



CLINICAL CASE STUDY: OCT+AI USE

Clear Margins in One Surgery:

Dr. Marie Lee's Success with Claire™

“

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
Moffitt Cancer Center

Patient and Clinical Background

DIAGNOSIS

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

AGE

60-year-old
white female

HISTORY

No pre-surgical therapy. No prior breast biopsy or pathology.



OCT+AI Impact Summary

Suspicious Margin (per OCT)

Anterior Primary Lump

Histopathology Result

Margin involvement (1.8mm focus, DCIS) was confirmed at the region identified using OCT+AI

Final Outcome

The OCT-directed shave resulted in accurate removal of residual disease resulting in fully clear margins. SOC-directed shaves were found to be false positive and contained no disease.

Note: OCT does not replace standard histopathology

Claire is a human-AI team. ImgAssist AI flags regions of interest to support surgeon review — it does not diagnose or independently determine margin status. The surgeon's clinical judgment, informed by OCT imaging, enabled the successful outcome in this case.

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 o'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 (ER/PR)

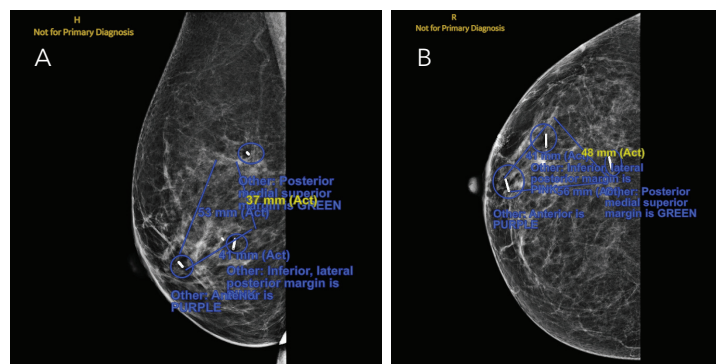


Image 1: Screening and diagnostic mammograms. (A) Localization film for Mediolateral Oblique (MLO), (B) Localization film for Cranial-Caudal (CC)



Intraoperative Steps

1. Surgeon performs standard of care resection

Right partial mastectomy with bilateral mammoplasty reduction. Specimen radiograph (Image 2) used to localize right breast smart clip. Inferior and medial margins assessed as suspicious by SOC; subsequent shaves appropriately taken.

2. Surgeon reviews Claire OCT images with ImgAssist AI

ImgAssist highlighted a region of interest on the anterior margin (Image 3). The surgeon reviewed the AI-flagged area and made the clinical decision to investigate further.

3. Surgeon directs OCT-guided shave from anterior cavity wall

Acting on clinical judgment informed by OCT imaging, Dr. Lee excised additional tissue from the anterior margin — the area Claire identified that SOC assessment alone had not flagged.

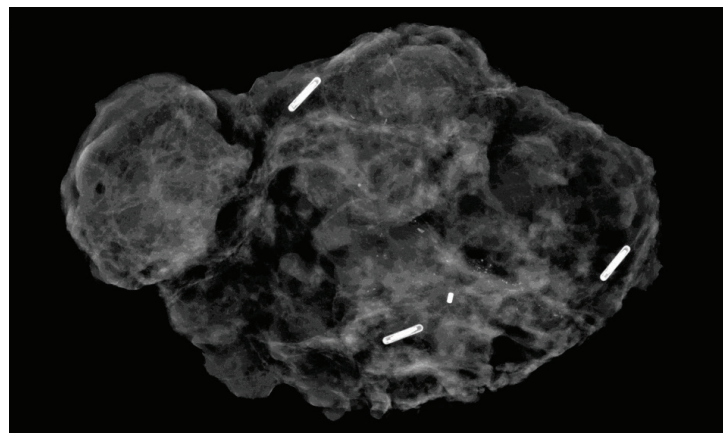


Image 2: Specimen Radiograph

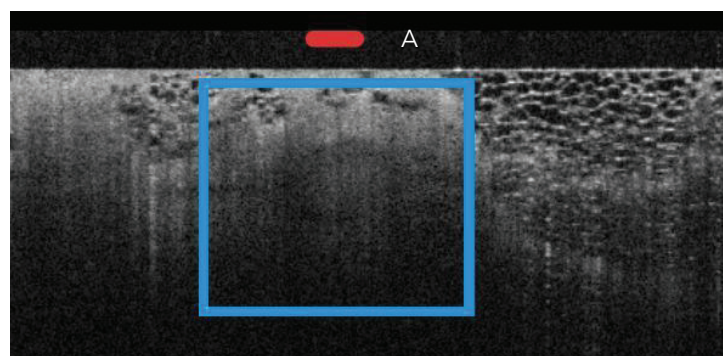


Image 3: ImgAssist detection (A) highlighted region for further surgeon review (annotated by the blue box). The surgeon excised additional tissue upon reviewing this flagged area

Final Pathology



All surgical margins clear

- DCIS high grade, solid pattern with comedo necrosis and microcalcifications
- Additional findings: atypical lobular hyperplasia, usual ductal hyperplasia, fibrocystic change, PASH, biopsy site changes, microcalcifications in benign acini and stromal calcifications

Claire Intended Use/Indications for Use

The Claire OCT System is an adjunctive three-dimensional imaging tool which provides volumetric cross-sectional, real-time depth visualization, coupled with an artificial intelligence computer-aided detection algorithm which identifies and marks focal areas suspicious for breast cancer and is used concurrently with physician interpretation of the images. Claire is intended for use in conjunction with other standard methods for evaluation of the margins of excised lumpectomy tissue during surgical procedures in patients with a biopsy-confirmed diagnosis of breast cancer.

Limitations of Use

The device is not intended for use in individuals who:

- Are under the age of 18
- Are male
- Have metastatic cancer (Stage IV)
- Have lobular carcinoma as their primary diagnosis
- Have had previous ipsilateral breast surgery for benign or malignant disease within 2 years (including implants and breast augmentation)
- Have multi-centric disease (histologically diagnosed cancer in 2 different quadrants of the breast), unless resected in a single specimen
- Have bilateral disease (diagnosed cancer in both breasts)
- Are currently lactating
- Are currently pregnant

The device is not intended for concurrent use in surgeries with cryo-assisted localization

Use clinical expertise and judgement for device use with specimen margins that have been destroyed, damaged, or are otherwise not intact prior to imaging.

Contraindications of Use

The Claire OCT System should not be used to replace standard tissue histopathology assessment. The Claire OCT System should not be used for diagnosis.

Safety

Adverse Events: (AEs) were comparable across all study arms (27.8–30.7%). Most AEs were minor, transient, and expected. None were related to Claire OCT System use.

Serious Adverse Events: (SAEs) were rare (<1.2%) across all arms, with none attributed to the device.

Unanticipated Device Effects: No unanticipated device effects (UADEs) were reported.

References

1. Perimeter Medical Imaging AI. NCT05113927. clinicaltrials.gov/study/NCT05113927
2. US FDA. Claire OCT System – P250008. PMA Approval Order. March 3, 2026.

No financial relationship exists between the surgeon and Perimeter Medical Imaging AI, Inc. in connection with this testimonial or otherwise. Perimeter's Claire OCT is not available for sale outside the USA.