Real-time opto-acoustic imaging system for clinical assessment of breast lesions

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Imagio & Breast Cancer Diagnosis

• Opto-acoustics can display real-time functional information about the \textit{metabolism} of tumors

• The Imagio system could be used as an \textit{additional diagnostic test} following mammographic screening
Findings

• Preliminary results illustrate that
  – the technology may have the capability to improve overall accuracy of breast tumor diagnosis
  – the potential to reduce biopsies
  – to characterize cancers that were not seen well with conventional ultrasound
Breast Cancer

- Over 38 million mammograms in USA per year\(^1\)
- 1.6 million breast biopsies in USA per year\(^2\)
  - Around \textbf{80\% of biopsies} performed are \textbf{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\(^2\)

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\(^1\) – Berg, W. et. al, JAMA 2012, Volume 307, No. 13
\(^2\) - Stavros, A. T., et al., Breast Ultrasound, Lippincott Williams & Wilkins, 2003
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 Technetium Gamma Imaging (BSGI) use ionizing radiation
  - MRI uses a gadolinium contrast agent which can have side effects
Imagio™ Breast Imaging System

Functional Contrast

deoxygenated
tumor

oxygenated
tumor

Short laser pulses

LASER 1  LASER 2
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
Oxygenation Level of Tumors

• Deoxygenated Tumor
  – Signifies Malignant (Bad) – Red

• Oxygenated Tumor
  – Signifies Benign (Good) - Green
Vessels in human arm

Normal Artery SO2 = 95-99%
Normal Vein SO2 = 60-80%

- vein  - artery
Breast Tumor

pF Subject 84-012 - Classical IDC, gr 3 - OA ff #1
Invasive Ductal Carcinoma (Malignant)
Breast Tumor #2

Invasive Ductal Carcinoma (Malignant)

Subject 58-711 - Classical IDC, gr 2 - OA ff #1
Breast Tumor #2

Invasive Ductal Carcinoma (Malignant)
Fibroadenoma (Benign)

Subject 08-734 - FA - OA ff #2
Breast Tumor #3

Fibroadenoma (Benign)
Conclusion

• Imagio can display real-time functional information about the metabolism of tumors
• Clinical results from an initial group of patients 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