Opto-Acoustic Imaging and Negative Biopsy Reduction: Results from PILOT Study in the USA

The New Kid in Town

Tom Stavros, MD, FACR
Medical Director
Seno Medical Instruments, Inc.
San Antonio, TX, USA
Opto-Acoustics (OA)

fusion imaging - 2 types of fusion

1. Fusion of laser optic imaging and ultrasound in real time (light in-sound out)
   • optics - high contrast resolution (about 20/1)
   • ultrasound - high spatial resolution & better penetration

2. Fusion anatomy and function anatomy
   • anatomy
     ✦ gray scale ultrasound anatomy
     ✦ OA demonstration of tumor neoangiogenesis vessels
   • function - OA demonstration of relative degrees of oxygenation / deoxygenation
Basis for OA in Diagnostic Breast Imaging

• cancers cannot grow beyond 2 mm diameter without developing neovascularity

• cancers are generally more metabolically active and deoxygenate blood more than do benign entities or normal tissue (relative oxygenation/deoxygenation, not O₂ saturation)
Opto-Acoustics

- get both function and anatomy in real time
- co-registered with widely available US modality
- quick and comfortable for patient
- relatively inexpensive
- no ionizing radiation
- no injection of:
  - contrast
  - radionuclide
Other Functional Breast Imaging Studies
OA Competitors and Their Disadvantages to OA

- Require IV injections
  - MRI
  - PEM and BSGI
  - contrast enhanced US

- Require or use ionizing radiation
  - PET/CT, PEM, BSGI

- Are very expensive
  - PET/CT and PEM
  - MRI
  - fMRI, MRS

- Offer only functional information (no morphology)
  - Diffuse optical imaging
  - PEM, BSGI

- Not real time
  - everything except contrast enhanced US
SEN0 IMAGIO® DEVICE

Imagio OA machine

Hand-held duplex OA probe*

*Hand-held duplex OA probe suitable for breast diagnosis, not designed for bilateral whole breast screening
SENO IMAGIO® DEVICE
Optical Absorption within Breast Tissues
- at two laser wavelengths

Absorption Capability, $\mu_a$ (cm$^{-1}$) x % content

- **OA short wave**
  - 757 nm
  - 750 nm
  - 800 nm

- **OA long wave**
  - 1064 nm

Wavelength, nm

- de-oxygenated Hgb peak
- oxygenated Hgb

Hgb: Hemoglobin
Opto-Acoustic (OA) and Ultrasound Images

Real-time hemoglobin map

- co-registered
- temporally interleaved
- real time
- color coded

- malignant: more deoxygenated hemoglobin
- benign: more oxygenated or absent hemoglobin
Invasive duct carcinoma, grade 3 - internal findings and lack of external findings
6-up or “6-on-1” Display - Order of Acquisition - each OA map is best for something

- de-oxy
- oxy

- gray scale
- OA combined
- OA short wave gray

- OA total
- OA relative
- OA long wave gray
MAESTRO Study - Post Marketing and Clinical follow-up study being performed in Europe

5 sites in the Netherlands
- 2 University Tertiary referral sites (Utrecht and Nijmegen)
- 3 Primary Screening and Diagnostic breast sites (Hengelo, Dortrecht, Arnhem)

200 masses (at 133/200 currently)
- all BI-RADS 4a or 4b
- all undergoing biopsy
- megacassette pathology and central pathologist

Endpoints
- better specificity with equal sensitivity to conventional diagnostic ultrasound (CDU)
- downgrade percentages
- real world investigator reading vs. blinded independent readers
- megacassette histopathologic correlation to boundary and peripheral zone OA findings