Shear-Wave Elastography of the Breast: Value of a Quality Measure and Comparison with Strain Elastography[1]

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Purpose: To determine whether addition of quality measure (QM) of shear-wave (SW) velocity (V_s) estimation can increase SW elastography sensitivity for breast cancer.

Materials and Methods: With written informed consent, this institutional review board–approved, HIPAA-compliant study included 143 women (mean age, 48.5 years ± 8.7) scheduled for breast biopsy. Mean lesion size was 16.4 mm ± 11.8; 95 (66%) lesions were benign; 48 (34%), malignant. If more than one lesion was present, lesion with highest Breast Imaging Reporting and Data System (BI-RADS) category was chosen. If there were more than one with highest BI-RADS category, a lesion was randomly selected. Conventional ultrasonography (US), strain elastography, and SW elastography were performed with QM. QM assesses SW quality to provide accurate V_s. Lesions were evaluated for V_s and QM (high or low). Lesions with V_s of less than 4.5 m/sec were classified benign; lesions with V_s of 4.5 m/sec or greater, malignant. Results were correlated with pathologic findings. V_s data with or without incorporating QM were used to determine SW elastography diagnostic performance. Binomial proportions and exact 95% confidence intervals (CIs) were calculated.

Results: In 95 benign lesions, 13 (14%) had no SW elastography signal; 77 (81%), V_s of less than 4.5 m/sec; and five (5%), V_s of 4.5 m/sec or greater. In 48 malignant lesions, eight (17%) had no SW elastography signal; 20 (42%), V_s of less than 4.5 m/sec; and 20 (42%), V_s of 4.5 m/sec or greater. QM was low in 17 of 20 (85%) malignant lesions with V_s of less than 4.5 m/sec. Without QM, using V_s of 4.5 m/sec or greater as test positive, SW elastography had lesion-level sensitivity of 50% (95% CI: 34%, 66%); specificity, 94% (95% CI: 86%, 98%); positive predictive value (PPV), 80% (95% CI: 59%, 93%); and negative predictive value (NPV), 79% (95% CI: 70%, 87%). Using QM where additional lesions with both low V_s and low QM were treated as test positive, SW elastography had lesion-level sensitivity of 93% (95% CI: 80%, 98%); specificity, 89% (95% CI: 80%, 95%); PPV, 80% (95% CI: 66%, 91%); and NPV, 96% (95% CI: 89%, 99%).

Conclusion: Addition of QM can improve SW elastography sensitivity, with no significant change in specificity.

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Ultrasonographic (US) elastography is a relatively newer technique that is being evaluated for improved detection and characterization of breast masses (1–8). There are presently two US elastography techniques available (9). Strain elastography is used to evaluate lesion deformations that occur when the lesion is compressed. Lesions that are soft deform more than those that are stiff. The elastography scale is based on the amount of tissue deformation. This is a qualitative measure, with the display scale being variable, depending on the tissue stiffness within the imaging field of view. Shear-wave (SW) elastography (4,9–11) uses a US push pulse (acoustic radiation force impulse, or ARFI) to generate SWs perpendicular to the push pulse. SW velocity (V_s) in the tissue is proportional to the square root of stiffness (Young modulus) of the lesion.

Investigators in previous studies have demonstrated that both strain elastography (1,3,7,12) and SW elastography (4,5) can help characterize breast lesions as benign or malignant on the basis of stiffness. It was noted that, with the use of strain elastography, malignant breast masses appeared larger in the elastogram while benign lesions appeared smaller (1,7,13). The ratio of the lesion size with strain elastography to the lesion size with B-mode US (E/B ratio) can be used to predict whether a lesion is benign or malignant, with a ratio of less than one suggestive of a benign lesion and a ratio of one or higher suggestive of a malignant lesion, with up to 100% sensitivity (3). Other methods of evaluating strain images have been proposed (9). With SW elastography, V_s in meters per second (or, converted to the Young modulus = $3V_s^2$, in kilopascals) is used to determine whether a lesion is benign or malignant (4,5,14), with researchers in previous studies using a value of less than 3.3 m/sec to 5.2 m/sec as a cutoff for benign lesions. It has been proposed that SW elastography be used to upgrade or downgrade Breast Imaging Reporting and Data System (BI-RADS) category 3 and 4a lesions. Using this algorithm, Berg et al (5) demonstrated an increase in specificity without a loss of sensitivity.

It has been noted that some breast cancers have low V_s with use of SW elastography, and these cancers are sometimes referred to as "soft" or "blue" cancers (15). These cancers often have a surrounding rim of high V_s. Barr (15) has suggested that the low V_s coding of these cancers is secondary to a poor-quality SW within the tumor. The SW in these lesions has substantial noise or minimal tissue displacement and is not accurately interpretable. The addition of a quality measure (QM) of the SW may be helpful in confirming that an adequate SW formed.

Our purpose was to determine whether the addition of a QM of V_s estimation can increase sensitivity of SW elastography for breast cancer.

Advances in Knowledge

- A quality measure (QM) of shear-wave (SW) velocity (V_s) in SW elastography of the breast can limit false-negative findings, with a sensitivity without QM of 50% (20 of 40; 95% confidence interval [CI]: 34%, 66%) and a sensitivity with QM of 93% (37 of 40; 95% CI: 80%, 98%), with $P = .0001$.
- Both strain elastography (sensitivity, 98% [47 of 48; 95% CI: 89%, 100%]; specificity, 87% [80 of 92; 95% CI: 78%, 93%]) and SW elastography with QM (sensitivity, 93% [37 of 40; 95% CI: 80%, 98%]; specificity, 89% [73 of 82; 95% CI: 80%, 95%]) have high sensitivities and specificities in characterization of breast masses as benign or malignant.

Materials and Methods

This protocol was approved by our local institutional review board and was Health Insurance Portability and Accountability Act compliant. Written consent was received from all participants. One author (R.G.B.) received an equipment grant from Siemens Ultrasound (Mountain View, Calif). The authors had complete control of all the data and analysis of the data.

Participants

Female patients scheduled for a US-guided breast biopsy of suspicious lesions identified by means of a physical examination, screening or diagnostic mammography, magnetic resonance imaging, or US were enrolled in this study. One hundred forty-three consecutive patients with 165 lesions were enrolled from March 2011 to June 2012. No patients were excluded. For patients with more than one lesion, the lesion with the highest US BI-RADS category was chosen. If there were multiple lesions with the same highest US BI-RADS category, one lesion was chosen randomly from that group. The mean patient age was 48.5 years ± 8.7 (standard deviation), and the range was 18–81 years. The mean lesion size

Implication for Patient Care

- Use of a QM of V_s can determine poor SW generation and can avoid inappropriate characterization of some cancers with a low V_s as benign.

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Abbreviations:
AUC = area under the ROC curve
BI-RADS = Breast Imaging Reporting and Data System
CI = confidence interval
E/B ratio = ratio of the lesion size with strain elastography to the lesion size with B-mode US
NPV = negative predictive value
PPV = positive predictive value
QM = quality measure
ROC = receiver operating characteristic
SNR = signal-to-noise ratio
SW = shear wave
V_s = SW velocity

Author contributions:
Guarantor of integrity of entire study, R.G.B.; study concepts/study design or data acquisition or data analysis/interpretation, R.G.B., Z.Z.; manuscript drafting or manuscript revision for important intellectual content, R.G.B., Z.Z.; approval of final version of submitted manuscript, R.G.B., Z.Z.; literature research, R.G.B.; clinical studies, R.G.B.; statistical analysis, Z.Z.; and manuscript editing, R.G.B., Z.Z.

Conflicts of interest are listed at the end of this article.

(B-mode US measurement) was 16.4 mm ± 11.8 (range, 2.0–86 mm).

Mammography

A patient's recent mammograms (within 4 weeks of US) and reports were obtained. Mammograms were both digital and analog. All mammograms were interpreted by one of six radiologists, all with more than 10 years of experience in mammography. The BI-RADS category of the mammographic findings assessed at the time of original interpretation (without knowledge of US results) was recorded. If a follow-up diagnostic mammogram was obtained in a patient, the result of that mammogram was recorded and that BI-RADS category was used.

US Examination

The US examinations were performed with a US unit (Siemens S2000; Siemens Ultrasound) modified to perform SW elastography with a QM of V_s of the generated SWs.

Conventional US and strain elastography examinations were performed with a probe with an L14–5 linear array. SW elastography was performed by using a probe with an L9–5 linear array. A standard US examination including B-mode and color Doppler imaging was initially performed. The US examinations were performed by one of two sonographers, each with more than 10 years of experience in breast US and 2 years of experience in strain elastography and SW elastography. All US scans were also obtained by a fellowship-trained body radiologist (R.G.B.) with more than 10 years of experience with breast US and breast elastography (both strain elastography and SW elastography). Lesions were prospectively classified according to BI-RADS US assessment categories.

QM of V_s

The V_s estimation method uses multiple echo signals sampled in the temporal domain. Therefore, measurement errors may occur in data acquisition, as well as in processing. The data acquisition process may experience patient and probe motion, and data processing may experience input of low signal-to-noise ratio (SNR) echo signals. The SNR in the acquired echo signals and SNR of the detected displacement data are indicative of the quality of the data. The QM of V_s includes these two parameters and is estimated on each sample position to generate a two-dimensional quality map. Similar to the noise rejection methods in color display, a cutoff confidence level can be set internally to indicate either a valid estimation of V_s or an invalid estimation of V_s. The QM is computed as a weighted combination of the echo SNR, displacement SNR, and normalized cross correlation coefficient between the two displaced waveforms. A QM of 0.87 is considered a reliable V_s measurement and is color coded green, a QM of 0.75–0.87 may be an unreliable V_s measurement and is color coded yellow, and a QM of less than 0.75 indicates that a V_s estimate is not possible and is color coded red. Figure 1 shows an example of this technique. The color-coded scale is presented in Figure E1 (online).

The quality map can be used to confirm that SW formation was adequate and to identify regions of the SW image where V_s estimations may be less accurate because of poor signal quality. For example, in some breast cancers, it can be difficult to adequately visualize and measure V_s because of high attenuation. In such cases, the estimate of V_s may be less than 4.5 m/sec because of the poor quality of the data. V_s measurements are reliable in locations of high signal quality, and these locations are represented in green on the quality map; measurements are unreliable in locations of low signal quality, and these locations are represented in yellow or red. When the SW quality is yellow or red, V_s measurements cannot be estimated accurately.

Elastography

Strain elastography and SW elastography were performed by using the previously described technique to minimize and standardize precompression (16). The technique requires minimal (approximately 0.1%) tissue deformation, usually accomplished by patient breathing and heart motion. If there was not enough deformation (no strain elastography results coded), additional manual "vibration" was performed using the probe. Strain elastography measurements were taken at the longest length of the lesion on a B-mode image. A shadow function was used to map the same location on the strain elastography image, and the measurement was adjusted to the size of the lesion on the strain elastography image. An E/B ratio of less than one was considered to indicate that the lesion was benign, and an E/B ratio of one or greater was considered to indicate that the lesion was malignant, on the basis of the results of our prior studies (1,3).

Lesions were evaluated for V_s, if a ring of high V_s was present, and the QM. All SW elastography images were obtained with the patient suspending respiration during the data acquisition (approximately 3 seconds). Three V_s measurements were obtained in each lesion, and the maximum V_s measurement obtained was used in the analysis. Lesions were classified as benign if the V_s was less than 4.5 m/sec, and they were classified as malignant if the V_s was 4.5 m/sec or greater, on the basis of our prior unpublished results in a different population. If the lesion and surrounding rim had a green QM, the highest V_s was utilized. If the lesion and surrounding rim had a yellow or red (low) QM, the lesion was considered low QM. If a lesion and/or rim had a mixed green and yellow or red (low) QM and the area of highest V_s was in an area of green QM and was 4.5 m/sec or greater, the lesion was considered malignant, while if the area of highest V_s was less than 4.5 m/sec in an area of green (15) QM but there were areas of yellow or red (low) QM, the lesion was considered low QM.

Three blinded reviewers, a physician with greater than 10 years of experience with elastography, a certified sonographer with 2 years of experience with elastography, and a medical student with 1 month of exposure to elastography, were presented with the

Figure 1

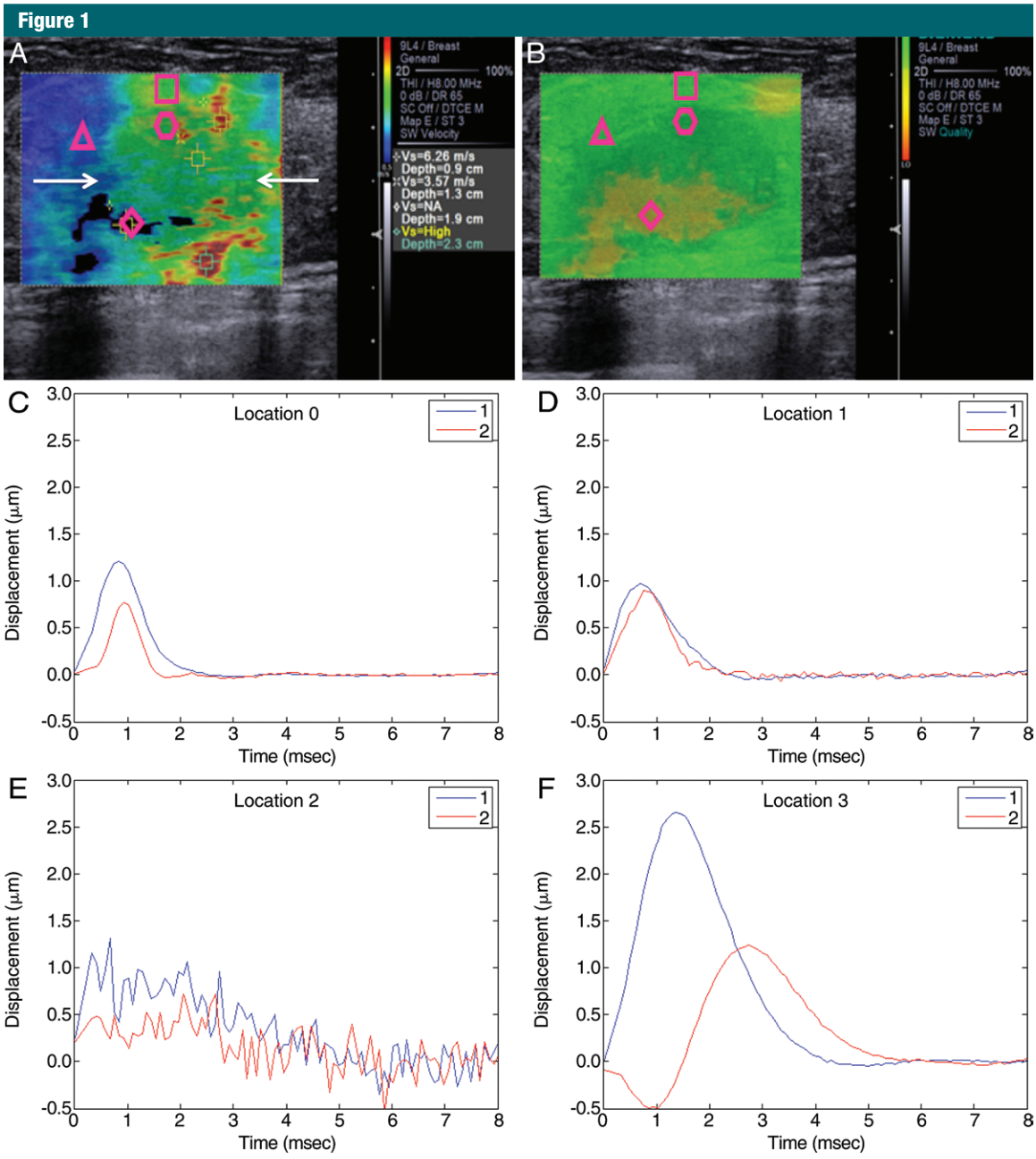

Figure 1: *A,* Velocity map of a biopsy-proven invasive ductal cancer (arrows) identified in a 58-year-old woman with a new mass identified on a screening mammogram. There are areas of V_s greater than 4.5 m/sec in the rim around the lesion, but most of the lesion has a V_s of less than 4.5 m/sec. *B,* QM map displays the quality of the SW, with green as good quality and yellow and red as poor quality. The detected displacement profiles and QMs for the locations labeled in *A* are presented in *C–F*. Color spectra on *A* and *B* correspond to color spectra on Figure E1 (online). Blue line 1 and red line 2 are two points where tissue displacements resulting from the acoustic radiation force impulse pulse were measured. In location 0 (□) and location 3 (△), the detected displacement profiles have high SNR and displacement, allowing for a QM of 0.99 color coded green in *B*. Location 1 (octagon) has increased SNR with a QM of 0.91, still representative of an accurate estimate and color coded green in *B*. In location 2 (◇), there is marked SNR, although there is adequate displacement with a QM of 0.57 color coded yellow.

143 velocity maps and quality maps from the study and were asked to determine whether the measurement taken was of high or low quality. They were not presented with any clinical information or additional images. The first two reviewers had perfect agreement (95% confidence interval [CI]: 97.45%, 100%), and the third

Table 1

Lesion Histologic Features

Features	No. of Lesions
Benign	
Abscess or mastitis	3
Complicated cystic mass	21
Fat lobule or lipoma	3
Fat necrosis	5
Fibroadenoma	15
Fibrocystic change or fibrosis	31
Hematoma	1
Intramammary node	1
Apocrine metaplasia	1
Papilloma	3
Scar	7
Sclerosis fibrosis	2
Seroma	1
Stromal fibrosis	1
All	95
Malignant	
Ductal carcinoma in situ	2
Invasive ductal cancer	38
Invasive lobular cancer	4
Lymphoma	1
Metastatic lymph node	1
Mucinous carcinoma	2
All	48

reviewer agreed with the first two in 142 of 143 cases (99.3%; 95% CI: 96.17%, 99.98%).

Histologic Diagnosis

All patients underwent a US-guided breast biopsy with a 12-gauge vacuum-assisted core biopsy needle (Celero; Hologic, Indianapolis, Ind), with three to eight samples obtained, or fine-needle aspiration if the lesion was cystic. If patients subsequently underwent surgical removal of the lesion, the pathologic findings at resection were used for diagnosis. There were 95 (66%) benign and 48 (34%) malignant lesions (Table 1).

Statistical Analysis

Using pathologic diagnosis as the reference standard, semiparametric receiver operating characteristic (ROC) curves were fitted for mammography BI-RADS, US BI-RADS, E/B ratio, and V_s (17). The area under the ROC curve (AUC) was calculated from the fitted curves. The 95% CIs were calculated through the bootstrap method (18). For dichotomized BI-RADS (category 3 and lower for benign lesions), E/B ratio (< 1.0 for benign lesions) and V_s (< 4.5 m/sec for benign lesions), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated as binomial proportions, and exact 95% CIs were provided. The comparisons for the sensitivities and specificities were performed by using the McNemar test. The analysis was performed with software (R 2.14.0; *www.r-project.org/*). A P value of less than .05 was considered to indicate a significant difference. An assessment of BI-RADS category 3 and BI-RADS category 4a lesions was performed by using elastography to upgrade or downgrade lesions.

Results

Mammography

Of the 143 lesions on mammograms, 13 (9.1%) were BI-RADS category 1; 13 (9.1%) were BI-RADS category 2; 24 (16.8%) were BI-RADS category 3; 34 (23.8%) were BI-RADS category 4A; 20 (14.0%) were BI-RADS category 4B; 17 (11.9%) were BI-RADS category 4C; and 15 (10.5%) were BI-RADS category 5. In seven of 143 (4.9%) lesions, mammography was not performed within 4 weeks of US.

The ROC curve of the mammography BI-RADS category is presented in Figure 2, with AUC of 0.905 (95% CI: 0.841, 0.977). The dichotomized mammography BI-RADS category score has a sensitivity of 94% (44 of 47; 95% CI: 82%, 99%), a specificity of 53% (47 of 89; 95% CI: 42%, 63%), a PPV of 51% (44 of 86; 95% CI: 40%, 62%), and an NPV of 94% (47 of 50; 95% CI: 83%, 99%).

Conventional US

With conventional US, of the 143 lesions, five (3.5%) were BI-RADS category 2, 34 (23.8%) were BI-RADS category 3, 30 (21.0%) were BI-RADS category 4A, 24 (16.8%) were BI-RADS category 4B, 25 (17.5%) were BI-RADS category 4C, and 25 (17.5%) were BI-RADS category 5. Patients with a low BI-RADS category of 1–3 underwent biopsy at the request of the patient or referring doctor. In all patients with a BI-RADS category 1 lesion at mammography, a lesion was noted at US.

The ROC curve of the US BI-RADS category is presented in Figure 2, with AUC of 0.968 (95% CI: 0.939, 0.991). The dichotomized US BI-RADS category had a sensitivity of 100% (48 of 48; 95% CI: 93%, 100%), a specificity of 41% (39 of 95; 95% CI: 31%, 52%), a PPV of 46% (48 of 104; 95% CI: 36%, 56%), and an NPV of 100% (39 of 39; 95% CI: 91%, 100%).

Strain Elastography

The E/B ratio for all lesions was a mean of 1.12 ± 0.50, with a range of 0.5–3.0. Eighty-one (57%) lesions had an E/B ratio less than one, and 59 (41%) lesions had an E/B ratio of one or greater; in three (2%) lesions, the E/B ratio could not be calculated because of the inability to accurately measure the lesion on B-mode or elastography images. For the pathologically benign lesions, the E/B ratio was a mean of 0.83 ± 0.16 (range, 0.5–1.3). There were 12 false-positive results (E/B ratio ≥ 1), which included fat necrosis (n = 2), fibrocystic change (n = 3), abscess and mastitis (n = 2), fibroadenoma (n = 2), surgical scar (n = 1), stromal fibrosis (n = 1), and nodular fibrosis (n = 1). For the pathologically malignant lesions, the E/B ratio was a mean of 1.67 ± 0.46 (range, 0.8–3.0). There was one false-negative result, which was a lymphoma.

The ROC curve of the E/B ratio is presented in Figure 2, with an AUC of 0.990 (95% CI: 0.968, 0.999). Excluding the three lesions without E/B ratios, the dichotomized E/B ratio had a sensitivity of 98% (47 of 48; 95% CI: 89%, 100%), a specificity of 87% (80 of 92; 95% CI: 78%, 93%), a PPV of 80% (47 of 59; 95% CI: 67%, 89%), and an NPV of 99% (80 of 81; 95% CI: 93%, 100%).

SW Elastography

In the 95 benign lesions, 13 (14%) had no SW elastography signal, 77 (81%) had a V_s less than 4.5 m/sec, and five (5%)

had a V_s of 4.5 m/sec or greater. In the 48 malignant lesions, eight (17%) had no SW elastography signal, 20 (42%) had a V_s less than 4.5 m/sec, and 20 (42%) had a V_s of 4.5 m/sec or greater. The QM was low in 17 of 20 (85%) malignant lesions with a V_s less than 4.5 m/sec and in four of 77 (5%) benign lesions with a V_s less than 4.5 m/sec. The QM was low in three of 20 (15%) malignant lesions with a V_s of 4.5 m/sec or greater and in two of five (40%) benign lesions with a V_s of 4.5 m/sec or greater. All lesions with no SW elastography signal had a low QM. Excluding the 21 lesions that had no SW elastography signal, without the QM considered, using V_s of 4.5 m/sec or greater as test positive, SW elastography had a sensitivity of 50% (20 of 40; 95% CI: 34%, 66%), a specificity of 94% (77 of 82; 95% CI: 86%, 98%), a PPV of 80% (20 of 25; 95% CI: 59%, 93%), and an NPV of 79% (77 of 97; 95% CI: 70%, 87%). Using the quality factor where additional lesions with both low V_s and low QM were treated as test positive, SW elastography had a sensitivity of 93% (37 of 40; 95% CI: 80%, 98%), a specificity of 89% (73 of 82; 95% CI: 80%, 95%), a PPV of 80% (37 of 46; 95% CI: 66%, 91%), and an NPV of 96% (73 of 76; 95% CI: 89%, 99%). The addition of a QM improves sensitivity of SW elastography ($P = .0001$), with slightly lower, but not significantly different, specificity ($P = .13$).

The ROC curve of V_s is presented in Figure 2, with an AUC of 0.789 (95% CI: 0.691, 0.878). A flowchart of SW elastography results is presented in Figure 3.

The summary of results for the various techniques is presented in Table 2. Figure E2 (online) shows an example of a true-positive strain elastography result and a false-negative SW elastography result but with a low QM, suggesting that the SW elastography result is positive for malignancy, and not negative, as suggested by the velocity map alone.

Use of Elastography to Upgrade or Downgrade Lesions

In our series, there were 34 US BI-RADS category 3 lesions that were all pathologically benign. Of the 34 lesions, strain elastography helped predict that 31 (91%) were benign, two (6%) were not evaluable (both fibrocystic change), and one (3%) was malignant (complex cystic mass). SW elastography helped predict that 29 (85%) were benign, four (12%) had no signal (all were complicated cysts), and one (3%) was malignant (lipoma) with a poor QM. Therefore, one BI-RADS category 3 lesion would have been inaccurately upgraded at strain elastography and none would have been upgraded if QM had been considered.

There were 30 BI-RADS category 4A lesions, with 27 (90%) benign lesions and three (10%) malignant lesions (two invasive ductal cancers, one lymphoma). In the three malignant lesions, strain elastography helped predict that two of two (100%) breast cancers were malignant; the lymphoma was predicted to be benign. Of the 27 benign lesions, strain elastography helped predict that 22 (81%) were benign, one (4%) (fibrocystic disease) was not evaluable, and four (15%) were malignant (two fibroadenomas, one case of mastitis, one case of stromal fibrosis). SW elastography helped predict that, in one case of invasive ductal cancer, the lesion was malignant, and in one case of invasive ductal cancer, no signal was

Figure 2

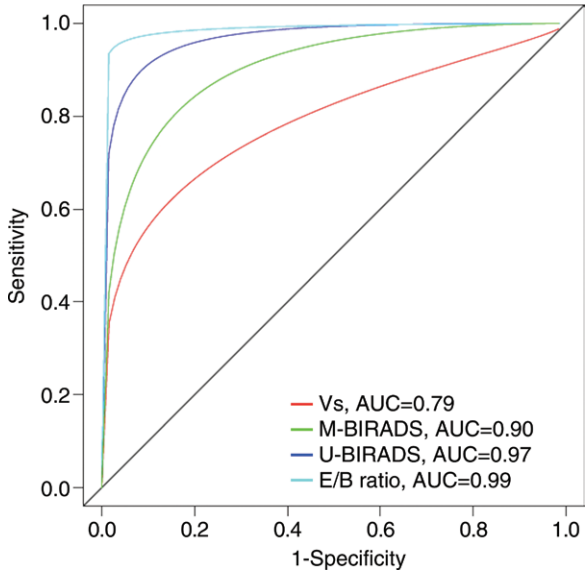

Figure 2: ROC curves of various techniques. The curves for mammography BI-RADS *(M-BIRADS),* conventional US BI-RADS *(U-BIRADS),* strain elastography (E/B ratio), and SW imaging without QM (V_s) are presented.

Figure 3

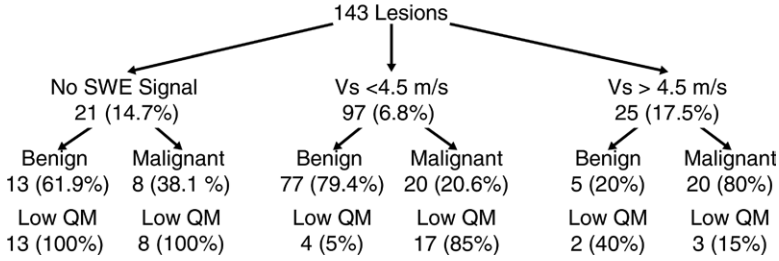

Figure 3: Flowchart of SW elastography *(SWE)* with QM results.

Table 2

Comparison of Techniques for Breast Lesion Characterization

Technique	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC
Mammography (n = 136)	94 (82, 99)	53 (42, 63)	51 (40, 62)	94 (83, 99)	0.905 (0.841, 0.977)
Conventional US (n = 143)	100 (93, 100)	41 (31, 52)	46 (36, 56)	100 (91, 100)	0.968 (0.939, 0.991)
Strain elastography (n = 140)	98 (89, 100)	87 (78, 93)	80 (67, 89)	99 (93, 100)	0.990 (0.968, 0.999)
SW elastography without QM (n = 122)	50 (34, 66)	94 (86, 98)	80 (59, 93)	79 (70, 87)	0.789 (0.691, 0.878)
SW elastography with QM (n = 122)	93 (80, 98)	89 (80, 95)	80 (66, 91)	96 (89, 99)	. . .
P value for SW elastography with QM vs SW elastography without QM	.0001	.13	. . .	. . .	. . .

Note.—Numbers in parentheses are 95% CIs.

observed without a high V_s ring and low QM. The lymphoma was predicted to be benign. Of the 27 benign lesions, SW elastography helped predict that 26 (96%) were benign and one (4%) was malignant based on internal V_s (fibroadenoma). Therefore, strain elastography would have accurately helped downgrade 22 lesions, and SW elastography would have accurately helped downgrade 26 lesions. Both strain elastography and SW elastography would have led to the inaccurate downgrading of a lymphoma.

Discussion

Both strain elastography and SW elastography have been shown to provide improved characterization of breast masses (1–3,5,7,19–21). As a qualitative measure, the display of strain elastography results varies, depending on the tissues in the field of view, which can lead to interpretation errors (9). Several methods have been proposed to interpret breast strain data, including the E/B ratio (1,3), a five-point color scale (7), and the lesion-to-fat ratio (6). Each of these methods has limitations (9). Reports (1,3,6,7,12,20,22) have shown sensitivity of these techniques from 80% to 100% and specificities from 80% to 95%. SW elastography is quantitative and provides a numerical value of the stiffness of the lesion expressed either in kilopascals or meters per second. Reports have shown that the maximum stiffness of a lesion can be used to characterize the lesion as benign or malignant (4,5,23). SW elastography is limited in depth, as the acoustic radiation force impulse push pulse is attenuated. With present equipment intended for breast application, the acoustic radiation force impulse can only generate sufficient SWs for measurement at approximately 4.5 cm (9). If adequate SWs are not generated, then no measurement is obtained, and the velocity map is not color coded. However, it has been noted that some cancers code with a low V_s in a portion of, or the entire, lesion, suggestive of a benign lesion (15,24). The development of a quality factor that confirms that an adequate SW is produced has been developed and evaluated in this article. This information can be displayed either as a second QM map or by suppressing pixels with poor-quality SWs by not color coding them on the velocity map. The rejection of SW data due to poor quality can be caused by lack of SW generation in cystic lesions or caused by poor SW generation and/or noise, which occurs in breast cancers. Therefore, if a lesion is not color coded or has a poor QM and is not cystic, it has a high probability of being a malignancy.

In this study, our results with strain elastography are consistent with those in previous work (3,12), with a very high sensitivity of greater than 95%. Specificities with this technique have been reported to be between 85% and 90% (1,3,12). The ROC curves in this study validate the cutoff of an E/B ratio of 1.0 or higher as indicative of a malignant lesion.

The SW elastography ROC curves in this study confirm a cutoff value of 4.5 m/sec for SW elastography for best sensitivity and specificity. For SW elastography, only 42% (20 of 48) of the malignancies demonstrated the V_s of the mass of 4.5 m/sec or greater. Seventeen percent (eight of 48) were not color coded because of nonmeasureable SW. The remaining 42% (20 of 48) had a V_s less than 4.5 m/sec, suggestive of a benign cause. However, of these 20 false-negative results, 83% (20 of 24) had poor QM, confirming that the SWs are not adequate for evaluation and should not be used for diagnosis. Another one of 24 (4.2%) had a high QM but was a lymphoma, which has a V_s of less than 4.5 m/sec. Therefore, the use of the QM of V_s increased the sensitivity of SW elastography for breast cancer from 50% (20 of 40) to 93% (37 of 40), with P = .0001, and changed specificity from 94% (77 of 82) to 89% (73 of 82), with P = .13. Thus, the addition of the QM significantly improved SW elastography sensitivity (a 43% increase) with a small (5%) decrease in specificity. This phenomenon has been described with both commercially available breast SW systems (S3000, Siemens Ultrasound; SuperSonic Imagine, Aux en Provence, France) (15).

The sensitivity of SW elastography in our study is lower than that in previous studies. Ianculescu et al (14) reported a sensitivity of 80.4% and a specificity of 73%, and Chang et al (25) reported a sensitivity of 96% and a specificity of 85%. One possible

explanation is that the amount of precompression was strictly controlled in our study (16). The addition of even small amounts of precompression can change the V_s of both benign and malignant lesions. On the basis of data in prior in vivo studies, there is approximately a 1 m/sec increase in the V_s of breast malignancies for a 20% precompression (16). Thus, the difference between our cutoff value of 4.5 m/sec and others of 5.2 m/sec can be accounted for by approximately a 14% amount of precompression that is well within the range used in normal B-mode scanning, assuming a linear response at mild degrees of compression. In our normal B-mode scanning, we use between 15% and 20% precompression to improve B-mode quality; however, we eliminate precompression when performing both strain elastography and SW elastography, with a resultant decrease in image quality in B-mode scanning.

Investigators in previous studies have reported the maximum V_s on the basis of the V_s of the lesion or surrounding rim. No comment is made in regard to whether the V_s of the lesion is significantly different than the rim. An artifact of a high V_s rim is identified both in vivo and in vitro if a stiff mass is present in a soft matrix (eg, a breast malignancy) and is also influenced by precompression (16,26). This phenomenon merits more study, as the rim may occur at lesser degrees of precompression in stiff lesions (malignancy) than soft (26) lesions. Evaluation of the rim artifact occurrence with graded compression may provide diagnostic information in regard to the stiffness of the lesion. Therefore, the amount of precompression should be strictly controlled for accurate evaluation of both strain elastography and SW elastography. Use of "light touch" as the only method of controlling precompression may not provide accurate control of precompression for comparison of studies.

Our study had several limitations. The population consisted of patients undergoing a diagnostic examination who had a known mass and who were referred for biopsy. This factor most likely accounts for our high sensitivity in mammography and conventional US. This study was a single-site prospective study, with multiple readers for the mammography and conventional US but one reviewer for the elastography imaging. Only one vendor's machine was assessed, and the performance of SW elastography was unexpectedly low compared with data in prior reports.

In this population of patients with a BI-RADS category 3 or higher lesion detected at mammography or conventional US who were referred for biopsy, the AUC results suggest that strain elastography (0.99) is better than SW elastography (0.79 without QM). Because both strain elastography and SW elastography are measuring the stiffness of the lesion, they should be similar in results. Findings in this study suggest that SW propagation with breast lesions is complicated. The algorithm for SW assumes a uniform tissue without interfaces. Breast cancers are far from this assumption and that factor may account for our findings. Additional work is required to understand the dynamics of SW propagation in breast tumors. Strain evaluation does not have these assumptions. From a clinical standpoint, having concordant strain and SW results would increase clinical confidence. Continued research into understanding what we are measuring within the tissues is needed to fully understand and optimize strain elastography and SW elastography for breast lesion characterization.

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