

Opto-acoustic Breast Imaging with Co-registered Ultrasound

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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 & 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 year¹
- 1.6 million breast biopsies in USA per year²
 - Around **80% of biopsies** performed are **negative**³
- 261,000 cases of breast cancer in USA per year²

[1] - FDA MQSA National Statistics, <http://www.fda.gov>

[2] - Gutwein, L. G., et. al , Utilization of minimally invasive breast biopsy for the evaluation of suspicious breast lesions, The American Journal of Surgery, Volume 202, Issue 2, pp127-132, August 2011


[3] - White, R. et al., "Impact of core-needle breast biopsy on the surgical management of mammographic abnormalities," Ann. Surg. 233, 769-777 (2001).

Diagnostic Imaging

- Initial screening with additional ultrasound and MRI can increase sensitivity but generate more false positives than mammography¹
- Ultrasound useful for characterizing breast tumors, but has low specificity and causes high percentage of negative biopsies²

[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

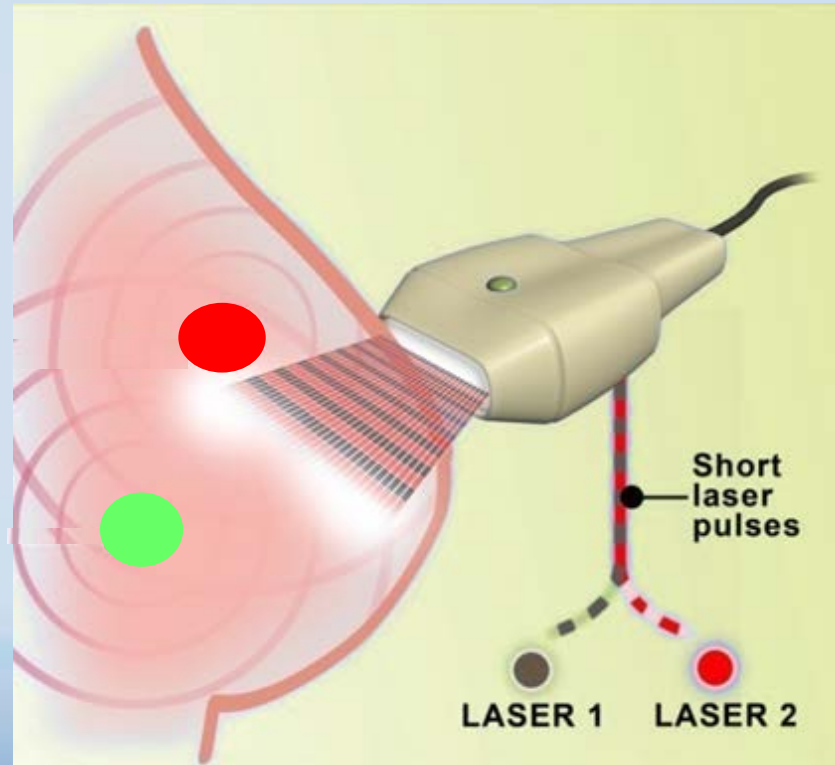
Tumor Metabolism

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

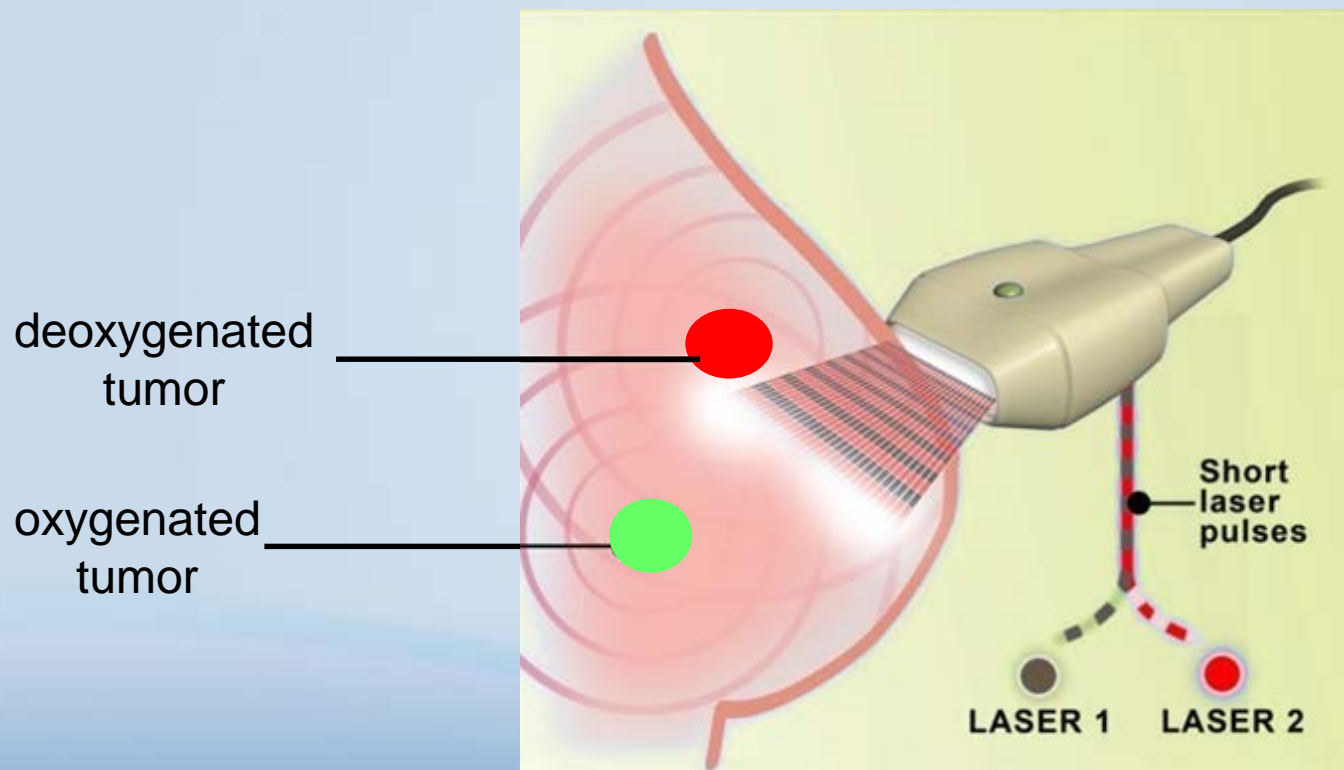


"IMAGINATION IS JUST THE BEGINNING."

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Imagio™ Breast Imaging System

Functional Contrast

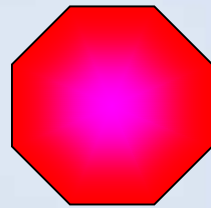


"IMAGINATION IS JUST THE BEGINNING."

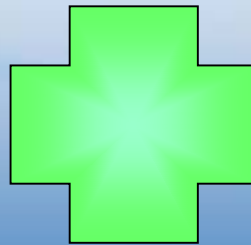
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Oxygenation Level of Tumors

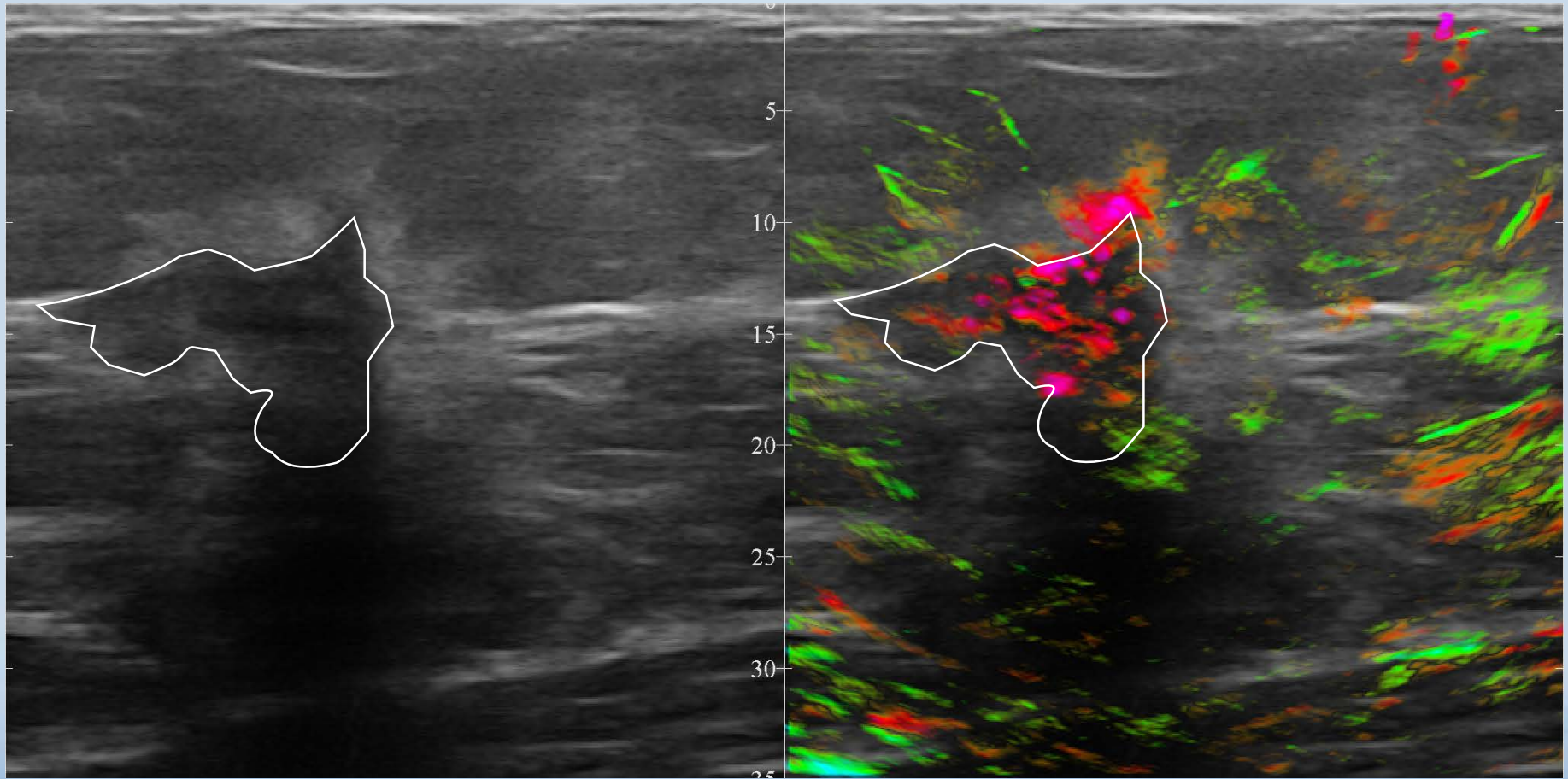
- Deoxygenated Tumor
 - Signifies Malignant (Bad) – Red



- Oxygenated Tumor
 - Signifies Benign (Good) - Green

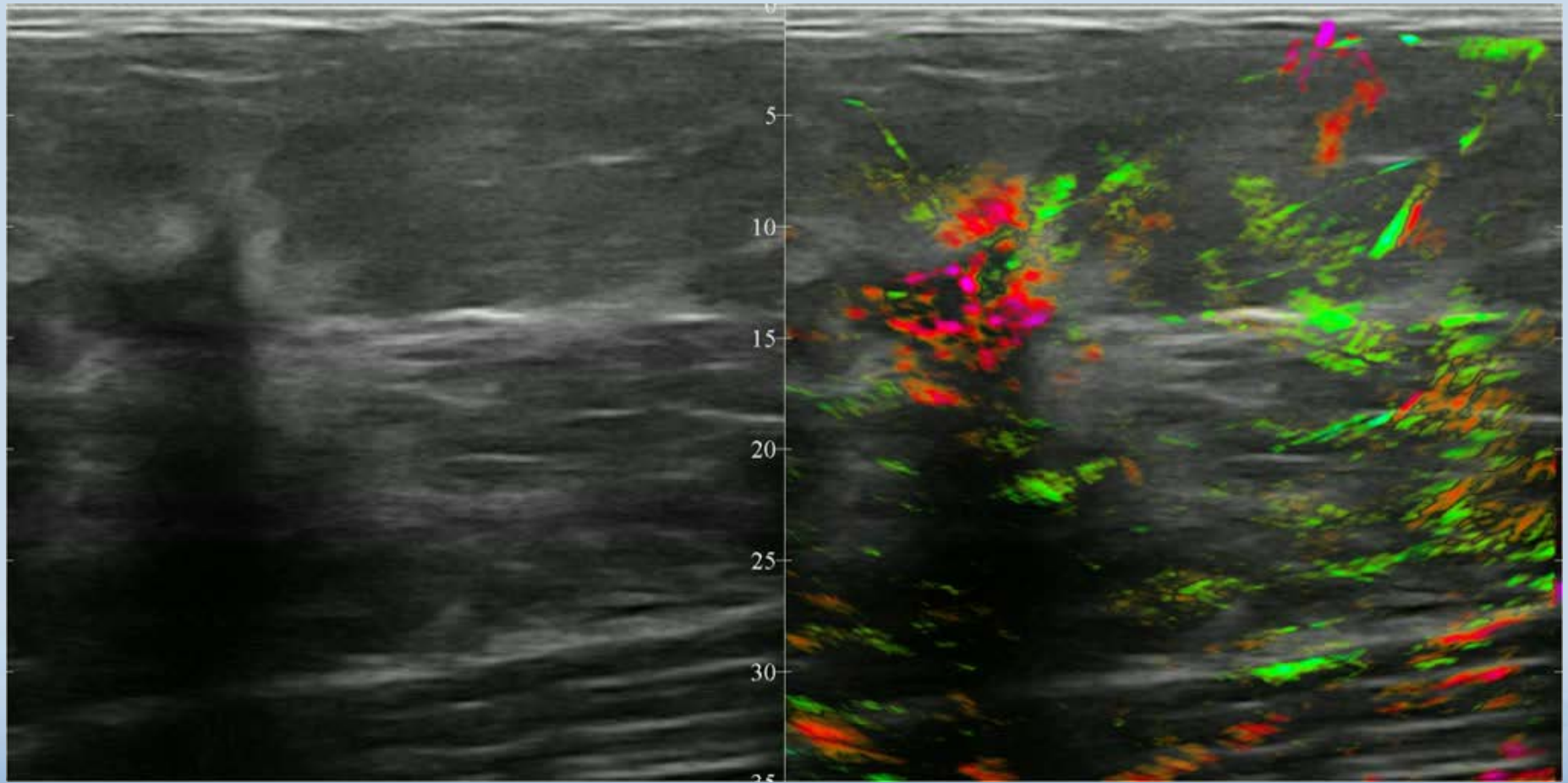


Invasive Ductal Carcinoma (Malignant)



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

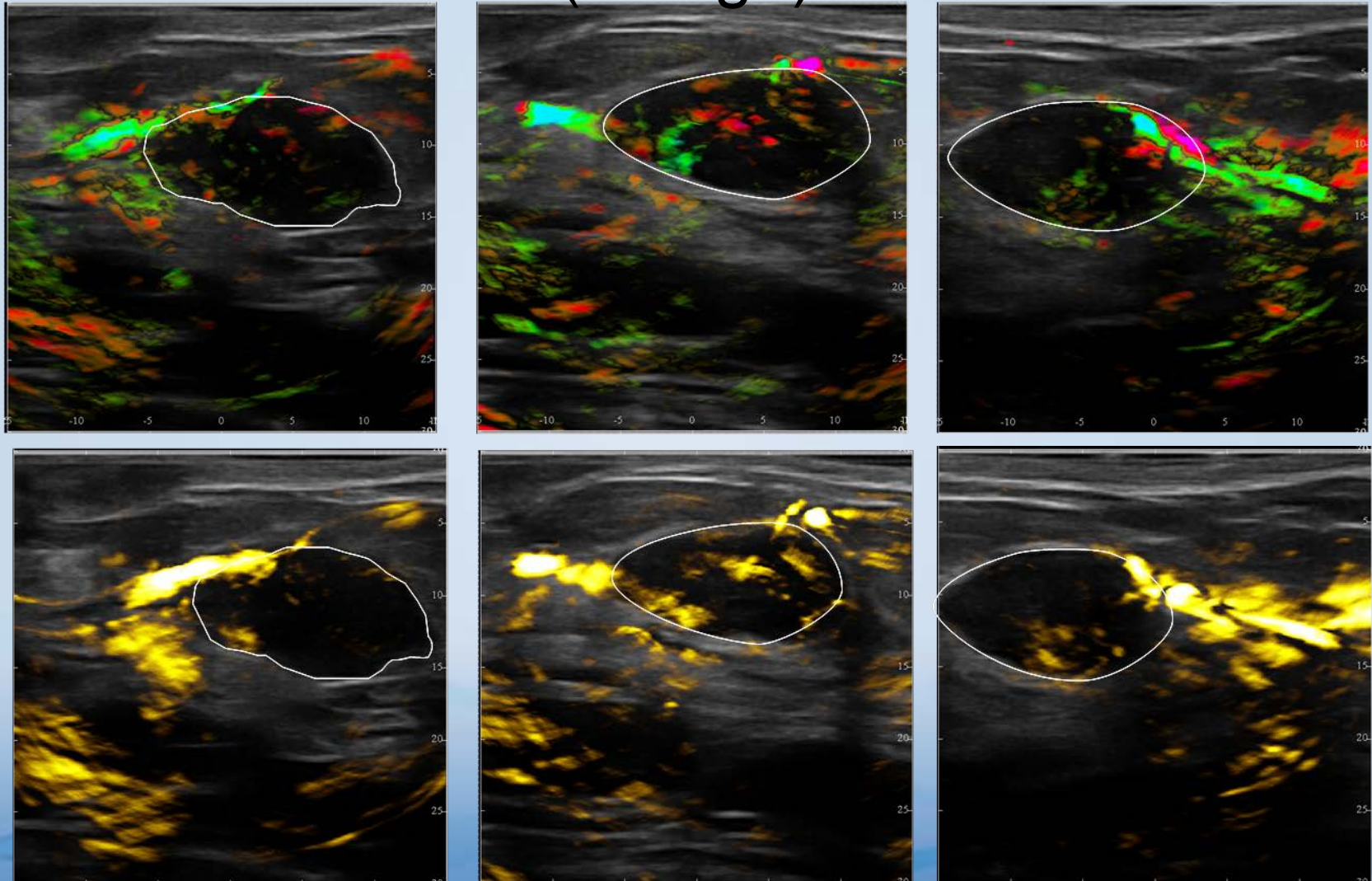
Invasive Ductal Carcinoma (Malignant)



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Fibroadenoma (benign)



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Clinical Phase II Trial Feasibility Study

- **155 subjects** with solid breast masses imaged with conventional diagnostic ultrasound underwent Imagio scans 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

- Probability of malignancy (POM) assigned by readers to each lesion based on **Imagio opto-acoustics (OA)** vs. **conventional diagnostic ultrasound (CDU)**
- Area under receiver operating characteristic (ROC) curve derived from POM compared to biopsy results and **sensitivity** and **specificity** were calculated
- OA had **same sensitivity** as CDU but **40% better specificity**

	OA	CDU
POM for all malignant lesions	73.6	62.1
Sensitivity	0.99	1.0
Specificity	0.237	0.161

Clinical Phase II Trial Feasibility Study

- Readers also classified lesions according to **BI-RADS** (Breast Imaging-Reporting and Data System) categories
- For 40 biopsied benign lesions, downgrades were achieved as follows
 - BI-RADS 3 ($\leq 2\%$ POM)
 - 5/5 (100%) remained BI-RADS 3
 - BI-RADS 4a ($>2\%$ to $\leq 10\%$ POM)
 - 12/22 (54%) downgraded to BI-RADS 3
 - BI-RADS 4b ($>10\%$ to $\leq 50\%$ POM)
 - 3/13 (23%) downgraded to BI-RADS 3
- All 34 biopsied cancerous lesions remained at original BI-RADS per site PI



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

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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