An Overview of Digital Breast Tomosynthesis

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ABSTRACT
Digital breast tomosynthesis is a new imaging technology, which provides a more accurate view of the breast as compared to digital mammography. Conventional digital mammography produces a two-dimensional image of overlapping tissue, potentially obscuring malignancies. In addition, complex areas of normal tissue may be perceived as suspicious. Digital breast tomosynthesis is being implemented at breast centers throughout the country as clinical data demonstrate it addresses the limitations of conventional mammography. Studies of breast tomosynthesis have shown decreased false-positive recall rates and increased rates of cancer detection associated with the technology’s ability to minimize the effect of superimposed tissue and improve lesion visibility and characterization. We have experienced favorable results with breast tomosynthesis at our facility.

INTRODUCTION
Screening mammography is an effective imaging tool for the detection of early-stage breast cancer and has shown to decrease breast cancer-related mortality.1-5 Despite its clearly documented benefit, it is well recognized that mammography is imperfect.

A mammogram provides a two-dimensional (2D) image of a three-dimensional (3D) structure. The resulting superimposition of normal tissue may obscure masses or other features of malignancy, particularly for women with dense breasts.6 The overlapping tissue may also mimic malignancy leading to false positive recalls for additional imaging.7,8 High false-positive recall rates from screening mammography may have adverse effects, including patient anxiety, increased cost, increased radiation exposure, and unnecessary biopsies.9,10

Digital breast tomosynthesis (DBT), also known as 3D mammography, is a new imaging technology, which allows the breast to be viewed in a 3D format and addresses the limitations of 2D mammography.

DBT TECHNOLOGY
The FDA approved the first commercial breast tomosynthesis system in February 2011.11 Currently, there are three FDA-approved DBT systems available in the US.

During DBT imaging, the breast is compressed and held stationary between the compression paddle and the detector, in a procedure similar to that used at 2D digital mammography. A DBT system can acquire images in standard mammographic orientations and can perform images with spot compression. Multiple low-dose x-ray projection images are acquired in an arc. These projection images are used to reconstruct a 3D image set of the breast, which minimizes the impact of overlapping breast tissue and improves lesion conspicuity.12,13 This 3D image set includes sections as thin as 1 mm in the plane that is parallel to the detector. The images are displayed on a dedicated workstation where the radiologist can scroll through the images individually.

DBT images are most often obtained by using a combination acquisition mode, in which 2D digital mammography and DBT are performed in the same examination during the same breast compression. The reader can toggle between the coregistered 2D and 3D datasets, comparing
findings on the DBT and 2D mammogram images. Use of combination acquisition also facilitates comparison with 2D images from prior examinations and evaluation of calcifications.

The radiation dose of DBT is comparable to the dose of 2D digital mammography (DM), which is approximately one-fifth lower than the dose of 2D screen-film mammography.\textsuperscript{14,15} The combination acquisition mode dose is approximately double the radiation dose as compared to DM alone but remains within the Mammography Quality Standards Act limit of 3 mGy per view. To put the dose levels in perspective, the average effective dose from natural background radiation in the United States is approximately 6 times that of the average effective dose from two-view DBT alone and 3 times that of 2-view combination acquisition mode.\textsuperscript{16}

A synthesized 2D image reconstruction algorithm (C-View 2D; Hologic, Bedford, Mass) has been FDA-approved.\textsuperscript{11} This software is used to create a synthesized 2D image from the DBT dataset. Replacement of the 2D digital mammogram with the 2D synthesized mammogram results in a lower patient radiation dose.\textsuperscript{17} This technology has been shown to perform comparably to combination imaging in the screening setting.\textsuperscript{18}

**DBT OUTCOMES**

Clinical studies have shown improved accuracy with the addition of DBT to 2D mammography.\textsuperscript{12, 13, 19-22}

In the screening setting, DBT in combination with 2D digital mammography is associated with reduced false-positive recall rates and increased breast cancer detection rates as compared to 2D mammography alone. Importantly, invasive cancers are better detected with DBT. Attention was turned toward DBT in 2007 when the favorable results of a reader study were presented by Elizabeth Rafferty, MD at a major national radiology conference. The results of this study and another reader study were later published and demonstrated improved diagnostic accuracy for DBT in combination with DM as compared to DM alone for all 27 radiologists who participated.\textsuperscript{12} Recall rates for the readers decreased 6-67%, and sensitivity for invasive cancer increased 15 and 22% in each study, respectively. The Oslo Tomosynthesis Screening Trial (OTST) trial, a large prospective trial of over 12,000 women, reported a significant decrease in false-positive recalls of 15% and an increase in cancer detection of 27%.\textsuperscript{13,19} The invasive cancer detection rate significantly increased by 40%. Another large prospective trial in Italy found a significantly decreased false-positive recall rate of 17% and a significantly increased cancer detection rate of 51%.\textsuperscript{20} Multiple retrospective US studies (21-26) have also demonstrated similar results.\textsuperscript{23-28} These include a large multicenter trial by Friedewald et. al. with a recall rate reduction of 15% and an increase in invasive cancer detection of 41%.\textsuperscript{28}

In the diagnostic setting, literature has suggested that DBT may replace supplemental 2D mammography, such as spot compression views, for noncalcified findings with similar or improved sensitivity and specificity.\textsuperscript{29-31}

DBT has shown improved accuracy across all breast densities, including women with dense breasts.\textsuperscript{13,26,32}
DECREASED FALSE POSITIVES WITH DBT

Frequently, suspicious findings seen at 2D mammography are due to the superimposition of complex yet normal areas of breast tissue. These findings mimicking malignancy are often better evaluated with DBT. By scrolling through the sections of the 3D image set, the reader is often able to determine that the appearance is due to summation of superimposed normal breast tissue.

*Left craniocaudal (CC) view from a 2D digital mammogram (Figure 1) demonstrated an asymmetry in the lateral left breast. Two slices from the coregistered left CC tomosynthesis image set (Figure 2) resolve that the asymmetry is due to areas of normal fibroglandular tissue superimposed and is benign.*

![Figure 1](image1.png) ![Figure 2](image2.png)

Also, findings that are benign, such as normal intramammary lymph nodes and skin lesions may be better characterized with tomosynthesis than with 2D mammography allowing for a confident benign assessment rather than necessitating a recall.

IMPROVED CANCER DETECTION WITH DBT

The conspicuity and characterization of lesions is improved with DBT, in part due to reduced obscuration by overlapping breast tissue. DBT is superior to 2D mammography in detecting architectural distortion, which is a common imaging manifestation of invasive breast cancer. Mass lesion margins become more apparent at DBT. DBT is helpful in localizing lesions in the breast that are only seen on one view and may also be superior to 2D imaging for estimating the extent of malignancies.
Left breast 2D mammogram (Figure 3) and DBT (Figure 4) show an area of architectural distortion in the left breast seen only on DBT. The 2D mammogram was initially interpreted as negative. Targeted left breast ultrasound demonstrated a corresponding suspicious hypoechoic mass with subsequent ultrasound-guided core biopsy revealing invasive ductal carcinoma.
LIMITATIONS OF DBT
Despite the advantages that DBT can provide, there are limitations.37 Because of decreased overlapping breast tissue, benign lesions that previously had been hidden are more readily detected at DBT and may prompt further workup. For example, well-circumscribed masses such as cysts and fibroadenomas and architectural distortion associated with radial scars, which are benign lesions, become much more obvious at DBT.

False negative results are also possible with DBT. Rarely, a noncalcified breast cancer does not manifest as a mass or architectural distortion and may not be detected with DBT. For example, invasive lobular carcinoma occasionally presents in a “sheet-like” pattern rather than as a mass or architectural distortion.

OTHER CONSIDERATIONS
An examination with DBT and DM is a higher monetary cost than a 2D mammogram alone. However, there is a potential for cost savings associated with reduced false positive recalls and detection of breast cancer at an earlier stage when treatment is less expensive. An economical analysis published in 2015 favored an overall cost savings with DBT as compared to DM alone.38

In November 2014, the ACR released a position statement that tomosynthesis “is no longer investigational” and “improves key screening parameters compared to digital mammography.”39 In 2015, CMS established codes for DBT.40 Even following these events, some private insurance companies failed to provide coverage for DBT and continued to characterize the technology as “investigational.” However, now most insurances are covering tomosynthesis.

The United States Preventative Services Task Force (USPSTF) breast cancer screening guidelines40 released in January 2016 acknowledge the benefits of DBT including reduced recall rates and increased cancer detection rates. However, they emphasize that current study designs cannot determine if there is an incremental benefit to finding these cancers earlier than with DM and that no DBT studies have analyzed the effect on breast cancer mortality, morbidity, or quality of life. Consequently, the USPSTF “found insufficient evidence to assess the balance of benefits and harms of DBT as a primary screening method for breast cancer.” Likewise, regarding adjunctive screening in women with dense breasts, the USPSTF, citing an article by Melnikow et al.41, stated that data on the effects of DBT on recall rates and biopsy rates are too limited to draw conclusions and that the increase in number of breast cancers detected by DBT does not allow for the conclusion that the DBT reduces morbidity and mortality in women with dense breasts.

Other considerations regarding implementation of DBT include requirements for larger examination room size, increased digital storage, and dedicated mammography/DBT reading stations. Image interpretation time is also increased with DBT.37
OUR EXPERIENCE
At the WVU Betty Puskar Breast Care Center, nearly all screening examinations are performed in the combination acquisition mode with DBT and 2D digital mammography. DBT was instituted in January 2015. Over the initial 12-month period of use, over 11,000 screening examinations with DBT were performed. The cancer detection rate in 2015 was 8.7/1000, which is above the benchmark of 4.3/1000 reported by the NCI Breast Cancer Surveillance Consortium.43 Our recall rate at the end of 2015 was decreased by 18% and our positive predictive value of biopsies (percentage of cancers determined after a biopsy was recommended) increased 7% as compared to the same time period the year prior when DBT was not available at our facility.

CONCLUSION
Breast tomosynthesis provides a 3D imaging capability that allows the more accurate evaluation of lesions by enabling better differentiation between overlapping tissues. Lower recall rates, higher positive predictive values for biopsy recommendations, and higher cancer detection rates are expected to result from the use of this new technology. Long term studies are needed to assess the effect of breast tomosynthesis on breast cancer morbidity, mortality, and quality of life. Based on data available to date, breast tomosynthesis should be a strong adjunct to both screening mammography and diagnostic mammography.

REFERENCES


