Clinical Value of True Breast Tomosynthesis
An evaluation of recent studies
The implementation of Digital Breast Tomosynthesis (DBT) into daily practice depends on the diagnostic performance. Multiple publications demonstrate superior diagnostic performance compared to Full Field Digital Mammography (FFDM) alone.

Digital mammography has improved the detection of breast cancer. However, as 2D mammography is a projection image, overlying tissue structures result in difficulties in interpretation, giving rise to limitations in sensitivity as well as false-positive findings, which in turn increase recall rates. The limitations caused by overlying tissue become even more relevant as breast tissue density increases.

Digital Breast Tomosynthesis makes it possible to acquire and display 3D volumes of the entire breast. These are displayed in slices to reduce the impact of overlapping tissue. The angular range and the number of projections in the volume acquisition are key to the system's ability to reduce the impact of overlapping tissue. Various commercially available systems use angles between 15 and 50 degrees, while the number of projections taken ranges between 9 and 25. Siemens Mammmomat Inspiration with True Breast Tomosynthesis offers the widest angular range with 50° and the highest number of projections, namely 25.

This paper presents the results of recent studies performed with Siemens Mammmomat Inspiration and summarizes their key findings. It addresses the following questions:

- What is the diagnostic performance of DBT?
- Is tomosynthesis only for diagnostics or does it also have a place in screening?
- How does tomosynthesis affect the detection rate and type of cancers found?
- What effect does tomosynthesis have on Mean Glandular Dose (MGD)?
- Does tomosynthesis lead to a reduction in false-positive recalls?
- How can reading time be reduced without compromising diagnostic accuracy?
- Is it possible to reduce the compression force to improve patient comfort without compromising image quality?
- Can tomosynthesis help in therapy planning and control?
- Does it help in the characterization of lesion type and size?
- How does it perform in comparison to other breast imaging modalities?

Glossary

ACR  American College of Radiology
BIRADS  Breast Imaging Reporting and Data System
DBT  Digital Breast Tomosynthesis
FBP  Filtered Back Projection
FFDM  Full Field Digital Mammography
JAFROC  Jackknife Alternative Free-Response Receiver Operating Characteristics
PMA  Premarket Approval
RM  Rotating Mammogram
SRSAR  Super Resolution and Statistical Artifact Reduction
US  Ultrasound
Diagnostic performance

For the implementation of DBT in daily practice, its overall diagnostic performance plays a significant role. Standard FFDM proved beneficial when used in conjunction with DBT.

<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Country</th>
<th>Year</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Siemens Medical Solutions USA, Inc.</td>
<td>USA</td>
<td>2015</td>
<td>FFDM + two-view DBT is superior in terms of diagnostic accuracy over FFDM alone.</td>
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<tr>
<td>Elizalde et al.</td>
<td>Spain</td>
<td>2014</td>
<td>Adding US and DBT to DM increases the sensitivity rate. However, US is a highly operator-dependent and time-consuming technique. Moreover, DM+DBT has a higher specificity than DM+US.</td>
</tr>
<tr>
<td>Tani et al.</td>
<td>Japan</td>
<td>2014</td>
<td>DBT plus rotating mammogram demonstrated superior diagnostic accuracy compared with FFDM alone, especially in the visualization of microcalcifications.</td>
</tr>
<tr>
<td>Uchiyama et al.</td>
<td>Japan</td>
<td>2014</td>
<td>SRSAR showed significant superiority for all tested parameters. In particular, the improvement of the diagnostic certainty related to microcalcifications with the novel FBP is noteworthy. It might even reduce out-of-plane artifacts.</td>
</tr>
<tr>
<td>Timberg et al.</td>
<td>Sweden</td>
<td>2013</td>
<td>SRSAR improved the visibility of spiculations.</td>
</tr>
<tr>
<td>Uchiyama et al.</td>
<td>Japan</td>
<td>2012</td>
<td>DBT + FFDM detect more cancers than FFDM alone. DBT as an adjunct to FFDM was able to detect early stage breast cancer and is not affected by breast density. The results indicated that adjunction of DBT to FFDM was superior to FFDM alone in diagnostic performance.</td>
</tr>
<tr>
<td>Andersson et al.</td>
<td>Sweden</td>
<td>2008</td>
<td>Comparing one-view FFDM to one-view DBT, 21 patients were upgraded on BIRADS classification. Comparing two-view FFDM to one-view DBT, 12 patients were upgraded on BIRADS classification. The results indicate that the cancer visibility with DBT is superior to FFDM, which suggests that DBT may have a higher sensitivity for breast cancer detection.</td>
</tr>
</tbody>
</table>
Sensitivity/detection rate

As mammography alone misses up to 30% of breast cancers, especially in dense breasts, tomosynthesis may be one way to overcome this limitation. Digital Breast Tomosynthesis shows a significant improvement in the detection of breast cancer and can detect breast cancer at earlier stages. It is less affected by breast density than FFDM and can be used as a stand-alone technique or as an adjunct to FFDM.

### Lång et al.
“Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmö Breast Tomosynthesis Screening Trial, a population-based study”

Sweden 2015
One-view DBT alone increased breast cancer detection rate by 43% compared to two-view FFDM. The results suggest that one-view DBT may be feasible as a single screening modality.

### Siemens Medical Solutions USA, Inc.
“PMA (P140011) study with MAMMOMAT Inspiration with Tomosynthesis Option”

USA 2015
Readers’ sensitivity increased with the addition of two-view DBT to FFDM.

### Extano et al.
“The additional role of tomosynthesis after normal mammography according according to ACR density patterns”

Spain 2013
DBT is useful in ACR III-IV dense breasts as well as for scattered fibroglandular breasts (ACR II), increases sensitivity compared to FFDM and detects more invasive cancers, in particular tubular cancers.

### Uchiyama et al.
“Diagnostic Impact of Adjunction of Digital Breast Tomosynthesis (DBT) to Full Field Digital Mammography (FFDM) and in Comparison with Full Field Digital Mammography (FFDM)”

Japan 2012
DBT + FFDM detects more cancers than FFDM alone. DBT as an adjunct to FFDM was able to detect early-stage breast cancer and is not affected by breast density.

### Dose

Breast tissue is sensitive to radiation and screening examinations are performed on healthy women. It is therefore immensely important to obtain the highest possible image quality at the lowest achievable dose. An independent study confirms that Siemens Mammmomat Inspiration operates at a lower dose than another vendor’s product. Furthermore, a new reconstruction mechanism enables the dose to be reduced by up to 50%.

### Timberg et al.
Detection of calcification clusters in digital breast tomosynthesis slices at different dose levels utilizing a SRSAR reconstruction and JAFROC

Sweden 2015
With SRSAR, it is possible to reduce the dose by 50% compared to standard FBP.

### Dance et al.
“Comparison of breast doses for digital tomosynthesis estimated from patient exposures and using PMMA breast phantoms”

UK 2012
The results conclude that the dose for tomosynthesis with the Siemens Mammmomat Inspiration system is lower than with another vendor’s product.
Clinical Value of True Breast Tomosynthesis

Specificity / recall rate
False-positive recalls result in unnecessary additional costs and anxiety in patients. Recall rates are therefore an important factor when evaluating a screening modality. It is often difficult to characterize a lesion as benign or malignant with FFDM. This results in an incorrect BI-RADS categorization and tends to increase false positive recalls. Digital Breast Tomosynthesis improves lesion characterization and diagnostic performance, reducing false-positive findings.

<table>
<thead>
<tr>
<th>Study</th>
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<tbody>
<tr>
<td>Heywang-Köbrunner et al.</td>
<td>Germany</td>
<td>2015</td>
<td>Due to higher specificity, diagnostic performance is improved if DBT replaces additional 2D FFDM views.</td>
</tr>
<tr>
<td>Siemens Medical Solutions USA, Inc.</td>
<td>USA</td>
<td>2015</td>
<td>The non-cancer recall rate was reduced by 19% for FFDM plus two-view DBT as compared to FFDM alone.</td>
</tr>
<tr>
<td>Bick U.</td>
<td>Germany</td>
<td>2014</td>
<td>In screening, DBT improved cancer detection rates while at the same time reducing recalls for false-positives.</td>
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</tbody>
</table>

Compression force
The need for compression with mammography is a cause of patient discomfort and one reason for reduced compliance in breast screening. If breast compression can be reduced without compromising image quality, this will improve patient comfort and possibly increase screening participation rates. The studies indicate that it is possible to reduce compression force with DBT, offering patients a more comfortable screening experience without loss of image quality.

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<tr>
<td>Lång et al.</td>
<td>Sweden</td>
<td>2015</td>
<td>DBT allows a 50% reduction of compression force in 90% of cases. Screening therefore becomes more comfortable for women.</td>
</tr>
<tr>
<td>Förnvik et al.</td>
<td>Sweden</td>
<td>2010</td>
<td>No difference in image quality was evident with reduced compression, indicating that DBT can be performed with substantially less compression force compared with 2D mammography. The majority of women examined felt that half compression was more comfortable than full compression.</td>
</tr>
<tr>
<td>Saunders et al.</td>
<td>USA</td>
<td>2009</td>
<td>For constant glandular dose, mass and microcalcification conspicuity remained constant at decreased compression.</td>
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</tbody>
</table>
Reading Time

As DBT consists of volume sets rather than single images, it takes more time to review than FFDM. New techniques such as slabbing reduce reading times without compromising image quality and detection rate.

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<tr>
<td>Dustler et al. “Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis”</td>
<td>Sweden</td>
<td>2014</td>
<td>It is possible to review DBT volumes with 2 mm slabs without compromising diagnostic accuracy, and the visibility of microcalcifications is improved.</td>
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</tbody>
</table>

Therapy planning and control

Several studies have shown that tomosynthesis is useful not only in screening and follow-up diagnostics, but also in therapy planning and control.

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<tbody>
<tr>
<td>Pina L. “Value of digital breast tomosynthesis for preoperative local staging of breast cancer”</td>
<td>Spain</td>
<td>2015</td>
<td>DBT increases the sensitivity of DM, detecting up to 32.4% additional cancers and changing the initial surgical treatment in 24.1% of patients.</td>
</tr>
<tr>
<td>Van Ovengal et al. “Is DBT the new standard in diagnostic imaging? How to implement in specialist training?”</td>
<td>Belgium</td>
<td>2014</td>
<td>DBT has the best diagnostic accuracy and the best early detection rate for breast lesions and is more accurate in determining lesion size compared to DM and US.</td>
</tr>
<tr>
<td>Schulz-Wendtland et al. “Full Field Digital Mammography (FFDM) versus CMOS Technology, Specimen Radiography System (SRS) and Tomosynthesis (DBT) – Which System Can Optimise Surgical Therapy?”</td>
<td>Germany</td>
<td>2013</td>
<td>The Mammmomat Inspiration with a tomosynthesis option had the highest sensitivity of the three systems tested. The rate of reexcisions was reduced compared to the results from FFDM.</td>
</tr>
<tr>
<td>Uchiyama et al. “Usefulness of Adjunction of Digital Breast Tomosynthesis (DBT) to Full-Field Digital Mammography (FFDM) in Evaluation of Pathological Response after Neoadjuvant Chemotherapy (NAC) for Breast Cancer”</td>
<td>Japan</td>
<td>2012</td>
<td>The adjunction of DBT to FFDM combined with other diagnostic modalities contributes to a more accurate assessment of response to NAC. The adjunction of DBT to FFDM improves the assessment of lesions and their margins without utilizing a contrast medium.</td>
</tr>
<tr>
<td>Förnvik et al. “Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammography.”</td>
<td>Sweden</td>
<td>2010</td>
<td>The tumor outline could be determined better with DBT and US than with FFDM. The size correlated well with pathology; staging was more accurate. The study indicates that DBT is superior to FFDM in the assessment of breast tumor.</td>
</tr>
</tbody>
</table>
Some studies were conducted with technology that is not yet commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

References

[1] Siemens Medical Solutions USA, Inc., MAMMOMAT Inspiration with Tomosynthesis Option, PMA P140011: FDA Summary of Safety and Effectiveness Data, April 21, 2015;


[3] Tani et al., DBT plus Rotating Mammogram demonstrated superior diagnostic accuracy compared with FFDM alone, especially in the visualization of microcalcifications; Breast Imaging Lecture Notes in Computer Science Volume 8539, 2014, pp 142–149;


[6] Lång et al., Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: results from the Malmö Breast Tomosynthesis Screening Trial, a population-based study; Eur Radiol. 2015 May 1;

[7] Extano et al., The additional role of tomosynthesis after normal mammography according to ACR density patterns; Presentation at the ECR 2013, March 7 – 11, Vienna / Austria;


[9] Timberg et al., Detection of calcification clusters in digital breast tomosynthesis slices at different dose levels utilizing a SRSAR reconstruction and JAFROC; Proc. SPIE 9416, Medical Imaging 2015: Image Perception, Observer Performance, and Technology Assessment, 941604 (March 17, 2015);


[12] Heywang-Köbrunner et al., Routine use of digital breast tomosynthesis (DBT) for the assessment of screen-detected cases; Satellite Symposia at the ECR 2015, March 4 – 8, Vienna / Austria;

[13] Bick et al., Tomosynthesis and the impact on patient management; Digital Breast Tomosynthesis Course at EUSOBI 2014, 4 – 5 March, Vienna / Austria;

[14] Galati et al., Added value of one-view DBT combined with DM according to readers’ concordance – changing in BIRADS rate and follow-up management: A preliminary study; Personal Correspondence;


[16] Dustler et al., A Study of the Feasibility of using slabbing to reduce Tomosynthesis Review Time; Proc. SPIE 8673, Medical Imaging 2013: Image Perception, Observer Performance, and Technology Assessment, 86731L (March 28, 2013);


[18] Saunders et al., Can compression be reduced for breast tomosynthesis? Monte Carlo study on mass and microcalcification conspicuity in tomosynthesis; Radiology. 2009 Jun;251(3):673-82;

[19] Pina L., Value of digital breast tomosynthesis for preoperative local staging of breast cancer; Satellite Symposia at the ECR 2015, March 4 – 11, Vienna / Austria;

[20] Van Ovengal et al., Is DBT the new standard in diagnostic imaging? How to implement in specialist training?; Siemens Breast Care Day at the ECR 2014, March 6 – 10, Vienna / Austria;


