MQSA

Certified facilities, as of October 1, 2014  0.720
Certification statistics, as of April 1, 2015
Total certified facilities/Total accredited units  0.748/14,140
Certified facilities with FDA-registered mammography units  0.032/1,014
FY 2015 inspection statistics, as of April 1, 2015
Facilities inspected  3,000
Total units at inspected facilities  4,116
Percent of inspections where the highest noncompliance score is:
Level 1 violation  6.7%
Level 2 violation  8.7%
Level 3 violation  2.8%
Percent of inspections with no violation  86.5%
Total annual mammography procedures reported, as of April 1, 2015 38,790,040

Caring for her at every stage of life.

Theory & Technology and advancement in 3D imaging

DBT

Imaging Modes

Three imaging modes available:
- Conventional full field digital mammography (2D only)
- Tomosynthesis imaging (3D only)
- “Combo imaging” (2D plus 3D)
  - Conventional 2D image plus tomosynthesis scan acquired during same compression, resulting in co-registered 2D and 3D images and both datasets are available for review
Mammography

Mammography, in particular digital mammography, is the gold standard in breast cancer screening.

Three manufacturers approved for Tomo
Hologic and GE, and Siemens

Mammography Screening Requirements for the United States
Systems must be capable of:

- Imaging the whole breast
- Image all types of breasts
- Image all lesion types, mass, calcification, distortion
- Fast and reasonable cost
- Low radiation dose

Why 2D Digital Mammography

2D FFDM it appears to be slightly more sensitive than digital breast tomosynthesis for the detection of calcification. Diagnostic performance as measured by area under the curve using BI-RADS was not significantly different. With improvements in processing algorithms and display, digital breast tomosynthesis could potentially be improved for this purpose.

Why Breast Tomosynthesis?

Breast tomosynthesis provides a 3D imaging capability that allows the more accurate evaluation of lesions by enabling better differentiation between overlapping tissues. A lower recall rate, higher positive predictive value for a biopsy recommendation. Higher cancer detection rates, fewer recalls, fewer biopsies, and improved radiologist confidence are expected to result from the use of this technology. Breast tomosynthesis should be valuable in both screening mammography and diagnostic mammography.
Potential Benefits of 3D

- Increased breast cancer detection
- Decreased workup rate for non-cancer cases
- Improved lesion margin visibility
- Precise lesion localization

Potential Benefits and why we need 3D imaging

Reduce recall rate of patients by reducing confusion which arises from tissue overlap.

Biopsy rate decreased as there is improvement in separation and visualization of parenchymal structures.

Time will possibly show improvement in cancer detection particularly in patients with dense breast tissue.

Fewer images required for diagnosis equals a reduction in dose.

Compression is a must at this time. NO changes yet but in future may be possible.

Tomo Visualization of Features

- In General
  - In-plane objects look similar to 2D but with less interfering superimposed parenchyma
  - Features appear fuzzy until bring in the plane slice
  - Persistence of shadows depends on object size

Invasive Cancer (numbers of CA)

<table>
<thead>
<tr>
<th>Type</th>
<th>2D</th>
<th>2D + 3D</th>
<th>Diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invasive CA</td>
<td>56</td>
<td>81</td>
<td>45%</td>
</tr>
<tr>
<td>&lt;15 mm</td>
<td>37</td>
<td>59</td>
<td>59%</td>
</tr>
<tr>
<td>LN neg</td>
<td>44</td>
<td>63</td>
<td>43%</td>
</tr>
<tr>
<td>Distortion</td>
<td>8</td>
<td>16</td>
<td>100%</td>
</tr>
<tr>
<td>Calcs</td>
<td>6</td>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>

Skeane, Radiology 2013

Why Breast Tomosynthesis?

Tomosynthesis should resolve many of the tissue overlap reading problems that are a major source of the need for recalls and additional imaging in 2D mammography exams.

The biopsy rate might also decrease through improved visualization of suspect objects.

Some pathologies that are mammographically occult will be discernible through the elimination of structure noise and tomosynthesis may therefore allow improved detection of cancers.

Rationale for using 2D plus 3D

- Comparison of current images with prior images is standard mammography practice and critical to perceive subtle changes which may be associated with a cancer.
- Obtaining a 2D exam along with the 3D exam will allow direct comparison of current 2D images with prior 2D images.
Tomosynthesis

Digital mammography provides images with improved dynamic range and SNR, as well as the ability to adjust image brightness and contrast after acquisition. Despite these improvements it is limited in the same manner as film/screen due to superimposition in a 2D image.

Why is There a Need for 3D Tomosynthesis

In 2D FFDM:
- Tissue superimposition hides pathologies in 2D
- Tissue superimposition mimics pathologies in 2D

Two objects (a spiculated lesion and ellipse) superimpose when the x-rays are at 0°, but the off-axis acquisitions shift the objects' shadows relative to one another in the images.

Projections are the basis of the “displayed “Slices”.
- While stabilizing the breast, images are acquired at a number of different x-ray source angles.
- Objects at different heights in the breast display differently in all projections.

3D Breast Tomosynthesis

- A 3D screening modality that preserves the very high resolution of 2D FFDM
- Multiple images of the breast are acquired at different angles during a sweep of the x-ray tube
- Allows radiologists to see around overlapping structures

Note that additional acquisitions are not required to enhance the visibility of objects at any given height—one set of acquired data can be reprocessed to generate the entire 3D volume set.
The final step in the tomosynthesis procedure is reconstructing the data to generate images that enhance objects from a given height by appropriate shifting of the projections relative to one another.

Why Digital Breast Tomosynthesis (3D)?
- 3D improves visibility by reducing tissue superimposition

Think of it as Raisin Breast

Slabbing
May not perceive calcifications as a cluster
Radiologist have ability to slab information
Look at a 10mm slab vs a 1mm slice
Calcifications

- Segmental and clustered calcifications are more easily and quickly appreciated with 2D because they can traverse multiple slices in 3D.
- By minimizing structure overlap, 3D optimally demonstrates masses and architectural distortion.

Example case with Calcs
The Solution is 3D Breast Tomosynthesis

Tomosynthesis is a three-dimensional mammographic examination that can minimize the effects of structure overlap within the breast.

2D Imaging vs. 3D Imaging

- **2D**
  - Either molybdenum or tungsten x-ray tube
  - 20 to 39 kVp
  - Moly or rhodium or silver filters
  - 100 mA
  - HTC grid

- **3D**
  - Tungsten x-ray tube
  - 20 to 49 kVp
  - Aluminum filter
  - 200 mA
  - No grid
  - No GRID when the tube is off axis (you would see grid lines)

How Does Hologic’s 3D Breast Tomosynthesis Work?

- Tube moves in a 15° arc
- 15 low dose images are acquired
  - 1 image at each degree
  - Four second sweep
- Images are reconstructed into 1 mm slices
- In combo-mode imaging, the 2D and 3D are taken in the same compression, with no additional positioning for the patient.

How Does GE Senoclaire Tomosynthesis work

- Tube moves in a 25° arc
- 9 low dose images are acquired
  - 1 image at 2.8 degree
- Images are reconstructed into 1 mm slices
- In combo-mode imaging, the 2D and 3D are taken in the same compression, with no additional positioning for the patient.

How Does Siemens Inspiration Tomosynthesis work

- Tube moves in a 50° arc
- 25 low dose images are acquired
  - 1 image at 2.0 degree
- Images are reconstructed into 1 mm slices
- In combo-mode imaging, the 2D and 3D are taken in the same compression, with no additional positioning for the patient.

Breast Tomosynthesis

The 3D image quality and depth resolution directly depend on the number of projections, angle size and reconstruction algorithm.
Performing the Acquisition

The breast is compressed in a standard way. While holding the breast stationary, the x-ray tube is rotated over a limited angular range. A series of low dose exposures are made every degree, creating a series of digital images.

1mm slices: Number of slices dependent upon compressed breast thickness that are reconstructed from projection images

- 50 1mm slices + 5
- Always adds 5 to clear the paddle

Projection Image

- Must have projection image to create slices
- Reconstruction images are born of projection image
- Projection image is checked for motion by technologist
- Slices are from detector to paddle in all views. Example
  - CC-foot to head
  - MLO-lateral to medial
The x-ray tube can move in a continuous or step-and-shoot motion. With continuous motion x-ray exposures must be short enough to avoid image blurring due to focal spot motion. If step-and-shoot motion is employed, the gantry must come to a complete stop at each angular location before turning on the x-rays, otherwise vibration will blur the image. Hologic has continuous motion.

Siemens Tomosynthesis

With True 3D Breast Tomosynthesis, Siemens has opened up a new chapter in mammography diagnostics. High spatial resolution and the largest acquisition angle allow for excellent resolution depth and superior reconstruction results. This leads to fewer artifacts and greater image detail, thereby improving diagnostic capabilities immensely.

Angular Range

Larger angular range gives increased reconstructed slice separation. Smaller angular ranges keep more structures in focus in a given slice. It might be desired for resolving closely lying structures but could impair the appreciation of a cluster of microcalcifications because the individual calcifications would appear in different slices or the appearance of spiculations lying in more than one narrow plane.

Modes of Acquisition

• The unit must perform existing 2D digital mammography images
• Tomosynthesis images must be able to be taken in all standard projections not just the CC and MLO
• Take a normal 2D mammogram and tomosynthesis image in the same compression

Angle of View

![Image showing the angle of view with 0 degrees and +25 degrees.]

Image Reconstruction

Image reconstruction is computing high-resolution images whose planes are parallel to the breast support plates. Reconstructed with slice separation of 1mm. A 5cm compressed breast tomosynthesis study will have 55 reconstructed slices. Reconstruction time must be 10 seconds or less.
Image Reconstruction

Display

Similar to CT reconstructed slices
View one at a time or display as a cine loop
2D images can also be viewed
2D and 3D acquired in the same compression are completely co-registered

Co-Registration

The positioning and compression are exactly the same on the 2D and 3D
allows the radiologist to view the 2D image and the tomosynthesis slices with perfect co-registration on top of each other or side by side.

Co-registered: same positioning 2D and 3D

What does a tomo exam look like?
• 1 mm /slice
• 40-60 slices
• Navigate with mouse
• Slices numbered from breast platform out
Scrolling

CC image, showing scrolling
Co-registration of 2D & 3D breast images

For Radiologists
- Facilitates comparison to priors and images from other facilities
- Single compression allows co-registration of 2D and 3D images

For Administration
- Reimbursement is available for 2D image and 2D CAD, allowing the facility to continue to generate revenue while offering latest technology
- Patient throughput is not impacted

For Technologists
- 2D and 3D scan acquired with a single positioning/view
- Workflow is same as FFDM; no learning curve

For Patients
- The clinical trials proved a reduction in recall rates.
- Reduced recalls can lead to reduced anxiety & reduced inconvenience
- No noticeable difference in breast screening experience

Visibility of low contrast objects are reduced
Even at 4x a conventional dose the digital mammogram (middle) shows inferior low contrast visibility to a tomosynthesis (right) using ¼ the dose

Co-registration of 2D & 3D breast images

3D Breast Tomosynthesis System

RADIOLOGIST READ TIME

Equated to going from film screen to digital
Now digital 2D to 3D same learning curve

CAD is applied to 2D images and then compared to slices what was marked on CAD
What is the projection image?
The images acquired during the tomo sweep
These images are used to create the individual slices
The tomo slices are born of the projection image

What is co-registration?
Positioning and compression are exactly the same on the 2D and 3D
Allows the radiologist to view the 2D image and the tomosynthesis slices with perfect co-registration on top of each other or side by side.

How many tomo slices are there in a routine tomo acquisition?
Depends on the compressed breast thickness
1mm slices plus 5 to clear the paddle

What is the dual acquisition mode called?
Combo-mode
Tomosynthesis DBT

Eliminating Superimposition by Reading the Slice(s) plus 2D

Tomosynthesis Dataset: 2D/3D (Combo Acquisition)

Eliminating Superimposition by Reading the Slice(s) plus 2D

Clinical Image Review

**Why is tomosynthesis going to revolutionize breast imaging?**

Images and data courtesy of:
- Hôpital Privé d’Antony, Paris France
- Massachusetts General Hospital, Boston MA USA
- Netherlands Cancer Institute – Antoni Van Leeuwenhoek Hospital, Amsterdam Holland
- Centre de Radiologie et d’Échographie du Docteur Joussier, Paris France
- Dartmouth Hitchcock Medical Center, Lebanon NH USA
- Magee Women’s Hospital, Pittsburgh PA USA
A 2D Mammography Image with a suspicious area identified and blown up.

The 2D Mammography Image next to one slice of a 3D Image Set.

The 2D Mammography Image next to one slice of a 3D Image Set.
Example 3
Superimposed Tissue Examples

A 2D Mammography Image with a suspicious area identified next to a 3D image set.

As you go thru the image set, you see that the suspicious area is nothing more than normal breast structures overlapping.

More Examples
FFDM vs F/S

- So why is digital better
  - Dynamic range
  - Contrast resolution
  - Can change image appearance and size at soft copy workstation

Why digital is not always better.…

- Processing algorithms may play a role
- Reduced spatial resolution lp numbers are lower
- Learning curve - interpretation

Screening with tomo

- Reduce recall rate
- Up to 2 times the dose if do combo

Tomosynthesis: Concepts and Rationale

- Online November 2011
- University of Pittsburg Medical Center
- Dr. Jules Sumkin
- Dr. Margarita Zuley
Because of the demonstrated improvement in the ROC area using 2D plus tomo imaging, researchers predicted that the expected sensitivity gain from using tomosynthesis in combo-mode would be considerable. The actual gain will likely vary by site based on individual radiologist’s thresholds on detection and recall rate. The exact improvement in cancer detection will not be known until the technology is more widely implemented in screening practices.

Screening with Tomo

Diagnostic

• Useful in lesion characterization

Technical Considerations

• Dose per view
• Angle of arc
• Processing algorithms

Motion

• Standard QC rules apply:
  – All of breast tissue must be imaged
  – Image must appear sharp (won’t appear sharp unless objects in plane being displayed.)
• Just as with 2D, motion can occur
  – Loco-regional
  – Entire breast
  – Subtle or gross
  – Radiologist will determine need for repeat
• Motion not major problem, as scan time is short (< 4 sec)

Calcifications and Tomo

• Confident improvement will be made and will be able to see calcifications as well as on FFDM

Tomoynthesis Compared to Ultrasound

No studies have been published directly comparing the performance of tomosynthesis to ultrasound in breast cancer screening. Nonetheless, several observations may be made about this. Tomosynthesis, like ultrasound, has a superior performance in dense breasts relative to mammography. However, unlike ultrasound, where the recall rate of 2D and ultrasound was 4 times that of 2D mammography alone as was seen in the ACRIN 6666 trial, tomosynthesis improves sensitivity without increasing the recall rate. Further clinical research will be needed to identify the respective roles of tomosynthesis and ultrasound, particularly in screening women with dense breasts.

2D Tomo
2D Tomo
Bottom line…

• Tomosynthesis is “under construction”

But will be finished one day…

THANK YOU