Implementing Tomosynthesis Into Your Practice?

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Attendee Background:
How many of you...?

- Do not have Tomo?
- Are planning for Tomo in the next year?
- Have partial Tomo?
- Have complete Tomo?
- For those with Tomo:
  - Acquired in past 12 months?
  - Acquired > 12 months ago?
My Background

• Hologic DM/DBT only

• Dartmouth–Hitchcock (21 years)
  – First Hologic DBT prototype – Pilot study 2004
  – 1/5 institutions Hologic PMA (Rafferty Rad 2014)
  – DBT clinical implement. February 2012

• Mallinckrodt Institute Radiology (1 year)
  – 27,000 Screens: 15,240 (DM), 11,715 (DM/DBT)
  – 12,420 Diagnostics: 7,505 (DM), 4,915 (DBT)
Start Up Considerations

- Vendors
- Marketing
- Implementation Strategies
FDA Approved DBT (April 2016)

- **Hologic Dimensions™**
  - FDA Approval: February 2011
  - Approved Screening Use: 2v DM +/- 2v DBT

- **Hologic Dimensions (Cview™)**
  - FDA Approval: May 2013
  - Approved Screening Use: 2v DBT +/- synthesized ‘2D’ image

- **GE SenoClaire™**
  - FDA Approval: August 2014
  - Approved Screening Use: 2v DM or MLO DBT/CC DM

- **Seimens Mammomat Inspiration™**
  - FDA Approval: April 2015
  - Approved Screening Use: 2v DM +/- 2v DBT
Future Vendors

- Fujifilm
- Philips (previously Sectra)
DBT System Specifications

- **Hologic Selenia Dimensions™**
  - Target/Filter=W/Al, Detector=Amorphous Selenium
  - 15 low dose exposures, 15° arc (continuous), 4sec
  - Resolution: DM 70\(\mu\)m, DBT 95\(\mu\)m vs. 117\(\mu\)m, 1mm slice thickness
  - Reconstruction: Filtered Back Projection

- **GE SenoClaire™**
  - Target/Filter=Mo-Rh/Mo-Rh, Detector=Amorphous Silicone
  - 9 low dose exposures, 25° arc (step and shoot), <10sec
  - Resolution: DM 100\(\mu\)m, DBT 100\(\mu\)m, 0.5-1.0mm slice thickness
  - Reconstruction: Iterative

- **Siemens Inspiration™**
  - Target/Filter=W/Rh, Detector=Amorphous Selenium
  - 25 low dose exposures, 50° arc (continuous), 25sec
  - Resolution: DM 85\(\mu\)m, DBT 85\(\mu\)m, 1mm slice thickness
  - Reconstruction: Filtered Back Projection
Inform medical staff and requesting providers

- Grand rounds – especially for primary care services (family practice, obgyn, internal medicine)
- Hospital system wide email, newsletter

Marketing

- Website – optimize your links
- Media (radio, newspaper, TV)

Facility level

- Fact sheet (pamphlet and poster) in waiting room
- Educate ALL your staff so that they can help and are on board
Implementation Strategies

• Complete vs. Limited Conversion to DBT
• Limited Conversion
  – Screening vs. Diagnostic DBT
  – All vs. subset of mammography units
    • Patient Triage or No Triage
DHMC Experience

• Phased Implementation,
  – Phase 1 - Screening, (1 / 3 units)
  – Phase 2 – Diagnostic, (1 / 2 units)
  – Phase 3 – DBT Biopsy (1 / 2 units)

• Triage based on:
  – Patient or Provider Request
  – Baseline or Baseline Equivalent
  – Dense Breasts
MIR Experience

- Phased Implementation:
  - Phase 1 - Diagnostic (all units)
  - Phase 2 - Screening (all units)

- Screening
  - No Triage (patients can “opt out”, e.g. dose, $)
  - Exclusions
    - Very large breasts (exceed image receptor size)
    - Pacemakers, Implants
    - Comorbidities (minimize blur from longer exposure time)
    - Age > 75 y.o. (DBT may have less benefit in women ≥ 70 y.o.) *Haas et al Radiology 2013;269:694-700
DBT Screening

- **Oslo Tomosynthesis Screening Trial** Skaane et al. Radiol. 2013;267:47-56
  - FP (< arbitration): DM 6.1%, DM/DBT 5.3%, ↓15%, p<0.001
  - CDR/1000: DM 6.1, DM/DBT 8.0, ↑1.9/1000 (31%), p=0.001
  - Invasive CDR: DM 56, DM/DBT 81 (10/25 Grade 2 or 3, ↑26%)
  - DCIS: DM 21, DM/DBT 20

- **STORM Trial** Ciatto et al. Lancet Oncology 2013;14:583-589
  - FP Recalls: DM 4.5%, DBT 3.5%, estimated 17% reduction in FP recalls if DM/DBT overrides DM only recall
  - CDR/1000: DM 5.3, DM/DBT 8.1, ↑2.8/1000 (52%)

- **US Service Screening** Friedewald JAMA. 2014;311(24):2499-2507
  - Recall Rate: ↓14.9%, DM=10.7%, DM/DBT= 9.1
  - CDR/1000: DM = 4.2, DBT = 5.4, ↑1.2/1000 (29%)
  - Invasive) DM = 2.9, DM/DBT 4.1, ↑1.2/1000 (41%)
  - DCIS) DM = 1.4, DBT = 1.4, No Δ
DM DBT
Postmenopausal screening (study)
Patient Course

- DBT performed as part of research protocol, could not impact clinical mg.
- Patient Recalled for Dx imaging.
- Asym persisted in MLO and ML projections
- Not visible on CC or US
- Stereotactic Bx = Fibrosis
Clinical Course

- Patient recalled for additional Imaging
- DM 90° Lateral Medial and targeted US performed

US Bx = LNG IDC

Radial US

Anti-radial US
DBT Screening: Practical Considerations
Interpretation Times

• Gur et al. AJR 2009 (Single Breast)
  – DM 1.22min, DBT 2.05min, DM/DBT 2.39min

• Wallis et al. RAD 2012
  – DBT vs. DM: Time Approx. Doubled

• Skane et al. RAD online 2013
  – DM 45sec vs. DBT 91sec
Addition of Tomo...: Effect on Image Interp Time of Screening Exams
Dang Radiol 2014;270:49-56

• 1 hr long session, 5 sessions per modality, per rad, 10 rads total, 1.5-21 yrs of exp., DBT>17m
• ‘real world’, priors available
• Mean exams/hour: DM 34, DM/DBT 24 p<0.0001, (9/10 rads significantly longer for DM/DBT)
• Mean time: DM 1.9m +/-0.6, DM/DBT 2.8m =/-0.9
• ↑time for DM/DBT with less experience (p=0.3), ↑40% most exp vs. ↑70% least exp
Screening DBT: Work Station Tips

• Integrate DBT into preexisting DM protocol
• Maximize hanging protocol for efficiency, consistency, accuracy benefit (work with vendors at initial apps, and schedule apps within few months of implement.)
• Create conducive environment to prevent distraction
Hanging Protocol Preferences

• SPP – DBT review early step in protocol to maximize cancer detection benefit (i.e. avoid using DBT as FP recall ↓ only)

• Some experienced users advocate:
  – Completely read DM (SM) first, use DBT to evaluate possible recalls and scan for addtl DM occult findings
  – Interpret DBT Right and Left Breast for each projection to appreciate asymmetry
Screening DBT: Work Station Tips

• Annotate DBT slice (and DM slice to help technologist with breast landmarks)
  – Facilitate communication for Dx w/u
  – Some PACS systems will display annotated screen capture

• Minimize repetitive trauma injury (special mouse or key pad, be wary of scrolling)
Screening DBT: Managing Volume

- Estimate DM/DBT interp time = 2x DM
- Consider ‘capping’ volume
  - Batch read (no more than 20 DBT’s in stack), larger batches → fatigue, distraction
  - Some practices distribute small batches to multiple rads to minimize ↑time for interp for each rad
DBT Diagnostic Imaging
DBT vs cone comp mag DM


• Subjects:
  – 354 ‘lesions’ in 341 women needing further mammo w/u detected scr. or dx mammo
  – 279 ‘soft tissue’ lesions, 75 calcs only
  – 103(29%) malignant: 80(78) invasive, 23(22) DCIS, 82(23) benign, 169(48) normal

• Readers:
  – Retrospective review by 7 readers with 6m-2y DBT experience
  – 2vDM+spotMag first -(2wks) – 2vDM+1vDBT [Hologic Inc.] in view best seen
  – Mammo finding type, Royal College (UK) classification (Normal-1, Benign-2, Indet/PB-3, Suspicious-4, Malig.-5)
ROC Results:

- AUC: (all lesions): DBT 0.93, ccMM 0.87, p=0.0014
- AUC (soft tissue only): DBT 0.97, ccMM 0.90, p=0.005
Other Results and Conclusions

• % Sens/Spec (all lesions)
  – DBT 99/64 vs. CCMM 95/54
  – False Negatives: 0/103 DBT, 3/103 ccMM

• ↓ RCR Cat 3 (~ BIRADS 4a) in DBT group

• Conclusion:
  – DM more accurate than ccMM in Dx eval. of mammo abnormalities
67 y Screening
Bx = Invasive Mammary Ca with Lobular Features
DBT Diagnostic Protocols

• Wide variation in protocols based on radiologist preference/experience with DBT (mixture of DM and DBT vs. DBT only)

• Protocol differs depending on:
  – nature of screening DM (only) vs. DM/DBT
  – finding type

• Calcifications only:
  – orthogonal focal Mag DM,
  – rarely DBT (?vascular, ?fat necrosis)
Sample Diagnostic Protocol: DM screen detection

• Asymmetry or Architectural Distortion
  – Repeat full field or spot DM/DBT in most suspect view (CC, MLO), full ML (or LM) DM/DBT

• Mass
  – Spot CC DM/DBT, full ML (or LM) DM/DBT
Sample Diagnostic Protocol: DM/DBT screen detection

- Asymmetry or AD in CC view
  - Rolled CC DM/DBT, full ML or LM DM/DBT

- Asymmetry or AD in MLO view
  - Spot MLO DM/DBT, full ML or LM DM/DBT

- Mass with circumscribed margins
  - US first, unless <8mm in large breast

- Mass without circumscribed margins
  - Spot CC DM/DBT, full ML or LM DM/DBT
Effect of DBT on addtl views and use of US for non calcified findings

- Hakim et al. AJR 2010
  - 4 exp readers, 25 ♀/lesions, DM/DBT vs. DM/addtl views
  - DM/DBT better 50%, equiv 31%, worse 19%
  - 12% - No US needed (primarily due to multiplicity)

- Brandt et al. AJR 2013
  - 3 inexp readers, 158 non-calcified DM scr recalls in 146 ♀
  - Dx w/u & 2 view DBT of affected breast
  - DM/DBT (scr) adequate for Dx eval in >90%
  - DM (scr) required mean of 3 addl DM dx views
  - No change in US utilization
DBT vs DM Recalls
Lourenco et al. Radiol2014;274:337-342

- DM Scr (12,577) vs. DM/DBT Scr (12,921) before and after DBT implementation
- RR: DM: 9.3%, DM/DBT 6.4% (↓31%, p<0.00001)
- DM: ↑RR for asym & focal asym (p<0.0001)
- DM/DBT: ↑ RR for mass, AD, Calcs (p<0.0001)
DBT vs DM Recalls
Lourenco et al. Radiol2014;274:337-342

- Add Views only: DM: 40.2%, DM/DBT 28.4% (p<0.0001)
- US only: DM: 2.6%, DM/DBT 28.3% (p<0.0001)
- Both: DM: 57.2%, DM/DBT: 43.3% (p<0.0001)
Clinical Considerations

- Management of DBT only findings
- Modality Limitations
DBT guided Biopsy

Path. = Invasive Ductal Carcinoma
Discussion: Tomo only AD

- Conflicting/Emerging data on significance of architectural distortion with or without DM correlate, with or without US correlate.
- Lack of US correlate usually indicates radial scar
  - Partyka et al. AJR 2014; 203:216-222
- Malignancy rate approaching 50% even in subset without MRI correlate
  - Freer Radiology 2015; 275:377-383
- Recommend tissue sampling
CC: DM vs DBT
Scout

SBx Pair

SBx Prefire Pair

SBx Post fire Pair
DBT Post Bx

Path = Sclerosing Adenosis
Managing DBT only AD w/out DBT biopsy

- US guided biopsy ONLY if certain of US Correlate
- Stereotactic Biopsy ONLY if reliable landmarks
- Do Post Biopsy combo (DM/DBT) to confirm biopsy change at site
- Low threshold for Bx Discordance: Benign should have ‘sclerosing’ in diagnosis (Radial/Complex Sclerosing Lesions, Sclerosing Adenosis, Sclerosing Papilloma)
- If discordant: WLE > MRI (avoid short term f/u)
DBT Limitations

• Misinterpreting Fat
• Low density mass
• Ignoring rules of conventional mammo
• In slice density
Trial Subject

Diagnosis = Cystic Papillary Carcinoma

Lobular mass with Partly Well Defined Partly Obscured Margins

Lobular mass with Well Defined Margins
43 y.o. self detected lump
US guided biopsy = Invasive Ductal Carcinoma
• Zuley et al. RSNA abstract 2014
  – retrospective review of cancer in 787 women with DM/DBT exams within 12 months of diagnosis
  – 15% (118/787) not visible
  – No difference by histology (p=0.15)
  – Most common cause of FN “DBT - looks like normal tissue”

• Droguett et al. RSNA abstract 2015 (RC215-04)
  – ‘13-’14, 223 sequential cancers with preceding DM/DBT
  – FN: 38/223 DM (seen with DBT mass,AD), 21/223 DBT
  – 21 vis with US, as microlob masses, intra-parenchymal location, w/o calcs or distortion
• Staffing
• Reporting and Audit
• Coding / Billing
• Network and Storage
• ~ doubling of rad interp time for DBT screening exams
• some increase in rad interp time of DBT dx exams
• ↓DBT screening recalls → ↓diagnostic volume (Dx = least efficient task for radiologist)
• ? ↓ number of diagnostic views (? diagnostic workflow more efficient)
• ? no change in Diagnostic US:
  – US avoided by multiplicity, ↑ confidence
  – US added by ↑ detection mass, AD
• ? slight increase in number of image guided biopsies
• Trade off: ↑ time for screening vs. ↓ time for diagnostic imaging (predicated ↓RR for DBT)
• Net effect on FTE demand depends on skill set of radiologists
• Good news: vendors are developing clustered reformat displays that will likely ↓↓ DBT interpretation time
• add DBT to options for electronic order entry
• notify provider that DBT performed
• Develop system that differentiate DBT screens from DM screens for separate audit (e.g. by billing code)
• include verbiage that DBT performed, (reconcile DBT billed with DBT reported)
• 2014: CPT for DBT valued (RUC) and approved (AMA CPT) as of January 1, 2015
• Bilateral Screening: CPT 77063 (+G0202)
• Unilateral / Bilateral Diagnostic: G0279 (in lieu of 77061, 77062) (+G0204, G0206)
• Medicare/Medicaid reimburse
• USPSTF draft and final recommendations → denials by some private carriers (modality investigational)
• Facility response – return to pre-CPT era
  – Waive fee for DBT
  – Informed consent/notification balance billing
• Anectdotal ↓DBT utilization (patient declines due to coverage concerns)
• RVU update committee (RUC) mandate to reevaluate the entire family of digital mammography codes in the next cycle
Understand Storage and Network Needs

• Based on:
  – Size of image sets
  – Patient volume
  – Radiologists workflow requirements
  – How many prior digital images in the archive (pre-fetch requirements of the radiologist)
  – Arrangement of image servers to Dx workstations
Data Set Sizes: FFDM

- 8 MB for a 100um 18x 23 cm image
- 22MB for a 70um 24x29 cm image
- 50 MB for a 50um 24x30 cm image
- 32 to 200 MB for a 4 view study
Archiving Needs

• For a facility seeing 100 pt/day the storage needs can be up to 20 GB per day or 4 TB per year just for screening FFDM

• Prior study comparison is required and so storage and display is required
Tomo Storage

• 250-300 MB per 4 view combo study if store using vendor storage solution because they have proprietary compression

• If DICOM tag enabled (BTO) or CTO ~ 500MB per 4 views for 2 / 3 approved vendors ~1 GB per study for other vendor
2D/3D Storage Estimates

- Facility does 20,000 screening exams per year
  - 2D storage 87 MB per 4 views (70u)
    - 1.74 TB per year
  - 3D storage 500MB per 4 views (~ 5.7X) DICOM
    - 10 TB per year
  - 2D/3D storage 1GB per 4 views
    - 20 TB per year

Courtesy of Rita Zuley MD
• 3 U.S. Approved DBT platforms, 2 near future
• Maximize efficiency: hanging protocols, viewing conditions, annotation, diagnostic protocols
• Expect impact on staffing (shift vs ↑)
• Plan for storage and network needs
• Understand billing and reimbursement issues
• 3 U.S. Approved DBT platforms, 2 near future
• Consensus Data
  – Screening: ↑ Cancer detection (8/1000 first DBT), ↑Invasive Cancer detection, ↓FP Recalls (~5%)
  – Diagnostics: DBT ≥ DM for non-calcified findings, DBT < DM for calcifications
  – ↑ interpretation time
• No ‘right way’ for partial implementation
• Inform (Market) – providers, patients, community
• Maximize efficiency: hanging protocols, viewing conditions, annotation, diagnostic protocols
• Anticipate impact on staffing (shift vs ↑)
• Plan for audit, storage and network needs
• Understand billing and reimbursement issues
• Anticipate DBT limitations (e.g. managing DBT only findings)
• Feel good about your practice for providing “a better mammogram”