Intraoperative Specimen Tomosynthesis

What the experts say
How it works
Clinical studies
I believe that 3-D tomosynthesis specimen X-ray is more accurate. It helps us beyond the other generation of two-dimensional imaging. Good for the patient because if we can be more accurate, of course it reduces the re-excision rate.”

“We want the patient to have the best possible results, a combination of least times having to go back for cancer or re-excision, but taking out the least amount of tissue to preserve the best cosmesis. So I think having 3-D specimen X-rays is letting us do both those things.”

“Now with specimen tomosynthesis you can run the slices through the specimen. You can actually see in real time where the target is in relation to all margins, which has been much, much better for us in the operating theater.”

“We feel strongly that Specimen Tomosynthesis is an integral part of our cancer center, especially in the breast care center, because we’re bringing more quality to what we do for our patients.”

“I would tell my fellow surgeons or other people that I know in breast surgery that the Tomosynthesis for specimen radiography is exceptional.”
Specimen tomosynthesis allows real time evaluation of the tissue removed from the breast, and this allows us to look not only in two dimensions but three dimensions by taking serial slices through the tumor to evaluate not only the medial and lateral margin but also the anterior and posterior margin. This allows us to remove less tissue and, therefore, if it’s eccentric in the specimen, to just focus the shave.

“By focusing the margins, we are able to remove less breast tissue, which leads to a better cosmetic result.”

Cynara Coomer, MD, FACS
Chief of Breast Surgery and Director of Comprehensive Breast Center,
Staten Island University Hospital, NY

“I liked specimen tomosynthesis from the get go. Hands down, it’s the best technology for specimen imaging in the operating room.”

“We are really able to see through that dense tissue so much more than what we were before.”

“The biggest benefit out of this is a reduction in re-excision, not just for myself, but all the surgeons that will utilize the imaging.”

Andrea Madrigrano, MD, FACS
Assistant Professor of Surgery
Rush University Surgeons, Chicago, IL

“You have a much better view with specimen tomosynthesis of exactly what needs to be removed. I avoid excessive tissue being taken from the patient, and the patient likes it, because the cosmetic result is better.”

“Specimen tomosynthesis is a no-brainer. If you’re a breast surgeon, and you want to provide the best care, this is it. To identify whether you’ve done the right operation, you need this.”

Cary Kaufman, MD, FACS
Associate Clinical Professor of Surgery
Bellingham Regional Breast Center

For the full testimonial video, please visit: kubtec.com/mozart-testimonial-video
Intraoperative specimen tomosynthesis is more accurate at identifying positive margins. Here’s why.

Digital Breast Tomosynthesis is rapidly gaining acceptance as the next gold standard for specimen mammography. Unlike its traditional 2-D X-ray counterpart, tomosynthesis allows the physician to see the breast specimen in 3 dimensions which improves accuracy and reduces false positives.

2-D

Figure 1

**Figure 1a:** Breast specimen with a lesion on a peripheral margin.

**Figure 1b:** The 2-D X-ray system creates a projection of the specimen.

**Figure 1c:** What the physician sees: a single planar view of a 3-D specimen with margins uninvolved.

In a traditional 2-D specimen X-ray, the three dimensional anatomy is compressed into a single planar view. All vertical perspective is lost.

Figure 1a, b, c shows a depiction of a lumpectomy that has a lesion on a peripheral margin. A 2-D image of the specimen, however, indicates that the margin is clear, indicating that the operation is successful.

*In this example the positive margin would be identified during final pathology, and the patient would be scheduled for re-excision.*

Note that even when orthogonal views are taken, the same inaccuracies are still encountered with both images.

Tomo

Figure 2

**Figure 2a:** Breast specimen with a lesion on a peripheral margin.

**Figure 2b:** Specimen tomosynthesis creates 1mm digital slices, each independent of the others.

**Figure 2c:** What the physician sees: Specimen tomosynthesis accurately shows the peripheral lesion on slice 4.

Specimen tomosynthesis enables analysis of the specimen in 1 millimeter digital slices (Fig 2b).

Each slice anatomically has its own margin, and can be viewed independently of all the other slices.

Using specimen tomosynthesis, a positive peripheral margin is seen on slice 4 (Fig 2c). The surgeon is able to analyze the location and the extent of the lesion, and involvement of the peripheral, anterior and posterior margins, completely unobscured by dense tissue above or below.

*In this example using specimen tomosynthesis, the surgeon sees a positive peripheral margin on slice 4, and can excise additional tissue at that precise location during the operation.*
Comparing specimen tomosynthesis and traditional 2-D imaging using clinical specimens.

This traditional 2-D image shows a marker seed, biopsy clip, and a cluster of microcalcifications near the center of the specimen. (Fig 3).

Using this image, the surgeon would conclude that they have successfully removed the clips and microcalcifications and that the margin is uninvolved.

Analysis of the same specimen using specimen tomosynthesis gives information not seen in the 2-D image. The tomosynthesis slices (Fig 4 & 5) reveal a cluster of microcalcifications less than 1mm from the anterior margin and extending to 7mm.

Using specimen tomosynthesis the surgeon would conclude that additional excision is required anteriorly, prior to completing the procedure, minimizing the risk of obtaining a positive margin on final pathology.

Only the MOZART System from KUBTEC uses specimen tomosynthesis to show your surgical margins as they really are.

For the full video on specimen tomosynthesis, please visit: kubtec.com/mozart
Clinical Study
Specimen tomosynthesis facilitates lower re-excisions by visualizing more information.

View for View, 3-D Specimen Tomosynthesis Provides More Data Than 2-D Specimen Mammography
Cary S. Kaufman, Karen Zacharias, Amber Rogers, Sid Nix, Jaymie O’Donnell, Karen Ness, Nancy Schnell, Laurie Hill
University of Washington Department of Surgery, Bellingham Regional Breast Center, Bellingham Ambulatory Surgery Center, Bellingham, Washington

Study Size: 210 patients
Study: Side by side comparison of 2-D and 3-D specimen images for intraoperative margin assessment.

Background/Objective:
Intraoperative digital specimen mammography (IDSM) has become the standard of care for intraoperative margin assessment. We report our current findings on the enhancement of intraoperative imaging in 43% of cases. By improved visualization of the target lesion, the surgeon can be sure they have removed the target lesion and not only the clip. Further use by others should validate these early findings.

Abstract:

Value of Specimen Tomosynthesis
- Accurately identifies target lesion (densities) in greater detail
- Excludes overlying skin and surrounding dense breast tissue
- Facilitates lower re-excisions by visualizing more information
- Periperal calcifications more noticeable due to scrolling
- Ease of use identical to 2D systems, uploads easily to PACS
- Time from image capture to 3-D view ~ 65 seconds
- Margins identified in three axes for intraoperative excision
- Provides anatomic orientation of close margins using Z-axis
- Confirms removal of vague mammographic findings

Key Findings
Intraoperative Specimen Tomosynthesis:
- Provides more information on the target lesion than 2-D X-ray.
- Facilitates reduction in re-excision (from 16% to 9%).
- Provides improved visualization of peripheral calcification.
- Provides superior visualization through dense tissue and/or skin.

2-D View vs. 3-D Slice
Mammography Images
Tomosynthesis Images

Overall: Tomosynthesis was more precise in 43% of lesions.

To see the full poster, please visit: kubtec.com/mozart
Clinical Study
Specimen tomosynthesis is more accurate than 2-D imaging for identifying positive margins.

3-D Tomosynthesis for Intra-Operative Margin Assessment During Breast Conserving Surgery
DM Black, G Rauch, J Leung, K Park, A Sahin, HM Kuerer
Department of Breast Surgical Oncology, Department of Diagnostic Radiology, Department of Pathology, MD Anderson Cancer Center

Study Size: 99 patients

Study: Retrospective comparison of specimen tomosynthesis with the facility’s Standard Extensive Processing for intraoperative margin assessment.

Key Findings
Intraoperative Specimen Tomosynthesis is:
- More accurate than 2-D X-ray and Standard Extensive Processing at identifying positive margins.
- Less likely to recommend unnecessary tissue excision.
- Less time consuming than Standard Extensive Procedure.

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 cases 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 ranking, orientation → 2-D image of the intact specimen → specimen sliced into 5 mm sections with gross examination 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 3-DT were compared.

Intra-operative Standard Extensive Processing
- 2-D Intact Specimen Image
- 2-D Sliced Specimen Image
- 3-DT Images: 1 mm digital sections of intact specimen

3-D Tomosynthesis Specimen Evaluation
- HD Surgeon guided excision of additional superior/posterior and medial tissue.
- HD Margin read as negative.
- HD Margin read as positive.
- Final pathology: T1, any grade, 0.7 cm IDC, closest margin 2 mm superior/posteriorly.

Results
- Clinicopathologic Features

<table>
<thead>
<tr>
<th>Clinicopathologic Feature</th>
<th>Number of Cases (n = 99)</th>
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<tbody>
<tr>
<td>Pathology</td>
<td></td>
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<tr>
<td>Invasive Ductal Carcinoma</td>
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<tr>
<td>Invasive Lobular Carcinoma</td>
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<tr>
<td>Mixed Ductal/Lobular Carcinoma</td>
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<tr>
<td>Invasive Micropapillary Carcinoma</td>
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<td>Phyllodes Tumor</td>
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<tr>
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<td>16</td>
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<td>&lt;1 cm</td>
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<tr>
<td>≥1 cm</td>
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<tr>
<td>Tumor Location</td>
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<tr>
<td>Intra-operative Specimen</td>
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<tr>
<td>Post-operative Specimen</td>
<td>93%</td>
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<tr>
<td>Positive Margin</td>
<td>28%</td>
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<tr>
<td>Negative Margin</td>
<td>72%</td>
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Detecting Positive Margins with 3-D Tomosynthesis
- 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.
- 15 (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.
- Defining Positive Margins with 3-D Tomosynthesis

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>72%</td>
</tr>
</tbody>
</table>

Accuracy of SEP versus 3-D Tomosynthesis
- 95% 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%.

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
- American Society of Breast Surgeons (ASBrS) Mastery (SM) Database
- American Society of Breast Surgeons (ASBrS) Mastery (SM) Database
- Following the SSO-ASTRO “No Ink on Tumor” Guidelines. Ann Surg Oncol.
The Mozart® Specimen Tomosynthesis System

- The only system to use tomosynthesis to give a better view of your surgical margins
- Integrated HD optical camera to ensure specimen orientation
- Voice control for hands-free operation
- Augmented Intelligence identifies microcalcifications and their locations.
- Only from KUBTEC

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