Improved Differentiation of Breast Tumors using Novel Imaging System based on Co-Registered Opto-Acoustic Tomography and Ultrasound

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Seno Medical Instruments
Disclosures:

- P. Otto
  - Medical Consultant, Seno Medical Instruments
  - 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 optical absorption in breast tissue with wavelengths and absorption capabilities indicated.](image-url)
Study Design

• 155 subjects (two TX sites) assessed
  – 79 biopsies: 39 benigns, 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
Limitations of Study

• Number of patients
• Real time Imagio imaging did not have co-registered images available to the physician scanning
Results: POM ROC AUC

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

Results: ROC Curves

• OA had an advantage for POM<10%
Results: Mean POMs

<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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Results: BIRADS

OA is helpful in confirming cancer

Mean POM by BIRADS Score

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<th>BIRADS</th>
<th>OA</th>
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## Results

### Sensitivity and Specificity by POM

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<th>IUS Spec</th>
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Summary

• OA POM ROC AUC exceeds 0.80
• OA IUS scores higher than CDU
  – IUS is certain to be non-inferior to CDU
  – OA may be superior to CDU
• OA readings highest for cancers
• 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
• Diagnoses BI-RADS 4b cases with 30.2% higher mean POM
• Detects BIRADS 5 malignancies 10% higher mean POM vs. mammography + diagnostic ultrasound

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