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Clinical Value of True 3D Breast Tomosynthesis

An evaluation of recent studies

Answers for life.

Digital Mammography has improved the detection of breast cancer immensely. 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 (DBT) 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 is the key to the system's ability to reduce the impact of overlapping tissue. Various commercially available systems use angles between 15 to 50 degrees, while the number of projections taken differs from 9 to 25. Siemens Mammomat Inspiration offers the largest angular range with 50° and the highest number of projections at 25.

This paper presents the results of recent studies performed with Siemens Mammomat Inspiration and summarizes their key findings.

This paper addresses the following questions:

- How does tomosynthesis affect the detection rate and type of cancers found?
- Does tomosynthesis lead to a reduction in recall rates?
- What effect does tomosynthesis have on Mean Glandular Dose and are there differences in the biological effects?
- Does it help in the characterization of lesion type and size?
- How can reading time be reduced without compromising image quality?
- Is it possible to reduce the compression force to improve patient comfort without compromising image quality?
- Is tomosynthesis only for diagnostics or does it have a place in screening?
- How does it perform in comparison to other breast imaging modalities?

Detection rate

As Full Field Digital Mammography (FFDM) alone misses approximately 30% of breast cancers[18], 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 Full Field Digital Mammography.

Zackrisson et al. "Performance of one-view breast tomosynthesis versus two-view mammography in breast cancer screening – First results from the MALMÖ BTST"[1]	Sweden	2014	One-view DBT alone increased breast cancer detection rate by 43% compared to 2-view FFDM. The results suggest that 1-view DBT may be feasible as a single screening modality.
Extano et al. "The additional role of tomosynthesis after normal mammography according to ACR density patterns"[2]	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)"[3]	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.

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. Digital Breast Tomosynthesis can improve the characterization of lesions, reducing false-positive findings and recall rates.

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"[4]	Italy	2014	The combination of two-view FFDM and one-view DBT increased concordance between readers for the BIRADS classification and reduced recalls.
Bick et al. "Tomosynthesis and the impact on patient management"[5]	Germany	2014	In screening, DBT improved cancer detection rates while at the same time reducing recalls for false-positives.

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 Siemens Mammomat Inspiration operates at a lower dose than another vendor. Another study found that the dose required for Digital Breast Tomosynthesis may result in less DNA damage compared to standard mammography and therefore may be biologically safer.

Schwab et al. "X-ray induced formation of γ-H2AX foci after full-field digital mammography and digital breast-tomosynthesis"[6]	Germany	2013	Mammography induces a small but significant increase of γ-H2AX foci in patients' systemic blood lymphocytes. This indicator of DNA damage was less prominent after DBT than FFDM.
Dance et al. "Comparison of breast doses for digital tomosynthesis estimated from patient exposures and using PMMA breast phantoms"[7]	UK	2012	The results conclude that the dose for tomosynthesis with the Siemens Mammomat Inspiration system is lower than other vendors.

Specificity

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 recall rates. Digital Breast Tomosynthesis improves the lesion characterization and diagnostic performance.

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"[8]	Italy	2014	The combination of two-view FFDM and one-view DBT increased concordance between readers for the BIRADS classification and reduced recalls.
Heywang-Köbrunner et al. "Use of Tomosynthesis for the assessment of screen-detected lesions"[9]	Germany	2013	Due to higher specificity, diagnostic performance is improved if DBT replaces additional 2D FFDM views.
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)"[3]	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.

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 will reduce reading times without compromising on image quality and detection rate.

Dustler et al. "Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis"[10]	Sweden	2014	It is possible to review DBT volumes with 2 mm slabs without compromising image quality and the visibility of micro-calcifications is improved.
Dustler et al. "A Study of the Feasibility of using slabbing to reduce Tomosynthesis Review Time"[11]	Sweden	2013	Slabbing in screening significantly reduces reading time.

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 maybe 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.

Lang et al. "Breast Tomosynthesis in Screening"[12]	Sweden	2014	DBT significantly increases breast cancer detection, reduces recall rates and allows a reduction in compression force. 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"[13]	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."[14]	USA	2009	For constant glandular dose, mass and microcalcification conspicuity remained constant at decreased compression levels.

Field of Application

Several studies have shown that tomosynthesis is a promising modality for screening, diagnostics and monitoring therapy. DBT is not only useful in screening and diagnostics, but also in therapy planning and control.

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?"[15]	Germany	2013	Mammomat Inspiration tomosynthesis system had the highest sensitivity of the three systems tested. The rate of re-excisions was reduced compared to results from FFDM systems.
Van Ongeval et al. "Is DBT the new standard in diagnostic imaging? How to implement in specialist training?"[16]	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.
Heywang-Köbrunner et al. "Use of Tomosynthesis for the assessment of screen-detected lesions"[9]	Germany	2013	Diagnostic performance is higher due to higher specificity if tomosynthesis replaces additional views.
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"[17]	Japan	2012	The adjunction of DBT to FFDM combined with other diagnostic modalities contributes to 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.

References

[1] Zackrisson et al., Performance of one-view breast tomosynthesis versus two-view mammography in breast cancer screening – First results from the MALMÖ Breast Tomosynthesis Screening Trial; Presentation at the ECR 2014, March 6 – 10, Vienna/Austria;

[2] 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;

[3] 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); Breast Imaging, 11th International Workshop, IWDM 2012, Philadelphia, PA, USA, July 8 – 11, 2012 Proceedings: LNCS 7361, pp 119-126;

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

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

[6] Schwab et al., X-ray induced formation of γ-H2AX foci after full-field digital mammography and digital breast-tomosynthesis; PLoS One, 2013 Jul 25;8(7):70660;

[7] Dance et al., Comparison of breast doses for digital tomosynthesis estimated from patient exposures and using PMMA breast phantoms; Breast Imaging, 11th International Workshop, IWDM 2012, Philadelphia, PA, USA, July 8 – 11, 2012 Proceedings: LNCS 7361, pp 316-321;

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

[9] Heywang-Köbrunner et al., Use of Tomosynthesis for the assessment of screen-detected lesions; Screening Assessment course at the ECR 2013, March 7 – 11, Vienna/Austria;

[10] Dustler et al., Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis; Breast Imaging, 12th International, Workshop IWDM 2014, Gifu City, Japan, June 29 – July 2, 2014 Proceedings: LNCS 8539, pp. 544–549;

[11] 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);

[12] Lang et al., Breast Tomosynthesis in Screening; Presentation at EUSOBI 2014, March 4 – 5, Vienna/Austria; Presentation at EUSOBI 2014, March 4 – 5, Vienna/Austria;

[13] Förnvik et al., The effect of reduced breast compression in breast tomosynthesis: human observer study using clinical cases; Radiat Prot Dosimetry. 2010 Apr-May;139(1-3):118-23;

[14] 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;

[15] 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?; Geburtshilfe Frauenheilkd. 2013 May; 73(5):422-427.;

[16] Van Ongeval 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;

[17] 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; Breast Imaging, 11th International Workshop, IWDM 2012, Philadelphia, PA, USA, July 8 – 11, 2012 Proceedings: LNCS 7361, pp 354-361;

[18] Andersson, Ingvar; Ikeda, Debra M. et al. (2008). Breast tomosynthesis and digital mammography: a comparison of breast cancer visibility and BIRADS classification in a population of cancers with subtle mammographic findings. Eur. Radiol. 18.p. 2817

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