

PRELIMINARY ASSESSMENT OF SHEARWAVE™ ELASTOGRAPHY FEATURES IN PREDICTING BREAST LESION MALIGNANCY

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Background: Shear wave elastography (SWE) provides a quantitative measurement of tissue stiffness with high spatial resolution and may improve characterization of breast masses.

Aims: To evaluate the reproducibility of SWE and impact of adding SWE¹ features to the BI-RADS® classification of breast masses from the first 1000 cases in a prospective multicenter trial.

Methods: SWE studies were performed on a on a prototype of the Aixplorer system (Supersonic Imagine, Aix-en-Provence, France). A subset of 192 breast lesions (42.71% malignant) was analyzed. Reproducibility of SWE images and measurements was assessed; logistic regression analysis was performed to predict the pathology findings. SWE features were added to the ultrasound BI-RADS to generate models that were challenged by comparing the areas under the ROC curves (A_z), and the sensitivity and specificity scores.

Results: In the preliminary analysis, intra-operator reproducibility of SWE size ($R \geq 0.93$) and mean elasticity ($R=0.88$) measurements were in near-perfect agreement. Using the best three-variable model (BIRADS + elasticity shape + maximum elasticity), the A_z increased from 0.77 to 0.93 specificity increased from 61.8% to 87.3%, although sensitivity decreased from 92.7% to 87.8%. Adding more variables did not effect further improvements.

Conclusions: In this ongoing study, SWE provided reproducible information (elasticity values and SWE mapping) that improved the characterization of breast lesions. These features are directly linked to the characteristics of SWE: local quantification and millimeter resolution. Further evaluation of the study is in progress.

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References: 1 Tanter M, Bercoff J, Athanasiou A, Deffieux T, Gennisson JL, Montaldo G, Muller M, Tardivon A and Fink M, Quantitative assessment of breast lesion viscoelasticity: initial clinical results using supersonic shear imaging. *Ultrasound Med Biol*, 2008. 34(9): p. 1373-86.

Figure: This suspicious lesion was classified as BI-RADS 4B on B-mode but SWE showed low kPa values (around 50kPa) so was reclassified as BI-RADS 3. Biopsy showed fibrocystic change only.

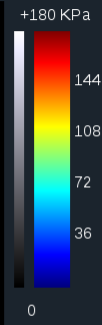
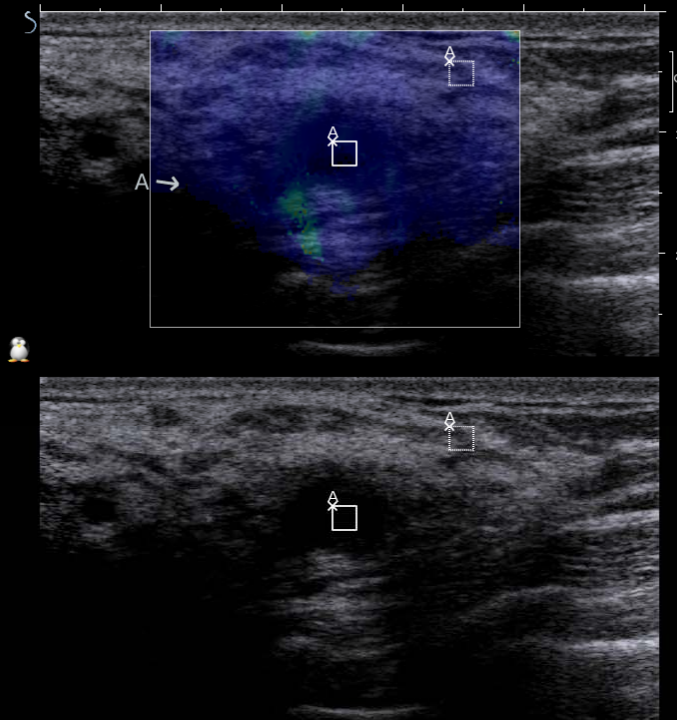
MEASURES [X]

Lesion A

NEXT

Mean (Kpa)	=	11.4 - 9.9
Max (Kpa)	=	51.5 - 12.7
Min (Kpa)	=	0.0 - 7.8
Stddev (Kpa)	=	11.0 - 1.0
Ratio	=	1.2
Mean	=	0 - 64
Max	=	0 - 146
Min	=	0 - 0
Stddev	=	0 - 27
Ratio	=	0.0

8/8 NEXT



Investigational Use Only – Not for Diagnosis

FPS : 6.7 -- Arbitration : qbox -- max echo id : 27/1506, ssix : 0 -- filter deactivated new persistence 0.547686

