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WHITE PAPER

Application of S-Shearwave Imaging™ on Breast Ultrasound

RS85 Prestige

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Introduction

Background

Sonoelastography is an ultrasound (US)-based technique which allows to non-invasively assess the mechanical properties of soft tissues. In particular, it is possible to obtain qualitative and quantitative information about tissue elasticity, or its counterpart the stiffness, in response to an imparted force (US elastography).

Considering that breast cancer is usually stiffer than surrounding breast fibroglandular tissue, various elastographic techniques have been developed over time to characterize focal breast lesions (FBLs) with encouraging results. In particular, Shear Wave Elastography (SWE) has been reported to increase the specificity of US in the characterization of FBLs, thus avoiding unnecessary biopsies.

Two Dimensional SWE (2D-SWE) is non-invasive technique capable of applying a dynamic, ultrasound-induced force to tissues and generating shear waves which travel perpendicularly to the US beam path. By measuring the speed of the shear waves in the tissues it is possible to quantify their stiffness: the higher is the velocity of shear waves the stiffer is the tissue explored. Data about stiffness are provided directly as velocity (cs) values ($cs=ms^{-1}$) or converted in kilopascal (kPa) with reference to Young's Modulus E: ($E=3\rho cs2$) where ρ is the density of the tissue. 2D-SWE provides reproducible, quantitative elasticity measurement of the tissue that has been reported to be reliable and clinical feasible diagnostic information in the diagnosis of breast masses detected on US. S-Shearwave Imaging™ (Samsung Medison Co., Ltd.) allows to image stiffness in real time by superimposing a colour box on the B-Mode image. Measurements of tissue stiffness are possible by the positioning of multiple region-of-interests (ROIs). A comparison between the stiffness of a breast mass and the adjacent adipose tissue is also possible: known as the "elasticity ratio". However, little has been reported on the performances of S-Shearwave Imaging™ and its clinical usage in breast US.

The purpose of this white paper is to assess the diagnostic performance of S-Shearwave Imaging™ in differentiating benign from malignant focal breast lesions (FBLs). Optimal cut-off values to applied in the clinical practice are also provided.

Materials and Methods

This prospective study was conducted under the approval of the institutional review board (IRB) of Policlinico Universitario P. Giaccone, Palermo, Italy (institution A) and Severance Hospital, Seoul, Korea (institution B). Written consent was obtained from all the women enrolled in this study.

Patients

From September 2020 to November 2022, 591 FBLs in 550 consecutive women (institution A: 300 FBLs in 300 women, institution B: 291 FBLs in 250 women) who were scheduled for breast US examinations with/without US-guided biopsy were included. All 591 FBLs were either pathologically confirmed via biopsy or surgery, found to be stable on serial follow up of more than 24 months, or had typically benign US features as defined in the American College of Radiology Breast Imaging Reporting And Data System (ACR BI-RADS).

SWE examination

Two experienced breast radiologists (more than 10 years of experience) performed baseline US and then elasticity assessment with 2D-SWE (S-Shearwave Imaging™) from a dedicated ultrasound machine (RS85 Prestige, Samsung Medison Co., Ltd., Korea) using a 2-14 MHz linear transducer (LA2-14A, Samsung Medison Co., Ltd., Korea). SWE images were obtained by applying the transducer very lightly to the skin above the targeted breast mass. Images of grayscale US and SWE were simultaneously displayed in split-screen mode with the semi-transparent SWE superimposed on the corresponding grayscale image. The probe was held very still for a few seconds to let the SWE image stabilize and the SWE image showing adequate image quality was saved. The ROI box was set to sufficiently include the FBL and surrounding breast parenchyma for quantitative SWE measurement (Fig 1). Tissue elasticity was obtained in color-coded map, ranging from blue (soft) to red (hard).

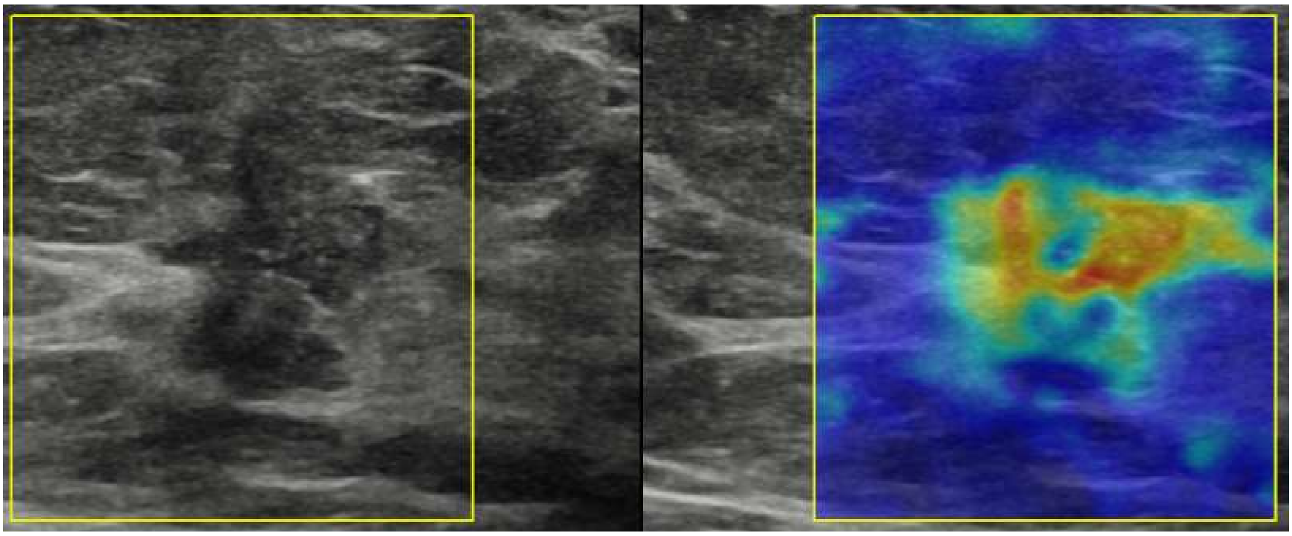

Fig. 1. ROI box was set to sufficiently include the FBL and surrounding breast parenchyma. Tissue elasticity was obtained in colour map, ranging from blue (soft) to red (hard).

To ensure the high image quality needed for 2D-SWE, a specific box (also called 'the elasticity image ROI' or 'the ROI box') is superimposed on the lesion allowing a visual evaluation of image quality by means of a color code: ranging from yellow (good image quality) to red (bad image quality). Furthermore, a Reliability Measurement Index (RMI) is generated and displayed on the US system.

Once the acquisition of SWE on a freeze image, users can measure elasticity and elasticity ratio. Quantitative SWE values were measured using two 2mm circular quantification ROIs, also known as 'Measure ROIs.': one at the stiffest area of the mass or immediately adjacent areas, and another at the normal parenchymal tissue showing homogeneously soft elasticity signals within the ROI box.

By setting the circle quantification ROIs, the system automatically generated and displayed the following elasticity values: (1) elasticity maximum (E_{max}); (2) mean elasticity (E_{mean}); (3) minimum elasticity (E_{min}); (4) elasticity ratio (E_{ratio}). The first three parameters are expressed either in kPa (Young's modulus) or in m/s (shear wave speed). Eratio is expressed as percentage, indicating the ratio between the lesion's mean elasticity value and that of fat, by positioning another circle ROI of the same size at the same level in the surrounding breast tissue (Fig 2).
US BI-RADS final assessment was given for each FBL by the radiologist.

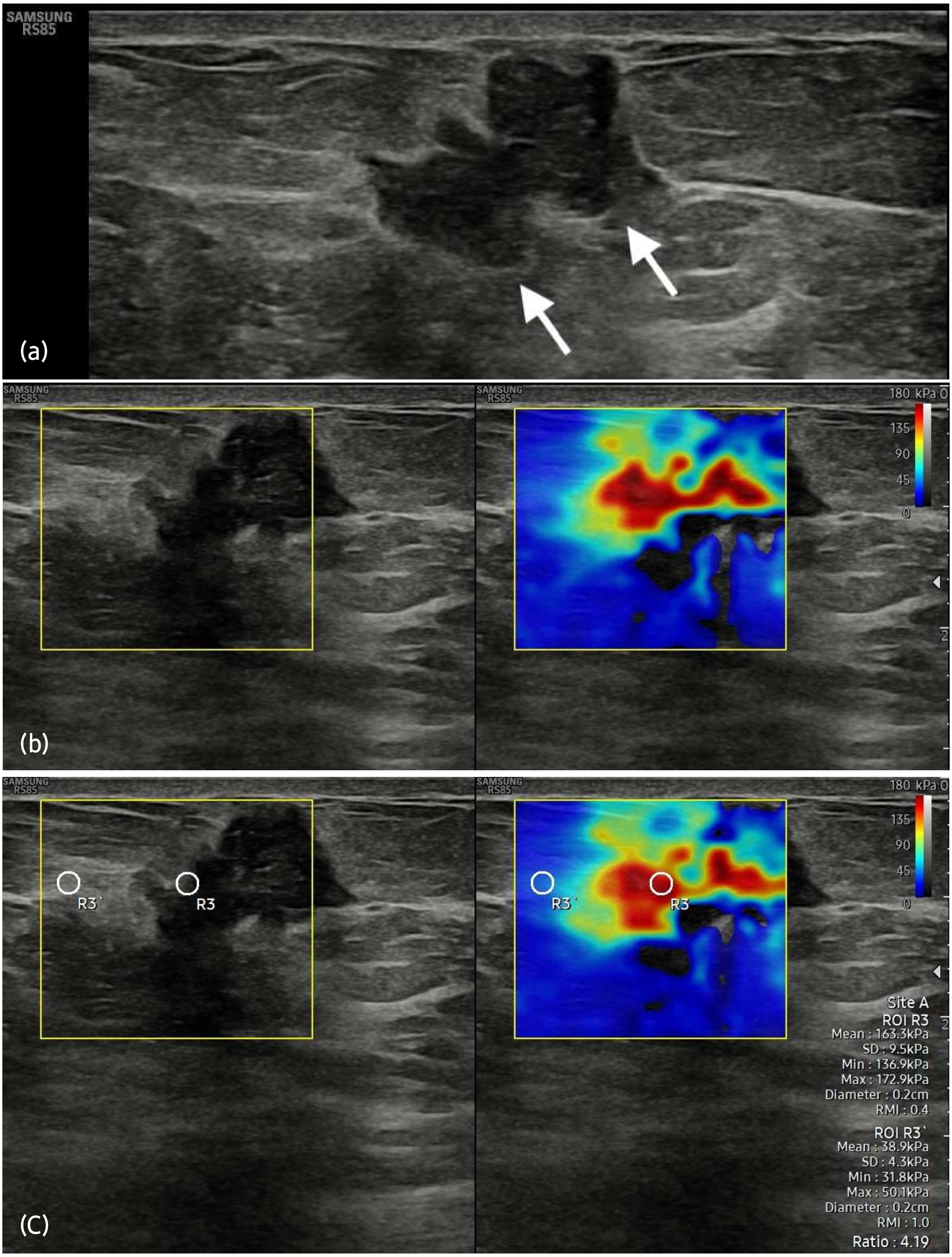

Fig. 2. Representative case confirmed as invasive ductal carcinoma. (a) Grayscale US image reveals a hypoechoic, irregularly-shaped mass (arrows). (b) SWE image shows the hard component of the mass in red. (c) 2D-SWE quantitative assessment provides measurement of the stiffness (Emax: 172.9 kPa - Emean: 163.3 kPa) - Emin: 136.9 kPa) and allows comparison with the surrounding fat (Eratio: 4.19).

Statistical Analysis

Diagnostic performances including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy was calculated and compared using generalized estimated equation (GEE) method. Cutoff values for each elasticity value were calculated using the area under the receiver operator characteristics (ROC) curve (AUC) and compared using the Delong's method.

Results

Of the 591 FBLs, 351 (59.4%) were benign and 240 (40.6%) were malignant. Mean elasticity values using SWE according to final pathologic diagnosis are summarized in Table 1.
Mean SWE values were significantly higher in all parameters for malignant masses compared to benign ones (all P<0.001, respectively).

Table 1. Mean SWE values for the 591 FBLs according to final pathology

	Benign (n=351)	Malignant (n=240)	P-value
Emean (kPa)	53.6	104.8	<0.001
Emax (kPa)	61.3	116.6	<0.001
Emin (kPa)	43.2	85.7	<0.001
Eratio	2.83	4.69	<0.001

AUC of the SWE parameters ranged from 0.716 to 0.802. AUCs for Emean and Emax did not show significant differences, 0.802 to 0.794 (P=0.417). AUC for Emean was significantly higher compared to Emin and Eratio, 0.802 to 0.781 and 0.716, respectively (P=0.04 and <0.001).
Cutoff values for each SWE parameter were calculated as follows: 69.85 kPa for Emean, 82.3 kPa for Emax, 59.9 kPa for Emin, and 3.14 for Eratio. Diagnostic performance of SWE parameters using the calculated cutoff values are summarized in Table 2.

Table 2. Diagnostic performances of SWE parameters with the calculated cutoff values for each parameters

	US	Emean	Emax	Emin	Eratio
Cutoff	-	69.9	82.3	59.9	3.14
Sensitivity (%)	86.3	80.8	76.3	75.8	71.7
Specificity (%)	96.3	79.5	82.6	80.3	71.5
PPV (%)	94.9	72.9	75.0	72.5	63.2
NPV (%)	91.1	85.9	83.6	82.9	78.7
Accuracy (%)	92.2	80.0	80.0	78.5	71.6
AUC	0.913	0.802	0.794	0.781	0.716

PPV: positive predictive value, NPV: negative predictive value, AUC: area under the receiving operator characteristics curve

Discussion

In our experience, mean quantitative 2D-SWE parameters significantly differed between benign and malignant breast masses.

In spite of the increasing number of published studies on using 2D SWE for breast US, a great heterogeneity still remains in terms of methodology, type of US equipment and cut-off values provided. As a consequence, it is highly recommended that each site assesses the most appropriate cut-off values and uses continued monitoring to adjust the cutoff as needed.

To this regard, the new cutoff values that we have found with S-Shearwave Imaging™ and that we used in this study do not differ significantly to those provided by a recent meta-analysis focusing on 2D SWE quantitative parameters. This latter study has shown that a co-variate cutoff value for Emax and Emean was higher than or equal to 70 kPa yielded significantly higher sensitivity than a lower cutoff (< 70 kPa).

Conclusion

In conclusion, our study provides new vendor-specific cutoff values for SWE using S-Shearwave Imaging™. Using the cutoff of 69.9kPa for Emean and 82.3kPa for Emax had the highest AUCs without statistical significance between the two parameters, indicating that either Emean or Emax can be applied during breast US examinations with similar diagnostic outcomes.

References

American College of Radiology. Breast Imaging Reporting And Data System, 5th ed. Reston, VA: American College of Radiology (2013).

Bamber J, Cosgrove D, Dietrich CF et al (2013) EFSUMB guidelines and recommendations on the clinical use of ultrasound elastography. Part 1: Basic principles and technology. Ultraschall Med 34(2):169-84. https://doi.org/10.1055/s-0033-1335205.

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

Bartolotta TV, Orlando AAM, Dimarco M, Zarcaro C, Ferraro F, Cirino A, Matranga D, Vieni S, Cabibi D. Diagnostic performance of 2D-shear wave elastography in the diagnosis of breast cancer: a clinical appraisal of cutoff values. Radiol Med. 2022 Nov;127(11):1209-1220. doi: 10.1007/s11547-022-01546-w. Epub 2022 Sep 17. PMID: 36114930.

Dietrich CF, Bamber J, Berzigotti A et al (2017) EFSUMB Guidelines and Recommendations on the Clinical Use of Liver Ultrasound Elastography, Update 2017 (Long Version). Ultraschall Med 38(4):e16-e47. https://doi.org/10.1055/s-0043-103952.

Săftoiu A, Gilja OH, Sidhu PS et al (2019) The EFSUMB Guidelines and Recommendations for the Clinical Practice of Elastography in Non-Hepatic Applications: Update 2018. Ultraschall Med 40(4):425-45. https://doi.org/10.1055/a-0838-9937.

Park SY, Kang BJ (2021) Combination of shear-wave elastography with ultrasonography for detection of breast cancer and reduction of unnecessary biopsies: a systematic review and meta-analysis. Ultrasonography 40(3):318–332. https:// doi. org/ 10. 14366/ usg. 20058

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