White paper

Next Generation Breast 2D-SWE

Minimizing false negative cases of breast cancer

Jorge Rosado Sotomayor, BS, RVT
Tanya Ratte, BS, RDMS, RVT
Gabriela Torres, PhD
Ultrasound Business Area Issaquah, Washington

siemens-healthineers.com/ultrasound

SIEMENS Healthineers

Introduction

Breast biopsy is the standard of care for managing patients with complicated lesions, with Ultrasound as a front-line imaging modality in diagnosing breast cancer, especially in women with dense breasts. Despite recent improvements in ultrasound technology, conventional Ultrasound is limited in characterizing lesions as benign or malignant.

Several pathological staging systems for breast cancer are used, but the Breast Imaging Reporting and Data System (BI-RADS®) is the most common. The American College of Radiology developed the BI-RADS classification system to promote reporting consistency in the mammographic interpretation of breast cancer.[1]

BI-RADS sonographic characteristics include:

- Shape, orientation, margins
- Echo pattern, posterior acoustic features
- Special characteristics
- Vascularity and surrounding tissue

Based on the below sonographic characteristics, BI-RADS defines the assessment categories shown in Table 1.[2]

As we follow the BI-RADS classification system in assessing lesions, the BI-RADS category 4 is where the patient's clinical pathway starts and is the most impacted.

Acoustic Radiation Force Impulse (ARFI) imaging is an ultrasound-based quantitative elastography technology that can be used in the noninvasive assessment of breast cancer. This shear wave elastography tool, known as 2D Shear Wave Elastography (2D-SWE), is based on the principle that as malignancy increases, there is an associated increase in lesion stiffness. With this principle in mind, identifying and staging breast cancer is an important factor to determine the patient's initial degree of disease, continued surveillance and treatment.

The Breast Imaging Reporting and Data System (BI-RADS) suggests the use of ultrasound elastography to upgrade BI-RADS 3 lesions and downgrade BI-RADS 3 and BI-RADS 4A lesions.

Category	Assessment	Management Recommendation
0	Incomplete – Need additional imaging evaluation	Recall for additional imaging
1	Negative	Routine screening
2	Benign	Routine screening
3	Probably benign	Short-term follow-up or continued surveillance
4	Suspicious 4A = Low suspicion for malignancy 4B = Moderate suspicion for malignancy 4C = High suspicion for malignancy	Tissue diagnosis
5	Highly suggestive of malignancy	Tissue diagnosis
6	Known biopsy-proven malignancy	Surgical excision if clinically appropriate

Table 1: BI-RADS assessment categories and management recommendations. Adapted from Mendelson et al., ACR 2013.[2]

The challenges of blue cancers on conventional 2D-SWE

Conventional 2D-SWE produces quantitative results, unlike Strain Elastography (SE). Multiple studies have shown that using both 2D-SWE and SE results in high sensitivity and specificity for characterizing breast lesions since malignant lesions are often significantly stiffer than benign lesions.[3]

Across different platforms, a conventional limitation of 2D-SWE in breast imaging is an artifact seen in very stiff lesions. These very stiff lesions can limit the expected propagation of shear waves and appear as blue or soft on the elastogram. Therefore, these lesions have become known as blue cancers.[4] Barr et al. (2020) have reported that up to 25% of cancers are artifactually soft or blue on 2D-SWE and do not reach the threshold values for defining malignancy.[5]

Per the WFUMB guidelines on breast elastography (2015), when a blue cancer is suspected, it is recommended to survey the tissue surrounding the lesion to identify additional stiffest regions in the lesion.[6] The heterogeneous and increased SWE stiffness map in surrounding tissues is relevant information to aid in characterizing the lesion as malignant. Using both 2D SWE and SE images can also aid in lesion assessment.

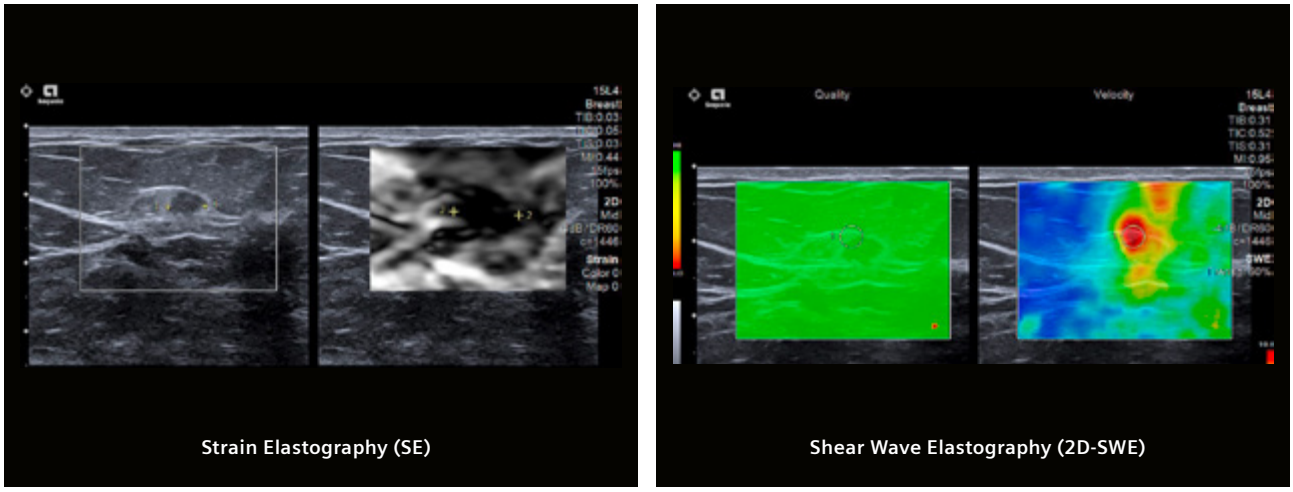

Figure 1: Example of SE and 2D-SWE to aid in characterizing breast lesions.

How 2D-SWE works

Ultrasound elastography allows the user to obtain information on the mechanical properties or stiffness of tissues. To obtain this type of information, tissue first needs to be deformed. Two main methods are used to deform the tissue in ultrasound using a transducer: manual compression and acoustic force.

Manual compression has been traditionally described as Strain Elastography (SE). While an effective technique, it can have a high degree of user variability. Additionally, using this type of compression to generate enough stress on deep tissue structures can be challenging. These challenges led to the development of the technology primarily used in ultrasound elastography today, ARFI.

To assess tissue stiffness, ARFI uses brief, high-energy ultrasound "push" pulses to deform tissue. These pulses induce a small amount of displacement in the tissue. As time elapses, shear waves propagate laterally away from the push pulse. These shear waves can be tracked by lower-energy ultrasound beams, which then measure the speed of the propagating shear wave. Additionally, since the push is generated by the transducer, user variability in the amount of applied pressure is minimized when compared to manual compression.

2D-SWE combines imaging and quantification in one color-coded image and can be complementary to information obtained by strain imaging. Given a user-defined ROI placed on an area of interest, 2D-SWE applies high-density push pulses sequentially across the ROI, which slightly compress the tissue. This causes shear waves to propagate across the ROI. A series of ultrasound detection pulses follow immediately in a quick push pulse-detect pulse sequence (Figure 2).

Shear wave speed estimates are then calculated for each pixel within the ROI at high color-coded resolution providing more clinical data to support the diagnosis. Measurement regions can be placed at precise locations within the ROI to measure shear wave speeds within a small region of interest (Figure 3) and are expressed in meters per second (m/s) and/or kilopascals (kPa).

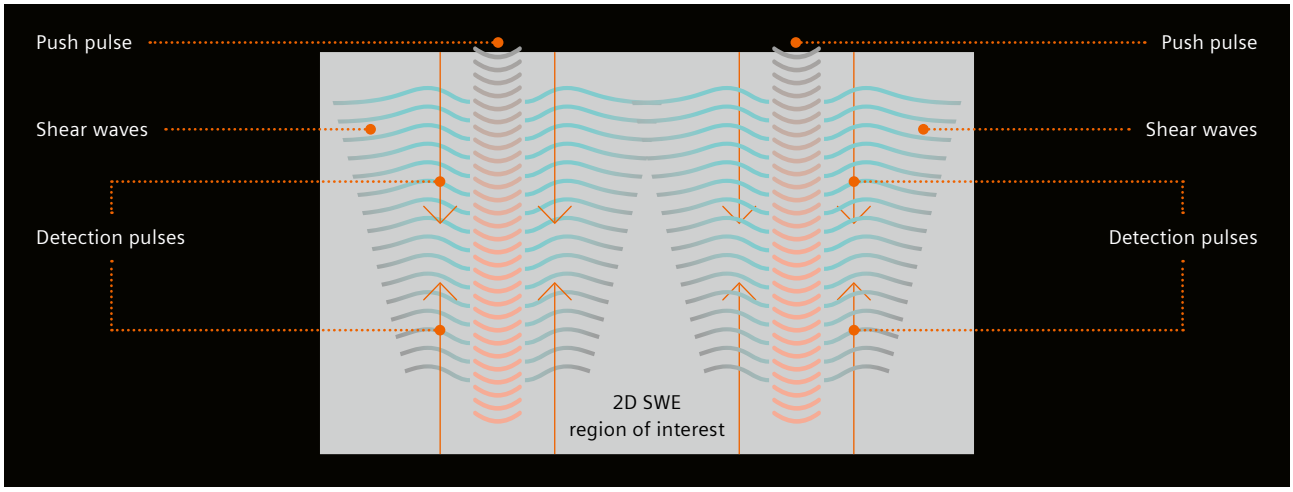

Figure 2: Example of SE and 2D-SWE to aid in characterizing breast lesions.

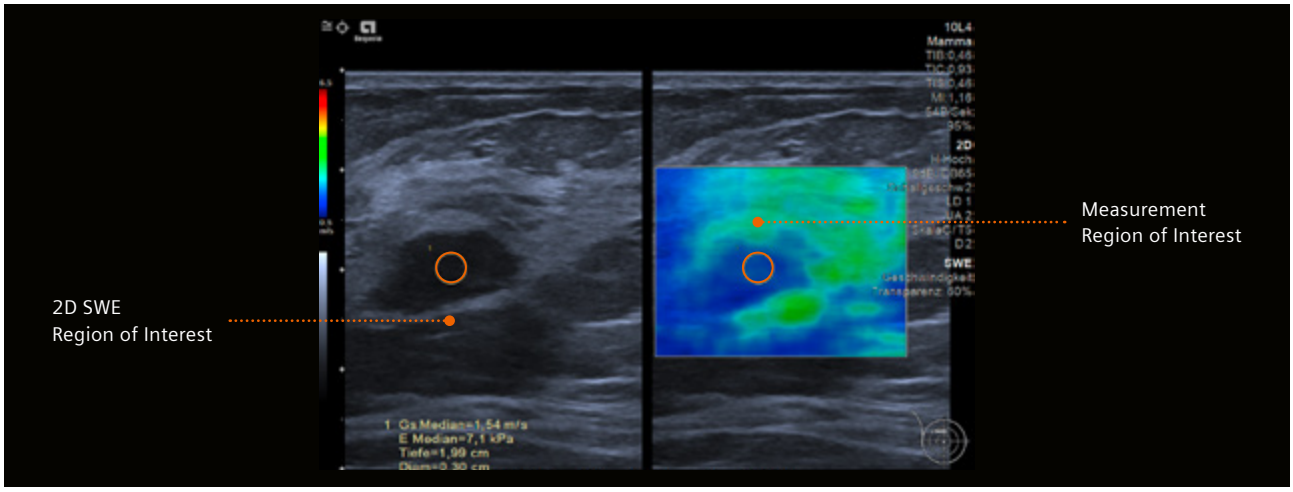

Figure 3: Example 2D-SWE region of interest and measurement regions.

Next Gen Breast 2D-SWE

Next Gen 2D-SWE improves the shear wave detection method resulting in an expanded dynamic range of the resulting displacement and elasticity maps. Our updated algorithm is based on particle-velocity shear-wave speed estimation that adapts to better characterize very stiff lesions. It allows improved performance in the delineation of small and stiff lesions, previously identified as blue cancers.[7]

A single-center study evaluation compared Next Gen 2D-SWE to conventional 2D-SWE in 298 patients with 398 lesions with biopsy-proven pathology or after a 2-year follow-up (Barr, 2023). Both technologies were compared on the same acquired image without transducer or user impact using reprocessing tools.

Findings from this study demonstrate that Next Gen 2D-SWE:

- Substantially **eliminates false negative** cases on 2D-SWE breast examinations
- Achieves an **area under the receiver operating characteristic curve was 0.95** (a significant improvement compared to 0.87 from conventional 2D-SWE) when using a cut-off value of 5.63 m/s
- Achieves a positive predictive value of 0.72 and a **negative predictive value of 1.00** when using a cut-off value of 5.0 m/s
- It provides the potential to allow for **downgrading** lesions **from BI-RADS 4 to BI-RADS 3.**
- This could potentially **decrease** the number of **benign biopsies.**

Next Gen 2D-SWE significantly improve the sensitivity of the elastography technique with a small decrease in specificity, virtually eliminating the false negative cases seen with 2D-SWE. With the high sensitivity and negative predictive value of this technique, the possibility of decreasing the number of benign biopsies and better radiology pathology correlation can be achieved.

The ACUSON Sequoia ultrasound system overcomes the industry challenge of blue cancers on conventional 2D-SWE with an updated algorithm based on particle-velocity shear-wave speed estimation that adapts to better identify and display blue cancers as red or stiff. Our new technology minimizes those false negative cases seen with conventional 2D-SWE and allows for downgrading BI-RADS 4 lesions.

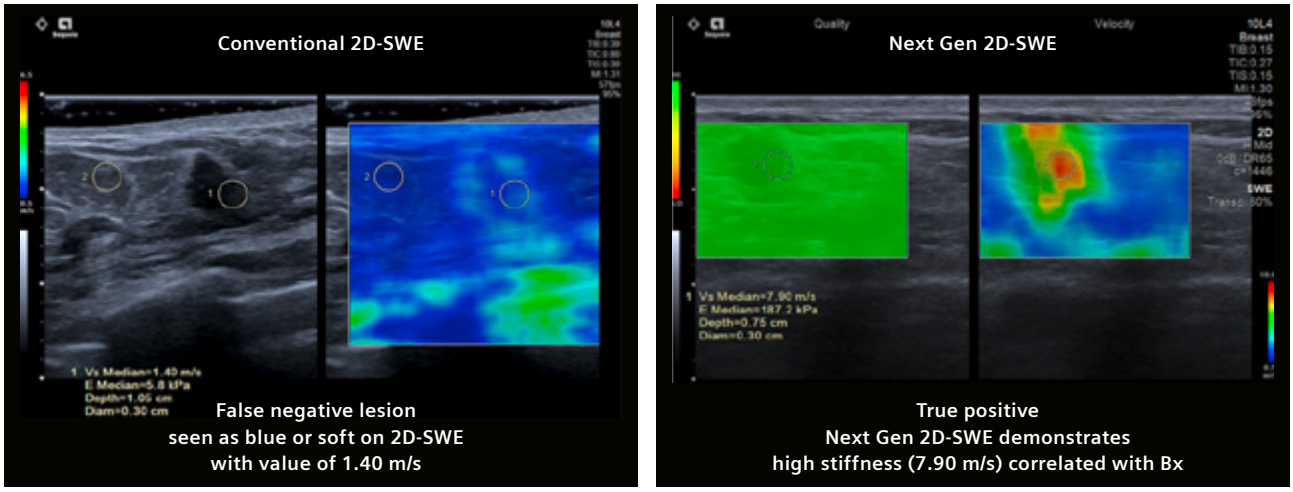

Figure 4: Case study 1, a 79-year-old female with an indication of an abnormal screening mammogram.

Case Study 1
A 79-year-old female with an indication of an abnormal screening mammogram. Biopsy results indicated an invasive pleomorphic lobular cancer.

Figure 4 displays the improvements of Next Gen 2D-SWE compared to conventional 2D-SWE. On the left, conventional 2D-SWE indicates a lesion of 1.40 m/s which would result in a false negative. On the right, Next Gen 2D-SWE demonstrates that the same lesion has a high stiffness of 7.90 m/s. This latter result correlates with biopsy.

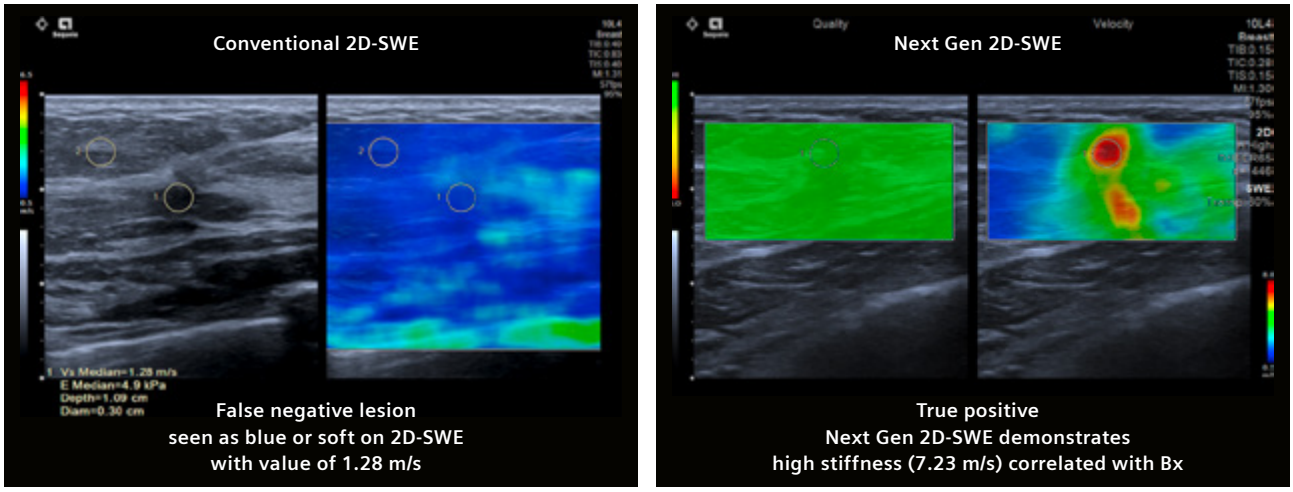

Figure 5: Case study 2, a 50-year-old female with an indication of a palpable mass left breast.

Case Study 2
A 50-year-old female with an indication of a palpable mass left breast. The following imaging results were given: Diagnostic 3D Mammography negative, extremely dense breasts. The biopsy results gave an indication of invasive lobular cancer.

Figure 5 displays the improvements of Next Gen 2D-SWE compared to conventional 2D-SWE. On the left, conventional 2D-SWE indicates a lesion of 1.28 m/s which would result in a false negative. On the right, Next Gen 2D-SWE demonstrates that the same lesion has a high stiffness of 7.23 m/s. This latter result correlates with biopsy.

Conclusions

Blue cancers are prevalent false negative cases seen in conventional 2D-SWE imaging due to artifacts in stiff and hypoechoic breast lesions. Next Gen 2D-SWE significantly improves the sensitivity of the elastography technique, virtually eliminating blue cancers seen with conventional 2D-SWE. Barr et al.'s clinical study highlighted the potential of decreasing the number of benign biopsies and improving patient clinical pathways by downgrading BI-RADS 4 lesions.
Read the published clinical study ↗**here**.

Citations

1 *ACR. ACR, American College of Radiology Breast Imaging Reporting and Data System (BIRADS) Ultrasound. 4th ed. 1st ed. 2003: Reston VA; American College of Radiology. 2013*

2 *Mendelson EB, Böhm-Vélez M, Berg WA, e al. ACR BI-RADS® Ultrasound. In: ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA: American College of Radiology; 2013.*

3 *Barr RG. Sonographic breast elastography: a primer. Journal of Ultrasound in Medicine: official journal of the American Institute of Ultrasound in Medicine. 2012;31(5):773-83*

4 *Berg WA, Cosgrove DO, Dore CJ, et al. Shear-wave elastography improves the specificity of breast US: the BE1 multinational study of 939 masses. Radiology. 2012;262(2):435-49*

5 *Barr RG. Breast Elastography: How to Perform and Integrate Into a "Best-Practice" Patient Treatment Algorithm. Journal of Ultrasound in Medicine: official journal of the American Institute of Ultrasound in Medicine. 2020;39(1):7-17*

6 *Barr RG, Nakashima K, Amy D, et al. WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 2: breast. Ultrasound in medicine & biology. 2015;41(5):1148-60*

7 *Barr RG, Engel A, Kim S, et al. Improved Breast 2D SWE Algorithm to Eliminate False-Negative Cases. Investigative Radiology. 2023*

The statements by Siemens Healthineers customers described herein are based on results that were achieved in the customer's unique setting. Because there is no "typical" hospital or laboratory and many variables exist (e.g., hospital size, sample characteristics, case characteristics), future customer results should be interpreted within an individual patient's given clinical context.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Manufacturer
Siemens Medical Solutions USA, Inc.
Ultrasound
22010 S.E. 51st Street
Issaquah, WA 98029, USA
Phone: 1-888-826-9702
siemens-healthineers.com/ultrasound

Published by Siemens Medical Solutions USA, Inc. · QR700000989 · 14063 0923 online