SIEMENS

Literature List

Benefits of True Breast Tomosynthesis

Bibliography with key findings

Summary

Following its introduction in 2009, a host of clinical studies on Digital Breast Tomosynthesis* have demonstrated the value of this technique for breast imaging. The following is a summary of key findings from the latest studies conducted with Mammomat Inspiration and True Breast Tomosynthesis.

Author and study title	Year	Key findings
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" ¹	2015	Breast cancer detection rate improved by 43%. Breast cancer screening with one-view DBT as a stand-alone modality seems feasible. Breast compression force can be reduced up to 50%.
Siemens Medical Solutions USA, Inc. "PMA (P140011) study with Mammomat Inspiration with Tomosynthesis Option" ²	2015	FFDM + 2-view DBT is superior in terms of diagnostic accuracy over 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.
Timberg et al. "Detection of calcification clusters in digital breast tomosynthesis slices at different dose levels utilizing a SRSAR reconstruction and JAFROC" ^{3*}	2015	With SRSAR reconstruction it is possible to maintain high detection performance for calcification clusters and reducing dose levels up to 50%.
Elizalde et al. "Additional US or DBT after digital mammography: which one is the best combination?" ⁴	2014	The combination of FFDM and additional US, DBT, or both, significantly increased the diagnostic per- formance. However, the results for the comparison of additional US and DBT to FFDM were comparable.
Mercier et al. "The role of tomosynthesis in breast cancer staging in 75 patients" ⁵	2014	Tomosynthesis found more lesions than mammography in 10% of patients, resulting in an adaption of the surgical planning.
Uchiyama et al. "Clinical Efficacy of Novel Image Processing Techniques in the Framework of Filtered Back Projection (FBP) with Digital Breast Tomosynthesis (DBT)" ⁶ *	2014	The novel FBP reconstruction was significantly superior to the standard FBP. In particular, the diagnostic certainty in the assessment of micro- calcifications with the novel FBP was improved.
Tani et al. "Assessing Radiologist Performance and Micro- calcifications Visualization Using Combined 3D Rotating Mammogram (RM) and Digital Breast Tomosynthesis" ⁷	2014	The visualization of microcalcifications was signi- ficantly better for all microcalcification-dominant cancer lesions with the adjunction of RM to DBT.
Dustler et al. "Image Quality of Thick Average Intensity Pixel Slabs Using Statistical Artifact Reduction in Breast Tomosynthesis" ⁸ *	2014	It is possible to review DBT-volumes with 2 mm slabs without compromising image quality, and the visibility of microcalcifications is improved.

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

Author and study title	Year	Key findings
Lång et al. "Breast cancer detection in digital breast tomosynthesis and digital mammography: a side-by-side review of discrepant cases" ⁹	2014	Lesion visualization with DBT is superior to FFDM, particularly for spiculated tumors suggesting that DBT is better than FFDM in visualizing breast cancer.
Pina et al. "Digital mammography vs digital breast tomosynthesis in an enriched sample" ¹⁰	2014	DBT significantly increases sensitivity of lesion detection.
Van Ongeval et al. "Is DBT the new standard in diagnostic imaging? How to implement in specialist training?" ¹¹	2014	Compared to FFDM and US, DBT has better diagnostic accuracy in early detection for breast lesions and is more accurate in determining lesion size.
Nagl et al. "Interpretation of calcifications in comparison to mammography" ¹²	2014	Detection and characterization of calcifications in DBT is at least equal to FFDM.
Bick et al. "Tomosynthesis and the impact on patient management" ¹³	2014	In screening DBT improved cancer detection rates and reduced recall rate for false-positives.
Pina et al. "Interpretation of masses, distortions and densities with Tomosynthesis" ¹⁴	2014	DBT increased the detection rate of breast cancer up to 27% and is very sensitive to spiculation and architectural distortions what results in a high PPV.
Zackrisson S, Houssami N. "Digital breast tomosynthesis: the future of mammography screening or much ado about nothing?" ¹⁵	2013	Overview about tomosynthesis and its improve- ments 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?" ¹⁶	2013	Mammomat Inspiration tomosynthesis system 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" ^{17*}	2013	Slabbing in screening reduces the reading time significantly.
Timberg et al. "Visibility of single spiculations in digital breast tomosynthesis" ^{18*}	2013	SRSAR improves visibility of spiculations and promises to be an alternative to FBP.
Slon et al. "The Role of Additional Ultrasound and Tomo- synthesis After Normal Digital Mammography: Comparison Between Both Techniques" ¹⁹	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" ²⁰	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.

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

Author and study title	Year	Key findings
Heywang-Köbrunner et al. "Use of Tomosynthesis for the assessment of screen-detected lesions" ²¹	2013	Due to higher specificity, the diagnostic per- formance is improved if DBT replaces additional 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)" ²²	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 tomo- synthesis estimated from patient exposures and using PMMA breast phantoms" ²³	2012	The results conclude that the patient dose for Tomosynthesis with the Siemens Mammomat Inspiration system is lower than the dose with other vendors' systems.
Uchiyama et al. "Usefulness of Adjunction of Digital Breast Tomosynthesis (DBT) to Full-Field Digital Mammography (FFDM) in Evaluation of Patho- logical Response after Neoadjuvant Chemo- therapy (NAC) for Breast Cancer" ²⁴	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" ²⁵	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" ²⁶	2012	The diagnostic performance of DBT+ FFDM was comparable to MRI. Further, DBT+ FFDM had the higher correlation for diagnostic and pathological size.
Förnvik et al. "Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammo- graphy and ultrasonography" ²⁷	2010	The study indicates that BT is superior to DM 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" ²⁸	2010	No difference in the image quality was evident with reduced compression force, indicating that DBT may be performed with substantially less compression force compared to 2D mammography. A majority of the examined women felt that half compression force was more comfortable than full compression force.

References

- [1] 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; http://link.springer.com/article/10.1007%2Fs00330-015-3803-3
- [2] Siemens Medical Solutions USA, Inc., Mammomat Inspiration with Tomosynthesis Option, PMA P140011: FDA Summary of Safety and Effectiveness Data, April 21, 2015; http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140011b.pdf
- [3] 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); http://proceedings.spiedigitallibrary.org/proceeding. aspx?articleid=2209258
- [4] Elizalde et al., Additional US or DBT after digital mammography: which one is the best combination?; Acta Radiol. 2014 Dec 18, pii: 0284185114563641; http://acr.sagepub.com/content/ early/2014/12/18/0284185114563641.abstract
- [5] Mercier et al., The role of tomosynthesis in breast cancer staging in 75 patients; Diagn Interv Imaging, 2014 Jul 30, pii: S2211-5684(14)00201-0; http://linkinghub.elsevier.com/retrieve/pii/S2211-5684(14)00201-0
- [6] Uchiyama et al., Clinical Efficacy of Novel Image Processing Techniques in the Framework of Filtered Back Projection (FBP) with Digital Breast Tomosynthesis (DBT); Breast Imaging, 12th International, Workshop IWDM 2014, Gifu City, Japan, June 29 July 2, 2014 Proceedings: LNCS 8539 pp. 320–326; http://link.springer.com/chapter/10.1007/978-3-319-07887-8 45
- [7] Tani et al., Assessing Radiologist Performance and Microcalcifications Visualization Using Combined 3D Rotating Mammogram (RM) and Digital Breast Tomosynthesis; Breast Imaging, 12th International, Workshop IWDM 2014, Gifu City, Japan, June 29 – July 2, 2014 Proceedings: LNCS 8539, pp. 142– 149;
 - http://link.springer.com/chapter/10.1007/978-3-319-07887-8_21
- [8] 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;
 http://link.springer.com/chapter/10.1007/978-3-319-07887-8
- [9] Lång et al., Breast cancer detection in digital breast tomosynthesis and digital mammography: a side-by-side review of discrepant cases; Br J Radio 2014 Aug; 87(1040); http://www.birpublications.org/doi/abs/10.1259/ bjr.20140080?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref. org&rfr dat=cr pub%3dpubmed&

[10] Pina et al., Digital mammography vs digital breast tomosynthesis in an enriched sample; Presentation at the ECR 2014, March 6-10, Vienna/Austria; http://ipp.myesr.org/esr/ecr2014/index.php?p=recorddetail&rid=

16180fa8db2863638cfd8271c5bbc5ae#pres5e9bce64e6afef41 ec1ae7bfb0d7a92f

- [11] 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; http://www.healthcare.siemens.com/mammography/ mammography-training-education/symposia-webinars
- [12] Nagl et al., Interpretation of calcifications in comparison to mammography; Presentation at EUSOBI 2014, March 4-5, 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] Pina et al., Interpretation of masses, distortions and densities with Tomosynthesis; EUSOBI Digital Breast Tomosynthesis Course, March 4-5, Vienna/Austria;
- [15] Zackrisson S, Houssami N., Digital breast tomosynthesis: the future of mammography screening or much ado about nothing?; Expert Rev Med Devices. 2013 Sep; http://informahealthcare.com/doi/abs/10.1586/17434440.2013. 835555
- [16] 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.;
 - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3864442/
- [17] 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); http://proceedings.spiedigitallibrary.org/proceeding. aspx?articleid=1673854
- [18] Timberg et al., Visibility of single spiculations in digital breast tomosynthesis; Proc. SPIE 8673, Medical Imaging 2013: Image Perception, Observer Performance, and Technology Assessment, 86731B (March 28, 2013); http://proceedings.spiedigitallibrary.org/proceeding. aspx?articleid=1673844
- [19] Slon et al., The Role of Additional Ultrasound and Tomosynthesis After Normal Digital Mammography: Comparison Between Both Techniques; Presentation at the ECR 2013, March 7-11, Vienna/ Austria;

http://posterng.netkey.at/esr/viewing/index. php?module=viewing_poster&doi=10.1594/ecr2013/B-0685

- [20] 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; http://posterng.netkey.at/esr/viewing/index. php?module=viewing poster&doi=10.1594/ecr2013/B-0813
- [21] Heywang-Köbrunner et al., Use of Tomosynthesis for the assessment of screen-detected lesions; Screening Assessment Kurs at the ECR 2013, March 7-11, Vienna/Austria;
- [22] 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; http://link.springer.com/chapter/10.1007/978-3-642-31271-7 16

[23] 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;

http://link.springer.com/chapter/10.1007/978-3-642-31271-7_41

- [24] 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; http://link.springer.com/chapter/10.1007/978-3-642-31271-7_46
- [25] Svahn et al., Breast tomosynthesis and digital mammography: a comparison of diagnostic accuracy; Br J Radiol. 2012 Nov;85(1019) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3500806/

[26] Uchiyama et al., Evaluation of correlation between pathological size and diagnostic size; ISBN: 978-953-51-0285-4, InTech, DOI: 10.5772/39188 http://www.intechopen.com/books/mammography-recentadvances/optimization-of-digital-breast-tomosynthesis-dbt-forbreast-cancer-diagnosis

- [27] Förnvik et al., Breast tomosynthesis: Accuracy of tumor measurement compared with digital mammography and ultrasonography; Acta Radiol. 2010 Apr;51(3):240-7; http://acr.sagepub.com/content/51/3/240.full.pdf+html
- [28] 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; http://rpd.oxfordjournals.org/content/139/1-3/118.long

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