SIEMENS

White Paper

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 Mammomat 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 Mammomat 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.

Siemens Medical Solutions USA, Inc. **"PMA (P140011) study with MAMMOMAT Inspiration with Tomosynthesis Option"**[1]	USA	2015	FFDM + two-view DBT is superior in terms of diagnostic accuracy over FFDM alone.
Elizalde et al. **"Additional US or DBT after digital mammography: which one is the best combination?"**[2]	Spain	2014	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.
Tani et al. **"Assessing Radiologist Performance and Microcalcifications Visualization Using Combined 3D Rotating Mammogram (RM) and Digital Breast Tomosynthesis (DBT)"**[3]	Japan	2014	DBT plus rotating mammogram demonstrated superior diagnostic accuracy compared with FFDM alone, especially in the visualization of microcalcifications.
Uchiyama et al. **"Clinical Efficacy of Novel Image Processing Techniques in the Framework of Filtered Back Projection (FBP) with Digital Breast Tomosynthesis (DBT)"**[4]	Japan	2014	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.
Timberg et al. **"Visibility of single spiculations in digital breast tomosynthesis"**[5]*	Sweden	2013	SRSAR improved the visibility of spiculations.
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)"**[8]	Japan	2012	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.
Andersson et al. **"Breast tomosynthesis and digital mammography: a comparison of breast cancer visibility and BIRADS classification in a population of cancers with subtle mammographic findings."**[8]	Sweden	2008	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.

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"[6]**	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"[1]**	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"[7]**	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)"[8]**	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 Mammomat 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[9]**	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"[11]**	UK	2012	The results conclude that the dose for tomosynthesis with the Siemens Mammomat Inspiration system is lower than with another vendor's product.

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 BIRADS categorization and tends to increase false positive recalls. Digital Breast Tomosynthesis improves lesion characterization and diagnostic performance, reducing false-positive findings.

Heywang-Köbrunner et al. **"Routine use of digital breast tomosynthesis (DBT) for the assessment of screen-detected cases"[12]**	Germany	2015	Due to higher specificity, diagnostic performance is improved if DBT replaces additional 2D FFDM views.
Siemens Medical Solutions USA, Inc. **"PMA (P140011) study with MAMMOMAT Inspiration with Tomosynthesis Option"[1]**	USA	2015	The non-cancer recall rate was reduced by 19% for FFDM plus two-view DBT as compared to FFDM alone.
Bick U. **"Tomosynthesis and the impact on patient management"[13]**	Germany	2014	In screening, DBT improved cancer detection rates while at the same time reducing recalls for false-positives.

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.

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"[6]**	Sweden	2015	DBT allows a 50% reduction of compression force in 90% of cases. Screening therefore becomes more comfortable for women.
Förnvik et al. **"The effect of reduced breast compression in breast tomosynthesis: human observer study using clinical cases"[17]**	Sweden	2010	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.
Saunders et al. **"Can compression be reduced for breast tomosynthesis? Monte Carlo study on mass and microcalcification conspicuity in tomosynthesis."[18]**	USA	2009	For constant glandular dose, mass and microcalcification conspicuity remained constant at decreased compression.

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.

Dustler et al. **"Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis"**[15]	Sweden	2014	It is possible to review DBT volumes with 2 mm slabs without compromising diagnostic accuracy, and the visibility of microcalcifications is improved.
Dustler et al. **"A Study of the Feasibility of using slabbing to reduce Tomosynthesis Review Time"**[16]	Sweden	2013	Slabbing in screening significantly reduces reading time.

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.

Pina L. **"Value of digital breast tomosynthesis for preoperative local staging of breast cancer"**[19]	Spain	2015	DBT increases the sensitivity of DM, detecting up to 32.4% additional cancers and changing the initial surgical treatment in 24.1% of patients.
Van Ovengal et al. **"Is DBT the new standard in diagnostic imaging? How to implement in specialist training?"**[20]	Belgium	2014	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.
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?"**[21]	Germany	2013	The Mammomat 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.
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"**[22]	Japan	2012	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.
Förnvik et al. **"Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammography."**[23]	Sweden	2010	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.

Some studies were conducted with technology that is not yet commercially available. Due to regulatory reasons, its future availability cannot be guaranteed.

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