3-D Tomosynthesis for Intra-Operative Margin Assessment During Breast Conserving Surgery

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Introduction

- A major limitation of breast conserving surgery (BCS) is incomplete tumor excision at the initial operation resulting in positive margins on final pathology.
- 20-30% of BCS patients undergo re-excision segmental mastectomy to obtain negative margins.
- Segmental mastectomy margins are commonly evaluated with gross examination, 2-D imaging, and, less commonly, frozen section analysis.
- An improved intra-operative technology that is accurate, rapid, and easy to use is needed.

Aim: Determine the ability of 3-D tomosynthesis to intra-operatively detect positive margins for segmental mastectomy specimens compared to our institution's standard extensive processing utilizing 2-D imaging.

Methods

- Study eligibility: Women ≥ 18 years of age undergoing segmental mastectomy for breast cancer.
- Intra-operative specimen analysis with standard extensive processing (SEP):

gross specimen inking & orientation → 2-D image of the intact specimen → specimen sliced into 5 mm sections with gross evaluation by breast pathologist → 2-D image of the sliced specimen reviewed by breast radiologist → surgeon excises additional tissue based on pathology and imaging evaluation.

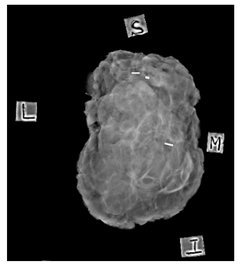
- 3-D tomosynthesis (3-DT) of the intact specimen was performed with the Mozart System (Kubtec Medical Imaging) at the time of surgery and retrospectively reviewed by a breast radiologist.

Methods cont.

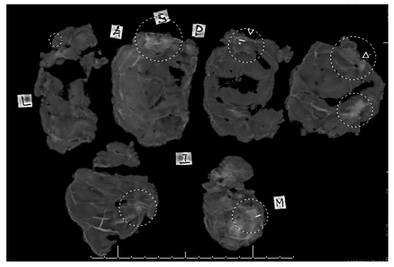
- Definitive margin status was based on permanent pathology evaluation.
- A positive margin was defined as tumor at ink.
- Clinicopathologic features and interpretation of specimen margin status with SEP and 3DT were compared.

Intra-operative Standard Extensive Processing

2-D Intact Specimen Image



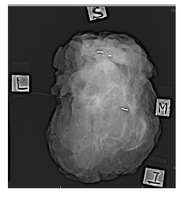
2-D Sliced Specimen Image



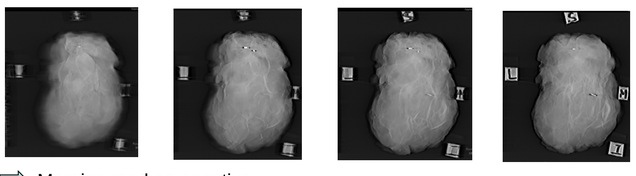
⇨ Surgeon guided to excise additional superior/posterior and medial tissue.

3-D Tomosynthesis Specimen Evaluation

Aggregate Specimen Image



3-DT Images: 1 mm digital sections of intact specimen



⇨ Margins read as negative

Final pathology: 0.7 cm IDC, closest margin 2 mm superior/posteriorly. Additional superior/posterior and medial tissue with no malignancy.

Results

Clinicopathologic Features

Characteristics	Number of Cases (n = 99)
Median Patient Age	60 years (range: 35 – 86 years)
Pre-operative Therapy	
Chemotherapy	9
Anti-estrogen therapy	3
Tumor Histology	
Invasive Ductal	73
Invasive Lobular	4
Mixed IDC/ILC	7
Phyllodes	2
Ductal Carcinoma in Situ	12
Pleomorphic Lobular Carcinoma in Situ	1
Tumor Size	
Tis	13
T1	66
T2	19
T3	1

Detecting Positive Margins with Standard Extensive Processing

- Intra-operative evaluation: 75% of specimens were read as having a positive margin(s) guiding the surgeon to excise additional tissue.
- Permanent pathology of lumpectomy specimen: 14% cases with tumor at ink.
- 16 (22%) cases with additional excised tissue had malignancy in the additional tissue.
- Final permanent pathology with excision of additional tissue: 6% cases with tumor at ink.

Additional Surgery to Obtain Negative Margins

- 8 patients underwent re-excision segmental mastectomy.
- 2 patients underwent skin sparing mastectomy.

Results cont.

Detecting Positive Margins with 3-D Tomosynthesis

- 32% of specimens were read as having a positive margin(s).
- 3-DT identified 13 of the 14 lumpectomy specimens that had positive margins on permanent pathology.
- Of the 16 cases having malignancy in additional excised tissue as guided by our SEP, 3-DT identified:
  - 11 of the cases.
  - 5 of the 6 cases that had a positive margin on permanent pathology.

-3-DT did not identify only 1 case that had focal DCIS in the additional excised tissue for a false negative rate of 1%.

Accuracy of SEP versus 3-D Tomosynthesis

	Standard Extensive Processing	3-D Tomosynthesis
Sensitivity	100%	93%
Specificity	28%	78%

Summary

- 3-DT is highly accurate for detecting positive margins intra-operatively in breast cancer patients undergoing segmental mastectomy compared to 2-D imaging and our institution's standard extensive processing.
- 3-DT is less likely to recommend excising additional tissue unnecessarily.

References

- Schulman AM et al. Reexcision Surgery for Breast Cancer: An Analysis of the American Society of Breast Surgeons (ASBrS) Mastery(SM) Database Following the SSO-ASTRO "No Ink on Tumor" Guidelines. Ann Surg Oncol. 2017 Jan;24(1):52-58.
- Cabioglu N, Hunt KK, Sahin AA et al. Role for Intraoperative Margin Assessment in Patients Undergoing Breast-Conserving Surgery. Annals of Surgical Oncology 2007; 14: 1458-1471.