View for View, 3-D Specimen Tomosynthesis Provides More Data Than 2-D Specimen Mammography

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Background/Objective:
Intraoperative Digital Specimen Mammography (IDSM) has become the standard confirmation method to ensure an image-guided procedure has removed the targeted breast lesion. We've seen improvements in camera acuity, faster processing and larger fields of view to facilitate the surgeon's identification of non-palpable cancers. The guidelines for clear margins have also been changing during this time. To obtain the so-called three-dimensional view (3-D), routine use of two orthogonal images have been utilized as a 3-D view. Yet in screening mammography, true 3-D mammography has now arrived as tomosynthesis, not simply two orthogonal MLO and CC views of the breast. Likewise for specimen imaging, true 3-D specimen tomosynthesis (IDST) provides more information than IDSM. It was possible to see more easily using IDST (see figure). Looking at all 210 lesions as a group, IDST was more precise in 43% of lesions.

Methods:
Between April 2015 and October 2016 we have obtained specimen imaging on 210 consecutive image-guided breast lumpectomies using two specimen imaging machines. One provided IDSM and the other provided IDST. Two orthogonal views of each specimen were taken with each machine. For patient management, intraoperative review of all images was available to the operating surgeon for their immediate action as appropriate. Comparison data was accumulated as to ease of use, time to first image, handling issues, re-excisions, mechanical issues as well as image comparisons. Images of breast lesions were categorized into three groups by their dominant findings: 1) densities, 2) calcifications and 3) clips. All images were forwarded from the operating room to the radiologists and permanent recording via standard PACS system.

Results:
The circulating nurse received the specimen from the surgeon and placed it sequentially in each of the machines in the exact same orientation. For equal comparisons, two orthogonal views were taken with each device, although the use of tomosynthesis obviates the need for two orthogonal images since the Z-axis is visible on a single image. Functionality of the two machines were very similar. Time to first image was prompt although there was a difference in the development time for the IDST, being almost twice as long as IDSM (65 seconds vs. 32 seconds). Of the 210 patients, specimen images were classified into 61% densities, 26% calcifications and 13% clips. All images were forwarded from the operating room to the radiologists and permanent recording via standard PACS system.

Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Total 210</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65 (range 33-90)</td>
<td>92</td>
<td>118</td>
</tr>
<tr>
<td>Stage N (in)</td>
<td>Total IDSM (210)</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>0</td>
<td>95% (116)</td>
<td>11%</td>
<td>9%</td>
</tr>
<tr>
<td>1</td>
<td>5% (14)</td>
<td>89%</td>
<td>91%</td>
</tr>
<tr>
<td>Size (cm)</td>
<td>1.72 (range 0.1-6.0)</td>
<td>128</td>
<td>155</td>
</tr>
<tr>
<td>Node Positive</td>
<td>19%</td>
<td>41%</td>
<td>43%</td>
</tr>
</tbody>
</table>

Re-excision rate

<table>
<thead>
<tr>
<th>Distribution of Imaging Findings</th>
<th>Densities</th>
<th>Clips</th>
<th>Calcifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>12%</td>
<td>55%</td>
<td>22%</td>
</tr>
<tr>
<td>2016</td>
<td>41%</td>
<td>26%</td>
<td>13%</td>
</tr>
</tbody>
</table>

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

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
- Peripheral 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

Re-excision rates dropped during the 20 months of use from 16% to 9%.

Average overall re-excision rate for the entire period was low at 12%.

KEY FINDING:
- In 70% of the densities, the Tomosynthesis images provided more information than Mammography.
- Lesions were easier to visualize, to define their extent, and were better able to recognize vague lesions.

SECOND FINDING:
- Results:
  - Re-excision rates dropped during the 20 months of use from 16% to 9%.
  - Average overall re-excision rate for the entire period was low at 12%.