Understanding Digital Breast Tomosynthesis

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Clinical Professor, Department of Radiology, University of Colorado –
Denver, School of Medicine, Aurora, CO
Objectives:

Upon completion, participant will be able to:

1. Understand the design and performance of different manufacturers' digital breast tomosynthesis systems

2. Describe the clinical application and performance differences between digital breast tomosynthesis and digital mammography

3. Understand the quality control tests technologists should be able to perform on digital breast tomosynthesis systems
Tomosynthesis Acquisition

- X-ray tube moves in an arc around the breast
- Series of low dose images are acquired at different angles
- Total dose similar to standard breast exam
Tomosynthesis Acquisition

- X-ray tube moves in an arc around the breast
- Series of low dose images are acquired at different angles
- Collected data permits reconstruction of parallel planes, each plane in-focus, with out-of-plane tissues blurred
Digital Breast Tomosynthesis Acquisition

- Each DBT acquisition consists of 9-25 separate projections that permit reconstruction of multiple planes in the breast, each plane “in focus”
- Overlapping “out-of-plane” tissues are blurred
- Yields clearer lesion margins than 2D in non-fatty breasts
DBT Acquisition and Reconstruction

Low-dose X-Ray sweep

Projection views

Height A
Height B

5 Projection Views

Reconstruction at Height B
Reconstruction at Height A

Plane B
Plane A
Effect of Sweep Angle

- Wider sweep angle gives more complete blurring of tissues outside the focal plane.
- Narrower sweep angle makes lesion margins appear sharper.
Reconstructed DBT Images Can Be Reconstructed as Planes or Slabs

Single Plane

11 cm Slab
3 DBT Systems Are FDA Approved for Clinical Use in the U.S.

• Hologic Dimensions
• GE SenoClaire
• Siemens Inspiration
FDA Approval of DBT

• Hologic Dimensions received FDA approval Feb 2011
  ▪ Hologic’s original approach: CC and MLO DBT + 2D DM
  ▪ Hologic’s new approach: CC and MLO DBT + Synthetic 2D (C-view)

• GE SenoClaire received FDA approval August 2014
  ▪ GE approach: 3D MLO DBT + 2D CC view

• Siemens Inspiration DBT received FDA approval in April 2015
  ▪ Siemens’ approach: CC and MLO DBT + 2D CC and MLO
## Differences Among FDA-approved DBT Systems

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Hologic Dimensions</th>
<th>GE SenoClaire</th>
<th>Siemens Inspiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detector motion</td>
<td>rotating</td>
<td>static</td>
<td>static</td>
</tr>
<tr>
<td>Detector pixel size (μm)</td>
<td>70 (140 DBT)</td>
<td>100</td>
<td>85</td>
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<tr>
<td>Tube motion</td>
<td>continuous</td>
<td>step-and-shoot</td>
<td>continuous</td>
</tr>
<tr>
<td>Angular range (degrees)</td>
<td>15</td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td>Number of projections</td>
<td>15</td>
<td>9</td>
<td>25</td>
</tr>
<tr>
<td>Scan time(seconds)</td>
<td>4</td>
<td>&lt; 10 s</td>
<td>25</td>
</tr>
<tr>
<td>Grid</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Reconstruction algorithm</td>
<td>FBP</td>
<td>iterative</td>
<td>iterative</td>
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</tbody>
</table>
### Step-and-shoot vs. Continuous

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**Diagram:**
- Step-and-shoot
- Continuous
Hologic DBT + 2D

15 Degree Sweep

15 projections in 4 seconds
GE 2D + DBT

DBT

Acquisition:

25 Degree Sweep

9 projections in ~10 seconds
Siemens DBT Acquisition

50 Degree Sweep

25 projections in 25 seconds
Example #1: Multifocal Cancer

DETECTION OF MULTIPLE LESIONS: DBT > MX

Images courtesy of Dr. Gisella Gennaro
Example #2: Invasive Ductal Cancer

Example images of breast cancer detected with DBT (Digital Breast Tomosynthesis). Images courtesy of Dr. Gisella Gennaro.
Radiation Doses in DBT

• Each individual DBT “projection” is very low dose
  - Hologic approach of acquiring DBT + 2D in both CC & MLO projections has a total dose that is about 2.0-2.5 x the dose of 2-view DM
  - Newer Hologic approach of acquiring only DBT views and reconstructing synthetic 2D views (C-view) has a total dose that is 1x-1.5x times that of DM
  - For GE, dose for a DBT view ~ dose for a 2D view
  - For Siemens, single-view DBT dose is 1.4 – 1.9 x higher than single-view DM dose, depending on breast thickness (bigger difference for thinner breasts)
Digital Breast Tomosynthesis (DBT) Radiologist’s Perspective

Jean Paquelet, MD, FACR
Director of Breast Imaging
McKee Medical Center
Loveland Colorado
and
Harmony Breast Diagnostic Center
Fort Collins Colorado
DBT: A Much Better Mammogram

• Decreased Recall Rates (improved specificity) compared to 2D mammography
  – Recall rates (currently 7-10 patients per 100 2D screening exams) for DBT reduced 10-42%
  – Decreased recalls primarily due to elimination of superimposed structures (summation densities)
  – The reduction in recall rates was most pronounced for patients undergoing their first mammogram and for patients with scattered fibroglandular densities and for heterogeneously dense breasts
DBT: A Much Better Mammogram

• Compared to conventional 2D digital mammography, DBT detects more breast cancers (increased sensitivity)
  – Sharpe et al reported a 54.3% increase in breast cancer detection rate with DBT compared to 2D mammography. In a screening population their cancer detection rate rose from 3.5 cancers per thousand women screened to 5.4 cancers per thousand
  – The additional cancers detected with DBT are almost all invasive cancers
  – Most noninvasive cancers (DCIS: Ductal carcinoma in situ) manifest as calcifications. Detection of calcification is not improved with DBT compared to 2D technique
DBT: A Much Better Mammogram

- How will your facility use it?
- Will all mammography units be DBT or just some?
- How will you triage patients? Randomly?
- By breast density?
- By patient preference or insurance coverage?
- By exam type? For screening? Diagnostic? Both?
Your workstation may dictate this choice
DBT better detects invasive cancer due to elimination of overlapping structures and to better lesion border depiction.
DBT: Interpretation

• For an “average” 55 mm thick breast, the radiologist will be viewing about 250 images
  – 2D or synthesized (composite) views: 4 images
  – DBT slices: 55 one mm thick slices for each CC and MLO view: 220 images
  – DBT slabs or thick slices: 6 one centimeter thick images for each CC and MLO view”: 24 images.

Viewing DBT images with thicker slices helps the radiologist appreciate calcification clusters
Currently, most DBT images are viewed on proprietary dedicated workstations. All work stations are not created equal. Some are multimodality. Interpretation from PACS

- Interpretation time for DBT slightly more twice that of 2D mammograms
- Increased interpretation time for screening exams may be partially offset by fewer recalls for DX
- In my practice we have increased FTE for radiologists by 33%
Invasive Ductal Cancer
Invasive Ductal Cancer

RCC tomo cine

RCC single tomo slice
DBT: Changing Work up of Screen Detected Findings

- Many masses seen at screening DBT do not require recall for additional views.
- The screening DBT images often define borders and triangulate the lesion well enough to proceed directly to US and avoid additional mammographic views.
- Even when a finding is seen on a single projection, DBT does provide more information for triangulation.
- However, most facilities report performing more ultrasound than was necessary prior to introduction of DBT. We have increased US staffing by 20%.
Simple Cyst (tomo slices)
DBT: Calcifications

Tomo Slice
High Grade DCIS
2D Mag view
**DBT: Calcifications**

Work-up of calcifications unchanged: Mag views, 90degree lateral
Features that look different on DBT vs 2D

Lumpectomy Scar

Scars are often much more impressive on DBT than on 2D imaging. Scar markers/Diagrams of scars/History particularly important.
Zipper Artifact from Marking Clip

Tomo cine LCC

2D LCC
Skin calcifications & skin lesions easily recognized on DBT
Key Points

- DBT detects more cancers and has fewer recalls than 2D mammograms.
- Additional cancers detected are nearly all invasive.
- Even with DBT, some cancers are missed. Typically the missed cancers are non-calcified, non-spiculated lesions in dense breasts.
- Introduction of DBT may require additional personnel due to increased US volume and radiologist’s increased interpretation time.
TOMOSYNTHESIS FOR TECHNOLOGISTS

Sharon Walenga, BS RT(R)(M)
Clinical Manager of Breast Health and Radiation Oncology
Advocate Lutheran General Hospital
Caldwell Breast Center
Caldwell Breast Center

- Breast Imaging Center of Excellence (BICOE) from American College of Radiology
- NAPBC- National Accreditation Program for Breast Centers
- Perform mammography, breast ultrasound and breast MRI examinations with biopsy capability in all modalities
- Consistent 99% patient satisfaction
- First in the Midwest to perform Tomosynthesis
Mammography- Through the Years...

- Xerography
- Analog
- Digital
- Tomosynthesis
Contrary to Popular Opinion...

- Digital Breast Tomosynthesis is not quite 3D.
The Path of Tomosynthesis

- Entered Hologic Pivotal Multicenter Tomosynthesis Trial with PI Betty Rafferty, MD at Massachusetts General Hospital, Boston, MA:
  - “A Multicenter, Controlled Trail to Evaluate the Hologic Tomosynthesis Mammography System”
- At LGH- 5 technologists and 4 Physicians trained for 8 hours each to consent, perform and interpret examinations
Beta Tomosynthesis Study at LGH

- Installed beta unit April 2010
- Total of 22 sites across country participating
  - Approximately 3,200 total subjects enrolled
- Imaged 120 patients at ALGH
- Involved in 2 arms of the study:

**Screening arm**
- No prior surgical procedures
- No biopsy clips
- Female

**Biopsy arm**
- Same as screening arm exclusion criteria
- Recommended for biopsy based on recent diagnostic examination
Overall Experience

- Technologist experience
  - Switch to new machine - very user friendly
  - Faster QC

- Patient experience
  - Little to no difference
  - Some patients concerned about additional radiation
  - Less painful

- Radiologist experience
  - Longer to interpret screening
  - Helpful in diagnostic setting
Transition to Commercial Use

- DBT was FDA approved in February 2011
- LGH was able to secure donated funds to purchase our Beta Unit
- Started imaging in June 13, 2011
- Purchased additional units in 2012, 2014 and 2016
Outcomes

- Oslo Breast Cancer Screening Trail - 2013
  - 40% increase in the detection of invasive breast cancers
  - 27% increase in the detection of all cancers (invasive and in situ cancers combined)
  - 15% decrease in false-positive rates

  - 41% increase in the detection of invasive breast cancers
  - 29% increase in the detection of all cancers
  - 15% decrease in the recall rates
Implementation
Your Team

- Project Manager
  - Lead Interpreting Radiologist, Manager
- Sales person, Field Engineer, Connectively specialist from your chosen vendor
- Maintenance
- Pacs Administrator/ Clinical Engineer
- Finance
- Charge master/RIS
- Medical Physicist
Considerations

- Which patients to image?
- How many images should you take?
- Reimbursement/charging patients
- Do you need an order?
- Educating referring physicians
- Should you consent the patients?
Which Patients to Image?

- FDA approval for both screening and diagnostic imaging
  - Who is the Focus? Screening or Diagnostic patients?
  - Do we designate patients who might be better Tomosynthesis candidates?
  - We have limited number of machines!
What we did

- Diagnostic patients (specifically call backs and patients who present with a problem) priority
- Patients requesting Tomosynthesis from the screening population scheduled.
- After more requests for DBT screening and obtaining a 2nd unit went to all Tomo after 3:00pm Monday-Friday and all day Saturday. Exception is request Diagnostic either by Radiologist or Referring Physician.
- With 4th room purchase in 2016-95% of screenings are performed with DBT
Volumes

- Screenings
- Diagnostic
- Total

Imaging

- **Screening**
  - Standard CC and MLO
  - Implant- ID only
  - Mosaic- Largest part

- **Diagnostic**
  - Architectural distortion- spot
  - Skin Calcifications and palpable abnormalities- omits tangential
Choices

- **Hologic**
  - Combo- 3D then 2D
  - Tomo- 3D only
  - Combo HD- 3D, 2D and C-view

- **GE**
  - 2D- CC and MLO
  - 3D only in MLO
  - Premium view
Replacement of 2D

- Synthesized 3D image to eventually replace 2D
- Can only be used on Standard imaging
  - Cannot be used on spots, mags or tangentials
  - Great for highlighting faint calcifications
Reimbursement

- 2015- CPT code 77063 for screening
- Medicare declared as “standard of care”
- Most private insurance companies are paying 2D + 3D plus physician component but very inconsistent.
Exploding Charge

“...The charge for the 3-D mammography will be set up so you will bill the regular mammography charge plus the add-on charge (they are still looking into the CAD component). The charge for the add-on will be about $X. Generally, insurance companies follow Medicare in their billing and payment methodologies. However, we have some insurance companies that pay us a flat rate for a mammography, whether it is analog, digital, 3D or whatever. We have also had an issue in the past where one insurance company would not pay for the CAD component which they considered experimental – although all other insurance companies would. This has since been resolved. We do not anticipate that the insurance companies will not cover this if ordered by a physician, but you never know for sure until we start billing it, and at that time we will work with them so it is covered.” – Beth Hickey, Director of Finance
Charge Master

- Contact Charge Master to create codes
  - FFDM Screening / Diagnostic
    - Implants
    - Unilateral
    - CAD/ No CAD
Do you need an Order?

- Currently, no additional orders are necessary for Tomosynthesis examinations, though many physician’s offices are requesting.
Education Referring Physicians

- Important to educate referring physicians
- Send a letter to hospital staff via email and regular mailboxes
- Visit offices to answer questions
- Inform marketing team with basics
Is a Consent Needed?

- No written consent is necessary since the examination is not invasive.
- May want to consider discussing:
  - Examination a few seconds longer under the same compression.
  - Machine moves on an arc with Tomosynthesis.
  - Advantage of “seeing through tissue” and potentially increasing detection of breast cancer and deceasing additional imaging.
Patient – Radiation dose

Tungsten target instead of Molybdenum

20% less dose on 2D

- Average glandular dose needs to be less than 300mrad
  - 2D Selenia = 193mrad
  - 2D Dimensions = 134mrad
  - 3D Portion = 156mrad
  - Combo 2D + 3D = 291mrad

Data based off phantom image- not patient dose
Upgrade needed - Manager

- 3 Hologic Selenia / 4 Dimensions plus 2 R2 checkers and 1 Cenova
- Anticipate all machines to be converted to Dimensions and therefore upgrade is needed for speed and viewing ease
- All SecurView software upgraded and Manager Hardware replaced (Power Edge T610)
- Purchased SecureXchange to pull priors when patient enters system (RIS)
Upgrade needed - Manager

- **Dell PowerEdge 2900 Server - Old**
  - Tower Chassis
  - (2) Quad-Core Processors
  - 4GB RAM Memory
  - 10/100/1000 BaseT Ethernet Interface

- **Dell PowerEdge T610 Server - New**
  - Windows Server 2003
  - Dual Quad-Core Processors at 2.5 GHz
  - Hard drives are RAID 5 3.5 TB

- This unit can handle 80 patients per hour assuming 2 prior studies for each patient. It can connect to up to 10 SVDX Client workstations.
PACS Memory

- **2D imaging - Screening (4 images)**
  - 8x10 uses 17 MB per image = 68 MB
  - 10x12 uses 27 MB per image = 108 MB

- **3D combo- 2D + 3D (4 view screening)**
  200 MB compressed file

*Currently the 3D images are not able to be visualized on Pacs though they are archived.*

*In future, there will be a fully compatible diacom but will require 400 MB.*
Cost

- **Mammography unit**
  - 2D Dimensions
  - 3D Option + License
  - CAD- Cenova + License

- **Options**
  - SecureView Reading Station
  - Secure Xchange
  - Localization kit
  - Paddle holder

- **Electrical requirements**

- **ACR**
We got the Power!

- Selenia- 220 line (208), 35 amp
- Dimensions 220 line (208), 40 amp
Money AND Time?

- **Installation** - 4 to 5 days
  - Remove old unit - 1 day
  - Installation of machine - 2-3 days
  - Physicist testing - 1 day
Education

- Technologist – application training on site – 8hrs required
- Radiologist – Webinar or Conference- 8 hrs required
2D Accreditation - ACR

New Unit addendum
If more than 13 months left on Accreditation
- $850 per unit now $1000
- Transfers of current expiration date

Initial/ Early Renewal
If less than 13 months left on Accreditation
- $1475 for first unit now $1700
- $1300 for additional units now $1500
- Good for 3 Years
2D Accreditation - ACR

- Submit to ACR via website
  - Physicist forms
    - MQSA Requirements for Mammography Equipment checklist
    - Medical Physicist’s QC Test Summary form
  - Withdrawn Unit Memo
  - New Unit Addendum
- Once confirmation is received, start 2D
FDA for 3D

http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm

- Mammography Evaluation Survey
- Phantom Image (3D mode)
- Certificate extension requirements form
No, tomos performed until...

The Food and Drug Administration (FDA) has approved your FullField Digital Mammography (FFDM) system. You may begin using your Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System unit for clinical use on patients.

Please see attached approval letter.

If you have any question, please contact me at 301-796-5919.

Denise Robinson
FDA/MQSA Program
Phone: 301-796-5919
denise.robinson@fda.hhs.gov
Positioning/Workflow

- **Benefits**
  - Fast paddle - better compression
  - Automatic MLO positioning both gantry and paddle
  - Fingerprint sign on
  - Error fixes

- **Drawbacks**
  - Precise Positioning
  - Faceshield
  - Motion
  - Not able to be viewed in PACs
Quality Control

- Geometry Calibration
  - Bi-annual- QC for individual tomo slices
- Compression Test
  - Bi-annual
- Compression Thickness Indicator
  - Bi-weekly
Quality Control - Weekly

- Flat field – Artifact Evaluation
  - Filter check
    - Rhodium- 2D
    - Silver- 2D
    - Aluminum- 3D

- Gain Calibration
  - Focal Spots
    - Tomo- resets digital pictures
    - Rh/Lg- Rhodium
    - Af/Lg- Silver
    - Rh/Sm- Rhodium done with mag stand
    - Af/Sm- Silver done with mag stand
Quality Control - Weekly

- Phantom
  - Combo
    - 2D
    - 3D - scroll until brightest specks (slice 15)

- CNR/SNR
  - No more calculations!
Quality Control

- Repeat Analysis
  - Can be done through website via IP address
  - Through unit

For any upgrades- make sure you check release notes- possible technique changes
GE - checklist

MAMMO QC CHECKLIST

WEEKLY QC

Core QC (always do core QC first)
1. Flat field acrylic phantom
2. CNR/MTF (IQST)
3. ACR Phantom WEEKLY QC, ACR PHANTOM QC01012016

STEREO STACTIC PHANTOM WEEKLY QC, STEREO STACTIC PHANTOM QC01012016

MTD 2D/3D
1. ACR Phantom WEEKLY QC, 2D MTD PHANTOM 2001012016 "SCORE ON ESSENTIAL" AP position
2. ACR Phantom WEEKLY QC, 3D MTD PHANTOM 3001012016 "SCORE ON IQ1" AP position

Printer QC
Put exams to viewed in eRad

MONTHLY QC

Core QC Core QC (always do core QC first)
1. Flat field acrylic phantom
2. CNR/MTF (IQST)
3. ACR Phantom WEEKLY QC, ACR PHANTOM QC01012016
4. AOP/SNR (triangle blocks)

STEREO STACTIC PHANTOM WEEKLY QC, STEREO STACTIC PHANTOM QC01012016

MTD 2D/3D
1. ACR Phantom WEEKLY QC, 2D MTD PHANTOM 2001012016 "SCORE ON ESSENTIAL"
2. ACR Phantom WEEKLY QC, 3D MTD PHANTOM 3001012016 "SCORE ON IQ1"
3. ACR Phantom WEEKLY QC, 3D MTD PHANTOM 3001012016 "SCORE ON IQ1"
4. Grid Texture Test (10 exposures using flat field acrylic phantom)
5. AOP/SNR (triangle blocks)
6. AOP/SNR
7. AOP/SNR

Visual Checklist

Put exams to viewed in eRad