

# Combining B-Mode Ultrasound and Opto-Acoustic Imaging to Evaluate Breast Lesions

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## Objective

The purpose of this study is to present data from a feasibility study performed to evaluate a novel emerging imaging technology that combines B-mode ultrasound and optoacoustic imaging.

## Methods

Breast lesions were imaged using high-resolution ultrasound coupled with visual data generated by short pulses of laser energy at two distinct wavelengths. One wavelength excites oxygenated hemoglobin while the other excites deoxygenated hemoglobin. The data is captured, color-coded (green=oxygenated hemoglobin, red = deoxygenated hemoglobin), and co-registered with the B-mode ultrasound image. This allows the reader to not only describe the morphology of the lesion but also address the relative concentrations of oxygenated hemoglobin, which suggests the benign process, or deoxygenated hemoglobin, which suggests a malignant process. Total blood flow representing the presence or absence of neo-vascularity is colored yellow.

The feasibility study evaluated 79 patients recommended for biopsy based on screening mammography and breast ultrasound from two clinical sites. The population underwent opto-acoustic imaging technology. A panel of 5 independent readers, blinded to the biopsy results, retrospectively reviewed all imaging studies. Traditional breast imaging studies (mammography, ultrasound) were compared with integrated B-mode ultrasound/opto-acoustic imaging and the probability of malignancy (POM) was determined across all BIRADS categories. The imaging findings were then correlated with the subsequent lesion pathology.

## Results

Of the 79 biopsies, 6 were removed from the study for technical reasons. Of the remaining 73, there were 39 benign cases and 34 malignant cases that were completely evaluated and make up the analysis.

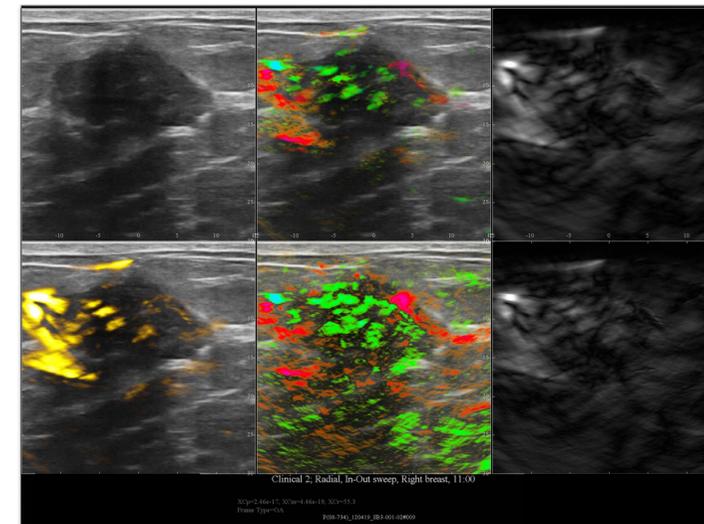
There were no adverse events related to the technology. Calculating the probability of malignancy (POM) at greater than 2% across all BIRADS categories, comparing optoacoustic imaging images to the original mammography and B mode ultrasound revealed:

1. Optoacoustic imaging was accurate in detecting >98% of all malignancies.
2. Optoacoustic imaging diagnosed BIRADS 4B cases 30.2% more accurately than the combination of conventional mammography and ultrasound
3. Optoacoustic imaging diagnosed BIRADS 5 malignancies 10% more accurately than the combination of conventional mammography and ultrasound

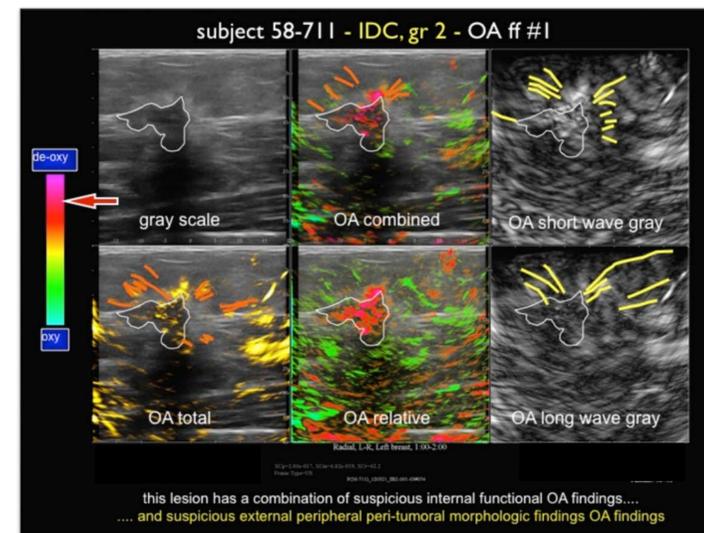
Optoacoustic imaging potentially spared 23.7% of patients from biopsy.

## Conclusion

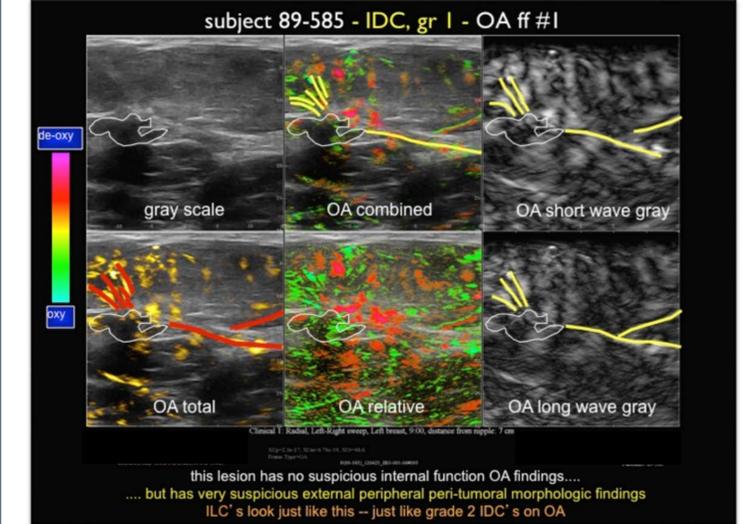
Information obtained from the opto-acoustic imaging dual modality opto-acoustic/ultrasound system is encouraging and may aid in the differentiation of benign versus malignant breast lesions. An ongoing study is being conducted to further evaluate the accuracy of this technology. Other potential applications include: assessment of the response to neo-adjuvant chemotherapy, intraoperative real-time evaluation of surgical margins, and the evaluation of blood flow to the nipple areola complex during nipple-sparing mastectomies.



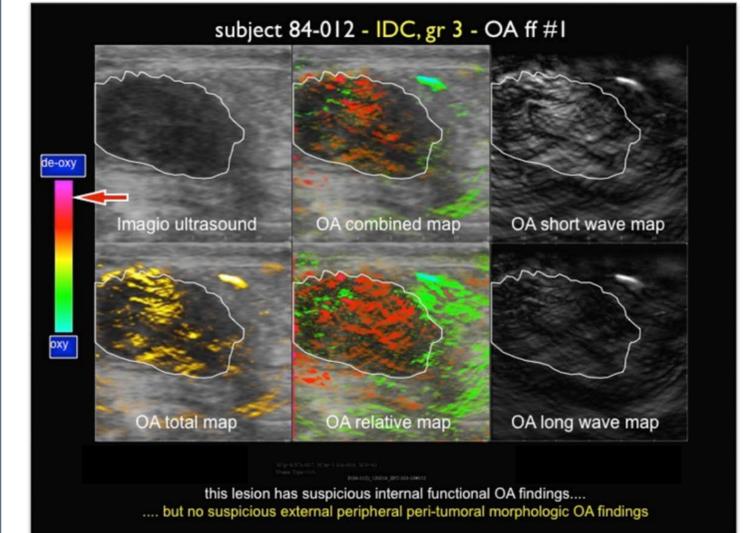
**Figure 1** This lesion has features suspicious enough to merit biopsy and turned out to be a benign fibroadenoma. With OA interpretation, readers assessed it as probably benign



**Figure 2** reveals an irregular solid lesion that demonstrates a combination of suspicious internal and external peri-tumoral morphologic findings. This was a grade 2 invasive ductal carcinoma



**Figure 3** a solid lesion with no suspicious internal opto-acoustic pattern, but very suspicious external peri-tumoral morphologic findings. This was a Grade 1 invasive ductal carcinoma.



**Figure 4** reveals a solid breast lesion with suspicious internal opto-acoustic but no suspicious external peri-tumoral morphologic findings. This was a grade 3 invasive ductal carcinoma.