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ORIGINAL ARTICLE

# Diagnostic Value of Elastography Using Acoustic Radiation Force Impulse Imaging and Strain Ratio for Breast Tumors

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**Purpose:** The aim of this study was to determine whether the combination of B-mode ultrasonography (BUS), acoustic radiation force impulse (ARFI) elastography, and strain ratio (SR) provides better diagnostic performance of breast lesion differentiation than BUS alone. **Methods:** ARFI elastography and SR evaluations were performed on patients with 157 breast lesions diagnosed by BUS from June to September 2013. BUS images were classified according to the Breast Imaging-Reporting and Data System. ARFI elastography was performed using Virtual Touch™ tissue imaging (VTI) and Virtual Touch™ tissue quantification (VTQ). In VTI mode, we evaluated the color-mapped patterns of the breast lesion and surrounding tissue. The lesions were classified into five categories by elasticity score. In VTQ mode, each lesion was assessed using shear wave velocity (SWV) measurements. SR was calculated from the lesion and comparable lateral fatty tissue. We compared the diagnostic performance of BUS alone and the combination of BUS, ARFI elastography, and SR evaluations. **Results:** Among the 157 lesions, 40 were malignant and 117 were benign. The mean elasticity score (3.7±1.0 vs. 1.6±0.8, $p<0.01$), SWV (4.23±1.09 m/sec vs. 2.22±0.88 m/sec, $p<0.01$), and SR (5.69±1.63 vs. 2.69±1.40, $p<0.01$) were significantly higher for malignant lesions than benign lesions. The results for BUS combined with ARFI elastography and SR values were 97.5% sensitivity, 92.3% specificity, 93.6% accuracy, a 79.6% positive predictive value (PPV), and a 99.1% negative predictive value. The combination of the 3 radiologic examinations yielded superior specificity, accuracy, and PPV compared to BUS alone ($p<0.01$ for each). **Conclusion:** ARFI elastography and SR evaluations showed significantly different mean values for benign and malignant lesions. Moreover, these two modalities complemented BUS and improved the diagnostic performance of breast lesion detection. Therefore, ARFI elastography and SR evaluations can be used as complementary modalities to make more accurate breast lesion diagnoses.

**Key Words:** *Breast neoplasms, Elasticity imaging techniques, Ultrasonography*

## INTRODUCTION

Breast cancer is the most frequent cancer among women worldwide and the second most common cancer in Korean women [1,2]. Early detection is critical for the successful management of breast cancer. B-mode ultrasonography (BUS) has been used to accurately estimate breast lesion whether it is malignant or not [3-5]. While BUS can be a useful method to differentiate breast lesions, this modality has the unavoidable limitation of low specificity [4,6-8].

To overcome this limitation, elastography was introduced [9]. Elastography is a noninvasive imaging modality to evaluate the stiffness of soft tissues [10]. In general, benign breast lesions tend to be softer than malignant lesions. This general characteristic provides the basis for using elastography to differentiate breast lesions [11]. The most frequently used elastography technique in the breast is strain elastography, which requires external compression [3,12]. Because external compression is performed manually, strain elastography is operator-dependent which influences its reproducibility [13]. Instead of using manual compression, a new trend of applying acoustic radiation force impulse (ARFI) imaging to elastography has arisen [9,11,14]. ARFI elastography has the advantage of being objective, reproducible, and less operator-dependent. With this modality, ultrasonography scanners are used to generate short-duration acoustic radiation forces that impart small, localized displacements in the tissue and create a static map of the relative stiffness of the tissues [9,14-16].

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Strain ratio (SR) is a semiquantitative measurement to determine the firmness of tissue and to differentiate benign and malignant lesions by comparing the difference in compliance between a breast lesion and adjacent fatty tissue [9,17,18]. Previous studies have proven that SR is a highly valuable and more objective parameter for differentiating malignant and benign breast lesions [18-22].

Given the properties described above, we evaluated the diagnostic efficacy of ARFI elastography and SR measurements. The aim of this study was to evaluate whether the combination of BUS, ARFI elastography, and SR improves the diagnostic performance of differentiating malignant and benign breast lesions.

## METHODS

### Patients

This study was reviewed and approved by the Kosin University Gospel Hospital Institutional Review Board (approval number, 91961-ABG-14-002). Between June and September 2013, patients who visited to the outpatient clinic for breast mass, pain and screening study were evaluated. Cases with normal finding on BUS and prior neoadjuvant chemotherapy and/or radiotherapy due to any primary cancer were excluded. Finally, 157 breast lesions were included in the current study. Regardless of the ultrasonographic findings, each lesion in the study underwent a histological examination with the consent of the patient. In patients with benign lesions diagnosed by core needle biopsy, an excisional biopsy was subsequently performed when the patient opted for surgical removal. BUS, ARFI elastography, and SR examinations were performed before surgery and biopsy. After the three radiologic examinations, each breast lesion was diagnosed pathologically by radical surgery (40/157, 25.5%), excisional biopsy (90/157, 57.3%), or core needle biopsy (27/157, 17.2%).

### Imaging techniques

BUS, ARFI elastography, and SR evaluations were performed with a Siemens ACUSON S2000 US system (Siemens Medical Solutions, Mountain View, USA) with a linear probe (9L4; Siemens Medical Solutions) by one operator (D.W.R.) with 9 years' experience in breast imaging. The operator was not informed of the patient's medical history before the three radiologic examinations.

First, we obtained BUS images of the lesions. The lesion was described by using the Breast Imaging-Reporting and Data System (BI-RADS) lexicon of ultrasonographic descriptors of mass shape, orientation, margin, lesion boundary, echo pattern, and posterior acoustic features.

Next, ARFI elastography sequences were performed to evaluate the elasticity scores of the breast lesions in Virtual Touch™ imaging (VTI) mode by displaying the target lesion on BUS, setting a region of interest (ROI) around the lesion, and ensuring that adequate surrounding breast tissue was included in the ROI. During the ARFI elastography examination, patients were instructed to continue breathing normally. In Virtual Touch™ quantification (VTQ) mode, an acoustic impulse and detection pulses were used to calculate shear wave velocity (SWV). To perform VTQ, a target region was identified with a fixed-size ROI of 5×5 mm. For the measurement, the marginal areas of the mass and surrounding tissues were included in the ROI, and the SWV was measured 3 times in these areas when measurements were feasible. The shear waves were detected by ultrasonographic detection pulses; numeric SWV values were calculated and displayed on the monitor (Figure 1). When measurements were outside the allowable range (0–9 m/sec) for SWV calculations, the SWV might be displayed as "X.XX."

The SR was measured on a static image including coupled B-mode and elastographic images. The calculation of the SR was based on a comparison of the average strain measured in the lesion and adjacent fatty tissue at the same depth. The strain of the lesion was determined by selecting an ROI from the lesion. The SR was automatically calculated and displayed on the monitor (Figure 2).

### Image analysis

An independent and blinded review of all lesions was performed by two radiologists (J.G.P. and B.S.K.) with 9 and 5 years of experience in breast imaging, respectively. The radiologists analyzed BUS, ARFI elastography, and SR values until

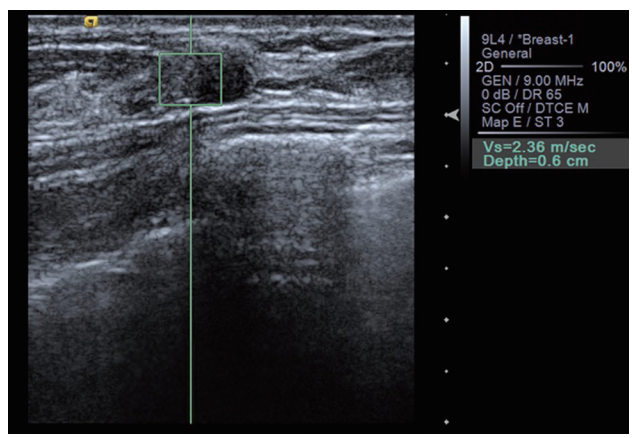


**Figure 1.** Calculation of shear wave velocity (Vs) of breast lesion. Marginal areas of mass and the surrounding tissues are included in the region of interest. The numeric value of the shear wave velocity is displayed on the monitor.

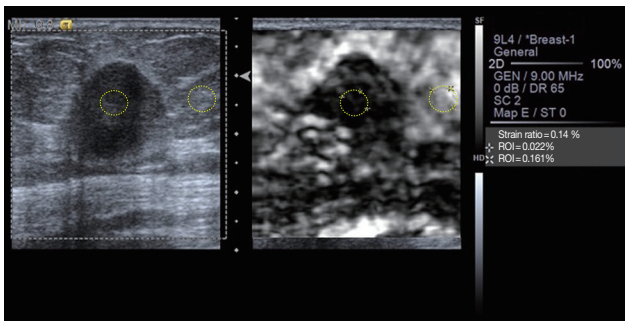


**Figure 2.** Measurement of strain ratio of breast lesion. Strain ratio is measured by comparing the average strain between breast lesion and surrounding adipose tissue. The numeric value of the strain ratio is displayed on the monitor.
ROI = region of interest.

consensus was reached.

BUS images were assigned to 1 of 5 categories according to BI-RADS: category 1, negative findings; category 2, benign findings; category 3, probably benign findings; category 4, suspicious of malignancy; and category 5, highly suggestive of malignancy.

To classify VTI-mode images, we evaluated the color-mapped pattern both in the lesion and in the surrounding breast tissue (i.e., the pectoral muscle and rib were excluded). The ARFI elastography image was displayed as a color map with each voxel representing the degree of strain within the ROI by using a scale ranging from purple (softest components) to blue (intermediate components) and red (hardest components). Referencing the work of Itoh et al. [23], the breast lesions were differentiated into 5 categories according to color pattern. A score of 1 indicated equivalent strain throughout the lesion (no red voxels were present in the lesion); a score of 2 indicated strain in most of the lesion with some areas of no strain (a mosaic pattern of red and other colors); a score of 3 indicated no strain in the central part of the lesion (only the central part of the lesion was colored red); a score of 4 indicated no strain throughout the lesion (the entire lesion was red); and a score of 5 indicated no strain throughout the lesion or the surrounding area (the entire lesion and its surrounding area were colored red) (Figure 3).

The roles of ARFI elastography and SR values in differentiating malignant and benign lesions were assessed as follows for each lesion. Using Youden's index (sensitivity+specificity-1), the optimal cutoff values were determined from a receiver-operating characteristic (ROC) curve analysis. Using these cutoff values, a modified BI-RADS score was calculated according to the following equation: modified BI-RADS = BI-RADS+α+β, where α and β are the ARFI elastography and SR scores, respectively. These scores were calculated as follows. When both the VTI and VTQ values were higher than the cutoff value in each evaluation, α was scored as +1; when only 1 of the values was higher, we calculated the α score as 0; when neither method was higher, the α score was estimated as -1. In cases of out-of-range SWV values ("X.XX" on VTQ mode), we calculated the α score based on the VTI image alone. When the VTI value was higher than the cutoff point, α was estimated as +1; when the value was lower than the cutoff point, it was estimated as -1. Moreover, when the SR value was higher than the cutoff point, β was scored as +1; when the SR value was lower than the cutoff point, β was scored as -1; when it was equal to the cutoff point, we estimated the β score as 0. When the modified BI-RADS score was calculated as less than 3, the score was recorded as 3; scores higher than 5 were recorded as 5.

### Statistical analysis

All statistical analyses were performed using PASW version 18.0 (SPSS Inc., Chicago, USA). Interobserver agreement for BUS categorizations and elasticity scores were estimated by using κ-values. A κ-value of 0.20 or less was considered slight agreement; 0.02 to 0.40, fair agreement; 0.41 to 0.60, moderate agreement; 0.61 to 0.80, substantial agreement; and 0.81 to 1.00, almost perfect agreement [24]. Differences in sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) between evaluation methods were assessed by McNemar's test. The optimal elasticity score cutoff point was determined by comparing Youden's index as determined by the ROC curve analysis. The mean SWV and SR values were calculated using Student t-test. All *p*-values were based on 2-sided testing; *p*-values $<0.05$ were considered statistically significant.

## RESULTS

### Pathologic diagnosis

Of the 157 breast masses, 40 (25.5%) were malignant and 117 (74.5%) were benign. The pathologic diagnoses of these lesions are shown in Table 1. The most common malignant and benign tumors were invasive ductal carcinoma (n = 36) and fibrocystic changes (n = 57), respectively.

### Interobserver variability

The agreement between the reviewers for the BI-RADS categorizations and elasticity scores were moderate (κ-value = 0.53, $p<0.01$) and almost perfect (κ-value = 0.97, $p<0.01$), respectively. If there was disagreement about the BI-RADS categorization and/or elasticity score of breast lesion, the two radiologists discussed until consensus was achieved.


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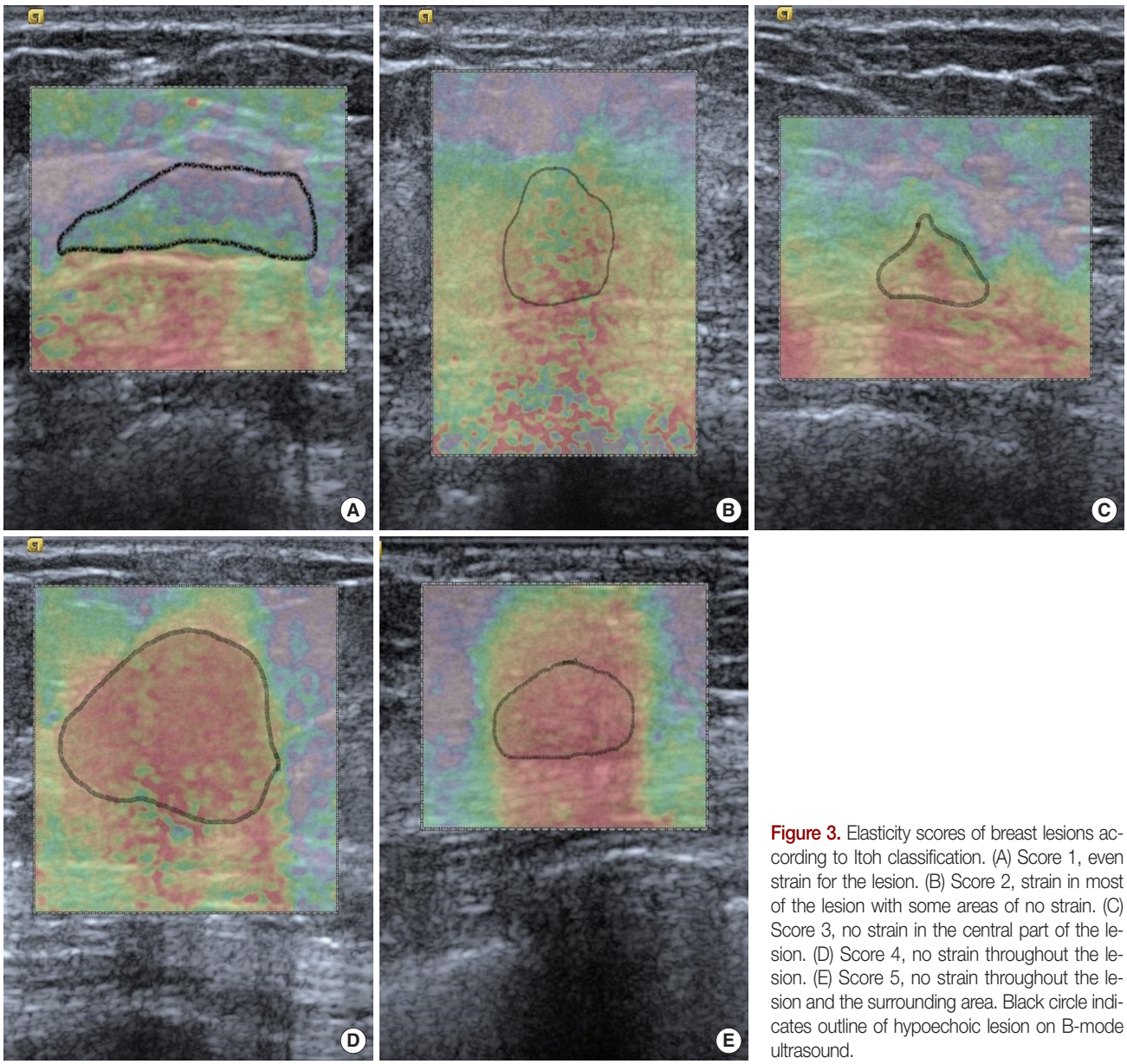


**Figure 3.** Elasticity scores of breast lesions according to Itoh classification. (A) Score 1, even strain for the lesion. (B) Score 2, strain in most of the lesion with some areas of no strain. (C) Score 3, no strain in the central part of the lesion. (D) Score 4, no strain throughout the lesion. (E) Score 5, no strain throughout the lesion and the surrounding area. Black circle indicates outline of hypoechoic lesion on B-mode ultrasound.

### ARFI elastography and SR for breast lesions

Distributions of elasticity scores according to pathologic diagnosis when ARFI elastography was displayed in VTI mode are shown in Table 2. The mean elasticity score was significantly higher for malignant lesions (3.7 ± 1.0) than for benign lesions (1.6 ± 0.8). Of the 40 malignant lesions, 31 (77.5%) lesions had elasticity scores between 3 and 5. In this group, nine lesions (22.5%) had a score of 1 or 2. Of the 117 benign lesions, 109 (93.2%) had scores of 1 or 2. None of the lesions in this group had a score of 5; four of the 19 lesions (21.1%) with scores of 4 were benign. Eight of the 12 lesions (66.7%) with scores of 3 and eight of the 50 lesions (16.0%) with scores of 2 were malignant. There was a high correlation between elasticity score and malignancy ($p < 0.01$). The optimal elasticity score cutoff point in this study was between 2 and 3, as this score showed the maximal sum of sensitivity and specificity (Table 3).

In VTQ mode, the mean SWV value of benign lesions (2.22 ± 0.88 m/sec) was lower than that of malignant lesions (4.23 ± 1.09 m/sec, $p < 0.01$). The SWV cutoff point for malignant lesions was estimated as 3.42 m/sec. In four cases of malignant lesions, the SWV was reported as "X.XX."

The mean SR value of benign lesions (2.69 ± 1.40) was significantly lower than that of malignant lesions (5.69 ± 1.63, $p <$

**Table 1.** Pathologic diagnoses of the examined malignant and benign breast lesions

| Pathologic diagnosis | No. of lesions (%) |
|---|---|
| Malignant (n=40) | |
| Invasive ductal carcinoma | 36 (90.0) |
| Invasive papillary carcinoma | 3 (7.5) |
| Invasive lobular carcinoma | 1 (2.5) |
| Benign (n=117) | |
| Fibrocystic change | 57 (48.7) |
| Fibroadenoma | 41 (35.1) |
| Intraductal papilloma | 6 (5.1) |
| Radial scar | 6 (5.1) |
| Sclerosing adenosis | 3 (2.6) |
| Atypical ductal hyperplasia | 2 (1.7) |
| Atypical lobular hyperplasia | 2 (1.7) |

**Table 2.** The distributions of elasticity scores according to pathologic diagnosis

| | Malignant No. (%) | Benign No. (%) | *p*-value |
|---|---|---|---|
| Elasticity score | | | <0.01 |
| 1 | 1 (2.5) | 67 (57.3) | |
| 2 | 8 (20.0) | 42 (35.9) | |
| 3 | 8 (20.0) | 4 (3.4) | |
| 4 | 15 (37.5) | 4 (3.4) | |
| 5 | 8 (20.0) | 0 | |
| Total | 40 (100.0) | 117 (100.0) | |

**Table 3.** Sensitivity and specificity of acoustic radiation force impulse elastography at various cutoff points for the diagnosis of benign and malignant lesions

| Cutoff point (elasticity score) | Sensitivity* No. (%) | Specificity† No. (%) |
|---|---|---|
| Between 1 and 2 | 39 (97.5) | 67 (57.3) |
| Between 2 and 3 | 31 (77.5) | 109 (93.2) |
| Between 3 and 4 | 23 (57.5) | 113 (96.6) |
| Between 4 and 5 | 8 (20.0) | 117 (100.0) |

Based on *40 malignant and †117 benign lesions confirmed by pathologic examination.

0.01). The SR cutoff point for malignancy was estimated as 3.52.

### Diagnostic performance of BUS alone and a combination of BUS, ARFI elastography, and SR evaluations for breast lesions

Table 4 shows the number of breast lesions in each BI-RADS and modified BI-RADS category. A BI-RADS score of 4 was adjusted to give a modified BI-RADS score of 3 for 34 lesions, and 12 cases were recategorized as a modified BI-RADS score of 5. Six lesions with BI-RADS scores of 5 were shifted to modified BI-RADS scores of 4. A BI-RADS score of 3 was changed to a modified BI-RADS score of 4 in 1 case, and 1 other case was recategorized as a modified BI-RADS score of 5.

**Table 4.** Breast Imaging-Reporting and Data System (BI-RADS) and modified BI-RADS categories for breast lesions

| Category | No. (%) |
|---|---|
| BI-RADS | |
| 3 | 74 (47.1) |
| 4 | 75 (47.7) |
| 5 | 8 (5.1) |
| Modified BI-RADS* | |
| 3 | 108 (68.8) |
| 4 | 34 (21.6) |
| 5 | 15 (9.6) |

*BI-RADS+α+β (α and β are the scores that are associated with the cutoff values of acoustic radiation force impulse elastography and strain ratio, respectively).

**Table 5.** B-mode ultrasound (BUS) alone and the combination of BUS, acoustic radiation force impulse elastography and strain ratio for differentiating breast lesions

| | Malignant | Benign | Total | *p*-value |
|---|---|---|---|---|
| BUS | | | | |
| Malignant* | 39 | 44 | 83 | <0.01 |
| Benign | 1 | 73 | 74 | |
| Combination of BUS, ARFI elastography and SR | | | | |
| Malignant† | 39 | 10 | 49 | <0.01 |
| Benign | 1 | 107 | 108 | |
| Total | 40 | 117 | 157 | |

Data are presented as number of patients.
ARFI=acoustic radiation force impulse; SR=strain ratio.
*Breast Imaging-Reporting and Data System (BI-RADS) ≥4; †Modified BI-RADS (i.e., BI-RADS+α+β, α and β are the scores that are associated with the cutoff values of ARFI elastography and strain ratio, respectively) ≥4.

**Table 6.** Diagnostic performance of B-mode ultrasound (BUS) alone and the combination of BUS, acoustic radiation force impulse elastography and strain ratio in the differentiation of breast lesions

| | BUS | Combination of BUS, ARFI elastography and SR | *p*-value |
|---|---|---|---|
| % Sensitivity | 97.5 (39/40) | 97.5 (39/40) | 1.00 |
| % Specificity | 62.4 (73/117) | 91.5 (107/117) | <0.01 |
| % Accuracy | 71.3 (112/157) | 93.0 (146/157) | <0.01 |
| % PPV | 47.0 (39/83) | 79.6 (39/49) | <0.01 |
| % NPV | 98.6 (73/74) | 99.1 (107/108) | 1.00 |

ARFI=acoustic radiation force impulse; SR=strain ratio; PPV=positive predictive value; NPV=negative predictive value.

The diagnostic performance of BUS alone and the combination of BUS, ARFI elastography, and SR for differentiating breast lesions are shown in Tables 5 and 6. When both the BI-RADS and modified BI-RADS scores were higher than 4, a diagnosis of malignancy was made. Using this value, BUS showed 97.5% sensitivity, 62.4% specificity, 71.3% accuracy, a 47.0% PPV, and a 98.6% NPV for malignant lesions. In the same way, BUS combined with ARFI elastography and SR


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presented 97.5% sensitivity, 92.3% specificity, 93.6% accuracy, a 79.6% PPV, and a 99.1% NPV for differentiating breast lesions. The specificity, accuracy, and PPV of BUS combined with ARFI elastography and SR were higher than those of BUS alone. Moreover, this result showed statistical significance between each of the methods ($p < 0.01$ for each).

## DISCUSSION

In this study, we investigated the qualitative and quantitative elasticity values of various breast lesions using ARFI elastography and SR. Additionally, we conducted a comparative efficacy analysis of BUS alone versus a combination of BUS, ARFI elastography, and SR evaluations. In VTI mode, the optimal elasticity score cutoff point in this study was between 2 and 3, as this score showed the maximal sum of sensitivity and specificity. With this value, we found that the mean elasticity score was significantly higher in malignant masses than in benign masses. Our findings are concordant with other previous studies using 5-point scoring systems [10,23,25]. In VTQ mode, each breast lesion was differentiated as a benign or malignant lesion using SWV measurements; malignant lesions showed significantly higher SWV values than benign lesions. This result is also consistent with other previous reports [3,11,13]. In our study, the values for 10% (4 of 40) of the breast lesions were expressed as "X.XX." Some reasons accounting for the "X.XX" values are as follows. Some investigators suggest that heterogeneous tissues substantially absorb ultrasonographic energy. It is also possible that the refraction of pulses entering at oblique angles to interfaces between structures differing in sound velocity may have affected the measurement results [13,26]. However, in the present study, "X.XX" values were only encountered in malignant lesions. Therefore, it seems that an "X.XX" value could be an indicator of malignancy.

We also investigated SRs for evaluating breast lesions. In some studies, the average SR of malignant lesions was higher than that of benign lesions [19,22]. Likewise, in the present study, we also showed that the SRs of malignant lesions were significantly greater than those of benign lesions. Therefore, we found that the cutoff values for ARFI elastography and SR could be used to modify the BI-RADS score.

Our study demonstrated that qualitative and quantitative elasticity is clinically relevant. The modified BI-RADS scores improved BUS specificity, accuracy, and PPV, with no statistical differences observed in test sensitivity or NPV in the differentiation of benign and malignant breast lesions. This result may mean that a combination of BUS, ARFI elastography, and SR could assist in the decision-making process regarding possible invasive procedures, such as biopsy.

This study has some limitations. Firstly, BUS, ARFI elastography, and SR evaluations were performed by only one operator. This limitation could result in operator-related selection bias. However, the sonographer carefully established a standard of reference based on the characteristic imaging findings of breast tumors. Secondly, almost all the malignant lesions included in our study were invasive ductal carcinoma, with only three cases of invasive papillary carcinoma and one case of invasive lobular carcinoma. The elasticity value according to histological differentiation is known to influence diagnostic performance [18,26]. Therefore, additional studies including a greater variety of breast tumors in a larger cohort will be needed. Thirdly, the diagnosis of 27 of the 117 benign breast lesions (23.1%) was based on a core needle biopsy. As this method is reported to have a false negative rate of about 3%, the results of this study may have been affected [27,28]. Lastly, an analysis of other confounding factors was not performed. Lesion depth, breast thickness, tumor size, histological grade, lymph node involvement, vascular invasion, age, and fatty tissue are related to mean stiffness values [29,30]. Thus, additional studies may be required to determine the correlations between elasticity values and other factors.

In conclusion, ARFI elastography and SR evaluations showed significantly different mean values for benign and malignant lesions. The combination of BUS, ARFI elastography, and SR could increase the diagnostic performance of BUS. Therefore, ARFI elastography and SR evaluations can be used as complementary modalities to make more accurate breast lesion diagnoses.

## CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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