
Response:	Select one code for each pathology identified. Report only breast cancer pathologies.
Values:	Any code from the Pathology Code Appendix, or a user-defined code.

113. Classification of lesion

In NMD? Y

Description:	Classification of lesion
Use:	Required
Response:	Select one per lesion reported. Refer to Pathology Code Appendix for classification by pathology code.
Values:	
1	Benign
2	High Risk
3	Malignant
99	Not applicable / Not available

114. Malignancy type

In NMD? Y

Description: Malignancy type**Use:** Required**Response:** Select one. Refer to Pathology Code Appendix for malignancy type by pathology code.**Values:**

1 Invasive

2 DCIS

88 Other

99 Not applicable / Not available

115. Pathological size of tumor

In NMD? Y

Description: Pathological size of tumor**Use:** Required if breast cancer pathology identified; not applicable otherwise**Response:** Indicate tumor size in mm.**Values:** 0 - 999.9

Description: Histology grade. For invasive carcinomas, the AJCC Cancer Staging Manual, 7th Edition (2010), recommends using the Nottingham combined histologic grade (Elston-Ellis modification of the Scarff-Bloom-Richardson grading system).

Use: Required

Response: Select one.

Values:

- 0 Invasive carcinoma: GX - Grade cannot be assessed
- 1 Invasive carcinoma: G1 - Low combined histologic grade (favorable)
- 2 Invasive carcinoma: G2 - Intermediate combined histologic grade (moderately favorable)
- 3 Invasive carcinoma: G3 - High combined histologic grade (unfavorable)
- 4 DCIS: Low grade
- 5 DCIS: Intermediate grade
- 6 DCIS: High grade
- 99 Not applicable / Not available

117. Nodes removed

In NMD? Y

Description: Nodes removed**Use:** Required**Response:** Indicate number of nodes removed.**Values:** Any integer between 0 and 99**118. Nodes positive**

In NMD? Y

Description: The number of nodes removed that were positive for breast cancer.**Use:** Required if "Nodes removed" > 0; not applicable otherwise**Response:** Indicate number of nodes positive for cancer.**Values:** Any integer between 0 and 99**119. Tumor stage**

In NMD? Y

Description: Tumor stage as defined in the AJCC Cancer Staging Manual, 7th Edition (2010).**Use:** Required**Response:** Select one.**Values:**

0 Stage 0

1A Stage IA

1B Stage IB

2A Stage IIA

- 2B Stage IIB
- 3A Stage IIIA
- 3B Stage IIIB
- 3C Stage IIIC
- 4 Stage IV
- 99 Not applicable / Not available

120 . Primary tumor**In NMD? Y**

Description: Primary tumor as defined in the AJCC Cancer Staging Manual, 7th Edition (2010)

Use: Required

Response: Select one.

Values:

- 1 TX
- 2 T0
- 3 Tis
- 4 Tis (DCIS)
- 5 Tis (LCIS)
- 6 Tis (Paget's)
- 7 T1
- 8 T1mi
- 9 T1a
- 10 T1b
- 11 T1c
- 12 T2

- 13 T3
- 14 T4
- 15 T4a
- 16 T4b
- 17 T4c
- 18 T4d
- 99 Not applicable / Not available

121. Regional lymph nodes**In NMD? Y**

Description: Regional lymph nodes as defined in the AJCC Cancer Staging Manual, 7th Edition (2010)

Use: Required

Response: Select one.

Values:

- 1 NX
- 2 N0
- 3 N1
- 4 N2
- 5 N2a
- 6 N2b
- 7 N3
- 8 N3a
- 9 N3b
- 10 N3c
- 99 Not applicable / Not available

Description: Distant metastases as defined in the AJCC Cancer Staging Manual, 7th Edition (2010)

Use: Required

Response: Select one.

Values:

- 1 M0
- 2 cM0(i+)
- 3 M1
- 99 Not applicable / Not available

DATA DICTIONARY

PATHOLOGY CODE APPENDIX

Benign:

AB	Abscess
AD	Adenosis
AL	Adenolipoma
AM	Apocrine metaplasia
AME	Adenomyoepithelioma
AMY	Amyloid (tumor)
ANA	Angiolipoma
ANH	Axillary node with reactive lymphoid hyperplasia
BAN	Benign axillary node
BC	Benign cyst
BCB	Benign cyst with blood
BCL	Benign Calcifications
CP	Intracystic papilloma
DE	Duct ectasia
DF	Diabetic fibrous mastopathy
DHU	Ductal hyperplasia, Usual
EBT	Ectopic (accessory) breast tissue
EC	Epidem inclusion cyst
FA	Fibroadenoma
FAH	Fibroadenomatoid hyperplasia
FAL	Fibroadenolipoma
FB	Foreign body (reaction)
FC	Fibrocystic change
FF	Focal fibrosis
FM	Fibromatosis
FN	Fat necrosis
GA	Galactocoele
GC	Granular cell tumor
GF	Giant fibroadenoma
GYN	Gynecomastia
HA	Hamartoma
HE	Hemangioma
HES	Hemangioma – nonparenchymal, subcutaneous
HEV	Hemangioma - venous
HM	Hematoma
IF	Inflammation
IMN	Intramammary lymph node
IN	Infarct
IP	Intraductal papilloma
JF	Juvenile fibroadenoma
JP	Juvenile papillomatosis
LA	Lactating adenoma
LB	Lipoma of the breast
LC	Lactational change
LM	Leiomyoma
MFB	Myofibroblastoma
MGA	Microglandular adenosis
MIP	Multiple intraductal papillomas
NA	No abnormality
NBT	Normal breast tissue
NFA	Neurofibroma
NFS	Neurofibromatosis
NPA	Nipple adenoma

Benign (continued):

PA	Papilloma
PL	Pleomorphic adenoma
PLC	Pseudolactational change
PSH	Pseudoangiomatous stromal hyperplasia
RS	Radial scar
SA	Sclerosing adenosis
SE	Seroma
SG	Silicone granuloma
ST	Scar tissue
TA	Tubular adenoma

High Risk:

ADH	Atypical ductal hyperplasia
ALH	Atypical lobular hyperplasia
LS	Lobular carcinoma in-situ (LCIS)
PDP	Peripheral duct papillomas
PT	Phyllodes tumor – benign

Malignant - Invasive:

ADC	Adenoid cystic carcinoma
AP	Apocrine carcinoma
AS	Angiosarcoma
CC	Mucinous (colloid) carcinoma
CED	Carcinoma with endocrine differentiation
FS	Fibrosarcoma
GRC	Glycogen-rich carcinoma
HAP	Hemangiopericytoma
ICC	Invasive cribriform carcinoma
ICP	Intracystic papillary carcinoma (may be either invasive or DCIS)
ID	Invasive ductal carcinoma
IL	Invasive lobular carcinoma
IMC	Invasive mammary carcinoma
INC	Inflammatory carcinoma
IPC	Invasive papillary carcinoma
LMS	Leiomyosarcoma
LPS	Liposarcoma
LRC	Lipid-rich (lipid-secreting) carcinoma
LVI	Lymphovascular invasion
MC	Medullary carcinoma
SC	Signet ring cell carcinoma
SJC	Secretory carcinoma
TC	Tubular carcinoma

Malignant - DCIS:

DCC	Ductal carcinoma in situ, comedo type
DCM	Ductal carcinoma in situ, micropapillary type
DCR	Ductal carcinoma in situ, cribriform type

Malignant – DCIS (Continued):

DCS	Ductal carcinoma in situ, solid type
ICP	Intracystic papillary carcinoma (may be either invasive or DCIS)
MCA	Microcalcifications associated with ductal carcinoma in situ
PC	Papillary carcinoma in situ
Malignant - Other:	
ANL	Axillary node with lymphoma
ANM	Axillary nodal with metastatic carcinoma
BCN	Basal cell carcinoma of the nipple
HL	Hodgkin's lymphoma
LI	Leukemic infiltration
LY	Lymphoma
MAN	Occult carcinoma presenting with axillary lymph node metastasis
MB	Metastatic cancer to the breast
MBC	Metastatic cancer to the breast from the colon
MBL	Metastatic cancer to the breast from the lung
MBM	Metastatic melanoma to the breast
MBO	Metastatic cancer to the breast from the ovary
MBS	Metastatic sarcoma to the breast
MIM	Metastasis to an intramammary lymph node
MMN	Malignant melanoma of the nipple
MPC	Metaplastic carcinoma
NHL	Non-Hodgkin lymphoma
NMS	Neoplasm of the mammal skin
OS	Osteosarcoma
PD	Paget's disease (of the nipple)
PLS	Plasmacytoma
PTB	Phyllodes tumor – borderline
PTM	Phyllodes tumor – malignant
PUS	Pleomorphic undifferentiated sarcoma
SCN	Squamous cell carcinoma of the nipple
SQ	Squamous cell carcinoma

Appendix

Sample Lay Letters

2013



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INTRODUCTION

Since 1999, it has been required that the interpreting physician send every patient who receives a mammogram a written mammography report expressed in terms easily understood by a lay person. Failure to comply with this reporting requirement will result in a citation by the FDA.

The following sample lay letters were developed by a multidisciplinary panel and have been updated to provide the most recent American Cancer Society guidelines. New language has been included to inform a woman if the mammogram shows that her breast tissue is dense.

These samples are provided for your convenience; you may use these as is, modify them, or create your own lay reports.

REVISIONS

Sample Lay Letter for Need Additional Imaging Evaluation (to be used with BI-RADS® 0)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

Your recent [mammogram **or** breast ultrasound **or** breast MRI] showed a finding that **requires additional imaging studies**, such as **additional** mammographic views or ultrasound, for a complete evaluation. Most such findings are benign (not cancer). Please call **[telephone #]** to schedule an appointment for these tests if you have not already done so.

A report of your results was sent to: **[referring health care provider]**.

Your images will become part of your medical record at **[facility name]**. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

Sample Lay Letter for Negative or Benign Finding(s) and Patient has Physical Findings, Signs or Symptoms (to be used with BI-RADS® 1-2)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

We wish to inform you that the results of your recent [mammogram **or** breast ultrasound **or** breast MRI] shows no sign of breast cancer. However, the area of concern in your breast that prompted this exam should be **further evaluated by your physician or other health care provider**. He/she will determine the necessary follow-up at that time.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

[Optional, if the woman has dense breasts] The mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. But dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you to raise your awareness. Use this report when you talk to your doctor about your own risks for breast cancer, which includes your family history. At that time, ask your doctor if more screening tests might be useful, based on your risk.

A report of your results was sent to: **[referring health care provider]**.

Your images will become part of your medical record at **[facility name]**. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

Mammogram: Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.

Clinical breast exam: a clinical breast exam is recommended every 3 years for women in their 20s and 30s and every year for women 40 and over.

Breast awareness and breast self-exam: Women should know how their breasts normally look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.

Sample Lay Letter for Negative or Benign Finding(s) (to be used with BI-RADS® 1-2)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

We are pleased to let you know that the results of your recent [mammogram **or** breast ultrasound **or** breast MRI] shows no sign of breast cancer.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

[Optional, if the woman has dense breasts] The mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. But dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you to raise your awareness. Use this report when you talk to your doctor about your own risks for breast cancer, which includes your family history. At that time, ask your doctor if more screening tests might be useful, based on your risk.

A report of your results was sent to: **[referring health care provider]**.

Your images will become part of your medical record at **[facility name]**. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

American Cancer Society Guidelines for Early Breast Cancer Detection in Women without Symptoms

Mammogram: Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.

Clinical breast exam: a clinical breast exam is recommended every 3 years for women in their 20s and 30s and every year for women 40 and over.

Breast awareness and breast self-exam: Women should know how their breasts normally look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.

Sample Lay Letter for Probably Benign Finding, but Initial 6-Month Follow-up Recommended (to be used with BI-RADS® 3)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

Your recent [mammogram **or** breast ultrasound **or** breast MRI] showed an area that we believe is **probably benign** (probably not cancer). However, in 6 months, you should **have a follow-up mammogram** to confirm that this area has not changed. Please call for an appointment at [telephone#].

A report of your results was sent to: [referring health care provider].

Your images will become part of your medical record at [facility name]. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

American Cancer Society Guidelines for Early Breast Cancer Detection in Women without Symptoms

Mammogram: Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.

Clinical breast exam: a clinical breast exam is recommended every 3 years for women in their 20s and 30s and every year for women 40 and over.

Breast awareness and breast self-exam: Women should know how their breasts normally

look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.

Sample Lay Letter for Abnormal Finding (to be used with BI-RADS® 4-5)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

As we discussed at your recent visit, your [mammogram **or** breast ultrasound **or** breast MRI] showed an **abnormality** that requires a biopsy. The only way that you can be sure that the abnormality is benign (not cancer) is to sample or surgically remove the area of concern and send these samples for pathological analysis. When these results are available, your health care provider or our facility will contact you concerning the results and any follow up tests or appointments that may be required.

A report of your results was sent to: **[referring health care provider]**. He/she has been informed about the need for this biopsy. You should contact your physician or other health care provider as soon as possible (if you have not already done so).

Your images will become part of your medical record at **[facility name]**. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

Sample Lay Letter for Abnormal Finding (to be used with BI-RADS® 6)

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

A report of your [mammography or breast ultrasound or breast MRI] results were sent to: [referring health care provider]. Please **contact your physician or other health care provider** to discuss the results and to determine what the next steps in your medical care should be.

Your images will become part of your medical record at [facility name]. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

Sample Lay Checklist Letter to be Handed to Patient if On-Line, Same Day Reading Is Done

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

Your recent mammogram breast ultrasound breast MRI was:

(circle all that apply)

- Normal/benign.** There was no sign of breast cancer.
- Probably benign.** Your examination showed an area that we believe is probably benign (probably not cancer). However, in 6 months you should have a follow-up mammogram to confirm that the area of concern has not changed. Please call for an appointment at [telephone#].
- Additional imaging studies needed.** Imaging, such as additional mammographic views or ultrasound, are necessary to complete the evaluation. Please call for an appointment at [telephone #].
- Previous mammograms needed.** There is a finding on your mammogram that needs to be compared to previous mammograms. We will send you the results once we have obtained the previous mammograms and made the comparison.
- Abnormal.** Your examination showed an abnormality that requires a biopsy. The only way that you can be sure that the abnormality is benign (not cancer) is to sample or surgically remove the area of concern and send these samples for pathological analysis. Your physician or referring health care provider will be informed about the need for this biopsy. You should contact him/her as soon as possible (if you have not already done so).

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

[Optional, if the woman has dense breasts] The mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. But dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you to raise your awareness. Use this report when you talk to your doctor about your own risks for breast cancer, which includes your family history. At that time, ask your

doctor if more screening tests might be useful, based on your risk.

A report of your results will be sent to: [referring health care provider].

Your images will become part of your medical record at [facility name]. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

American Cancer Society Guidelines for Early Breast Cancer Detection in Women without Symptoms

Mammogram: Yearly mammograms are recommended starting at age 40 and continuing for as long as a woman is in good health.

Clinical breast exam: a clinical breast exam is recommended every 3 years for women in their 20s and 30s and every year for women 40 and over.

Breast awareness and breast self-exam: Women should know how their breasts normally look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.

Sample Lay Letter for Review of Previous Mammograms if Not Available at Time of Current Mammogram

Name of Facility, Address and Phone Number

Name of Patient/ID

Date of Breast Imaging

Dear Patient:

This is to inform you that we have reviewed your previous mammograms and compared them to your most recent mammography examination. There is no significant change and no sign of breast cancer.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

[Optional, if the woman has dense breasts] The mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. But dense breast tissue can make it harder to find cancer on a mammogram. Also, dense breast tissue may increase your breast cancer risk. This information about the result of your mammogram report is given to you to raise your awareness. Use this report when you talk to your doctor about your own risks for breast cancer, which includes your family history. At that time, ask your doctor if more screening tests might be useful, based on your risk.

A report of your results was sent to: **[referring health care provider]**.

Your images will become part of your medical record at **[facility name]**. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this mammogram was done.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D.
Interpreting Radiologist

American Cancer Society Guidelines for Early Breast Cancer Detection in Women without Symptoms

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Breast awareness and breast self-exam: Women should know how their breasts normally look and feel and report any breast change promptly to their health care provider. Breast self-exam (BSE) is an option for women starting in their 20s.

Breast MRI: Some women, because of their family history, a genetic tendency, or certain other factors, should be screened with MRI in addition to mammography. (The number of women who fall into this category is small: less than 2% of all the women in the US.) Talk with your doctor about your history and whether you should have additional tests at an earlier age.



QUALITY IS OUR IMAGE

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