Opto-acoustic Image Fusion Technology for Diagnostic Breast Imaging in a Feasibility Study

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Feasibility Study Findings

- Feasibility Study showed preliminary evidence that fused opto-acoustic and ultrasonic images
  - improves specificity over that of conventional diagnostic ultrasound
  - can potentially reduce the number of negative biopsies performed without missing cancers
Imagio Pivotal Study

- Currently underway at 16 leading institutions in the US
- Enrolment of over 2000 subjects has been completed
- Final results will be forthcoming and require completion of supplemental follow-up visits with Imagio for some subjects
Imagio & Breast Cancer Diagnosis

- Opto-acoustics can display real-time functional information about the metabolism of tumors
- The Imagio system could be used as an additional diagnostic test following mammographic screening
Breast Cancer

- Over 38 million mammograms in USA per year\(^1\)
- 1.7 million breast biopsies in USA per year\(^2\)
  - Over 80% of biopsies performed are negative\(^3\)
- 261,000 cases of breast cancer in USA per year\(^2\)

\(^1\) - FDA MQSA National Statistics, http://www.fda.gov
Diagnostic Imaging

- Initial screening with additional ultrasound and MRI can increase sensitivity but generate more false positives than mammography\(^1\)

- Ultrasound useful for characterizing breast tumors, but has low specificity and causes high percentage of negative biopsies\(^2\)

\[1\] – Berg, W. et. al, JAMA 2012, Volume 307, No. 13
\[2\] - Stavros, A. T., et al., Breast Ultrasound, Lippincott Williams & Wilkins, 2003
Functional Opto-acoustic Imaging
Tumor Metabolism

As compared to normal tissue and benign tumors
- cancers are metabolically more active
- cancers have more blood vessels and more blood
- cancers have irregular branching vessels
- cancers pull more oxygen out of blood and thus de-oxygenate tissues more
- cancers can have hypoxic or necrotic regions of tissue

• Functional opto-acoustics provides information about tumor metabolism
• OA demonstrates this relatively greater de-oxygenation within malignant tissues
• OA demonstrates this increased internal blood within lesions
Imagio™ Breast Imaging System

Functional Contrast
Imagio™ Breast Imaging System

Functional Contrast

deygenated lesion

oxgenated lesion
Invasive Ductal Carcinoma (Malignant)
Invasive Ductal Carcinoma (Malignant)
Fibroadenoma
(benign)
Fibroadenoma
(benign)
Clinical Phase II Trial Feasibility Study

• 155 subjects with solid breast masses imaged with conventional diagnostic ultrasound were scanned with Imagio at two IRB approved sites

• 79 biopsies performed
  – 40 benign
  – 34 malignant
  – 6 excluded

• Images retrospectively interpreted by 5 independent readers blinded to biopsy results
Clinical Phase II Trial Feasibility Study

- readers assigned probability of malignancy (POM) score to each lesion
- POM > 2% is a positive finding
- POM ≤ 2% is a negative finding
- biopsy is used as “gold standard”

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<tr>
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<th>OA</th>
<th>CDU</th>
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<tbody>
<tr>
<td>Sensitivity</td>
<td>0.99</td>
<td>1.0</td>
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<tr>
<td>Specificity</td>
<td>0.237</td>
<td>0.161</td>
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OA safer than competitive functional imaging tests

- OA uses no ionizing radiation and no contrast agents, making Imagio completely safe for use on patients
  - PET/CT, PEM and BSGI use ionizing radiation
  - MRI uses a gadolinium contrast agent which can have side effects
Conclusion

• Imagio can display real-time functional information about the metabolism of tumors

• Clinical results from Feasibility Study illustrate that
  – the technology may have the capability to improve overall accuracy of breast tumor diagnosis, monitoring and treatment
  – the potential to reduce the number of biopsies
  – to characterize cancers that were not seen well with conventional ultrasound

• Further study in a large population is being underway at multiple sites
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