

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 **metabolism** of tumors
- The Imagio system could be used as an **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 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

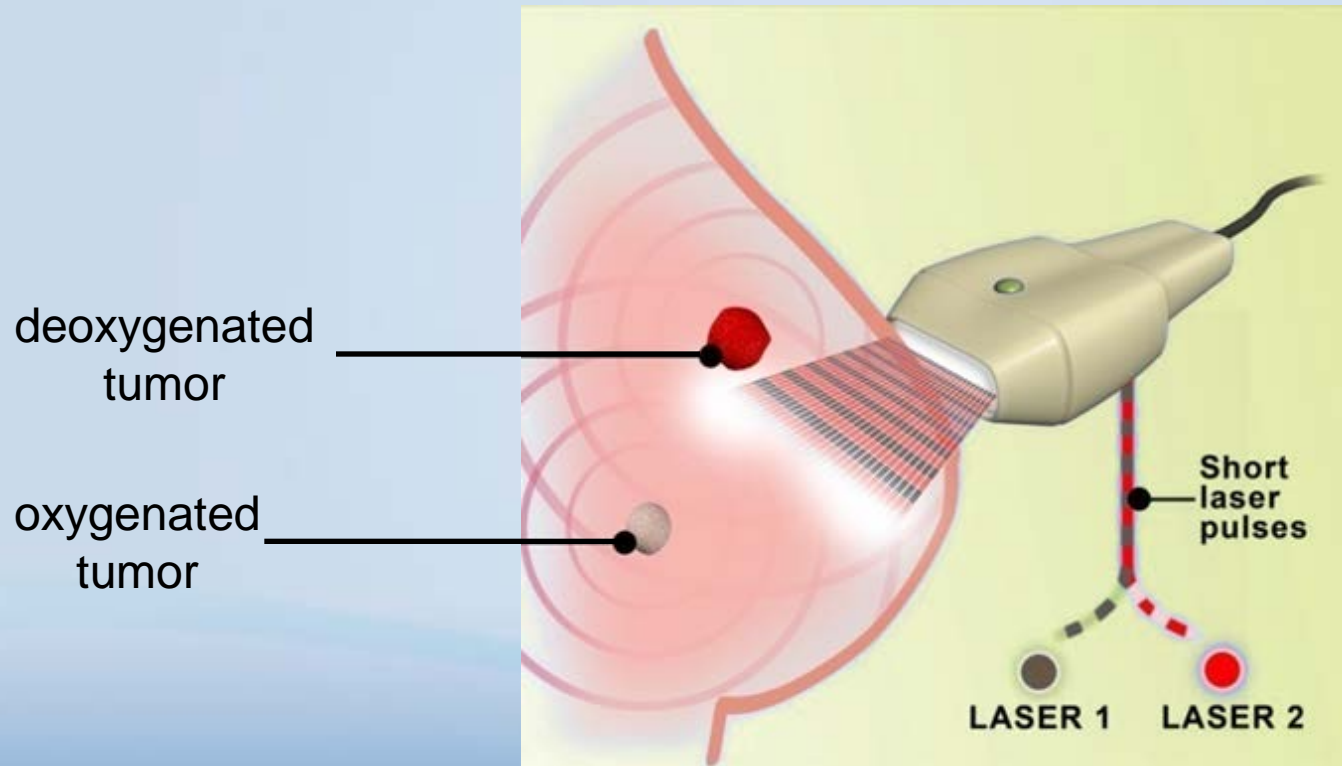
[2] - Stavros, A. T., et al., Breast Ultrasound, Lippincott Williams & Wilkins, 2003

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



"IMAGINATION IS JUST THE BEGINNING."

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Functional Opto-acoustic Imaging

Tumor Metabolism

As compared to normal tissue and benign tumors

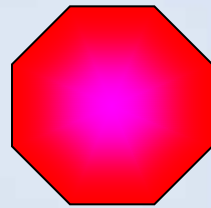
- cancers are **metabolically more active**
 - cancers have **more blood vessels** and **more blood**
 - cancers have **irregular branching vessels**
 - cancers **pull more oxygen out of blood** and thus **de-oxygenate tissues more**
 - cancers can have **hypoxic or necrotic regions of tissue**
- Functional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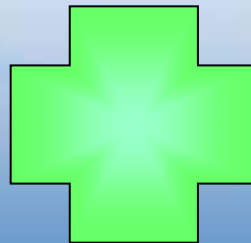
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Oxygenation Level of Tumors

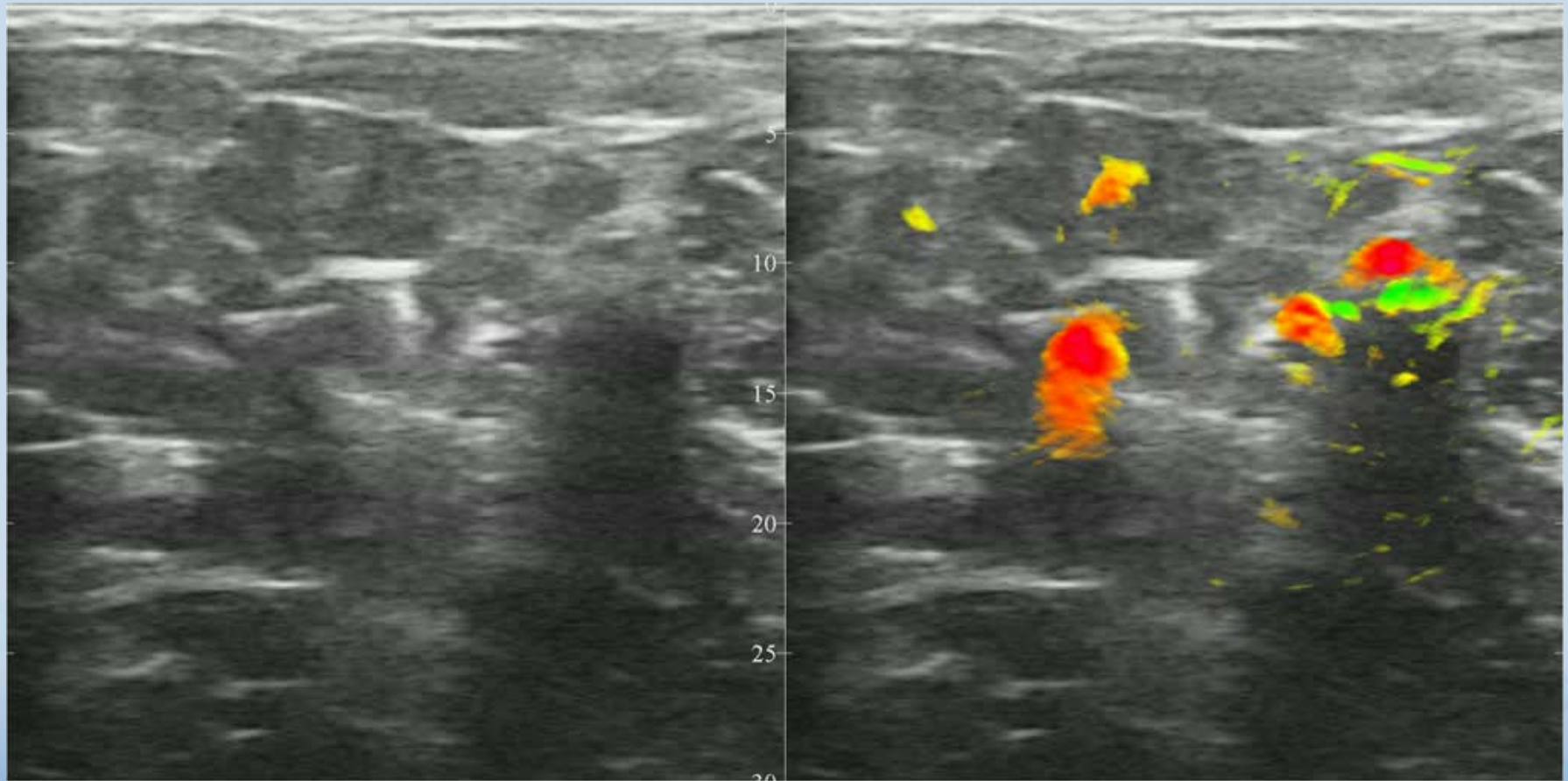
- Deoxygenated Tumor
 - Signifies Malignant (Bad) – Red



- Oxygenated Tumor
 - Signifies Benign (Good) - Green



Vessels in human arm



Normal Artery SO₂ = 95-99%

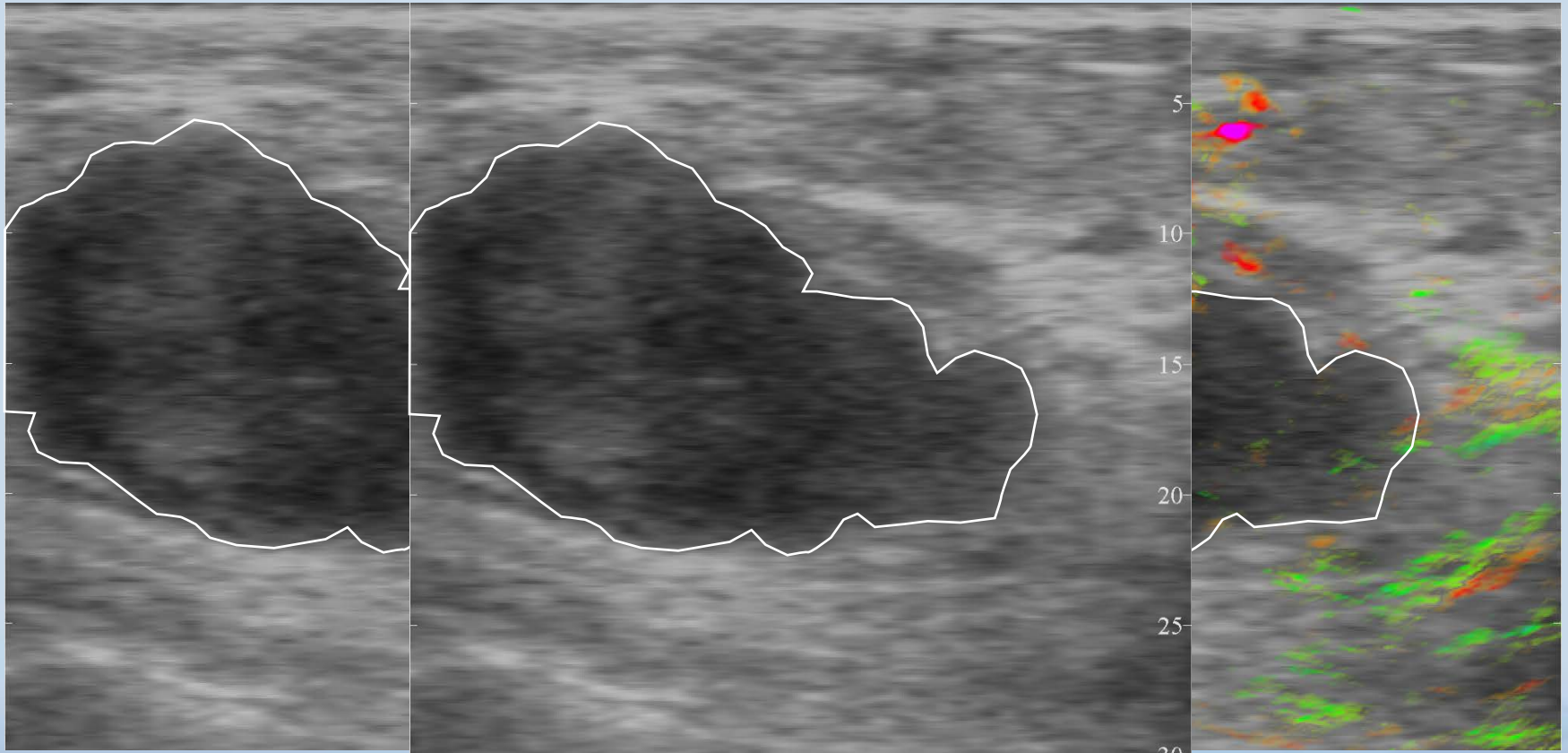
Normal Vein SO₂ = 60-80%

● - vein ● - artery

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Breast Tumor

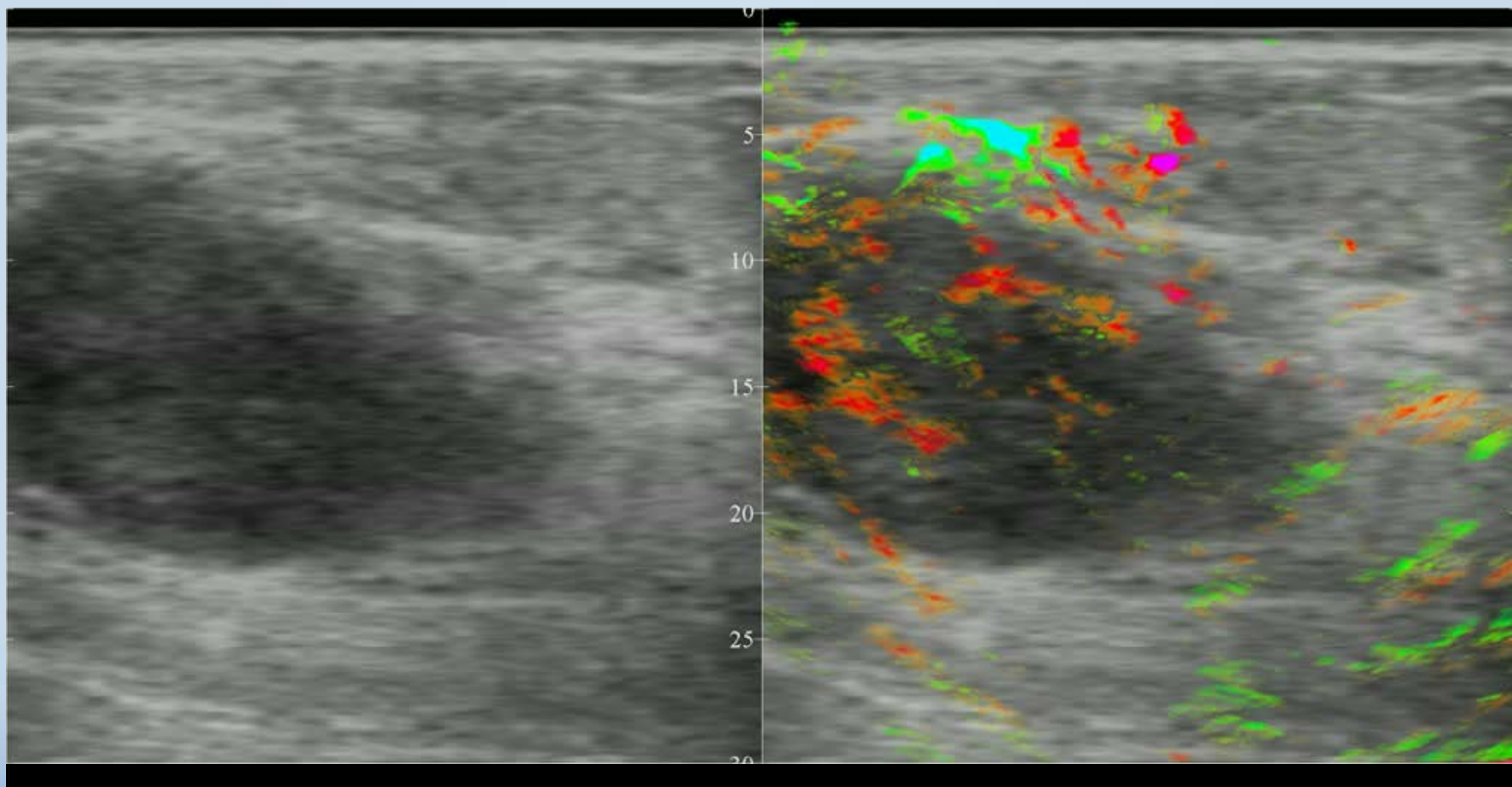


pF Subject 84-012 - Classical IDC, gr 3 - OA ff #1

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Breast Tumor

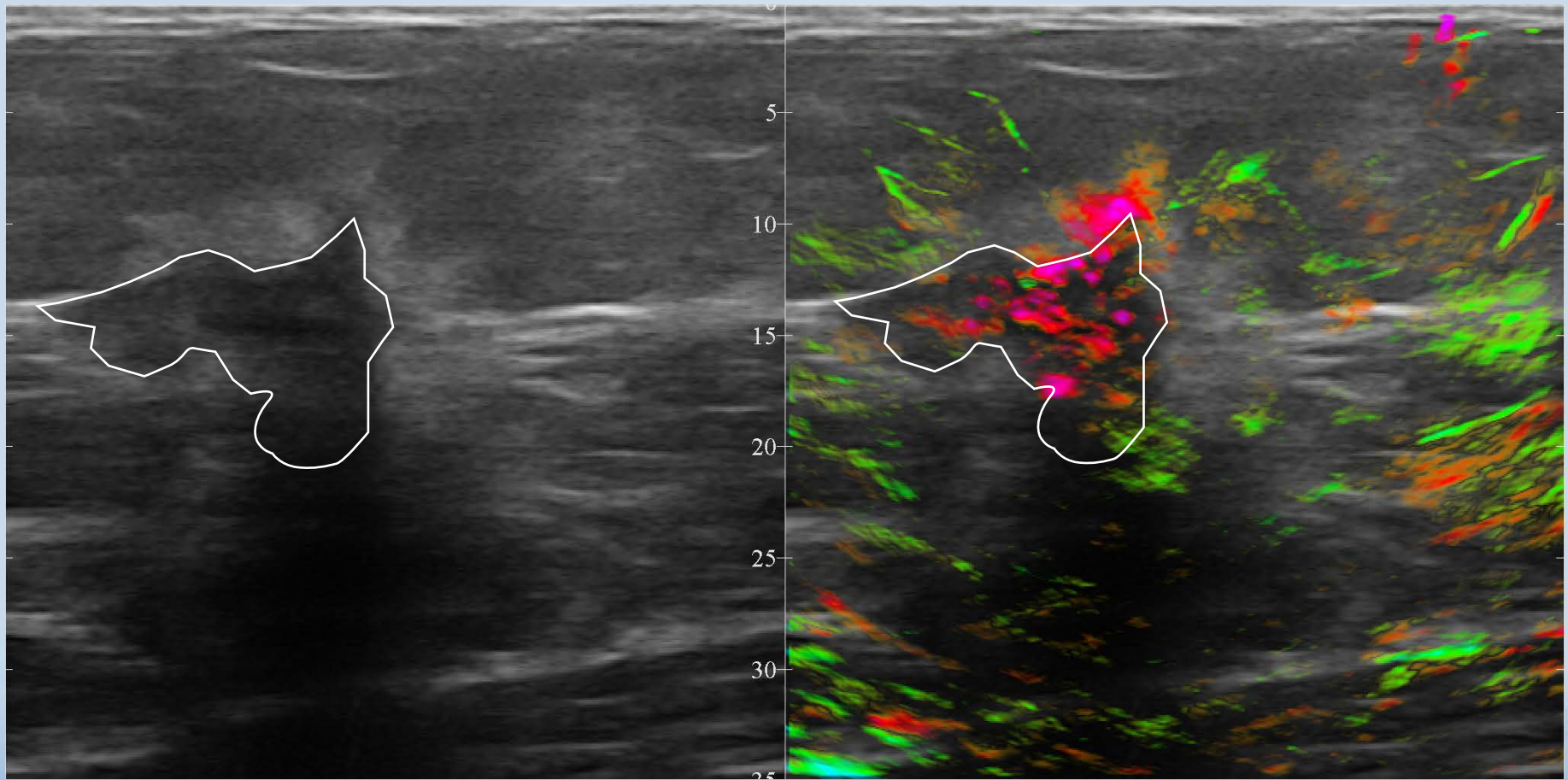


Invasive Ductal Carcinoma (Malignant)

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Breast Tumor #2



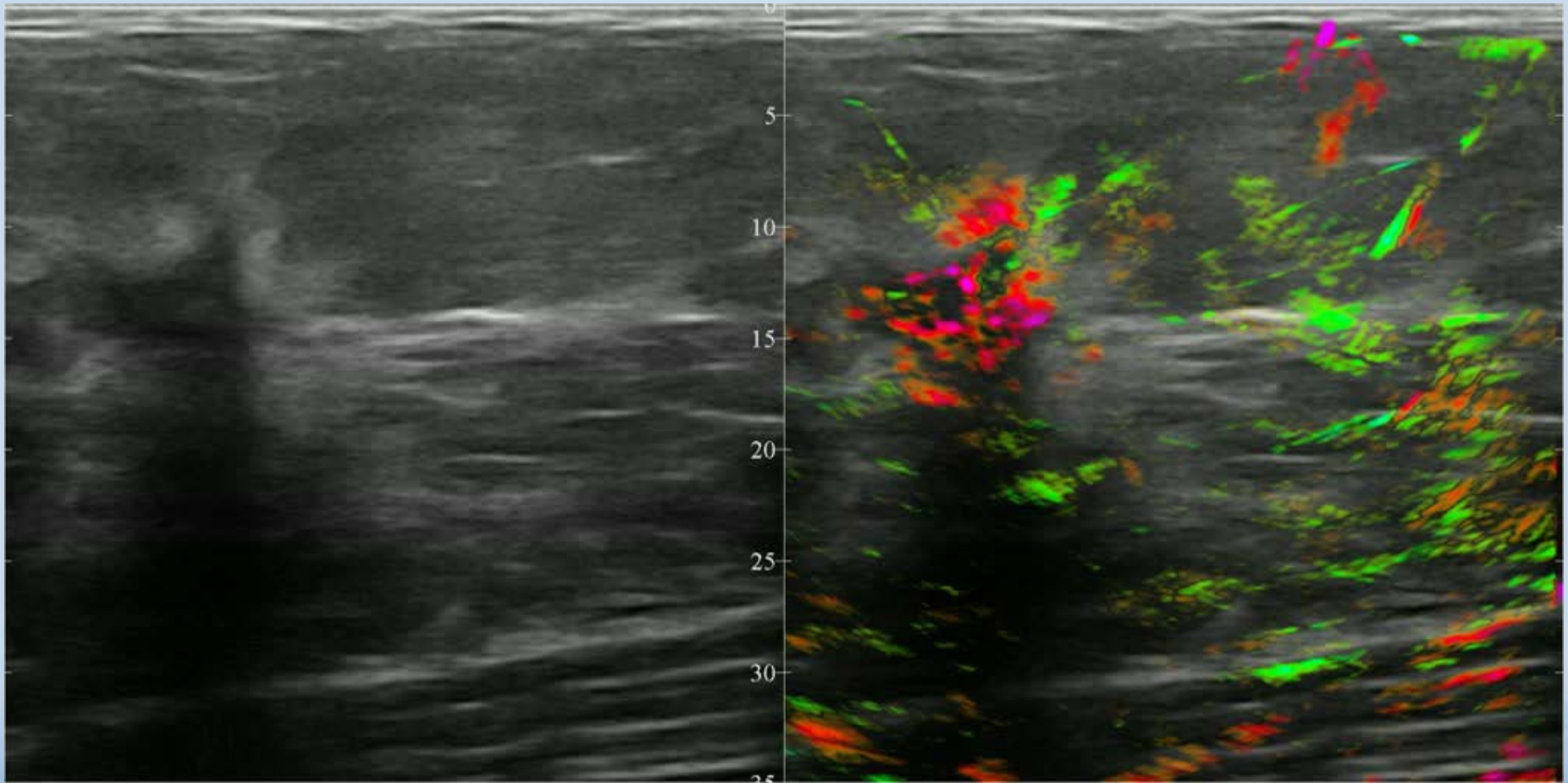
Invasive Ductal Carcinoma (Malignant)

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

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Breast Tumor #2

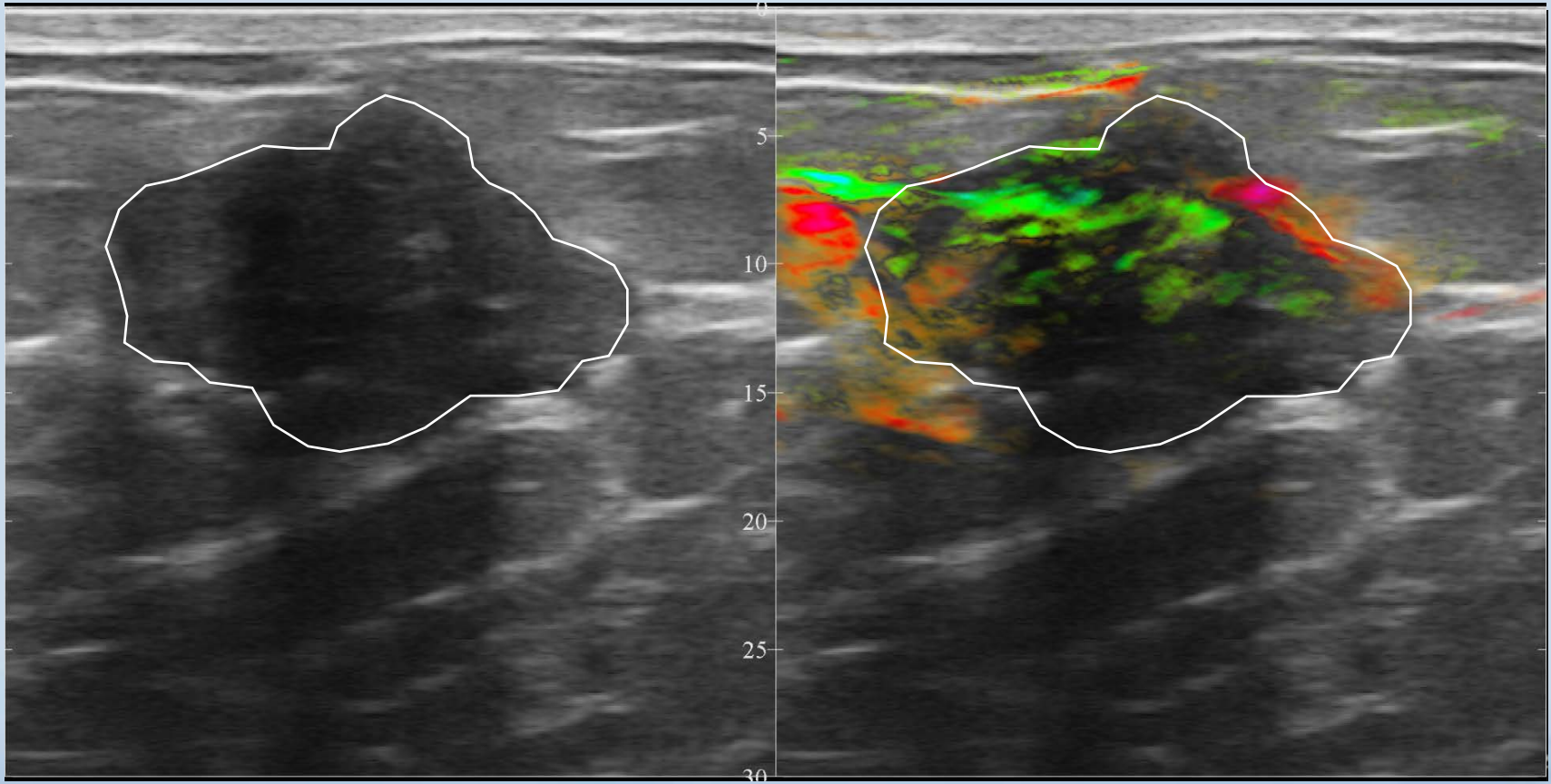


Invasive Ductal Carcinoma (Malignant)

"IMAGINATION IS JUST THE BEGINNING."

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Breast Tumor #3



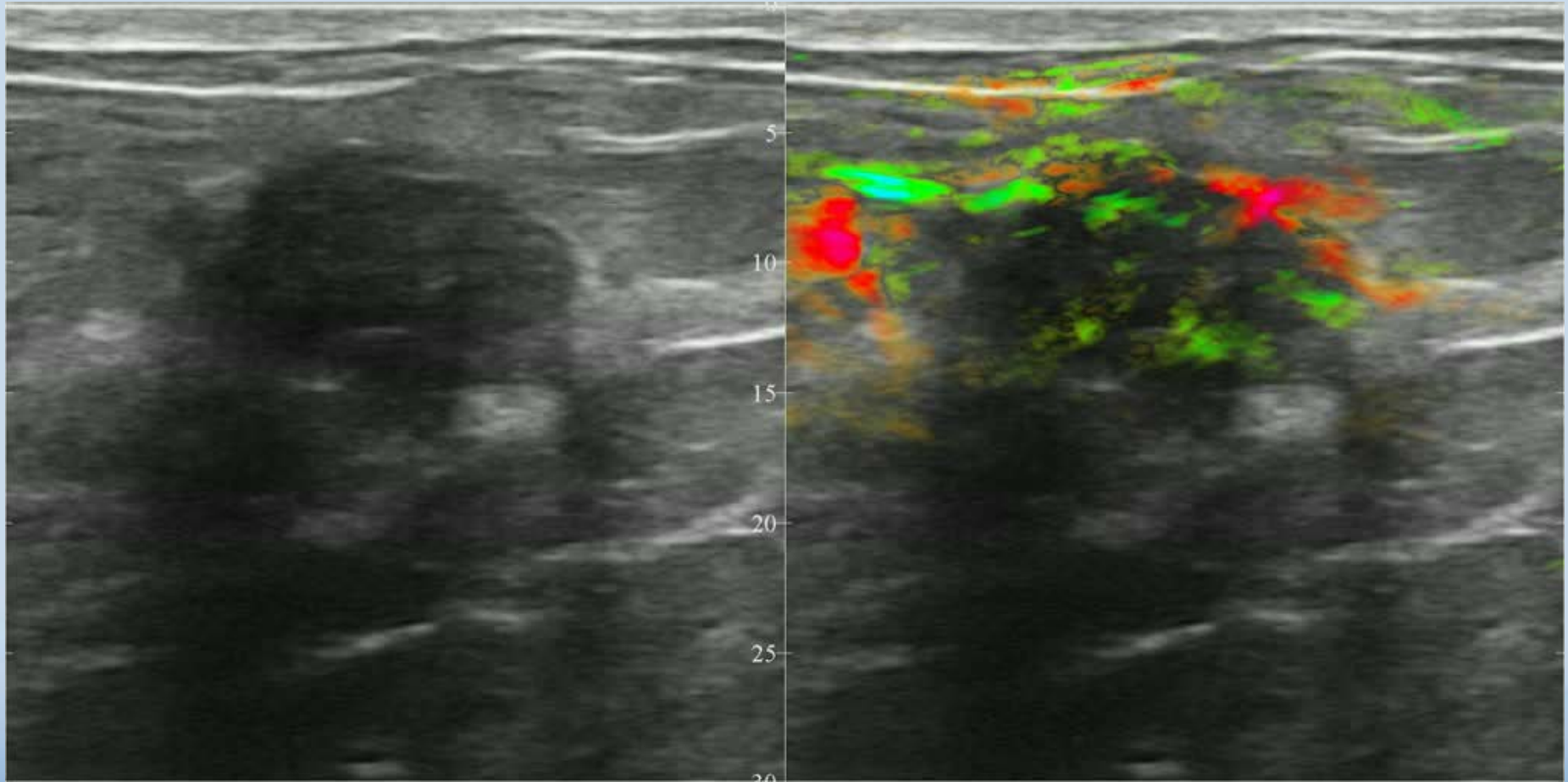
Fibroadenoma (Benign)

Subject 08-734 - FA - OA ff #2

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Breast Tumor #3



Fibroadenoma (Benign)

"IMAGINATION IS JUST THE BEGINNING."

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