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Use of Adjunct Wide-Field Optical Coherence Tomography to Visualize Margins During Breast Conserving Surgery: A Case Series

Amelia Tower, DO, FACOS, FACS
Breast Surgical Oncologist-Breast Associates of Texas
Assistant Dean of Academic Affairs-Transition to Residency
Associate Professor, Department of Medical Education
Texas A&M University College of Medicine

AMERICAN COLLEGE OF OSTEOPATHIC SURGEONS

Disclosures

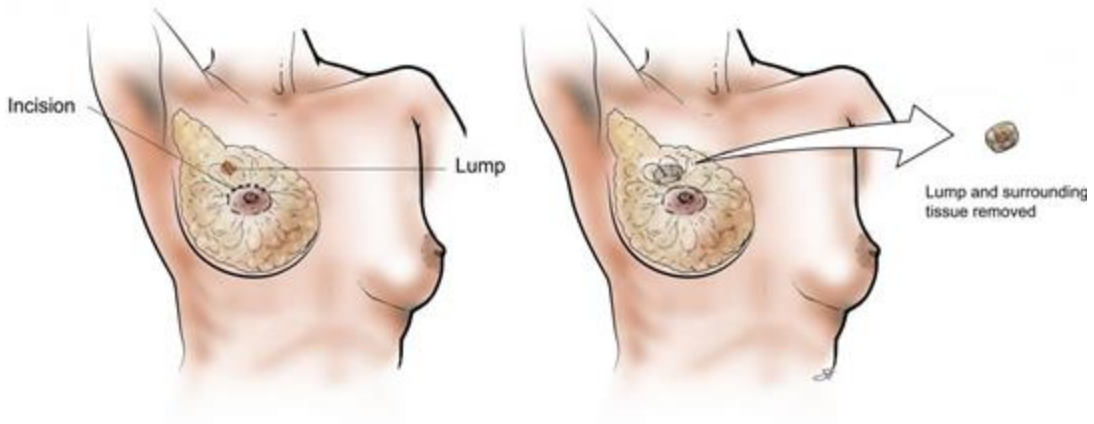
My remarks during this presentation and the information contained herein are based on my own independent clinical experience and research. I previously served as a paid consultant and key opinion leader for Perimeter Medical Imaging AI. At the time of this presentation, I no longer have a financial relationship with the company.

Objectives

1. Overview of Re-excision “Epidemic” in Breast Conserving Surgery
2. Introduce Optical Coherence Tomography (OCT) technology
3. Implementation of OCT into breast surgical practice
4. Case Reviews using OCT

Background: Breast Conserving Surgery

- Breast Conserving Surgery/Lumpectomy
  - Procedure=Most performed surgical treatment for early-stage breast cancer
  - Goal=Remove tumor with a small amount of surrounding noncancerous breast tissue
  - Results=Fewer complications, shorter recovery time[1]



[1]Fisher B, Anderson S, Bryant J, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med*. 2002;347(16):1233-1241. doi:10.1056/NEJMoa022152

Background: Reoperations

Professional societies have created Guidelines and a Toolbox to address the lumpectomy re-excision **"Epidemic"**

THE AMERICAN SOCIETY OF Breast Surgeons – Official Statement –

Consensus Guideline on Breast Cancer Lumpectomy Margins

Purpose

To provide an algorithm for re-excision surgery after lumpectomy or breast conservation for breast cancer (invasive and in-situ).

Associated ASBrS Guidelines or Quality Measures

1. Print Consensus Statement: Position statement on breast cancer lumpectomy margins – Revised January 16, 2013
2. Quality Measure: Specimen Orientation for Partial Mastectomy or Excisional Breast Biopsy – Updated March 27, 2014
3. Guideline: Performance and Practice Guidelines for Breast-Conserving Surgery-Partial Mastectomy – Revised February 22, 2015

Methods

Literature review inclusive of meta-analyses evaluating the impact of margin positivity on local recurrence rates, randomized controlled trials on rates of margin re-excision with technique, and large-sample retrospective reviews of data associated with margin re-excision. This is not a complete systematic review but a comprehensive review of the modern literature on this subject. The ASBS Research Committee developed a consensus document which was reviewed and approved by the ASBS Board of Directors.

Summary of Data Reviewed

1. Margin status: The presence or absence of malignant cells on the edge or close to the edge of a partial mastectomy specimen is called the surgical margin status. This margin status serves as a surrogate marker of residual disease in the breast and has an impact on patient risk of in-breast tumor recurrence (IBTR). There is evidence of significant variation in margin definitions, positive margin rates, and re-excision lumpectomy rates (RELR) in patients undergoing BCS.[1-15] Surgeon opinion of a negative surgical margin ranges from "ink negative" to greater than 1 cm, providing one potential explanation for variation in surgical re-excision rates.[1-4,9-10,12,15-18]
2. Surgical specimen orientation: Indeterminate, high-risk, or confirmed breast cancer tissue specimens should have margins oriented intraoperatively by the surgeon, accompanied by clear communication with pathology and radiology.[19-22] After the

Annals of SURGICAL ONCOLOGY

REVIEW ARTICLE – BREAST ONCOLOGY

Society of Surgical Oncology–American Society for Radiation Oncology–American Society of Clinical Oncology Consensus Guideline on Margins for Breast-Conserving Surgery with Whole-Breast Irradiation in Ductal Carcinoma In Situ

Monica Morrow, MD[1], Kimberly J. Van Zee, MD[2], Lawrence J. Solin, MD[3], Nehmat Houssami, MBBS, PhD[4], Mariana Chavez-MacGregor, MD[5], Jay R. Harris, MD[6], Janet Horton, MD[6], Shelley Hwang, MD[7], Peggy L. Johnson, MD[8], M. Luke Marinovich, PhD[4], Stuart J. Schnitt, MD[9], Irene Wapnir, MD[10], and Meena S. Moran, MD[11]

[1]Breast Service, Department of Surgery, Memorial Sloan Kettering Cancer Center, New York, NY; [2]Department of Radiation Oncology, Albert Einstein Healthcare Network, Philadelphia, PA; [3]Screening and Test Evaluation Program (STEP), Sydney School of Public Health, Sydney Medical School, The University of Sydney, Sydney, NSW, Australia; [4]Departments of Medical Oncology and Health Service Research, University of Texas MD Anderson Cancer Center, Houston, TX; [5]Department of Radiation Oncology, Harvard Medical School, Boston, MA; [6]Department of Radiation Oncology, Duke University Medical Center, Durham, NC; [7]Department of Surgery, Duke University Medical Center, Durham, NC; [8]Advocate in Science, Susan G. Komen, Kansas City; [9]Department of Pathology, Harvard Medical School, Boston, MA; [10]Department of Surgery, Stanford University School of Medicine, Stanford, CA; [11]Department of Therapeutic Radiology, Yale School of Medicine, Yale University, New Haven, CT

ABSTRACT

Purpose. Controversy exists regarding the optimal negative margin width for ductal carcinoma in situ (DCIS) treated with breast-conserving surgery and whole-breast irradiation.

Methods. A multidisciplinary consensus panel used a meta-analysis of margin width and ipsilateral breast tumor recurrence (IBTR) from a systematic review of 20 studies including 7,883 patients and other published literature as the evidence base for consensus.

Results. Negative margins halve the risk of IBTR compared with positive margins defined as ink on DCIS. A 2-mm margin minimizes the risk of IBTR compared with smaller negative margins. More widely clear margins do not significantly decrease IBTR compared with 2-mm margins. Negative margins narrower than 2 mm alone are not an indication for mastectomy, and factors known to affect rates of IBTR should be considered in determining the need for re-excision.

Conclusion. Use of a 2-mm margin as the standard for an adequate margin in DCIS treated with whole-breast irradiation is associated with lower rates of IBTR and has the potential to decrease re-excision rates, improve cosmetic outcomes, and decrease health care costs. Clinical judgment should be used in determining the need for further surgery in patients with negative margins narrower than 2 mm.

Breast-conserving therapy (BCT), defined as surgical excision of the primary tumor with a margin of surrounding

Review Article

Update of the American Society of Breast Surgeons Toolbox to address the lumpectomy reoperation epidemic

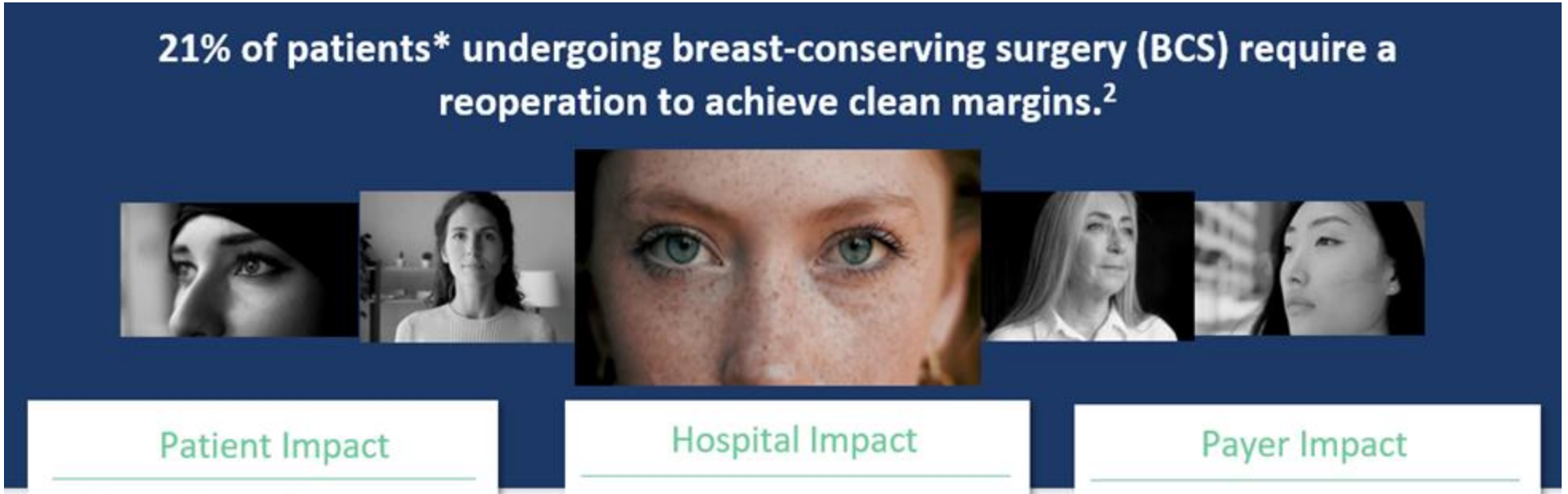
Maureen P. McEvoy[1], Jeffrey Landercasper[2], Hussani R. Naik[3], Sheldon Feldman[4]

Introduction

Background

McEvoy MP, Landercasper J, Naik HR, Feldman S. Update of the American Society of Breast Surgeons Toolbox to address the lumpectomy reoperation epidemic. Gland Surg. 2018; 7: 536-553. doi: 10.21037/gs.2018.11.03 3.
Landercasper J, Attai D, Atisha D et al. Toolbox to Reduce Lumpectomy Reoperations and Improve Cosmetic Outcome in Breast Cancer Patients: The American Society of Breast Surgeons Consensus Conference. Ann Surg Oncol. 2015; 22: 3174-3183. doi: 10.1245/s10434-015-4759-x 4.
Moran MS, et al. Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer. Ann Surg Onc. 2014 Mar;21(3):704-16.

Background: Reoperation Impact

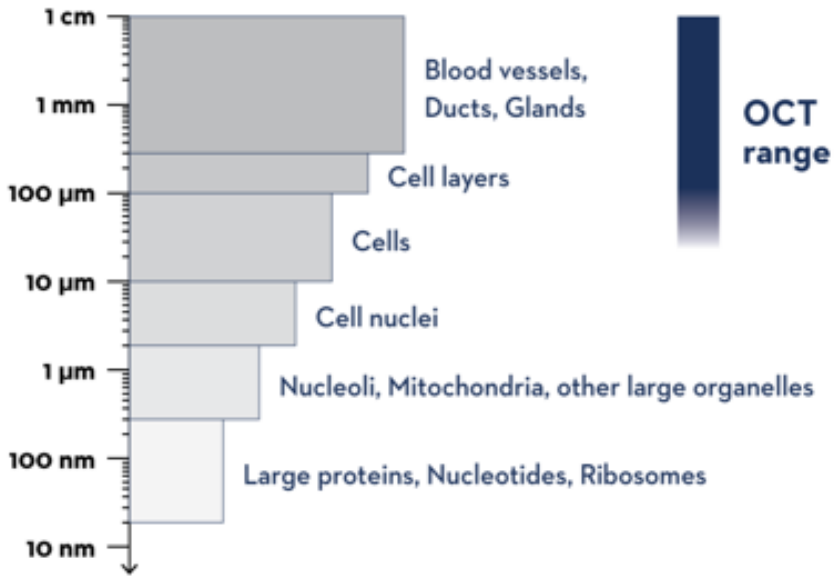


2. Kim Y, Ganduglia-Cazaban C, Tamirisa N, Lucci A, Krause TM. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing BreastConserving Surgery. Ann Surg Oncol. 2024 Feb 6. doi: 10.1245/s10434-024-14902-z. Epub ahead of print. PMID: 38319511. https://link.springer.com/article/10.1245/s10434-024-14902-z
3. Baliski, Chris; Bakos, Brendan. Patient reported outcomes following breast conserving surgery are improved by minimizing re-excisions and excessive breast tissue removal. The American Journal of Surgery, Volume 224, Issue 2, 716 - 721
4. Riba, L.A., Gruner, R.A., Fleishman, A. et al. Surgical Risk Factors for the Delayed Initiation of Adjuvant Chemotherapy in Breast Cancer. Ann Surg Oncol 25, 1904–1911 (2018)
5. Chakedis, J.M., Tang, A., Savitz, A. et al. Economic Impact of Reducing Reexcision Rates after Breast-Conserving Surgery in a Large, Integrated Health System. Ann Surg Oncol 29, 6288–6296 (2022). https://doi.org/10.1245/s10434-022-12127-6
6. Matar-Ujvary R, Haglich K, Flanagan MR, Fuzesi S, Sevilimedu V, Nelson JA, Gemignani ML. The Impact of Breast-Conserving Surgery Re-excision on Patient-Reported Outcomes Using the BREAST-Q. Ann Surg Oncol. 2023 Sep;30(9):5341-5349. doi: 10.1245/s10434-023-13592-3. Epub 2023 Jun 12. PMID: 37306849; PMCID: PMC10782578
7. https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-value-patient-experience-050517.pdf

What is Optical Coherence Tomography (OCT)?

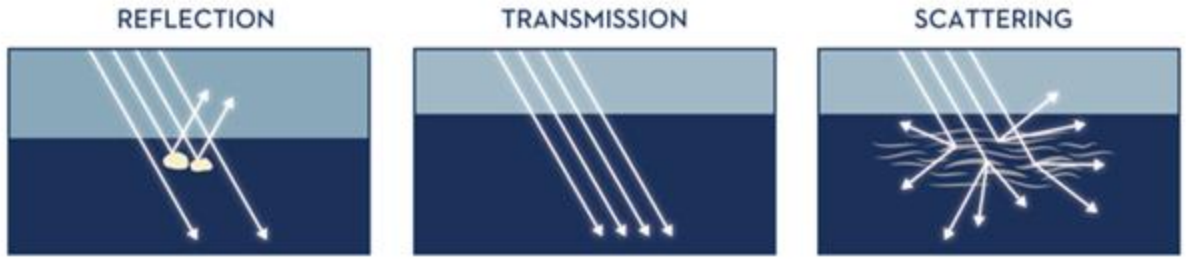
OCT Overview

OCT provides ultra-high-resolution, 3D cross-sectional images of sub-surface tissue structures down to 2mm



OCT optimal structures visualization capability

OCT is analogous to ultrasound imaging, but uses light instead of sound



Very dense features will reflect the light completely:

- Calcifications
- Surgical clips, wires

Less dense features allow light to pass through them:

- Adipose tissue
- Cysts

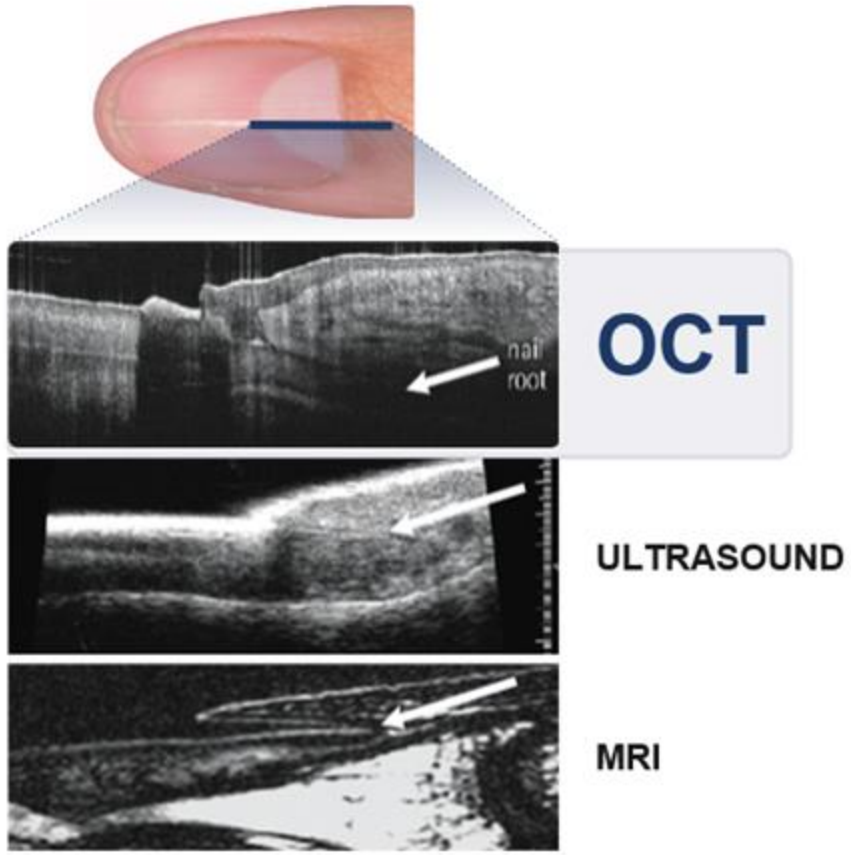
Denser features cause the light to scatter:

- Fibrous tissue

https://perimetermed.com/how-oct-works/

OCT Imaging Capabilities

- **Ultra-high-resolution imaging** of tissue microstructures
- **10x sharper than ultrasound & X-Ray**
- **100x more detailed than MRI**
- **Proven in clinical fields:** Retina, heart, skin



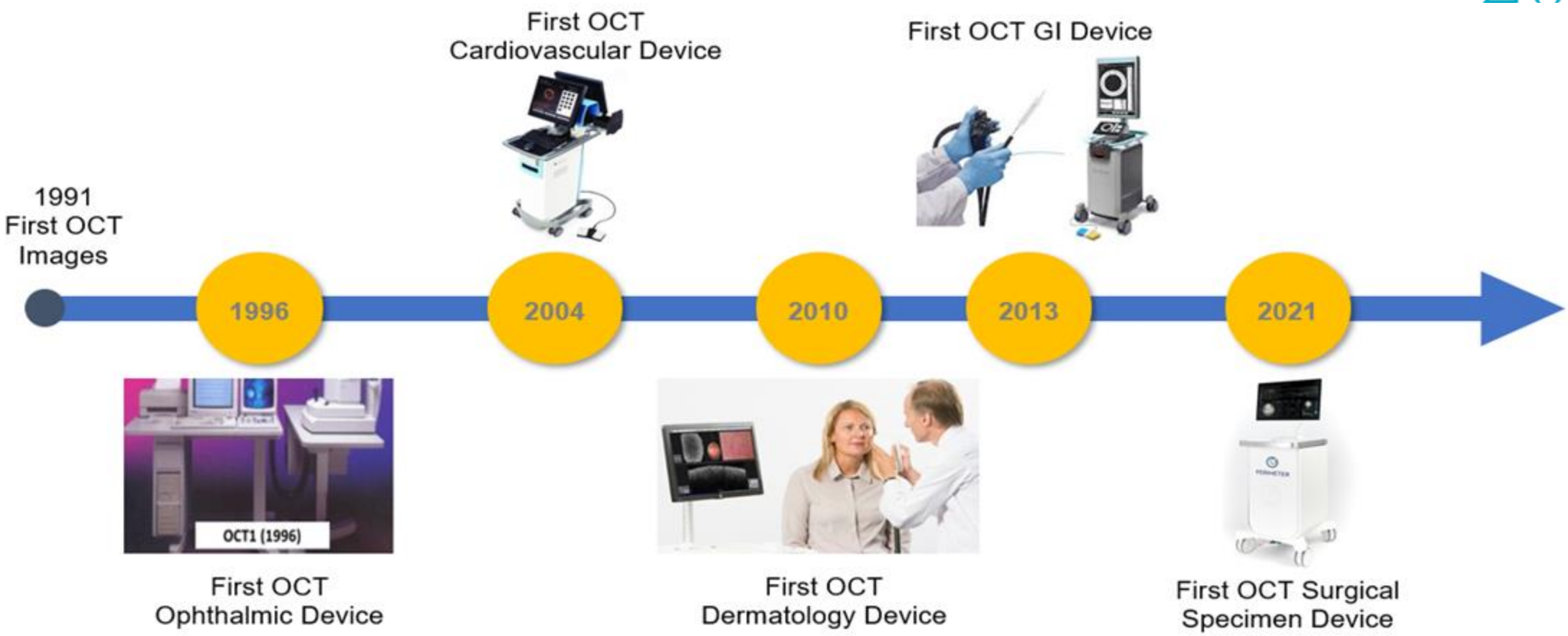
Cellular-level visualization

Subsurface imaging down to 2mm

No injectables & non-invasive

https://perimetermed.com/how-oct-works/

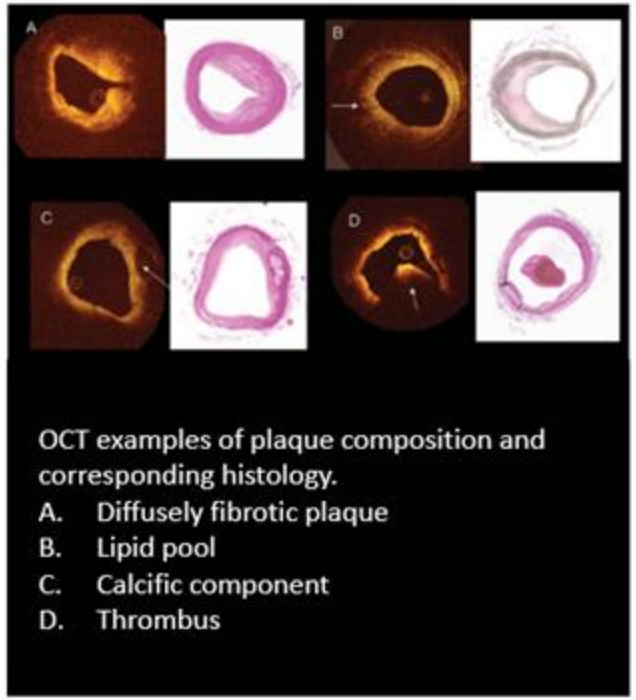
History of OCT Utilization



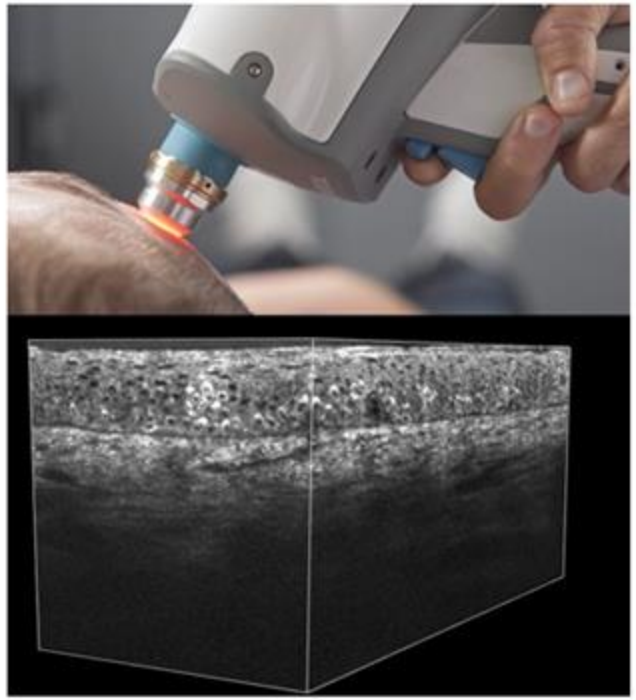
Wang J, Xu Y, Boppart SA. Review of optical coherence tomography in oncology. J Biomed Opt. 2017; 22: 1-23. doi: 10.1117/1.JBO.22.12.121711 15. Optical Coherence Tomography: Technology and Applications. Switzerland AG: Springer International Publishing; 2015.

OCT: Current Uses

Ophthalmology



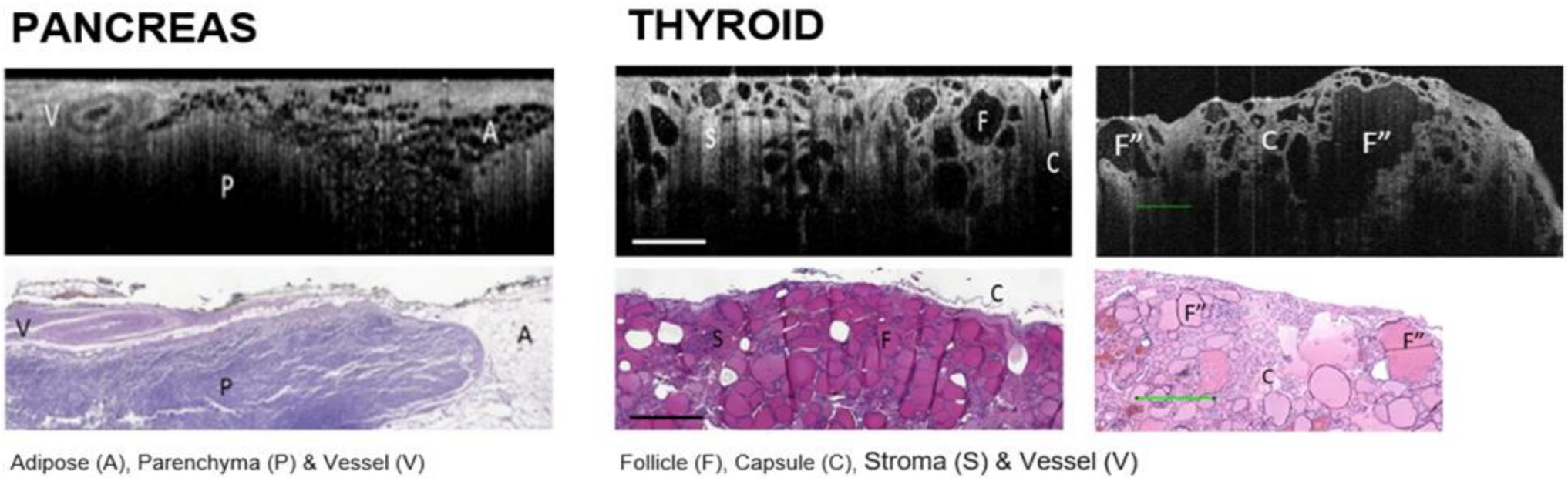
Cardiology



Dermatology

Schmidt H, Connolly C, Jaffer S et al. Evaluation of surgically excised breast tissue microstructure using wide-field optical coherence tomography. Breast J. 2020; 26: 917-923. doi: 10.1111/tbj.13663

Future OCT Uses :
Ex vivo OCT Images Correlated with Histopathology



Adipose (A), Parenchyma (P) & Vessel (V)

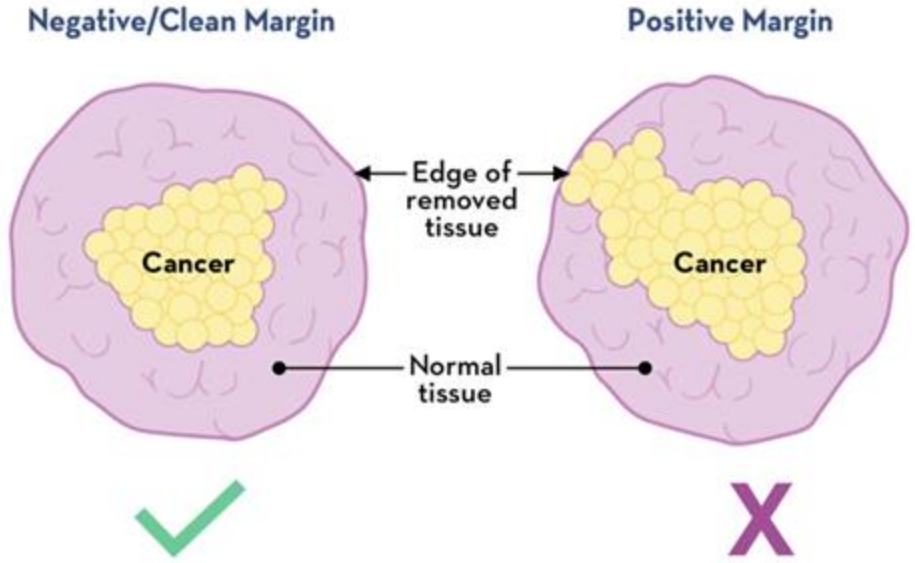
Follicle (F), Capsule (C), Stroma (S) & Vessel (V)

Wang J, Xu Y, Boppart SA. Review of optical coherence tomography in oncology. J Biomed Opt. 2017; 22: 1-23. doi: 10.1117/1.JBO.22.12.121711 15. Optical Coherence Tomography: Technology and Applications. Switzerland AG: Springer International Publishing; 2015.

New Use for OCT: Breast Conserving Surgery/Lumpectomy

Breast Conserving Surgery Goals and Options

Goal = Clean Margins



Standard of Care Intraoperative Margin Assessment Modalities

- Palpation
- Specimen X-ray
- Intraoperative Path Review
- Ultrasound
- Radiofrequency spectroscopy
- Visual inspection

Implementing OCT into the Surgical Workflow

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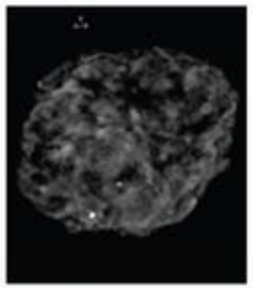
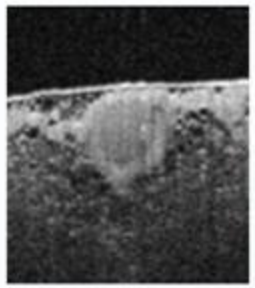
1. Remove the specimen

2. Perform X-ray to locate seeds, biopsy clips and calcifications (or usual method for specimen assessment)

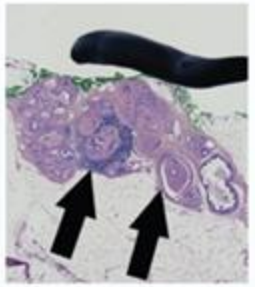


3. **Perform OCT scan of the margins and review images**



4. **Take directed shaves in regions of interest as needed; scan**

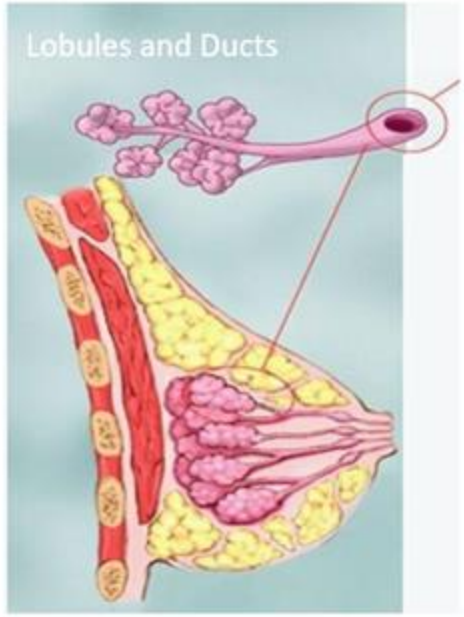
5. Confirm final results with Pathology

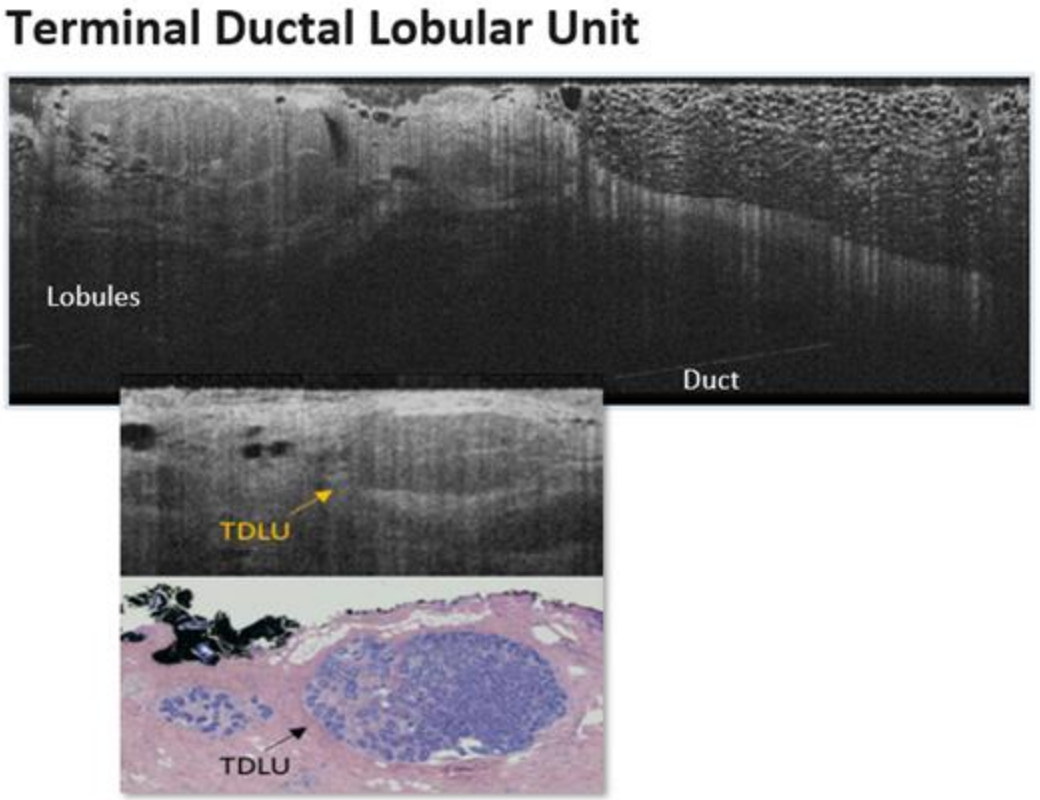


INTRAOPERATIVE

POSTOPERATIVE

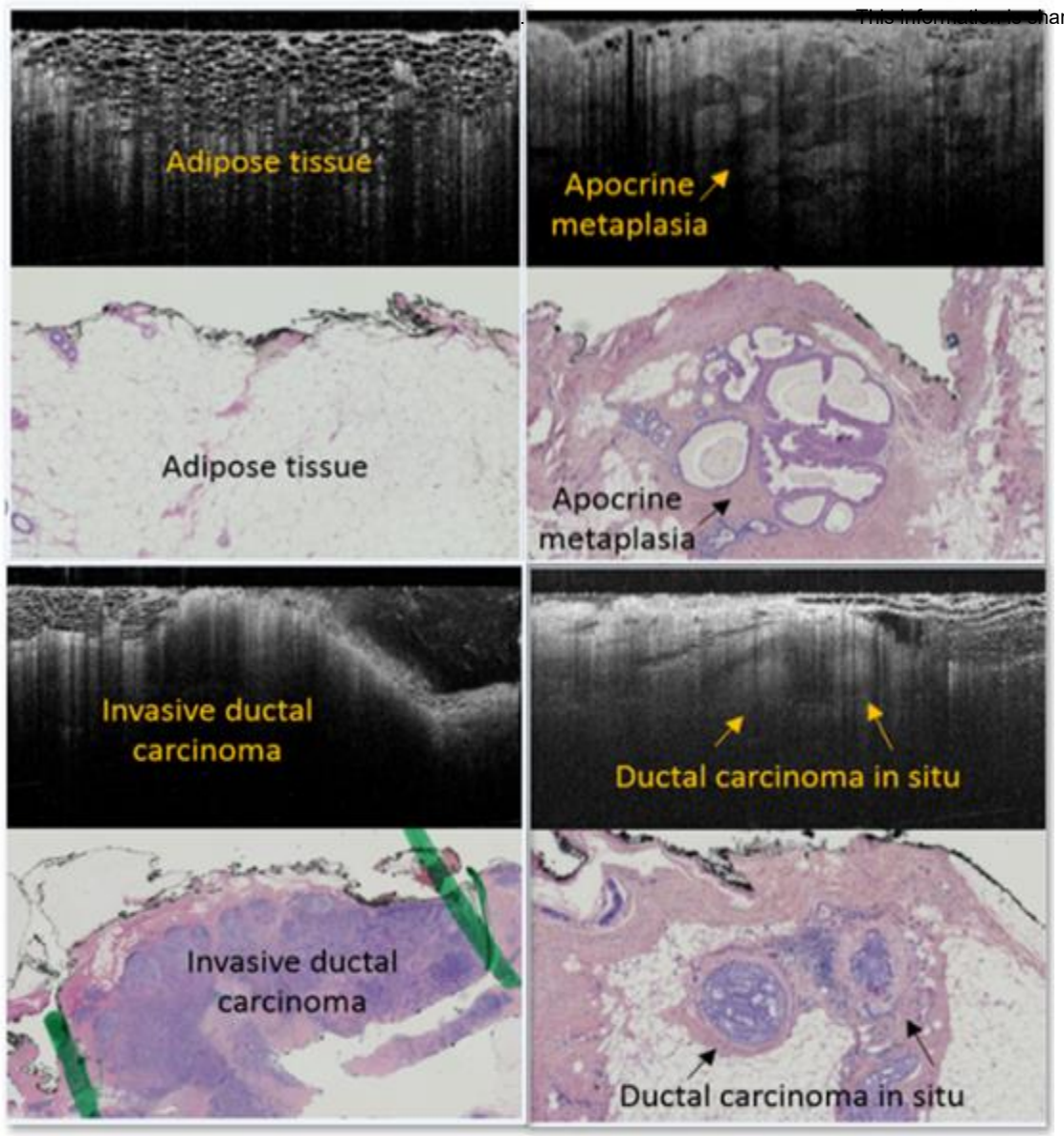
OCT Real-Time *Ex-Vivo* Visualization





OCT Images provided by Dr. Adriana Corden, The Mount Sinai Hospital, NY, IRB 16-01026

Intraoperative OCT Image Correlations with Histopathology



Images provided by Dr. Adriana Corden, The Mount Sinai Hospital, NY, IRB 16-01026

Case Reviews

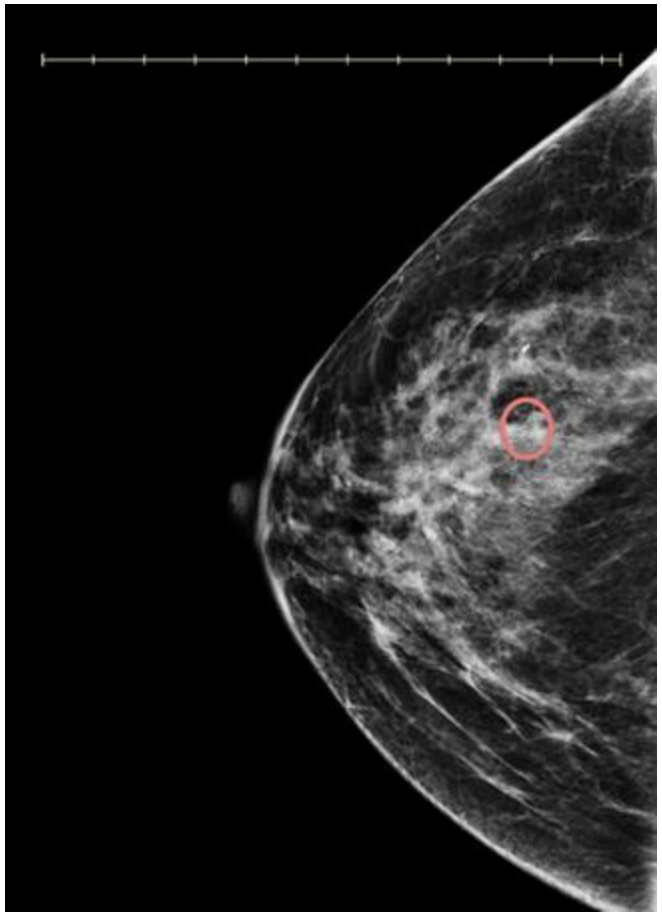
Case #1

PATIENT PROFILE

- 76 y/o female
- Biopsy-proven right DCIS
- ER/PR positive

DIAGNOSTICS

- 1.6 cm area of clustered heterogeneous calcifications
- BI-RADS 4B



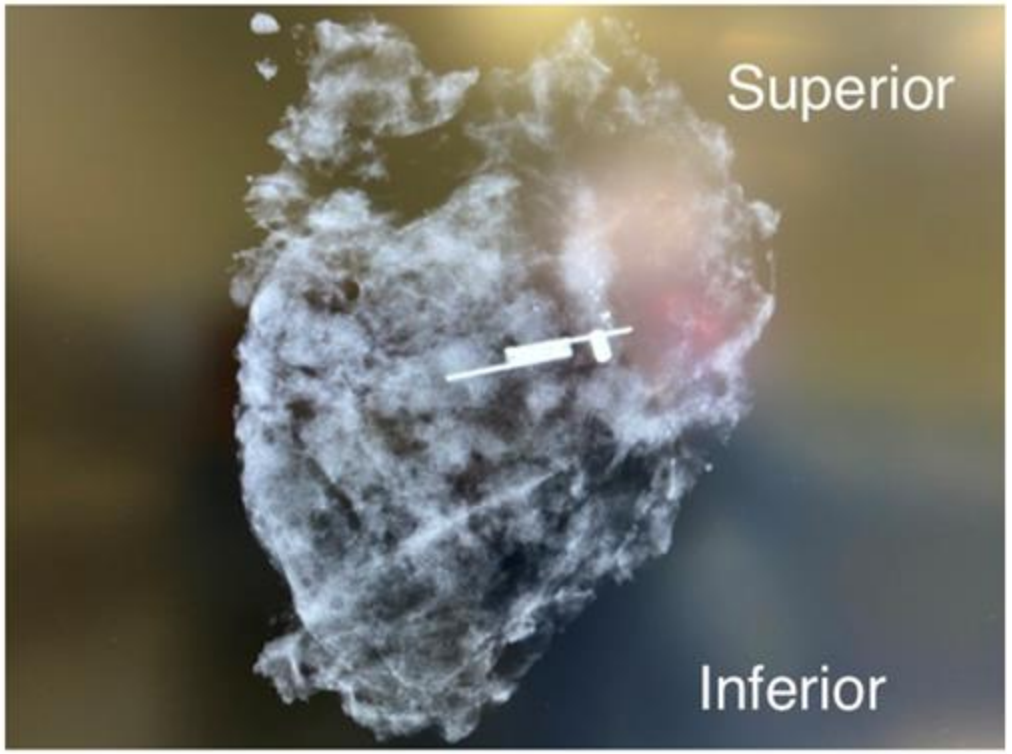
Case #1-Surgery

Right Wireless Localized Partial Mastectomy

- Specimen size = 4 x 3.7 x 3.2cm

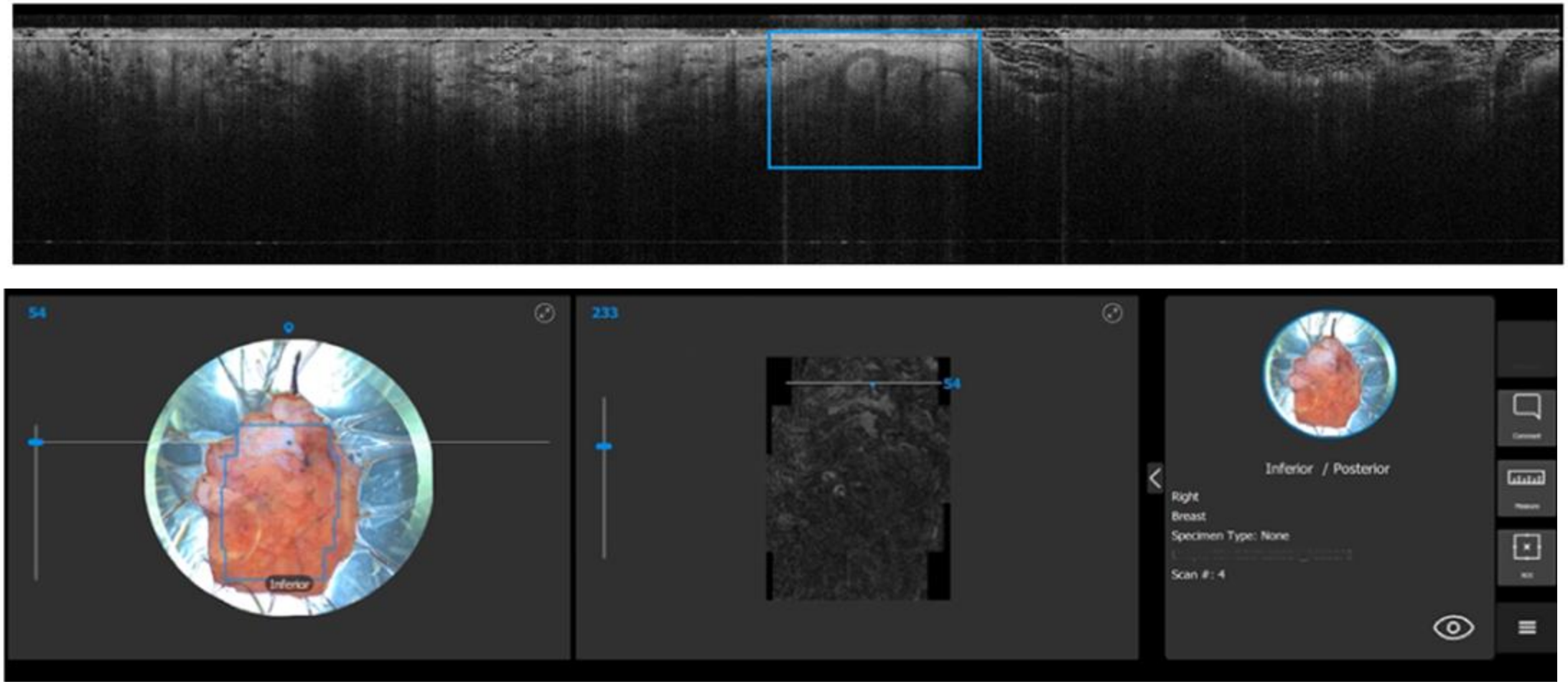
Intraoperative Specimen Radiograph

- Previous biopsy clip & localization reflector within the specimen
- Margins appeared satisfactory

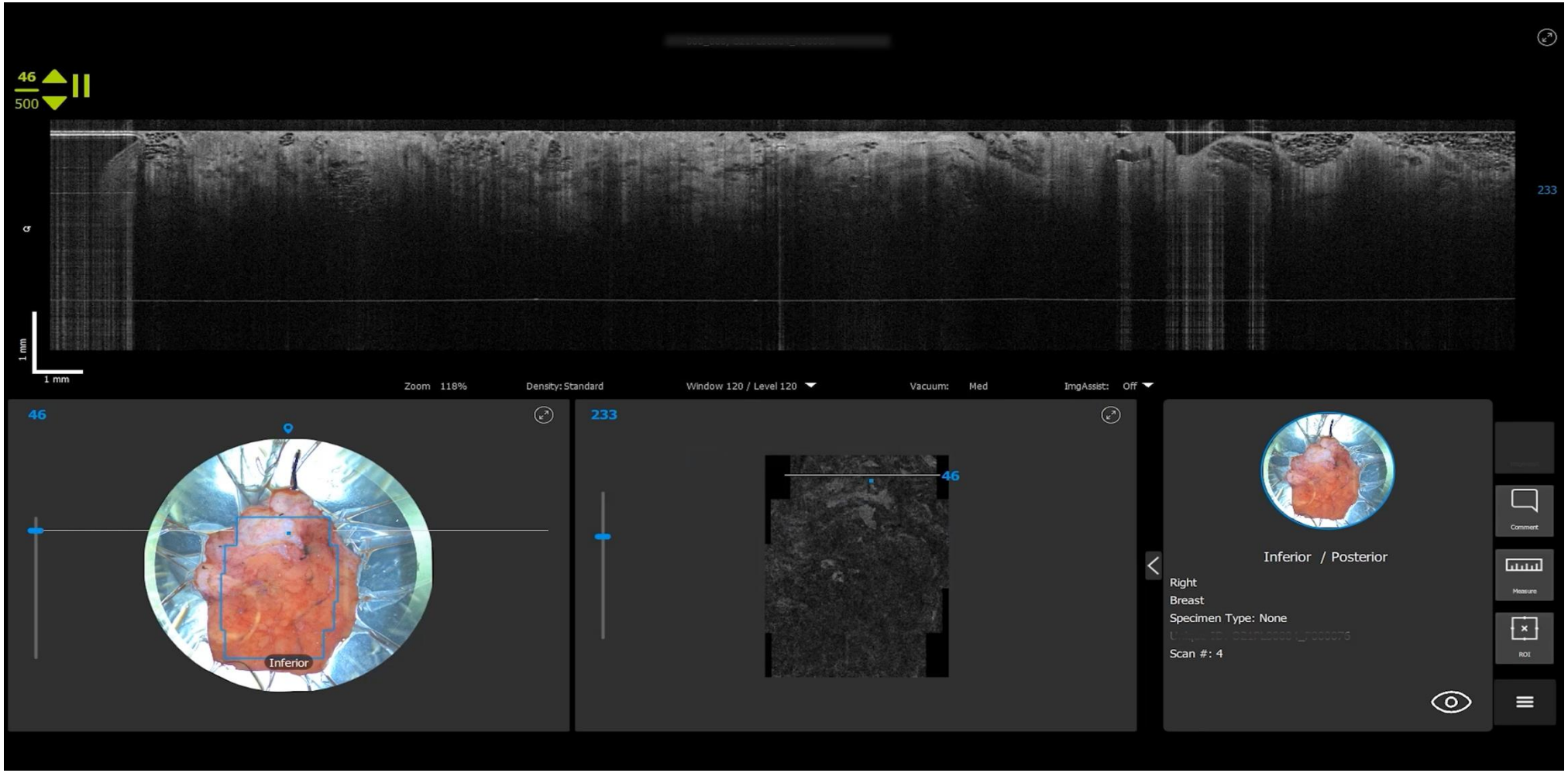


Intraoperative Specimen Radiograph

Case #1-OCT Images: Inferior Margin



Case #1-OCT Images: Inferior Margin



Case #1-Surgical Pathology

SPECIMEN(S) SUBMITTED

1. Right wireless localized partial mastectomy

2. New inferior margin
   - Excised due to suspicious region noted using OCT on Inferior Primary Margin

DIAGNOSIS

1. Breast, Right (Partial Mastectomy):
   Extensive Ductal Carcinoma in Situ
   - DCIS present and involves INFERIOR margin
   - No invasive carcinoma identified

2. Breast, Right, New Inferior Margin (Partial Mastectomy):
   - Ductal Carcinoma in situ, 0.1 cm extent; final margin-negative
   - New surgical margin total=1.1 cm

Case #1-Surgical Pathology

Specimen Collected	DCIS at margin?	Invasive Disease at margin?	Clear Margins?
Breast, Right wireless localized partial mastectomy	Yes Involves Inferior Margin	None	No
New inferior margin (OCT-aided shave) • New surgical margin total=1.1 cm	0.1 cm extent; Final margin negative	None	Yes

Case #2

PATIENT PROFILE

- 64 y/o female
- Biopsy-proven left DCIS
- ER/PR positive

DIAGNOSTICS

- Suspicious cluster of pleomorphic calcifications left breast
- Measures 1cm
- BI-RADS 4B

Case #2-Surgery

Left Wireless Localized Partial Mastectomy

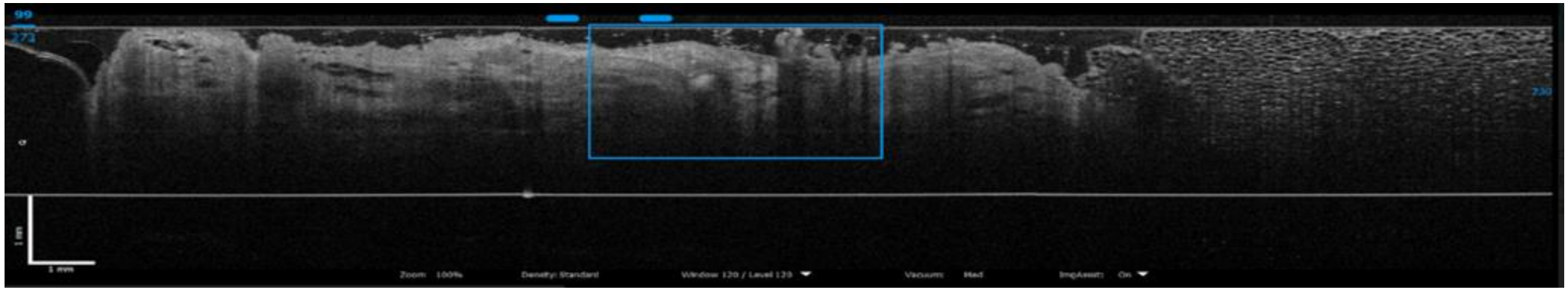
- Specimen Size = 4x3.5x3.5cm

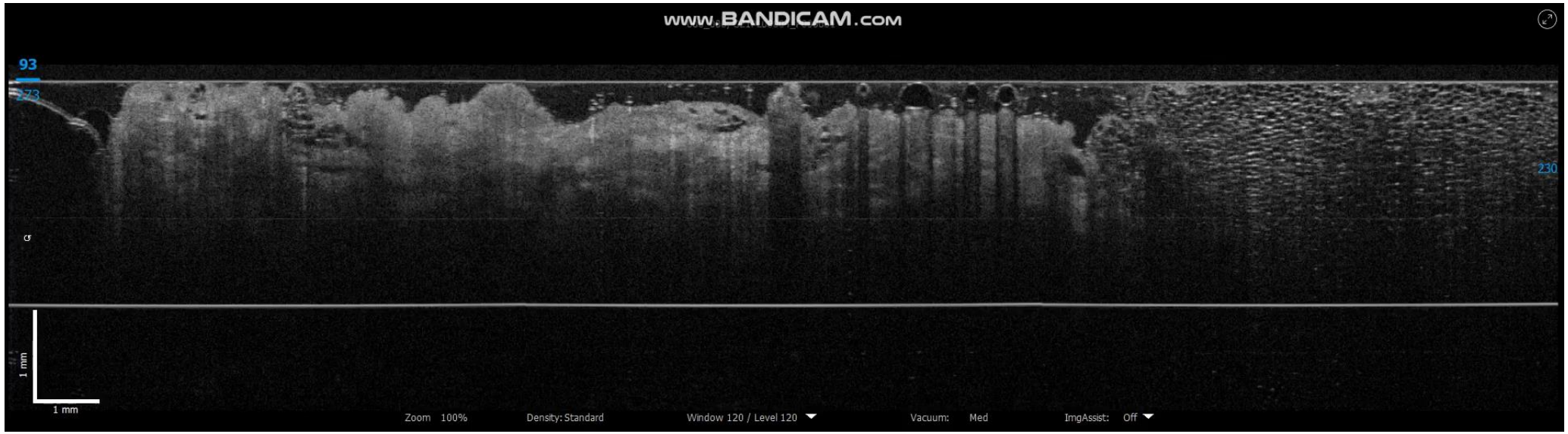
Intraoperative Specimen Radiograph

- Previous biopsy clip & localization reflector within the specimen
- Margins appeared satisfactory

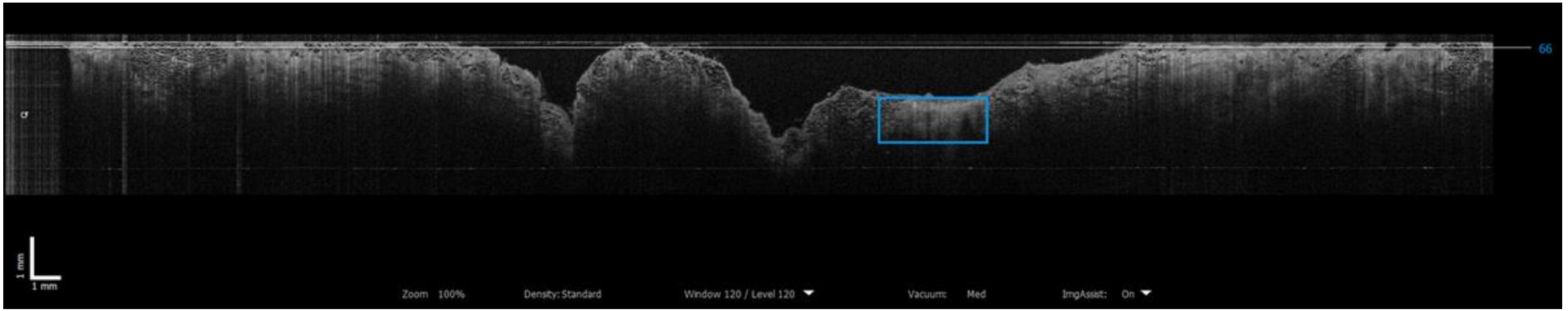
Intraoperative Specimen Radiograph

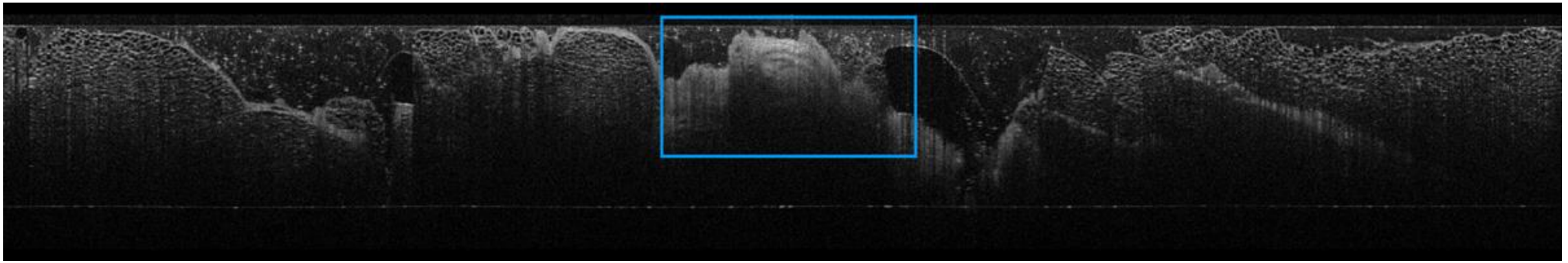
Case #2-OCT Image: Inferior Margin





Case #2-OCT: Posterior Margin





Case #2-Surgical Pathology

SPECIMEN(S) SUBMITTED

1. Left Wireless Localized Partial Mastectomy
2. New Inferior Margin
   - Excised due to suspicious region noted using OCT on Inferior Primary Margin
3. New Posterior Margin
   - Excised due to suspicious region noted using OCT on Posterior Primary Margin

DIAGNOSIS

1. Breast, Left (Partial Mastectomy):
   - Ductal carcinoma in situ -10mm total
   - DCIS present focally and within 1mm at inferior margin
   - Pleomorphic lobular carcinoma in situ, focal, present microns from posterior margin
   - No invasive carcinoma identified
2. Breast, left, new inferior margin (partial mastectomy):
   - Benign fibroglandular tissue, no atypia or malignancy identified
   - New margin total=1 cm
3. Breast, left, new posterior margin (partial mastectomy):
   - Pleomorphic lobular carcinoma in situ, present with negative final margin
   - No ductal carcinoma in situ or invasive carcinoma identified
   - New margin total=8 mm

Case #2-Surgical Pathology

Specimen Collected	DCIS at margin?	Invasive Disease at margin?	Clear Margins?
Breast, Left wireless localized partial mastectomy	Yes; DCIS present focally and within 1mm at inferior margin Pleomorphic lobular carcinoma in situ, focal, present microns from posterior margin	None	No
New inferior margin (OCT-aided shave) • New margin total=1 cm	Final margin negative	None	Yes
New posterior margin (OCT-aided shave) • New margin total=8 mm	Pleomorphic lobular carcinoma in situ, present with negative final margin	None	Yes

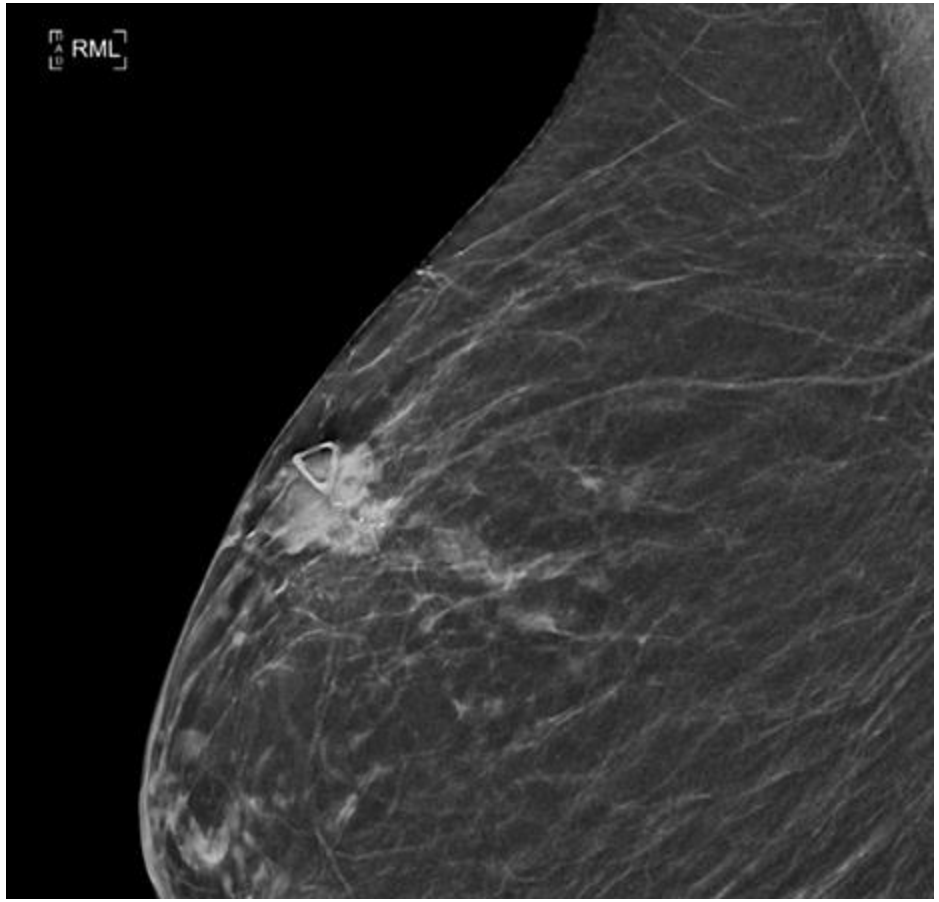
Case #3

PATIENT PROFILE

- 76 y/o female
- Biopsy-proven right IDC
- ER/PR positive; HER-2/neu negative

DIAGNOSTICS

- Suspicious mass at 12:00
- Measures = 1.9 x 1.9 x 1.7cm
- BI-RADS 5



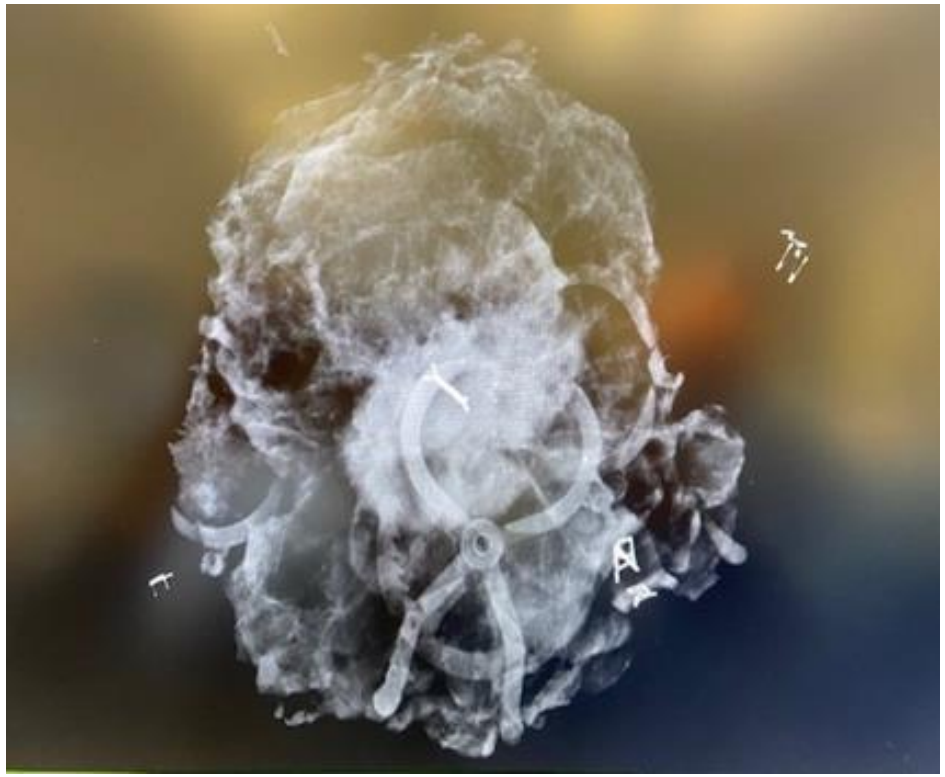
Case #3-Surgery

Right Partial Mastectomy

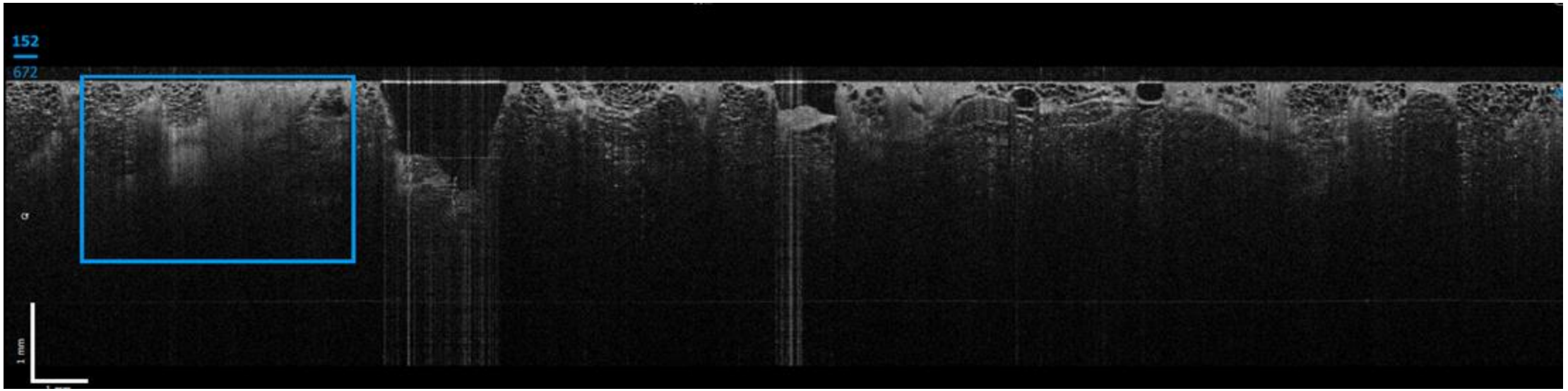
- Specimen = 4.5 x 4.3 x 4.2cm

Intraoperative Specimen Radiograph

- Previous biopsy clip centered within the specimen
- Margins appeared satisfactory



Case #3-OCT: Lateral Margin



Case #3-Surgical Pathology

Specimen(s) Submitted

1. Right, Partial Mastectomy-12:00

2. R New Lateral Margin
   - Excised due to suspicious region noted using OCT on Lateral Primary Margin

3. R SLN #1-blue; 1942

4. R SLN #2 blue; 1113

Diagnosis

1. Right breast at 12 o'clock (partial mastectomy): infiltrating ductal carcinoma, grade 3 (2.5cm)
   - Extensive Ductal Carcinoma In Situ, High Grade Solid Type with Necrosis, Extending up to 15mm on a Single Slide, Mostly Outside Contours Of Invasive Component (20% of Tumor Area)
   - Invasive Carcinoma Margins - Negative, all final margins more than 10mm
   - DCIS Margins - Focally, present less than 1mm from lateral margin

2. Right, new lateral margin of Partial Mastectomy 12 o'clock
   - Ductal carcinoma in situ present, 5mm from final margin
   - Final margin — Negative

Case #3-Surgical Pathology

Specimen Collected	DCIS at margin?	Invasive Disease at margin?	Clear Margins?
Breast, Right wireless localized partial mastectomy • Specimen= 4.5 x 4.3 x 4.2cm	Yes, Focally less than 1 mm from Lateral Margin	None	No
Right new lateral margin (OCT-aided shave)	5mm from final margin	None	Yes

Final Thoughts

- Intraoperative application of WF-OCT can assist in achieving negative margins in BCS
  - Decreases necessity for re-excisions
  - Reduces physical, emotional, financial, and logistical burdens re-excisions impose on patients
- WF-OCT enhances surgical outcomes benefiting patient care in breast cancer management
- Further research is warranted

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Questions