

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

"IMAGINATION IS JUST THE BEGINNING."

300454 Rev 6

seno
MEDICAL INSTRUMENTS INC.

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

SENO IMAGIO[®] DEVICE



Imagio OA machine

Hand-held duplex OA probe*

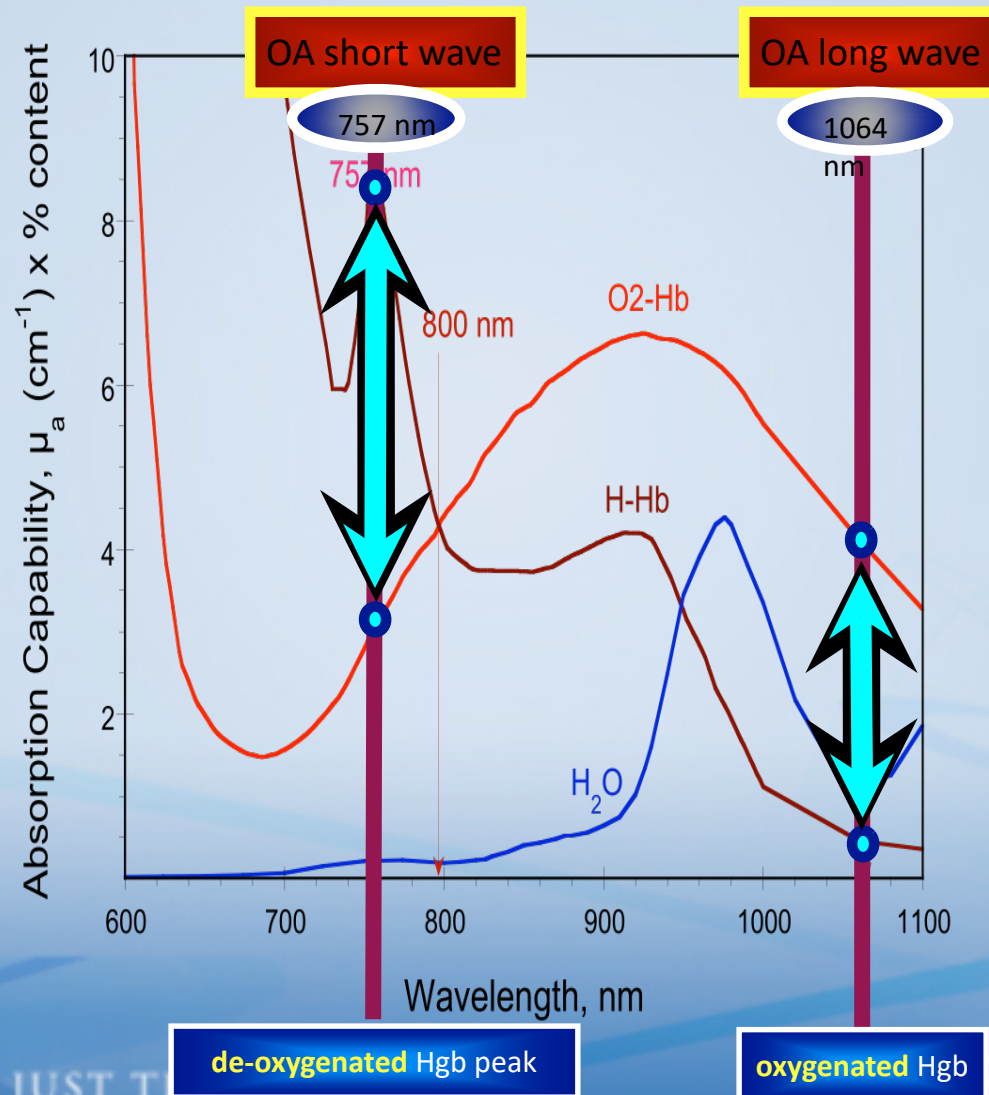
*Hand-held duplex OA probe suitable for breast diagnosis,
not designed for bilateral whole breast screening

SENO IMAGIO[®] DEVICE



Optical Absorption within Breast Tissues

- at two laser wavelengths



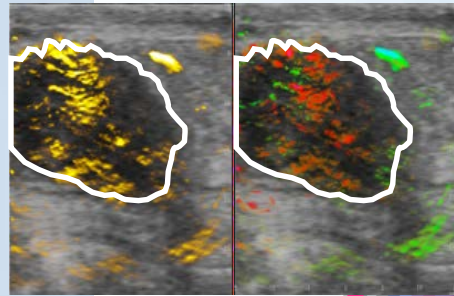
Opto-Acoustic (OA) and Ultrasound Images

Real-time hemoglobin map

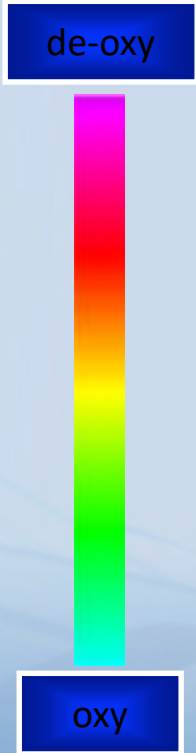
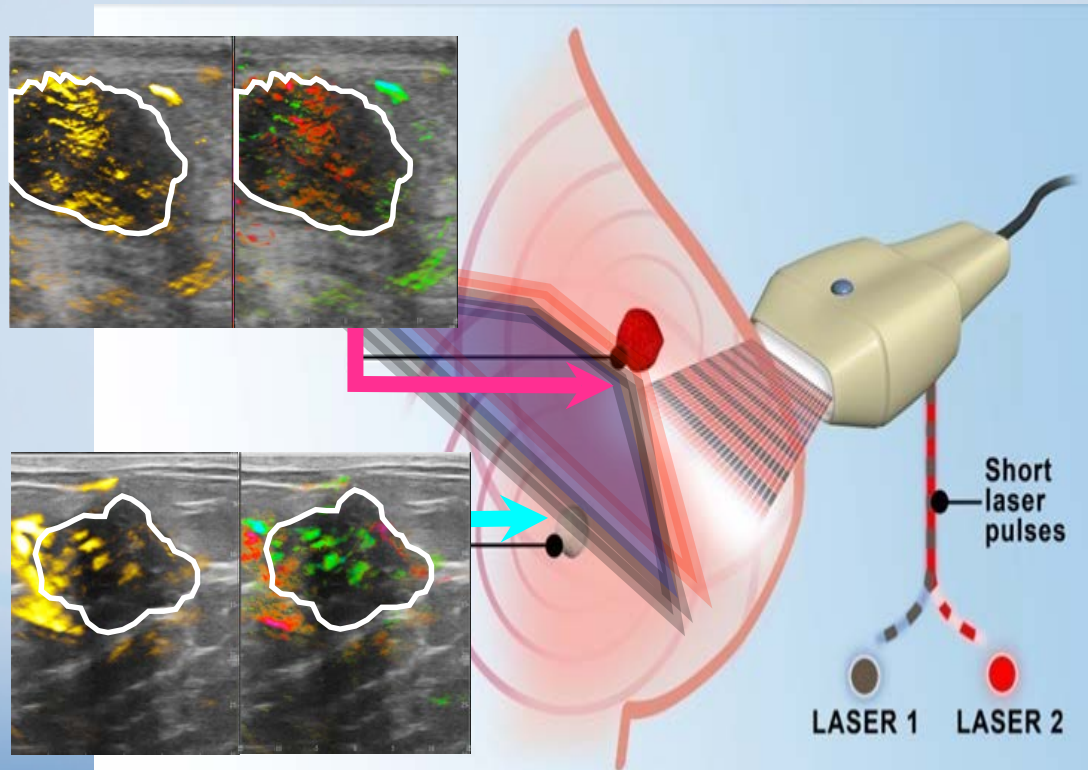
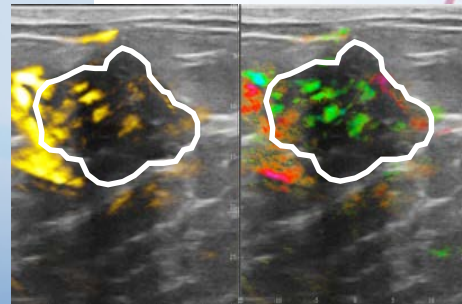
co-registered
temporally interleaved

- real time
- color coded

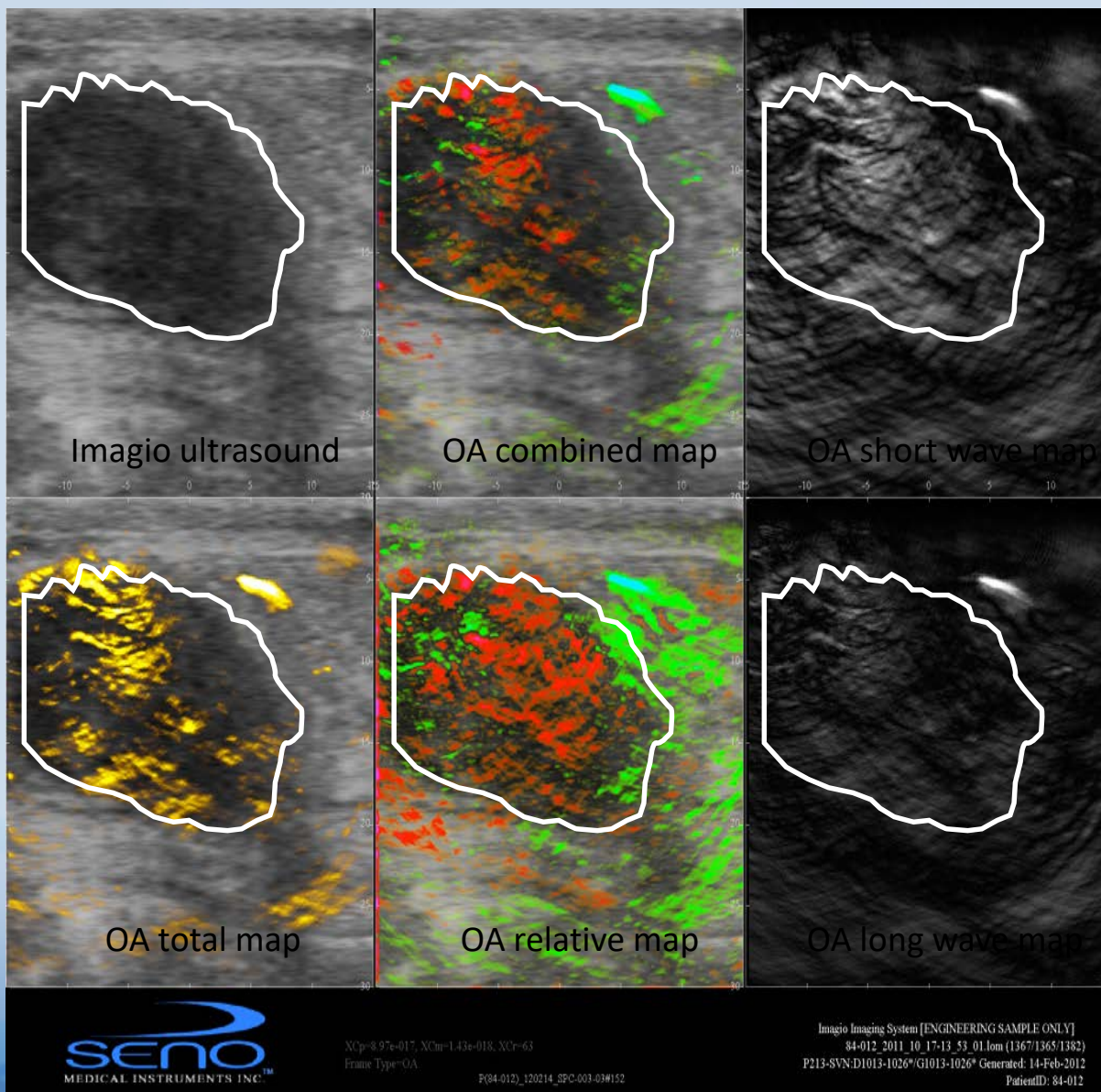
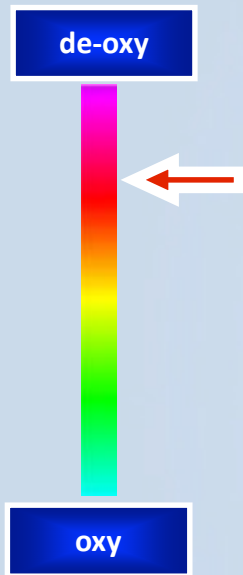
malignant
more
deoxygenated
hemoglobin



benign
more oxygenated
or absent
hemoglobin

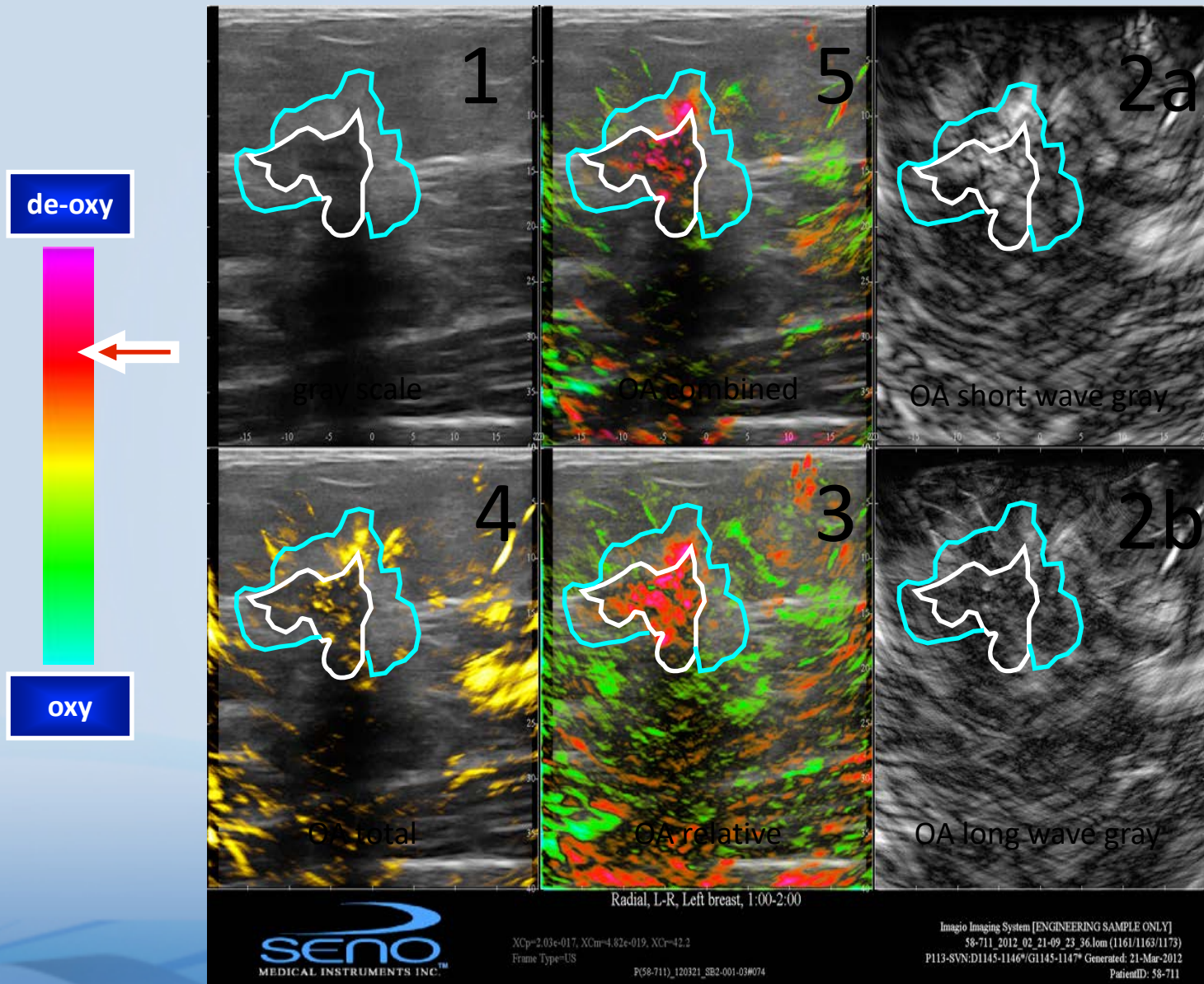


Invasive duct carcinoma, grade 3 - internal findings and lack of external findings



“IMAGINATION IS JUST THE BEGINNING.”

6-up or "6-on-1" Display - Order of Acquisition - each OA map is best for something



"IMAGINATION IS JUST THE BEGINNING."

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, Dordrecht, 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