

White Paper

Application of S-Shearwave Imaging™ for diagnosis of breast mass using ultrasound elastography

V8

Ji Hyun Youk, MD, PhD

Department of Radiology, Gangnam Severance Hospital,
Yonsei University College of Medicine, Seoul, Korea

Introduction

▪ Background

Breast cancer incidence rates have been increased for past few decades [1], and ultrasonography (US) has been widely used as a noninvasive method [2]. Gray-scale ultrasound in breast application is documented in ACR BI-RADS® (American College of Radiology Breast Imaging Reporting and Data System) [3].

Shear-wave elastography (SWE) is an ultrasound technique used to allow to quantify tissue stiffness. SWE has been widely used for noninvasive diagnosis of breast lesions with successful results and well established in the chain of clinical workflow [4]. SWE provides reproducible, quantitative elasticity measurement with reliable and clinically feasible diagnostic information in the diagnosis of breast masses [5,6].

▪ Purpose

There are many clinical trials on each SWE by providing their diagnostic performance and cutoff values to differentiate benign and malignant mass in a real clinical environment. The cutoff values are, however, system-specific due to manufacturer differences including push pulse shape, probe specifications, scanning scheme, and post processing algorithm [7].

S-Shearwave Imaging™ has been released on V8 ultrasound system (Samsung Medison Co., Ltd.) with multi beam based shear wave elastography.

We aim to evaluate the diagnostic performances of S-Shearwave Imaging™ on V8 ultrasound system for differentiating breast masses, and generate appropriate cutoff elasticity values to apply in clinical practice.

Materials and Methods

This prospective study was conducted under the approval of the institutional review board (IRB) of Gangnam Severance Hospital in Seoul, Korea. Written consent was obtained from all the women enrolled in this study.

▪ Patients

Total 103 cases from 98 patients were collected from June 2021 to November 2022 among women scheduled for breast US examinations at our institution for analysis. All of the breast masses were either pathologically confirmed via percutaneous biopsy or surgery, or stable on follow-up for more than 24 months by the ACR BI-RADS® [4]. Of the 103 cases, 64 cases were benign and 39 cases were malignant with invasive ductal carcinoma (n=32), ductal carcinoma in situ (n=5), malignant phyllodes tumor (n=1), and solid papillary carcinoma in situ (n=1). Mean size of the 103 breast masses was 12.08 ± 6.68 mm.

▪ S-Shearwave Imaging™ examination

Using an V8 ultrasound system with a LA2-14A linear probe (Samsung Medison Co., Ltd.) and S-Shearwave Imaging™ function, the 103 breast masses were examined with 2D-SWE examinations. Images of gray-scale US and S-Shearwave Imaging™ were simultaneously displayed in a split-screen mode with the semi-transparent S-Shearwave Imaging™ superimposed on the corresponding gray-scale image, as shown in Fig. 1. The stiffness map (on the right) is scalable by users either in the unit of kPa (measured in Young's modulus) or m/s (in shear wave speed). Tissue elasticity was displayed on a color-coded map, ranging from blue (soft) to red (hard).

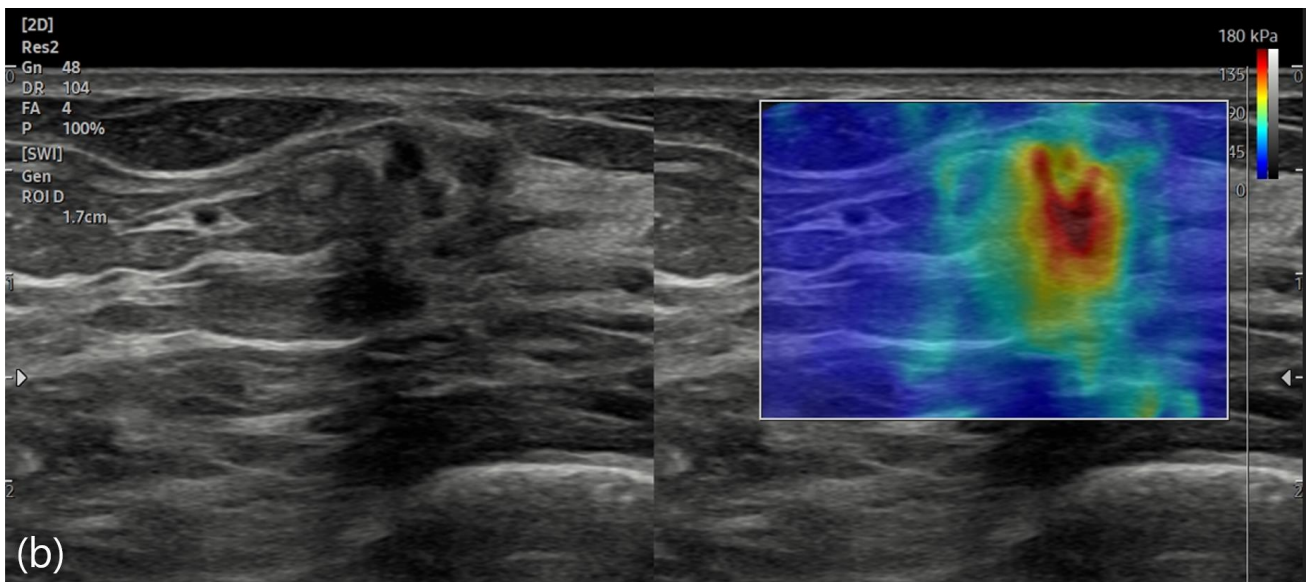
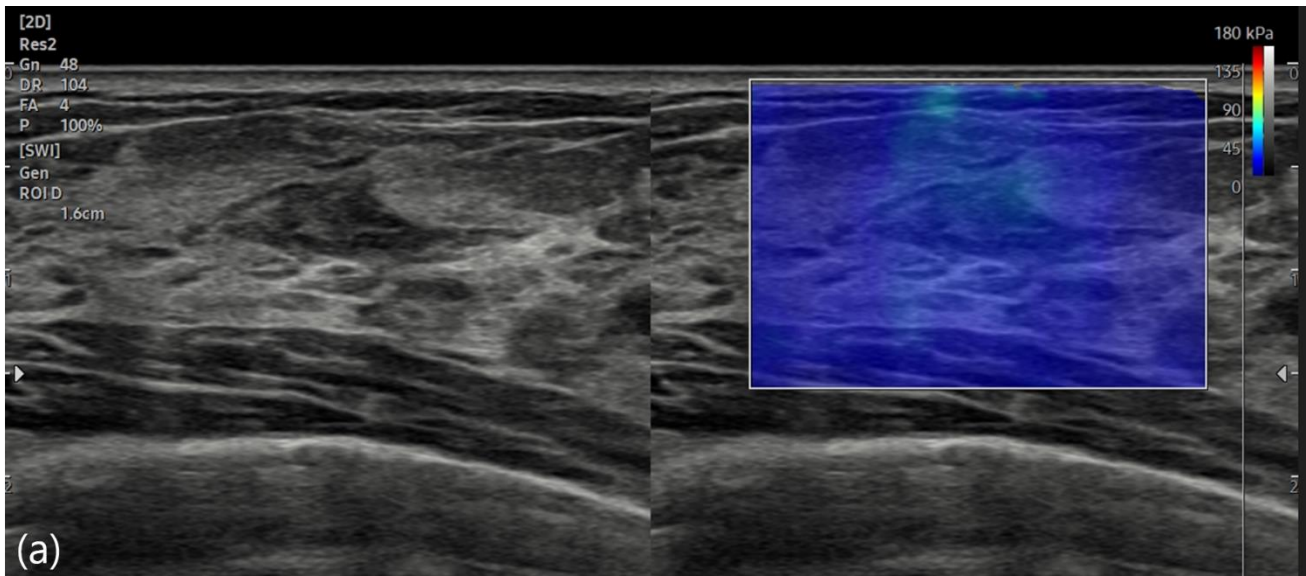


Figure 1. Sample images of S-Shearwave Imaging™ breast examination. Both gray-scale US image and elasticity image are displayed side by side. S-Shearwave Imaging™ stiffness is displayed semi-transparently imposed on the corresponding gray-scale image. ROI box was set to include the mass and surrounding breast parenchyma for further measurement. Image (a) shows a benign case, and (b) shows a malignant case.

S-Shearwave Imaging™ examination was performed with the probe very lightly touching the skin above the targeted breast mass [5] and held still for a few seconds to let the S-Shearwave Imaging™ image stabilized for the S-Shearwave Imaging™ image with adequate quality to be saved. Region of interest (ROI) was set to include the mass and the surrounding breast parenchyma for quantitative S-Shearwave Imaging™ measurement (Fig. 1).

Quantitative S-Shearwave Imaging™ values were measured using two 2-mm round sub-ROIs:

one at the stiffest area of mass or the immediately adjacent areas, and the other at the normal fatty tissue showing homogeneously soft elasticity values, as shown in Fig. 2. By setting the round sub-ROIs, the system automatically generated and displayed the following elasticity values: maximum elasticity (E_{max}), mean elasticity (E_{mean}), minimum elasticity (E_{min}), and elasticity ratio (E_{ratio} : the ratio of the stiffest value to fat).

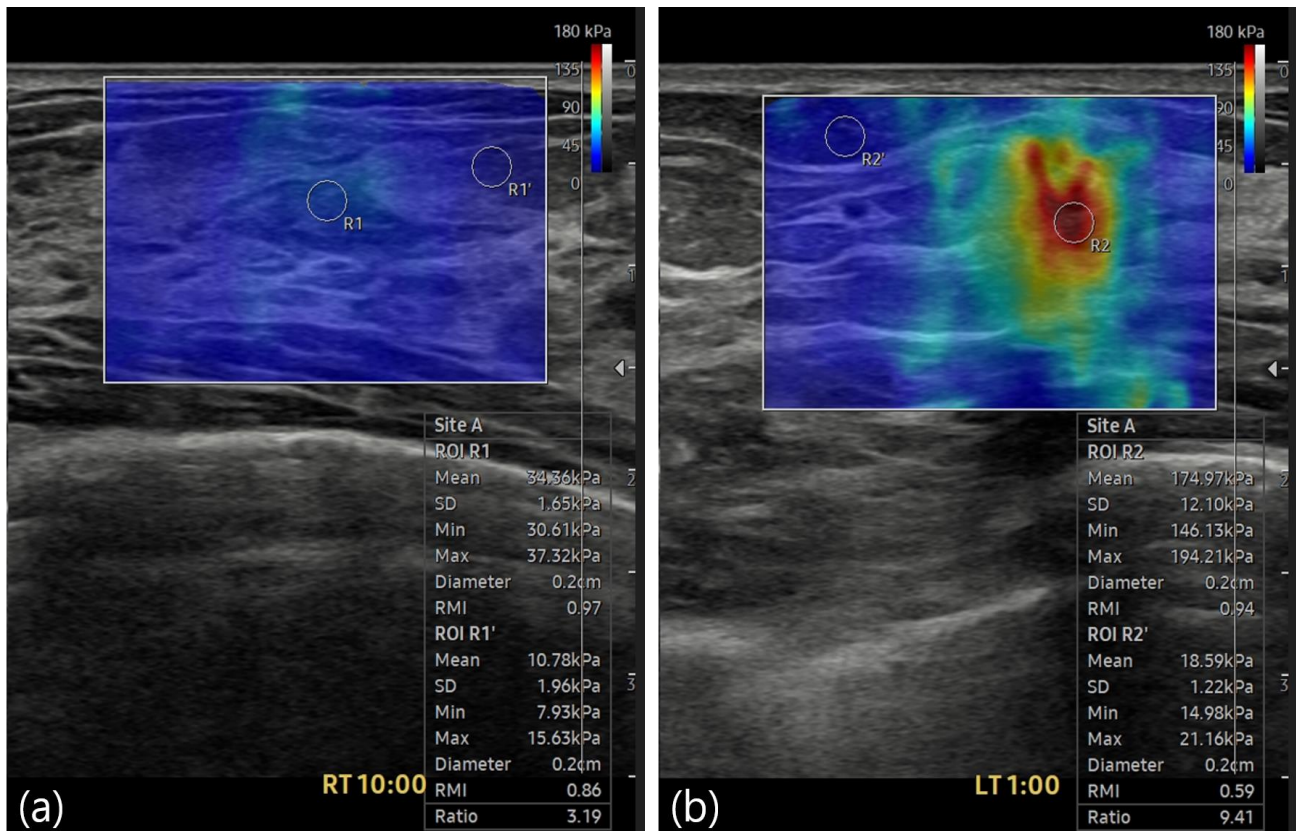


Figure 2. Measuring elasticity values with sub-ROIs. Each figure corresponds to the cases shown in Figure 1.

▪ Statistical Analysis

An independent two-sample t-test was used for comparison of mean elasticity values between benign and malignant masses. Diagnostic performances including sensitivity, specificity, and accuracy were calculated by Receiver Operating Characteristics (ROC) analysis for the optimum cutoff values. P values of less than 0.05 were considered to indicate statistical significance.

Results

Of the 103 breast masses, 64 cases (62.1 %) were benign and 39 cases (37.9 %) were malignant. Box plots of the benign and malignant cases are shown in Fig. 3 for Emax, Emean, Emin, and Eratio.

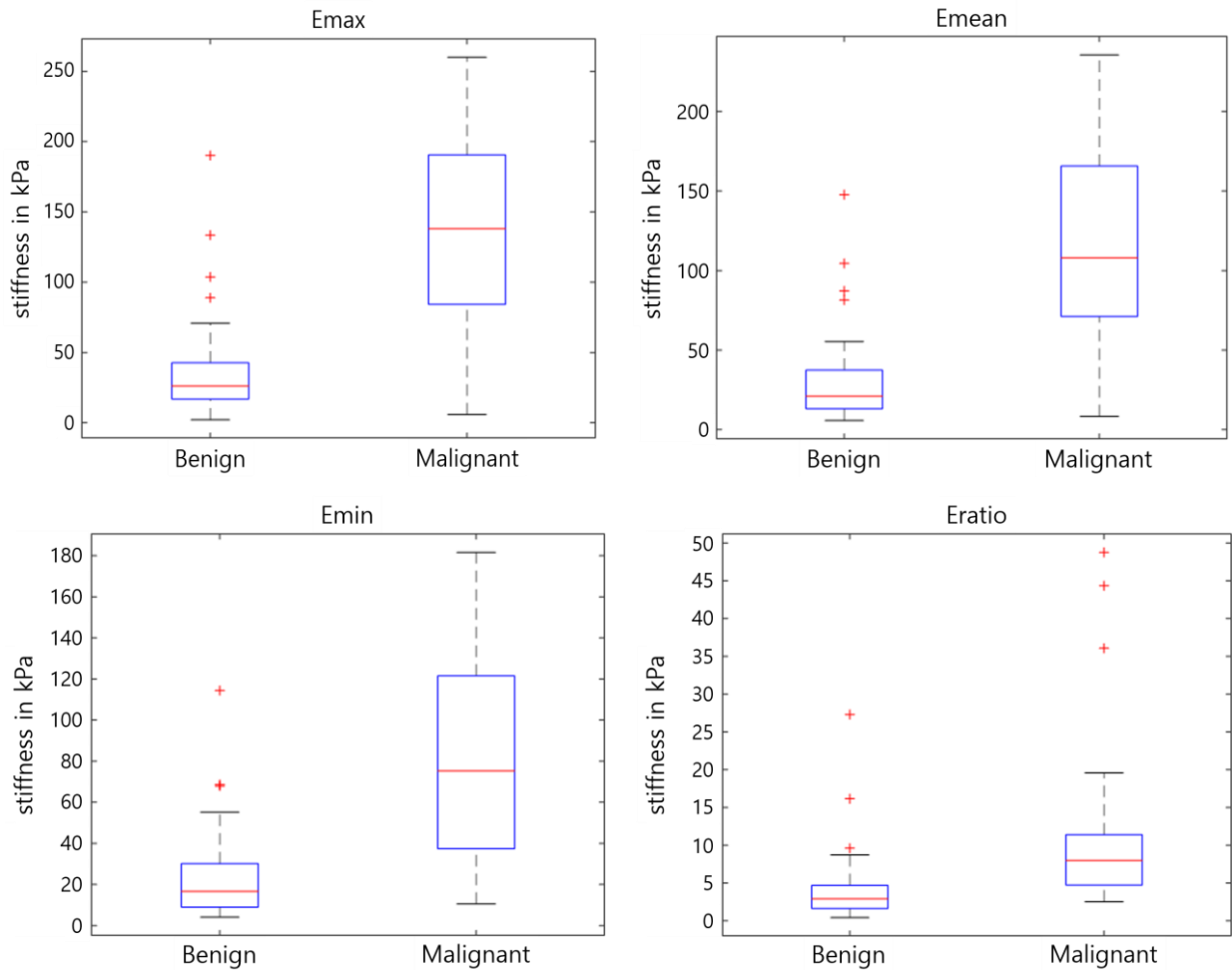


Figure 3. Box plots for Emax, Emean, Emin, and Eratio.

Also, mean of elasticity parameters using S-Shearwave Imaging™ among the 103 breast masses according to final diagnosis is summarized in Table 1. Mean of elasticity parameters was significantly higher in all parameters for malignant masses compared to benign (all P values <0.001).

Table 1. Comparison of mean elasticity parameters according to final assessment of the 103 breast masses

	Benign (n=64)	Malignant (n=39)	P value
E _{max} (kPa)	35.6±30.7	135.1±69.7	<0.001
E _{mean} (kPa)	29.2±24.6	111.4±60.0	<0.001
E _{min} (kPa)	21.9±18.6	80.7±47.9	<0.001
E _{ratio}	3.8±3.9	10.9±10.5	<0.001

ROC analysis results are summarized in Table 2 for E_{max}, E_{mean}, E_{min}, and E_{ratio}. The cutoff values for each elasticity parameter were calculated using the Youden index as follows: 82.3 kPa for E_{max}, 51.3 kPa for E_{mean}, 42.9 kPa for E_{min}, and 4.0 for E_{ratio}.

Table 2. Diagnostic performances of S-Shearwave Imaging™ parameters for breast masses

	Gray-scale image	E _{max}	E _{mean}	E _{min}	E _{ratio}
Cutoff (kPa)*	-	82.3	51.3	42.9	4.0
Sensitivity (%)	76.9	79.5	82.1	74.4	87.2
Specificity (%)	95.3	93.8	92.2	93.8	70.3
Accuracy (%)	88.4	88.4	88.4	86.4	76.7
AUC**	0.882	0.903	0.903	0.891	0.857

*The Youden index was used to calculate the cutoff value.

**AUC: area under the receiver operating characteristics curve

Compared with gray-scale image, E_{max} and E_{mean} showed better sensitivity and AUC, and slightly lower specificity.

Conclusion

In this study, cutoff values of S-Shearwave Imaging™ on V8 ultrasound system for breast diagnosis have been proposed. Either Emax or Emean can be applied during breast US examinations. Color map features can be visually assessed on the spot before measuring elasticity quantitatively. S-Shearwave Imaging™ allows the user to visualize the tissue stiffness by color and to analyze the elasticity quantitatively. S-Shearwave Imaging™ with gray-scale US image can help differentiate benign from malignant mass in breast.

Supported Systems

- V8 / H8 / XV8 /
XH8 / RS9 / XR9
/ V8-RUS
- V7 / H7 / XV7 /
XH7 / RS7 / XR7 /
V7-RUS
- V6 / H6 / XV6 /
XH6 / V6-RUS

References

1. Giaquinto AN, Sung H, Miller KD, Kramer JL, Newman LA, Minihan A, Jemal A, Siegel RL. Breast Cancer Statistics, 2022. *CA Cancer J Clin.* 2022 Nov;72(6):524-541.
2. Barr RG et al. WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 2: breast. *Ultrasound Med Biol.* 2015 May;41(5):1148-60.
3. American College of Radiology. Breast imaging reporting and data system. 5th ed. Reston, VA: American College of Radiology 2013.
4. Bartollota TV, Orlando AA, Dimarco M, Zaecaro 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.
5. Berg WA, Cosgrove DO, Dore CJ, Schafer FK, Svensson WE, Hooley RJ, et al. Shear-wave elastography improves the specificity of breast US: the BE1 multinational study of 939 masses. *Radiology.* 2012;262(2):435-49.
6. Youk JH, Gweon HM, Son EJ. Shear-wave elastography in breast ultrasonography: the state of the art. *Ultrasonography* 2017;36(4):300-309
7. Barr RG, Wilson SR, Rubens D, Garcia-Tsao G, Ferraioli G. Update to the society of radiologists in ultrasound liver elastography consensus statement. *Radiology* 2020; 296(2): 263-274.

Disclaimer

- * The features mentioned in this document may not be commercially available in all countries. Due to regulatory reasons, their future availability cannot be guaranteed.
- * Do not distribute this document to customers unless relevant regulatory and legal affairs officers approve such distribution.
- * Images may have been cropped to better visualize its pathology.
- * This clinical practice review is a result of a personal study conducted by collaboration between Samsung Medison and Prof. Ji Hyun Youk
- * This review is to aid customers in their understanding, but the objectivity is not secured.

- * 본 자료는 삼성메디슨이 연구자와 협업하여 산출된 연구의 결과물입니다.
고객의 요청에 따라 이해를 돕기 위해 제공하는 자료일 뿐 객관성은 확보되지 않았습니다.

For more information, please visit the official website www.samsunghealthcare.com



SAMSUNG MEDISON CO., LTD.

© 2023 Samsung Medison All Rights Reserved.

Samsung Medison reserves the right to modify any design, packaging, Specifications and features shown herein, without prior notice or obligation.