

Projected Healthcare Economic Benefit Associated with Opto-Acoustic Imaging: Potential for Reducing Breast Biopsies

Erin Neuschler, MD (eneuschl@nm.org)¹ • Jay R. Parikh, MD² • Arthur Lerner, MD³ • A. Thomas Stavros MD⁴ • Philip Lavin, PhD⁵ • Reni Butler, MD⁶

¹Feinberg School of Medicine, Department of Radiology • ²University of Texas MD Anderson Cancer Center • ³Advanced Breast Technologies Consulting • ⁴Seno Medical Instruments, Inc. • ⁵Boston Biostatistics Research Foundation • ⁶Yale University

BACKGROUND

Imagio[®] is an investigational diagnostic opto-acoustic (OA) device that may improve distinction between benign and malignant breast masses. Gray-scale ultrasound is limited in its specificity for characterization of breast masses. This limited specificity results in false positive and negative biopsies which increases health care expenses. Seno Medical's OA imaging fuses real time co-registered, interleaved laser optic and ultrasound imaging showing dual functional findings (hemoglobin deoxygenation) and morphology (angiogenesis) for breast masses using a hand-held probe. Data from a 100 subject blinded reader pilot study demonstrated the potential of OA to downgrade benign masses and potentially spare negative biopsies.

BASIS FOR OPTO-ACOUSTIC (OA) IMAGING

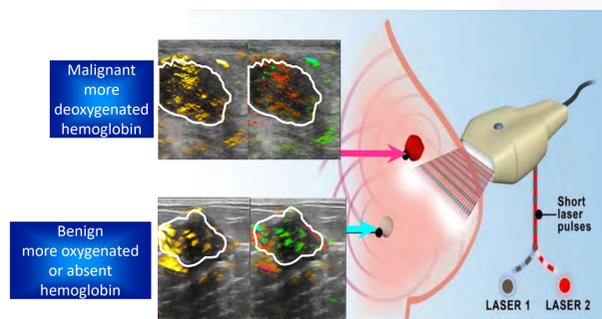
Cancers do not grow beyond 2-mm without developing new vessels, or neovascularity¹. This results in increased blood flow to cancerous tissue. Cancers are generally more metabolically active and deoxygenate hemoglobin more than benign entities or normal tissue. Optical energy from a laser is absorbed by oxygenated and deoxygenated hemoglobin and is emitted as a sound wave^{2,3,4}

LIGHT IN – SOUND OUT

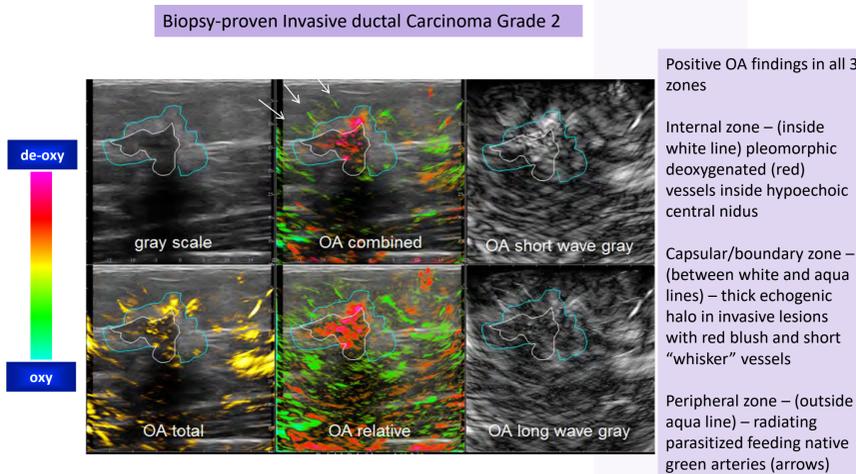
A hand-held linear probe, which can perform both gray-scale ultrasound as well, emits optical pulses via a class 3b laser. Dual wavelength laser pulses generate the OA images. Red light (757 nm) is absorbed predominantly by hypoxic (deoxygenated) blood. Near-infrared light (1064 nm) is absorbed by normally oxygenated blood. OA images are co-registered with gray-scale ultrasound.



REAL-TIME HEMOGLOBIN MAP



OA 6 ON 1 DISPLAY



METHODS

In the 100 subject blinded reader study, women were referred for diagnostic breast ultrasound due to a palpable mass or a suspicious mammographic finding. Patients with BI-RADS 3, 4a, 4b, 4c and 5 lesions at conventional diagnostic ultrasound (CDU) were eligible for the study.

Investigators obtained gray-scale images with the Imagio device, the internal ultrasound control (IUC), immediately before acquiring the OA images. Independent readers (IRs) were blinded to clinical data, site imaging and pathology. Seven IRs were trained by expert reader to identify and score three OA internal features and two OA external features for each mass.

RESULTS

In the pilot study, using OA, seven independent readers were able to downgrade biopsy-proven benign masses coded by the site investigator as follows:

BI-RADS 4b to 3 in 23% of cases

BI-RADS 4a to 3 in 37% of cases

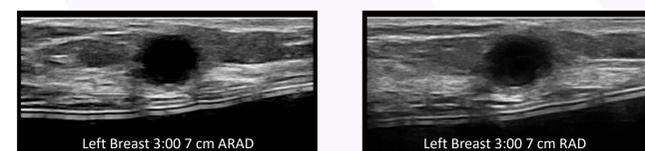
BI-RADS 4a to 2 in 16% of cases

BI-RADS 3 to 2 in 33% of cases

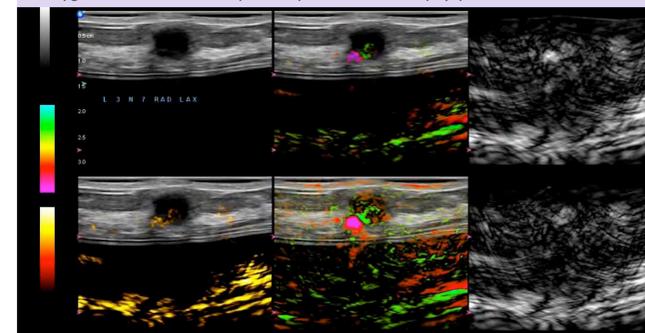
Downgrades to BI-RADS 3 may decrease the number of negative biopsies and downgrades to BI-RADS 2 may decrease negative biopsies as well as short interval follow-up exams.

Downgrades from BI-RADS 4a and 4b to BI-RADS 3 and 2 represent potentially substantial cost savings for patients and the healthcare system.

DOWNGRADE FROM 4b TO 3 USING OA



Irregularly shaped, markedly hypoechoic 9-mm mass with microlobulated margins. Coded 4b by site radiologist. On OA imaging there is an absence of internal findings and a single central feeding artery which is oxygenated and normal post-capsular vein. Biopsy-proven fibroadenoma.



POTENTIAL AREAS OF COST SAVINGS

Sparing a biopsy for a benign mass avoids a \$1,000-\$1,500 cost (including histopathology), and sparing subsequent follow-up visits avoids a \$200-\$500 cost (excluding other diagnostic imaging studies).^{*5,6}

Potential Downgrades

BI-RADS 4b to 3

BI-RADS 4a to 3

BI-RADS 4a to 2

BI-RADS 3 to 2

Potential Areas of Cost Savings

Biopsy

Biopsy

Biopsy and/or follow-up

Biopsy and/or follow-up

*Cost savings based on Medicare only^{5,6}

CONCLUSION

Imagio appears to prospectively help identify benign masses that do not require biopsy, and in some cases, also reduce the need for short interval follow-up. This is being validated in a larger pivotal trial. Downgrading benign-appearing masses to BI-RADS 3 or 2 without missing cancers potentially offers significant cost saving implications for both patients and the healthcare system, as well as helps spare women from the anxiety associated with breast biopsies.

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