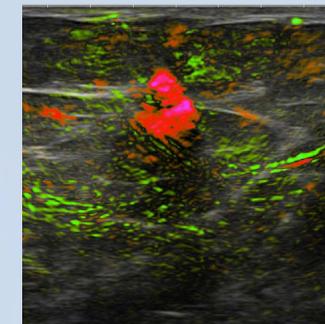
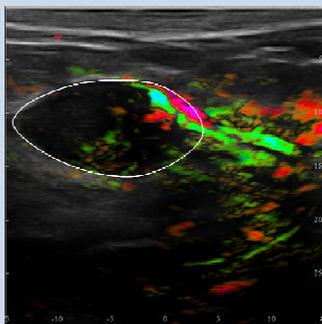


Opto-acoustic Image Fusion Technology for Diagnostic Breast Imaging in a Feasibility Study



SPIE Medical Imaging 2015, Orlando, Florida
February 22, 2015

Jason Zalev¹, Bryan Clingman¹, Don Herzog¹, Tom Miller¹,
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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

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Breast Cancer

- Over 38 million mammograms in USA per year¹
- 1.7 million breast biopsies in USA per year²
 - Over **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] - Silverstein, Melvin J., et al. "Image-detected breast cancer: state-of-the-art diagnosis and treatment." Journal of the American College of Surgeons (2009): 504-520.

[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

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Functional Opto-acoustic Imaging

Tumor Metabolism

As compared to normal tissue and benign tumors

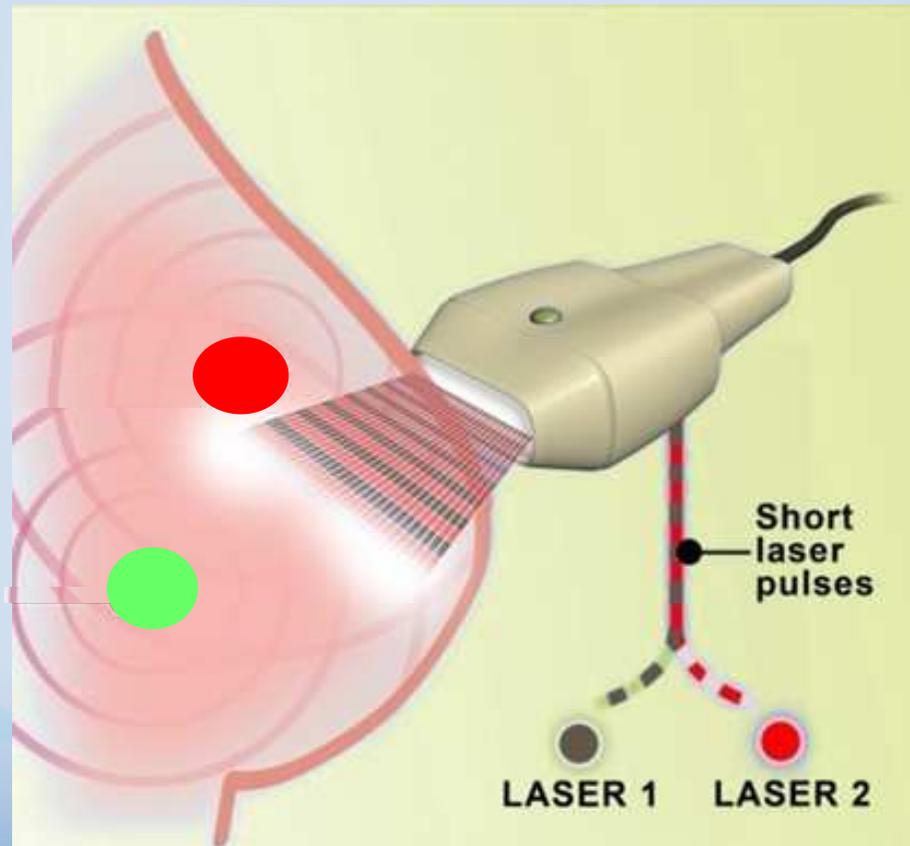
- cancers are **metabolically more active**
 - cancers have **more blood vessels** and **more blood**
 - cancers have **irregular branching vessels**
 - cancers **pull more oxygen out of blood** and thus **de-oxygenate tissues more**
 - cancers can have **hypoxic or necrotic regions of tissue**
- Functional 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

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Imagio™ Breast Imaging System

Functional Contrast

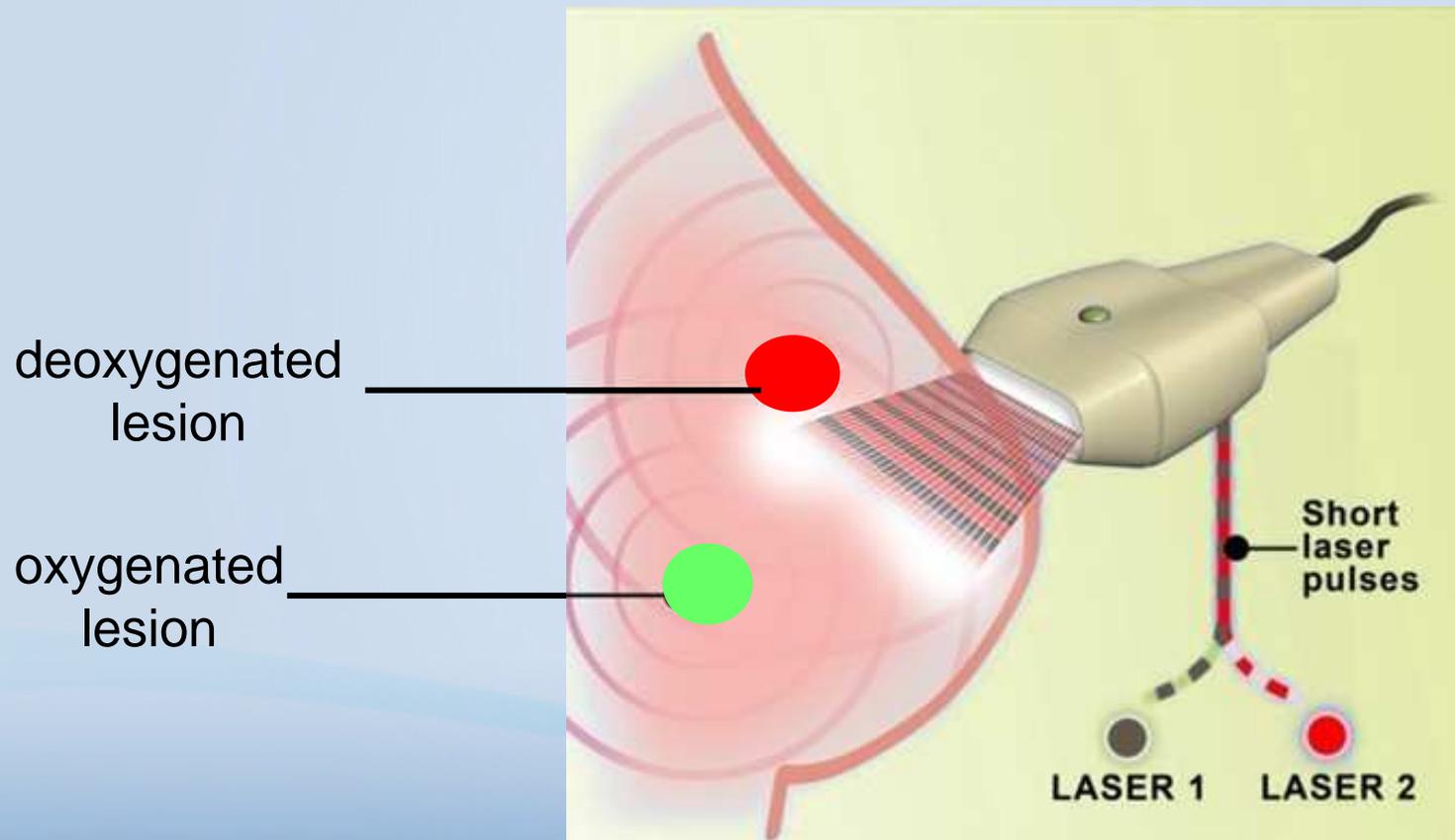


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Imagio™ Breast Imaging System

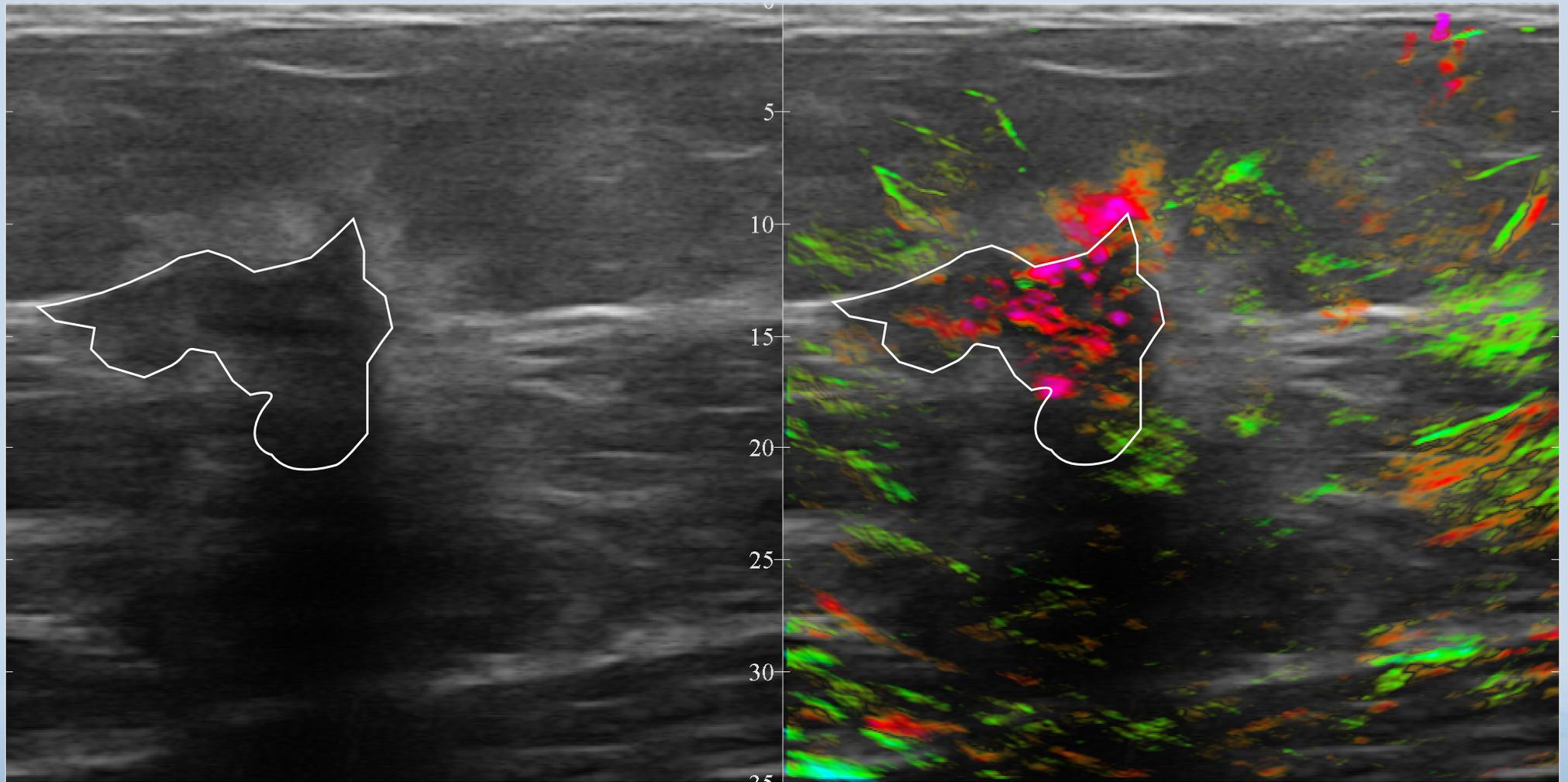
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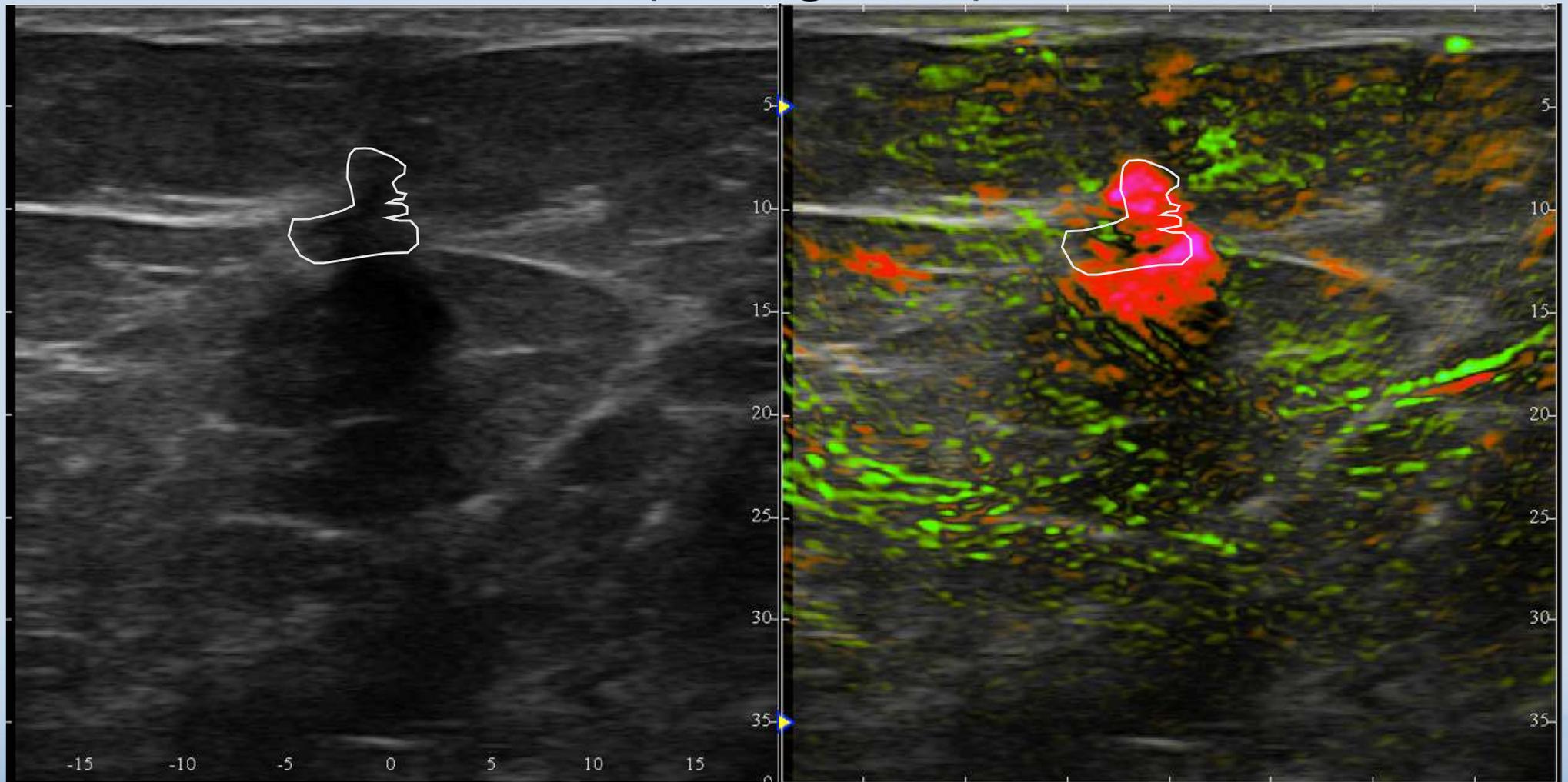
Invasive Ductal Carcinoma (Malignant)



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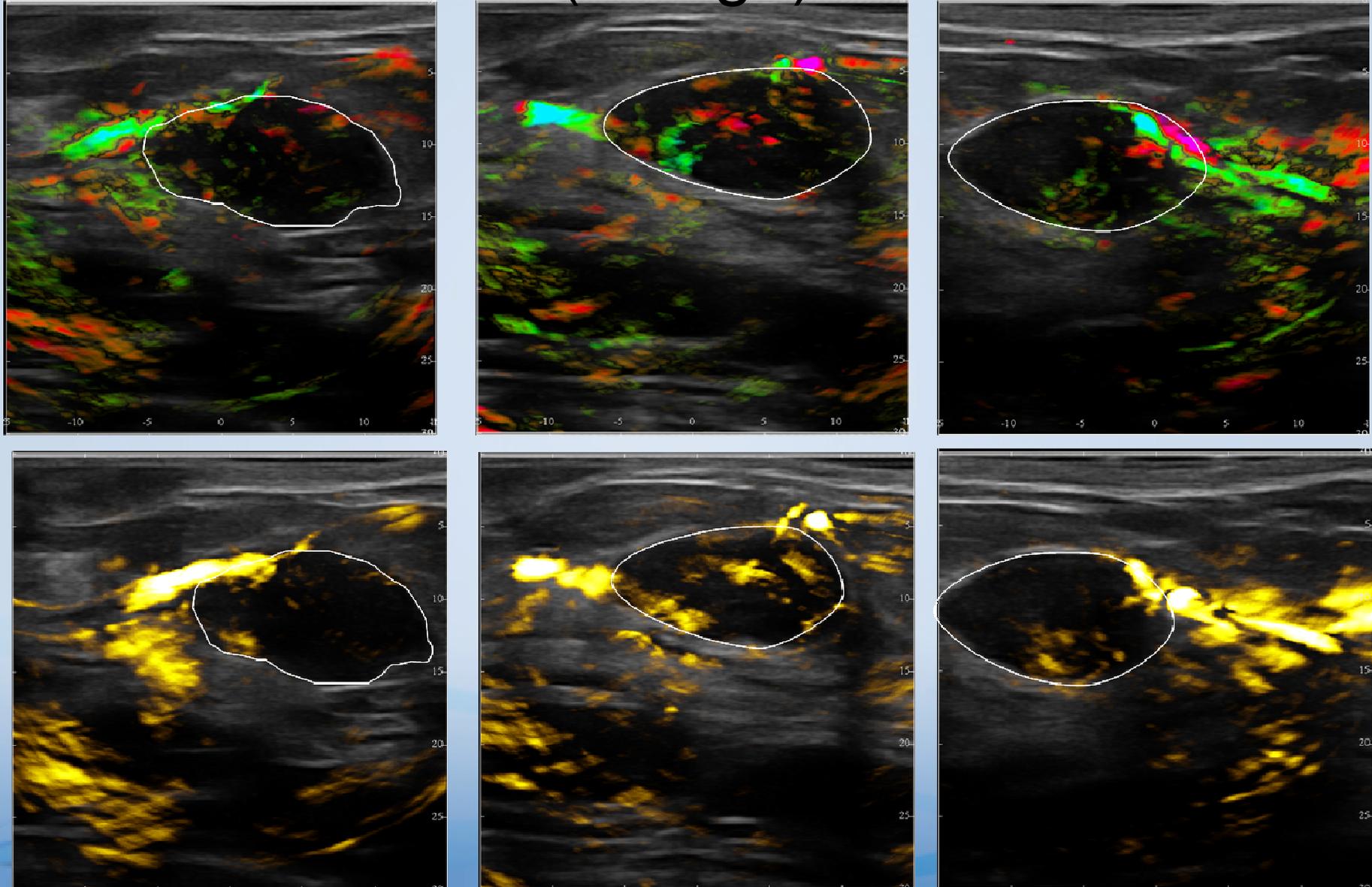
Invasive Ductal Carcinoma (Malignant)



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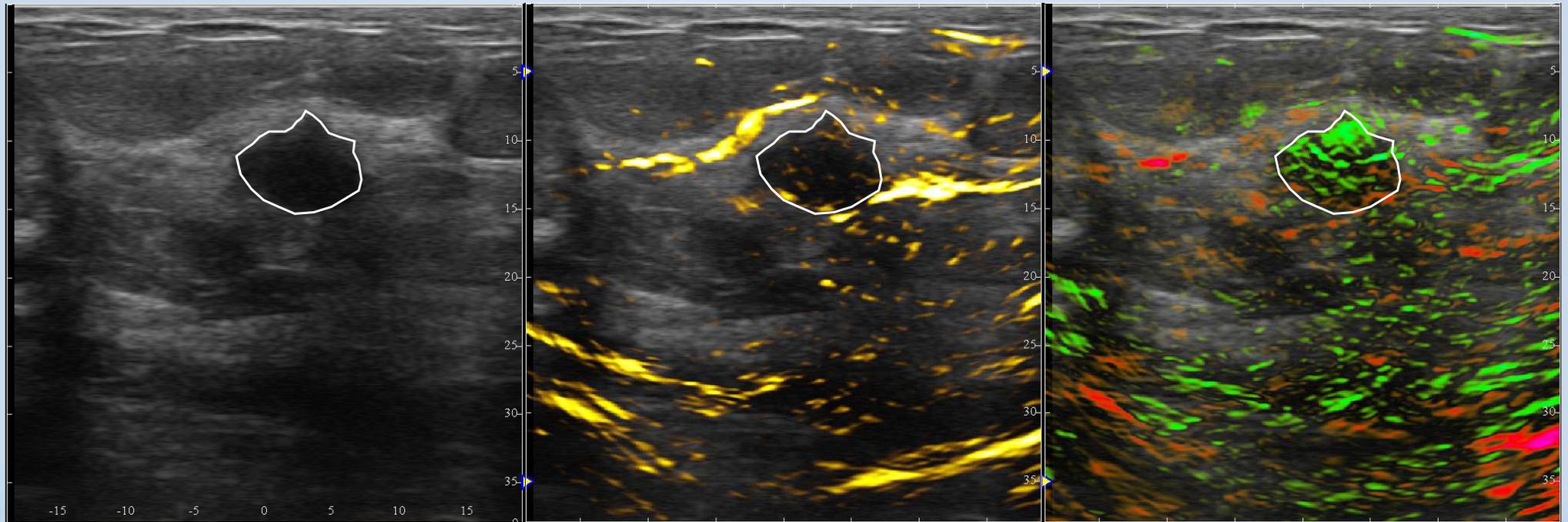
Fibroadenoma (benign)



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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 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

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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”

	OA	CDU
Sensitivity	0.99	1.0
Specificity	0.237	0.161

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

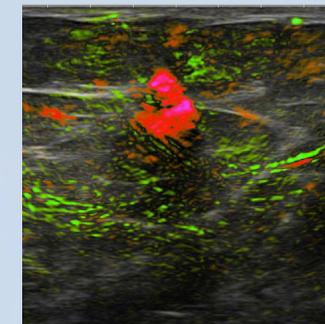
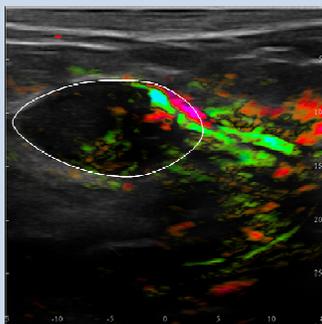
Conclusion

- 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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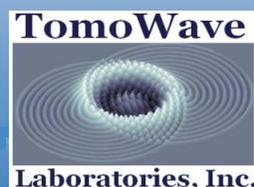


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