

Digital Breast Tomosynthesis: Lessons Learned from Early Clinical Implementation¹

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Abbreviations: DBT = digital breast tomosynthesis, DCIS = ductal carcinoma in situ, DM = digital mammography, FDA = Food and Drug Administration, IDC = invasive ductal carcinoma, MLO = mediolateral oblique, OR = odds ratio, 3D = three-dimensional, 2D = two-dimensional

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See discussion on this article by Feig (pp E103–E105).

SA-CME LEARNING OBJECTIVES

After completing this journal-based SA-CME activity, participants will be able to:

- Describe the principles of DBT and how information obtained at 3D DBT may replace the need for some 2D diagnostic imaging in the evaluation of suspicious breast lesions.
- Discuss how a combination of DM and DBT can be used to decrease callback rates, increase cancer detection, and assist with problem solving.
- Identify the limitations of DBT and issues to consider in clinical implementation.

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The limitations of mammography are well known and are partly related to the fact that with conventional imaging, the three-dimensional volume of the breast is imaged and presented in a two-dimensional format. Because normal breast tissue is similar in x-ray attenuation to some breast cancers, clinically relevant malignancies may be obscured by normal overlapping tissue. In addition, complex areas of normal tissue may be perceived as suspicious. The limitations of two-dimensional breast imaging lead to low sensitivity in detecting some cancers and high false-positive recall rates. Although mammographic screening has been shown to reduce breast cancer deaths by approximately 30%, controversy exists over when and how often screening mammography should occur. Digital breast tomosynthesis (DBT) is rapidly being implemented in breast imaging clinics around the world as early clinical data demonstrate that it may address some of the limitations of conventional mammography. With DBT, multiple low-dose x-ray images are acquired in an arc and reconstructed to create a three-dimensional image, thus minimizing the impact of overlapping breast tissue and improving lesion conspicuity. Early studies of screening DBT have shown decreased false-positive callback rates and increased rates of cancer detection (particularly for invasive cancers), resulting in increased sensitivity and specificity. In our clinical practice, we have completed more than 2 years of using two-view digital mammography combined with two-view DBT for all screening and select diagnostic imaging examinations (over 25,000 patients). Our experience, combined with previously published data, demonstrates that the combined use of DBT and digital mammography is associated with improved outcomes for screening and diagnostic imaging. *Online supplemental material is available for this article.*

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TEACHING POINTS

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Introduction

Population-based screening trials have demonstrated that mammographic screening can reduce breast cancer deaths by 30% (1). In addition, it has been shown that digital mammography (DM) has an improved screening performance when compared with analog imaging, particularly in premenopausal women, women younger than 50 years, and women with dense breasts (2). However, controversy still exists over when and how often screening mammography should occur. In 2009, the U.S. Preventive Services Task Force on Screening Mammography recommended that screening for average-risk women begin at age 50 years instead of at age 40 years and that screening should occur every other year rather than annually (3). However, many professional societies, including the American College of Radiology and the American Cancer Society, continue to recommend routine annual screening mammography beginning at age 40 years (4–6).

The limitations of conventional mammography have been well established. DM provides a two-dimensional (2D) image of a three-dimensional (3D) structure, and the superimposition of normal tissue can obscure masses or other important features of malignancy. The overlapping of breast tissue at 2D imaging leads to low sensitivity for cancer detection, high false-positive recall rates, and low positive predictive values of biopsy recommendations, particularly for women with dense breasts.

After 10 years of undergoing annual screening mammography, more than half of women will receive at least one false-positive recall, and 7%–9% will receive a false-positive biopsy recommendation (7). The high false-positive recall rates may have adverse effects, including patient anxiety, increased cost, increased radiation exposure, and unnecessary biopsies (8,9). The psychologic effects of an unnecessary biopsy can persist even after cancer has been excluded and can last for months or even years in some women (9).

Digital breast tomosynthesis (DBT) is rapidly being implemented in breast imaging clinics across the world as early clinical data demonstrate that this innovative technology may address some of the long-standing limitations of conventional mammography. DBT image acquisition allows the breast to be viewed in a 3D format, which minimizes the effect of overlapping breast tissue. Early data have shown that use of DBT improves the accuracy of screening and diagnostic breast imaging (10–13).

This article focuses on our early clinical experiences with DBT in both screening and diagnostic settings. One year after instituting DBT

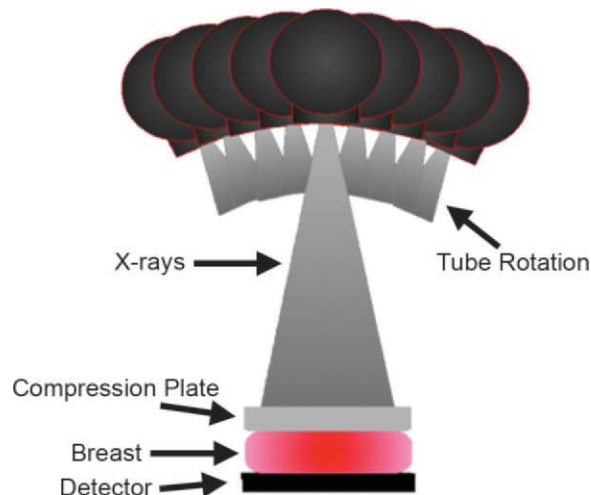


Figure 1. Drawing shows how DBT images are obtained. Multiple low-dose x-ray projection images are acquired in an arc and used to reconstruct a 3D image of the breast.

in our clinical practice, we significantly reduced the patient callback rate and saw a trend toward increased cancer detection.

DBT Background

Image Acquisition

The origins of DBT can be traced to both linear tomography and computed tomography (CT); as such, DBT shares many of the features of these predicate technologies. In all currently available commercial DBT systems, multiple low-dose x-ray projection images are acquired in an arc (Fig 1). These projection images are used to reconstruct a 3D image of the breast, which minimizes the impact of overlapping breast tissue and improves lesion conspicuity (12,13).

Patient positioning at DBT is similar to that at DM, with DBT screening typically conducted using standard craniocaudal and mediolateral oblique (MLO) projections. As with DM, additional projections (eg, mediolateral, rolled, spot compression, and exaggerated views) are possible with DBT. However, geometric magnification tomosynthesis is currently not possible.

During DBT image acquisition, the x-ray tube pivots in an arc that varies between 15° and 60° (depending on the manufacturer) in a plane aligned with the chest wall. The compression paddle and breast support remain stationary. Depending on the manufacturer, the detector may rotate during the acquisition to follow the x-ray tube, or the detector may remain stationary. Also, depending on the manufacturer, the x-ray tube may move continuously during image acquisition, or it may be held stationary during each acquisition (called a “step-and-shoot” acquisition method).

Table 1: DBT System Designs by Manufacturer

Features	GE Healthcare (Waukesha, Wis)	Hologic (Bedford, Mass)	IMS (Bologna, Italy)	Siemens Healthcare (Erlangen, Germany)
Model	Senographe Essential	Selenia Dimensions	Giotto Image	Mammomat Inspiration
Scan angle	25°	15°	34°	50°
Projections	9	15	13	25
Scan time	7 sec	3.7 sec	10 sec	25 sec
Tube motion	Step and shoot	Continuous	Continuous	Continuous
Detector motion	No	Yes	No	No
Reconstruction	Iterative	FBP	Iterative	FBP

Note.—FBP = filtered back projection.

Three-dimensional DBT images are reconstructed from the projection images. There are various methods for reconstruction, including filtered back-projection and iterative techniques. In all cases, a 3D image of the breast is created that consists of multiple 2D sections aligned parallel to the breast support; the planes are separated by a fixed increment (typically 1 mm).

Currently, four DBT systems are commercially available in Europe; only one system is available in the United States. These systems are summarized in Table 1. In Europe, it is permissible to obtain DBT images alone or in combination with DM images. In the United States, the Food and Drug Administration (FDA)-approved Selenia Dimensions system must be operated in “combo mode.” In combo mode, 3D DBT images are obtained along with 2D DM images during the same compression. In this article, we describe our clinical experience with the Selenia Dimensions system.

As in linear tomography, the images created at DBT have exceptionally high spatial resolution in the plane of reconstruction; this is because the in-plane spatial resolution is determined by the method in which the signal from the small detector elements of the x-ray detector is combined in the tomographic image (14). DBT images also have a large format, similar to DM images (eg, Hologic reconstructions typically are 1664 × 2048). In contrast, CT images typically have much larger pixels and a smaller format (typically 512 × 512).

An axial CT image is a relatively accurate estimate of the x-ray attenuation coefficients of the tissue located in that body section; the values are presented in Hounsfield units. In DBT, as in linear tomography, the imaging section depicts those objects that are in focus in that plane; objects located above and below the plane of focus are blurred to varying degrees, depending on the distance of the object from the plane and the size

of the object. Thus, small objects such as microcalcifications and fibrils rapidly blur out of focus as the reader scrolls through the stack of images. Small high-contrast structures, such as surgical clips, can cause readily identifiable artifacts outside the plane of focus. In comparison, large objects, such as large regions of glandularity, will influence many sections distant from the glandular tissue—even influencing the gray level of the skin. Fortunately, these artifactual densities are featureless because no internal structures are preserved outside the plane of focus, and thus they have no clinical importance.

DBT Image Set

The Selenia Dimensions combined DBT and DM image set consists of three image series: a conventional 2D mammogram, source projection images, and multiple reconstructed images presented as the DBT image stack. The various images are coregistered, which allows the reader to toggle between image sets for problem solving. The 15 source projection images can be viewed sequentially, giving the reader the perception that the breast is being rotated; this has value in the assessment of gross patient motion.

Reconstructed DBT images, spaced in 1-mm increments, can be displayed either in cine mode or individually and scrolled through manually by the reader. The first image of the stack is the reconstructed section from either side of the breast (medial or lateral for the MLO view; cranial or caudal for the craniocaudal view). Therefore, as a lesion is identified by the reader, the 3D localization within the breast may be inferred, which helps to triangulate the lesion. This is particularly important when a lesion is seen only at DBT or only on one view. **By creating 3D images of the breast, DBT can overcome many of the challenges of DM by minimizing the effects of overlapping breast tissue and improving lesion detection and localization.**

Table 2: Interval Analysis of Impact of DBT on Breast Cancer Screening Population after 1 Year

Imaging Modality	No. of Patients	Callback Rate*	Cancer Detection Rate [†]
DM (September 1, 2010–August 31, 2011)	10,751	10.4%	4.4 cancers/1000
Combined DBT and DM (September 1, 2011–August 31, 2012)	11,115	8.8%	5.4 cancers/1000

* $P < .001$, OR = 1.24 when controlled for reader volumes.

[†] $P = .26$.

The reader can also display “slab” images, which are maximum intensity projection renderings of multiple sections. Both the center and thickness of the slab can be varied. Slab views have particular value for viewing calcification clusters; for example, if calcifications are seen on multiple consecutive 1-mm-thick reconstructed sections, the reader can change the thickness of the reconstruction, allowing the entire cluster of calcifications to be viewed in a single slab.

Outcomes with DBT

Some early studies have shown improved accuracy in both screening and diagnostic settings with the addition of DBT (10–13). Reductions in false-positive callback rates that range from 6% to 67% have been reported, with stable or slightly increased cancer detection rates (12,13,15,16). Studies have also demonstrated improved sensitivity and specificity for breast cancer detection with use of combined DBT and DM versus 2D DM (12,13,17–21).

Interval analysis of 12,631 women in the prospective Oslo Tomosynthesis Screening Trial (combined DBT and DM vs DM) has shown a 27% increase in the cancer detection rate ($P = .001$), including a 40% increase in the detection rate for invasive breast cancer across all breast densities ($P < .001$). The trial has also demonstrated a 15% reduction in the false-positive callback rate ($P < .001$) (13). Early results from prospective trials in the United States have shown reduced callback rates and increased rates of cancer detection with use of combined DBT and DM (22–24), findings that begin to address the major concerns regarding conventional screening mammography.

Our early clinical experience supports these published data. The following sections highlight lessons learned from early clinical implementation.

Impact of DBT on Our Screening Population

We began screening with DBT (using the Selenia Dimensions system) in September 2011. An interim data analysis was performed 1 year after the

introduction of DBT. A total of 11,115 patients were screened by using the bilateral two-view combo mode (DM and DBT images acquired in a single compression). Outcome measures were compared with those from the prior year, when 10,751 patients were screened by using DM alone. Callback rates and cancer detection rates were compared for both years. The readers remained stable during the 2-year period.

After the implementation of DBT in our screening population, the callback rate was significantly reduced, from 10.4% with DM to 8.8% with combined DBT and DM. When controlled for variable reader volumes, the odds ratio (OR) was 1.24 ($P < .001$); therefore, the probability that a woman would be called back decreased by 24% with DBT. In addition, there was a trend toward an increased cancer detection rate with use of combined DBT and DM versus DM alone (5.4 cancers per 1000 vs 4.4 cancers per 1000, respectively; $P = .26$) (24). These data are summarized in Table 2.

True-Positive Findings: Improved Cancer Detection

Early studies of DBT have shown improved conspicuity and characterization of lesions, in part due to reduced obscuration by overlapping breast tissue (15,25). In particular, architectural distortion and lesion margins become more apparent at DBT. Studies have also shown that DBT is superior to 2D imaging for estimating the extent of malignancies (11,26,27).

Our early clinical experience supports these findings. As discussed earlier, 1 year after instituting DBT in our screening population, we saw a trend toward increased cancer detection. In a number of cases, the DM findings were initially interpreted as negative, but corresponding DBT images demonstrated an abnormality that was proven to be cancer at biopsy. In many cases, these “DBT-only” cancers effaced on conventional spot compression images, and subsequent ultrasonography (US) and possible biopsy might not have

Teaching Point

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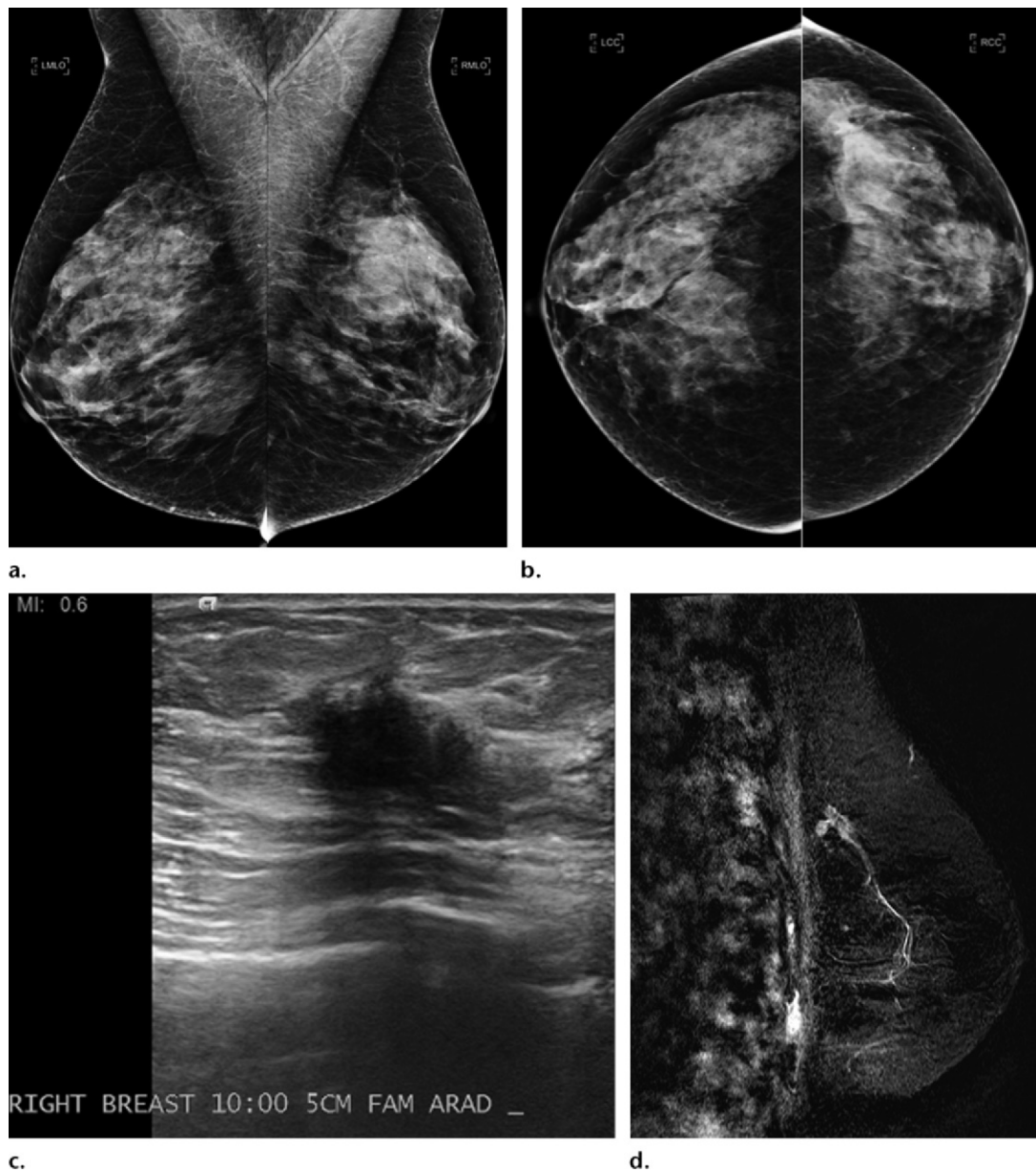


Figure 2. Invasive lobular carcinoma in a 68-year-old woman. (**a, b**) Findings on bilateral MLO (**a**) and craniocaudal (**b**) 2D screening mammograms were initially interpreted as negative. Corresponding DBT images (Movies 1, 2) show architectural distortion and an irregular mass in the upper outer right breast, findings not seen at DM. (**c**) US image of the right breast shows an irregular mass at the 10-o'clock position, 5 cm from the nipple. (**d**) Sagittal contrast-enhanced fat-saturated T1-weighted magnetic resonance (MR) subtraction image of the right breast helps confirm the DBT findings. Pathologic analysis demonstrated invasive lobular carcinoma.

been performed if DBT had not been included in the screening study (Fig 2; Movies 1, 2).

Figure 3 depicts a DBT-only cancer that was detected in a 72-year-old woman at screening mammography. Findings on bilateral craniocaudal DM images were initially interpreted as negative; however, corresponding DBT images showed a spiculated mass in the medial right breast (Movie 3). US of the right breast was performed on the basis of the DBT findings and depicted an irregular hypoechoic mass with shadowing, a finding that corresponded

to the abnormality seen at DBT. Pathologic analysis of the core biopsy sample revealed IDC.

Figure 4 is another example of a DBT-only cancer that was detected at screening mammography. Bilateral MLO and craniocaudal DM images showed subtle architectural distortion in the lateral subareolar right breast, a finding that was more conspicuous on DBT images. The extensive nature of the abnormal distortion was appreciated at DBT (Movies 4, 5). MR images depicted extensive abnormal nonmasslike enhancement in

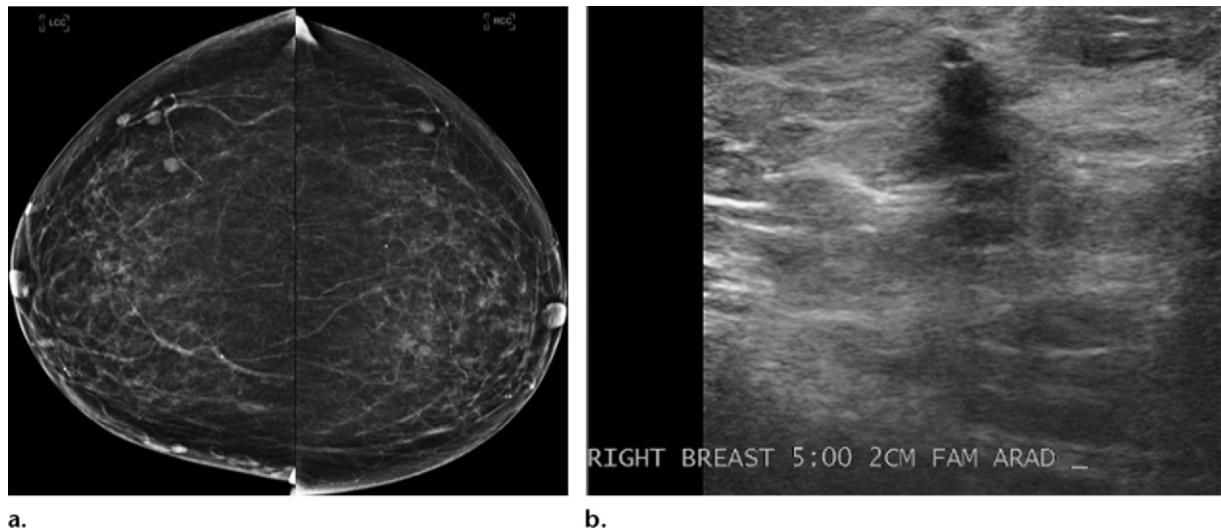


Figure 3. Invasive ductal carcinoma (IDC) in a 72-year-old woman. **(a)** Findings on these bilateral craniocaudal screening DM images were initially interpreted as negative, but DBT images (Movie 3) show a spiculated mass in the medial right breast. **(b)** US image of the right medial breast shows an irregular hypoechoic mass with shadowing, a finding that corresponds to the abnormality seen at DBT. Pathologic analysis revealed a 5-mm IDC.

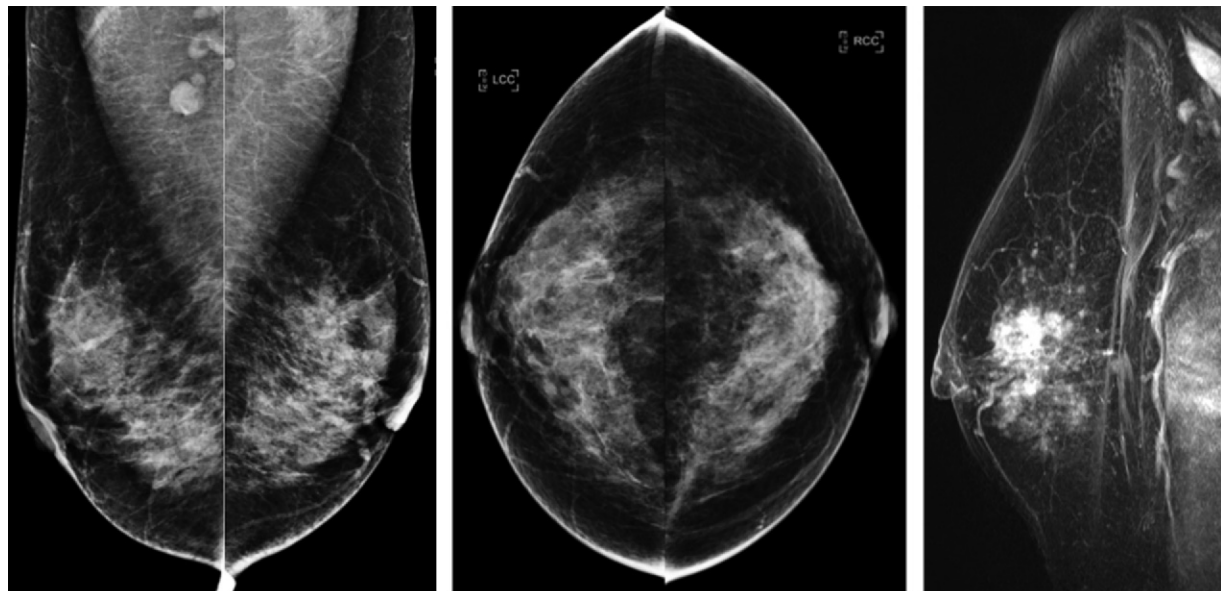


Figure 4. IDC in a 42-year-old woman. **(a, b)** Bilateral MLO **(a)** and craniocaudal **(b)** screening DM images show subtle architectural distortion in the lateral and subareolar right breast, a finding that is more conspicuous on DBT images (Movies 4, 5). The extensive nature of the finding is also appreciated on the DBT images. **(c)** Sagittal contrast-enhanced fat-saturated T1-weighted MR subtraction image of the right breast shows patchy extensive enhancement in the region of architectural distortion. Pathologic analysis confirmed extensive IDC.

the region of architectural distortion; pathologic analysis of the excised specimen revealed extensive IDC with a background of ductal carcinoma in situ (DCIS).

True-Negative Findings: Reduction in False-Positive Callback Rates

Frequently, suspicious findings seen at DM are actually due to the superimposition of complex yet normal areas of breast tissue (16). These

“pseudo lesions” are often better evaluated on DBT images because the areas of confounding superimposed normal breast tissue may be scrolled through in the DBT stack of reconstructed sections (Figs 5, 6; Movies 6, 7).

As discussed earlier, after implementation of DBT in our screening population, the callback rate was significantly reduced. Other studies have shown reductions in callback rates of 6%–67% (12,13,15,16).

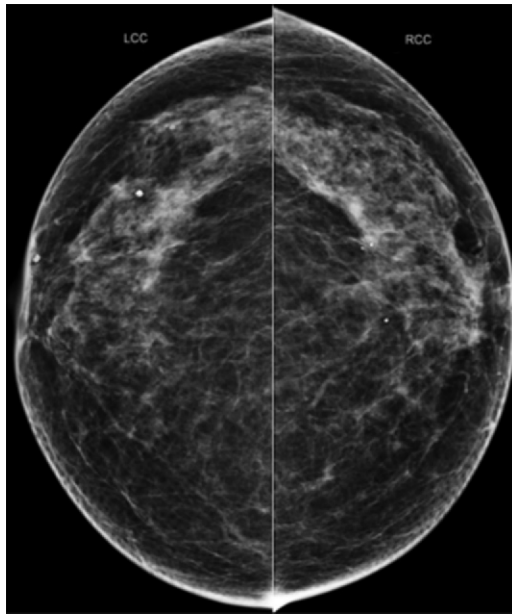


Figure 5. Craniocaudal screening DM images in a 55-year-old woman show a focal asymmetry in the lateral right breast. DBT images (Movie 6) demonstrate the abnormality to be related to overlapping breast tissue. No further workup is needed.

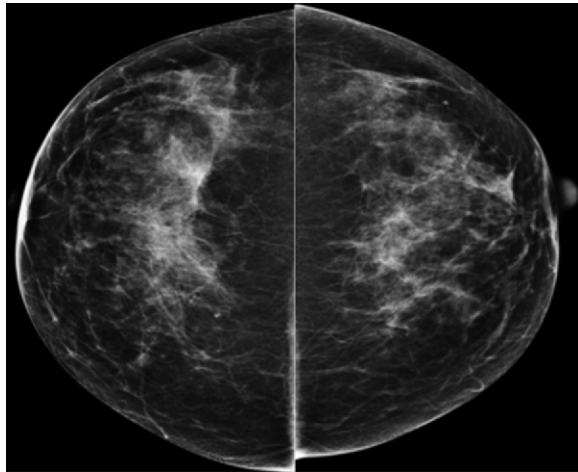


Figure 6. Craniocaudal screening DM images in a 47-year-old woman show a focal asymmetry in the lateral left breast; corresponding DBT images (Movie 7) show no abnormality. The findings at DM are related to tissue superimposition. No further workup is needed.

False-Positive Findings: Benign Lesions Seen Only at DBT

Despite the advantages that DBT can provide, there are limitations. Because of decreased overlapping breast tissue, benign lesions that previously had been concealed (ie, cysts, lymph nodes) are more readily detected at DBT and may prompt further workup. In particular, architectural distortion associated with benign lesions such as radial scars becomes much more obvious at DBT

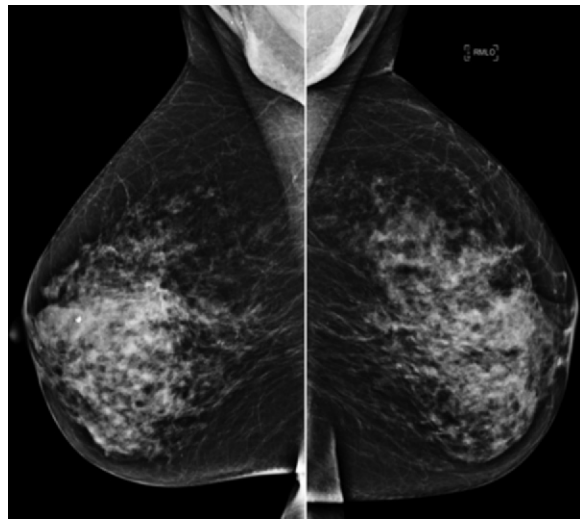


Figure 7. Findings on these MLO screening DM images of the right breast in a 62-year-old woman were initially interpreted as negative; however, a subtle architectural distortion was identified in the upper right breast on DBT images (Movie 8). Pathologic analysis revealed a radial scar with atypical ductal hyperplasia.

(Fig 7, Movie 8). Lesion features associated with benign outcomes (ie, macroscopic fat, localization in the skin) must be recognized so that unnecessary callbacks do not occur when typically benign lesions are “seen better” with DBT.

False-Negative Findings: Not All Cancers Are Visible at DBT

We have had a few cases in which both DM and DBT did not clearly demonstrate a malignant lesion, which then was detected with another modality or manifested as a symptomatic lesion. Figure 8 and Movies 9–11 describe a case in which suspicious calcifications were detected in the patient’s right breast at both DM and DBT, and pathologic analysis of the sample from stereotactic biopsy revealed DCIS. An MR imaging examination performed for staging demonstrated extensive nondistorting but suspicious enhancement in the contralateral breast, which at mastectomy proved to be a 6-cm invasive lobular carcinoma with extensive lobular carcinoma in situ. This finding was not depicted at either DM or DBT. This case emphasizes the fact that although masses and architectural distortion often are better detected and better characterized with DBT than with DM, if a malignancy does not manifest with these imaging characteristics, it may not be detectable with DBT.

Impact of DBT on Our Diagnostic Population

There currently is no set standard as to which patient populations should be imaged with DBT. Although we initially imaged all screening

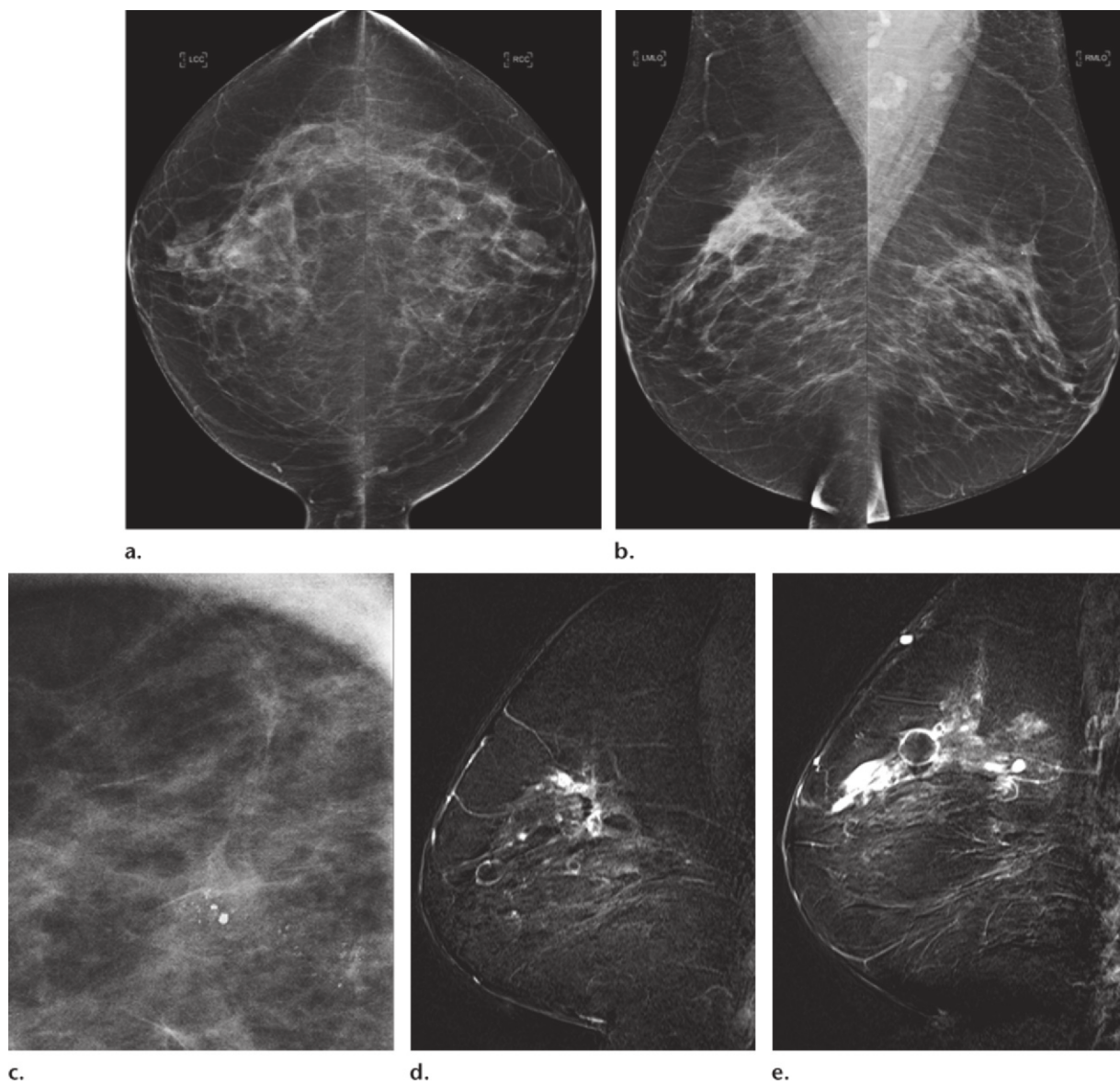


Figure 8. DCIS and invasive lobular cancer in a 45-year-old woman. **(a–c)** Suspicious calcifications are seen in the upper outer right breast on craniocaudal **(a)** and MLO **(b)** screening DM images. The calcifications are also seen on a zoomed-in DM image **(c)**. DBT images show calcifications in the right breast (Movies 9, 10) and also depict a cyst in the left breast, which otherwise is normal (Movie 11). Pathologic analysis revealed a 2-cm DCIS in the right breast. **(d, e)** Sagittal contrast-enhanced fat-saturated T1-weighted MR subtraction images of the right **(d)** and left **(e)** breasts obtained for staging show enhancement of the known DCIS in the right breast and extensive suspicious enhancement in the left breast, a finding that was originally interpreted as negative on the DM and DBT images. Pathologic analysis showed a 6-cm invasive lobular cancer in the left breast, with extensive lobular carcinoma in situ.

patients with DBT, we have expanded to include all breast cancer survivors, to aid with detection of new or recurrent tumors. We also now use DBT to assist with diagnostic problem solving, in addition to using standard spot compression and magnification views at 2D DM.

Early studies have shown similar or improved performance of DBT for analyzing lesion margins compared with use of standard 2D diagnostic DM, which suggests that standard 2D diagnostic DM could possibly be replaced with DBT (25,28–31). Additionally, the total radia-

tion dose from combo-mode DBT screening could ultimately prove to be less than the total radiation dose for a patient imaged with only DM who is recalled for multiple additional DM views (29). **The ability to problem solve with DBT images may expedite patient workup by alleviating the need for additional diagnostic images, thus minimizing patient anxiety associated with a callback and leading to a potentially decreased overall radiation dose.**

These findings indicate that DBT will improve the predictive value and diagnostic yield

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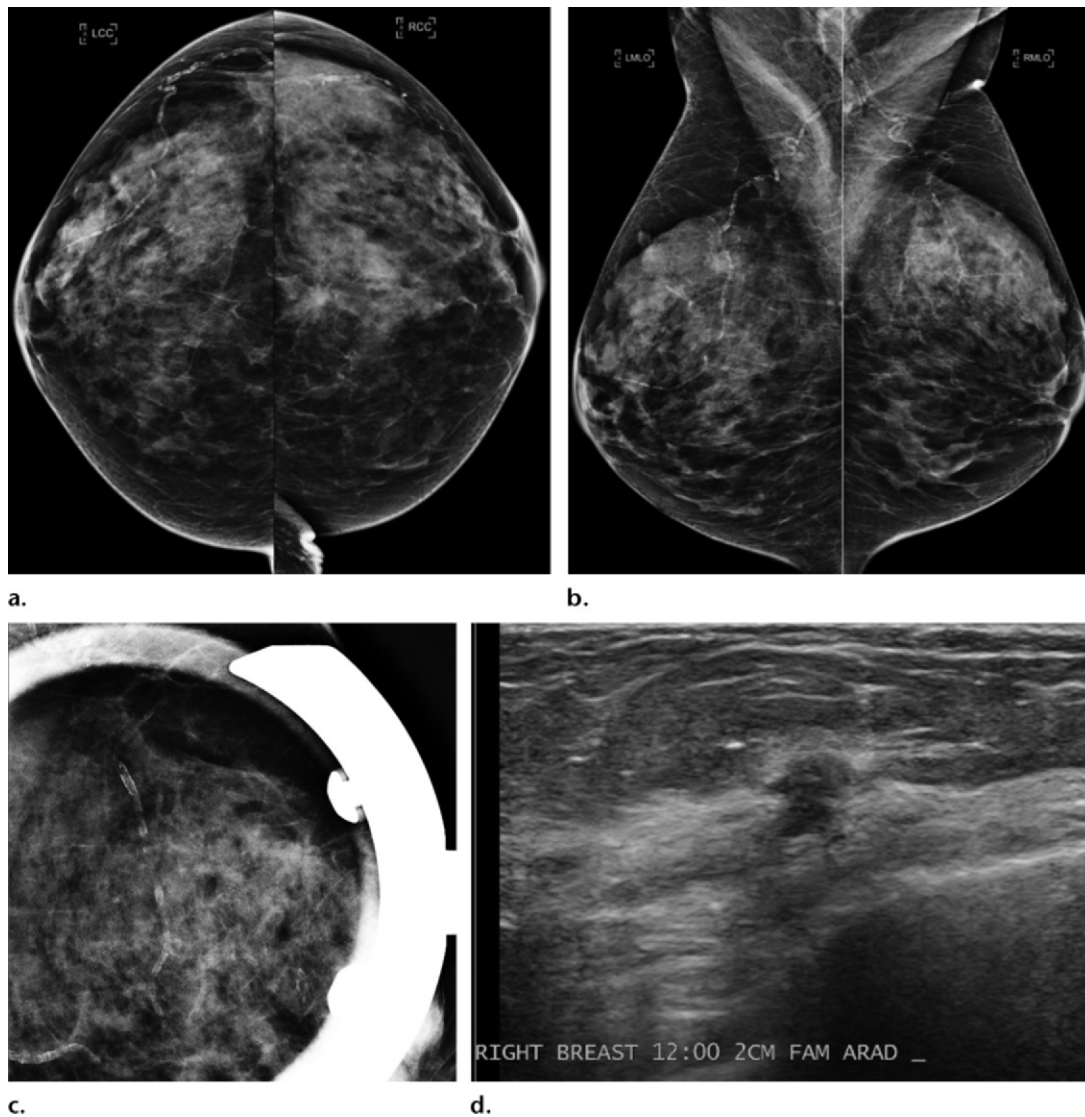


Figure 9. IDC with DCIS in a 57-year-old woman. **(a, b)** Craniocaudal **(a)** and MLO **(b)** screening DM images show a questionable focal asymmetry in the upper outer left breast. DBT images of the left breast (Movies 12, 13) show no abnormality, and no abnormality was seen on corresponding US images (not shown). The finding on the DM images is due to superimposition. However, a suspicious area is seen in the upper posterior right breast on DBT images (Movie 14). **(c)** Spot compression image of the right breast shows no definite abnormality because of tissue effacement. **(d)** US image of the right breast shows a hypochoic mass at the 12-o'clock position, 2 cm from the areolar margin, a finding that corresponds to the abnormality seen at DBT. Pathologic analysis revealed an 8-mm IDC with DCIS in the right breast.

of cancer when incorporated into screening or diagnostic imaging (24).

Improved Lesion Characterization and Triangulation

As discussed earlier, we have had a number of cancers that were detected only on DBT images. Some of our DBT-only cancers frequently effaced on conventional spot compression images and might not have been pursued if the DBT appearance had not been concerning (Fig 9, Movies 12–14).

DBT is particularly helpful for triangulating lesions that are seen on only one view, there-

fore alleviating the need for additional mammographic projections for lesion localization or confirmation. The 3D localization of a lesion from only one DBT projection is a substantial improvement over DM. On the basis of the lesion's location within the DBT stack, a targeted US image can be obtained or a biopsy can be performed for further workup (Figs 10, 11; Movies 15–19).

DBT is also extremely helpful for localization of lesions and calcifications in the skin. As the reader scrolls through the image stack, the skin surface becomes readily apparent, and lesions or calcifications viewed within the same imaging

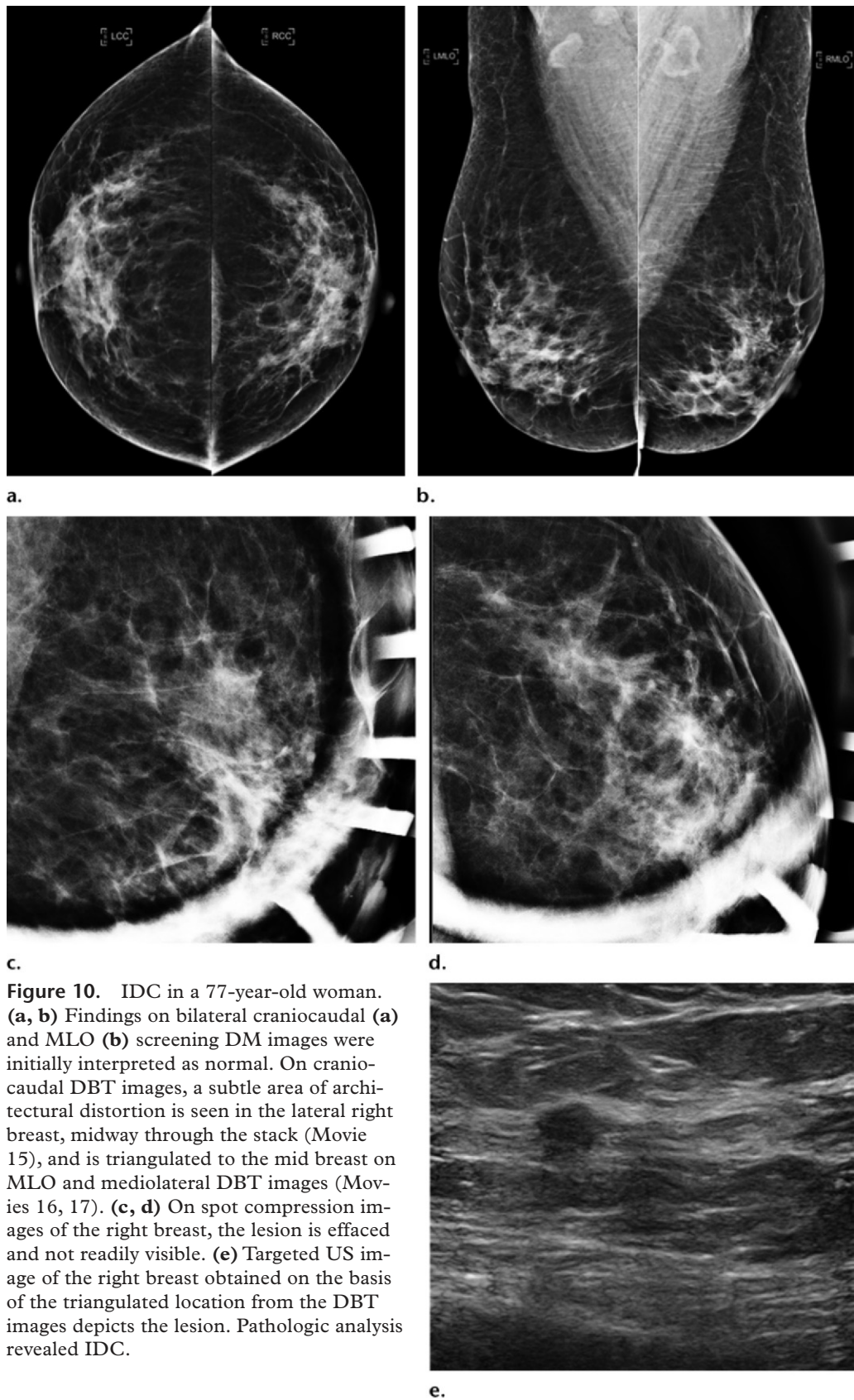
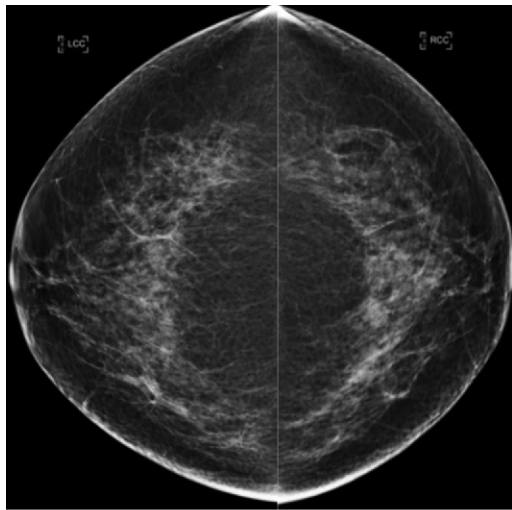


Figure 10. IDC in a 77-year-old woman. (a, b) Findings on bilateral craniocaudal (a) and MLO (b) screening DM images were initially interpreted as normal. On craniocaudal DBT images, a subtle area of architectural distortion is seen in the lateral right breast, midway through the stack (Movie 15), and is triangulated to the mid breast on MLO and mediolateral DBT images (Movies 16, 17). (c, d) On spot compression images of the right breast, the lesion is effaced and not readily visible. (e) Targeted US image of the right breast obtained on the basis of the triangulated location from the DBT images depicts the lesion. Pathologic analysis revealed IDC.



a.



b.



c.

Figure 11. IDC in a 60-year-old woman. (a, b) Findings on bilateral craniocaudal (a) and MLO (b) screening DM images were initially interpreted as negative. DBT images show a subtle area of architectural distortion in the mid left breast, a finding best seen on an MLO DBT image (Movie 18). The distortion is not definitely seen on craniocaudal DBT images (Movie 19). Since the MLO DBT stack goes from medial to lateral and the lesion is viewed toward the end of the stack, the lesion was triangulated from the MLO view to the lateral mid breast. The lesion then could be localized on craniocaudal DBT images. Spot magnification images showed no abnormality, but the ability to triangulate from the DBT stack guided US evaluation. (c) US image of the left breast shows an irregular hypoechoic mass at the 3-o'clock position, 5 cm from the areolar margin, a finding that corresponds to the architectural distortion seen at DBT. Pathologic analysis revealed a 4-mm intermediate-grade IDC.

section can be easily localized as being within the skin (Fig 12, Movie 20).

Localization of DBT-Only Lesions for Excision

In cases where a suspicious abnormality was better visualized or was seen only on DBT images, we used the ability to triangulate the location from DBT images to biopsy these lesions. Movies 21–24 illustrate subtle architectural distortion that was appreciated only on DBT images. By using an alphanumeric grid in conjunction with DBT, we were able to perform needle localization.

Challenges with DBT Implementation

Despite promising early data on DBT outcomes, there are important issues to consider when implementing this new technology into daily clinical practice.

Dose

In a phantom study, Feng et al (32) found that the average radiation dose for a combination DBT and DM study of a 5-cm-thick breast phantom with 50% glandularity was 2.50 mGy per DBT view, which is below the limit of 3.0 mGy per view

set by the Mammography Quality Standard Act. The mean glandular dose was only 8% higher for combined DBT and DM than for a full-field DM acquisition (1.30 mGy and 1.20 mGy, respectively). However, at combo-mode imaging, DBT images are obtained with DM images, which leads to an overall increase in dose for a screening examination. Essentially, when the combo mode is used, women are exposed to a radiation dose equivalent to twice that of DM. The actual patient dose varies significantly depending on breast size and composition (13). Recently, the FDA has approved the use of reconstructed synthetic 2D images obtained from the DBT acquisition (33–36). In early studies, the diagnostic accuracy of tomosynthesis with synthetic imaging has been shown to be similar to that of tomosynthesis combined with standard 2D DM. Therefore, in many cases, the additional dose from 2D DM imaging will be unnecessary, thus lowering the overall radiation dose of tomosynthesis imaging.

Calcifications

Detection of calcifications may be challenging with DBT. Large calcifications may cause substantial artifacts, which appear on multiple imaging sections as out-of-focus white objects bordered by dark shadows. Conflicting data have been reported regarding detection of microcalcifications at DBT (37,38). In addition, there currently is no commercially available computer-aided detection (CAD) system for DBT, although active research in this field suggests improved performance of 3D CAD compared with DM CAD (39–43).

Learning Curve and DBT Training

As with any new imaging technology, there is a substantial learning curve for interpreting DBT studies. In our practice, we had a slight initial increase in the overall screening callback rate. We believe that this was related to detection of DBT-only cancers early in our screening experience with DBT and the associated need to establish a new operating point to balance the sensitivity and specificity of screening. Some readers began recalling patients with more subtle DBT findings in hopes of finding additional DBT-only cancers. In addition, previously overlooked benign masses and architectural distortion often appeared more conspicuous, which prompted further workup. With increased reader experience, our callback rate stabilized and had decreased significantly within 6 months.

Currently, radiologists, physicists, and technologists are required by the Mammography Quality Standards Act to complete 8 hours of dedicated tomosynthesis training before clinical implemen-

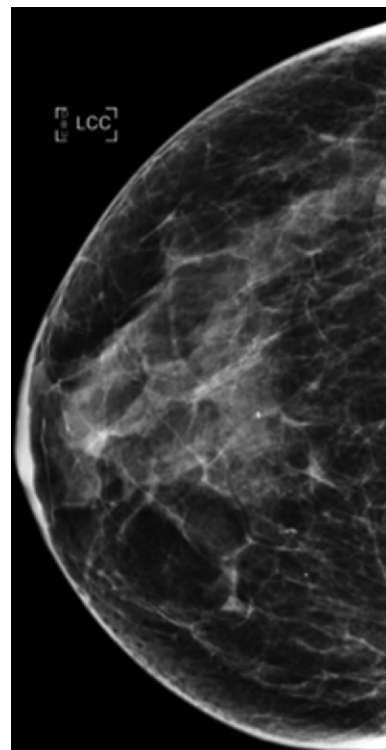


Figure 12. DBT used to localize calcifications to the skin. Cranio-caudal DM image of the left breast shows clustered calcifications, findings that are clearly visible in the skin layer on the DBT images (Movie 20).

tation (44). Although initial training is invaluable, experience is the only true trainer. In our opinion, when DBT is implemented in a clinical practice, it is best to start with high-volume screening so that the large variation in normal and benign findings can be appreciated with DBT before implementing the new technology in more complicated settings, such as diagnostic workup or in patients who have had breast conservation therapy, where scars and radiation changes may make diagnosis extremely challenging.

Other Considerations

Currently there is no approved current procedural terminology (CPT) code or standard additional reimbursement for DBT imaging, but as additional data from large prospective trials become available, it is hoped that a new reimbursement code will be created.

With the additional images in the reconstructed DBT stack, interpretation times will undoubtedly increase. Recent studies have estimated that the addition of DBT images to DM images in the combo mode will approximately double interpretation times (13,16,45). Although this is a challenge, we were able to handle the increased interpretation time required without

increasing our staffing or dramatically changing our schedule.

Because both the DM images and DBT projections must be stored, picture archiving and communication system (PACS) storage requirements will increase. The average combined DBT and DM study produces approximately 1 GB of data. The data can be stored at 4:1 lossless compression to decrease the total size of the dataset to 250 GB, although this is more than 10 times greater than the size of a compressed four-view DM set (46).

Conclusions

DBT is a promising new technology that has shown improved accuracy for screening and diagnostic breast imaging. Our early clinical experience supports these findings. One year after implementing DBT for all screening patients, we demonstrated a substantial reduction in our overall callback rate and a trend toward increased cancer detection.

In our diagnostic population, we showed improved conspicuity of lesions with use of DBT, particularly for architectural distortion and masses. The 3D localization that is possible with DBT offers substantial improvements over conventional imaging. The use of DBT in the diagnostic setting can expedite workups by reducing the number of 2D images needed (ie, spot compressions and additional projections for localization).

As with any new technology, several issues must be considered when implementing DBT into daily practice. Ongoing large-scale prospective trials will help guide the evidence-based utilization of this new technology.

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Digital Breast Tomosynthesis: Lessons Learned from Early Clinical Implementation

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By creating 3D images of the breast, DBT can overcome many of the challenges of DM by minimizing the effects of overlapping breast tissue and improving lesion detection and localization.

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Some early studies have shown improved accuracy in both screening and diagnostic settings with the addition of DBT. Reductions in false-positive callback rates that range from 6% to 67% have been reported, with stable or slightly increased cancer detection rates. Studies have also demonstrated improved sensitivity and specificity for breast cancer detection with use of combined DBT and DM versus 2D DM.

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After the implementation of DBT in our screening population, the callback rate was significantly reduced, from 10.4% with DM to 8.8% with combined DBT and DM. When controlled for variable reader volumes, the odds ratio (OR) was 1.24 ($P < .001$); therefore, the probability that a woman would be called back decreased by 24% with DBT. In addition, there was a trend toward an increased cancer detection rate with use of combined DBT and DM versus DM alone (5.4 cancers per 1000 vs 4.4 cancers per 1000, respectively; $P = .26$)

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Early studies of DBT have shown improved conspicuity and characterization of lesions, in part due to reduced obscuration by overlapping breast tissue. In particular, architectural distortion and lesion margins become more apparent at DBT. Studies have also shown that DBT is superior to 2D imaging for estimating the extent of malignancies.

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The ability to problem solve with DBT images may expedite patient workup by alleviating the need for additional diagnostic images, thus minimizing patient anxiety associated with a callback and leading to a potentially decreased overall radiation dose.