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Innovation in breast imaging techniques is leading to better breast cancer detection. Concurrently, breast cancer screening recommendations are changing, and breast density is becoming a more significant factor in breast cancer screening. Digital mammography has become the preferred screening method, with more breast imaging centers including the use of digital breast tomosynthesis (DBT). The technology’s role in breast imaging has not been clarified fully, and several clinical trials are addressing DBT. This article presents research findings on digital mammography and DBT and explores the future role of 3-D breast imaging.

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ith the exception of skin cancer, breast cancer is the most commonly diagnosed malignancy among American women, and only lung cancer accounts for more deaths than breast cancer (see Table 1). As of January 2014, more than 3.1 million U.S. women were living with a breast cancer diagnosis. Mammography is the standard imaging examination for breast cancer detection, reducing breast cancer mortality by approximately 49% in women who are screened. In 2016, nearly 4 million mammography procedures were performed by 8737 facilities certified under the Mammography Quality Standards Act (MQSA).

Three types of mammography assist radiologists in screening for and diagnosing breast cancer: film-screen systems, full-field digital mammography (FFDM), and digital breast tomosynthesis (DBT). The first FFDM system was approved for breast cancer screening in 2000 by the U.S. Food and Drug Administration (FDA), and FFDM eventually became the digital breast screening examination of choice. FFDM is considered a modality by the FDA and is subject to MQSA requirements. At one point, separate terms were used for digital mammography (in which early images had small fields of view and primarily consisted of spot images) and FFDM. As larger field detectors were developed, the terms digital mammography and FFDM became virtually synonymous; both are types of 2-D breast imaging.

As of July 2015, more than 96% of mammography units in use in the United States were FFDM units. Film-screen mammography is becoming a technique of the past, a fate similar to the early technique called xeroradiography. Converting from film-screen mammography to FFDM is essential today as health care transitions to full electronic image viewing and storage.

The goal of screening is to identify cancers while they are small and localized, which offers women a greater range of treatment options and a better

After completing this article, the reader should be able to:

- Explain critical changes in American Cancer Society breast screening recommendations.
- Identify reasons why breast density is significant to breast cancer screening and diagnosis.
- Analyze results from recent clinical trials comparing the clinical performance of digital breast tomosynthesis (DBT) with full-field digital mammography.
- Explain how DBT affects breast dose.
- Discuss the challenges associated with the exclusive use of DBT for breast cancer screening.

Marlene M Johnson, MEd, R.T.(R)
population-based screening programs. The ACS considered a comprehensive review of 5 critical outcomes of screening mammography: breast cancer mortality, life expectancy, false-positive findings, overdiagnosis, and quality-adjusted life expectancy. Evidence has demonstrated that screening mammography in women aged 40 to 69 years is associated with fewer breast cancer deaths and supports efficacy of breast cancer screening for healthy women 70 years and older.  

The evidence supported strength-based recommendations that reflect the consensus of the guideline development group. A strong recommendation indicates the belief that the benefits of screening outweigh any undesirable effects of the procedure. Qualified recommendations mean that although the evidence points to clear benefits of screening, the balance between benefit and harm is not clear; in addition, a patient’s values and preferences could affect the decision to undergo screening.

The 2015 ACS guidelines strongly recommend that women with an average risk of breast cancer undergo regular screening mammography starting at 45 years of age (see Table 2). Physicians are encouraged to use the time that normally would have been dedicated to a clinical breast examination to instruct a woman on the importance of screening; the potential benefits, harms, and limitations of screening mammography; how to watch for breast changes; and other aspects of preventive care. The American College of Radiology (ACR) and the Society of Breast Imaging (SBI) endorse the 2015 ACS guidelines for women at average risk for breast cancer.

The U.S. Preventive Services Task Force (USPSTF) expressed concern about advocating regular screening mammography starting at 45 years of age (see Table 2). Physicians are encouraged to use the time that normally would have been dedicated to a clinical breast examination to instruct a woman on the importance of screening; the potential benefits, harms, and limitations of screening mammography; how to watch for breast changes; and other aspects of preventive care. The American College of Radiology (ACR) and the Society of Breast Imaging (SBI) endorse the 2015 ACS guidelines for women at average risk for breast cancer.

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Breast density describes the tissue composition of the breast as displayed on a mammogram. Breast breasts are made up of lobules, ducts, and fatty and connective tissues (see Figure 1). Lobules produce milk and often are referred to as glandular tissue. Ducts are the small vessels that carry breast milk from the lobules to the nipples. Fibrous tissue and fat make up breast size and shape and hold other tissues in place. Fibroglandular tissue is the combination of glandular and connective tissue. The relative amount of glandular and connective tissue vs fatty tissue varies among women. Breasts are considered to be dense if they have more fibrous or glandular tissue than fatty tissue.

Breast density cannot be felt and is apparent only with breast imaging. A radiologist most commonly determines breast density during image interpretation based on breast composition appearance on the imaging study. A category is identified and recorded in the report. On mammograms, areas of increased breast density appear white because glandular and connective tissue block the passage of x-rays to a higher degree than does fatty tissue.

Reactions to Recommendation Changes

The ACR and SBI have stated publicly that overdiagnosis claims are inflated because of the methodology that the USPSTF used when calculating overdiagnosis rates. Overdiagnosis is likely in 1% to 10% of women screened largely because of ductal carcinoma in situ (DCIS). Few if any invasive carcinomas are overdiagnosed. Most women recalled after screening receive additional mammography or sonography. Only 1% to 2% of women have a needle biopsy as a result of a mammogram.

According to one radiologist, of 1000 women screened in the United States, approximately 100 (10%) are recalled for further evaluation; this equates to the percentage of women recalled after abnormal cervical (Pap) screening results. Of the 100 women recalled, about 56 have additional mammography projections or a sonogram that demonstrates no cancer is present. Approximately 25 have a “probably benign finding” that is followed up in 6 months. Only 1% to 2% of screened women are referred for image-guided needle biopsies. In total, 15% of lesions prove to be cancerous.

Figure 1. Anatomy of the breast. © ASRT 2010.
tissue, resulting in the description of a “50/50 breast.” Later studies proved that the 50/50 breast was a false assumption. Today, radiologists assign 1 of 4 categories of breast density when interpreting mammograms (see Figure 2). The 4 levels, along with the percentage of U.S. women who have each, are:

- Almost entirely fatty (10%).
- Scattered areas of fibroglandular density (40%).
- Heterogeneously dense (40%).
- Extremely dense (10%).

Breast density is influenced by genetics and affected by age, pregnancy or menopausal status, body weight, use of alcohol, and use of certain drugs such as tamoxifen. Some combinations of menopausal drugs also increase breast density. Typically, breast density decreases with age. As women get older, fatty tissue gradually replaces fibroglandular tissue.

In recent years, clinicians have become more interested in the challenges of imaging women who have dense breast tissue. Having dense breasts is closely correlated with primary risk factors for interval cancers (those occurring between screenings or < 12 months after a negative mammogram), particularly in younger women. The ACS reported that a woman with dense breast tissue faces a relative risk of developing breast cancer that is 4 or more times higher than risk for those without dense breast tissue. The reason dense breast tissue is linked to increased breast cancer risk remains under study. The risk could be from a tendency for dense tissue to mask a cancer or because tumors grow more rapidly in dense breasts. High breast density has not been linked to an increased risk of death among breast cancer patients.

High breast density can cause difficulty for radiologists interpreting mammograms and is associated with reduced diagnostic accuracy. Nearly all cancers can be demonstrated in fatty breasts, but mammography sensitivity in women who have extremely dense breast tissue could be as low as 30% to 48%. An increase in breast density has been associated with an increased likelihood of false-positive results from film-screen and FFDM screening.

The Breast Density and Mammography Reporting Act, introduced in 2015, would require mammography facilities to develop an evidence-based process for informing women of facts related to breast density and breast cancer risk. In an effort to improve communication regarding breast density, the law would require mammography facilities to include information regarding each patient’s individual measure of breast density in the written reports of mammography results provided to the patient’s physician and to the patients. The provider determines which qualitative assessment tool of breast density to use. Under the proposed law, the summary...
must include a statement regarding the patient’s risk of developing breast cancer based on breast density and encourage women to discuss with their physicians supplemental screening tests and any questions they might have on the report. As of fall 2016, there has been no agreement on the best method for imaging dense breast tissue. Supplemental imaging recommendations are unclear. As of 2016, the ACS recommends that women at moderate risk for breast cancer (ie, those with a 15%-20% lifetime risk) discuss with their physicians the possibility of adding breast MR screening to their yearly mammogram. However, research has demonstrated that sonography can detect more cancer than mammography alone when screening women with dense breast tissue yet increases the likelihood of false-positive results. Harms of supplemental screening with sonography or MR of women with dense breasts include higher recall and biopsy rates compared with digital mammography alone. DBT has demonstrated the ability to increase cancer detection rates in all breast density types and reduce the frequency of false-positive results, which decreases unnecessary biopsies. DBT might prove useful in the future after more rigorous comparative studies of supplemental screening for women with dense breasts have been completed.

More specific research is needed to understand fully the biologic components responsible for breast density. Clinical trials also are needed on the cost-effectiveness and feasibility of supplemental imaging and best practices for screening women with dense breasts. In the future, clinicians and recommendations might stratify women into specific screening regimens based on their breast density and its significance and challenges in imaging of breast cancer.

**Digital Mammography**

Mammography requires 4 functions to produce images: acquisition, processing, display, and storage. In analog imaging, processing and display functions depend on the film-screen combination. This process is inefficient and introduces opportunities for errors at each step. In digital acquisition, processing and display of the image occur independently of one another, allowing potential optimization at each step. Further, with FFDM, the time between acquisition and display is a matter of seconds. Digital images consist of picture elements, or pixels. A matrix is a 2-D collection of pixels, referred to in terms of the number of pixels in the length and width of the matrix (eg, 540 × 540). The maximum achievable spatial resolution is determined by the size and number of pixels. The smaller the pixel size or the larger the matrix, the higher the maximum spatial resolution. Spatial resolution is critical in breast imaging and refers to the minimum resolvable separation between high-contrast objects.
Full-Field Digital Mammography and Digital Breast Tomosynthesis

A second large-scale study published in 2011 by Glynn et al reported on film-screen mammography and FFDM performed from 2004 through 2009. The study included 66 479 mammograms, of which 32 600 were performed using film-screen systems and 33 879 using FFDM. Results demonstrated that the use of FFDM increased cancer detection rates and positive predictive values and decreased recall percentages.26

In nearly 15 years of research comparing the diagnostic accuracy of digital and film-screen mammography, digital mammograms have been shown to be equivalent to or better than film-screen mammograms in a general screening population. FFDM has helped improve radiologists’ ability to identify abnormalities and interpret differences between benign and malignant lesions.22 Digital mammography is superior to film-screen mammography in screening younger women with dense breasts because on digital images the physician can selectively optimize contrast in areas of dense breast tissue. Radiologists can enhance image contrast with simple window leveling performed by computer functions that provide FFDM a wider dynamic range. These tailored image processing techniques lead to easier image manipulation.7,12,26,32

The use of FFDM for screening improves clinical workflow and helps breast imaging departments or centers increase typical daily examination volume. Digital technology also makes it easier for mammographers to conduct quality control procedures. Further, FFDM helps eliminate physical image storage and problems related to lost or misplaced images.24 FFDM images are easier to share and can be displayed more rapidly. Radiologists can view images and interpret and report results at the same workstation, facilitating more rapid diagnosis. In addition, the radiologist can remain at the same workstation when viewing images from various breast imaging modalities.24 Teaching techniques have improved and the practice of telemammography has become possible.22 Patients have reported less anxiety with FFDM than with film-screen mammography because the examination takes less time and patients can receive a more immediate diagnosis.10,22,24

Digital mammography supports the addition of breast diagnosis technology, including DBT and computer-aided detection (CAD). CAD uses software algorithms that can recognize breast abnormalities and highlight areas on the mammogram that might need further review by a radiologist.33 CAD technology is used widely in breast cancer screening today despite limited and conflicting data on its clinical effectiveness. In a 2013 study that involved 163 000 women aged 67 to 89 years who had a mammogram between 2001 and 2006, researchers analyzed the mammograms acquired through either FFDM with CAD or FFDM alone. The women who had FFDM with CAD had a 17% increase in DCIS diagnosis and a slight increase in early-stage invasive cancer findings. The authors concluded that although CAD helped physicians find more DCIS and identify invasive cancers at an earlier stage in older women, it also led to increased use of diagnostic examinations.34

**Picture Archiving and Communication Systems**
PACS are necessary for electronic storage of all digital images. The storage requirements for images acquired with FFDM and FFDM-CAD are much greater than storage needed for digitized film-screen examinations. An
FFDM study with CAD markings requires 3 to 10 times the amount of storage space needed for an average CT examination. MQSA requires that breast imaging facilities retain mammography images and records for at least 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility. If a facility fails to retain mammograms for the length of time specified, even in the event of a PACS failure, the facility is in violation of the law. Many institutions do not purge mammography images because physicians might need past images for future reference. All breast imaging centers and departments should invest in backup storage, ensure that staff is trained properly on how and when to perform data backups, and follow manufacturers’ recommendations for equipment maintenance, including software upgrades.

Radiation Dose in Digital Mammography

Medical physicists, physicians, clinical personnel, and patients should understand the dose from any medical imaging modality that uses ionizing radiation. This understanding is critical to comparing the possible harm radiation could cause with the benefits the examination provides to the patient. Radiation dose concerns include dose from screening mammography, especially for women aged 40 to 49 years who typically begin having annual mammograms at age 40 years. The younger the woman, the more sensitive the breast tissue is to radiation.

Still, mammographers should reassure patients that the amount of radiation exposure received from a mammogram today on any type of equipment is small and the risk of harm is minimal. Further, breast dose from mammography is highly regulated by MQSA, which requires that the mean (average) glandular dose for a single projection to an FDA-approved breast phantom not exceed 3 mGy. The average dose equivalent for a typical mammogram with 2 projections of each breast is about 0.4 mSv. In comparison, the average American is exposed to approximately 3 mSv of radiation a year from natural resources. A screening mammogram delivers about the same amount of radiation as a woman would receive from background sources during a 7-week period.

In the 1960s and 1970s, medical physicists developed the core science of breast dosimetry that has become today’s standard. During this era, medical physicists began to realize that the dose to the breast’s glandular tissue and lymph nodes was a primary concern vs dose to skin, bone marrow, and adipose tissue. In the late 1980s, physicists developed a unit specific to mammography, the mean glandular dose, which is based on use of an approved phantom simulating 50% adipose and 50% glandular tissue. Actual patient dose depends on many factors, such as features of the equipment used; acquisition technique factors; and the composition, thickness, shape, and lateral dimension of the patient’s breasts. Generally, dose increases with larger breast size and higher breast density.

The complexity of breast tissue and imaging have led medical physicists to develop sophisticated techniques for measuring radiation dose to the breast. Estimates of average glandular dose for various sizes and compositions of breasts can be formulated using Monte Carlo simulations in place of a breast phantom. Monte Carlo techniques offer an alternative method to estimate the radiation dose realistically. The simulations are based on different breast compositions (eg, 0% glandular, 50% glandular, and 100% glandular) and the amount of photon transmission through the phantom. The simulation quantifies the amount of energy deposited in the glandular portion of the breast for various combinations of adipose and glandular tissue. The Monte Carlo method simulates dose for various types of breast composition; it would be nearly impossible to take into account the infinite number of tissue distributions that occur normally in human breasts. Although the Monte Carlo method could overestimate actual patient glandular dose, it provides a way to compare the dosimetry of various imaging techniques and protocols.

The use of Monte Carlo simulations in medical imaging research is widespread because the technique is flexible and helps quantify a factor (ie, dose) that is difficult to measure precisely. The metric reported in Monte Carlo dosimetric studies related to mammography involves conversion coefficients called the normalized mean glandular dose (DgN). DgN is defined as the ratio of the absorbed dose in the glandular tissue.
of the breast divided by the free-in-air kerma at the center of the field of view and the entrance surface of the breast. 43,45-47,49

**Radiation Effects**

Two major clinical studies published in 2011 evaluated the risk of death from the radiation received during mammography breast cancer screening. 40,41 The de Gelder study explored the benefit-risk ratio of screening women before age 50. 41 Estimating a mean glandular dose of 1.3 mGy per projection, biennial mammography screening between ages 50 and 74 years was predicted to induce 1.6 breast cancer deaths per 100,000 women as compared with 1121 avoided deaths due to breast cancer. Lowering the age limit for biennial screening to include women ages 40 to 74 years was predicted to induce 3.7 breast cancer deaths per 100,000 women and prevent 1302 deaths from breast cancer. 41 The second study by Yaffe and Mainprize assessed the risk of radiation-induced breast cancer caused by mammography screening. 40 Estimates were made of the potential number of breast cancers, cancer deaths, and woman-years of life lost because of radiation exposure received in a variety of mammography screening scenarios. For a population of 100,000 women, each receiving a dose of 3.7 mGy to both breasts, screened annually from age 40 to 55 years and biennially age 55 to 74 years, researchers predicted 86 cancers would be induced and 11 deaths due to radiation-induced breast cancer. 40 Both studies concluded that the benefits of mammography screening between the ages of 40 and 74 years outweigh the risk of radiation-induced breast cancer, and the risk is small compared with the expected mortality reduction provided by mammography screening. 40,41

The DMIST researchers compared the radiation dose delivered by film-screen mammography and FFDM. The mean glandular dose from digital systems was 22% lower than the dose delivered by film-screen mammography for each projection acquired. 30 Most other studies analyzing FFDM dose have demonstrated that FFDM delivers a lower radiation dose to the breast than film-screen mammography. 30,32,41,45,47

**Challenges of Digital Mammography**

Digital mammography has introduced new challenges to breast imaging and has not alleviated all the difficulties associated with film-screen mammography. Initially, the clinical availability of FFDM systems was delayed several years because the FDA had not developed an approval process for the modality. This delay slowed the development of equipment and progress of clinical trials. 30 Many institutions had concerns about replacing film-screen equipment with FFDM systems and believed there was too little evidence to support the initial high cost of equipment and the substantial time needed to train mammographers and radiologists. 24,55,56

In addition, DMIST results indicated that film-screen mammography often was more effective in women 50 years and older with fatty breasts. Because this group constitutes a large portion of the Medicare population, FFDM was considered a risky investment. 30

The 2 projections provided by film-screen mammography or FFDM do not allow the radiologist to assess fully abnormalities and distinguish true lesions from other breast tissue. The nature of 2-D mammography makes it difficult to demonstrate potential lesions within dense breast tissue or to identify properly 2 or more normal features only separated vertically and appearing suspicious. 25 On average, the sensitivity of film-screen mammography and FFDM for breast cancer detection is about 70%. The sensitivity of mammography drops to 30% to 48% for women with very dense breasts. 9 Breast density and anatomical noise, a masking effect caused by tissue superimposition, are the 2 main reasons for false-positive results and recalls. 57 False-positive findings are not unusual in breast cancer screening. A number of factors appear to increase the likelihood of a false-positive result:

- If it is the patient’s first mammogram.
- Greater breast density.
- Use of premenopausal hormone therapy.
- Screening with digital mammography.
- Longer intervals between screening.
- Lack of comparison images from previous mammograms. 11

The greatest potential harm of a false-positive result is an unnecessary biopsy, 58 and imaging facilities make every effort to minimize false-positive results that require the patient to be recalled. 9,24,26,30

In addition to false-positive findings, a key challenge associated with FFDM is an inconclusive mammogram.
that leads to a recall. The use of digital mammography has increased recall rates compared with routine use of film-screen imaging. Recalls are problematic because they increase a patient’s anxiety, increase patient dose, and have a negative effect on the department’s workflow. Follow-up studies add to a facility’s imaging volume and the amount of time a radiologist dedicates to the entire study.

At the same time, recalls improve breast cancer detection, and a balance is needed between increased sensitivity and improved specificity. Women who have been recalled are more likely to return for regular screening, which can reduce the number of false-positive findings. The median recall rate in the United States is approximately 10%, and U.S. recall rates are about 2 times higher than in Europe. Most women who are recalled for additional imaging do not have cancer.

**Digital Breast Tomosynthesis**

Following conversion to FFDM, breast imaging centers faced a new question: whether to complete the costly and time-consuming conversion to DBT. Tomosynthesis primarily was developed to overcome the limitations of 2-D imaging. The cost of DBT equipment is substantially greater than the cost of FFDM systems, and facilities must absorb additional expenses related to the increase in data storage. The FDA approved the first DBT equipment in 2011. The agency approved DBT as a diagnostic technique or as a breast cancer screening method when FFDM images are acquired along with the DBT study.

**Tomosynthesis Systems**

In tomosynthesis, a designated plane of the body, referred to as a slice, is displayed in focus while motion blurs the anatomy above and below the plane. The x-ray tube generally is mounted above the patient and moves in one direction while the image receptor moves in the opposite direction (see Figure 3). The development of DBT detectors, along with video game technology that runs on graphic processing units, made tomosynthesis for breast imaging a clinical possibility.

The structure and function of DBT systems vary among manufacturers. The systems differ in angular range of x-ray tube motion, number of views acquired, and scan duration time. Resolution, noise, artifact level, dose, tissue volume, examination time, and scan parameters depend on the structural geometry of the DBT system.

Tomesynthesis acquisition generally operates in 1 of 2 methods: the sweep mode or the step-and-shoot technique. With the sweep mode, the x-ray tube moves in a continuous manner across the breast and is pulsed at the frame rate of the detector. In the step-and-shoot method, the x-ray tube moves to the next position between 2 acquisitions, stops, and then transmits the angled x-ray beam while the tube is stationary. The tube might move in an arc around a point within the breast or sweep across a linear path. Some detectors are stationary and others move simultaneously with the tube.

With the moving detector system, the tube and receptor typically continue in a synchronous pattern, but the receptor is not firmly connected to the tube. This type of system relies on isocentric C-arm geometry in which the source and detector both rotate, or
Data Processing

Once the DBT system acquires volumetric 3-D data, a radiologist can view images individually or as a continuous loop. The size of DBT data is problematic compared with FFDM. Data from DBT studies require more time and electronic resources for reconstruction, viewing, and storage of images. Mammographers generate hundreds of images of each breast on thousands of women every year, resulting in huge amounts of data that must be stored for extended periods. Depending on the pixel matrix of the detector, each projection creates approximately 20 MB of raw data. On average, a compressed breast thickness of 50 mm results in 50 slices of anatomy and 600 MB of data. Saving the raw and reconstructed data from each projection could equate to 900 MB of data for a complete DBT mammogram and require an estimated 3600 MB of storage.

The specific data requirements are influenced by technical factors, such as detector and pixel size, number of projections, and slice interval.

Image reconstruction for DBT relies on mathematical algorithms. An algorithm is a formula or process used to solve a problem and is required for image reconstruction and postprocessing. Each algorithm affects specific image characteristics; image quality depends on factors, such as noise, image contrast, and computing speed.

Two main algorithm classifications are used for tomosynthesis reconstruction: analytical and iterative. Analytical algorithms—widely used in computed tomography—consist of reconstruction filters, called filtered back projection, that compensate for scanning over a limited angular range and minimize artifacts. Iterative reconstruction can affect image noise and computing time. Two examples of iterative reconstruction techniques are maximum likelihood and simultaneous algebraic reconstruction. Modified algorithms combine algebraic and analytical techniques and primarily are used to keep blurring and other artifacts minimized. Examples of modified algorithms are iterative deblurring and nonlinear back projection.

Clinical Applications of DBT

As of December 2016, the FDA had not yet developed accreditation standards for 3-D tomography, which has created a situation similar to the introduction of FFDM to the market. The FDA has implemented a strict premarket approval process for each individual...
DBT system and considers DBT equipment an extension of FFDM. In addition, for MQSA accreditation purposes, inspectors only review 2-D images. Facilities that use DBT for screening must submit either the FFDM images acquired during the DBT study or the 2-D images generated from the DBT data set using an algorithm, referred to as synthesized mammography.\textsuperscript{5,65,69-71} MQSA allows certified mammography facilities to use accredited DBT equipment based on the unit’s 2-D imaging component. Data from 2-D digital mammography is considered less effective than DBT at displaying certain abnormalities, specifically microcalcification clusters. Still, FFDM images are necessary for comparison of prior 2-D studies.\textsuperscript{77,78} As a result, DBT systems available on the market today can acquire images through a number of techniques, including FFDM alone, DBT alone, FFDM-DBT, or DBT-synthesized mammography.\textsuperscript{69-71,73-75} For facilities using a 3-D system in clinical practice, the FDA only certifies the 2-D component of the unit, which means facilities must submit FFDM images or synthesized 2-D images for review.\textsuperscript{4}

As of December 2016, more than 30 FFDM and DBT systems had been approved, cleared, or accepted by the FDA since 2000. The FDA considers each manufacturer’s system a new, separate mammography modality under MQSA, and personnel operating DBT equipment must meet standard MQSA requirements for training on a new modality.\textsuperscript{6}

Each manufacturer has designated indications for use and methods of image capture for breast cancer screening.\textsuperscript{5,65} For example, the Siemens Mamnomat Inspiration had a premarket approved function called 2D+Tomo-Scan. When in use, the first image acquisition produces a conventional 2-D image set by having the swivel arm at a 0° angle. The acquisition of 3-D data follows the 2-D acquisition.\textsuperscript{74}

In contrast, Hologic’s Selenia Dimensions 3-D system with C-view software can acquire 2-D images directly from the 3-D image set, eliminating the need for FFDM images.\textsuperscript{69,75} The practice of acquiring 2 projections of each breast with FFDM for screening is the most common protocol in the United States. The double-reading practice of acquiring FFDM-DBT images is applied most often in countries other than the United States.\textsuperscript{77,80}

**Clinical Performance Trials on DBT**

The clinical use of DBT has gained acceptance and DBT research has increased.\textsuperscript{57} Clinical trials and studies have investigated the advantages and disadvantages of DBT for breast cancer screening, cancer detection rates, microcalcification display, recalls, false-positive rates, breast dose, and physician interpretation times. DBT offers the advantages of FFDM, including fewer artifacts, consistent quality, and digital image processing.\textsuperscript{5}

**Diagnostic Accuracy and Cancer Detection**

The malignant features of breast cancers can be classified as mass, focal asymmetry, architectural distortion, and microcalcification. DBT offers potential advantages for evaluating masses, areas of architectural distortion, and diagnosing asymmetries over conventional 2-D mammograms. DBT can discern microcalcification clusters effectively from an underlying mass and has proved to be more accurate at determining the true size of tumors.\textsuperscript{77-85}

From 2011 to 2014, the FDA approved only 2 DBT systems for market.\textsuperscript{66} However, several DBT systems have been available since 2008 in other countries.\textsuperscript{77,78} The first 2 large breast cancer screening trials evaluating the performance of FFDM-DBT were conducted in Europe. These trials were the Oslo Tomosynthesis Screening Trial, referred to as the Oslo or OTST study, and the Screening with Tomosynthesis or Mammography Trial (STORM).\textsuperscript{77,78}

The preliminary results of the Oslo trial, published in 2013, demonstrated that cancer often overlooked or not visible on FFDM can be seen on DBT. During the study, FFDM and DBT images were collected on 12,631 women aged 50 to 69 years. The readers interpreted the FFDM images first, followed by interpretation of the FFDM-DBT image set. The use of FFDM-DBT compared with FFDM alone increased cancer detection by 27%, from 6.1 per 1000 to 8 per 1000, and decreased false-positive rates from 6.1% to 5.3%. Among the women studied, 121 had cancers, 77 of which were found with FFDM alone. A total of 101 cancers were detected with FFDM-DBT.
The use of FFDM-DBT detected 25 additional cancers not diagnosed with FFDM. The trial’s most important finding was the 40% increase in the detection of invasive cancers that were diagnosed on FFDM-DBT images but not from FFDM alone.  

Investigators with the STORM trial in Italy released their results in April 2013. A total of 7292 women aged 54 to 63 years were invited to screen. One group was screened with FFDM alone, and the other with FFDM-DBT. Of the 59 cancers detected, 39 were found on FFDM alone and all 59 were demonstrated on FFDM-DBT images, representing a 34% increase in cancer detection.  

A similar study was conducted between 2013 and 2015 in the United Kingdom, comparing the performance standards of FFDM-DBT with FFDM alone. The tomosynthesis with digital mammography investigation, or TOMMY trial, included 7060 women aged 47 to 73 years, 1158 of whom had cancer. The results demonstrated an increase in specificity with the use of FFDM-DBT compared with FFDM alone and a marginal improvement in sensitivity.  

DBT is being used frequently in the United States and other countries. Supporting evidence from recent clinical trials suggests that DBT imaging of masses has demonstrated good patient acceptance, physician preference for DBT images, and improvement in sensitivity and characterization of lesions (see Figure 4). The 3-D technique more clearly portrays benign findings such as lymph nodes or skin calcifications than routine FFDM and might be superior to FFDM for preoperative measurement of breast lesion size.  

In a small study published in 2007, Poplack et al analyzed data from 98 patients recalled after FFDM who underwent diagnostic evaluation using film-screen mammography and a DBT examination. The authors found that clinical image quality of DBT was either equivalent or superior to film-screen technology. In 2008, Andersson et al found that malignancies were more visible on FFDM-DBT studies than on images acquired with FFDM alone, and in 2013, Yang et al reported improved diagnostic accuracy for noncalcified lesions on the DBT images.  

The most significant U.S. study of DBT breast cancer screening was published in 2014 by Friedewald et al. This was an important study because of the large number of women participating and the inclusion of academic and nonacademic institutions. The investigators retrospectively analyzed data from 13 sites that reported results for women screened with FFDM alone and those screened with the addition of DBT. They compared screening performance measures from 281 187 FFDM images with those of 173 663 FFDM-DBT images. The study demonstrated a 41% increase in invasive cancer detection in the women who had FFDM-DBT.

Microcalcification Detection

Microcalcifications are tiny deposits of calcium in the breast tissue frequently observed on mammography. Most calcifications are not cancerous but can indicate carcinoma in situ. Microcalcifications are relatively easy for radiologists to identify on FFDM images as high-contrast individual specks or clusters.
The literature is limited regarding clinical microcalcification assessment with DBT. The engineering, physics, and reconstruction of various manufacturers’ equipment can lead to different results and even opposing conclusions. The x-ray source, motion, pixel size, reconstructive algorithms, and method used during interpretation all can affect the ability to see microcalcifications on DBT images. Microcalcifications have slightly less contrast on DBT than on FFDM and appear individually on separate slices. Clusters can be more difficult to assess when they are not all seen at the same time and when adjacent structures have similar contrast.9,86,87,90,91

Research on DBT’s effectiveness in displaying microcalcifications has produced inconsistent results. Poplack et al reported that 14% of recalled studies involved calcifications. In 11% of the microcalcification cases, radiologists deemed the DBT images inferior to FFDM, and of all studies in which DBT was considered inferior, 72% were deemed so because of calcifications.44 In another study, Sprangler et al compared FFDM images with DBT images.90 The results demonstrated a nonsignificant improvement in sensitivity and specificity with FFDM compared with DBT when demonstrating microcalcifications.90

Tomosynthesis can be as effective as FFDM in demonstrating microcalcifications when the resolution of the DBT images is maximized with small pixel sizes.14,89 Kopans et al analyzed 100 cases of microcalcifications with FFDM and DBT using small pixel sizes.99 The authors found that 92% of the cases acquired with DBT had equal or superior clarity for detecting microcalcifications compared with FFDM. A volume rendering technique also has been suggested to improve diagnosis of microcalcification clusters on DBT. Radiologists should ensure that they interpret DBT images in the slab mode in addition to each slice.14,89-91 To date, the general consensus is that the industry must address the issue of microcalcification display on DBT before DBT can be considered as a stand-alone screening technique.6,7,14,35,44,46,90

Visit asrt.org/asrt?3vTu34 to see how calcifications can be difficult to perceive on planes through volume but are more easily appreciated on slab images (see the article’s Figure 3).

Recalls
Recalls refer to recommendations for further imaging or workup following a screening mammogram. Approximately 25% of patients are recalled for a second mammogram following FFDM because of tissue superimposition.92 On DBT images, overlapping tissues are separated, nearly eliminating recalls related to superimposed tissue.14 Breast imaging centers also frequently recall women following FFDM screening because the radiologist is certain there is an abnormality, but the lesion is not evident on both mammogram projections; therefore, the physician is uncertain of the abnormality’s location. With DBT imaging, the radiologist can determine the location of a lesion based on where it appears in the data set.94

In numerous clinical studies, the use of FFDM-DBT imaging decreased recall rates from as much as 30% to 40% compared with FFDM alone.14,38,39,41,42,88,93,94 In a study by Haas et al, the investigators analyzed screening performance measures for 6100 women who underwent FFDM-DBT examinations and 7058 women who underwent FFDM alone.88 The authors noted a decrease in recall rates from 12% in the women who had FFDM alone to 8.4% in women who had FFDM-DBT. After adjusting for differences in age, breast density, and risk factors, the authors reported a 38% reduction in recall rates with the use of FFDM-DBT. The recall rate reduction was significant for all breast density categories with the exception of women with fatty breasts and for all age groups except women 70 years and older.99

When determining whether a woman needs a biopsy, the radiologist relies on the positive predictive value (PPV) of the mammography finding. The PPV of mammograms resulting in recommendation for biopsy ranges between 20% and 40%, with a median of 31.4%.13,14,38,39,41,42,88,93,94 The use of DBT imaging in breast cancer diagnosis has been shown to increase the PPV of a suspected lesion found during mammography screening, particularly in young women and women with dense breasts.77-82 For example, Friedewald et al reported a significant reduction in recall rates, from 10.7% with FFDM alone to 9.1% with FFDM-DBT. The authors also reported a statistically significant increase in PPV for recalls from 4.3% with FFDM alone to 6.4% with FFDM-DBT.92

In an article by Rose et al, the authors analyzed recall rates from a single clinical site before and after the
Introduction of DBT. They examined a total of 13,856 FFDM screenings without DBT and 9,499 screenings with DBT. The authors noted a significant reduction in recall rates, from 8.7% with FFDM alone to 5.5% with FFDM-DBT. The results also demonstrated a statistically significant increase in PPV for recalls, from 4.7% with FFDM alone to 10.1% with FFDM-DBT. Among women undergoing screening for the first time, the recall rates were 13.6% with FFDM alone and 9.6% with FFDM-DBT.

Different approaches for measuring DBT dose consider the unique conditions and factors of DBT acquisition. The air kerma for the tube output (Gy/mAs) can be estimated using 3 factors: the incident dose at the breast surface, a correction factor for breast granularity, and a factor related to the anode/filter combination. To formulate a breast dose table, factors for various beam qualities or half-value layers and compressed breast thicknesses are applied and a mathematical estimate is established. Determining the normalized glandular dose coefficients for different beam energies, breast thicknesses, and x-ray spectra also can be used to convert the entrance ion dose to glandular dose.

MQSA standards regulate DBT dose; dose from the FFDM acquisitions acquired during the DBT study are evaluated to discern whether the system is delivering acceptable levels according to MQSA. The examination’s FFDM acquisitions must not exceed 3 mGy, the MQSA limit for a single-projection screening mammography study for a CC-equivalent of an average breast. The CC projection in DBT imaging is performed in acquisition mode with the x-ray tube at the 0° position.

One of the first U.S. clinical sites to incorporate DBT into its clinical practice found higher exposure levels for FFDM-DBT acquisitions than for FFDM alone. As more research followed, results consistently showed that FFDM-DBT acquisitions increased a patient’s breast dose in a range from 34% to 61%. In studies where FFDM-DBT systems replaced film-screen mammography without previous use of FFDM alone, the mean glandular dose for a single FFDM-DBT projection resulted in a dose higher than that of film-screen mammography.

The protocol for FFDM-DBT screening used routinely in the United States requires exposing a patient to radiation during FFDM and DBT acquisition; this protocol is the primary reason breast dose is significantly higher with FFDM-DBT compared with FFDM alone. The decision to examine the breast with the FFDM-DBT protocol often is left to the physician and patient. Some breast imaging centers have begun routine use of FFDM-DBT for screening. At these facilities, a woman might receive a full FFDM-DBT acquisition automatically.

The breast radiation dose from a single DBT projection is about the same as from one FFDM projection.
Patient positioning, particularly the DBT MLO projection, can cause a 5% to 13% variation in mean glandular dose.\textsuperscript{44} One way to limit breast dose in DBT is to use the synthesized mammography images from the DBT data and eliminate the FFDM exposure. Using synthesized DBT images can reduce the mean glandular dose by 45% compared with FFDM-DBT.\textsuperscript{50,70,71,73,95-98} Research results on premarket approved systems with synthesized mammography have demonstrated that use of synthesized images alone or in combination with tomosynthesis is comparable in performance to FFDM alone or FFDM-DBT, while successfully decreasing the dose.\textsuperscript{73,74}

Eliminating FFDM acquisition improves patient comfort because the breast is compressed for 2 projections instead of 4 projections.\textsuperscript{84} The ability to produce DBT synthesized mammography images is relatively new and not available at all clinical sites. Further, all health insurance plans might not cover fully the use of synthesized DBT images for breast cancer screening.\textsuperscript{37,46,71}

Another approach to decreasing DBT dose is to allocate more (approximately 50%) of the x-ray tube output to the central projection of the DBT and distribute the remaining half over other projections.\textsuperscript{57} A third option for decreasing DBT breast dose is acquiring a single DBT projection and using DBT as a standalone technique. Although the exact projection to use as the single image remains under investigation, early results indicate that a single projection DBT is equal or superior to FFDM studies in cancer detection and lowers total breast exposure from DBT.\textsuperscript{99}

In theory, the ability to acquire DBT diagnostic quality images with equal or higher quality than FFDM requires a slightly higher dose than FFDM alone. The amount of quantum noise in an image is indirectly proportional to dose. In digital imaging, the amount of quantum noise is a product of quantum mottle plus the noise that is produced from detector electronics. This type of inherent noise remains fairly constant and is influenced primarily by the efficiency of the DBT detectors. During a DBT acquisition, each individual projection is delivered at a much lower dose than in FFDM because the total dose is divided among the projections. The low exposure significantly increases the amount of quantum noise in each individual projection, while the electronic noise accumulates with each projection.

The only way for DBT dose to equal that of FFDM is if the noise in each individual projection is determined primarily by quantum noise with minimal contribution from the electronic noise. When this is true, the individual projections can be used to reconstruct an image slice that is comparable to an FFDM image. Electronic noise produced in DBT imaging cannot be eliminated entirely, resulting in a slightly higher dose than in FFDM imaging. Noise is the main reason high-efficiency detectors with minimal electronic noise are essential for DBT imaging.\textsuperscript{99,57,67}

**Computer-aided Detection**

The use of CAD in conjunction with DBT is mostly experimental; a limited number of studies had been published as of summer 2016.\textsuperscript{49,100-102} The large volumes of data that would be created if CAD data were applied to each DBT image are problematic. CAD systems used for FFDM cannot be used with DBT without modification. The most common approach to developing DBT-CAD systems is to create an algorithm that addresses a specific concern in breast imaging diagnosis.\textsuperscript{49} DBT-CAD systems could prove useful to detect breast masses using projection images, reconstructed slices, or a combination of the two. Combining multiple slices into a thicker slab might prove helpful in adding CAD because the combined image would more closely resemble FFDM images.\textsuperscript{100}

DBT-CAD systems also could be used to help characterize lesions and detect microcalcifications.\textsuperscript{99,101} A clinical study involving DBT-CAD for microcalcification detection reported a sensitivity of 85%; however, the false-positive rate was too high for clinical use.\textsuperscript{103} In the future, more CAD prototypes will need to be developed and tested if DBT is to be used consistently for screening.\textsuperscript{102}

**Operational Challenges of DBT**

Wide adoption of tomosynthesis requires addressing some challenges of the technology, including artifacts, interpretation time, workflow issues, and training. In tomosynthesis, high-contrast objects such as surgical clips can cause substantial artifacts.\textsuperscript{44} A DBT phenomenon called undersampling also can occur. Undersampling of an object, such as a breast lesion,
Diagnostic mammography requires additional radiologist time that ranges from a few minutes to several hours if the physician performs image-guided biopsy. The possibility of using only one projection from the DBT data set for interpretation also would decrease DBT interpretation time if this becomes standard clinical practice.\textsuperscript{14,57,103,104,106}

\textbf{Conclusion}

The benefits of FFDM in breast cancer screening and diagnosis have been well established in the past 15 years, and the use of FFDM has become prominent in clinical practice. The introduction of DBT imaging has initiated a new approach to digital breast imaging. Research on the effectiveness of DBT is encouraging, particularly in the areas of breast cancer detection, dense breast imaging, and reducing the frequency of false-positive results and recalls. Further technological advances continue to optimize imaging parameters. Incorporating DBT with other modalities is being studied; this includes possible contrast-enhanced tomosynthesis that creates breast images similar to MR imaging. Automated breast sonography with DBT is emerging and could prove useful in the screening of dense breasts.

Significant clinical challenges in DBT imaging include breast dose, dense breast imaging, and demonstration of microcalcifications. Breast imaging practices also need to address the issues of equipment costs and implementation strategies to include longer interpretation times, data storage, and training before converting to DBT imaging.

Data strongly supports investment in large-scale population screening trials, particularly aimed at solutions to the double acquisition of images required for 2-D and 3-D mammograms. Other research is focused on evaluating integrated synthesized and digital mammography.

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Digital Breast Tomosynthesis and Full-Field Digital Mammography

1. The American Cancer Society’s 2015 breast screening recommendations include all of the following guidelines except:
   a. annual clinical breast examinations by a physician or qualified health care professional.
   b. annual screening for women begins at age 40 years.
   c. annual screening performed on women between ages 45 and 54 years.
   d. biennial screening performed on women 55 years and older.

2. In recent years, there has been more clinical interest in women who have dense breast tissue because high breast density:
   a. is associated with an increased risk of death among cancer patients.
   b. increases with age.
   c. is linked to breast cancer risk.
   d. increases the positive predictive value of a breast lesion.

3. The results of the Digital Mammography Imaging Screening Trial in 2008 reported that full-field digital mammography (FFDM):
   a. was not as effective as film-screen mammography.
   b. proved more effective in breast cancer detection in women older than 65 years.
   c. improved cancer detection in women 49 years and younger.
   d. improved recall rates in women 65 years and older with fatty breasts.

4. Which of the following statements is true regarding computer-aided detection (CAD) of breast images?
   a. Adoption of CAD technology remains low.
   b. CAD uses software algorithms to recognize and highlight possible abnormalities.
   c. It is difficult to add CAD to FFDM.
   d. Studies have shown that CAD decreases diagnosis of ductal carcinoma in situ.

*Your answer sheet for this Directed Reading must be received in the ASRT office on or before this date.*

continued on next page
5. According to the Mammography Quality Standards Act, the mean glandular dose received from a mammography study acquired with either analog or digital imaging should **not** exceed ______ mGy per exposure.
   a. 0.2
   b. 0.3
   c. 2.0
   d. 3.0

6. According to the article, the 2 primary reasons for recalls following FFDM are:
   a. breast density and anatomical noise.
   b. superimposition of structures and artifacts.
   c. motion and lack of adequate compression.
   d. tissue overlap and lack of radiologist expertise.

7. Which of the following factors increases the likelihood of false-positive results in mammography?
   1. patient’s first mammogram
   2. shorter intervals between screenings
   3. lack of images from previous screening examinations
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

8. When using digital breast tomosynthesis (DBT) for breast screening, FFDM images still are necessary partly because:
   a. some radiologists have little to no experience with DBT interpretation.
   b. only 2-D images can load on most interpretation display monitors.
   c. benign lesions are easier to detect with FFDM images.
   d. radiologists must have them for comparison of prior 2-D images.

9. The results of the Oslo Tomosynthesis Screening Trial published in 2013 demonstrated the use of FFDM-DBT compared with FFDM alone increased cancer detection and decreased:
   a. recall rates.
   b. breast dose.
   c. false-positive rates.
   d. artifacts.

10. DBT likely is superior to FFDM for:
    1. clearly portraying benign findings.
    2. reducing image artifacts.
    3. preoperative measurement of breast lesions.
    a. 1 and 2
    b. 1 and 3
    c. 2 and 3
    d. 1, 2, and 3

11. In a 2014 study from Friedewald et al, investigators compared FFDM-DBT with FFDM alone. They noted a 20% increase in invasive cancer detection for women who had DBT-FFDM compared with FFDM alone.
    a. true
    b. false

12. Which of the following factors affects the amount of breast dose received during a DBT study?
    1. scanning parameters
    2. breast composition
    3. breast size
    a. 1 and 2
    b. 1 and 3
    c. 2 and 3
    d. 1, 2, and 3

*continued on next page*
13. One way to decrease the amount of breast dose received during DBT imaging is to use:
   a. less compression.
   b. synthesized images from the DBT data set.
   c. the maximum tomographic angle.
   d. less filtration.

14. On average, interpretation of FFDM-DBT imaging requires ______% more time than interpretation of FFDM alone.
   a. 12
   b. 24
   c. 47
   d. 53