Functional Images of Hemoglobin and Blood Oxygen Saturation Co-registered with Ultrasound Provide Accurate Differentiation of Breast Tumors

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Disclosures:

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  ▫ Employees of Seno Medical Instruments
Co-registration of Opto-Acoustic and Ultrasound Images

- OA technology combines and co-registers images based on optical and acoustical contrast.
- Co-registered OA+US imaging has the merit of providing both functional information based on specificity of optical contrast in blood and morphological information due to the high resolution of ultrasonic imaging.
Molecular Components of Optical Absorption in Breast Tissue

![Graph showing absorption capability in breast tissue at different wavelengths with peaks at 757 nm, 800 nm, and 1064 nm for 
O2-Hb, H-Hb, and H2O, respectively.](image)
1) normally polar branching feeding and draining vessel 2) mostly green internal signal
Invasive ductal carcinoma

1) internal red vessels 2) internal red blush 3) internal increased Hgb 4) superficial draining vein
Study Design

• 155 subjects (two TX sites) assessed
  – 73 biopsies: 39 benign, 34 cancers
• All had OA imaging prior to biopsy
• Biopsy was the gold standard
• Images read by 5 independent readers
  – Blinded to clinical data
  – No site guidance
Image Sets

- CDU
- IUS
- OA + Mammography
- OA + Mammography + CDU
- Mammography + CDU
Effectiveness Endpoints

• Probability of malignancy (POM)
  – Benign vs. malignant
  – BI-RADS 4ab: benign vs. malignant
  – Reader consistency
• ROC AUC (primary) from POM
• Sensitivity
• Specificity
Results: POM ROC AUC

• All image sets produced AUC > 0.8 (0.5 random)

Results: ROC Curves

• OA had an advantage for POM<2%
## Results: Mean POMs

OA is helpful in confirming cancer

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>OA</th>
<th>IUS</th>
<th>I+M</th>
<th>CDU</th>
<th>H+M</th>
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<td>31.5</td>
<td>19.9</td>
<td>29.6</td>
<td>19.9</td>
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<td>73.6</td>
<td>64.1</td>
<td>79.8</td>
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<td>44.2</td>
<td>50.2</td>
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<td>50.3</td>
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## Results

### Sensitivity and Specificity by POM

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<th>POM Cut Point</th>
<th>OA Spec</th>
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Limitations of Study

- Number of patients
- Real time Imagio imaging did not have co-registered images available to the physician scanning
Summary

• OA POM ROC AUC exceeds 0.80
• OA IUS scores higher than CDU
  – IUS is non-inferior to CDU
  – OA may be superior to CDU
• OA has a higher POM for malignant lesions than CDU
Summary

OA+US Imaging as a Clinical Technology

Preliminary Statistical Analysis of Clinical Feasibility Study: (5 blinded readers, adjudicated and independently analyzed)

- Potential to spare 40% more biopsies
- Provides >42.1% mean POM difference between benign and malignant tumors for all variety of lesions
- Detects BIRADS 5 malignancies 10% higher mean POM vs. mammography + conventional diagnostic ultrasound

Co-registered OA + US may substantially improve Sensitivity and Specificity compared to the present standard of care
Thank you