White paper

Benefits of 50° wide-angle tomosynthesis

Bibliography with key clinical and scientific findings

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Summary

Following its market introduction in 2009, several clinical studies on Digital Breast Tomosynthesis* have proceeded to demonstrate the value of this technique for breast imaging. The following is a summation of key findings from studies conducted with 50° wide-angle tomosynthesis.

Glossary

AUC	Area Under the (ROC) Curve
BIRADS	Breast Imaging Reporting and Data System
CNR	Contrast-to-noise ratio
DBT	Digital Breast Tomosynthesis
EMPIRE	Enhanced Multiple Parameter Iterative Reconstruction
FBP	Filtered backprojection
FFDM	Full Field Digital Mammography
FP	False Positives
Insight 2D	Synthetic mammogram
Insight 3D	Rotating synthetic mammogram
Insight Breast Density	Volumetric Breast Density Assessment
JAFROC	Jackknife Alternative Free-response Receiver Operating Characteristics
LL	Latero-lateral
MGD	Mean Glandular Dose
MRMC	Multi Reader Multi Center (study)
MTF	Modulation transfer function
NAC	Neoadjuvant chemotherapy
NPV	Negative Predictive Value
PMA	Premarket Approval
PMMA	Polymethylmethacrylate (phantom)
PPV	Positive Predictive Value
ROC	Receiver Operating Characteristic
US	Ultrasound

* *Some studies contain technologies that are not commercially available. Due to regulatory reasons its future availability cannot be guaranteed.*

Author and study title	Year	Key findings
Georgian-Smith et al. "Can Digital Breast Tomosynthesis Replace Full-Field Digital Mammography? A Multireader, Multicase Study of Wide-Angle Tomosynthesis" [1]	2019	Wide-angle two-view DBT alone has greater diagnostic accuracy than FFDM for most radiologists, even for those inexperienced with DBT technology.
Clauser et al. "Synthetic 2-Dimensional Mammography Can Replace Digital Mammography as an Adjunct to Wide-Angle Digital Breast Tomosynthesis" [2]	2019	Wide-angle DBT, either combined with FFDM or synthetic mammograms, increases sensitivity and diagnostic accuracy without reducing specificity compared with FFDM alone. No differences were seen between synthetic mammograms or FFDM in DBT-combined readings, so synthetic mammograms should replace FFDM for combined readings with wide-angle DBT.
Zackrisson et al. "One-view breast tomosynthesis versus two-view mammography in the Malmö Breast Tomosynthesis Screening Trial (MBTST)" [3]	2018	In this prospective population-based screening trial, an increase in the cancer detection rate of 34% was achieved with one-view DBT only. At the same time, the breast compression force was lowered by 40% and the radiation dose reduced by 15%. It is the only prospective screening trial that has proven higher diagnostic accuracy with DBT at a lower radiation dose compared to the current screening standard.
Rodriguez-Ruiz et al. "One-view digital breast tomosynthesis as a stand-alone modality for breast cancer detection: do we need more?" [4]	2018	Detection performance with one-view DBT is not inferior to two-view FFDM or to two-view FFDM plus two-view DBT. Training may lead to one-view DBT being sufficient for screening.
Scaduto et al. "Impact of angular range of digital breast tomosynthesis on mass detection in dense breasts" [5]	2018	The simulation results show for DBT an increased in-plane detectability of masses with increasing angular range. This is confirmed by clinical results showing that masses are more conspicuous in wide-angle DBT than narrow-angle DBT. The detection of mass lesions in dense breasts can be improved by increasing the DBT angular range.
Neubauer et al. "Multiple Angulated Mammography Reconstructions in Digital Breast Tomosynthesis for the Diagnosis of Microcalcifications - Added Value to Standard Stack Reconstructions and Synthesized Mammography" [6]	2018	The depiction of microcalcifications is better in the slices with 50° wide-angle DBT compared to synthetic mammograms, but reading time is increased. Synthetic mammograms allow for faster reading times, with Insight 3D having a better depiction of calcification clusters compared to Insight 2D, at equal reading time, diagnostic accuracy and inter-reader agreement.
Rodriguez-Ruiz et al. "New reconstruction algorithm for digital breast tomosynthesis: better image quality for humans and computers" [7]	2017	Image reconstruction with EMPIRE provides better contrast and image quality, fewer artifacts, and improved visibility of calcifications than standard reconstruction, as well as improved detection performance with deep-learning algorithms.

Author and study title	Year	Key findings
Galati et al. "Added value of one-view digital breast tomosynthesis combined with digital mammography according to readers concordance: changing in BIRADS rate and follow-up management" [8]	2017	The addition of 1-view DBT to 2-view FFDM reduced the inter-reader variability for BIRADS classification and recall rate. DBT+FFDM also increased the number of BIRADS 1-2 and BIRADS 4-5, while reducing the number of cases with BIRADS 0 and 3 (uncertain cases).
Amer et al. "Digital breast tomosynthesis versus full-field digital mammography – Which modality provides more accurate prediction of margin status in specimen radiography?" [9]	2017	DBT significantly improves the accuracy of specimen radiography regarding identification of the closest margin and sensitivity regarding margin status assessment compared to FFDM. This could reduce re-excision and re-operation rates.
Maldera et al. "Digital breast tomosynthesis: Dose and image quality assessment" [10]	2017	In-depth resolution improved with increasing scan angle but was also affected by the choice of reconstruction and post-processing algorithms. The highest z-resolution was provided by Siemens.
Rodriguez-Ruiz et al. "Evaluation of the technical performance of three different commercial digital breast tomosynthesis systems in the clinical environment" [11]	2016	DBT systems with a wider angular range yield a higher depth resolution.
Siemens Medical Solutions USA Inc. "MRMC study to demonstrate the superior accuracy of Siemens DBT to FFDM as a replacement for FFDM screening mammography" [12]	2016	The average AUC ROC was significantly higher with DBT as a stand- alone modality and the readers' average non-cancer recall rate was significantly lower. DBT also resulted in a lower inter-observer variability compared to FFDM.
Clauser et al. "Diagnostic performance of digital breast tomosynthesis with a wide scan angle compared to full-field digital mammography for the detection and characterization of microcalcifications" [13]	2016	50° wide-angle DBT enables similar detection and characterization performance for microcalcifications as with FFDM.
Whelehan et al. "Clinical performance of Siemens digital breast tomosynthesis versus standard supplementary mammography for the assessment of screen-detected softtissue abnormalities: a multi-reader study" [14]	2016	50° wide-angle DBT demonstrates equivalent diagnostic accuracy according to ROC curve analysis when used in place of supplementary mammographic views in screen-detected soft-tissue mammographic abnormalities.
Lång et al. "False positives in breast cancer screening with one-view breast tomosynthesis: An analysis of findings leading to recall, work-up and biopsy rates in the Malmö Breast Tomosynthesis Screening Trial" [15]	2016	FPs increased with DBT screening mainly due to the recall of stellate distortions. The FP recall rate was still well within the European guidelines and showed evidence of a learning curve. The characterization of rounded lesions was improved with DBT.
Uchiyama et al. "Diagnostic Usefulness of Synthetic MG (SMMG) with DBT (Digital Breast Tomosynthesis) for Clinical Setting in Breast Cancer Screening" [16]	2016	Insight 2D plus DBT demonstrated higher AUC and superior diagnostic accuracy with regards to sensitivity, specificity, and NPV compared to Insight 2D and FFDM alone ($p < 0.05$). Also the 40% decrease of radiation dose allows for two-view Insight 2D plus DBT in breast cancer screening instead of FFDM.

Author and study title	Year	Key findings
Elizalde et al. "Additional US or DBT after digital mammography: which one is the best combination?"[17]	2016	The combination of FFDM and additional US, DBT, or both, significantly increased the diagnostic performance (AUC) of FFDM.
Pozzi et al. "Digital Breast Tomosynthesis in Addition to Conventional 2D-Mammography Reduces Recall Rates and is Cost-Effective"[18]	2016	Adding DBT to FFDM results in a significant reduction in recall rates preventing unnecessary burden on women and the healthcare system. Earlier, less costly treatment strategies can be applied.
Van Ongeval "The role of the Synthetic Mammogram"[19]	2016	Diagnostic performances of Insight 2D and FFDM are comparable for detecting T1 stage breast cancers. There is an improvement of specificity of Insight2D+DBT compared to FFDM alone.
Timberg et al. "Breast Density Assessment Using Breast Tomosynthesis Images"[20]	2016	Insight Breast Density is a promising approach using low dose central projection DBT images in order to obtain radiologist-like density ratings similar to results obtained from FFDM.
Scaduto et al. "Digital breast tomosynthesis with minimal breast compression"[21]	2015	Image acquisition is optimized for reduced compression in DBT without compromising image quality or increasing MGD. Measurements on phantoms and patients suggest comparable lesion conspicuity for DBT with no appreciable difference in patient motion due to minimal compression.
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"[22]	2015	Interim results: The breast cancer detection rate improved by 43% and breast cancer screening with one-view DBT as a stand-alone modality seems feasible. Breast compression can be reduced by 50%. (The final results of the study have been published in 2018, see ref. 3)
Siemens Medical Solutions USA, Inc. "PMA (P140011) study with MAMMOMAT Inspiration with Tomosynthesis Option"[23]	2015	FFDM + 2-view DBT is superior in terms of diagnostic accuracy (AUC) to FFDM alone. Readers' sensitivity increased with the addition of 2-view DBT to FFDM. Non-cancer recall rate was reduced by 19% for FFDM plus 2-view DBT as compared to FFDM alone.
Mercier et al. "The role of tomosynthesis in breast cancer staging in 75 patients"[24]	2015	Tomosynthesis found more lesions than mammography in 10% of patients, resulting in an adaptation of the surgical planning.
Urano et al. "Digital mammography versus digital breast tomosynthesis for detection of breast cancer in the intraoperative specimen during breast-conserving surgery"[25]	2015	DBT can detect breast cancer more accurately than FFDM in LL views, indicating its potential to more precisely diagnose vertical invasion.
Baptista et al. "Dosimetric characterization and organ dose assessment in digital breast tomosynthesis: Measurements and Monte Carlo simulations using voxel phantoms"[26]	2015	Taking into account an average breast with a thickness of 4.5 cm, the MGDs for FFDM and DBT acquisitions were below the achievable value (2.0 mGy) defined by the European protocol.

Author and study title	Year	Key findings
Timberg et al. "Detection of calcification clusters in digital breast tomosynthesis slices at different dose levels utilizing a SRSAR reconstruction and JAFROC"[27]	2015	Compared to standard FBP, the detection performance for calcification clusters is increased with EMPIRE. Alternatively, for the same detection performance as standard FBP the dose level can be reduced by 50% with EMPIRE.
Abdurahman et al. "Optimizing High Resolution Reconstruction in Digital Breast Tomosynthesis Using Filtered Back Projection"[28]	2014	Image reconstruction with EMPIRE preserves micro-calcifications at high spatial resolution while maintaining noise levels acceptable for clinical interpretations. Contrast and sharpness of microcalcifications have been increased and morphology of calcification clusters are preserved. Furthermore, the CNR of soft tissue regions was improved while the details of spiculated masses such as architectural distortions were preserved.
Miglio 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"[29]	2014	The combination of two-view FFDM and one-view DBT increased the concordance between the readers for the BIRADS classification, and reduced recalls.
Uchiyama et al. "Clinical Efficacy of Novel Image Processing Techniques in the Framework of Filtered Back Projection (FBP) with Digital Breast Tomosynthesis (DBT)"[30]	2014	EMPIRE was significantly superior to the standard FBP. In particular, the diagnostic certainty in the assessment of microcalcifications was improved.
Tani et al. "Assessing Radiologist Performance and Microcalcifications Visualization Using Combined 3D Rotating Mammogram (RM) and Digital Breast Tomosynthesis"[31]	2014	The visualization of microcalcifications was significantly better for all microcalcification-dominant cancer lesions with the adjunction of Insight 3D to DBT.
Dustler et al. "Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis"[32]	2014	It is possible to review DBT volumes with 2 mm slabs without compromising image quality, and the visibility of microcalcifications is improved.
Lång et al. "Breast cancer detection in digital breast tomosynthesis and digital mammography: a side-by-side review of discrepant cases"[33]	2014	Lesion visualization with DBT is superior to FFDM, particularly for spiculated tumors suggesting that DBT is better than FFDM in visualizing breast cancer.
Bernathova M "Digital breast tomosynthesis – another milestone in breast imaging"[34]	2014	DBT has comparable or superior image quality and a higher conspicuity of lesions. It improves the specificity and accuracy, increases the detection rate and has the potential to decrease the recall rate.
Van Ongeval et al. "Is DBT the new standard in diagnostic imaging? How to implement in specialist training?"[35]	2014	Compared to FFDM and ultrasound, DBT has better diagnostic accuracy in early detection for breast lesions and is more accurate in determining lesion size.
Bick et al. "Tomosynthesis and the impact on patient management"[36]	2014	In screening, DBT improved cancer detection rates and reduced recalls for false-positives.

Author and study title	Year	Key findings
Pina et al. "Interpretation of masses, distortions and densities with Tomosynthesis"[37]	2014	DBT increases the detection rate of breast cancer up to 27% and is very sensitive to spiculations and architectural distortions, resulting in a high PPV.
Zackrisson S, Houssami N "Digital breast tomosynthesis: the future of mammography screening or much ado about nothing?"[38]	2013	Overview of tomosynthesis and its improvements compared to standard mammography.
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?"[39]	2013	The MAMMOMAT Inspiration with 50° wide-angle DBT had the highest sensitivity of the three systems tested. The rate of re-excisions was reduced compared to the results of FFDM.
Dustler et al. "A Study of the Feasibility of using slabbing to reduce Tomosynthesis Review Time"[40]	2013	Slabbing in screening reduces the reading time significantly.
Timberg et al. "Visibility of single spiculations in digital breast tomosynthesis"[41]	2013	EMPIRE improves the visibility of spiculations and promises to be an alternative to FBP.
Slon et al. "The Role of Additional Ultrasound and Tomosynthesis After Normal Digital Mammography: Comparison Between Both Techniques"[42]	2013	The study results show that DBT detected additional cancers not visible on FFDM and increased the detection rate.
Extano et al. "The additional role of tomosynthesis after normal mammography according to ACR density patterns"[43]	2013	DBT is useful in ACR III-IV dense breasts as well as for scattered fibroglandular breasts (ACR II), increasing the sensitivity compared to FFDM, and detects more invasive cancers, in particular tubular cancers.
Heywang-Köbrunner et al. "Use of Tomosynthesis for the assessment of screen-detected lesions"[44]	2013	Due to higher specificity, the diagnostic performance is improved if DBT replaces additional views.
Abdurahman et al. "Out-of-Plane Artifact Reduction in Tomosynthesis Based on Regression Modeling and Outlier Detection"[45]	2012	The authors propose a technique for reconstructing a set of super-resolution DBT slices and predicting the artifact-free voxel intensity based on statistical artefact reduction. The experiments show that the reconstructed images are de-blurred and streak-like artifacts are reduced. The visibility of clinical features, contrast and sharpness are improved and thick-slice reconstruction is possible without the loss of contrast and sharpness.
Marshall et al. "Measurements of system sharpness for two digital breast tomosynthesis systems"[46]	2012	Wide-angle tomosynthesis has a higher depth resolution (z-plane PSF) because of the wider tomographic angle used.

Author and study title	Year	Key findings
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)"[47]	2012	DBT+FFDM detect more cancers than FFDM alone. DBT as an adjunct to FFDM was able to detect early-stage breast cancer and it is not affected by breast density.
Dance et al. "Comparison of breast doses for digital tomosynthesis estimated from patient exposures and using PMMA breast phantoms"[48]	2012	The dose for tomosynthesis with the Siemens MAMMOMAT Inspiration system is lower than with systems of other vendors.
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"[49]	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 the lesion and its margins without utilizing a contrast medium.
Svahn et al. "Breast tomosynthesis and digital mammography: a comparison of diagnostic accuracy"[50]	2012	The diagnostic accuracy of DBT was significantly better than that of FFDM.
Uchiyama et al. "Evaluation of correlation between pathological size and diagnostic size"[51]	2012	For evaluating the extent of a lesion, FFDM plus DBT was superior compared to US or FFDM only. In addition, FFDM plus DBT showed a strong correlation with MRI.
Förnvik et al. "Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammography and ultrasonography"[52]	2010	The study indicates that DBT is superior to FFDM in the assessment of breast tumor size and stage.
Förnvik et al. "The effect of reduced breast compression in breast tomosynthesis: human observer study using clinical cases"[53]	2010	No difference in the image quality was evident with reduced compression, indicating that DBT may be performed with substantially less compression force compared with 2D mammography. A majority of the examined women felt that half compression was more comfortable than full compression.
Zhao et al. "Experimental validation of a three-dimensional linear system model for breast tomosynthesis"[54]	2009	The detection of masses with DBT can be improved by increasing the angular range, as it improves the MTF at low frequencies, resulting in better detection of large-area, low-contrast lesions.
Mertelmeier et al. "Optimization of Tomosynthesis Acquisition Parameters: Angular Range and Number of Projections"[55]	2008	For DBT, a larger angular range increases the depth resolution and also improves the visibility of low-frequency objects, i.e. the detection of masses.
Zhou et al. "A computer simulation platform for the optimization of a breast tomosynthesis system"[56]	2007	The in-depth resolution of DBT can be improved by increasing the angular range, whereas pixel binning (2x2) would cause more degradation to the in-plane MTF than the blur caused by the moving focal spot and the image reconstruction.

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