Opto-Acoustic Nomograms for Improving Breast Cancer Diagnosis
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BACKGROUND
Imagio® (Sono Medical Instruments, Inc.) is currently an investigational medical device being tested in a Phase I Study for FDA approval. Imagio is a fusion of real-time 2D ultrasound imaging with a novel opto-acoustic 3D imaging in a fusion of real-time vs. registered ultrasound and gray-scale contrast. It shows high functional and morphological data in a single 3D image. The advantage of this novel technology is the ability to detect and analyze 3D breast masses.

OBJECTIVES
Diagnostic specificity remains disappointing low for breast imaging modalities that are approved to address non-viable cancer. Opto-acoustic (OA) imaging is an emerging tool that provides high-quality images that show both functional and morphological information. The purpose of this study was to evaluate the diagnostic performance of opto-acoustic imaging in a novel platform and assess its potential for identifying and assessing breast masses.

METHODS
162 masses from a sample of 159 patients with BI-RADS 4/5 lesions (82 L, 80 N) were blindly evaluated and their features scored by 23 independent radiologists and one expert radiologist using the BI-RADS lexicon. All images were correlated with histopathology, mammography, and MR imaging. The OA images were analyzed by two expert radiologists and 21 non-expert radiologists. The scores were assigned using the OA criteria, and the images were evaluated using a reference gold standard.

RESULTS
There were consistent significant differences between the feature distributions for benign vs. malignant breast masses. OA imaging was more sensitive than mammography and MR imaging in detecting malignant masses. The OA images were always higher with lower scores for benign vs. malignant.

CONCLUSION
The study results indicate that:
- OA findings differentiate between benign and malignant masses.
- OA imaging is independent and quickly measured by projecting the OA images consistently differentiates between benign and malignant breast masses.
- OA images may offer further confidence in diagnostic decision making to improve specificity for helping readers use the individual features scores together more efficiently.

REFERENCES

IMAGINATION IS JUST THE BEGINNING
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