Downgrading BI-RADS 4a and 4b benign masses using functional images of hemoglobin and blood oxygen saturation co-registered with ultrasound provide differentiation of breast tumors

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Objective

- A novel opto-acoustic (OA) system combining OA with co-registered ultrasound produced images which were independently tested by blinded readers to evaluate the ability to downgrade BI-RADS 4a and 4b cases according to conventional diagnostic ultrasound

Technology

- OA employs near-infrared laser pulses at two different wavelengths
- OA provides contrast between oxygenated hemoglobin in benign lesions and de-oxygenated hemoglobin in malignant lesions
- OA illuminates tissues through a fiberoptic bundle incorporated into a prototype hand-held opto-acoustic-ultrasound probe
- OA detects the laser pulse induced acoustic pressure waves that are then used for reconstruction of two-dimensional functional and anatomical images
- OA maps of total hemoglobin and blood oxygen saturation provide functional information that is co-registered with the morphological information from B-mode gray scale ultrasound images

Study Methodology

- A prospective observational clinical study
- A consecutive series of BI-RADS 3, 4, and 5 patients
- A total of 73 patients underwent biopsy
- A total of 74 breast masses were assessed with OA
- Histology was the gold standard
- All OA images were read by five independent readers without access to:
    - Subject history
    - Biopsy report
    - Histology report
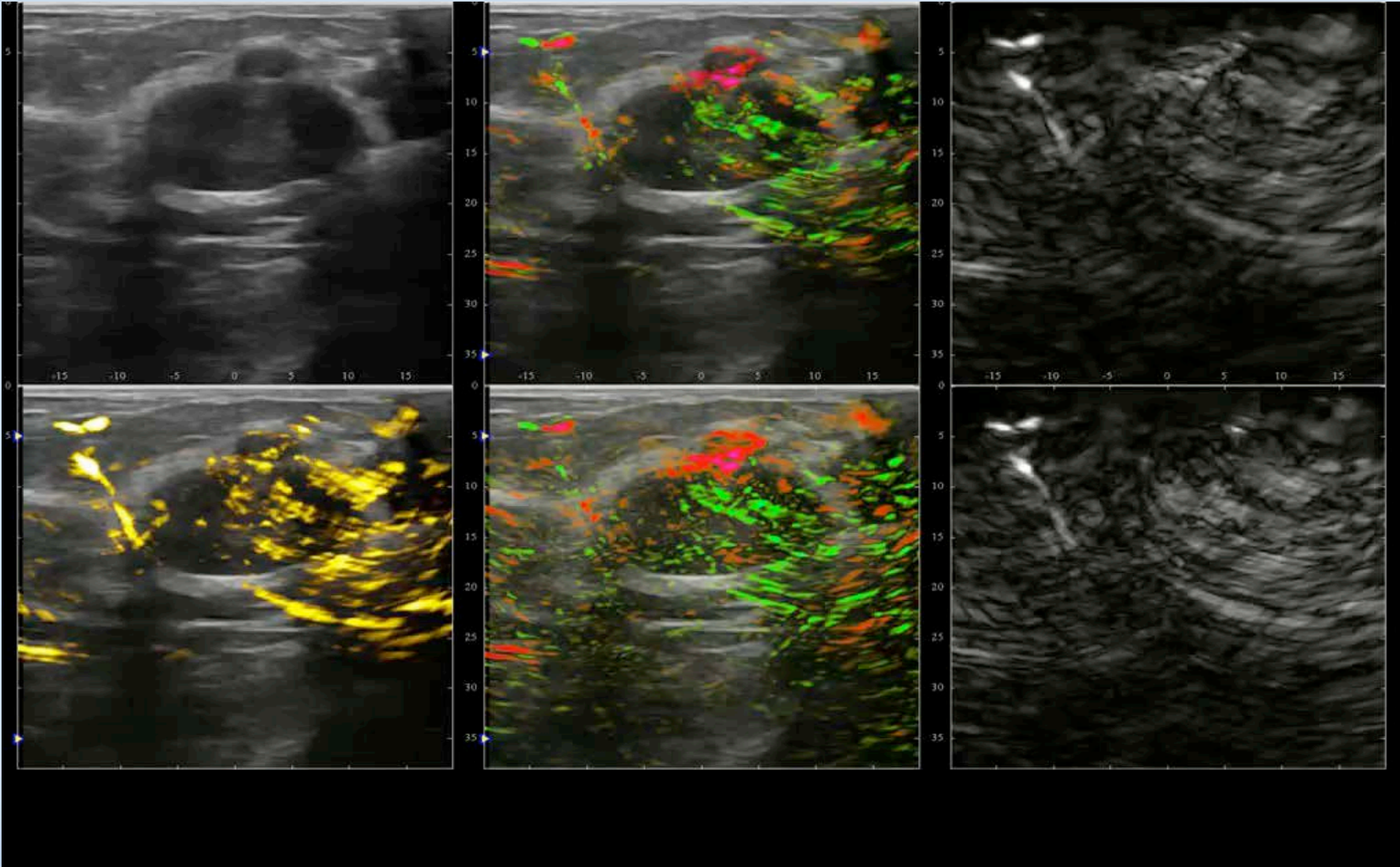   - Clinical records
    - Follow-up

BI-RADS Classification

BI-RADS	Probability of Malignancy
3	≤ 2%
4a	>2% but ≤10%
4b	>10% to ≤50%

BI-RADS 4 – Fibroadenoma
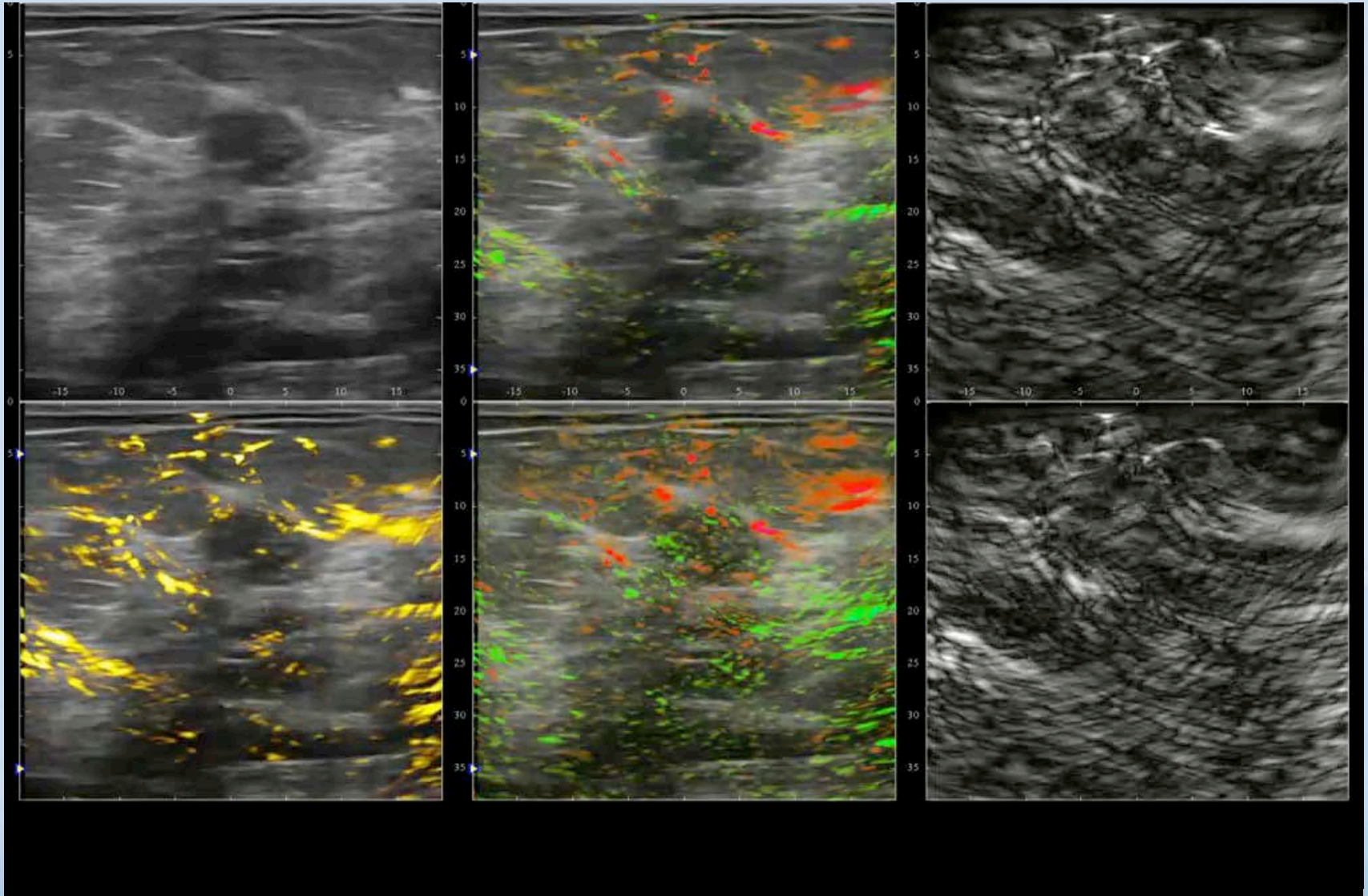
BI-RADS 4 – Fibroadenoma

Results

- All 34 cancer masses remained at original BI-RADS per site PI
- For 40 biopsied benign masses, downgrades were achieved as follows:
  - BI-RADS 3: 5/5 (100%) remained BI-RADS 3
  - BI-RADS 4a: 12/22 (54%) downgraded to BI-RADS 3
  - BI-RADS 4b: 3/13 (23%) downgraded to BI-RADS 3
- OA could potentially spare 50% of BI-RADS 4a cases and 20% of BI-RADS 4b cases

Conclusion

- The fused functional OA and gray scale anatomic information significantly improved downgrading of benign breast masses, especially within the critical BI-RADS 4a and 4b categories

- A multi-center pivotal study is underway to confirm this finding