

## Intraoperative Optical Breast Tissue Characterization Device for Tumor Margin Assessment

J. Quincy Brown, Ph.D.<sup>1</sup>, Torre M. Bydlon, B.S.<sup>1</sup>, Stephanie A. Kennedy, B.S.<sup>1</sup>, Lisa Richards, B.S.<sup>1</sup>, Marlee S. Junker, M.S.<sup>1</sup>, Gregory M. Palmer, Ph.D.<sup>2</sup>, Joseph Geradts, M.D.<sup>3</sup>, Lee G. Wilke, M.D.<sup>4</sup> and Nirmala Ramanujam, Ph.D.<sup>1</sup>.

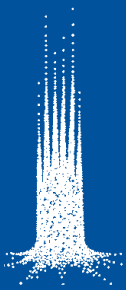
<sup>1</sup> Dept. of Biomedical Engineering, Duke University

<sup>2</sup> Dept. of Radiation Oncology, Duke University Medical Center

<sup>3</sup> Dept. of Pathology, Duke University Medical Center

<sup>4</sup> Dept. of Surgery, Duke University Medical Center

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# Problem: Cancer is not Always Completely Removed during Surgery



US Breast Cancer Incidence

250,000 Women

Stage 0, I, II Breast Cancer

215,000 Women

BCS Instead of Mastectomy

180,000 Women

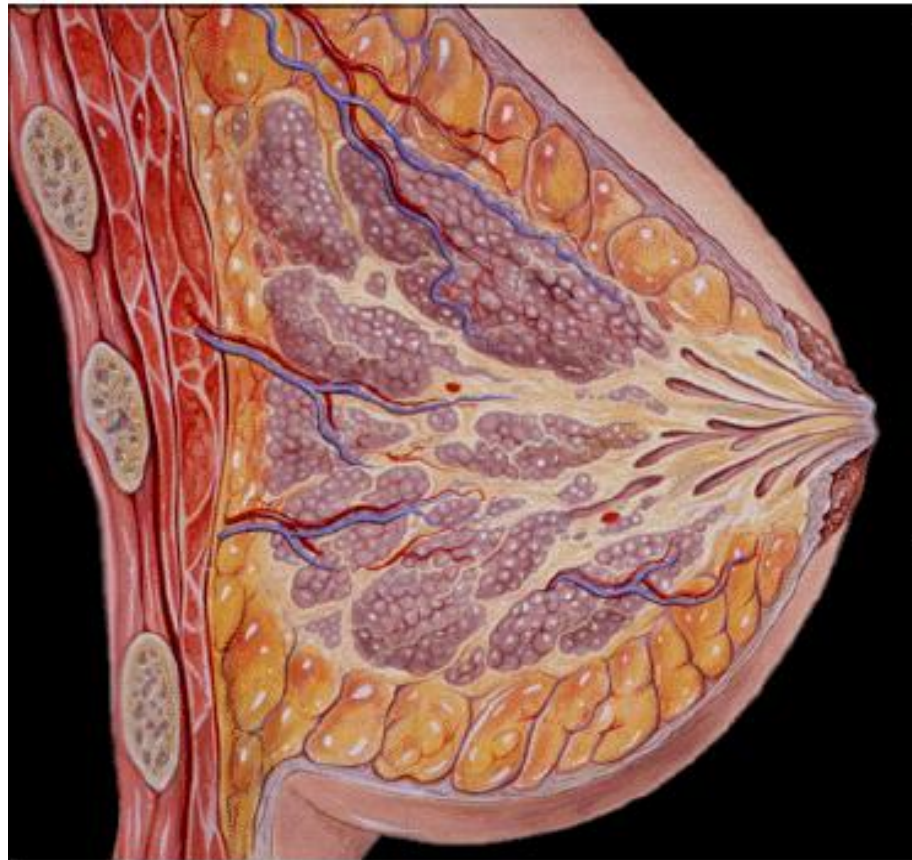
**Surgery (lumpectomy)**



Lump and surrounding tissue is removed

**20-70% require a 2<sup>nd</sup> surgery!<sup>1</sup>**

# Optical contrast in the breast



## *Oxygenation/ Metabolism*

- Hemoglobin oxygenation
- Total hemoglobin content
- Redox ratio
- Porphyrins

## *Cellular proliferation / death*

- Size, density of cellular components

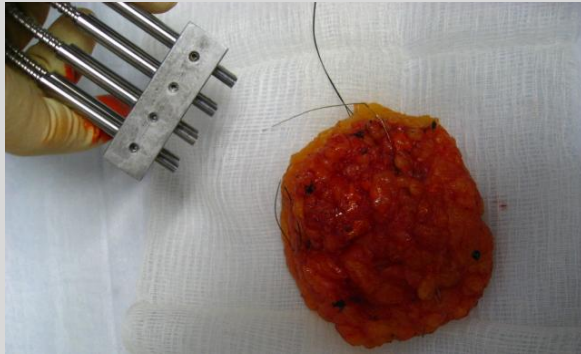
## *Extracellular matrix*

- Collagen (stroma)
- $\beta$ -carotene (adipose tissue)

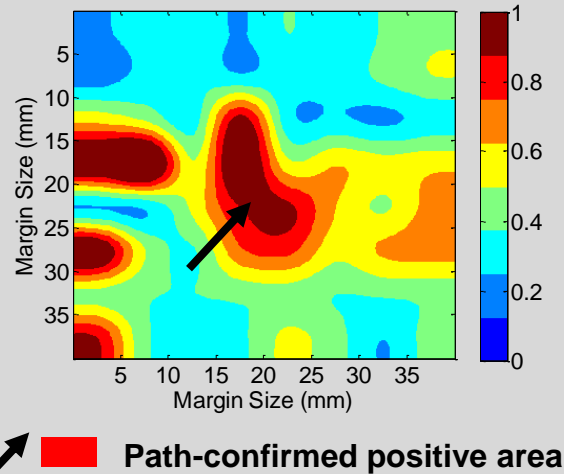


# Our Solution: Handheld Optical Spectral Imaging Probe

## I. Tumor margins imaged with probe array



## II. Informative margin maps



## III. Margin Classification & Feedback to Surgeon



**Study endpoint: In 150 patient study, estimate the reduction in missed positive margins, and unnecessary tissue removal, that intra-operative use of the probe would provide.**

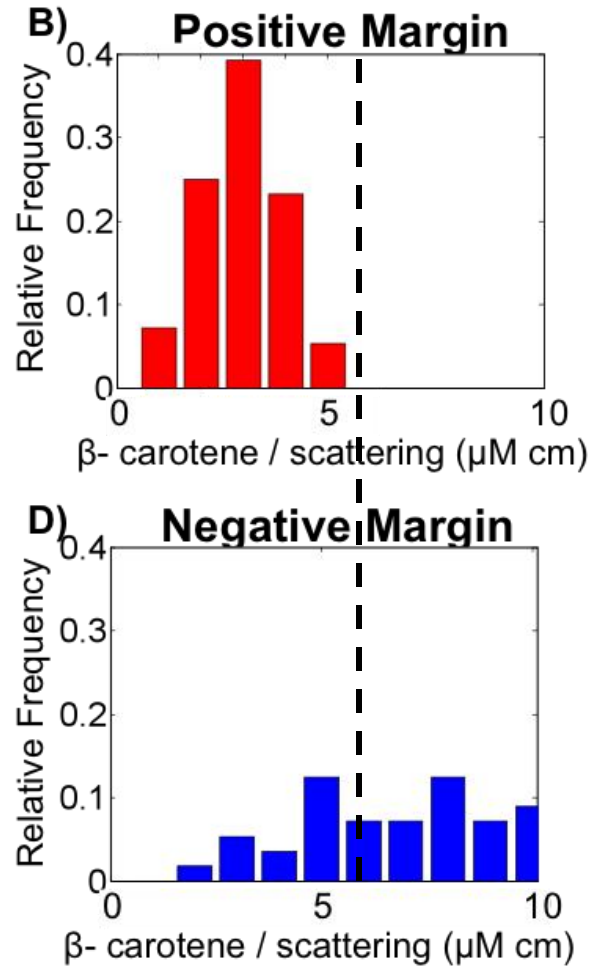
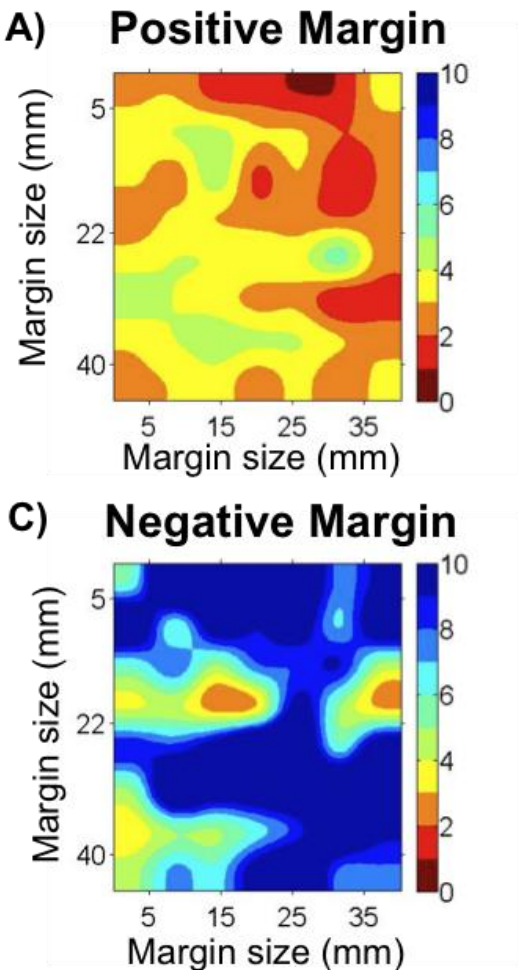


# Current Methods for Intra-operative Margin Assessment

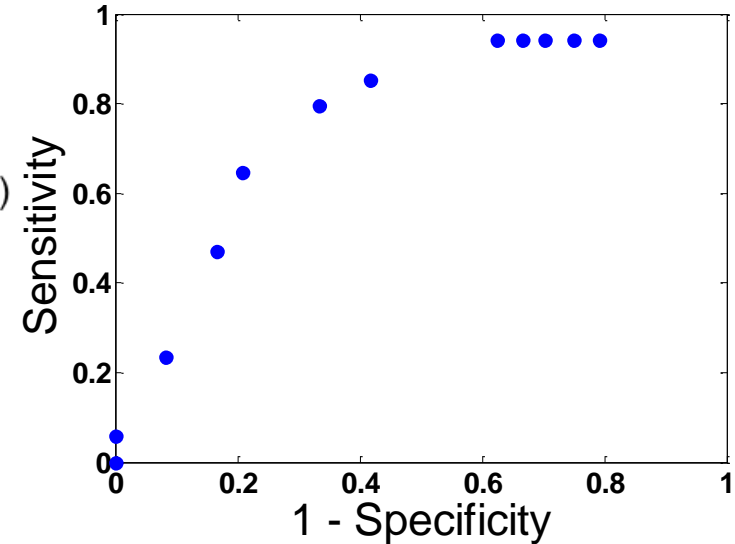


Method / Technology	Touch-Prep	Frozen Section	Optical Imaging Probe
Pathologist required in OR?	Yes	Yes	Pathologist not required
Percentage of Margin Examined	~100%	<1%	Entire margin
Time Required	~20 min	~20 min	< 20 min
Interferes with pathology?	No	Yes	Non-destructive
Problematic with fatty tissues	No	Yes	Able to use on all tissues
Sensing Depth	Surface only	Up to 2 cm (focal)	1 - 2mm (standard of care)

# Image Analysis and Predictive Model



**ROC curve from cross-validated predictive model**



**Sensitivity = 80%**

**Specificity = 67%**

**AUC = 0.77**

# Margin Classification Performance (Results from 50 patients)



## *Surgeon*

	Path Positive	Path Negative
Predicted Positive	19	16
Predicted Negative	15	5
Total	34	21

**Sensitivity: 56%**  
**Specificity: 24%**

## *Surgeon + Probe*

	Path Positive	Path Negative
Predicted Positive	32	7
Predicted Negative	2	14
Total	34	21

**Sensitivity: 94%**  
**Specificity: 67%**

Use of the probe in conjunction with the surgeon's judgment would result in:

- >7-fold reduction in false-negatives
- >2-fold reduction in false-positives

# Summary and Conclusions



- Quantitative optical spectral imaging provides molecular composition maps of the specimen surface
- Imaging technology allows rapid, intra-operative coverage of the entire specimen surface
- Results from 50 patients show that in combination with the surgeon's judgment, the probe reduces missed positive margins by 87% and unnecessary tissue removal by 56%
  - The probe alone reduces missed positives by 56% and unnecessary tissue removal by 53%
- Technology has a sensing depth (2 mm) that is consistent with standard-of-care pathology