Clinical White Paper

Breast Elastography

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Breast Elastography

How to Perform and Integrate Into a "Best-Practice" Patient Treatment Algorithm

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Breast elastography has been available for more than 15 years but is not widely incorporated into clinical practice. Many publications report extremely high accuracy for various breast elastographic techniques. However, results in the literature are extremely variable. This variability is most likely due to variations in technique, a relatively steep learning curve, and variability in methods between vendors. This article describes our protocol for performing breast elastography using both strain elastography and shear wave elastography, which produces high sensitivity and specificity. Additionally, we will describe the most commonly known false-positive and false-negative lesions as well as how to detect them.

Key Words—breast; breast cancer; breast tumors; elastography; sonoelastography; strain elastography; shear wave elastography

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Abbreviations

2D, 2-dimensional; BI-RADS, Breast Imaging Reporting and Data System; E/B, elastographic-to-B-mode; ROI, region of interest; SE, strain elastography; SWE, shear wave elastography; US, ultrasound

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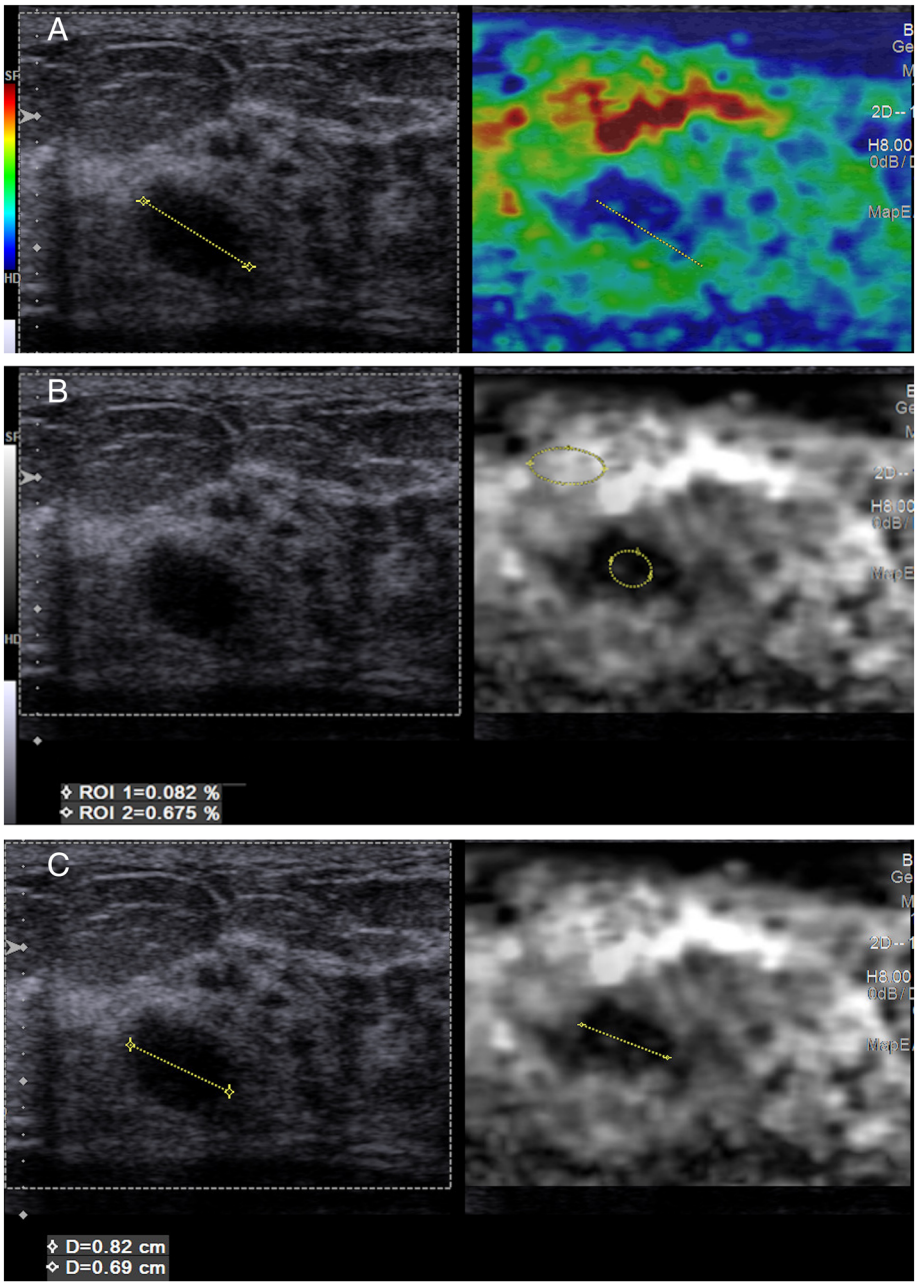
Breast elastography has been clinically available for more than 15 years. Based on in vitro studies, elastography should be highly sensitive and specific for characterizing breast lesions, as the stiffness of malignant lesions is substantially greater than that of benign lesions with very little overlap.[1] However, elastography has not been widely accepted as a standard procedure in breast imaging. This is likely due to variations in technique, a relatively steep learning curve, and differences in methods between vendors. A similar problem has been seen in assessments of liver stiffness by 2-dimensional shear wave elastography (2D-SWE) in patients with chronic liver disease, although this variability has been minimized by the Quantitative Imaging Biomarker Association, which has worked with vendors to standardize their systems.[2] To date, no such attempt has been made for breast elastographic imaging. Both strain elastography (SE) and 2D SWE have been used to evaluate breast lesions, and numerous studies have reported improvement in characterization of breast lesions to various degrees using elastography.[3–14]

Strain imaging is a relative technique. The elastogram does not provide a specific numeric value of lesion stiffness but instead reflects relative stiffness compared with other tissues in the field of view.[15] A unique feature of breast elastography for both SE and SWE is that malignant breast lesions appear larger on elastography than on B-mode ultrasound (US) images, whereas benign breast lesions appear smaller on elastography than on the corresponding B-mode images.[15] The mechanism of this difference in size is poorly understood. For SE, 3 techniques have been proposed for interpretation of the elastogram (Figure 1). First, a 5-point color scale can be used, with a score of 1 when the lesion is soft, a score of 2 when there are both soft and stiff components in the lesion, a

Figure 1. The 3 proposed methods for interpretation of breast strain elastography for a 24-year-old patient with a known fibroadenoma. **A**, On the 5-point color scale with blue as stiff and red as soft, the lesion (dotted line) is stiff, whereas the fatty tissue is soft. The lesion appears smaller than the B-mode image. Therefore, this would have a score of 3. **B**, To calculate the strain ratio, an ROI is placed in the lesion and in fatty tissue. In this case, the strain of fat is 0.675, whereas the strain of the lesion is 0.082, giving a ratio of 8.2, suggestive of a malignant lesion. This measurement is highly dependent on the amount of precompression and the specific US vendor. **C**, To calculate the E/B ratio, the lesion is measured on the B-mode image and on the elastogram. The ratio calculated in this case is 0.69/0.82, equal to 0.84, which is suggestive of a benign lesion.



score of 3 when the lesion is stiff and smaller than on the B-mode image, a score of 4 when the lesion is stiff and the same size as on the B-mode image, and a score of 5 when the lesion is stiff and larger than on the B-mode image. Second, a semiquantitative method, the fat-to-lesion ratio, also known as the strain ratio, has been proposed. Since fat in the breast has relatively constant stiffness between patients, it can be used as a reference standard. In this technique, a region of interest (ROI) is placed on the lesion and also in an area of fat, preferably at the same depth of the lesion. The US system then calculates the ratio of lesion stiffness compared to fat. The third method compares the size of the lesion on elastography and B-mode imaging by measuring the length of the lesion on the elastogram in the longest dimension and dividing this number by the length of the lesion on the comparable B-mode image, yielding the elastographic-to-B-mode (E/B) ratio. For the 5-point method, a cutoff score of 3 is usually considered the most accurate in differentiating benign from malignant lesions, with scores of 4 and 5 suggestive of malignancy. For the strain ratio method, each vendor has its own method of determining the strain value of an ROI, and the fat-to-lesion ratio is, therefore, very vendor dependent.[4] Additionally, compression of the tissue will also add variance to the measurement, as the stiffness of fat increases faster than that of other tissues in the breast with compression.[15] The E/B method requires that the lesion be accurately measured on both the B-mode image and the elastogram, which are obtained and displayed simultaneously. An E/B ratio of 1 or higher is reported as malignant, whereas an E/B ratio lower than 1 is reported as benign. A meta-analysis of the literature on SE found that the E/B ratio was more sensitive and specific than the other 2 methods.

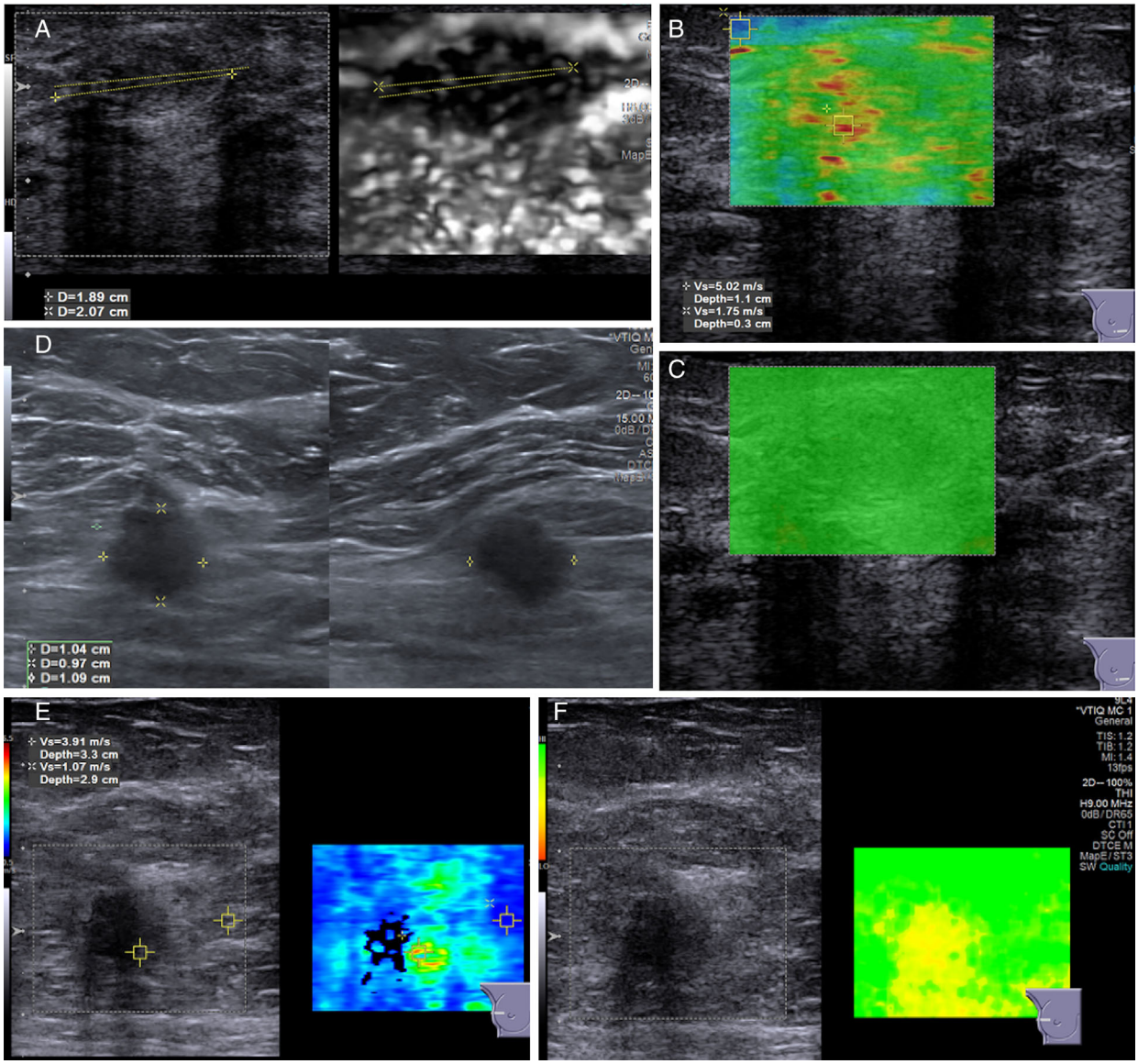
Shear wave elastography provides a quantitative estimate of the lesion stiffness based on the speed of shear waves generated by applying an acoustic radiation force impulse push pulse. The shear wave movement is tracked by B-mode tracking pulses, and the shear wave speed is estimated.[4] Shear wave elastography can be performed in a single ROI (point SWE) or over a larger field of view (2D SWE). A color map is used to display the shear wave velocities in 2D SWE. As breast cancer stiffness is very heterogeneous, point SWE should not be used, as the area of maximum stiffness cannot be readily identified. With 2D SWE, the various stiffness values within the breast cancer or adjacent few millimeters can be visualized, and the area of maximal stiffness can be selected for measurement. Several articles have demonstrated improvement in breast lesion characterization using SWE. However, shear wave propagation does not occur in many breast cancers. These will not be color coded, as the system cannot estimate a shear wave speed. There may be a ring of high stiffness surrounding the tumor. In some cancers, only noise is identified, and the US system therefore estimates this as a slow shear wave speed, which could be interpreted as a false-negative finding. The addition of a quality map, which evaluates the quality of the shear waves, is helpful in identifying these false-negative cases (Figure 2).[5] These "blue" or "soft" cancers are usually category 4B, 4C, or 5 lesions according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS).

The major reasons for the lack of acceptance of these elastographic techniques are nonreproducibility, poor technique, and application and vendor variability. In this article, we review our technique and protocol using both SE and SWE, which has produced high sensitivity and specificity in characterization of breast lesions. We highlight the requirements that have helped us obtain high-quality, reproducible results in our clinical practice. In addition, we will demonstrate how we integrate the results from breast elastography in our clinical practice to improve sensitivity and specificity in the evaluation of breast masses, thereby reducing unnecessary biopsies, patient anxiety, and health care costs without decreasing sensitivity in the diagnosis of breast cancers. This article details our method of performing breast elastography, which we have developed over the last 10 years. The protocol was developed on the basis of our prior studies[3,5,13,16–20] with the knowledge gained regarding false-positive and false-negative cases. The combination of both SE and 2D SWE overcomes many of the problems encountered in each when performed individually.

Methods

A standard US evaluation of the breast is performed by using grayscale and color Doppler imaging, and a BI-RADS

Figure 2. A–C, Images from a 39-year-old patient with a history of bilateral breast reductions who presented with a new palpable mass. Her mammographic findings were negative; however, she had density D breasts. **A**, Elastogram shows that the lesion (dotted line) measures 1.89 cm on B-mode imaging and 2.07 cm on SE, with an E/B ratio of 1.1, suggestive of a malignant lesion. **B**, Two-dimensional SWE of the lesion shows that the maximum stiffness in the lesion is 5.02 m/s, consistent with a malignant lesion. **C**, The quality map corresponding to **B** shows high quality (green) throughout the 2D SWE. The lesion proved to be fat necrosis on biopsy, a known cause of a false-positive result. **D**, B-mode images from a 32-year-old patient with an abnormal mammogram shows a 1.1-cm BI-RADS category 4C lesion. **E**, On 2D SWE, the lesion has a maximum stiffness value of 3.9 m/s, which is suggestive of a benign lesion. However, on the quality map (**F**), the shear wave quality is poor (yellow), so the measurement should not be trusted. In this case, the SE image (not shown) was suggestive of a malignant lesion. The lesion was poorly differentiated invasive ductal cancer, which was estrogen receptor positive, progesterone receptor positive, and human epidermal growth factor receptor 2 negative on biopsy.



category score is assigned to each lesion or area of interest. We then perform both SE and 2D SWE on each lesion or area of concern. Institutional Review Board approval was not required for this report, as it is a review article.

Strain Elastographic Technique

Ultrasound systems with SE that does not require manual compression/release are used. Strain elastography should be performed with a linear transducer. Most systems have

linear transducers from 9 to 18 MHz that can be used for SE breast imaging. In larger breasts, a lower-frequency transducer may provide better images. Using these systems, simply holding the transducer still will provide high-quality elastograms, with the applied stress coming from patient breathing and heartbeat cardiac pulsations. There are 2 primary signal-processing approaches for generating a strain image: either estimating the strain based on the radiofrequency/quadrature data or estimating the strain based on the (log-magnitude) detected image. The systems (Siemens Medical Solutions [Mountain View, CA], Philips Healthcare [Bothell, WA], and Mindray [Mahwah, NJ]) that we have validated with reproducible results use the radiofrequency/quadrature data to estimate the strain.

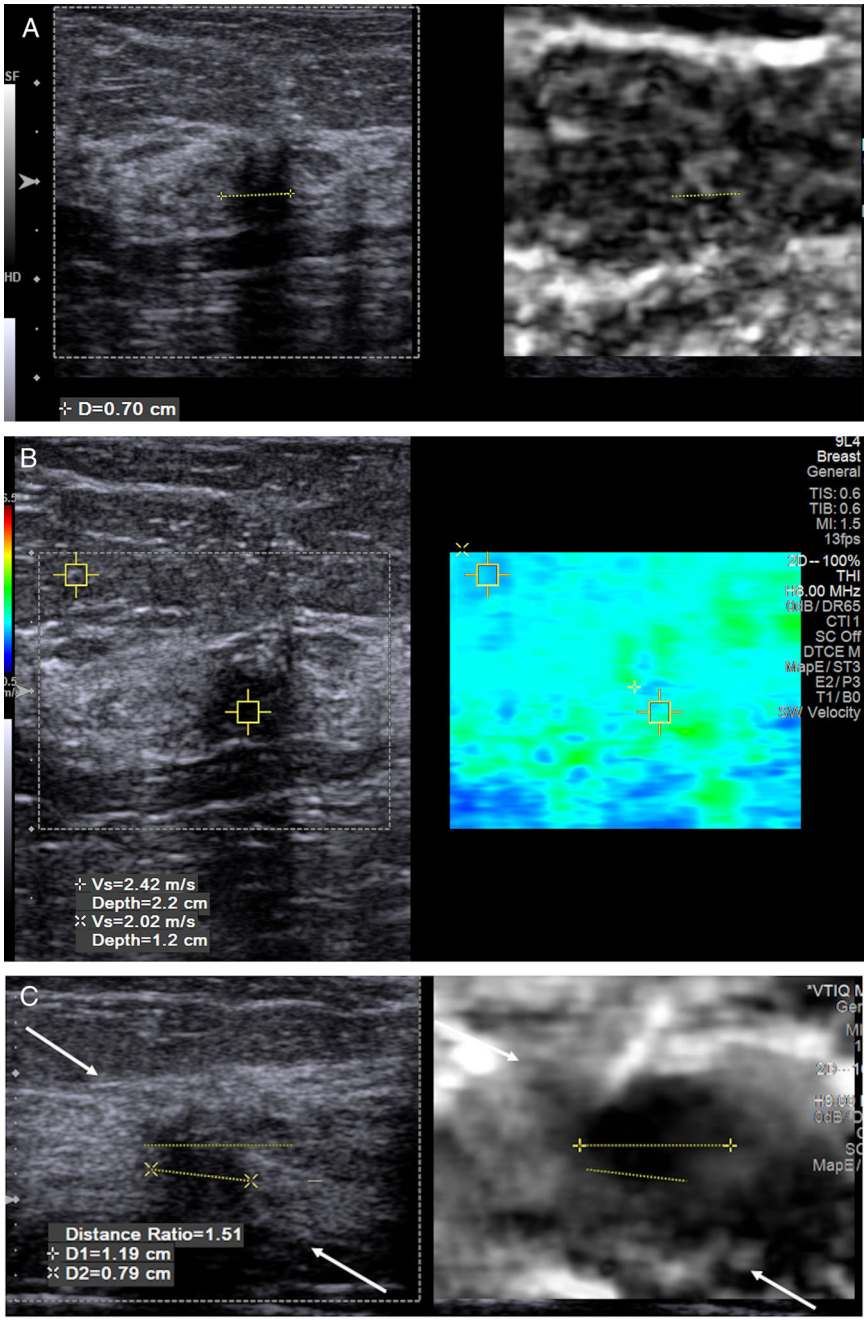
We chose to use a grayscale map, as this has been shown to be the most accurate in a meta-analysis.[13] The most important technical factor is not to compress the breast with the transducer.[20] The use of ample coupling gel is helpful. After obtaining the B-mode image, the transducer is lifted until it just barely contacts the skin to ensure that the breast is not compressed by the transducer when the elastogram is obtained. It is helpful to choose and observe a structure in the far field as the transducer is lifted. The object in the far field will move deeper to the skin surface as the transducer is lifted. The elastogram is obtained when the object is as deep in the far field as possible and adequate contact is still maintained. The B-mode image may suffer, but this is important for obtaining an optimal elastogram. With this technique, there should be consistent images on a cine clip from SE, confirming that the appropriate technique is being used. It may be difficult to keep the transducer stable without movement and to maintain the same amount of minimal pressure. Supporting the arm or wrist on the patient is important for controlling the transducer pressure. An elastographic maximum length–to–B-mode maximum length (E/B) ratio is used as a semiquantitative method of analysis. The measurement can be taken in any plane and any location, although the center of the lesion is preferred. The E/B ratio can be up to 3; therefore, taking the measurement in an area of the lesion that is approximately 1 cm is recommended. An E/B ratio lower than 1 is classified as a benign lesion, whereas an E/B ratio of 1 or higher is considered malignant. Low-grade tumors such as mucinous cancers and ductal carcinoma in situ can have ratios close to 1.[21] Three measurements are made, and the one with the highest ratio is used.

When a benign lesion such as a fibroadenoma or fibrocystic change is present in fibroglandular tissue, the stiffness of these benign lesions and fibroglandular tissue is similar. Therefore, identifying the length of the lesion becomes problematic. In this situation, comparing the stiffness with the fibroglandular tissue is helpful. If the lesion is benign, the stiffness is similar to the fibroglandular tissue, whereas if it is malignant, the lesion will be easily identified, as it is substantially stiffer than the fibroglandular tissue (Figure 3).

Two-Dimensional SWE Technique

In our experience, the 2D SWE systems from multiple vendors provide similar results with less intervendor variability compared with SE. A linear transducer that is optimized for breast elastography should be used. The frequency varies by vendor and can range from 9 to 15 MHz. With a higher-frequency transducer, imaging of denser or large breasts may not provide shear wave results greater than 4 cm deep. As in SE, pressure from the transducer markedly affects the elastographic results. A method of obtaining consistent results has been described.[20] Breast cancers often are not color coded or give false-negative results due to the marked stiffness of breast cancers.[5,17] These are sometimes referred to as "blue cancers" or "soft cancers" (ie, very stiff cancers may look soft on SWE). The use of a quality map is helpful in identifying this artifact. The artifact is discussed in detail elsewhere.[5] We use a cutoff value of 4.5 m/s (60 kPa) to characterize breast lesions based on our previous studies, and this number is applicable for multiple vendors. However, this cutoff is extremely dependent on the amount of pressure applied with the transducer. Each center should have a standard method of controlling the degree of compression, so that all examiners perform the measurements uniformly. Three measurements are taken within the lesion or the surrounding ring if present (3 mm) in the area with the highest stiffness. The ROI should only include the area with the highest stiffness. The stiffest value in the ROI is used. The average of the 3 maximum values is used as the final result.

Figure 3. When a benign lesion such as a fibrocystic change is present surrounded by glandular tissue, the stiffness values of both are similar, and it is difficult to identify the lesion on SE. **A**, On this SE image of a 60-year-old patient with a palpable lump and negative mammographic findings, the lesion (dotted line) is seen in the B-mode image (left). On SE, the lesion is difficult to identify. The dotted line on the B-mode image has been copied to the SE image. This is because the lesion has similar stiffness as the surrounding tissue. **B**, However, on 2D SWE, it has benign stiffness with a stiffness value of 2.42 m/s. If the lesion were malignant, it would be stiffer than the surrounding glandular tissue, as in **C**. Note that the white arrows point to the glandular tissue, whereas the dotted line measures the mass on B-mode imaging and SE. The malignant lesion is clearly identified on SE as black; the glandular tissue is light gray; and fat is white. In this case, the E/B ratio is 1.51, concordant with the biopsy result of invasive ductal cancer.



Interpretation and Integration Into a Best-Practice Patient Treatment Algorithm

In our experience, SE has higher sensitivity for the detection of malignancy in breast lesions, whereas 2D SWE has higher specificity in characterization of breast lesions as benign or malignant.[5] However, it is important to recognize that SE and 2D SWE are complementary imaging techniques. A major interpretation problem with SE is that benign lesions have similar stiffness as fibroglandular tissue. Therefore, benign lesions are often difficult to identify in glandular tissue, making it difficult to perform an accurate E/B measurement. However, if the lesion is the same stiffness as the surrounding glandular tissue, it has a high probability of being benign. On the other hand, if the lesion is substantially stiffer than the surrounding glandular tissue, it has a high probability of malignancy. Also, these lesions can be identified by 2D SWE as benign, as these lesions all have low stiffness values even though they may not be clearly distinguished from the fibroglandular tissue based on the color map. An example of this is presented in Figure 3. On the other hand, 2D SWE often does not provide a stiffness value or may provide a false-negative stiffness value in malignant lesions.[5] Often these false-negative values can be detected by using a quality map that evaluates the displacement curves used to estimate the stiffness value. The map uses a "stoplight" color map: green indicating go (good data); yellow, caution (poor data); and red, stop (inaccurate data). However, in solid lesions where the velocity map is not color coded or soft, but the quality map is poor (yellow or red), the SE results should be considered positive (Figure 2). In these cases, the SE results suggest malignancy. Thus, the use of both SE and 2D SWE can overcome the problems of each individually. Hence, SE and 2D SWE are best considered as complementary techniques.

When both SE and 2D SWE suggest that a breast lesion is malignant, biopsy should be performed regardless of the BI-RADS category score. False-positive lesions include fat necrosis,[22] mastitis,[23] complex sclerosing lesions (radial scars), and a small number of fibroadenomas.[22] Some cases of fat necrosis and all cases of mastitis have surrounding edema, which is poorly visualized on B-mode imaging but substantially increases the stiffness of the surrounding tissue. If the patient has clinical symptoms of mastitis, the patient is treated, and a follow-up examination in 3 to 6 months is performed to confirm complete resolution. If the patient's mammogram has calcifications suggestive of fat necrosis, a 6-month follow-up is advised. Also, if the patient has had surgery at the site and fat necrosis is suspected, consideration of a 6-month follow-up is recommended.

When both SE and 2D SWE are suggestive of a benign lesion with a BI-RADS category score of 4A or less, the lesion is classified as benign. For BI-RADS category 4B lesions with SE and 2D SWE findings consistent with a benign lesion, either a 6-month follow-up or biopsy is advised according to the patient's preference. Our previous published results confirm that with a pretest probability of 50% (all BI-RADS category 4B and lower lesions) and SE results suggestive of a

Figure 4. With some US systems (those vetted in this article), both simple and complex cysts have a bull's eye artifact. This artifact is composed of a black outer rim (blue arrow), a white central dot (red arrow), and a distal white dot (green arrow). This artifact is 100% sensitive and 100% specific for a benign simple or complicated cyst.

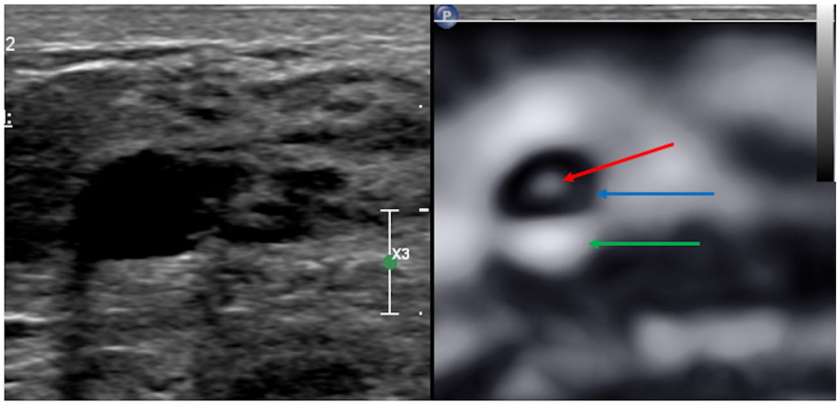
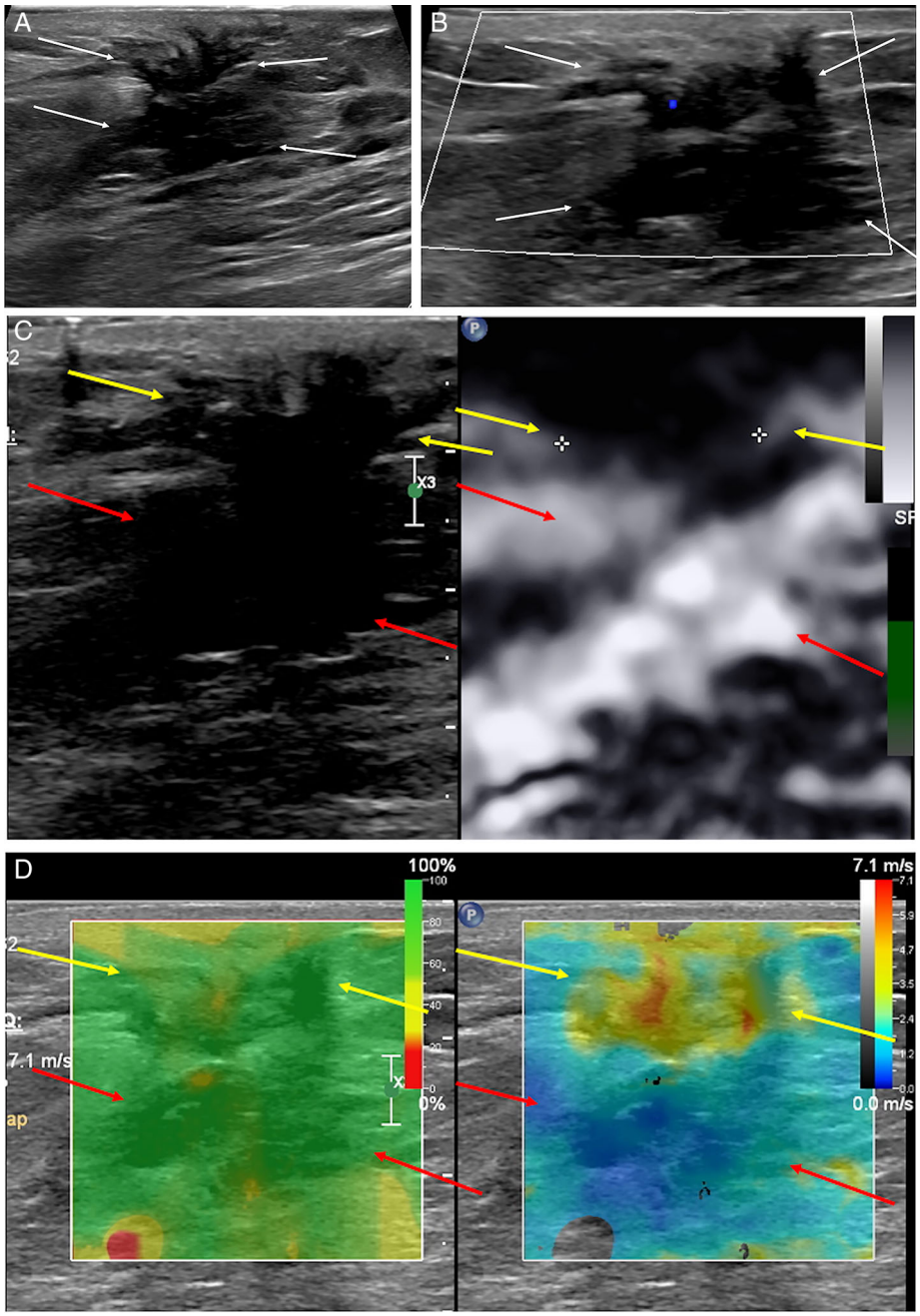


Figure 5. Recurrence in a surgical scar can be detected with elastography. The recurrence is stiffer than the surgical scar. This 85-year-old patient had a left lumpectomy 12 years previously and presented with a changing scar on a physical examination. **A**, B-mode image of the postsurgical scar (white arrows). The lesion is an irregular hypoechoic mass. **B**, A Doppler evaluation shows a small amount of flow in the superior portion of the mass. **C**, On SE, the upper third of the scar (yellow arrows) is very stiff, whereas the remainder of the scar is soft (red arrows). **D**, On 2D SWE, the same stiffness pattern is identified, with the superior third having a stiffness value of 7.3 m/s (yellow arrows) and the remainder of the scar having a stiffness value of 2.1 m/s (red arrows). Biopsy of the stiff portion of the scar confirmed recurrence of invasive ductal cancer. It is important to note that elastography can be used to help direct and focus biopsy.



benign lesion, the posttest probability of malignancy is 2%.[13] Brest Imaging Reporting and Data System category 4C and 5 lesions are biopsied even if the elastographic results are suggestive of benign disease. The only false-negative lesion that we have observed is lymphoma. Lymphoma in the breast, whether primary or secondary, presents as a well-circumscribed hypoechoic lesion with markedly increased blood flow on color or power Doppler imaging[24] and is soft on elastography. Lesions with these characteristics of lymphoma are biopsied, especially if the patient has a known diagnosis of lymphoma.

If SE is suggestive of a malignant lesion and 2D SWE is suggestive of a benign lesion, but the 2D SWE results are of poor quality, the lesion is biopsied. These cases reflect the artifact seen in 2D SWE. If the lesion is suggestive of malignancy on SE, biopsy is recommended whether the 2D SWE image is consistent with a benign lesion with high 2D SWE quality or a malignant lesion.

If SE is suggestive of a benign lesion and 2D SWE is suggestive of a malignant lesion, the first thing to do is to confirm that minimal transducer pressure was used when obtaining the 2D SWE image. Also, one should confirm that the stiffness of fat in the image is within the normal range (1.2–1.4 m/s). If high stiffness is confirmed on 2D SWE, the lesion is biopsied. In our experience, this is a rare occurrence.

Special Cases

Bull's Eye Artifact

With the validated SE vendors, there is an artifact (bull's eye artifact) that is specific for benign cystic lesions, whether simple or complex (Figure 4). This artifact occurs when all of the material within the cyst is mobile. However, it may not occur if the fluid is extremely viscous. If there is a solid component in the cyst, it will appear as a defect in the artifact (Figure 4). This has been validated in a large study using the Siemens system[19] and had 100% sensitivity and 100% specificity for a benign cystic lesion. The artifact does not occur in mucinous or colloid cancers.

Postsurgical Scars

Postsurgical scars are often intermediate in stiffness (below the cutoff value for malignancy). When a residual or recurrent tumor is present, it will appear as a stiffer area, usually above the cutoff value for malignancy (Figure 5).[22]

Architectural Distortion

If there are areas of architectural distortion or a palpable mass is present, but no B-mode abnormality is identified, elastography is also extremely helpful. If the area is stiff (above the cutoff value for 2D SWE and stiffer than glandular tissue on SE), the area is biopsied. This can be seen in cases of ductal carcinoma in situ and invasive lobular cancer.

These guidelines have been retrospectively applied to a previously published prospectively collected data set of US-guided breast lesions.[5] Applying these criteria to our previously published series,[5] we would have had sensitivity of 100% (95% confidence interval, 94.2%–100%), specificity of 90.3% (83.2%–95.0%), a positive predictive value of 84.9% (74.6%–92.2%), a negative predictive value of 100% (96.4%–100%), a positive likelihood ratio of 10.3 (5.9–17.5), and a negative likelihood ratio of 0 (0–0.6). A multicenter prospective study is needed to fully validate our protocol and patient treatment algorithm.

Discussion

When high-quality reproducible elastography can be performed on breast lesions, the number of breast biopsies with negative results can be substantially decreased. Since we incorporated elastography in our practice over the last 10 years, our positive biopsy rate has increased from approximately 20%[16] to 80% without missing breast cancers.

It is our observation that SE systems that require manual compression and release have more artifacts and have a substantial learning curve, making their results less accurate and reproducible. We also believe that using color maps in which small stiffness changes translate into large color changes is also problematic. This was also reported in a large meta-analysis of SE for characterization of breast lesions.[13]

Although, to our knowledge, no study comparing the stiffness values of various vendors using 2D SWE has been published, in our experience, there is no notable difference between vendors, although the cutoff values may be slightly different. The World

Federation for Ultrasound in Medicine and Biology guidelines have reviewed the literature and have given general cutoff values.[4] We have noted that there is a slight difference in 2D SWE systems with regard to false-negative cancers, with some systems having a higher number of false-negative cases. This is most likely related to the acoustic radiation force impulse pulse strength.

A multicenter prospective study is needed to validate our protocol. However, based on the results from our center, the number of callbacks, short-interval US follow-ups, and biopsies with negative results can be substantially decreased by using this protocol. We have found the elastographic results from this protocol to be the most sensitive and specific parameters for characterizing breast lesions. If confirmed by larger studies, a requirement for the addition of elastography to the US BI-RADS should be strongly considered.

In conclusion, both high sensitivity and specificity for breast lesion characterization can be obtained by combining results from SE and 2D SWE, which has important implications for patient treatment, with the potential for substantially decreasing the number of breast biopsies with negative results, thereby improving patient care, reducing patient anxiety, and saving health care dollars. Knowledge of false-positive and false-negative lesions also improves the accuracy of interpretation. Careful attention to technique is critical to ensure accurate and reproducible outcomes.

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