

Opto-acoustic imaging of the breast: downclassification and upclassification of suspicious breast masses

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Purpose

- The Imagio[®] device is an opto-acoustic (OA) breast imaging system designed to concomitantly collect and present OA images interleaved with conventional diagnostic ultrasound (CDU). This technology provides information that the physician uses to make the determination between benign and malignant masses.
- In this interim analysis of the post-market surveillance and clinical follow-up study, we report the results of the first 75 patients who had breast masses classified as BI-RADS 4A and 4B by CDU.
- We assessed OA's sensitivity, specificity, and its ability to downgrade benign masses and upgrade malignant masses based on the probability of malignancy (POM) and BI-RADS category.

Methods

- Seventy-five patients with 78 breast masses that were classified as BI-RADS 4A or 4B with CDU were evaluated with OA prior to biopsy.
- For each mass, the radiologist scored five OA features, and assigned a POM and a BI-RADS category.
- OA sensitivity, specificity, and BI-RADS downgrade and upgrade percentages were assessed with and without contribution from a previously derived nomogram.

Results

- The mean POM difference between malignant and benign masses was higher for OA (37%) than for CDU (27%).
- OA specificity over CDU was 43% without the nomogram and 68% with the nomogram.
- OA sensitivity was 97% with and without the nomogram, while CDU presented 100% sensitivity.
- With OA, 43% of benign masses could be downgraded, and 47% of malignant masses could be upgraded in BI-RADS category (figures 1 and 2).

Conclusions

- These results appear to support the previously reported ability of OA to improve the differentiation between benign and malignant masses compared to CDU alone, to potentially decrease negative biopsies, and to upgrade the BI-RADS category in malignant masses.
- The complete MAESTRO study (n=200) may further confirm these results.

OA & Ultrasound

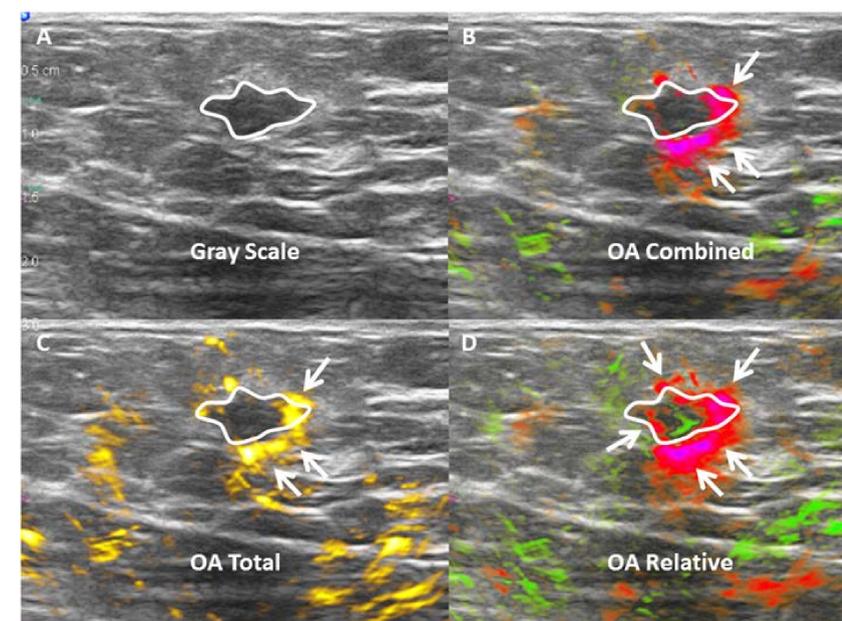


Figure 1: A fifty-nine-year-old patient with a lesion classified as BI-RADS 4B in CDU. A) The lesion seen in ultrasound Gray Scale (a ROI was drawn around the lesion and propagated co-registered to OA maps to facilitate visualization). B) The OA Combined map shows predominantly deoxygenated hemoglobin (red areas indicated by the arrows). C) OA Total map shows the total hemoglobin (oxygenated and deoxygenated). There are large vessels surrounding the lesion (arrows), which is a sign of malignancy. D) The OA Relative map shows the deoxygenated internal and the boundary zone blushes of the lesion. There is a predominantly red signal inside and outside the lesion (arrows). The OA POM assigned by the investigator was 90%, and the mass was upgraded from BI-RADS 4B (CDU) to 4C. The histopathological results revealed an invasive ductal carcinoma.

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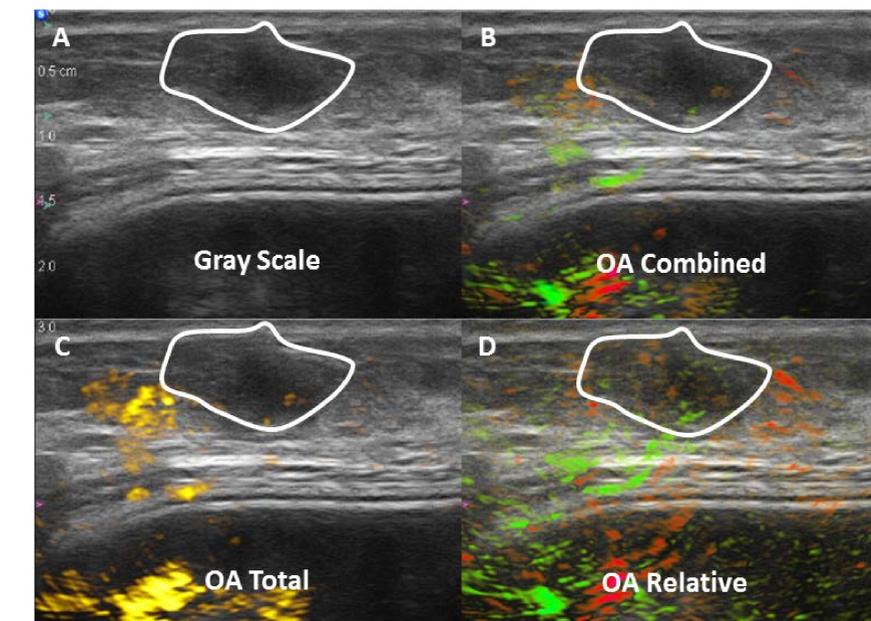


Figure 2: A forty-seven-year-old patient with a lesion classified as BI-RADS 4A in CDU. A) The lesion seen in ultrasound Gray Scale (a ROI was drawn around the lesion to facilitate visualization). B) The OA Combined map shows normal internal vessels and almost no branches (in red or green) are seen. C) OA Total map shows minimum internal hemoglobin. D) The OA Relative map shows mild internal speckle and the amount of green signal inside the lesion equals the amount of red signal. All of these descriptors match the criteria for a benign lesion. The POM according to the nomogram was 1.9%, and the mass was downgraded from BI-RADS 4A (CDU) to 3 (after the nomogram). The histopathology revealed a fibroadenoma.