Digital Mammography

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IN 1992, A NATIONAL Cancer Institute expert panel determined that, of all emergent technologies, full-field digital mammography (FFDM) held the greatest potential for improving breast cancer detection.[1,2] The transition to digital mammography is a necessary step in the ongoing process of improving mammographic image quality and advancing toward the goal of earlier breast cancer detection. Digital mammography will also enable the completion of the conversion of radiology departments to fully digital operation.

The potential of digital imaging in the field of diagnostic and screening mammography is made clear in an evaluation of conventional screen-film mammography. Screen-film mammography is widely accepted as an effective breast cancer screening modality. Large randomized screening trials have shown that routine screen-film mammography reduces the breast cancer mortality rate in women age 50 years and older by up to 30% when compared with unscreened controls.[3-5] Moreover, cancers found by screening mammography tend to be smaller and less advanced than those found by breast physical examination, and patients with early stage breast cancer tend to have better survival rates.[6,7]

The success of screen-film mammography is based on the high spatial resolution and the low contrast sensitivity achieved through improvements in x-ray tube design, screen-film combinations, grids, and film processing. The result has been better image quality, lower patient dose, and most importantly, the ability to detect small, nonpalpable breast cancers. However, despite these advances, film-screen mammography operates with a sensitivity rate for women with dense breasts of less than 70%.[8] The relatively poor sensitivity in dense glandular women is in part because of insufficient display contrast between the potentially malignant lesion and the surrounding benign glandular breast tissue. This lack of display contrast is because of the limited range of exposures over which screen-film systems can display subtle contrast differences. Because of the shape of the screen-film exposure response curve, the range of x-ray exposures and optical densities displayed on any single film (called the latitude of the film) is quite limited (Fig 1).

When a lesion is detected mammographically, the specificity, or the ability of the radiologist to predict whether the lesion represents a malignancy, is unfortunately quite low. The additional workup necessary to characterize a mammographically detected lesion may include multiple additional images such as spot compression, magnification views, or images using different exposures. Frequently, these additional images are necessary because of the technical limitations of the screen-film system. Unfortunately, only 5% to 40% of mammographically detected breast lesions prove to be malignant at biopsy.

Digital mammography is believed to have the potential to be more sensitive and specific than screen-film mammography. The sensitivity may be improved by the wide dynamic range of the digital detector, which allows improved detection of lesions in all areas of the breast with a single exposure. The specificity may be improved by the ability to manipulate the image data after acquisition to optimize detection in all breast types (Fig 2). Because digital systems acquire, display, and store the image data independently, each of these functions can be individually optimized. A comparison of these and other characteristics of film-screen and digital mammography is provided in Table 1.

TECHNICAL CONSIDERATIONS

Image Specification

In digital mammography, 12 to 15 bits per pixel are recorded. In some systems, these data may then be stored logarithmically with 10 or 12 bits per pixel. In general, the more bits stored in an image, the better one can depict low contrast objects in the mammogram. There are limitations because more bits per pixel also better record any intrinsic noise sources. The large range of exposures recorded in a digital mammogram represents one of the big challenges in displaying digital mammograms. As

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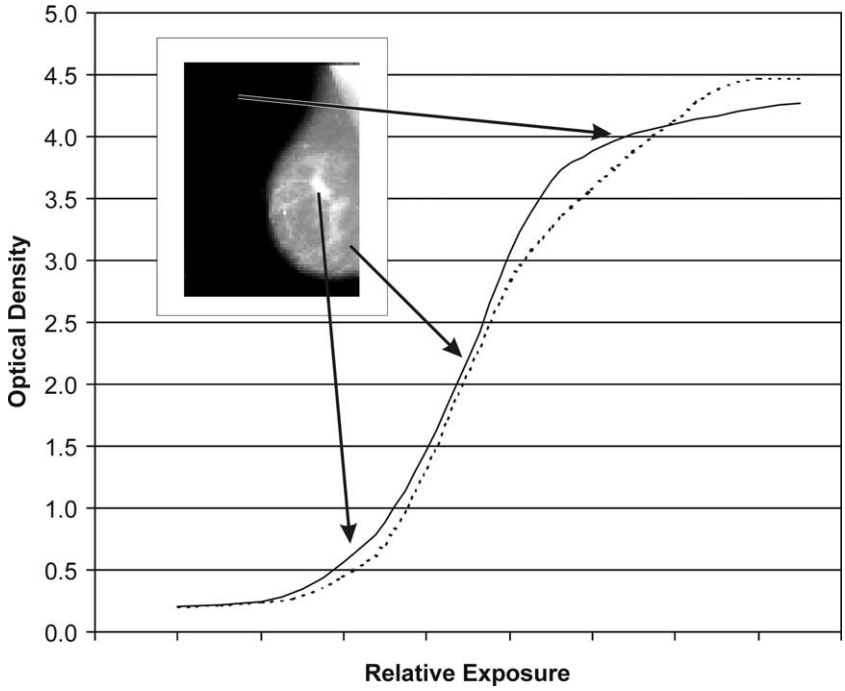

Fig 1. An example of the characteristic curves for 2 different modern, mammographic screen-film systems. For illustrative purposes, the different densities of a mammogram are mapped to regions of the Hurter and Driffield curve.

is discussed later, this is the subject of much research.

In a digital imaging system, the spacing of pixels is given by the "pixel pitch," or the distance between the center of one pixel and the center of its immediate neighbor either horizontally or vertically. The number of pixels in an image will be determined by the area to be imaged and the desired pixel pitch. In digital mammography, the detector size needs to be close to that of the film used currently. Thus, the detector will need to be between 18 $\times$ 24 cm and 24 $\times$ 30 cm in area. Current, experimental data would indicate that a pixel pitch of between 40 μm (0.040 mm) and

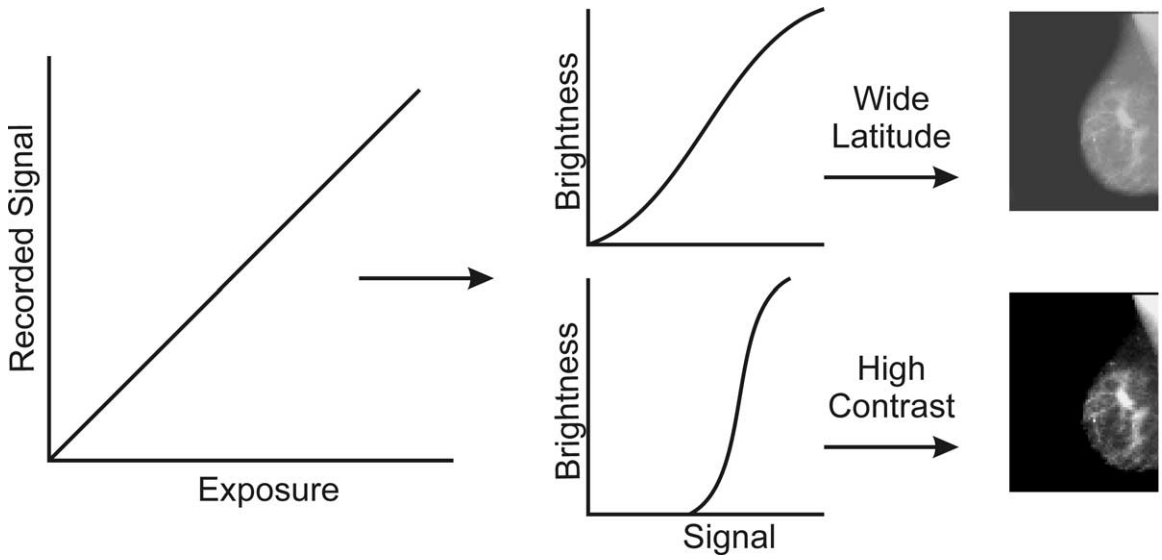

Fig 2. An example of the acquisition and display characteristics of a digital imaging system. The recorded signal is linear with exposure. Thus, if the exposure is doubled, the signal is doubled too. The signal is then mapped through a "look-up table" to determine how the image is displayed. Two examples of possible display parameters are shown.

Table 1. Comparison of the Merits and Problems of Screen-Film Mammography and Digital Mammography

	Film	Digital
Latitude	Moderate	Large
Display contrast	Fixed	Variable
SNR	Limited by film	Limited by radiation
Portability	Easy	Difficult
Archive security	Moderate-poor	Moderate-good
Ease of copying	Poor	Easy
CAD	Requires digitizer	Easy
Teleradiology	Difficult	Easy
Image processing	Not possible	Easy
3-D imaging	Not possible	Possible

100 μm (0.1 mm) is needed in digital mammography. This would lead to very large images of between 1,800 $\times$ 2,400 pixels and 6,000 $\times$ 7,500 pixels. As is discussed later, the size of the image represents another one of the main challenges in displaying the acquired digital data.

Digital mammography remains a work in progress. Over the next few years, digital mammography is expected to very rapidly evolve and mature. There are many unresolved issues, such as the best detector size, pixel size, number of bits, and image processing. For example, there is a factor of 2.5 difference in pixel size between the 4 Food and Drug Administration (FDA)-approved digital mammography systems; this translates into more than a factor of 6 difference in image data size. It is likely that experience will lead to uniformity of design.

The large image format results in difficulties in displaying digital mammography images. The largest image format of the currently available digital mammography systems is 4,800 $\times$ 6,400 pixels. The largest video monitors currently available are approximately 2,500 $\times$ 3,000 pixels and are very expensive. The largest monitors normally used in PACS are just 2,048 $\times$ 2,560 pixels. This means that digital mammograms must be displayed at reduced resolution on a computer monitor. Radiologists have to involve themselves in the time-consuming task of manually magnifying each region of the breast to search for calcifications. It is possible that combining computer-aided diagnosis (CAD) with display systems may obviate the need for manual searching. The number of gray levels in digital mammography images also presents challenges. Today, digital mammograms have between 12 and 15 bits (4,096 and 32,768 gray levels, respectively), whereas typical displays support 256 or 1,024 gray levels. Dynamic range compression must be used to display mammographic data on a computer monitor with adequate contrast. One method, called peripheral equalization,[9] suppresses the large-scale structures such as the roll-off in intensity near the skin line and the pectoralis muscle, thereby allowing finer structures to be displayed with greater contrast.

Current Imaging Technology

There are many different ways to produce a digital mammogram. These can be conveniently grouped into 3 categories: film digitizers, computed radiography, and fully digital mammography. A comparison of the three approaches is summarized in Table 2.

Film Digitizers

Although lacking all of the benefits of true digital acquisition, digitization of mammographic films will become quite common over the next few years. Film digitizers will be used for many reasons. The most common reason, today, is the existence of commercial computer-aided diagnosis devices. Film digitizers have the advantage that they can be used with existing mammography equipment and screen-film cassette systems so they require little initial expenditure. Film digitizers will also be common in the future as more radiology facilities become filmless. Digitizers will be used to convert old images on film into electronic images for comparison and future filmless storage.

All film digitizers work by the same principle. Light is shone through the film on a pixel by pixel basis and recorded. The amount that the light is attenuated is determined by the optical density of the film at that exact location. The light intensity is measured and digitized to produce the pixel value. This process is repeated pixel by pixel until the

Table 2. Comparison of the Different Types of Digital Mammography Systems

	Digitizer	CR	DM
Initial price	Low	Moderate	High
Operating costs	High	Moderate-low	Low
Latitude	Moderate	Moderate-high	High
Noise	Moderate-high	Moderate-high	Low
Spatial resolution	Moderate-high	Moderate	Moderate-high
Contrast resolution	Moderate	Moderate-high	High

Fig 3. A picture of a laser film digitizer. A laser beam scans the film in 1 direction; the film is physically moved in the other direction. In this way, an image is constructed pixel by pixel. (Courtesy of Lumisys, Sunnyvale, CA.)

image is completely digitized. The actual method by which this is accomplished is dependent on the manufacturer. The most common method uses a small, focused beam of laser light that is shone on the film. The beam is swept across the film in 1 direction. At each step across the film, the light is recorded and digitized. In this way, 1 line of an image is recorded. The film is then physically moved 1 line width, and the process is repeated (Fig 3).

By digitizing film, one gains the ability to separate detection and display. Regions of the image can be enhanced to increase contrast. The image is suitable for CAD and other forms of computer analysis. The image can be stored, retrieved, and reprinted without further loss of resolution. However, digitization is not a panacea. The cost of the film represents an ongoing expense for a radiology practice. It is also expensive in terms of labor because all of the handling costs of film exist, and there are additional costs associated with operating the digitizer. But perhaps the greatest problem is associated with the physical performance of such systems. The screen-film combination, with its restrictive latitude, nonlinear response, and mottle all act to degrade the image before digitization. Digitization cannot correct for these effects. Moreover, the process of digitization adds additional noise to the recorded image. Additional concerns related to FDA approval of using digitized films are addressed later.

Computed Radiography

Computed radiography (CR) systems for breast imaging are much like CR systems used in general radiography, differing only in the cassette used and the image processing applied to the image. A CR system consists of 2 components: a CR cassette and a CR reader (Fig 4). The cassette is identical to a film cassette in shape; therefore, can be used in existing mammography machines. The CR cassette, containing a photostimulable phosphor plate, is simply used in replacement of the film cassette. Once the cassette and plate have been exposed in a mammography system, the cassette is then placed in a CR reader. The CR reader removes the photostimulable phosphor plate from the cassette and places it into the reader assembly. A photostimulable phosphor is capable of storing a latent image in the phosphor when exposed to x-rays. The latent image can be read by shining a red laser on the plate. This stimulates the emission of a blue light, which is detected, amplified, and digitally recorded. An image is produced by scanning a laser across the plate in a line and recording the image point by point. The plate is then advanced into the reader 1 line, and the process is repeated until, line by line, the complete image is formed (Fig 5). There is only 1 CR manufacturer involved in clinical trials at the time of publication. The system under evaluation (Fuji Medical Systems, Stamford, CT) has 50- or 100-μm pixels and is

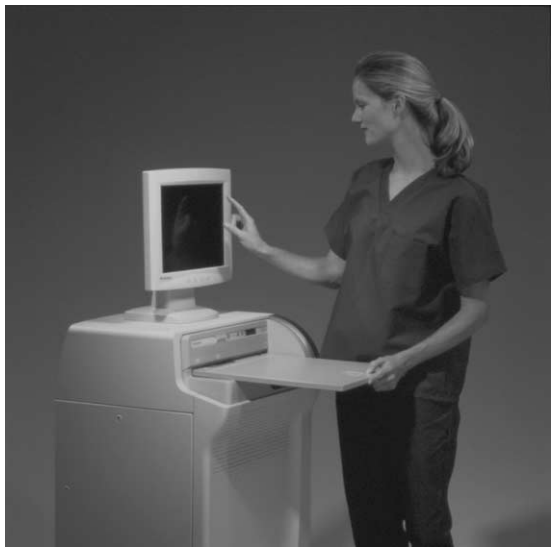

Fig 4. A picture of a compact, modern CR plate reader. (Courtesy of Fuji Medical Systems, Stamford, CT.)

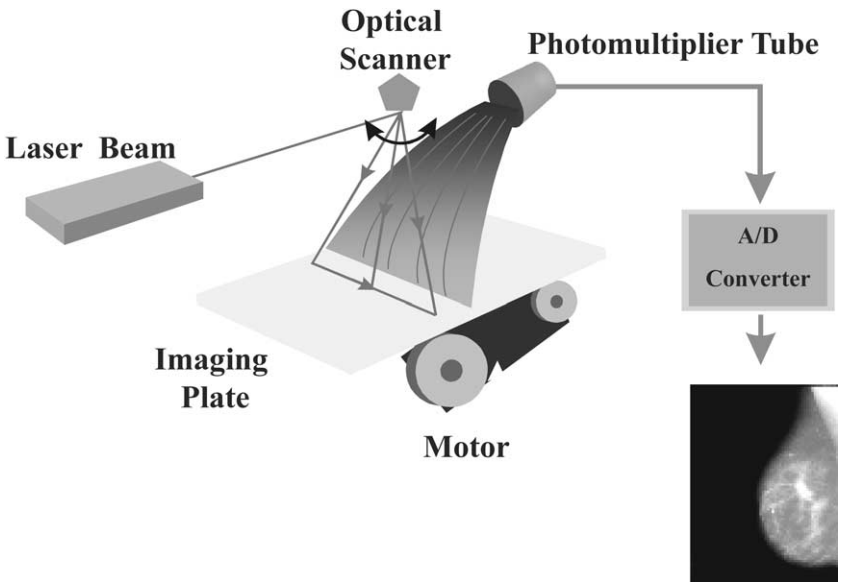

Fig 5. In CR, a laser scans the image plate from side-to-side, while a motor moves the plate under the laser. Light is emitted where x-rays stimulated the phosphor during the exposure. This process is called photostimulated luminescence. After readout, it is necessary to condition the plate before reuse (not shown). (Courtesy of Fuji Medical Systems, Stamford, CT.)

available in 18 cm × 24 cm and 24 cm × 30 cm format cassettes

CR mammography has several advantages over other methods. First, the CR cassettes can be used in the existing mammography machines. Secondly, CR can support both cassette size formats. Thirdly, a single CR reader is capable of supporting the workload from several mammography rooms. Thus, many centers will prefer CR because it is less expensive to install. However, the reduced capital costs will be offset in part or in whole by increased operating expenses. With CR, it is still necessary to have the technologist change the cassette between each image, and it is necessary to carry the cassette to the CR reader. This takes time. Moreover, CR phosphor plates have a limited life expectancy (typically on the order of 10,000 exposures). Thus, a busy imaging center might need to replace each plate every 1 to 2 years. The plates themselves are relatively expensive. For this reason, many sites lease the CR cassettes and plates. Questions have also been raised within the United States and Canada as to whether the image quality is clinically acceptable. By comparison, however, CR mammography is already extensively used in Europe and the Orient. It is generally believed that the questions of operating costs and image quality are best handled in clinical trials, at least one of which, the American College of Radiology Imaging Network (ACRIN) trial, is ongoing.

Fully Digital Mammography

Fully digital mammography (FDM) detectors are the final class of detectors. These detectors are sealed units that are permanently mounted to a mammography system. FDM detectors are electronic devices that directly capture x-ray images. In general, such devices require that a new mammography system be installed. Moreover, there is a requirement of one detector per mammography unit. This increases the initial capital cost of converting an existing mammography facility to digital. However, the operating costs should be much lower because the technologist does not have to handle cassettes, the image can be evaluated for image quality in the mammography room and repeats can be performed immediately, and the detectors have a relatively long life expectancy compared with CR plates. There are a number of different FDM detector designs, and these are discussed later.

Optical Detectors

There are 3 competing technologies available or in clinical trials at this time. The first (Lorad Digital Breast Imager; Lorad Inc, Danbury CT) is based on a detector design used in a number of digital core biopsy units. The detector consists of a phosphor screen, a charged coupled device (CCD) camera, and a fiberoptic taper to couple the light from the screen to the camera. The CCD camera takes the optical image produced by the phosphor

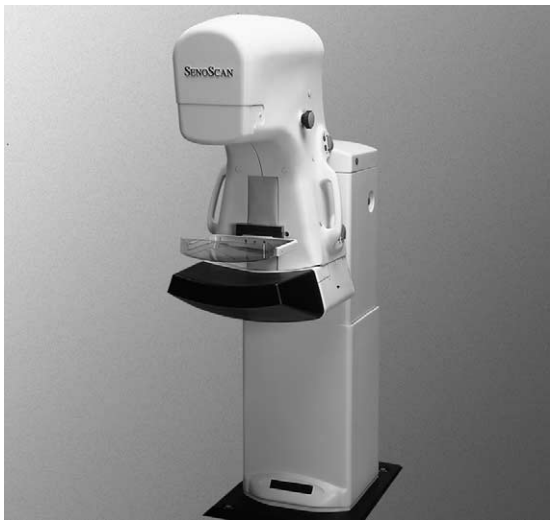

Fig 6. A picture of the Fischer Senoscan scanning digital mammography system. The detector housing on this unit is curved to allow the scanning motion. Because of this curvature, positioning methods differ slightly from existing mammography systems. (Courtesy of Fischer Imaging, Denver, CO.)

and records it to produce an electrical signal. The detector differs from those in biopsy systems in that it consists of a 3 × 4 array of detector elements, each butted tightly to its neighbors. The Lorad system is 18.6 × 24.8 cm, with a 42-μm pixel size. This detector has the smallest pixel size of all of the systems currently available. It also has the largest image matrix size (6,400 × 4,800 pixels). The small pixel size results in very high spatial resolution, but the penalty is a very large image format, which makes display more difficult. This system is now being phased out in favor of a newer amorphous-selenium–based detector described later.

Scanning Detectors

The second FDM detector type (Fischer Senoscan; Fischer Imaging Corp, Denver CO) is also based on a phosphor, fiberoptic, and CCD. However, in this case, the detector is long and narrow (22 × 1.3 cm), as shown in Figures 6 and 7. A complete image of the breast is acquired by scanning the detector array across the breast. This type of detector has the advantage that scattered radiation is almost entirely removed from the x-ray beam, with no dose penalty to the patient (unlike grids in which up to 30% of the primary radiation is absorbed in the grid). As a result, the Fischer system can operate at a lower dose than the other detector types. However, these devices are more complicated and require x-ray tubes and generators that are more powerful. This system produces images that are 4,096 × 5,625 pixels, with 54-μm pixels (22.1 × 30.4 cm). The Fischer system also has a high-resolution mode with 27-μm pixels. This system has the advantage that is covers the largest physical area of any of those currently available.

Thin-Film Transistor Detectors

The final FDM detector type is based on thin-film transistor (TFT) arrays. TFT x-ray detectors can be made in 2 ways. First, they can have a phosphor screen bonded to the TFT array, in which the TFT collects the light produced by the phosphor. Alternatively, they can have a photoconductor coupled to the TFT array, in which x-rays liberate electrons and the TFT array collects the charge. These devices have the advantage that they are relatively simple to produce and have no moving parts. They have the further advantage that they share the same technology as flat-panel computer displays. Thus, although they are expensive today, this is likely to change with mass production. The GE digital mammography system detector (Senographe 2000D; General Electric Medical Systems, Milwaukee, WI) is 18 × 23 cm, with 100-μm pixels (Fig 8). This detector has the largest pixel size of the available FDM systems. It has the advantage that the digital images are quite small (1,800 × 2,300 pixels). Unfortunately, the tradeoff

Fig 7. A computer representation of the scanning detector from the Fischer Senoscan digital mammography system. The detector consists of a phosphor screen (top), optical coupling element, and the optical sensor. The long narrow slot format allows the detector to be scanned across the breast quickly, thereby producing a high-quality image with a minimum of scatter. (Courtesy of Fischer Imaging, Denver, CO.)

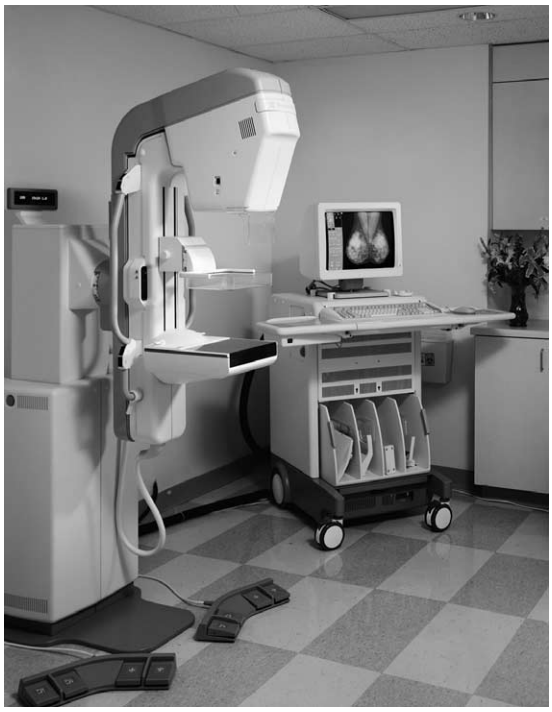

Fig 8. A clinical installation of the GE digital mammography system. The gantry appears much like a conventional GE DMR mammography system. Note that the detector assembly is different. In the background is the technologist's workstation, where images are acquired and previewed before acceptance. (Courtesy of General Electric Medical Systems, Milwaukee, WI.)

is that this device also has the poorest spatial resolution. Although deemed by many radiologists as being clinical acceptable (the GE system is FDA approved), there remains debate in the community as to whether 100-μm pixels are adequate. This is the subject of current research efforts.

Lorad (Lorad Selenia, Lorad Inc, Danbury CT) has also developed a TFT detector that is now FDA approved. This digital mammography detector uses an amorphous selenium photoconductor as the x-ray attenuator. The device has 70-μm pixels and a format of approximately 23 $\times$ 29 cm.

The FDA and Digital Mammography

In the United States, a digital mammography system may only be used if it is FDA approved and it meets 1 of the 2 following criteria. Either the unit must be accredited if a state accreditation body or ACR has received FDA approval to accredit the specific model FFDM unit or the mammography site must have the FDA extend its film-screen certification to cover its FFDM unit.

The FDA's Office of Device Evaluation has approved the following FFDM units for commercial use:

1. GE Senographe 2000D: hardcopy review (approval date: January 28, 2000)
2. GE Senographe 2000D: softcopy review (approval date: November 13, 2000)
3. Fischer Imaging SensoScan (approval date: September 25, 2001)
4. Lorad Digital Breast Imager (approval date: March 15, 2002)
5. Hologic/Lorad Selenia FFDM System (approval date: October 2, 2002)

General Electric's Senographe 2000D systems can be accredited by the American College of Radiology as of February 15, 2003. The remaining manufacturers' FFDM systems must be operated with a FDA-approved extension to an existing film-screen accredited site. In addition to those FFDM systems listed earlier, there are a number of additional systems from a number of different manufacturers that are currently undergoing device development and/or clinical trials.

Each FDA approval was issued with specific requirements for image interpretation. For example, the first approval of the GE Senographe 2000D (January 28, 2000) specifically stated that review of the images must be in hard copy. It was not until November 13, 2000, that the FDA approved a premarket approval supplement to allow softcopy review of images on the GE Review WorkStation. The Lorad Digital Breast Imager was only ever approved for hardcopy review; however, this device is no longer available from the manufacturer. It's replacement (the Lorad Selenia) and the Fischer Senoscan are both approved for both hardcopy and softcopy review. All 3 digital mammography systems approved by the FDA for softcopy review are provided with proprietary workstations. Review of digital mammograms must occur on one of these workstations. Similarly, each device is approved to be used with only one of a limited number of hardcopy laser printers. The absence of a generic FDA-approved digital mammography workstation represents one of the greatest hurdles in the general acceptance of digital mammography. Fortunately, several groups are approaching this task.

Under FDA rules, it is permissible to review digitized film images on a workstation and print such images when needed. However, currently the

FDA requires that film images (whether digitized or not) must meet all physical test criteria, including limiting spatial resolution and contrast specifications for phantom images. As a result, digitization with approximately 25-μm pixels is necessary, and specific printer calibration is required. Also, the display devices must be FDA approved for digital mammography (Chakraborty K, personal communication, April 2003). As a result, digitizing film-screen mammograms is not a practical proposition today in the United States.

PACS Requirements for Digital Mammography

Digital mammograms present specific technical challenges to PACS systems. First, as described earlier, the image data are substantially larger than other image types. The smallest digital mammograms are 2,300 $\times$ 1,800 pixels of dimension 100 μm. The largest digital mammograms are 4,096 $\times$ 5,625 pixels of dimension 54 μm (the Lorad DBI has a larger format but is no longer available). The image data use between 12 and 15 bits per pixel. Images are normally obtained in sets of 4 (left and right medial-laterial oblique [MLO] and craniocaudal [CC] views). In addition, multiple additional views and multiple comparison years can rapidly swell studies to 20 images or more. These place stringent demands on the network, display workstation, and archive. As currently implemented, a 4-view mammography study will be between 32 and 176 MB. Frequently, 3 or more comparison years will be presented, pushing studies to 1 GB of data or more. At the same time, mammography studies must be read very rapidly (typically within a few minutes). The data must also be presented in a variety of different ways, with easy access to the full resolution data (eg, left CC [LCC] *v* right CC, followed by left MLO *v* right MLO, followed by LCC this year *v* LCC last year, and so on). For this reason, dedicated digital mammography workstations are necessary. It is important, however, to ensure that such workstations are validated with digital mammographs from all of the manufacturers of digital mammography systems.

It is also important to recognize that digital mammograms will need to be archived for substantially longer than other radiographs. Current American federal regulations require mammograms to be kept for the life of the patient. This places unusual requirements on the PACS archive.

Digital Mammography and DICOM

Beginning in February 1996, Working Group 15 of DICOM was established to address the needs of digital radiography, including digital mammography. The previous version of DICOM did not make adequate provision for recording many necessary details. The image acquisition parameters, the detector geometry and the anatomy viewed were poorly specified. There was no useful grouping by series, and multiple exposures per image were allowed. There was no specification on the relationship between x-ray intensity and grayscale intensity, and the preferred presentation state was not specified.

DICOM has addressed the needs of digital mammography in a number of separate supplements. DICOM Supplement 32 was conceived and written to provide an information object definition (IOD) specific to digital radiography (DX). Included in that supplement was an IOD specific to digital mammography (MG). The supplement includes the corresponding image storage service-object pair (SOP) classes so that the IODs can be used in network and media storage exchanges. This supplement has since been incorporated into the complete DICOM document in PS 3.3, 3.4, and 3.6.[10-12]

Digital Mammography IOD and SOP

The scope of the MG IOD includes acquisition of image data by CCD-based sensors; stimulable phosphor-imaging plates, amorphous selenium, and scintillator-based amorphous silicon thin-film transistor sensors; and secondary-capture of film-based images. When possible, the IOD used existing attributes and modules, particularly from the computed radiography, x-ray angiography, and XRF IODs. However, new modules were defined to allow for specific characteristics of DM to be described, to mandate the presence of key attributes, and to allow for a broad range of clinical contexts.

The MG IOD specifies an image that has been created by a digital mammography projection radiography imaging device. The MG IOD is used in 2 SOP classes (as defined in PS 3.4 storage service class[11]), a SOP class for storage of images intended for presentation, and a SOP class for storage of images intended for further processing before presentation. This latter class was developed with the mindset that certain CAD algorithms require raw (ie, unprocessed) image data. These 2 SOP classes

are distinguished by their SOP class unique identifier, and the value of the mandatory attribute, presentation intent type (0008,0068).

There are several mandatory MG IOD modules including patient, general study, general series, general equipment, general image, image pixel, and SOP common. These are standard to most IODs. However, the MG IOD further requires the following modules: DX series, mammography series, DX anatomy imaged, DX image, DX detector, mammography image, acquisition context, and value of interest look-up table (VOI LUT) (provided presentation intent = "for presentation").

The mammography series model specifies such attributes as the gantry angle, image laterality, and view code sequences and modifiers. The view codes describe the mammographic view relative to the real-world patient orientation. The descriptors were adapted for the ACR BIRADS lexicon. Included are such descriptors as "MLO, Medial-Lateral Oblique," and modifiers such as "AT-Axillary Tail."

Presentation State

One specific feature of the DICOM MG IOD was the mandatory inclusion of a VOI LUT specification. The desire is to provide a reproducible image presentation state, regardless of the display device. Thus, a paper print, laser film image and grayscale monitor should all provide similar grayscale renditions. This is achieved by specifying a VOI LUT using the DICOM Grayscale Standard Display Function.[13] This requires that the images be stored with reference to perceptually linear *P* values. The displayed image is then rendered with reference to these *P* values to ensure that equal differences in image signal values at various intensities are always displayed as being perceptually equal, regardless of the display device.

Achieving contrast consistency requires action on the parts of the service class user (SCU or the modality) and the service class provider (SCP or the workstation). The SCU must provide a preset contrast, either as a window and level or a VOI LUT, based on the standard display function. The SCP must incorporate a standardized display device that has been calibrated and must be subject to ongoing quality control.

Partial Images

In September 2000, the MG IOD was modified as a result of change proposal CP-193. This proposal added support for multiple images, each containing partial views of a single breast. The feature is implemented using an enumerated partial view field (0028,1350), a referenced image sequence (0008,1140), and partial view description (0028,1351). Thus, a large breast can be imaged with 2 or more digital images per view, and the relationship between the views can be maintained.

Structured Reporting

The advent of the MG IOD has led to the integration of digital mammography into departmental PACS. In so doing, 2 weaknesses were exposed. Computer-aided diagnosis (CAD) imaging systems required some method of communicating results to the PACS, and these results needed to be displayed in some useful and predictable manner. DICOM Working Group 15 was assigned the task of developing a mammography CAD structured reporting SOP class. The class is described in DICOM supplement 50, finalized in May 2001, and now incorporated into the full DICOM Standard (PS 3.3, 3.4, and 3.6). The supplement proved the means for encoding a CAD system's mammographic analysis for transmission and storage to a PACS. A structured reporting methodology is used.[14] More recently, a breast imaging report templates supplement has been drafted and is currently in the public comment phase (DICOM supplement 79). This supplement also is based on structured reporting methods.

CLINICAL CONSIDERATIONS

Clinical Trials

It is likely that the benefits of digital mammography will be first realized in clinical trials. There have been a number of clinical trials to date. One of the first trials, funded by the US Department of Health and Human Services Office of Women's Health, compared digital mammography with screen-film mammography in a diagnostic patient population. Three manufacturers were represented (Lorad Inc, Danbury, CT; Fischer Imaging, Denver, CO; GE Medical Systems, Milwaukee, WI). Two hundred women with heterogeneous or dense breasts were enrolled in 2 patient cohorts at 7 centers across the country. Cohort A included 165 consecutive patients that were referred for problem solving mammography and then were scheduled for a biopsy procedure; cohort B was a random sample of 35 women who also presented for

problem solving mammography but were not recommended for biopsy.[7,15] Eighteen radiologists interpreted all of the hardcopy images, either in screen-film format, the manufacturer's digital recommended format, or in 1 of 2 processed digital formats. ROC analysis was performed on all 4 of these modalities, and the performance was compared for lesion type (mass *v* calcifications) and other patient and machine variables.[16-18] There was no significant difference in the cancer detection rate by the 2 modalities, but there was a difference between machine, processing algorithms, and lesion type. This study served as a pilot study for a larger Department of Defense trial, which began enrolling patients at multiple centers across the country late in the fall of 2000.

The second large-scale federally funded screening trial was conducted at The University of Massachusetts and the University of Colorado using softcopy interpretations.[19] In total, 6,768 women were enrolled.[20] The researchers prospectively identified 51 breast cancers. Screen-film alone detected 16 cancers, digital alone detected 9 cancers, and 18 cancers were detected by both modalities. No significant difference was found in the cancer detection rate. When the cancer cases were reviewed, the major reasons given for discordance in findings between film and digital images were "fortuitous positioning" or "minor differences in opinion" of the readers on subtle cases. There was, however, a reduced recall rate with the digital studies (11.5%) compared with the screen-film studies (15%).[20] The ability to magnify and window and level during the softcopy evaluation of the digital images is thought to, at least in part, contribute to the reduction in the recall rate and hence an improvement in specificity.

The largest trial is one currently being conducted by the ACRIN. Thus far, the improvements of digital mammography over screen-film in specificity appear real. Unfortunately, because of the small number of cancers occurring in a screening population, a very large, prospective trial is necessary to determine if there is a significant difference in the sensitivity of cancer detection between screen-film and digital mammography. The ACRIN trial will overcome these limitations because it will involve nearly 50,000 women across the United States and Canada at more than 30 different sites using 4 different technologies. It is hoped that this trial will provide the long sought after justification for digital mammography.

Operation of a FDM System

Outwardly, a digital mammography machine based on a FDM detector will not look significantly different from a conventional mammography system. The x-ray tube and gantry will be very similar. In fact, most of the digital systems being proposed are actually based on existing film-screen mammography systems. Necessarily, the cassette tray will be absent, and in its place will be a FDM detector of approximately the same overall size. It is unlikely that the FDM detector will be removable. At this time, most FDM detectors are approximately the size of a small cassette bucky. Although the digital detectors are likely to get larger, it is unlikely that digital mammography systems will have both a large and a small detector because of the cost of each detector. Thus, it will not be possible or even necessary to switch detectors.

Positioning the patient may be different with some digital systems because of the size and shape of the detector assembly. Optimal detector designs have a very narrow front profile to ensure that the detector projects well into the axilla in the MLO view. In scanning systems, the detector assembly and compression plate may need to be curved to accommodate the scanning motion of the detector, complicating positioning and compression. Given the relatively small detector size, more patients will require multiples images of each view to completely image the breast.

The FDM system console for the technologist is considerably changed from existing mammography systems. Technique factors are typically chosen manually because most devices currently do not yet provide automatic exposure control. It is also necessary to enter demographics and other information so that the recorded images can be correctly identified. In sites that have mature PACS, the technologist should be able to select all of the demographics using a DICOM modality worklist.

After a FDM image is acquired, additional image information will be recorded such as the technique factors, automatic exposure control settings, and so on. The image will be processed and displayed at the technologist's console to allow the technologist to examine immediately the acquired image for positioning, motion, and image quality.

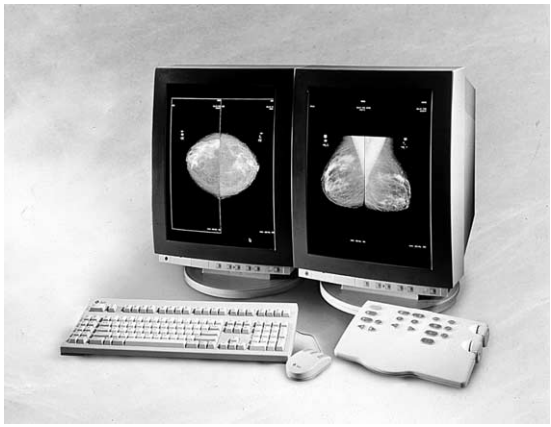

Fig 9. An example of a radiologist's review workstation. Such workstations are expected to be used in the future for softcopy diagnosis. Workstations will allow the radiologist to compare views within one study or among many studies. Tools such as window and level, electronic magnification and measurements will be provided to aid in diagnosis. (Courtesy of General Electric Medical Systems, Milwaukee, WI.)

The technologist should be able to immediately accept or reject the image. If the image is rejected, it is normally possible to specify a reason for the rejection and then repeat the view. If the image is accepted, the next view can be acquired. By the end of the study, the images should have automatically been transferred for diagnosis. Thus, the use of a FDM detector-based mammography system should tremendously improve technologist productivity.

The radiologists may review the images in 2 fashions. In the first, a hardcopy image is produced by printing the image on a sheet of film using a laser film printer. The alternate and preferred method is when the radiologist reads a softcopy image on a computer workstation (Fig 9). Early in the development of digital mammography systems, it was necessary to print hardcopy images. This was made possible because a few experimental high-resolution laser printers were built. Commercial printers are now available. More recently, manufacturers have been developing computer workstations designed specifically for reading digital mammography studies. To date, such workstations have been developed for dedicated use with a single manufacturer's digital mammography system. Computer workstations allow the reader to manipulate the images to optimize the display of the image data. Thus, the radiologist can adjust the window and level of an image, magnify, or otherwise enhance the image to better display the breast. However, to read digital mammograms efficiently, the workstations must be designed to optimally process and hang the images on the screen. Current computer displays are simply not capable of displaying all of the information in the digital images, making this task harder. Softcopy display will only be feasible when computers are capable of displaying cases and allowing reading in the same amount of time as with film.

Breast Center Design

Breast imaging centers of the future are likely to be quite different from existing centers. Two staples of current centers will be absent: darkrooms and filerooms. The backbone of a fully digital breast imaging center will be a high-speed computer network linking all imaging and display devices in the center. When a patient is scheduled or registered at the center, patient demographics will be used in the FFDM modality worklist and the event will be used to initiate retrieval of any old exams for the patient. Each digital mammography room will feed data onto the network. In a screening environment, a complete case might take as little as 5 minutes. In a diagnostic environment, the technologist can telephone or visit the radiologist to determine if additional views are required after the patient's images have been acquired. In principle, the radiologist should be able to view the images as they are acquired and immediately order additional views. In a diagnostic environment, ultrasound machines, magnetic resonance imaging (MRI), and stereotactic core biopsy units could all be on the same computer network so that, with a single workstation, the radiologist could compare multiple modalities.

Economics of FFDM

Despite the expected benefits of digital mammography, the acceptance of the technology may be slow because of the difficulties in cost justification.[2] Currently, many screen-film programs are financially in danger because of low reimbursement rates. Centers across the country have closed because of the increasing demand for support staff to manage the large amount of necessary paperwork to oversee high-quality imaging and patient care as required by Mammography Quality Standards Act. With the reimbursement rate barely covering the overhead, many centers have been forced to close or shift

Table 3. Profits on Screening Mammographic Studies: Screen-Film Versus Digital Technology

	Film ($)	Digital ($)
Radiologists reading $/case*	5.00	10.00
Technical cost		
Film/chemistry	7.00	0
Tech/receptionist†	10.00	7.00
Archiving	10.00	10.00
Billing	10.00	10.00
Expendibles†	5.00	3.00
Equipment/maintenance	5.00	30.00
Facility overhead†	7.00	5.00
Total costs	59.00	75.00
Reimbursement		
Technical	47.08	77.86
Professional	22.15	56.38
Total	69.23	134.24‡
Profit/Loss	+10.23	+59.24

*Assuming rate of $5/min, film reading time = 1 min. For digital, 2 min. at softcopy workstation.

†Assuming 20 cases/d per screen-film unit; 30 cases/d per digital unit.

‡New reimbursement by announced by Medicare, January 8, 2001. Effective April 1, 2001 (22,23).

to more lucrative imaging procedures such as outpatient MRI or computed tomography (CT). This financial crisis is occurring as the demand for high-quality breast imaging is increasing. The backlog to obtain an appointment has reached multiple months at some centers.

Digital mammography may certainly help improve the productivity of centers by eliminating the need for technologists processing films during each examination, but the initial startup cost to go digital will be large. FDM units cost approximately $500,000, significantly more than the approximately $70,000 required for a screen-film unit. In addition, a laser printer (approximately $70,000) will always be necessary even when softcopy reading is the preference. There will always be referring physicians that do not have access to a PACS that will need printed hardcopy images to review. There is, however, some good news regarding reimbursement rates for digital mammographic imaging. Effective on April 1, 2001, FFDM (irregardless of screening or diagnostic indications) will be reimbursed at a rate of 150% of that of diagnostic mammography.[21,22] Therefore, the reimbursement for digital screening mammography will be higher than that for conventional screening mammography. A scheme comparing the potential profits for digital compared with screen-film screening is presented in Table 3. Any higher reimbursement is thought unlikely unless digital mammography is proven to be superior to screen-film in both sensitivity and specificity. Hopefully, the large screening trial overseen by ACRIN will show additional benefits in specificity and patient satisfaction as well as improved sensitivity.

FUTURE OF DIGITAL MAMMOGRAPHY

The true strength of digital mammography is its ability to enable advanced image acquisition and image processing techniques. A few such techniques are described.

Teleradiology

The separation of acquisition and display and the intermediate storage of images in a digital form have numerous advantages. First, the physical location of digital mammography systems can be quite distant from the location in which the images are read. This feature allows a single reading room or even a single radiologist to cover many different mammography facilities. One requirement of such teleradiology installations is the existence of adequate and modern telecommunications equipment. Truly remote locations require the establishment of satellite communications. A number of trial projects have shown the feasibility of such approaches. A number of groups now have or are planning to provide telemammography from a mobile van with satellite communications. These advances in telemedicine are allowing underserved and geographically remote populations access to the latest in breast health care. It is anticipated that telemammography, with concurrent acquisition and review of images, will allow the complete workup of patients in a single visit. This removes the need for callbacks, which are often poorly attended.

Image Processing

The digital format also allows digital image processing to be applied to images. Such processing is designed to use a priori information about cancers, benign lesions, and normal tissue to enhance features that should be brought to the attention of the radiologists. One type of simple image enhancement is contrast enhancement, a process whereby the contrast with which different structures in the breast is altered to improve display. Different methods to perform this exist, including those that deal with the problem regionally and

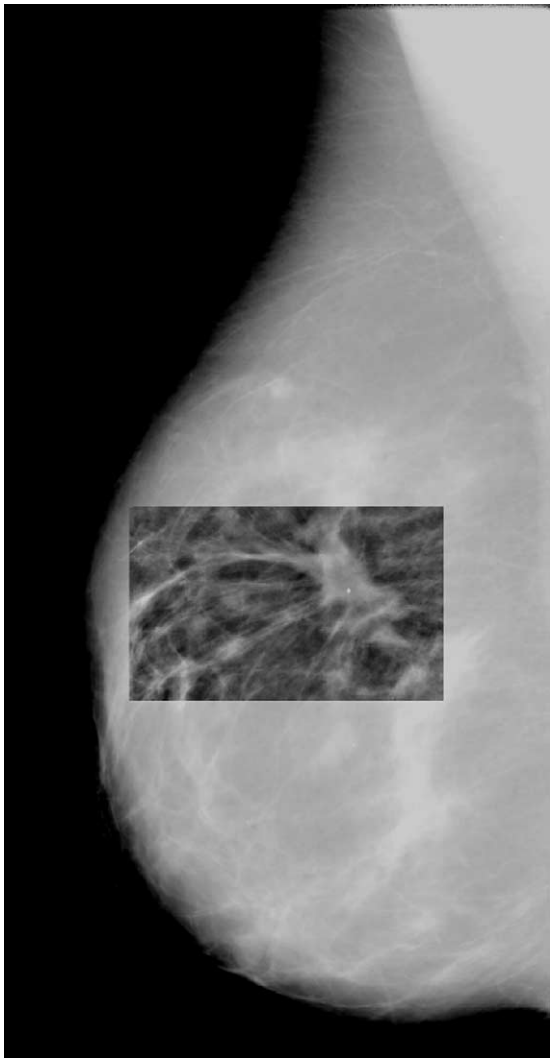

Fig 10. An example of image processing applied to an image. In this instance, a small region of the mammography has been modified to enhance the contrast (conspicuity) of a cancer.

globally. An example of a regional enhancement is shown in Figure 10. Global enhancement of contrast includes a concept known as peripheral equalization. This is a process whereby the areas under the pectoralis muscle and near the periphery of the breast are made brighter or darker to match the appearance of the tissue in the center of the breast. This allows the radiologist to view the entire breast without manual adjustments to the viewing window or level.

It is also possible to alter the spatial display of the mammogram by enhancing edges or smoothing the image. Enhancing edges has the benefit of making small objects more visible, such as speculations or calcifications. Unfortunately, the penalty that is paid is an increase in the displayed noise. Smoothing an image will suppress edge information but will make large low-contrast objects, such as cysts or lymph nodes, easier to see. More complicated methods of image processing are also being investigated, including wavelets, neural networks, genetic algorithms, and nonlinear processing techniques.

CAD

There is one particularly exciting application that combines image processing with artificial intelligence algorithms to produce CAD.[23] It is hoped that these CAD systems will be able to act as a second reader for radiologists. Several commercial CAD systems are now FDA approved and commercially available at the time of writing. The systems algorithmically evaluate digitized film mammograms for evidence of suspicious masses or calcifications. After reading the mammogram, the radiologist can display the computer findings and use these to double check their findings. At the current time, several manufacturers are adapting their screen-film CAD algorithms to support the various FFDM systems that are available. The final role of CAD in digital mammography remains to be determined.

3-Dimensional Imaging and Other Applications

The digital image format also allows us to consider other more esoteric approaches to imaging the breast. For example, image data from 2 or more views of the breast can be combined to produce 3-dimensional images of the breast. If the data are acquired over a small angle (3°-8°), then the images can be viewed stereoscopically. If more views are acquired over a larger angle (30°-45°), then it is possible to present truly 3-dimensional tomosynthetic images of the breast, where the breast can be divided into slices and viewed slice by slice. If additional views are acquired (90° or more), then CT-like images are possible. Such techniques offer the opportunity to remove the clutter of overlaying tissue that often obscures lesions. These techniques also allow the radiologist to differentiate between artifactual superposition of distinct tissues from true lesions. Three-dimensional techniques that provide CT-like image data should

also allow the differentiation of tissue by the attenuation coefficients (a fundamental property of tissues). For example, it may be possible to distinguish between the 2 most common forms of calcifications by this method.

Another technique that has been proposed is digital angiography of the breast.[24-27] This is sometimes also called contrast-enhanced mammography. In this approach, an intravenous contrast agent is injected into the patient. Lesions with an advanced blood supply are more likely to take up the contrast agent preferentially as compared with the surrounding tissue.[28] The result is that the lesion may be made more visible. This is the underlying mechanism for perceiving cancers in breast MR. However, the x-ray technique has the advantage that the contrast-enhanced lesion can be easily correlated with the unenhanced x-ray images. Also, the x-ray approach is amenable to image-guided biopsy. Finally, the x-ray technique would be less expensive than breast MR.

CONCLUSIONS

The transition to digital mammography is a necessary step in the ongoing process of improving mammographic image quality and advancing the early detection of breast cancer. Yet, digital mammography remains a work in progress. Initial results already have shown that the transition to digital mammography will result in improved mammographic image quality. It still remains to be shown whether digital mammography will make it possible to detector cancers earlier. However, initial evidence does show that digital mammography can better image women with dense breasts. It is hoped that these advances will lead to a reduction in the number of callbacks in screening and a reduction in the number of biopsies that must be performed in the diagnostic environment.

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