

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

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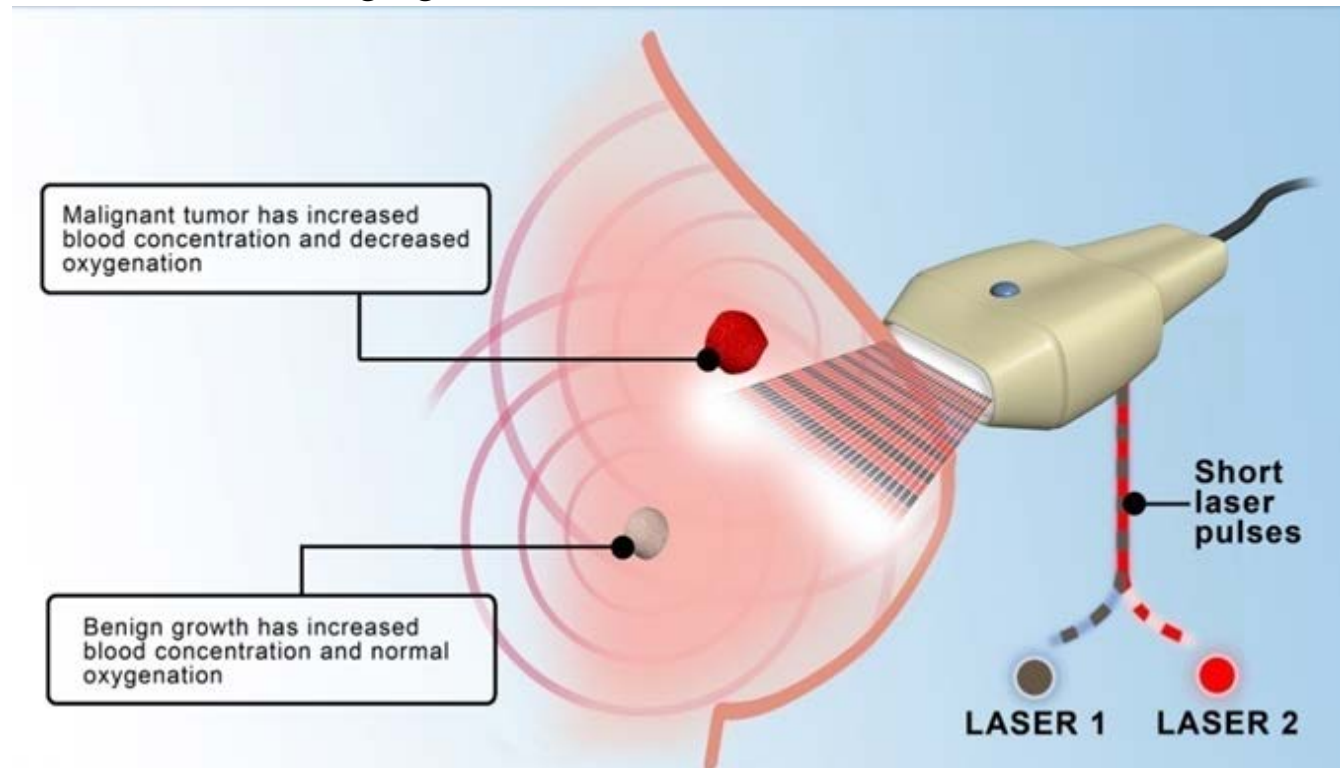
**Seno Medical Instruments**

# Disclosures:

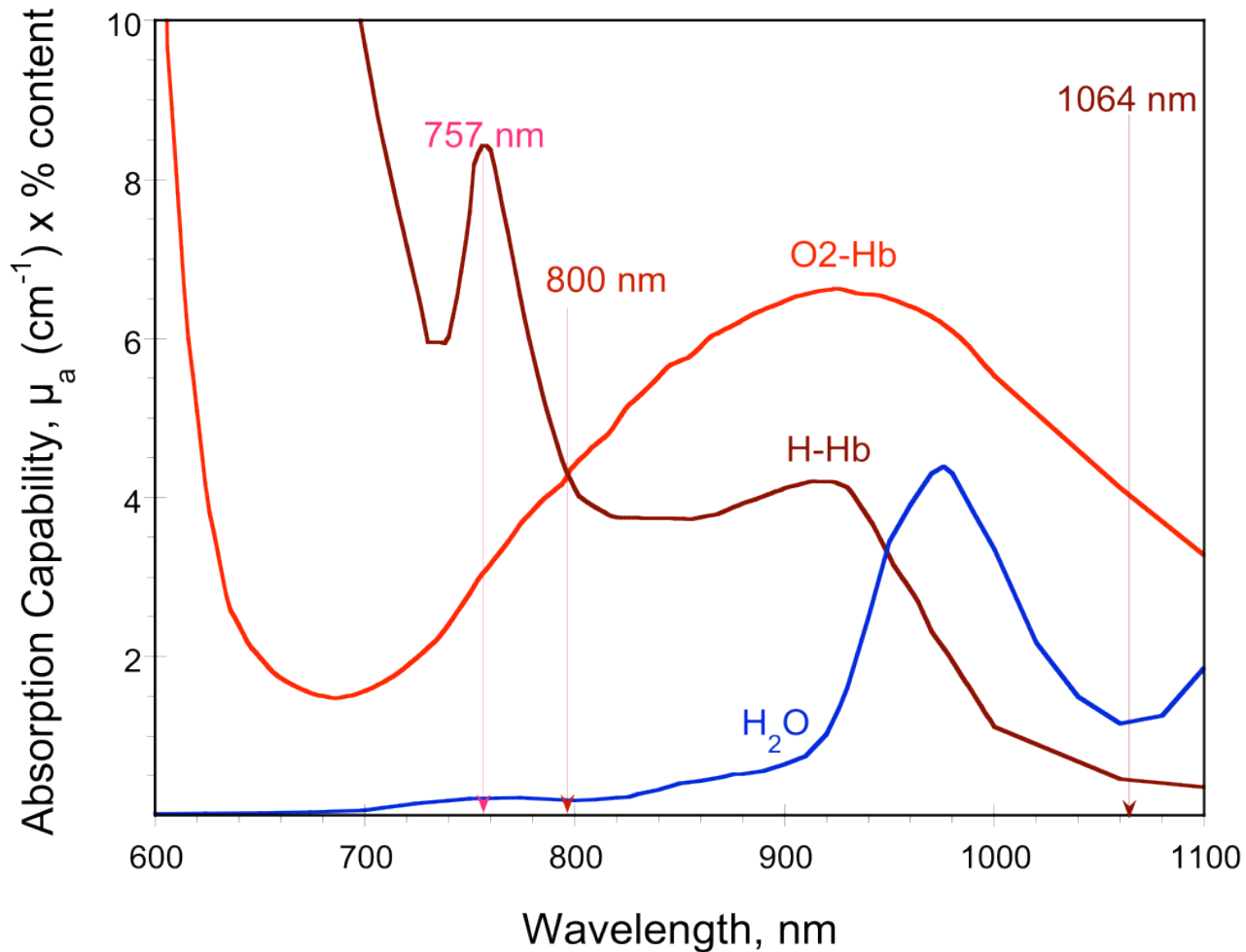
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# Co-registration of Opto-Acoustic and Ultrasound Images

- 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



# 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



## Mean POM

	n	OA	IUS	I+M	CDU	H+M	All Images
BENIGN	39	31.5	19.9	29.6	19.9	18	21.7
<b>MALIGNANT</b>	34	<b>73.6</b>	64.1	<b>79.8</b>	62.1	68.3	<b>80.7</b>
Difference		42.1	44.2	50.2	42.2	50.3	59

# Results: BIRADS

OA is helpful in confirming cancer

Mean POM by BIRADS Score

	N	BIRADS	OA	IUS	I+M	CDU	H+M	All Images
BENIGN	2	3	23.2	12.5	23.5	13.1	19.3	15.8
BENIGN	22	4a	18.1	13.1	18.4	13.3	12	11.8
<b>BENIGN</b>	<b>13</b>	<b>4b</b>	<b>47.9</b>	<b>27.6</b>	<b>43.6</b>	<b>26.1</b>	<b>22.7</b>	<b>31.9</b>
BENIGN	1	4c	71.6	19	61	26.2	12.8	46.4
BENIGN	1	5	92.2	84.6	91.4	92.6	95.6	92.2
<b>MALIGNANT</b>	<b>2</b>	<b>4b</b>	<b>64</b>	<b>29.8</b>	<b>72.5</b>	<b>33.8</b>	<b>35.9</b>	<b>67.1</b>
MALIGNANT	6	4c	71.5	66.3	77.2	61.6	71	83.8
MALIGNANT	26	5	74.8	66.2	80.9	64.4	70.2	81

# Results

## Sensitivity and Specificity by POM

POM Cut Point	OA Spec	OA Sens	IUS Spec	IUS Sens	CDU Spec	CDU Sens
0	0	1	0	1	0	1
1	0.058	1	0.058	1	0.026	1
<b>2</b>	<b>0.237</b>	<b>0.988</b>	<b>0.183</b>	<b>1</b>	<b>0.161</b>	<b>1</b>
3	0.368	0.976	0.351	0.988	0.363	0.994
4	0.389	0.976	0.356	0.988	0.389	0.988
5	0.4	0.976	0.366	0.988	0.389	0.988
<b>10</b>	<b>0.437</b>	<b>0.976</b>	<b>0.524</b>	<b>0.976</b>	<b>0.513</b>	<b>0.976</b>
15	0.5	0.929	0.644	0.94	0.606	0.898
20	0.526	0.929	0.66	0.934	0.622	0.886
<b>25</b>	<b>0.547</b>	<b>0.923</b>	<b>0.691</b>	<b>0.922</b>	<b>0.658</b>	<b>0.867</b>

# 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**