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# Screening Mammography–detected Cancers: Sensitivity of a Computer-aided Detection System Applied to Full-Field Digital Mammograms[1]

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**Purpose:** To retrospectively evaluate the sensitivity of the performance of a computer-aided detection (CAD) system applied to full-field digital mammograms for detection of breast cancers in a screening group, with histologic findings as the reference standard.

**Materials and Methods:** This study had institutional review board approval, and patient informed consent was waived. A commercially available CAD system was applied to the digital mammograms of 103 women (mean age, 51 years; range, 35–69 years) with 103 breast cancers detected with screening. Sensitivity values of the CAD system according to mammographic appearance, breast composition, and histologic findings were analyzed. Normal mammograms from 100 women (mean age, 54 years; age range, 35–75 years) with no mammographic and clinical abnormality during 2-year follow-up were used to determine false-positive CAD system marks. Differences between the cancer detection rates in fatty and dense breasts for the CAD system were compared by using the $\chi^2$ test.

**Results:** The CAD system correctly marked 99 (96.1%) of 103 breast cancers. The CAD system marked all 44 breast cancers that manifested as microcalcifications only, all 23 breast cancers that manifested as a mass with microcalcifications, and 32 (89%) of 36 lesions that appeared as a mass only. The sensitivity of the CAD system in the fatty breast group was 95% (59 of 62) and in the dense breast group was 98% (40 of 41) ($P = .537$). The CAD system correctly marked all 31 lesions of ductal carcinoma in situ (DCIS), all 22 lesions of invasive ductal carcinoma with DCIS, the single invasive lobular carcinoma lesion, and 45 (92%) of 49 lesions of invasive ductal carcinoma. On normal mammograms, the mean number of false-positive marks per patient was 1.80 (range, 0–10 marks; median, 1 mark).

**Conclusion:** The CAD system can correctly mark most (96.1%) asymptomatic breast cancers detected with digital mammographic screening, with acceptable false-positive marks (1.80 per patient).

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Full-field digital mammography has more advantages, which include higher contrast resolution, better dynamic range, and lower noise, than does screen-film mammography (1,2). One of the limitations of screen-film mammography is that the film serves simultaneously as the image receptor and display medium. In full-field digital mammography, the image is captured by the digital detector and displayed on a monitor. Despite the expectation that full-field digital mammography is better than screen-film mammography, two trials failed to find any difference between full-field digital mammograms and screen-film mammograms in breast cancer detection (3,4). Recently, the Digital Mammographic Imaging Screening Trial (known as DMIST), however, found that the accuracy of full-field digital mammography is significantly higher than that of screen-film mammography in women younger than 50 years of age, in women with heterogeneously dense or extremely dense breasts at mammography, and in premenopausal or perimenopausal women (5,6).

Computer-aided detection (CAD) systems have been developed to reduce the number of false-negative interpretations at screening mammography, and they are capable of helping to reduce the rate of false-negative interpretations for the detection of masses and calcifications (7). Warren Burhenne et al (8) reported that CAD systems correctly marked missed findings in 77.4% (89 of 115) of prior false-negative mammograms. In a series conducted by Freer and Ulissey (9), 12 860 screening mammograms were interpreted with the assistance of a CAD system. When they compared the performance of radiologists with and without the CAD system, the authors observed a 19.5% (eight of 41) increase in the number of cancers detected with the CAD system and an increase in the recall rate from 6.5% to 7.5%; moreover, the percentage of early-stage (stage 0 and I) malignancies that were detected increased from 73.2% (30 of 41) to 77.6% (38 of 49). The mammogram (film) was digitized for CAD system application in these studies.

With digital mammography, the CAD system does not require a digitizer and allows display of the marks of the CAD system rapidly after image acquisition. CAD systems for full-field digital mammography are now commercially available. However, there is little in the literature on the application of a CAD system to full-field digital mammography in a screening group (10). Thus, the purpose of our study was to retrospectively evaluate the sensitivity of the performance of a CAD system applied to full-field digital mammograms for the detection of breast cancers in a screening group, with histologic findings as the reference standard.

### Advances in Knowledge

- A computer-aided detection (CAD) system correctly marked 96.1% of cancers detected by using digital mammographic screening, with acceptable false-positive marks (1.80 per patient).
- The CAD system can miss detection of noncalcified breast cancer masses, but calcified cancers were always detected in our study.

## Materials and Methods

### Women with Abnormal and Normal Mammograms

This study was conducted with institutional review board approval; informed consent was waived by the institutional review board. Of 30 000 full-field digital mammograms obtained from November 2003 to October 2005 in a screening group of women, 111 (0.37%) consecutive women had histologically proved breast cancer (asymptomatic, nonpalpable). From these 111 patients, we excluded six patients with more than one mammographically visible suspicious lesion per image and two with bilateral cancers from the study to simplify statistical analysis, as in prior similar studies (11). Therefore, 103 patients with 103 screening-detected breast cancers constituted the patient study group (Fig 1). These cancers were initially detected by radiologists without the use of a CAD system and were surgically excised at our facility. Preoperative ultrasonographic examination of the bilateral whole breasts was performed in all patients (12) and revealed no suspicious findings in the contralateral breast. The mean age of these 103 women was 51 years (range, 35–69 years).

To determine the false-positive mark rate, 100 consecutive women with normal screening mammograms were selected. Normal mammograms had been interpreted as category 1 or 2 according to the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiology (13). All women underwent 2 years of mammographic follow-up. At all 2-year follow-up examinations, no mammographic and clinical abnormality was demonstrated in these 100 women. Digital mammograms with normal findings had been obtained in November 2003. The mean age of the 100 women with normal mammograms was 54 years (range, 35–75 years).

### Mammograms

Bilateral mammograms had been obtained by using a full-field digital mammographic system (Senographe 2000D; GE Medical Systems, Buc, France). All patients underwent a standard two-view examination (craniocaudal and mediolateral oblique mammograms) of

**Published online before print**
10.1148/radiol.2441060756

**Radiology 2007;** 244:104–111

**Abbreviations:**
BI-RADS = Breast Imaging Reporting and Data System
CAD = computer-aided detection
CI = confidence interval
DCIS = ductal carcinoma in situ

**Author contributions:**
Guarantor of integrity of entire study, W.K.M.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, S.K.Y., W.K.M., N.C., J.S.P., S.M.K.; clinical studies, S.K.Y., W.K.M., N.C., J.S.P., J.H.C., S.M.K., S.J.K.; statistical analysis, S.K.Y., J.S.P.; and manuscript editing, S.K.Y., W.K.M., J.H.C., S.M.K., S.J.K., J.G.I.

Authors stated no financial relationship to disclose.

each breast performed by an experienced radiologic technologist (three technologists with 5–10 years of experience). In total, there were 412 mammographic images from the 103 patients with breast cancer and 400 mammographic images from the 100 women with normal mammographic findings.

All mammograms were retrospectively analyzed in consensus by two radiologists (S.K.Y., N.C.) with 3–6 years of experience with breast imaging by using a 5-megapixel (2560 × 2048-pixel) liquid-crystal display system (ME511L; Totoku Electric, Tokyo, Japan). The liquid-crystal display monitor was calibrated according to the manufacturer's specifications for mammograms. The largest mammographically visible diameter of the detected lesions was determined. The mean size of the lesions was 2.2 cm (median, 1.8 cm; range, 0.5–7.0 cm). Lesions were divided according to their mammographic appearance as masses, microcalcifications, or masses with microcalcifications. Thirty-six lesions were described as masses, 44 were described as microcalcifications, and 23 were described as masses with microcalcifications (Fig 1).

Of the 103 patients with breast cancer, 13 (12.6%) had homogeneously fatty breasts (BI-RADS category 1 density), 49 (47.6%) had scattered fibroglandular tissues in fatty breasts (BI-RADS category 2 density), 31 (30.1%) had heterogeneously dense breasts (BI-RADS category 3 density), and 10 (9.7%) had extremely dense breasts (BI-RADS category 4 density) (13). Of the 100 women with normal mammograms, 11 (11%) had homogeneously fatty breasts (BI-RADS category 1 density), 40 (40%) had scattered fibroglandular tissues in fatty breasts (BI-RADS category 2 density), 37 (37%) had heterogeneously dense breasts (BI-RADS category 3 density), and 12 (12%) had extremely dense breasts (BI-RADS category 4 density).

### Histologic Findings as Reference Standard

One radiologist (S.K.Y.) reviewed the postoperative pathology reports of all lesions and then classified lesions according to their histologic types as invasive ductal carcinoma, ductal carcinoma in situ (DCIS), invasive ductal carcinoma with DCIS (invasive ductal carcinoma containing more than 25% of a DCIS component), or invasive lobular carcinoma. The most common histologic findings were invasive ductal carcinoma (47.6%, 49 of 103), followed by DCIS (30.1%, 31 of 103), invasive ductal carcinoma with DCIS (21.4%, 22 of 103), and invasive lobular carcinoma (1.0%, one of 103). For treatment, mastectomy was performed in 23 patients and lumpectomy or breast conservation therapy was performed in 80 patients.

### Analysis of Mammograms with the CAD System

A commercially available CAD system (ImageChecker M1000-DM, version 3.1; R2 Technology, Sunnyvale, Calif), which was developed for full-field digital mammography, was used for this retrospective study. This CAD system, which was embedded in the full-field digital mammographic unit, was applied to the mammograms of all 103 patients with breast cancer and to the mammograms of healthy 100 patients by one of three radiologists (S.K.Y., S.J.K., J.H.C.) with 3–6 years of experience with breast imaging. It took 1 second to activate and display the marks of the CAD system at the workstation of the digital mammographic system mentioned before. Digital images may contain zero or more CAD system marks, which indicate areas where the detection algorithm recognizes a pattern that warrants evaluation by the radiologist. An asterisk indicates a pattern suggestive of a mass or an area of architectural distortion, whereas a triangle indicates an area of clustered bright spots that are suggestive of microcalcifications. Images with CAD system marks were saved in the review workstation and then forwarded to a picture archiving and communication system. We used these images with CAD system marks in the picture archiving and communication system for data analysis.

The locations of marks of the CAD system that corresponded to mammographically detected and histologically confirmed cancerous lesions were analyzed by two radiologists (S.K.Y., N.C.) in consensus to determine whether the CAD system had correctly marked the lesion. CAD system marks were considered positive if, on at least one view, they correctly identified the corresponding mammographic lesion location. In addition, lesion mark types (ie, a mass or microcalcifications) also had to agree with the mammographic characteristic (a mass or microcalcifications) of the lesion. If both mass and

**Figure 1**

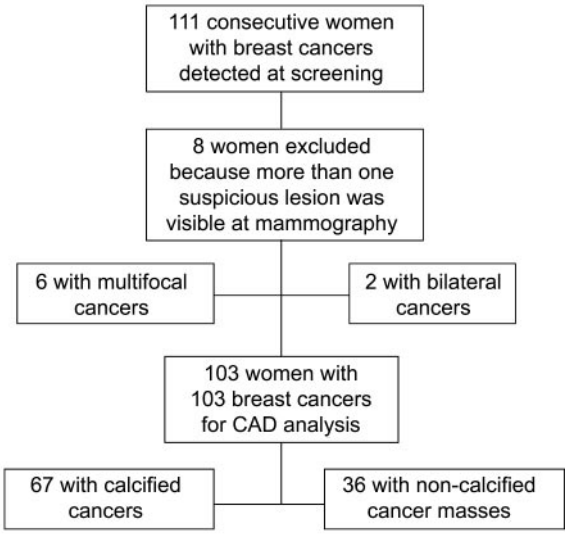



**Figure 1:** Flow diagram of the study group.

**Figure 2**

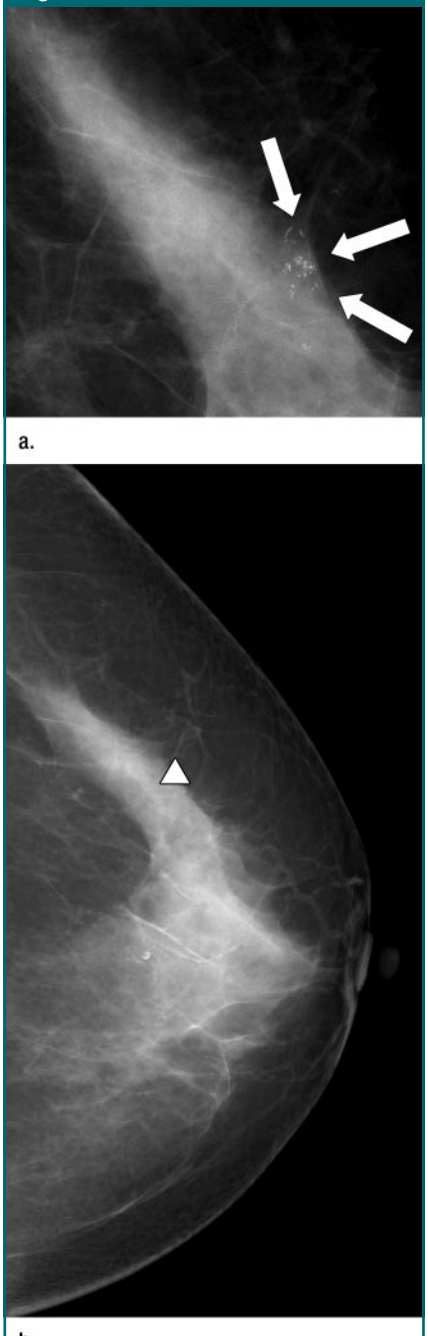


**Figure 2:** **(a)** Craniocaudal magnification digital mammogram in a 53-year-old woman with DCIS, which was detected as clustered microcalcifications (arrows) at screening mammography. **(b)** Craniocaudal screen-capture image of a CAD display. The CAD system correctly marked the microcalcifications (triangle).

microcalcification features were noted for the lesion, then either mark type was considered correct. All CAD system marks that did not mark the known malignancy or did not agree with the lesion characteristic were defined as false-positive marks.

All CAD system marks on normal mammograms were counted as false-positive marks, and these were assessed individually for masses and microcalcifications. The design of the CAD system we used limits the total number of marks per patient (14). Therefore, theoretically, in patients with cancer, the maximum number of false-positive marks was limited by the number of marks required to indicate cancers. For this reason, we used normal mammograms as well as abnormal mammograms to determine the number of false-positive marks per patient.

### Statistical Analysis

In the 103 women with breast cancers, the total number of marks for masses, the number of marks for microcalcifications, and the number of true-positive and false-positive marks were calculated. We counted the same lesion as marked twice if the CAD system marked it on both the craniocaudal and mediolateral oblique views. The sensitivity of the performance of the CAD system was calculated as the number of lesions correctly marked divided by the total number of lesions and was provided with 95% confidence intervals (CIs). The sensitivity values for the CAD system with respect to mammographic appearances and histologic findings were then determined. The mean size of lesions that were missed with the CAD system was compared with that of lesions detected with the CAD system by using the independent-sample *t* test. Each breast was allocated to one of the two following groups according to its composition (ie, fatty [BI-RADS categories 1 and 2 density] or dense [BI-RADS categories 3 and 4 density]), and it was then determined whether sensitivity values of the performance of the CAD system were related to breast composition. Differences between the cancer detection rates of the CAD system for use in fatty and dense breasts were compared by using the $\chi^2$ test.

For the normal mammograms of the 100 women with 400 images, the mean numbers of false-positive marks per patient and per image were calculated and provided with the range and median. False-positive marks were individually assessed for masses and microcalcifications. Differences between fatty and dense breasts with respect to false-positive marks were compared by using $\chi^2$ analysis. A difference with a *P* value of less than .05 was considered statistically significant. Statistical analysis of the results was performed by using software (SPSS, version 10.0 for Windows; SPSS, Chicago, Ill).

## Results

### CAD System: Women with Breast Cancer

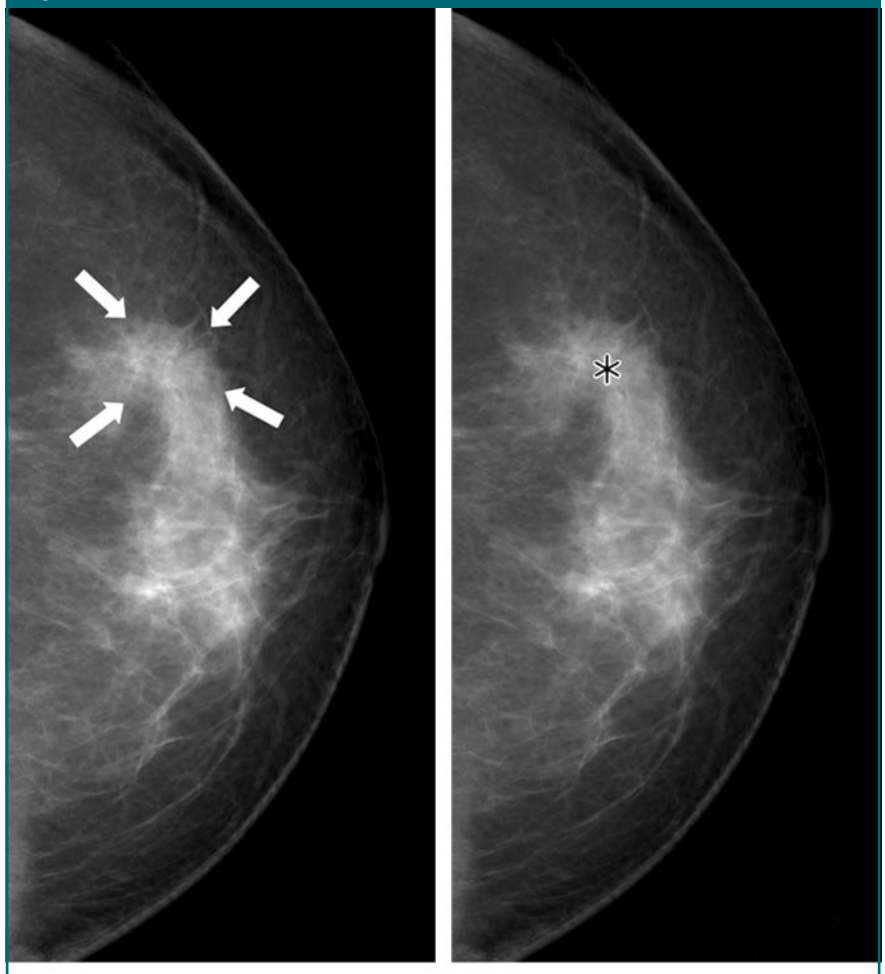
A total of 442 marks were placed by the CAD system, with 182 marks for masses and 260 marks for microcalcifications. Of the 182 marks for masses, 84 were true-positive marks and 98 were false-positive marks. Of the 260 marks for microcalcifications, 208 were true-positive marks and 52 were false-positive marks. The mean number of false-positive marks per patient was 0.95 mark for masses (range, 0–3 marks; median, 1 mark) and 0.50 mark for microcalcifications (range, 0–2 marks; median, 0 marks), with the overall false-positive mark rate per patient of 1.45 (range, 0–5 marks; median, 1 mark). The CAD system correctly marked 99 (96.1%) of 103 breast cancers (95% CI: 90.1%, 98.8%), with 83 cancers marked on both views and 16 cancers marked on only one view. The system marked all 44 breast cancers that manifested as microcalcifications only (sensitivity, 100%; 95% CI: 93.1%, 100%) (Fig 2) and all 23 breast cancers that manifested as a mass with microcalcifications (sensitivity, 100%; 95% CI: 87.5%, 100%). Of the 67 cancers, 59 cancers were marked on both views and eight cancers were marked on only one view. Thirty-two of 36 cancers that appeared as a mass only were marked correctly by the CAD

system (sensitivity, 89%; 95% CI: 74.1%, 96.2%) (Figs 3, 4), with 24 cancers marked on both views and eight cancers marked on only one view. In the group of 23 cancers that manifested as a mass with microcalcifications, the CAD system marked both components in 12, a mass in three, and microcalcifications in eight.

The CAD system correctly marked all 31 DCIS lesions (sensitivity, 100%; 95% CI: 90.4%, 100%) (Fig 2), all 22 lesions of invasive ductal carcinoma with DCIS (sensitivity, 100%; 95% CI: 87.0%, 100%), and the single invasive lobular carcinoma lesion (sensitivity, 100%; 95% CI: 16.8%, 100%). Forty-five of 49 lesions of invasive ductal carcinoma were marked correctly by the CAD system (sensitivity, 92%; 95% CI: 80.3%, 97.3%) (Table). The mean size of lesions that were missed with the CAD system was 1.7 cm ± 0.5 (range, 1.2–2.3 cm), whereas that of lesions that were detected with the CAD system was 2.2 cm ± 1.5 (range, 0.5–7.0 cm). The difference was not statistically significant ($P = .447$).

The sensitivity of the performance of the CAD system in the fatty breast group was 95% (59 of 62), with 95% CI of 86.2% to 98.9%, and in the dense breast group was 98% (40 of 41), with 95% CI of 86.3% to 100%, and this difference was not significant ($P = .537$). The sensitivity values of the performance of the CAD system for detection of masses, microcalcifications, and masses with microcalcifications in the fatty breast group were 90% (26 of 29), with 95% CI of 72.8% to 97.2%; 100% (17 of 17), with 95% CI of 83.8% to 100%; and 100% (16 of 16), with 95% CI of 82.9% to 100%, respectively. The sensitivity values of the performance of the CAD system for detection of masses, microcalcifications, and masses with microcalcifications in the dense breast group were 86% (six of seven), with 95% CI of 46.7% to 99.5%; 100% (27 of 27), with 95% CI of 89.2% to 100%; and 100% (seven of seven), with 95% CI of 67.8% to 100%, respectively. The sensitivity of the performance of the CAD system for detection of mass lesions was higher in fatty breasts than it was in dense breasts, but the difference was not significant ($P = .766$).

**Figure 3**



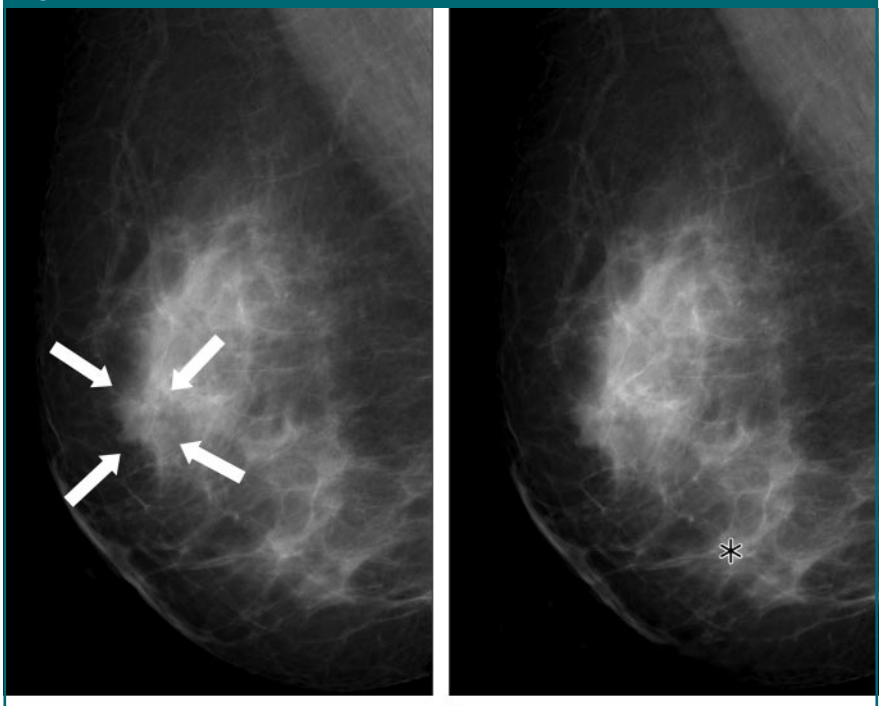
a. b.

**Figure 3:** **(a)** Craniocaudal digital mammogram in a 47-year-old woman with invasive ductal carcinoma detected as an ill-defined mass (arrows) at screening mammography. **(b)** Craniocaudal screen-capture image of a CAD display. The CAD system correctly marked the mass (*).

### CAD System: Women with Normal Mammograms

For the 100 normal mammograms, the mean number of false-positive marks per patient was 1.80 (range, 0–10 marks; median, 1 mark), with 1.16 marks (range, 0–4 marks; median, 1 mark) for masses and 0.64 mark (range, 0–8 marks; median, 0 marks) for microcalcifications (ie, 0.45 false-positive mark per image, with 0.29 mark for masses and 0.16 mark for microcalcifications). There were 1.55 false-positive marks for masses (range, 0–40 marks; median, 1 mark) and 0.65 false-positive mark for microcalcifications (range, 0–8 marks; median, 0 marks) per patient in fatty normal breasts, with a total of 2.20 false-positive marks (range, 0–10 marks; median, 2 marks) per patient in this breast pattern. On the other hand, the mean number of false-positive marks per patient in patients with dense normal breasts was 1.39 (range, 0–8 marks; median, 1 mark), with 0.76 false-positive mark for masses (range 0–4 marks; median, 0 marks) and 0.63 false-positive mark for microcalcifications (range,

**Figure 4**



a. b.

**Figure 4:** **(a)** Mediolateral oblique digital mammogram in a 61-year-old woman with invasive ductal carcinoma detected as an irregularly shaped mass (arrows) at screening mammography. **(b)** Mediolateral oblique screen-capture image of a CAD display of the CAD system output. The CAD system could not mark the mass. Only a single false-positive mark for a mass (*) was noted.

**Sensitivity of the CAD System on the Basis of Histologic Findings and Mammographic Appearances of Lesions**

| Histologic Findings | Mass | Microcalcifications | Mass with Microcalcifications | All Patients |
|---|---|---|---|---|
| Invasive ductal carcinoma | | | | |
| No. with lesion* | 32 (65) | 5 (10) | 12 (25) | 49 |
| No. in whom CAD marked lesions | 28 | 5 | 12 | 45 |
| CAD sensitivity (%) | 87.5 | 100 | 100 | 91.8 |
| Invasive ductal carcinoma with DCIS | | | | |
| No. with lesion* | 0 | 16 (73) | 6 (27) | 22 |
| No. in whom CAD marked lesions | ... | 16 | 6 | 22 |
| CAD sensitivity (%) | ... | 100 | 100 | 100 |
| Invasive lobular carcinoma | | | | |
| No. with lesion* | 1 (100) | 0 | 0 | 1 |
| No. in whom CAD marked lesions | 1 | 0 | 0 | 1 |
| CAD sensitivity (%) | 100 | ... | ... | 100 |
| DCIS | | | | |
| No. with lesion* | 3 (10) | 23 (74) | 5 (16) | 31 |
| No. in whom CAD marked lesions | 3 | 23 | 5 | 31 |
| CAD sensitivity (%) | 100 | 100 | 100 | 100 |

* Numbers in parentheses are percentages.

0–8 marks; median, 0 marks) per patient.

In regard to false-positive marks for masses, 38 (75%) of 51 patients with fatty breasts had two or fewer false-positive marks for masses, whereas the remaining 13 (25%) had three or more false-positive marks. In patients with dense breasts, 45 (92%) of 49 patients had two or fewer false-positive marks for masses, whereas the remaining four (8%) had three or more false-positive marks. There were significantly fewer false-positive marks for masses in patients with dense breasts than in patients with fatty breasts ($P = .001$). A further analysis of the number of patients with no false-positive marks for microcalcifications revealed that 34 (67%) of 51 patients with fatty breast tissue had zero false-positive marks for microcalcifications, whereas the remaining 17 (33%) had one or more false-positive marks for microcalcifications. In patients with dense breasts, 34 (69%) of 49 had no false-positive marks for microcalcifications, whereas the remaining 15 (31%) had one or more false-positive marks for microcalcifications. The distribution of false-positive marks for microcalcifications did not differ significantly between patients with fatty breasts and patients with dense breasts ($P = .96$).

In 33 (65%) of 51 patients with fatty breast tissue, two or fewer total false-positive marks were observed, whereas in the remaining 18 (35%) patients, three or more false-positive marks were observed. Of the 49 patients with dense breasts, 40 (82%) had two or fewer total false-positive marks, whereas nine (18%) had three or more false-positive marks. There were significantly more total false-positive marks in patients with fatty breasts than in patients with dense breasts ($P = .02$).

## Discussion

In our study, a CAD system was applied to full-field digital mammograms, and 96.1% (99 of 103) of asymptomatic nonpalpable breast cancers were marked, with 1.80 false-positive marks per patient. This result is better than the find-

ings of 83.6% (906 of 1083) and 89.0% (809 of 956) for the CAD system when it was used to mark the same cancers on digitized screen-film images in a similar study group (8,14). However, interstudy comparisons cause problems, as case selection can substantially affect the CAD system evaluations. Our study group included only breast cancers detected by using mammographic screening, and 30% of these lesions proved to be DCIS lesions.

Baum et al (10) reported on the use of a commercially available CAD system for full-field digital mammography and recorded a sensitivity value of 87.3% (55 of 63) and a false-positive mark rate of 2.44 per patient. They used an older version of the CAD system that we used in our study. However, in their study, single-view mammograms were used in 15 patients. The same group also reported that the CAD system shows a decreasing number of overlooked carcinomas with increasing BI-RADS assessment category (15).

CAD performance may depend on background breast density (14) and tumor histologic findings (16,17), as well as on the case selection criteria adopted and the software version used. In our study, the sensitivity of the performance of the CAD system for detection of breast cancer was similar in fatty breasts and dense breasts (95% vs 98%, $P = .537$). This result is consistent with the findings of investigators in a previous study (14) who found that breast density did not affect overall breast cancer detection by using a CAD system. In our study, all four false-negative lesions detected by using the CAD system were manifested only as a mass. The early detection of breast cancer without microcalcifications, particularly in patients with dense breasts, appears to be a difficult task for both radiologists and CAD systems (7–10,17,18). Several CAD algorithms for detection of masses by using full-field digital mammographic images have been reported to offer improved detection rates (19,20). In our study, the four lesions that were missed with the CAD system were invasive ductal carcinomas, and these lesions had smaller mammographic sizes (mean, 1.7 cm ± 0.5) than did the lesions detected with the CAD system (mean, 2.2 cm ± 1.5), although this difference was not significant ($P = .447$). However, CAD systems appear to be highly effective at detection of DCIS lesions and invasive lobular carcinoma (16,17,21).

Primary digital CAD systems have some advantages versus CAD systems that are based on analog images. Primary digital CAD systems do not require digitization, which is essential for the application of a CAD system in screen-film mammography and which incurs time and cost. Digitization also can be a source of variability and of false-positive marks in CAD systems that are applied to screen-film mammograms (22). Primary digital CAD systems also allow CAD system marks to be displayed rapidly after image acquisition. In our study, it took only 1 second to activate and display CAD system marks at a workstation.

A large number of false-positive marks can markedly hinder the usefulness of CAD by distracting the interpreting radiologist. Therefore, the maximum number of marks per patient is limited by commercial systems. In our study, 1.80 false-positive marks were observed per patient in normal craniocaudal and mediolateral oblique views, and these results were notably lower than the 2.4–5.2 achieved by using a system that is based on analog images (8,9,14,16). Zheng et al (23) assessed the performance of seven radiologists for the detection of masses and microcalcification clusters on digitized mammograms by using different CAD cuing environments. Their results showed that a value of 2.0 false-positive marks per patient was not distracting, whereas a value of 8.0 false-positive marks per patient was distracting for all observers. Current CAD software versions tend to produce fewer false-positive marks per patient.

Our study had limitations. We did not evaluate radiologist performance. Nawano et al (24) performed a study with CAD by using digital mammograms from 86 women, and they found that the average area under the receiver operating characteristic curve increased significantly ($P < .02$) when radiologists used the CAD system. However, it remains to be shown whether a CAD system implemented in a full-field digital mammographic system can improve the radiologist's performance at detection of breast cancer. The small sample size of the present study is also a limitation.

In conclusion, the results of the present study suggest that the CAD system used with full-field digital mammographic images can mark most (96.1%) asymptomatic breast cancers, with acceptable false-positive marks (1.80 per patient). False-negative lesions were confined to noncalcified invasive ductal carcinoma.

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