

# A Breast Surgeon's Use of Three Dimensional Specimen Tomosynthesis

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The primary goal of a breast surgeon is to remove the tumor completely, preferably in a single procedure and with optimal breast conservation techniques. To do this, the surgeon must be confident that they have achieved a clear oncological margin at the first attempt.

This paper discusses the challenges the surgeon faces, together with the impact that Digital Specimen Tomography can have on improving the success rate in achieving their primary goals.

The situation is complicated by the fact that no two cases are alike. In some cases, the cancer may present as a palpable lesion, in others it may appear as calcifications on a mammogram, and in others it may display as a spiculated lesion. The myriad of presentations do not alter a surgeon's obligations. The goal of each surgeon, regardless of whether they perform 200 procedures a year or two, is to remove the entire tumor in a single procedure.

#### Not All Lesions Are The Same

When planning and performing a lumpectomy, the surgeon must consider not just the location of the tumor but also its shape. Biopsy clips and manual palpation may determine the central mass of a lesion, but many lesions have fingerlike extensions in random directions, may be multicentric, or have scattered clusters of calcifications. Intraoperatively, it may be difficult to determine the extent of the lesion, as these extensions can often penetrate what we perceive to be normal tissue beyond where the lesion appears to end.

To address this, surgeons often excise additional tissue margins around the perceived center of the lesion in the hope of capturing any three dimensional cancer projections extending from the specimen. However, as we know from re-excision and positive margin rates, that method is likely to be wrong 20 to 40% of the time.

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According to Laurence E. McCahill, MD, "Failure to achieve appropriate margins at the initial operation will require additional surgery with re-excision rate estimates ranging from 30% to 60%. These additional operations can produce considerable psychological, physical and economic stress for patients and may delay use of recommended adjuvant therapies. A high percentage (10%-36%) of women requiring re-excision undergo total mastectomy. Thus, the effect of re-excision on altering a patient's initial treatment of choice is significant."<sup>1</sup>

Although the SSO-ASTRO consensus conference on margins has created a definition of a clear margin, it does not assist the surgeon in making intraoperative decisions, as it only applies to the final pathology report that defines the need for re-excision. In addition, the SSO-ASTRO consensus statement does not apply to pure DCIS, which is a common cause of calcifications noted at the margins. That notwithstanding, surgeons would generally prefer to have an intraoperative indication that patients have an adequate clear margin, regardless of the existence of a consensus statement.

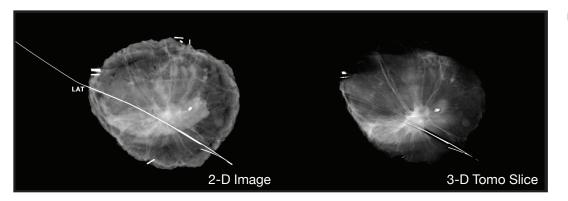


Figure 1: From the 2-D image, you can get a general idea that there are spiculations emanating from the center of the lesion. Looking at the 3-D Tomo Slice, however, the spiculations radiating from this small cancer are shown with greater clarity together with the adequate margins surrounding it. This is a clear demonstration that, whereas the 2-D image may show a suggestion of the lesion, the 3-D image shows the true character of the lesion.

#### 2-D Single View Specimen Mammography vs. 2-D Two Orthogonal View Mammography vs. True 3-D Specimen Tomosynthesis Mammography

Of the multiple methods available to assist the surgeon to measure the adequacy of margins intraoperatively, specimen mammography is the most widely used in the United States. In the past, surgeons depended on a single view AP two dimensional specimen mammography to confirm that all the clips had been retrieved and to determine the approximate extent of the tumor in relation to the visualized margin. Although this method may be acceptable in some situations, single view two dimensional specimen mammography does not adequately determine a clear margin. This may have been valuable before the use of core needle biopsy when many breast excisions were for diagnosis and not for treatment. Now that surgical excisions are expected to have clear margins in all directions, single view 2-D imaging is unacceptable. The three dimensional nature of breast specimens requires a more advanced technology to visualize the entire 3-D architecture of the specimen.

"Now that surgical excisions are expected to have clear margins in all directions, single view 2-D imaging is unacceptable." Left over from the age of surgical biopsy instead of core needle biopsy, there is an assumption that having removed the area identified by the clips and guide needles, the lesion has been successfully removed. Without the benefit of improved technology to confirm the successful removal of the entire lesion, surgeons must wait for pathologic confirmation.

As a result of this transition from surgical biopsy to surgical excision, the American Society of Breast Surgeons has suggested the implementation of two-view orthogonal specimen mammography, which provides surgeons with a proxy for a three dimensional view of the shape, size and extent of the targeted cancer. However, two orthogonal views of a specimen are similar to a PA and Lateral Chest X-ray. Although you may be able to see the lesions in the lungs, the exact location and relationship to the periphery or other sites in the chest is better defined by a CT scan or tomosynthesis. Two orthogonal views have helped progress in this field, but the positive margin and re-excision rates still remain too high. Although useful, two-view orthogonal 2-D specimen mammography still fails to determine the exact location (in the x, y and z-axis) and extent of an asymmetric breast lesion.

Fortunately, the use of true 3-D tomosynthesis of specimens in one or two views dramatically increases the ability of the surgeon to intraoperatively answer these questions.

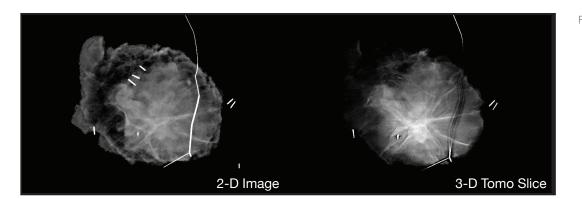


Figure 2: Look at the 2-D view first and you can see a central distortion. Look then at the 3-D Tomo Slice and notice the clarity of spiculations that can be seen, leaving no doubt that the lesion is centered in the specimen. Also note the three clips above the lesion in the 2-D are out of the slice in the 3-D view.

#### **3-D Tomography Changes Our Orientation**

Tomosynthesis, which has been studied for years by Dr. Daniel Kopans, among others, has greatly enhanced the ability of radiologists to identify cancers and to substantially reduce callbacks. Compared to 2-D standard mammography (MLO and CC views), tomosynthesis, or multiple slices, has greatly enhanced the success of initial mammograms by enabling physicians to determine if a lesion exists, in addition to identifying its character and exact location. Centers performing screening mammogram tomosynthesis typically have callback rates less than 50 % of those centers using 2-D mammography.

According to Dr. Kopans, "In our experience, 25% of the women recalled after screening are found merely to have superimposition of normal tissue that forms a summation shadow that looks like a lesion. With conventional imaging, the patient is recalled, and several (sometimes many) additional images are obtained to try to determine whether a real lesion is present in the breast or if summation of normal structures has been found. DBT (Digital Breast Tomography) eliminates this reason for recall because tissues no longer are superimposed, so summation shadows cannot occur."<sup>2</sup>

The significant improvement of 3-D tomosynthesis is due to the superior visualization of breast findings obscured by layers of normal tissue that are wiped away with serial tomographic images. The value that 3-D tomosynthesis produces for screening mammograms directly correlates to similar improvements in intraoperative specimen mammography. "Once the location of the targeted lesion is best visualized, surgeons can follow the imaged tumor three dimensionally in all directions to document margins."

Tomosynthesis provides a specific depth of field, which allows surgeons to examine a specimen in one millimeter increments and visualize the exact slice that best identifies the targeted tumor. Here exact spiculations can be seen, multiple calcifications identified, and close margins better visualized using serial imaged slices of the specimen. Once the location of the targeted lesion is best visualized, surgeons can follow the imaged tumor three dimensionally in all directions to document margins. If the lesion presents as multiple calcifications, the surgeon can identify calcifications three dimensionally and track them out to the margin in the Z-axis, which is not possible with 2-D orthogonal views.

Surgeons are well aware of the benefits of tomosynthesis. Both an abdominal film and a CT of the abdomen show the intestinal gas patterns, the liver and spleen. However, there is much more information on a CT scan; no surgeon would be satisfied with an abdominal film when they have the option of a CT scan of the abdomen.

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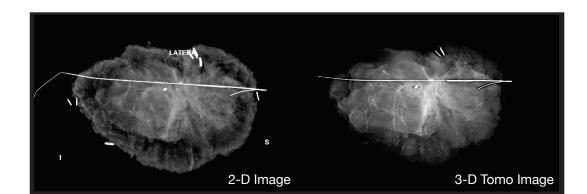


Figure 3: Again look at the 2-D view first and you can see a central density without remarkable spiculations. Then look at the 3-D Tomo Slice and notice the clarity of spiculations, giving clear vision of a small spiculated mass to the right of the clip in the 3-D view, not apparent in 2-D.

#### Digital Specimen Tomography: 3-D Imaging for Breast Specimens

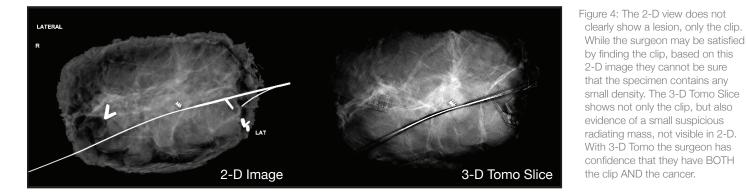
The breast surgeon's goal is to remove the entire extent of the cancer in a single procedure with adequate but not excessive margins, and to do this with the spectrum of shapes, sizes and locations of tumors. A major challenge is to know as precisely as possible where the lesion begins and ends.

Specimen tomosynthesis identifies the extent of a lesion more precisely than two dimensional imaging and has the advantage of determining orientation in the third "Z-axis". While 2-D imaging can say the medial margin is 2 mm from the calcification, 3-D imaging can say the medial margin is 2mm from the calcification located at 5 mm from the anterior margin. Three dimensions gives each site the x, y and z axis of location, making further surgery more accurate. Likewise, when a subtle spiculated lesion is contained within a thick specimen, it is difficult to know whether it is contained in the 2-D image. However, 3-D tomosynthesis slices provide a clear image of the spiculations at the level of the lesion without the need to look "through" the surrounding breast tissue. In excisions that contain a segment of skin which obscures the 2-D specimen, the 3-D slicing provides an image without any skin obscurity. Although not every specimen image requires 3-D slicing, it is not possible to know when this technique will be most valuable.

Another area where tomosynthesis demonstrates value is with shaved margins. Recently it has become more popular for lumpectomy surgeons to take shaved margins, effectively removing more tissue circumferentially as a precaution. While this may decrease the positive margin rate, it can also result in a poorer cosmetic result. Proper shaved margins include a shave of the entire size of the margin, which dramatically increases the actual breast tissue removed. Alternatively, reducing the size of shaved margins may not achieve the goal of definitively clear margins.

"Specimen tomosynthesis identifies the extent of a lesion more precisely than two dimensional imaging"

One might consider using 3-D specimen tomosynthesis to substitute for shaved margins. As described, 3-D tomosynthesis identifies the location of the closest or positive margins in the specimen and enables surgeons to determine if more tissue removal is necessary which in turn may maintain the cosmetic result.



Two 2-D Orthogonal Views Are Not Equivalent to Tomosynthesis

As described, the original specimen mammograms were a single AP 2-D image. When many specimens were found to have positive margins, it was suggested that a better three dimensional view should be obtained. At the time, that was described as two orthogonal 2-D views of the specimen. To this day, most surgeons believe that two view orthogonal 2-D view is actually a three dimensional view. Unfortunately, it is not a 3-D view but only two 2-D views. A true three dimensional view only occurs with tomosynthesis, providing serial images of the Z-axis. Like a CT scan, only serial images can provide a true three dimensional view of tissue. It will be some time before many surgeons truly understand the difference between two 2-D orthogonal views and 3-D tomosynthesis imaging.

"Use of specimen tomosynthesis ... allow surgeons to take less healthy breast tissue and more targeted involved breast tissue."

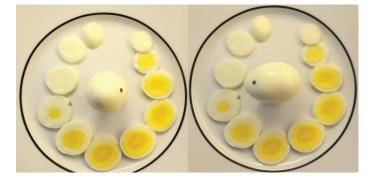


Figure 7: Two orthogonal views are not the same as three dimensional slices. To visualize the difference, we marked the outside of a boiled egg with a dot to represent a positive margin on a specimen, as shown in the figure above. Using two 2-D orthogonal views of the egg, it appears that the dot is within the perimeter of the specimen, suggesting that the specimen has a clear margin. However, by viewing the specimen in slices, it is clear that on one slice the spot is at the margin edge. The serial slices show the true margin, while the two orthogonal views can mislead the surgeon by showing an apparent negative margin when the margin is actually positive. The images seem to speak for themselves.

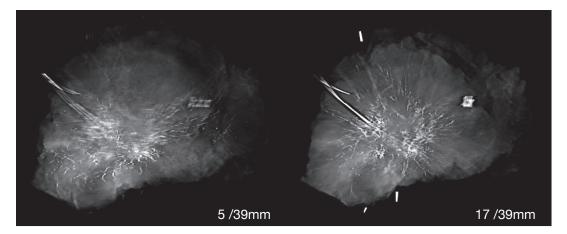


Figure 5: These two images are from a 3-D tomosynthesis series of an impressive calcified lesion which give the surgeon essential information not available in a 2-D view. The tissue was measured to be 39mm in thickness and the two Tomo Slices shown here are those 5mm and 17mm from the ground level respectively. On the 5mm slice, the positive borders with calcifications at the margin are on the far right, far left and inferior margins. On the 17mm slice, the positive margins are superior, superior to the left and inferior. At this level, the far right margin is quite clear. This demonstrates that the borders which are positive are at different depths within the specimen. This enables more specific, informed intraoperative decisions to be made using information not previously available with 2-D imaging.

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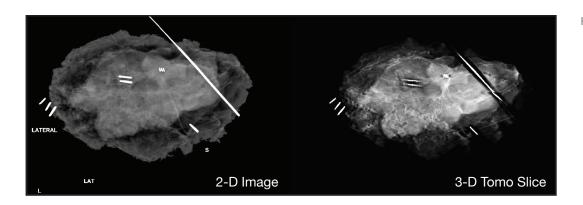


Figure 6: This specimen has a small spiculated lesion just inferior to the clip. Whereas the 2-D image only shows it as a density, fine spiculations can be clearly seen on the 3-D Tomo slice.

Surgeons familiar with 2-D orthogonal views have incorporated a compensation in their practice for the limitations of 2-D technology. Because 2-D imaging does not identify where the close margins or calcifications are in relation to the Z axis, a positive or close margin on 2-D orthogonal views forces a large excision of that margin. The surgeon may take full thickness tissue from the anterior to the deep breast to increase the likelihood that the margin will be clear. In essence, the limitations of 2-D technology force surgeons to assume that full margin re-sections are necessary. Use of specimen tomosynthesis in those cases would identify that close margins at the edge of the specimen are closer to the anterior or the posterior aspect of the specimen and allow surgeons to take less healthy breast tissue and more targeted involved breast tissue. The accommodation for 2-D orthogonal views is ingrained in surgeons and only after using tomosynthesis for a while do they realize the value of true three dimensional vision.

"Three dimensional tomosynthesis is the future of specimen mammography, and I am pleased to be utilizing it for my patients."

Finally, it should be restated that two orthogonal two dimensional views are not equivalent to three dimensional specimen imaging. Tomosynthesis with multiple slices through the specimen allows surgeons to rely on slices that highlight the tumor, as well as the location and extension of the lesion. Three dimensional tomosynthesis is the future of specimen mammography, and I am pleased to be utilizing it for my patients.

3-D tomosynthesis images generated using: The MOZART® System with TomoSpec® Technology provided by Kubtec® <u>www.kubtec.com/mozart</u>

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### Cary S. Kaufman MD, FACS

is a breast surgeon for over 30 years. His prior accomplishments include serving 4 years as the Chairman of the National Accreditation Program for Breast Centers, three years as the President of the National Consortium of Breast Centers, three years as a Board Member and Committee Chair of the American Society of Breast Surgeons and the author of many published articles and book chapters. He is on the clinical faculty of the University of Washington and has lectured in the US and 15 other countries regarding diagnosis, treatment and management of breast cancer. One of his areas of interest is intraoperative imaging by breast surgeons. He has no disclosures regarding any statements in this monograph.

#### The Mozart® System with TomoSpec® Technology

is a patented specimen radiography system designed to provide improved visualization of tumors during breast cancer surgery. The Mozart System uses tomosynthesis to provide the surgeon with true 3D images of breast specimens in 1mm slices, giving definitive actionable information on the nature and location of lesions within an excised specimen.

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