Categorized References on Hologic 3D Mammography

This document serves as a categorized quick guide of recent selected publications. Most are available as a summary card, except where indicated.

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A) Screening

Hologic 3D Mammography increases cancer detection and decreases recall rates

   *Key Point: In this largest screening study involving over 450,000 examinations, 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. The authors also conclude that the PPV3 improved by 21% after the introduction of tomosynthesis.

   *Key Point: The authors concluded that patients screened with combined 2D/3D digital breast tomosynthesis resulted in increases in cancer detection rate (for cancer overall and for invasive cancers) and also resulted in decreases in the recall rate. The results also demonstrated a significantly higher positive predictive value for recalls.

3. Effect of integrating 3D-mammography (digital breast tomosynthesis) with 2D-mammography on radiologists’ true-positive and false-positive detection in a population breast screening trial.
   *Key Point: Variability in performance among radiologists using 2D mammography was also reflected in variability with the addition of 3D mammography, however there was less variability in true positive reads using 3D mammography. The authors conclude that the addition of tomosynthesis to 2D conventional mammography either reduced the false positive rate or improved the cancer detection rate, with most readers achieving both improvements.

4. Initial experience with combination digital breast tomosynthesis plus full field digital mammography or full field digital mammography alone in the screening environment. (No summary card available).
   *Key Point: The authors conclude that the addition of breast tomosynthesis to digital mammography significantly reduced the recall rate by ~63% detection rate, with most readers achieving both improvements.

5. Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program.
   *Key Point: In a screening study involving over 12,000 women, the addition of tomosynthesis to digital mammography resulted in a 40% increase in the cancer detection rate for invasive cancers, and a simultaneous significant decrease in false-positive rate. The increase was observed across all breast densities.

   *Key Point: Integrated 2D and 3D mammography significantly improves breast-cancer detection and has the potential to reduce false positive recalls. Twenty of the 59 cancers detected were visible only after the addition of tomosynthesis. Cancer detection increased 51% across all ages and breast densities for integrated 2D and 3D mammography compared to 2D mammography.

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*Key Point:* Six radiologists interpreted screening mammography studies without (n = 13,856) and with (n = 9499) the use of tomosynthesis. The study results demonstrated a significant reduction in recall rates (~37%) along with a non-significant increase in the cancer detection rate (35% overall, 54% for invasive cancers) after the introduction of tomosynthesis in the clinical practice. These improvements were distributed over all breast density categories. The results also demonstrate that the PPV3 improved by -50% by the introduction of tomosynthesis.


*Key Point:* In this study, 13,158 screening mammography examinations and 6,100 combo examinations were retrospectively review. The study results demonstrated a significant reduction in recall rates (~30%, the greatest reductions seen for women younger than 50 years old and in women with dense breasts, ~50%) along with an increase in the cancer detection rate (9.5% overall) after the introduction of tomosynthesis in the clinical practice.

9. Implementing Digital Breast Tomosynthesis (DBT) in a Screening Population: PPV1 as a Measure of Outcome.

*Key Point:* The implementation of tomosynthesis in a large screening program demonstrated a reduction in recall rates and an increase in cancer detection rates that varied by reader. The screening outcomes for each reader, as measured by PPV1, showed significant improvements for 5 of 6 readers and stability for 1 reader.

10. Imaging and Histopathology Findings of Breast Lesions Detected by Tomosynthesis.
Fajardo L, Limin Yang L, Park J. Radiological Society of North America annual meeting, Chicago, IL November 2013, SSK01-08.

*Key Point:* 50 biopsy recommendations were made in 4350 women that underwent screening from September 2012 to March 2013, including 15 biopsies in 2,610 women choosing to undergo tomosynthesis as part of their screening exam. The authors conclude that 30% more cancers are detected by the addition of tomosynthesis to FFDM in their screening program. They also conclude that biopsy PPV3 improved with the addition of tomosynthesis to their practice.

11. The role of additional tomosynthesis combined with digital mammography.

*Key Point:* 9301 combo studies were retrospectively reviewed. The study concludes that the addition of DBT to conventional 2D screening mammography increases the cancer detection rate by 61%. No statistical differences were found among the three density patterns, so tomosynthesis can be useful not only in dense patterns but also in pattern 2.

Hologic 3D Mammography benefits patients with a wide range of breast densities


*Key Point:* 12631 women who gave written consent from November 22, 2010 to December 31, 2011 participated in this prospective screening study. The authors concluded that the addition of tomosynthesis to digital mammography in the screening population resulted in a significant increase in cancer detection rate (27% gain), particularly for invasive cancers (40% gain), and a simultaneous significant decrease in false-positive rate (15% reduction). The increase in cancer detection was observed across all breast densities.

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2. Diagnostic accuracy and recall rates for digital mammography and digital mammography combined with one-view and two-view tomosynthesis: results of an enriched reader study.


*Key Point:* The authors conclude that the addition of one-view tomosynthesis to digital mammography improved the diagnostic accuracy and reduced the recall rate. However, the addition of two-view tomosynthesis to digital mammography resulted in twice the diagnostic performance gain at the same time further reducing the recall rate. Two-View 3D in combination with 2D had a large gain in diagnostic accuracy for imaging women with dense breasts; in fact the diagnostic accuracy for women with dense breasts was equivalent to 2D alone for women with nondense breasts.

3. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study.


*Key Point:* Integrated 2D and 3D mammography significantly improves breast-cancer detection and has the potential to reduce false positive recalls. Twenty of the 59 cancers detected were visible only after the addition of tomosynthesis. Cancer detection increased 51% across all ages and breast densities for integrated 2D and 3D mammography compared to 2D mammography.


*Key Point:* Six radiologists interpreted screening mammography studies without (n = 13,856) and with (n = 9499) the use of tomosynthesis. The study results demonstrated a significant reduction in recall rates (~37%) along with a non-significant increase in the cancer detection rate (35% overall, 54% for invasive cancers) after the introduction of tomosynthesis in the clinical practice. These improvements were distributed over all breast density categories. The results also demonstrate that the PPV3 improved by ~50% by the introduction of tomosynthesis.

5. Comparison of tomosynthesis plus digital mammography and digital mammography alone for breast cancer screening.


*Key Point:* In this study, 13,158 screening mammography examinations and 6,100 combo examinations were retrospectively review. The study results demonstrated a significant reduction in recall rates (~30%, the greatest reductions seen for women younger than 50 years old and in women with dense breasts, ~50%) along with an increase in the cancer detection rate (9.5% overall) after the introduction of tomosynthesis in the clinical practice.

2-View tomosynthesis is superior to 1-View tomosynthesis in breast cancer screening

1. Diagnostic accuracy and recall rates for digital mammography and digital mammography combined with one-view and two-view tomosynthesis: results of an enriched reader study.


*Key Point:* The authors conclude that the addition of one-view tomosynthesis to digital mammography improved the diagnostic accuracy and reduced the recall rate. However, the addition of two-view tomosynthesis to digital mammography resulted in twice the diagnostic performance gain at the same time further reducing the recall rate. Two-View 3D in combination with 2D had a large gain in diagnostic accuracy for imaging women with dense breasts; in fact the diagnostic accuracy for women with dense breasts was equivalent to 2D alone for women with nondense breasts.


*Key Point:* The study included 106 patients who received both 2D mammography and tomosynthesis in both the views (mediolateral oblique and craniocaudal) in one year in both screening and diagnostic setting. The study results demonstrated that obtaining both views is necessary to ensure that a cancer will be optimally visualized and derive the greatest potential benefit from tomosynthesis.

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**Hologic 3D Mammography increases cancer detection in a double reading environment**

1. **Prospective trial comparing full-field digital mammography (FFDM) versus combined FFDM and tomosynthesis in a population-based screening programme using independent double reading with arbitration.**


   *Key Point:* 2D and 3D imaging were performed during the first year on 12,629 consenting women. The study results demonstrated that double reading of 2D plus 3D significantly improves cancer detection rate compared to 2D alone during mammographic screening.

2. **Breast screening using 2D-mammography or integrating digital breast tomosynthesis (3D-mammography) for single-reading or double-reading - Evidence to guide future screening strategies.**


   *Key Point:* 3D mammography was found to offer significantly higher cancer detection than 2D mammography using either single or double reading. The authors suggest that based on this evidence, screening practices may be made more effective by employing 3D mammography rather than 2D mammography.

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B) Hologic Low-dose 3D Mammography with generated 2D images

**Generated 2D images plus tomosynthesis provides similar clinical performance as 2D plus tomosynthesis while reducing the radiation dose**


*Key Point:* Eight radiologists prospectively interpreted independently 24,901 screening examinations including digital mammography plus tomosynthesis and C-View software plus tomosynthesis. The use of synthesized 2D images combined with DBT performed comparably to FFDM plus DBT when interpreting screening mammograms in terms of cancer detection rates and false-positive scores. The authors also conclude that the use of generated 2D images (Hologic's C-View software) constituted an average dose reduction of 45% while not resulting in any clinically meaningful differences in diagnostic accuracy.

2. Comparison of Two-dimensional Synthesized Mammograms versus Original Digital Mammograms Alone and in Combination with Tomosynthesis Images.


*Key Point:* Eight academic women's imagers retrospectively performed a reader study on 123 cases. The authors conclude that the use of synthetic mammograms whether alone or in combination with tomosynthesis has similar diagnostic accuracy and may eliminate the need for FFDM in a routine clinical study. The authors also conclude that the use of synthetic mammograms reduces the radiation dose in patients that are undergoing tomosynthesis-based screening mammography.

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C) Diagnostic Imaging

**Hologic 3D Mammography is superior to FFDM in diagnostic evaluations**

1. Digital breast tomosynthesis in the analysis of fat-containing lesions. *(No summary card available).*


   *Key Point:* Evaluation and classification of fat containing lesions using tomosynthesis differs from that using digital mammography.


   *Key Point:* The authors conclude that performing MRI on patients who had been evaluated by DM with DBT and US had very little gain in sensitivity and no gain in overall accuracy.

3. Digital breast tomosynthesis versus supplemental diagnostic mammographic images for evaluation of non-calcified breast lesions.


   *Key Point:* Tomosynthesis significantly improved diagnostic accuracy for non-calcified lesions compared to supplemental mammographic views.

4. Can digital breast tomosynthesis replace conventional diagnostic mammography views for screening recalls without calcifications? A comparison study in a simulated clinical setting. *(No summary card available).*


   *Key Point:* The authors conclude that DBT offers similar sensitivity and specificity compared to conventional digital mammography for the evaluation of non-calcified findings recalled from screening mammography. The authors also concluded that for more than 90% of the findings, two-view DBT was sufficient for further mammographic evaluation, and can replace conventional diagnostic mammography.

5. Digital breast tomosynthesis (DBT): initial experience in a clinical setting.


   *Key Point:* The authors studied the performance of tomosynthesis in imaging work-up and found the potential for increasing sensitivity, especially for cancers manifesting as spiculated masses and distortions.


   *Key Point:* The addition of tomosynthesis improved the diagnostic accuracy in the assessment of screen detected soft tissue lesions compared to full-field digital mammography and film-screen mammography combined and film-screen mammography alone.

7. Comparison of Lesion Detection and Characterization in Invasive Cancers Using Breast Tomosynthesis versus Conventional Mammography. *(No summary card available).*


   *Key Point:* The authors conclude that cancers presenting with architectural distortion were detected significantly better with tomosynthesis as compared to digital mammography. Similar effect was observed in characterizing cancer morphology.
8. Tomosynthesis in Breast Cancer Visualization as a Function of Mammographic Density.


*Key Point: In this study, 246 cancers (in 201 women) imaged with the combo mode (Tomo plus 2D mammography) that were diagnosed between 10/3/2011 and 1/16/2013 were reviewed by 7 radiologists. Tomosynthesis imaging is especially beneficial for visualizing non-calcification breast cancers in 80% women with scattered and heterogeneously dense breasts. It is also better in visualizing lesions associated with architectural distortion, invasive lobular histology that is difficult to detect and in visualizing small tumors.


*Key Point: The authors conclude that the number of patients categorized as BI-RAD3 needing follow-up will be reduced with the use of tomosynthesis in diagnostic mammography.

10. Comparative Study with Digital Mammography (DM) vs. DM Combined with Digital Breast Tomosynthesis (DBT) for the Detection of Invasive Lobular Carcinoma (ILC).


*Key Point: Six radiologists retrospectively interpreted 56 examinations of women. The study results demonstrated an increase in the sensitivity and diagnostic accuracy in the detection of ILC using digital breast tomosynthesis. The effect was more pronounced in women with dense breasts.

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D) Impact on Biopsy

**Hologic 3D Mammography increases PPV of biopsy**

1. **Breast Cancer Screening Using Tomosynthesis in Combination With Digital Mammography.**
   *Key Point:* In this largest screening study involving over 450,000 examinations, 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. The authors also conclude that the PPV3 improved by 21% after the introduction of tomosynthesis.

2. **Implementation of breast tomosynthesis in a routine screening practice: an observational study.**
   *Key Point:* Six radiologists interpreted screening mammography studies without (n = 13,856) and with (n = 9499) the use of tomosynthesis. The study results demonstrated a significant reduction in recall rates (~37%) along with an increase in the cancer detection rate (35% overall, 54% for invasive cancers) after the introduction of tomosynthesis in the clinical practice. These improvements were distributed over all breast density categories. The results also demonstrate that the PPV3 improved by ~50% by the introduction of tomosynthesis.

3. **Imaging and Histopathology Findings of Breast Lesions Detected by Tomosynthesis.**
   Fajardo L, Limin Yang L, Park J. Radiological Society of North America annual meeting, Chicago, IL November 2013, SSK01-08.
   *Key Point:* 50 biopsy recommendations were made in 4350 women that underwent screening from September 2012 to March 2013, including 15 biopsies in 2,610 women choosing to undergo tomosynthesis as part of their screening exam. The authors conclude that 30% more cancers are detected by the addition of tomosynthesis to FFDM in their screening program. They also conclude that biopsy PPV3 improved with the addition of tomosynthesis to their practice.
E) Workflow Improvement

**Hologic 3D Mammography improves diagnostic workflow and is cost effective**

1. Digital breast tomosynthesis versus supplemental diagnostic mammographic images for evaluation of non-calcified breast lesions.
   
   
   *Key Point:* Tomosynthesis significantly improved diagnostic accuracy for non-calcified lesions compared to supplemental mammographic views.

   
   Philpotts L, Kalra V, Crenshaw J, Butler R. Radiological Society of North America annual meeting, Chicago, IL November 2013, SSK01-09.
   
   *Key Point:* 11,101 screening and 5,357 diagnostic exams were performed for an overall increase to 16,438 total exams. The authors conclude that the addition of tomosynthesis resulted in fewer images per diagnostic case which resulted in faster patient diagnostic workup and better patient throughput and resource utilization.

   
   Kalra V, Haas B, Forman H, Philpotts L. Radiological Society of North America annual meeting, Chicago, IL November 2012, LL-BRS-WE5C.
   
   *Key Point:* Combined DBT had a direct cost savings of $10,185 per 1,000 women screened resulting from decreased callback rates. Given that there also appears to be a trend for improved cancer detection rate, combined DBT appears to be preferable to FFDM alone for screening mammography.

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