Current Concepts in Breast Imaging

Catherine A. Moses, M.D.
Diagnostic and Interventional Radiologist

Department of Diagnostic Imaging
Los Robles Hospital and Medical Center
Thousand Oaks Radiology
Conejo Medical MRI and CT
American Cancer Society
Recommendations for Screening

• **Annual mammogram** beginning at 40 years, continue as long as in good health
• **Clinical Breast Exam (CBE)** every 3 years in 20s and 30s; annually for 40 and older
• **Breast Self Exam (BSE)** every month beginning in 20s
3D MAMMOGRAPHY IS HERE.

Everything is sharper and clearer in 3D.
2D Mammography Challenges

• Prompt annual mammography has shown the ability to reduce the mortality rate from breast cancer in a population by 15% to 50% \(^1\text{-}^3\)

• As many as 20% of breast cancers will be missed by mammography \(^4\)

• In the U.S. ~10% of women are recalled for additional diagnostic work-up
  – A significant portion prove to have no abnormality, resulting in unnecessary anxiety and cost \(^5\)

5. http://radiology.rsna.org/content/244/2/381.full#T3
2D Mammography Limitations

• A major factor contributing to the limited performance of mammography is the tissue superimposition that is created by the overlap of normal breast structures in a two-dimensional mammographic projection.

• These overlapping structures can obscure a lesion making it more difficult to perceive or rendering it completely mammographically occult.

• Superimposition can hide or mimic pathology.
Full-field Breast Tomosynthesis
DBT (Digital Breast Tomosynthesis)

• Think Mammogram is 2D; Tomosynthesis is 3D
• FDA approval in May 2011
• Acquire serial breast x-ray images with the x-ray tube at multiple angles during a short scan time
• Can display images individually one after another or in a rapid loop like a movie
• Eliminates tissue overlap—easier to see cancers, fewer “call back” exams.
• Radiation dose is not much higher than standard mammography*
Breast Tomosynthesis: Principle of Operation

- X-ray tube moves in an arc across the breast
- A series of low dose images are acquired from different angles
- Total dose approximately the same as one 2D mammogram
- Projection images are reconstructed into 1 mm slices
Why Breast Tomosynthesis?

- Tissue superimposition hides pathologies in 2D
- Tissue superimposition mimics pathologies in 2D
Why combo mode?
Rationale for using 2D plus 3D imaging

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

- Facilitates current to prior exam review
- Maintains important details from tomosynthesis slices
  - Interpreted in combination with tomosynthesis images
Clinical Benefits of Tomosynthesis

Breast cancer screening with tomosynthesis finds cancers missed with conventional 2D mammography\(^1\)-\(^2\)

Tomosynthesis gives radiologists the confidence to reduce recall rates\(^3\)-\(^4\)

Masses, distortions and asymmetric densities are better visualized with tomosynthesis\(^4\)

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\(^3\) FDA PMA submission P080003.

Image Comparison: Case 1

2D

Tomosynthesis Slice

Generated 2D

June 2013

Hologic Proprietary - For Educational Use Only - rev002 PRE-00380
Cancer Case 1

2D RCC

Tomo RCC
Cancer Case 2

2D

RMLO

2D Breast Tomosynthesis
Slice 16

Screening Combo 12/01/11

May 2013
Cancer Case 6

2D

3D
Tomosynthesis Clinical Efficacy*

• Breast cancer screening with tomosynthesis significantly increases cancer detection with:\(^1\)
  – 40% increase in invasive cancer detection
  – 27% increase in cancer detection

• Compared to FFDM, sites report a significant reduction in recalls with tomosynthesis:\(^2-3\)
  – 20-40% reduction in recall rates (based on site practices)

• Patients across all age groups and breast densities benefit from the addition of tomosynthesis screening\(^1\)

*Studies utilized Hologic Selenia Dimensions systems

Breast cancer screening using tomosynthesis in combination with digital mammography


Objective
To study how 3D mammography (breast tomosynthesis) in combination with 2D mammography when used in breast cancer screening has impacted patient care at 13 academic and community based sites in the U.S.

Materials and Methods
A total of 454,850 examinations (n = 281,187 digital mammography; n = 173,663 digital mammography + tomosynthesis) for 13 centers interpreted by 139 radiologists over two time periods were retrospectively analyzed to determine if 2D mammography combined with 3D mammography improved performance of breast screening programs. Period 1 included a full year of screening with 2D mammography alone, ending on the date of 3D mammography introduction at each institution. Period 2 included screening with 2D mammography + 3D mammography until December 31, 2012. The 13 participating centers all used the only FDA-approved 3D Mammography device (Selenia® Dimensions®, Hologic) during these screening periods.

The primary measured outcomes were recall rate (proportion of patients requiring additional imaging based on a screening examination result), cancer detection rate, positive predictive value for recall (PPV1 – proportion of patients recalled after screening who were diagnosed as having breast cancer) and positive predictive value for biopsy (PPV3 – proportion of patients undergoing biopsies who were diagnosed as having breast cancer).

Results
This is the largest study reported to date on the effectiveness of 3D mammography. An analysis of the data (summarized below) indicated that 3D mammography outperformed conventional 2D mammography. Eleven (11) of the 13 sites showed simultaneous improvement for the key metrics of cancer detection and recall rates; the two sites that did not see these combined benefits had used 3D mammography for a short time or imaged very few women.

<table>
<thead>
<tr>
<th></th>
<th>2D</th>
<th>2D+3D Mammography</th>
<th>Relative Change</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPV for Recall</td>
<td>4.3%</td>
<td>6.4%</td>
<td>+49%</td>
<td>P&lt;.001</td>
</tr>
<tr>
<td>PPV for Biopsy</td>
<td>24.2%</td>
<td>29.2%</td>
<td>+21%</td>
<td>P&lt;.001</td>
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Conclusion
The authors conclude that the addition of 3D mammography to 2D mammography demonstrated an increase in cancer detection rate and a decrease in the recall rate. For complete findings and full-text, please click here.
DBT in Clinical Practice

- Which patients should be offered 3D?
- Which patients benefit most from 3D?
- When and how should 3D imaging be used for diagnostic evaluations?
- What about radiation dose from 3D? Is it higher than standard 2D? Does it matter?
Which patients should be offered 3D Mammography?

- All patients should be offered the technology since benefit has been established in all ages and for all tissue densities.
- Economic issues and payer reimbursement
  - CMS has established billing codes and increased reimbursement for Medicare patients.
  - Other third party payers are variable. Most do not provide increased reimbursement at this time.
  - Decision to charge patients an additional fee and how much.
- Eventually 2D+3D will be standard exam for everyone when technology is universally available.
Which patients benefit most from screening 3D mammography?

- Studies indicate increased cancer detection over 2D in all women, regardless of age or breast density.
- One large screening study demonstrated benefit as a “bell curve” with greatest benefit for Type 2 and Type 3 density.
- Why? Better intrinsic tissue contrast in these tissue types compared to Type 1 (almost all fatty) and Type 4 (almost all dense—”white out”).
3D: Screening vs. Diagnostic Evaluations

- Clinical studies demonstrate increased cancer detection and decreased recall rates in screening populations.
- 2D “spot” compression views becoming obsolete. 3D screening images usually confirm or exclude a true mass.
- 3D superior in diagnostic setting to characterize masses—tumor size, margins, extent of lesions, staging.
- Many times can go straight to ultrasound after 3D exam to characterize mass, plan biopsy.
- 2D magnification views still gold standard for microcalcifications.
Radiation Doses: 2D vs. 3D

- Two separate data acquisitions—2D+3D requires approximately 2x dose than 2D alone
- Computer software exists to “create” the 2D images from the 3D data but the images are of inferior technical quality at this time
- Another option for dose reduction is to acquire one-view 3D (usually the MLO) which reduces radiation dose but may detect fewer cancers than two-view 3D (CC+MLO)
Radiation Doses: 2D vs. 3D

![Graph showing comparison of radiation doses for 2D Hologic System, 2D Plus Tomosynthesis, Average Annual Background US, and Average Annual Background Colorado. The graph indicates higher radiation doses for 3D, particularly for Average Annual Background Colorado.]
3D Case #1

- 76 y/o female. Screening 2D+3D. No family history of BCA. No prior breast biopsy
- Breast density: Type 2
- No definite abnormality on 2D
- Small spiculated density in the right upper outer quadrant on 3D images
- Small solid mass found on US images
Can you find the cancer?
3D slices show the hidden cancer
Focused Ultrasound
Specimen Radiograph
Pathology

- Diagnosis: Invasive lobular carcinoma
- Very small cancer, 4-5 mm
- Successfully treated with J-wire localization and lumpectomy
3D Case #2

- 63 y/o female with history of uterine CA, diagnosed 6 months prior. Screening 2D+3D. Family history of BCA—maternal cousin. No prior breast biopsy. Implants
- Right MLO implant displaced view with small spiculated density on 3D images, not seen on the CC images
- Screening whole breast ultrasound also ordered—small cysts in both breasts. Mass not seen
MLO Implant-displaced
Can you find the cancer?
3D Case #2

• Patient called back for “focused” US exam knowing where the density is located using 3D images
• Focused US demonstrated 6x5x4 mm solid mass at 11:30 position, superior and medial—difficult area to image with mammography
• US-guided biopsy performed
Focused Ultrasound
Increased blood flow as a sign of malignancy
Pathology

Invasive ductal carcinoma
What are dense breasts?

- More *glandular* elements than *fatty* elements in the breasts—"white" vs. "black" tissue on mammogram
- Dense breasts: Type 3 and 4
- 24 States now with legislation requiring patients to be informed of their density status
- FDA in process of amending MQSA standards in 2015 to require density reporting (all 50 states)
American College of Radiology (ACR)
Breast Composition Categories

- Type 1: The breasts are almost entirely fatty
- Type 2: There are scattered areas of fibroglandular density
- Type 3: The breasts are heterogeneously dense, which may obscure small masses
- Type 4: The breasts are extremely dense, which lowers the sensitivity of mammography
Breast Density
Dense Breasts: Why is it important?

• Strong research evidence that increased breast density is an independent risk factor for BCA
• Estimates of 4-6x increased risk for BCA
• *Radiology* 2011, King, V. et al: Increased background enhancement of breast tissue on MR imaging indicated increased risk of BCA
Dense breasts: Increased risk of BCA

- *Radiology*, August 2015
- Women at *high risk* for BCA underwent screening MRI. Breast parenchymal enhancement (BPE) qualified (minimal, mild, moderate or marked)
- Mean follow-up 5.6 years
- Results: Women with BPE greater than “minimal” were 9x more likely to develop BCA
- No difference in BCA with varying mammogram density or amount of tissue on MRI
Why does increased density increase the risk for BCA?

- MRI/BPE study suggests that increased risk for BCA is mediated by the presence of estrogen receptors in the tissue.

- *Increased enhancement* on MRI is an independent biomarker of estrogen responsive breast tissue prone to malignant transformation.
Dense Breasts: What do we tell patients?

• Patients must be informed that they have dense breast tissue

• Individual clinical risk assessment; many models exist

• Tailor clinical management
  – Consider screening MRI for patients with greater than 20-25% lifetime risk for BCA. Assess BPE and stratify risk
  – Direct chemoprevention strategies (eg Tamoxifen)
  – Assist in complex decisions (eg prophylactic mastectomies)
Dense Breasts and Ultrasound

• Increased usage of ultrasound for evaluation of dense breast tissue
• Whole breast screening: hand-held vs. ABUS (automated whole breast ultrasound)
• Korean study, Sept 2013, very large sample size
  – Supplemental WB US found 2.4 more breast cancers per 1000 exams than screening mammography alone
  – Increased false positive findings on ultrasound that resulted in negative biopsies
Advances in Imaging: Has it led to overdiagnosis and overtreatment of breast cancer?

- Heated debate. Lots of media attention
- Too much screening? Too much radiation? Too many “inconsequential” cancers found? Too much treatment? Too many operations? Too much morbidity? Too much cost?
- July 2015 study published—Study found counties with greater screening and cancer detection rates had no significant difference in cancer deaths
The Overdiagnosis Debate

• We are treating small early cancers that may not cause sickness or death
• Technology is remarkable. Screening finds smaller cancers, pre-CA (ADH), LCIS, DCIS…but are we saving lives, improving quality of life?
• Screening mammography saves lives, proven with numerous large population studies over the last 40 years—~20% reduction in death rates
• Continuing debate—what ages to screen and how often?
Best Breast Practices. Best Breast Care

• The more we learn about cancer (and breast cancer), the more we learn it is not one disease, possibly hundreds of diseases
• Tumor biology. Biological markers. Individual genetics and risk stratification
• “Aggressive” cancer versus “quiescent” cancer
• Analogous debate: prostate cancer in men
• Active surveillance or “watchful waiting”
Lots of great information… What do I do with it?

• The age of “one size fits all” medicine is coming to a close, especially in cancer care
• With increasing molecular and genetic profiling of patients and tumors and the evolution in treatment options, cancer care is becoming more customized to the individual patient
• Become informed. Understand your risks and options. Determine what is important to you. Align with trusted healthcare professionals
• Make the best decision for YOU!
Thank you for your attention!!