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Differentiation of benign and malignant breast lesions using shear wave elastography; estimation of the most accurate parameters

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ABSTRACT

Aim. Breast elastography is a sonographic imaging technique, used additionally in diagnosis of breast lesions. The place of shear-wave elastography (SWE) in breast imaging is still unclear, the literature is limited and the interpretation of SWE results is undefined. The aim of our study was to evaluate the diagnostic accuracy of SWE in relation to histopathology and to estimate the probable cut-off value of SWE parameters, which would indicate malignancy.

Material and methods. The study included 53 consecutive patients with suspicious breast lesions. Each patient underwent the SWE of the breasts, and every visualized lesion was biopsied.

Results. 56 lesions were found; 24 of them were classified as malignant and then confirmed as cancer. Malignant tumours presented with significantly higher SWE parameters, except elasticity value of fat tissue surrounding the lesion (Efat), as compared to benign lesions. The optimal cut-off point was determined using the Youden Index. The receiver-operating characteristic curve (ROC) curve analysis established cut-off val-

ues of: Emax 63.4 kPa (p < 0,000001, AUC 0.94), Emean of 40.8 kPa (p = 0.000003, AUC 0.87), Emax/Efat ratio of 5.64 kPa (p < 0.000001, AUC 0.92) and Emean/Efat ratio of 4.31 kPa, (p = 0.000006, AUC 0.86), which indicate malignancy. The sensitivity and specificity were 100% and 87.5% respectively for Emax and 100% and 75% for Emean. There were no differences in SWE parameters between cancer subtypes.
Conclusions. In our study SWE indicated correctly all malignant lesions. Moreover, we established cut-off values of SWE parameters that may be useful in differentiating malignant and benign breast lesions.

Introduction

Breast elastography is a technique that has been recently used more frequently as an additional tool in the diagnosis of breast lesions. Elastography allows for the measurement of the lesion's elasticity and comparison of its stiffness to the surrounding tissue. Malignant lesions are usually stiffer than normal breast tissue, therefore elastography may potentially increase the specificity of B-mode ultrasonography (US) [1]. There are two main methods used to measure tissue stiffness: strain elastography (SE) and shear-wave elastography (SWE). SE is based on manual compression and provides a qualitative tissue elasticity assessment via color display analysis (for example, using the Tsukuba Score) [2]. SWE, on the other hand, uses acoustic waves emitted from the transducer and propagated throughout the tissue. SWE provides not only a qualitative analysis by means of color display but also a quantitative measurement of tissue elasticity in kilopascals [kPa] or wave propagation speed in meters per second [m/s] [2].

B-mode US, while highly sensitive with a sensitivity rate of up to 95%, suffers from a low specificity range of 13–81%. This high sensitivity indicates that B-mode US is effective in detecting abnormalities, but its low specificity results in a high rate of false positives, leading to unnecessary biopsies and anxiety for patients. A meta-analysis conducted by Park et al. revealed that incorporating SWE into the diagnostic process could enhance US specificity by 28% while causing only a minor decrease in sensitivity (between 1 to 5%) [3]. Other studies have also highlighted the ability of SWE to improve the specificity and overall diagnostic accuracy of US [4–6].

As a supplementary tool to B-mode US, elastography can assist in determining which lesions warrant a biopsy. Given that SWE is a more objective and reproducible method compared to SE, it holds promise for reducing the number of unnecessary biopsies [3,7,8]. This reduction in redundant procedures is beneficial not only for patient comfort and mental well-being but also for the efficiency and cost-effectiveness of healthcare systems.

Despite its potential, the role of SWE in breast imaging remains unclear, and the current literature is limited. No standardized cut-off values for kPa have been established for different breast lesions, leading to ambiguity in the interpretation of SWE results. This lack of clarity underscores the need for further research to refine the diagnostic parameters and establish robust guidelines for SWE application in breast imaging.

Aim

The aim of our study was to evaluate the diagnostic accuracy of SWE in breast lesions in relation to histopathology and to estimate the probable cut-off value of SWE parameters indicating malignancy. By doing so, we hope to contribute to the growing body of evidence supporting the clinical utility of SWE and to provide insights that could lead to more precise and reliable diagnostic protocols.

Materials and methods

Patients

This prospective study was approved by the local Bioethical Committee, and the requirement for informed written consent was necessary. Patients involved in the study were invited to participate after being recalled from the breast cancer screening programme. As recommended by the guidelines, patients with BIRADS (Breast Imaging Reporting and Data System) score 0 or ≥ 4 were recalled from screening [9, 10]. Addi-

tionally, patients referred to our institution due to palpable breast tumours were included as well.

Specific exclusion criteria were applied to ensure the accuracy and relevance of findings. Patients with a history of breast cancer or prior breast surgery were excluded from the study, as these factors could potentially affect the elasticity measurements of breast tissue. Additionally, the study did not include patients who did not provide consent.

Upon agreeing to participate, each patient underwent a comprehensive evaluation that included both ultrasonography and shear-wave elastography.

Methods

All the examinations were performed between April 2021 and May 2022 by an experienced radiologist using a Canon Aplio i600 ultrasound system. The imaging protocol included capturing multiple measurements of each lesion to ensure accuracy and reliability. All lesions identified during the imaging sessions were histopathologically verified either by a US-guided core-needle biopsy or a US-guided vacuum-assisted biopsy. The choice between core-needle and vacuum-assisted biopsy was based on the lesion's characteristics, size, and location. Core-needle biopsies involve the use of a hollow needle to extract tissue samples from the lesion, while vacuum-assisted biopsies employ a vacuum-powered instrument to collect larger tissue samples, which can be particularly useful for small or complex lesions.

The histopathological results of the biopsies were classified according to the B code classification system, as established by the UK National Coordinating Committee for Breast Screening Pathology (NCCBSP). This classification system categorizes biopsy results into several categories (B1 to B5), ranging from normal tissue (B1) to malignant lesions (B5). This standardized approach ensured a consistent and accurate interpretation of the biopsy results across all cases [11].

Following the biopsy, the cancer lesions were further analyzed based on their immunohistochemistry results. This analysis included the assessment of estrogen receptor (ER) and progesterone receptor (PR) expression levels, HER2 status, and Ki67 proliferation index. ER and PR expression levels were categorized as increased if more than 1% of the tumor cells were positive and decreased if 1% or fewer cells were positive. HER2 status was determined using immunohistochemical staining and/or fluorescence in situ hybridization (FISH), with results classified as positive or negative based on established guidelines. The Ki67 index, which indicates the proportion of tumor cells undergoing mitosis, was also recorded as part of the tumor characterization process.

US and SWE examinations

Examinations were performed using a Canon Aplio i600 device (Canon Medical Systems Europe B.V., The Netherlands) with a PLT-1005-BT linear probe (frequency range of 5–14 MHz). All lesions were examined using B-mode US, followed by SWE.

The SWE parameters obtained were maximum elasticity value (Emax), mean elasticity value (Emean), elasticity value of fat tissue surrounding the lesion (Efat), the Emax/Efat and Emean/Efat ratios. Emax value was obtained by placing a circular, 2–3 mm wide region of interest (ROI) on the stiffest area of the lesion. Emean value was obtained by drawing a free-hand ROI following the margins of the entire lesion. Efat value was obtained by placing a circular ROI on the fat lobule near the lesion. The device's software calculated the ratios.

A radiologist with 15 years of experience in breast imaging, including an 8-month training period in SWE examinations prior to the study, performed all examinations.

By employing a rigorous methodology and thorough analysis, our study aimed to provide a comprehensive evaluation of SWE's diagnostic accuracy in breast lesion assessment and contribute to the development of standardized guidelines for its use in clinical settings.

Statistical analysis

The calculations were made using Statistica 13 by TIBCO and PQStat by PQStat Software. The level of significance was $\alpha = 0.05$. The result was considered statistically significant when $p<\alpha$. The normality of the distribution of variables was tested with the Shapiro-Wilk test. Quantitative variables were compared in two groups using the Student's t-test (for a normal distribution of a variable in the groups under analysis) or the

Mann-Whitney's test (for a variable with non-normal distribution). Associations between continuous variables were evaluated using Spearman's rank correlation coefficient (R). Receiver-operating characteristic curve (ROC) analysis was performed to determine the optimal cut-off point. The optimal cut-off point was determined using the Youden Index. Sensitivity and specificity were determined for such a point. The determined areas under the curve were compared with each other using the Z statistics.

The area under the curves (AUC) with 95% confidence intervals was determined. The non-parametric DeLong method was used for this.

Results

53 consecutive patients with suspicious breast lesions were included in the study. Each patient underwent the SWE of the breasts, and every visualized lesion was biopsied.

56 lesions were found, 32 of them were classified as B2 (benign) and 24 as B4 (suspicion of malignancy). Finally, all 24 suspicious tumors were histopathologically confirmed as cancer. The average age of the patients was 60.2 years, and the average lesion size was 11.4 mm.

Benign vs malignant comparison

The comparison of SWE results of benign and cancer lesions is presented in **Table 1**. Malignant tumors presented with significantly higher Emax, Emean, Emax/Efat ratio and Emean/Efat ratio than benign lesions. There were no statistical differences in lesion size and Efat between groups.

Cut-off value

Based on the ROC curve analysis, cut-off values of different SWE parameters for differential

Table 1. Comparison of SWE parameters between benign and malignant lesions. Values are presented as median (standard deviation).

	Benign	Malignant	P value
Number Of Lesions	32	24	>0.05
Average Lesion Size [Mm]	10.19 (4.19)	12.96 (8.74)	>0.05
Emax [Kpa]	39.94 (27.65)	101.49 (25.17)	0.00001
Efat [Kpa]	10.18 (6.26)	10.40 (4.30)	>0.05
Emax/Efat Ratio [Kpa]	4.45 (2.44)	11.08 (4.86)	0.00001
Emean [Kpa]	36.2 (26.25)	71.64 (20.70)	0.00001
Emean/Efat Ratio [Kpa]	4.00 (2.39)	7.63 (2.91)	0.00001

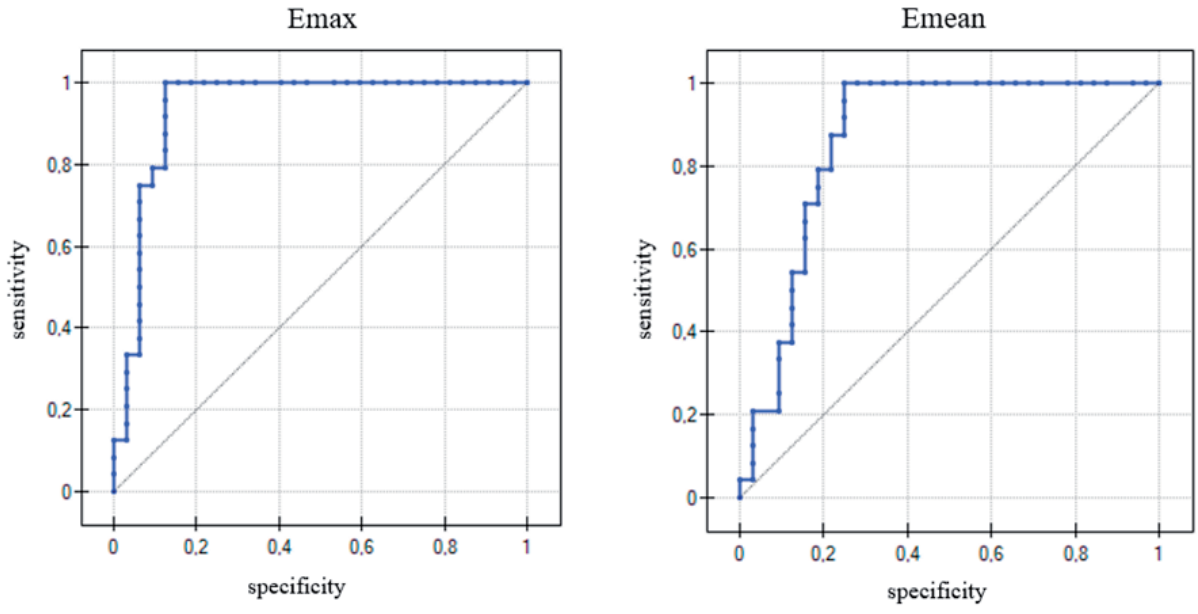

Figure 1. The ROC curve analysis estimated cut-off values of Emax and Emean for differential diagnosis of benign and malignant lesions.

diagnosis of benign and malignant lesions were established. The Emax cut-off value was 63.4 kPa (p < 0,000001), with AUC 0.94; the sensitivity and specificity were 100% and 87.5% respectively. The Emean cut-off value level was 40.8 kPa (p = 0.000003), with an AUC of 0.87, a sensitivity of 100% and a specificity of 75% (see **Figure 1**). The Emax/Efat ratio level was 5.64 kPa (p < 0.000001), with an AUC of 0.92, a sensitivity of 95.8% and a specificity of 65.6%. The Emean/Efat ratio level was 4.31 kPa, (p = 0.000006), with AUC 0.86, a sensitivity of 100% and a specificity of 68.8%.

Malignant lesions analysis

Malignant lesions were divided and evaluated depending on ER and PR expression, as well as HER2 status. There were 19 lesions with increased ER and 5 with decreased ER expression. The statistical analysis indicated no significant differences between groups in the Emax, Emean, Emax/Efat ratio and Emean/Efat ratio. Likewise, in the context of PR expression (17 lesions with increased and 7 with decreased PR expression) there were no significant differences in Emax, Emean, Emax/Efat ratio and Emean/Efat ratio. There were 19 HER2-positive cancer lesions and 5 HER2-negative lesions, and the statistical analysis indicated no significant differences in Emax, Emean, Emax/Efat ratio and Emean/Efat ratio between groups. What is more, the Ki67 level did not affect SWE results either (there was no significant correlation between Ki67 level and either Emax, Emean, Emax/Efat ratio and Emean/Efat ratio level (p > 0.05)). Adequate data are presented in **Table 2**.

Discussion

In our study, the SWE parameters directly related to the lesion's stiffness (Emax, Emean, Emax/Efat, and Emean/Efat ratios) had significantly higher mean values in malignant lesions compared to benign ones. Conversely, there was no significant difference in Efat mean values for both benign and malignant findings (see **Table 1**). This indicates that while lesion stiffness is a key differentiator between benign and malignant lesions, the surrounding fat tissue stiffness (Efat) does not significantly vary between these categories.

As a result of the ROC curve analysis, we established cut-off values for two main SWE parameters: Emax at 63.4 kPa and Emean at 40.8 kPa (see **Figure 1**). These results differ from those stated in the literature, likely due to differences in the devices used. For example, Song et al. reported Emax and Emean cut-off values of 145.7 kPa and 89.1 kPa, respectively, using the Aixplorer (Hologic) system [12]. Similarly, Au et al., using the same system, estimated cut-off values of 46.7 kPa for Emax and 42.5 kPa for Emean [13]. Kim et al., working with a Toshiba device, established values of 50.85 kPa and 42.08 kPa for Emax and Emean, respectively [14].

In Aixplorer systems, the SWE parameters such as maximum elasticity, mean elasticity, and elasticity ratio are automatically calculated by the device's software after measuring the stiffest part of a lesion [13]. However, in Canon and Toshiba systems, the measurement process differs. We obtained Emax by placing a circular ROI on the stiffest part of a lesion and Emean by

Table 2. Comparison of SWE parameters between different malignant lesions subtypes. Values are presented as median (standard deviation). No significant differences were found (p > 0.05).

	ER+	ER-	PR+	PR-	HER2+	HER2-
Emax [Kpa]	98.28 (24.37)	116.63 (30.36)	97.35 (24.80)	113.15 (26.89)	114.20 (33.04)	98.79 (24.15)
Emean [Kpa]	70.48 (21.60)	82.98 (11.22)	69.65 (22.51)	81.15 (10.94)	76.86 (12.32)	71.76 (22.05)
Ratio Emax/Efat [Kpa]	10.88 (4.32)	12.24 (8.16)	10.85 (4.57)	11.88 (6.38)	13.47 (7.45)	10.62 (4.40)
Ratio Emean/Efat [Kpa]	7.68 (3.02)	8.06 (2.69)	7.61 (3.18)	8.13 (2.21)	8.62 (2.32)	7.56 (3.04)

drawing a free-hand ROI along the lesion margins. Efat was measured by placing a circular ROI on a fat lobule surrounding the examined lesion (see **Figure 2**). The standard deviations of each parameter as well as the Emax/Efat and Emean/Efat ratios were automatically calculated by our device's software. These technical differences in measurement processes between US systems could account for the different results observed.

In our clinical experience, Emax proved to be the most accurate parameter for differentiating benign and malignant lesions. The nature of obtaining Emean measurements, which requires a free-hand drawn ROI, makes it a problematic parameter for routine use. Malignant lesions often have irregular margins, complicating the drawing of the Emean ROI and making the process time-consuming. Emax, in contrast, is relatively easier and faster to obtain while maintaining good predictive value for distinguishing between malignant and benign lesions [12, 14].

We also analyzed cancer lesions and evaluated the correlation between SWE parameters and immunohistochemistry characteristics. No correlation was found between ER and PR expression and SWE variables. Furthermore, HER2 status and Ki67 levels had no significant effect on any of the examined SWE measurements (see **Table 2**). In contrast to our findings, Chang et al. reported that more aggressive types of breast cancer (e.g., tri-ple-negative) and tumours with higher histological grades exhibited higher mean stiffness [15]. Kim et al. found that PR-negative tumours had higher Emax values and that the Emax/Efat ratio was higher in tumours with Ki-67 ≥ 14% [14]. However, some researchers found no significant correlation between SWE parameters and immunohistochemistry characteristics in breast cancer tumours, as well as in breast cancer axillary metastases [16, 17, 18]. The conflicting results from different studies highlight the need for more research on the correlation between SWE parameters and breast cancer immunohistochemistry characteristics.

As previously mentioned, obtaining SWE measurements varies between different US systems.

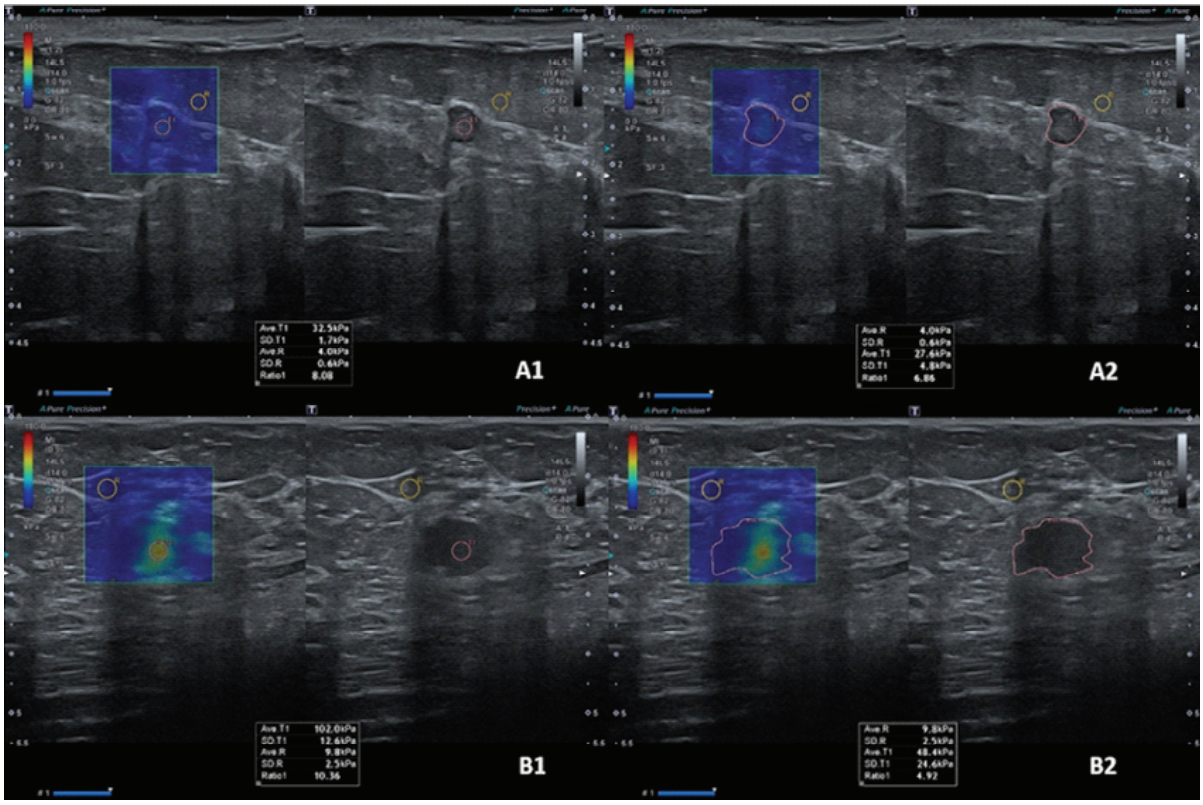

Figure 2. Comparison of benign and malignant lesions in SWE. Lesion A presented with Emax of 32.5 kPa (A1), Emean of 27.6 (A2) and Efat of 4 kPa. It was later biopsied and histopathologically verified as breast papilloma. Lesion B presented with Emax of 102 kPa (B1), Emean of 48.4 kPa (B2) and Efat of 9.8 kPa. The lesion was biopsied and histopathologically verified as intermediate-grade ductal carcinoma in situ.

To our best knowledge, there are significantly fewer studies using Can-on/Toshiba devices compared to Aixplorer systems. As the use of SWE increases, there is a growing need for universal guidelines for SWE interpretation, regardless of the US system manufacturer. If establishing strict cut-off values proves infeasible, proposing universal interpretation principles, such as the proportion of lesion's Emax to Efat, could be beneficial.

It is well known that SWE presents certain limitations. Lesions located too close to the skin or chest wall often display incorrect wave propagation, resulting in false-positive SWE results [19]. Such outcomes could be due to precompression occurring during SWE examinations of lesions in these areas [20, 21]. The distribution of lesion depths using descriptors proposed by Stavros is presented in Figure 3 [22]. The influence of location on SWE results can be seen in **Figure 3**, comparing wave propagation in two papillomas located at different depths of breast tissue. This aspect limits the possible clinical application of SWE based on lesion location. What is more, some malignant lesions exhibited stiffness exceeding the maximum kPa values of our US system. Expanding the maximum range of kPa in US systems could help overcome this limitation. We also found that in malignant lesions surrounded by significant edema, wave propagation was incorrect.

Feldman et al. demonstrated on Aixplorer system that malignant lesions were more heterogeneous on SWE stiffness maps, exhibiting higher stiffness and ratio values compared to benign lesions [23]. However existing literature indicates that invasive ductal or lobular carcinomas, as well as mucinous or intraductal carcinomas, can sometimes present as false-negative cases in SWE imaging [24]. However, numerous studies have highlighted that both qualitative and quantitative parameters obtained using SWE show significant differences between benign and malignant breast lesions [24–28]. Jiang et al. proved that the benign lesion group had significantly lower SWE parameters, and the diagnostic value

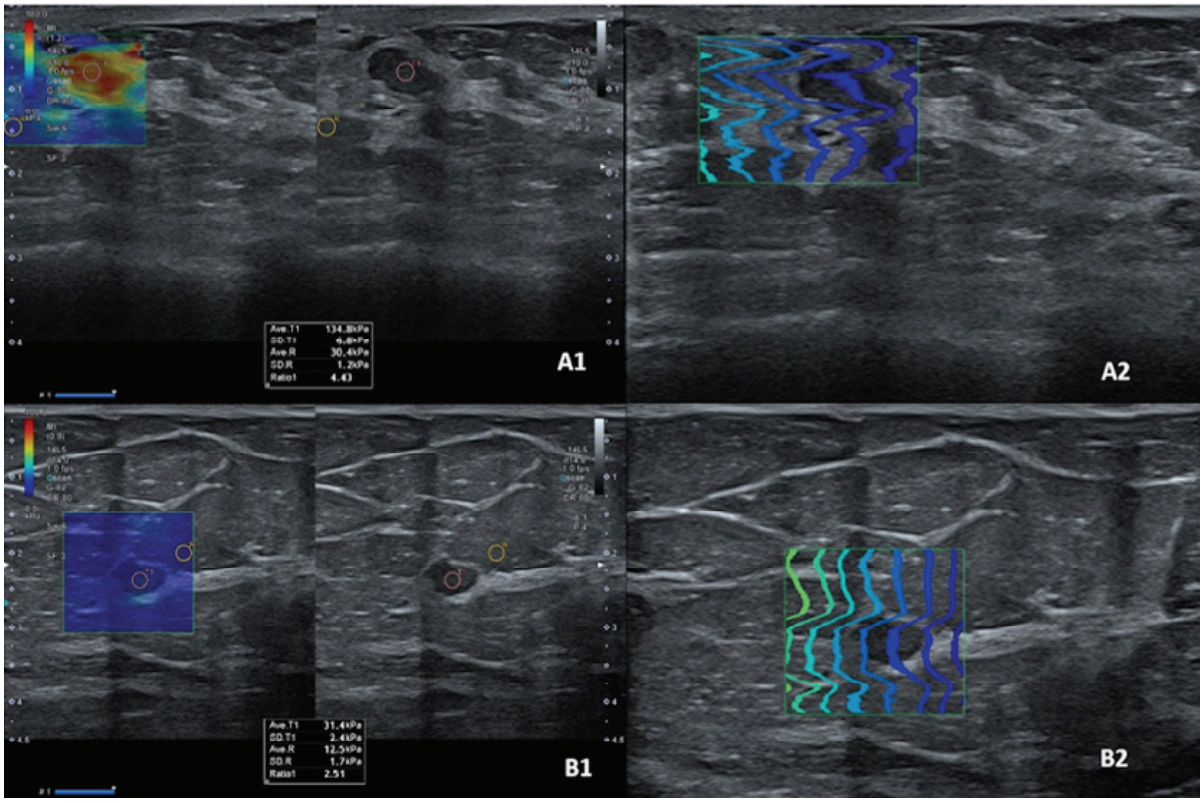

Figure 3. Comparison of wave propagation in papillomas located on different depths. Lesion A was located near the skin, which resulted in falsely increased SWE parameters (Emax of 134.8 kPa; A1), due to incorrect wave propagation (A2). Lesion B was located in the middle depth of the breast, which resulted in accurate SWE parameters (Emax of 31.4 kPa; B1) and correct wave propagation (B2).

of SWE in combination with string elastography exceeded SWE alone [29]. When SWE is incorporated into the BI-RADS 4a and 4b lesions assessment, it significantly increases the ultrasound's specificity without a corresponding sensitivity loss [30]. This enhancement in diagnostic accuracy suggests that SWE could play a crucial role in patient management by reducing the number of unnecessary biopsies, thereby sparing patients from invasive procedures and reducing healthcare costs. Such advancements underscore the potential of SWE to refine breast cancer screening and diagnosis, ultimately improving patient outcomes.

Screening is widely regarded as one of the most successful approaches to reducing breast cancer mortality in average-risk women and is recommended by the World Health Organization (WHO) [31]. However, breast density presents a significant challenge in breast cancer screening. Breast density is an independent risk factor for the development of breast cancer and also decreases the sensitivity of mammography, leading to potential underdiagnosis. This issue is particularly pronounced in women with extremely dense breast tissue, where the dense tissue can mask tumours, making it harder to detect cancer early [32]. As a result, there is an urgent need to establish more specific and sensitive imaging modalities that can improve the early detection of breast cancer in these patients, thereby decreasing the number of late-diagnosed cases.

By incorporating SWE into the screening process, particularly for women with dense breast tissue, clinicians can potentially improve the specificity and sensitivity of breast cancer screening. This could lead to earlier detection and treatment of breast cancer, reducing the mortality rate associated with the disease. Furthermore, the enhanced diagnostic accuracy provided by SWE can help reduce the number of unnecessary biopsies, which are often performed due to the lower specificity of traditional imaging techniques in dense breasts.

Our study has several limitations. It is a single-center study with a relatively small number of patients. All the examinations were performed by one radiologist, even if we take into account that SWE is considered to be highly reproducible. A multi-center study with a larger sample size is warranted to confirm our findings. As stated above, SWE measurements vary between different US systems. Therefore, a study comparing different methods of obtaining SWE measurements could be beneficial in establishing universal cut-off values. Additionally, including a more diverse patient population could help generalise the findings to a broader clinical context. These future studies could provide more definitive evidence and potentially lead to standardized SWE guidelines for breast lesion assessment.

Perspectives

Our study demonstrated the excellent performance of shear-wave elastography (SWE) in correctly characterizing breast lesions as benign or malignant. Through meticulous analysis, we established cut-off values for maximum elasticity (Emax) and mean elasticity (Emean) that effectively facilitate the differentiation of benign from malignant breast lesions.

Moreover, our data suggest that Emax is superior to Emean in everyday clinical practice. The superior performance of Emax not only simplifies the diagnostic workflow but also enhances the accuracy of SWE, thereby potentially reducing the number of unnecessary biopsies. SWE can improve patient comfort and reduce healthcare costs by providing a more precise and less invasive diagnostic tool.

In summary, our findings highlight the significant role of SWE in breast cancer diagnosis. The cut-off values established in our study provide a practical and reliable tool for clinicians, supporting the integration of SWE into routine clinical practice. Further multi-centre studies with larger sample sizes are recommended to validate our results and refine the diagnostic criteria for SWE. As SWE technology evolves, its application could lead to more accurate, non-invasive breast cancer diagnostics, ultimately improving patient outcomes and streamlining clinical workflows.

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Authors' contributions
All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Antonina Godlewska, Natalia Andryszak and Anna Pasiuk-Czpeczynska. The first draft of the manuscript was written by Antonina

Godlewska and Natalia Andryszak, all authors commented on previous versions of the manuscript. The final draft of the manuscript, the supervision, review and editing: Dariusz Godlewski, Marek Ruchała, Rafał Czepczyński. All authors read and approved the final manuscript.

Conflict of interest statement
The authors declare no conflict of interest.

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