Using a Nomogram to Improve Breast Cancer Diagnosis with Opto-Acoustics

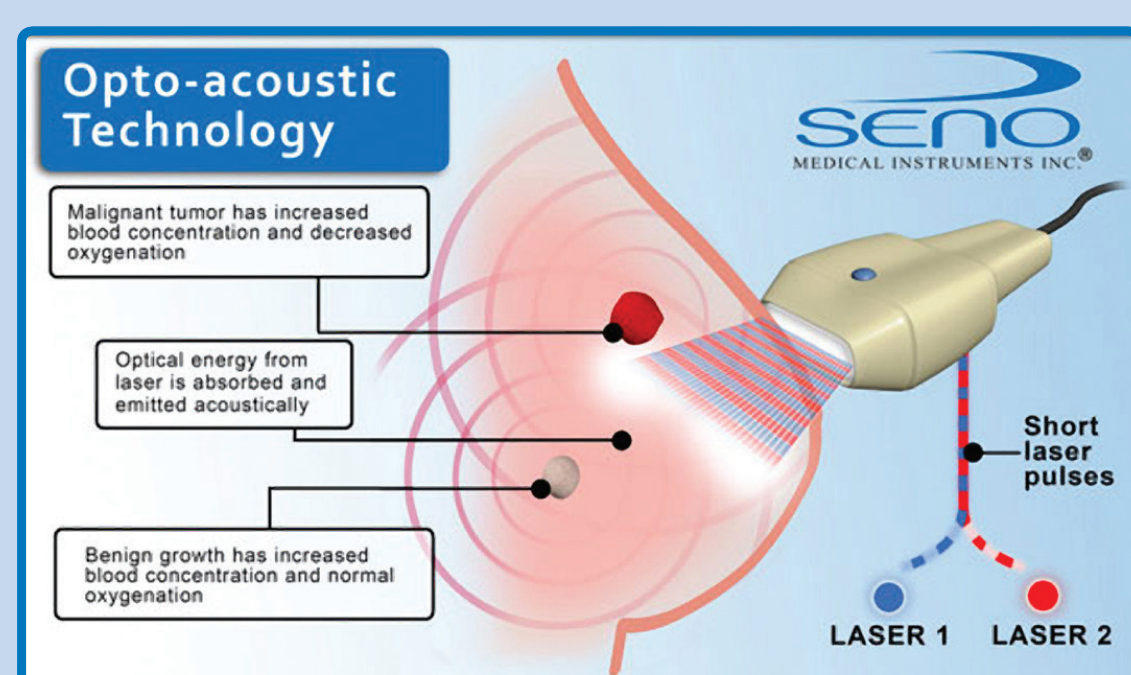## Philip T. Lavin, PhD[1] and A. Thomas Stavros, MD[2]

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BACKGROUND

Diagnostic specificity remains disappointingly low for methodologies optimized to achieve near 100% sensitivity. Seno's Imagio® imaging technology is a fusion of real time, co-registered, interleaved, laser opto-acoustic (OA) and ultrasound images showing dual functional findings (hemoglobin relative de-oxygenation) and morphology (angiogenesis) for breast masses using a hand-held probe.

OBJECTIVES

In the PILOT Study, we validate and show gains using prospectively defined nomograms based on prospectively defined OA features to predict the Probability of Malignancy (POM) using OA compared to the Imagio ultrasound component (IUS).

METHODS & MATERIALS

An expert radiologist (ER) blinded to histologic outcomes evaluated IUS and OA for 79 masses (41 benign, 38 cancer) classified BI-RADS 4 prior to biopsy. Linear regression was used to model and to predict ER POM while logistic regression was used to model and to predict Benign vs. Malignant. Subject-specific nomogram predictions were then immediately offered to 3 independent quality assurance radiologist readers (QAR reader) using their feature scores for prediction. Nomogram sensitivities and specificities were evaluated for each QAR reader: first for IUS, then for OA, and finally using the nomogram.
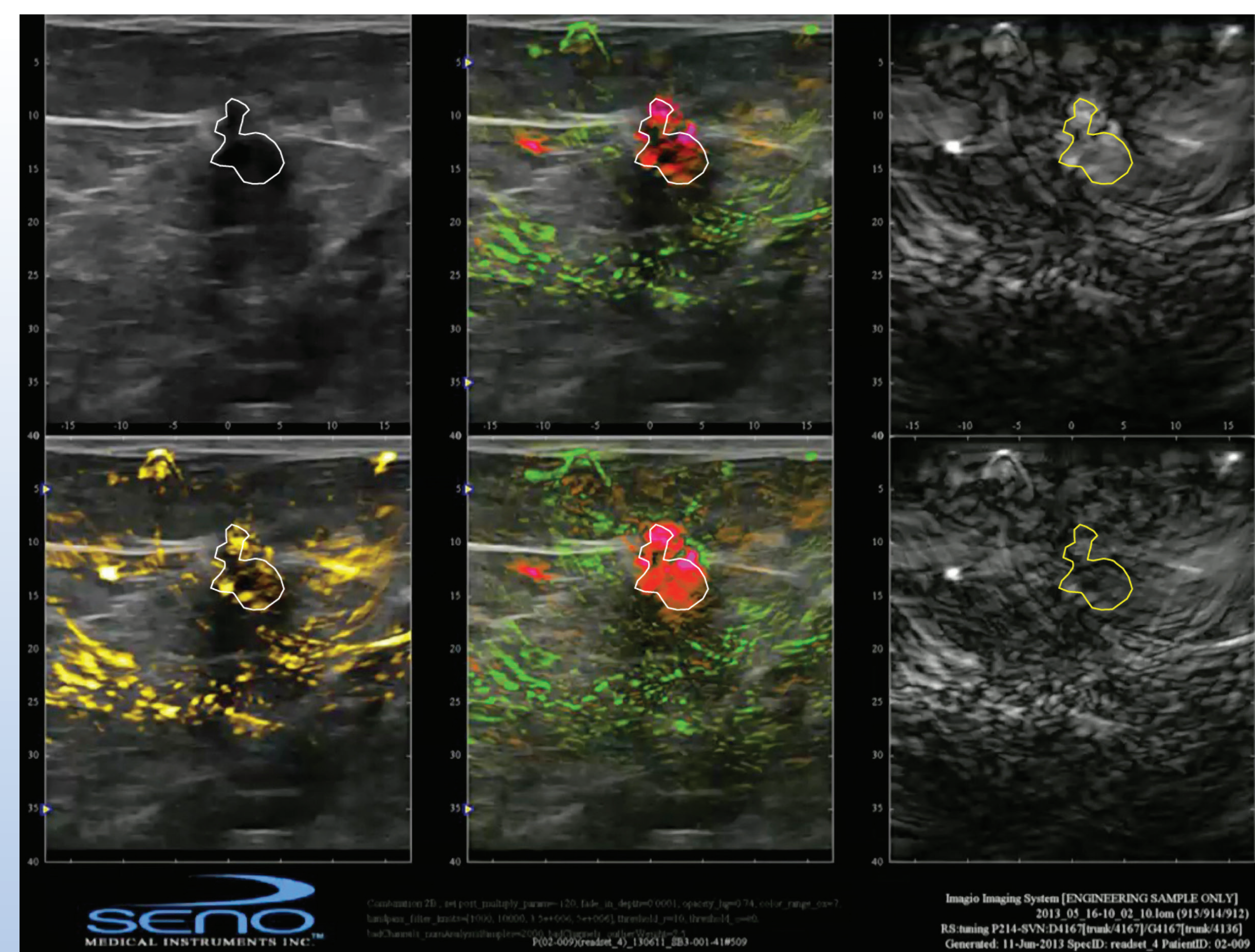

Figure 1: Positive opto-acoustic examination. 6-on-1 imaging shows increased hemoglobin and de-oxygenation (red) within and around a 4 mm grade 2 tubulolobular carcinoma.
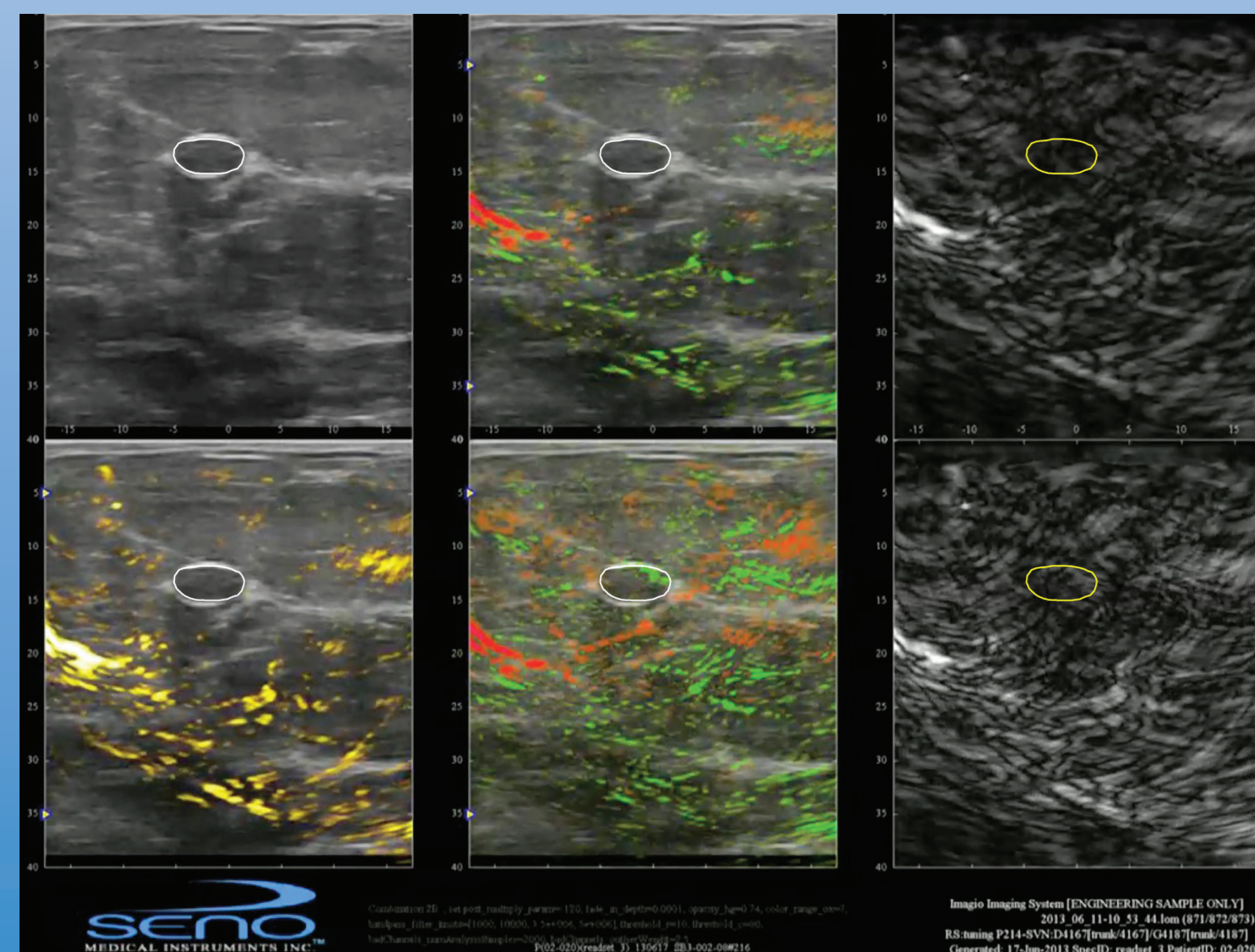

Figure 2: Negative opto-acoustic examination. 6-on-1 imaging shows absent OA signal within and around this benign fibroadenoma.

RESULTS

OA sensitivities were 100%. IUS specificities per QAR reader were 22%/22%/0%, OA specificities improved to 33%/46%/25%, and nomogram specificities improved to 50%/58%/38% (shown in Table 1). Specificity net gains were 28%/36%/38% for the nomogram vs. IUS.

CONCLUSION

In the PILOT Study, significant improvements in specificity resulted for OA vs. IUS with further improvements using the nomogram. The nomogram can help radiologists declare masses to be benign. This real-time solution can potentially train and guide readers how to downgrade. If subsequently confirmed in a 2,000 subject FDA PMA trial, OA nomogram findings may improve a reader's ability to characterize solid masses and spare biopsies.

TABLE 1

	QAR Reader		
Outcome Metric	QAR 1	QAR 2	QAR 3
IUS Sensitivity	100%	94.6%	100%
Imagio Sensitivity	100%	100%	100%
IUS Specificity	22.2%	22.0%	0%
Imagio Specificity	33.3%	46.3%	25%
Specificity Gain*	+11.1%	+24.3%	+25%
Nomogram Specificity	50%	58.5%	37.5%
Nomogram Further Specificity Gain*	+16.7%	+12.2%	+12.5%
Total Potential Specificity Gain*	+27.8%	+36.5%	+37.5%

*All specificity gains are expressed as absolute improvements

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