



PIVOTAL TRIAL CASE STUDY

Clear Margins in One Surgery: Dr. Marie Lee's Success with OCT and ImgAssist



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The opportunity to use this cutting edge technology in improving the real-time care of patients is a gift. In this particular case, OCT was critical to preserving this patient's breast and optimizing her overall and cosmetic outcome.

Marie Catherine Lee | MD FACS
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Patient and Clinical Background

Diagnosis

Right breast **Lower Outer Quadrant DCIS** (ductal carcinoma in situ)

Age

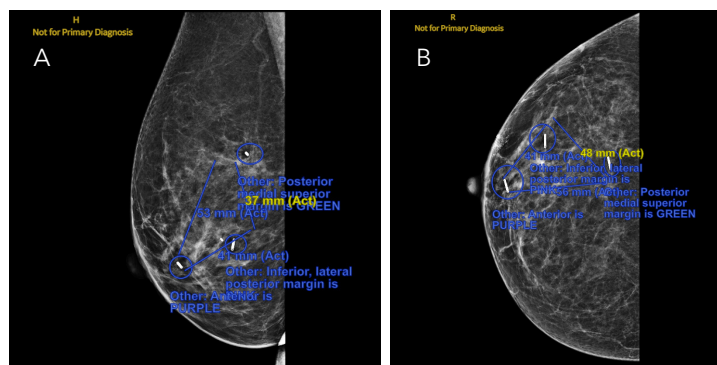
60-year-old white female

History

- No presurgical therapy
- No prior history of breast biopsy or breast pathology

Pre-surgical Findings

- Bilateral screening mammogram - multiple new calcifications central/upper outer central right breast; left focal asymmetry
- Bilateral diagnostic mammogram, left Ultrasound - right pleomorphic calcifications 9'clock spanning 4cm AP, suspicious. Left asymmetry resolved on compression, 4mm simple cyst seen sonographically
- Right stereotactic biopsy - DCIS with associated calcifications; negative for estrogen and progesterone hormone receptors



A Localization film: Mediolateral Oblique (MLO)

B Localization film: Cranial-Caudal (CC)

Image 1: Screening and diagnostic mammograms



Standard of Care Surgical Procedure

- Right partial mastectomy and bilateral mammoplasty reduction
- Specimen radiograph was used to localize right breast smart clip
- The inferior and medial margins of the primary specimen were found to be suspicious, and subsequent SOC shaves were excised

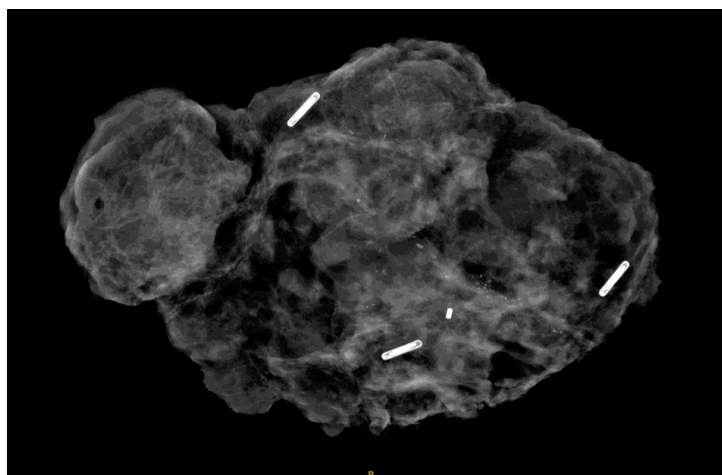
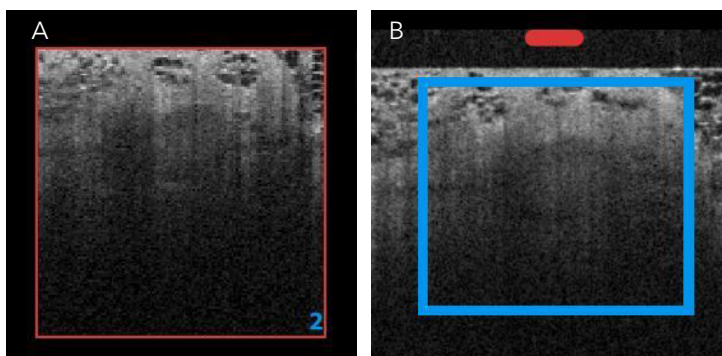


Image 2: Specimen Radiograph

Intraoperative OCT Evaluation

- A suspicious area was identified on the anterior margin of the primary specimen with the aid of ImgAssist
- A subsequent OCT-directed shave was excised from the anterior cavity wall



A ImgAssist thumbnail for intraoperative surgeon review
B Region of Interest highlighting suspicious feature

Image 3: ImgAssist detection highlighted this region (outlined in blue box). Surgeon agreed with the suspicious finding and excised additional tissue

Final Pathology Diagnosis

- All surgical margins clear
- DCIS high grade, displaying a solid pattern, with comedo necrosis and microcalcifications
- Other findings include: atypical lobular hyperplasia, usual ductal hyperplasia, fibrocystic change, Pseudoangiomatous Stromal Hyperplasia (PASH), biopsy site changes, microcalcifications in benign acini and stromal calcifications

OCT Impact Summary

Suspicious Margin (per OCT)

Anterior Primary Lump

Histopathology Result

DCIS = 1.8mm (+)

(Accurate OCT detection)

Final Outcome

Additional tissue excised
resulting in no residual disease