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Digital Mammography

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1. Introduction

Full-field digital mammography has transformed mammography over the past decade. The technology has reached a level of maturity that has caused an increase in its utilization in hospitals and clinics world-wide. This chapter will discuss the advantages and disadvantages of the technology as compared to screen-film mammography, a discussion on the basic physics of digital mammography and the currently available detector technologies. In addition to the technical aspects, this chapter will explore the clinical trials published to date regarding the technology performed compared to screen-film mammography in both screening and diagnosis, and evaluate the various imaging process algorithms that have been applied to digital mammography. Finally, digital mammography's impact on daily clinical workflow will be discussed along with future directions for this technology.

Digital mammography has become part of everyday clinical practice across much of the developed world. However, I find it interesting that most of the radiologists in training (residents and fellows) have no concept of what "film" is and was to our practice of mammography. They are used to the digital age of computers, personal electronic devices and electronic social networking through the internet. To the present generation, softcopy display in some form is a way of daily life. To others who have devoted their medical career in screening and in the diagnostic evaluation of women for breast cancer, it has and continues to be a learning and transitional process. In order to understand and fully appreciate the advances in mammography technology, it is important to understand the natural history of breast cancer and the challenges and changes that our specialty has undergone and how it continues to evolve.

Cancer of the breast is not a new disease. It has been present since ancient times and was documented by the early Egyptians, Greeks, Babylonians and Chinese (Bland, 1998). If a woman presented to her local "healer/physician" with a lump in her breast, treatment may have stemmed from charms and chants to applied ointments or possibly intervention with a knife and hot irons for cauterization. For women, treatment for breast cancer was similar for centuries and prognosis was generally poor.

It was not until 1913, when Albert Salomon, a German surgeon, evaluated 3,000 mastectomy specimens in a radiology-histological study on comparing the x-ray findings with microscopic pathology that it became evident to evaluate radiography technology for breast cancer detection. In the 1920's and 30's, several attempts to implement radiography for the diagnosis of breast abnormalities were done by O. Kleinschmit, W. Vogel, J. Goyanes, and

Gershon-Cohen; however, it was not until four decades later that the use of x-rays for the diagnosis of breast became more established (Picard, 1998).

The modern era of mammography began in the late 1960's as the technique was refined with dedicated equipment, such as that developed by the physicist C. Gros (Van Steen & Van Tiggelen, 2007). During this time, the film industry began to develop dedicated mammography film with high-quality images, reliable capture parameters and reduced radiation dose to the patient. Previously, a general x-ray tube with industrial film (low sensitivity) with high radiation exposure to the patient was used to image the breast. By the late 1970's and 80's, dedicated mammography was established, and mammography was identified as the most reproducible and cost effective modality to screen the general population. In clinical studies with follow-up of patients, it was shown that early detection of breast cancer has led to a reduction of the mortality rate (range 18-30%) (Elmore, 2005; Hendrick, 1997; Nystrom, 1993; Strax, 1973; Tabar, 2011).

It is estimated that 1.38 million women were diagnosed with breast cancer worldwide in 2008. This accounted for approximately a tenth (10.9%) of all the new cancers and 23% of all female cancers (Ferlay, 2010). Female breast cancer rates vary. The highest rates are in Europe and the United States and the lowest are currently in Africa and Asia. Currently, breast cancer is the second leading cause of death in the women of the United States (Center of Disease Control, 2010) and the United Kingdom (Ferlay, 2010). Because of these cancer-related deaths and the continued incidence of the disease worldwide, further emphasis has been placed on using mammography as screening tool for early detection.

2. Physics of digital mammography

2.1 Comparison of screen film mammography

Screen-film mammography (SFM) has been (and continues to be in some countries) the standard imaging modality for detecting suspicious lesions at an early stage in the breasts of asymptomatic women. Film is a very useful medium that has been optimized over the past 50 years. SFM has a high sensitivity (100%) in detecting suspicious lesions in breasts composed primarily of fatty tissue (Dujm, 1997; Saarenmaa, 2000). However, that value is significantly decreased in breasts composed of dense glandular tissue because breast cancers are frequently similar in radiographic density to the fibroglandular tissue. Consequently, 10-20% of breast cancers are not visualized (Burrell et al., 1996). Also, part of this decrease in lesion conspicuity may be due to the film itself since it serves as the medium of image acquisition, display and storage. After the film is exposed and processed, the image cannot be significantly altered and portions of the mammogram may be displayed with suboptimal contrast. Only slight improvements can be made with a "hot light" or magnifying glass. If improvements cannot be made, the patient may need to undergo another mammographic image and consequently be exposed to more radiation dose.

Another limitation of film is that different regions of the breast image are represented according to the characteristic response of the mammographic film. There is a trade-off between the dynamic range (latitude) and contrast resolution (gradient). This is illustrated in Figure 1 by the sigmoid Hurter and Driffield (H&D) curve that is characteristic for a given type of SFM system under specific conditions. The H&D curve demonstrates the relationship between x-ray exposure, image density and contrast (Feig & Yaffe, 1998).

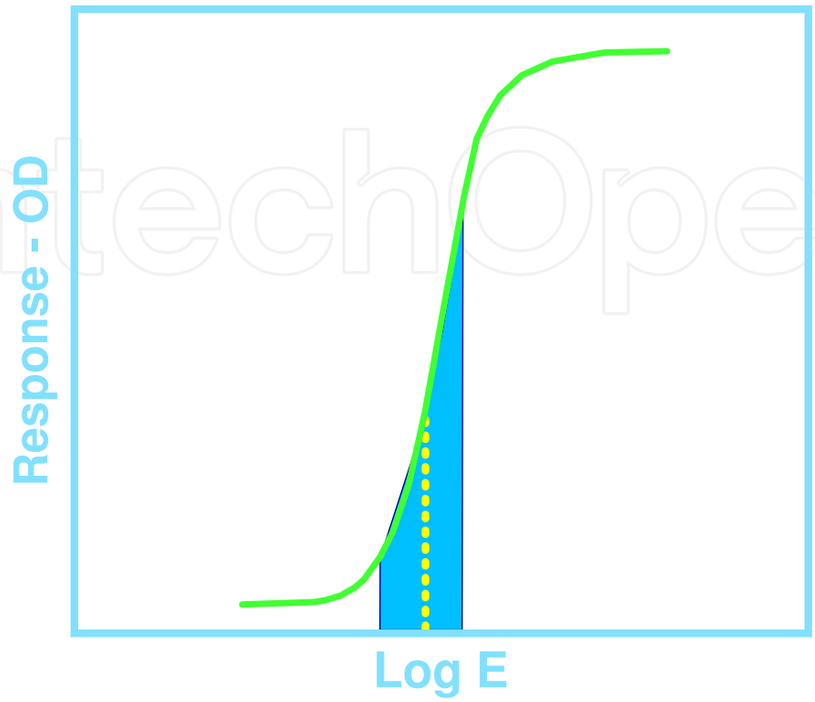


Fig. 1. Hurter and Driffield (H&D) curve for a SFM system where Log E represents the relative exposure and OD is the optical density.

With the limited range of soft-tissue densities in the breast, mammography requires high contrast. The fixed characteristics of an H&D curve mean that if high contrast is to be obtained in intermediate-density tissue, there must be lower contrast within the thicker, denser fibroglandular tissues represented at the toe of the curve and the fatty tissue represented at the shoulder of the curve (Feig & Yaffe, 1998). Consequently, mammographic film has a limited dynamic range.

Digital mammography offers several advantages over SFM. The digital system separates the process of x-ray detection from image display and storage. Since image acquisition and display are separated, each can be optimized. Digital detectors have a wider dynamic range (linear response) compared to film as seen in Figure 2. Digital detectors have increased efficiency at a lower radiation dose in the detection and depiction of the x-ray photons compared to film (Pisano, 1998; Feig, 1996). In addition, digital detectors (even with a lower spatial resolution than film) also appear to improve lesion conspicuity through their improved efficiency of absorption of x-ray photons, a linear response over a wide range of radiation intensities and low system noise (Feig & Yaffe, 1998). Plus, post-processing software can be utilized to assist the radiologist in evaluating the images for suspicious findings by altering contrast and brightness automatically or manually. With digital mammography, computer aided detection software can be utilized at a push of a button instead of waiting for someone to digitize the film images for each case. With digital mammography, the images can be displayed with hard and softcopy formats.

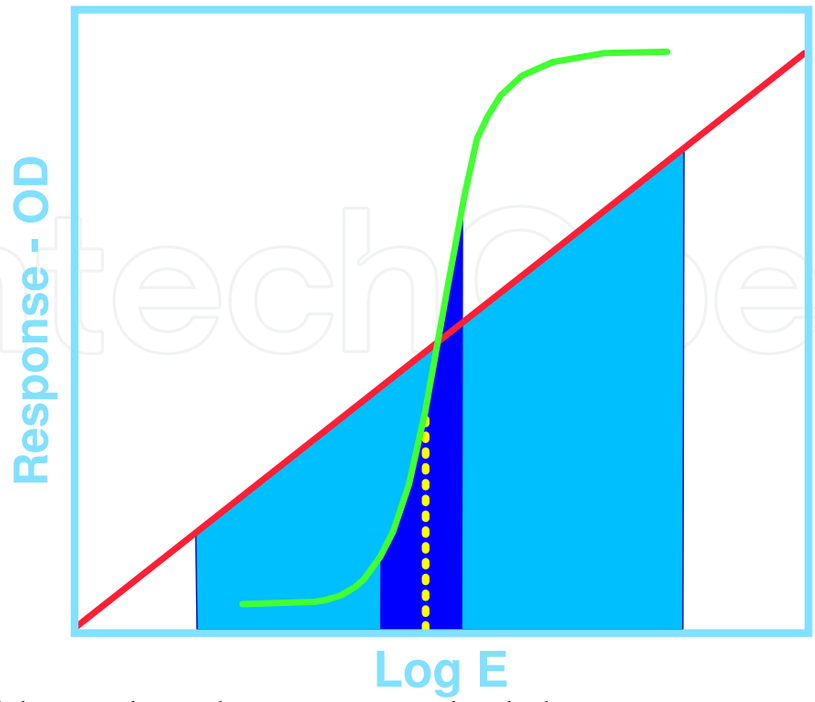


Fig. 2. Digital detectors have a linear response and wide dynamic range compared to SFM. The digital response is seen as the diagonal line. Log E represents the relative exposure and OD is the optical density.

2.2 Image acquisition

To obtain a mammographic image, x-rays must be generated from a target. A metal filter in the system will remove the majority of non-desirable energies of the beam before it enters the patient. In a SFM system, the automatic exposure control (AEC) will end the film exposure when the tissue above the AEC has transmitted a suitable number of x-rays to expose the film where its gradient (slope of the H&D curve) will be near or at its maximum value and there will be acceptable image brightness (Yaffe, in Bick & Diekmann, 2010). However, other areas of the breast may be suboptimally exposed - dense areas underexposed. In the SFM system, the intensifying screen produces light that is proportional to the amount of energy deposited by the x-rays. The now exposed film will be chemically processed to produce the permanent mammographic image of the different optical densities. The mammographic film serves the three roles of image acquisition, display and storage.

In digital mammography, a detector replaces the screen-film system. The detector will still be exposed to x-rays just as in a SFM system. The detector produces a signal that is linearly proportional to the intensity of the photons transmitted by the breast; therefore, it is possible to produce a better representation of the x-ray transmission of all parts of the breast (Feig & Yaffe, 1998). For digital mammography, AEC still plays a role. Unlike SFM where it was important in determining image contrast, in digital mammography the AEC aids in obtaining a predetermined signal-to-noise ratio and a reasonable radiation dose to the breast. After being exposed, the digital detector produces an electronic signal that is

digitized and stored. With digital mammography, wet chemical processing is eliminated and the detector's only role is image acquisition. Another added benefit of a digital detector is the elimination of film granularity that adds noise to a system.

2.3 Properties of digital images

Spatial resolution in SFM is commonly based on the limiting resolution in terms of line-pairs/mm from a bar pattern, Figure 3. This test can be very subjective. Therefore, in order to evaluate spatial resolution more quantitatively, it can be evaluated with the modulation transfer function (MTF). The MTF describes how well the entire imaging system or one of its components is performing in the form of a sinusoidal shape (Bunch, 1987; Pisano, 2004). The MTF describes how well each spatial frequency is transferred through a system. The MTF of a system is the product of the MTFs of the components of each system. As seen in Figure 4, at low spatial frequencies the MTF value is at or near the value of 1.0 and the MTF value decreases with increasing spatial frequency. The MTF of SFM extends beyond 20 cycles/mm and it is predominately the result of the screen since film has a very high MTF (Pisano et al., 2004). In a digital system, the MTF will be based on the focal spot, patient motion, lateral spread of signal (light or electronic charges) in the detector, and spatial sampling.

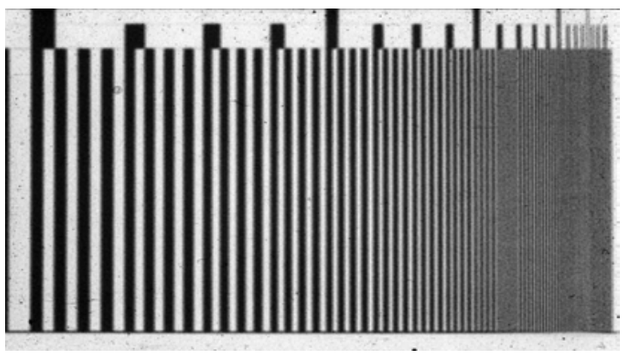


Fig. 3. Bar pattern of line-pairs/mm for determining spatial resolution for SFM.

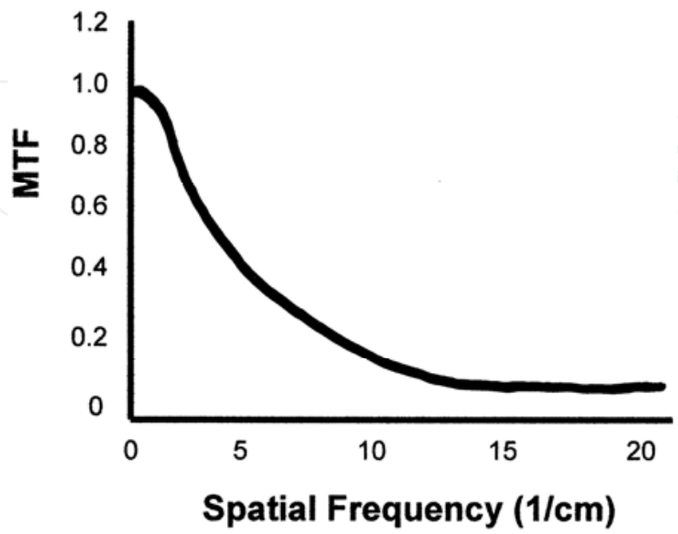


Fig. 4. Modulation Transfer Function (MTF) of a screen film system.

Spatial sampling is unique to digital mammography and affects resolution. The signal from each detector element (del) is averaged over the sensitive region or aperture (d). This will result in a decrease of the MTF of a detector (Pisano et al., 2004). The size of the del will supply the information displayed in one pixel. Dels can range from ~ 44 to 100 μm (0.04-0.1 mm). Dels are arranged with a specified center-to-center distance or pitch (p), Figure 5. If the pitch is too large, information will be lost in the sampling process.

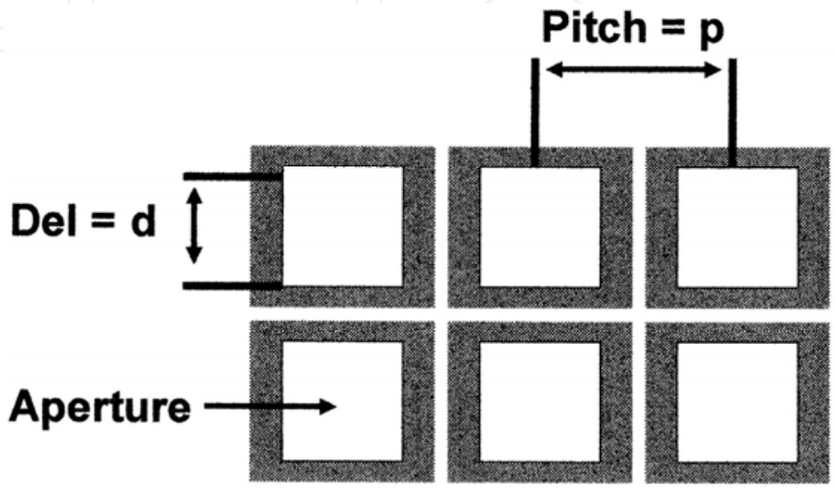


Fig. 5. Example of a detector composed of detector elements (d) that contain a sensitive region called the aperture. The distance between the centers of dels is the pitch (p).

2.4 Radiation dose

The flexibility of digital with decoupling allows for decreased radiation dose compared to SFM. Several factors account for this decreased dose. First, image brightness (display) is now independent of acquisition. Since brightness is not dependent on the amount of x-ray exposure needed to produce the image, it allows the user to determine the dose selection. Secondly, digital detectors have higher detective quantum efficiency with decreased signal-to-noise-ratios than a SFM image receptor (Pisano et al., 2004). Consequently, a more penetrating x-ray beam can be used with digital mammography, and this result in a lower patient dose. Currently, some digital mammography systems have dose reductions of 25-30% compared with SFM (Heddson, 2007; Hendrick, 2010; Yaffe, in Bick & Diekmann, 2010).

3. Digital mammography detectors

The detector is one of the key components of a digital mammography system. It produces an electronic signal that represents the pattern of x-rays transmitted by the breast. Optimally, a detector should include the entire range of x-ray intensities transmitted by different areas of the breast without loss of information. Besides the detector interacting with x-rays transmitted by the breast and absorption of the energy carried by the x-rays, it performs several other important functions. These other functions (in order) include: conversation of the transmitted and absorbed energy to a usable signal (light or electronic charge), collection of this signal, secondary conversion if needed (phosphor-based detectors), readout of the charge, amplification, and finally digitization of the information (Pisano et al., 2004; Yaffe, in

Bick & Diekmann, 2010). To provide high quality images, all of these steps need to be optimized. As a result, detectors are characterized by their quantum efficiency, sensitivity, spatial resolution, noise, dynamic range and linearity of response.

3.1 Quantum efficiency & noise

Quantum interaction efficiency describes the quantity of x-rays that reach the detector and interacts with it to produce signal. The quantum interaction efficiency of a detector can be increased by increasing the thickness of the detector. However, quantum interaction efficiency can be reduced by using higher energies since this will decrease the x-ray attenuation coefficient (Pisano et al., 2004). An exception to this is when the x-ray energy exceeds an absorption edge of the detector material, as in CsI. Thus, quantum detection efficiency will influence the sensitivity of detector. Detector sensitivity will also be dependent on the amount of energy required to produce an electron or light quantum to be measured¸ the efficiency of signal collection and measurement of the charge produced (Yaffe, in Bick & Diekmann, 2010).

Quantum noise (or mottle) is the result of random fluctuation in the x-ray beam. It is independent of breast density composition. Quantum noise can be statistically described by the Poisson distribution (Pisano et al., 2004). To decrease the quantum noise of an image (increase the signal-to-noise ratio), the amount of x-rays absorbed by the detector have to be increased. This can be performed by using a detector with better quantum detection efficiency or by increasing exposure (mAs).

Another source of fluctuation or noise that decreases image quality is structural noise. With the use of a detector, digital mammography has eliminated the structural noise of film granularity (random structure of the grains of silver halide) (Bunch, in Van Metter & Beutel, 1997). However, in digital mammography there is some structural difference across the detector and this is associated with spatial variations in detector sensitivity. Because these differences may remain constant over time, they do no represent traditional noise. In digital mammography this is referred to as "fixed pattern noise" or "structural noise". Through the use of image correction with flat-fielding or gain correction this can be removed as seen in Figure 6.

3.2 Detector systems

There are two main types of digital mammography imaging systems. One type uses a full-field detector to be imaged, Figure 7. The detector in this system is stationary and the system may utilize a grid to remove x-ray scatter, thereby increasing the signal-to-noise ratio. The second major type of digital mammography system is a scanned-slot device that uses a detector rectangular in shape, Figure 8. The detector in this type of mammography system scans/moves across the inferior portion of the breast support at the same time a collimated x-ray beam moves during the image acquisition. The detector and the x-ray beam move in synchrony. In this latter type of system, no grid is needed since there is less scatter radiation from a narrower x-ray beam. Regardless of system type, it is important that the system is able to image as close to the chest wall as possible and for the system to accommodate all breasts sizes.

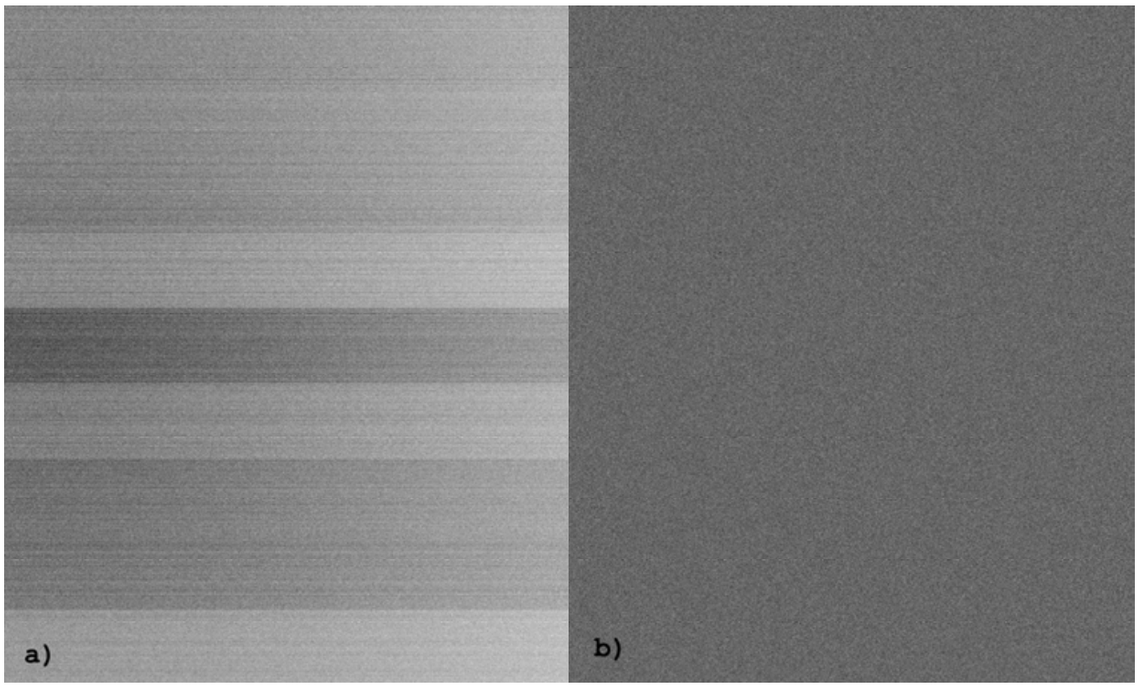


Fig. 6. Example of flat-field correction. a) Uncorrected image. b) Image after flat-field correction. Courtesy of Martin Yaffe, PhD; Sunnybrook Health Sciences Centre, Toronto, Canada. (from Digital Mammography, eds. ED Pisano, MJ Yaffe, CM Kuzmiak. Lippincott, Williams & Wilkins, a Walters Kluwer Company, 2004. With permission.)

Fig. 7. Example of a FFDM detector system. Pictured is the General Electric Senographe Essential.

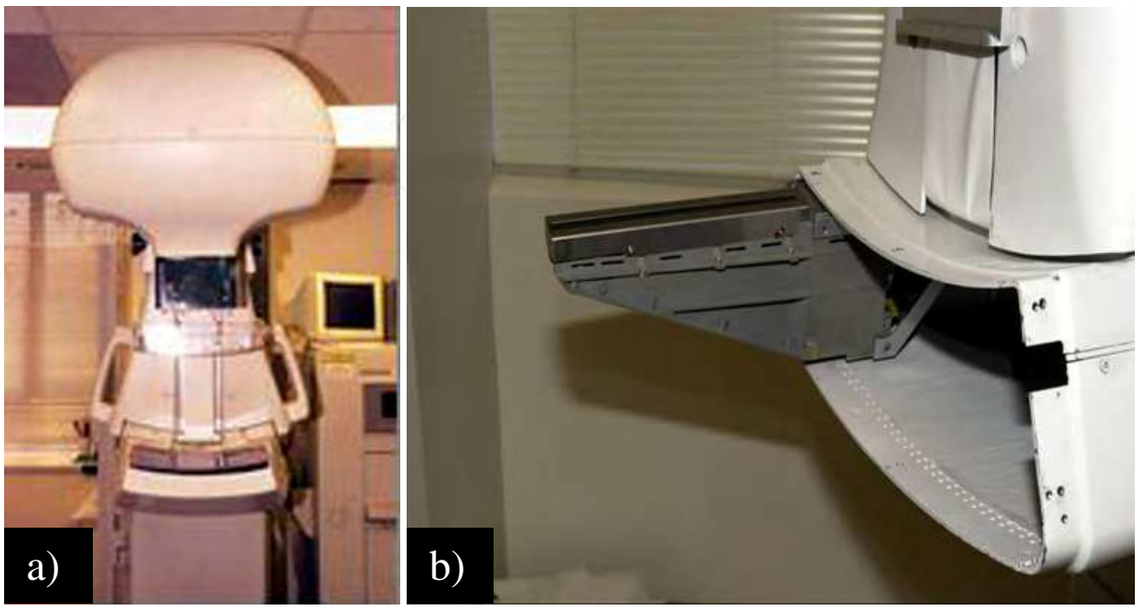


Fig. 8. Example of a scanned-slot digital mammography system. a) Pictured is a Fisher SenoScan mammography unit. b) Image of the detector.

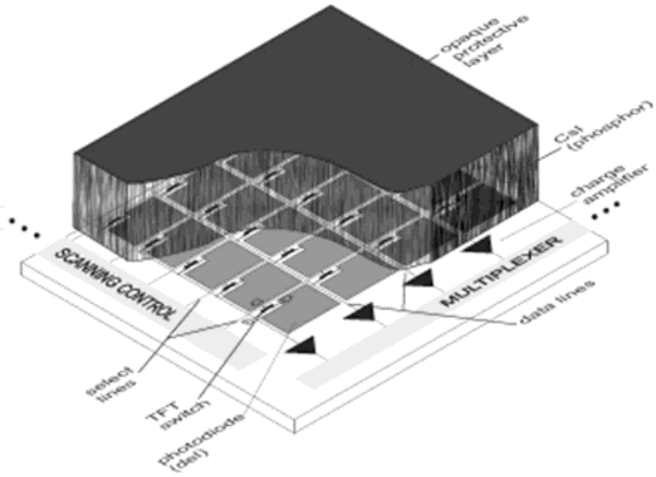
3.3 Detector types

Many different types of detectors are used for digital mammography and these will be briefly described in this section. The first four discussed are used in direct radiography (DR) mammography systems and the last one is used in a computed radiography (CR) system.

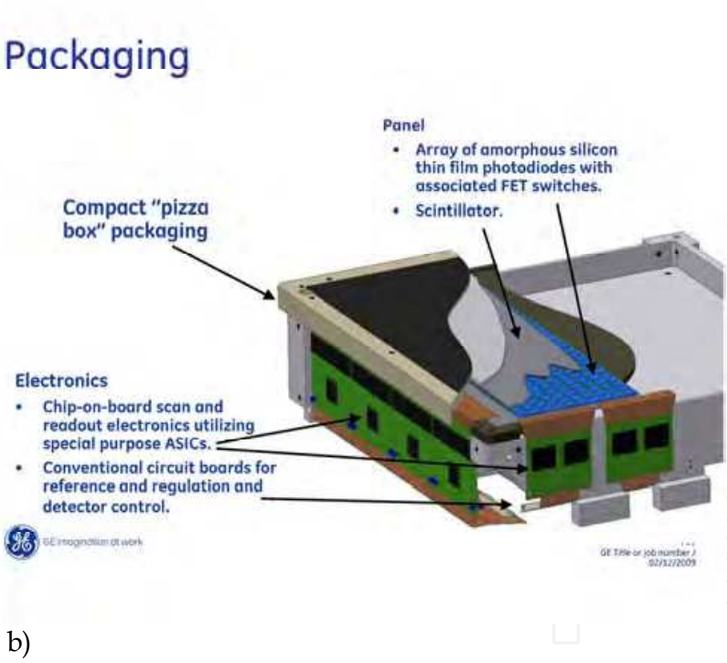
3.3.1 Phosphor flat panel

A phosphor flat panel detector, Figure 9, is constructed of a plate of amorphous silicon. Through solid-state manufacturing, a rectangular array of light-sensitive photodiodes with a layer of thallium-activated cesium iodide phosphor, CsI (Tl) are deposited onto the plate. The photodiodes are the dels of the detector. These dels will detect the light emitted by the phosphor and create and store an electric charge.

Besides each del containing a photodiode, it also contains a thin film transistor (TFT) switch, and these are interconnected with an array of control and data lines. A readout line is present along each column of the detector, and when a control line is activated it activates all the TFTs in that row (Yaffe, in Bick & Diekmann, 2010). The signal from the row of activated dels is then transferred to an amplifier and digitizer. The digitized information from one del will represent the information corresponding to a pixel of the image.



a)



b)

Fig. 9. Illustrations of a CsI-amorphous silicon photodiode flat panel detector. a) Generic detector. Courtesy of Martin Yaffe, PhD; Sunnybrook Health Sciences Centre, Toronto, Canada (from Digital Mammography, eds. ED Pisano, MJ Yaffe, CM Kuzmiak. Lippincott, Williams & Wilkins, a Walters Kluwer Company, 2004. With permission. b) Commercial detector. (Courtesy of General Electric Medical Systems, Milwaukee, WI).

In this type of detector, CsI is used because of its crystal structure. These crystals can be commercially grown to form needle-like or columnar structures. Unlike granular phosphors that allow the produced light upon x-ray absorption to move laterally in the system leading

to increased line-spread function in SFM, CsI crystals used in digital systems are more efficient at transferring the light produced (Pisano et al., 2004). This increase in efficiency is because the CsI crystals act as fiber optics. Consequently, the detector can be made thicker without loss of resolution.

An example of a commercial system with this detector is produced by General Electric Medical Systems (Milwaukee, WI), Figure 7. The field size is 24 cm x 31 cm, the del pitch is 100 μm, and the digitization is 14 bits (Ghetti et al., 2008). Of interest, to correct for inhomogeneous areas in the detector, flat-fielding or gain correction requires that an offset value and a gain be measured for each del (Pisano et al., 2004).

3.3.2 Phosphor-CCD system

A phosphor-CCD system also uses CsI(Tl) as the material for x-ray absorption to light conversion in the detector. However, the CsI(Tl) is deposited on a rectangular fiber-optic coupling plate. The fibers conduct the light from the CsI to a charge-coupled device (CCD) array. The CCD is an electronic chip containing rows and columns of light-sensitive elements. The CCD converts the light into an electronic signal that is digitized.

The phosphor-CCD system detector is long, narrow and rectangular in shape, approximately 1 cm x 24 cm as seen in Figure 8b. The x-ray beam is collimated into a narrow band since it and the detector scan across the breast in synchrony, Figure 10. The charge created in the CCD is transferred down the columns from row to row at the same rate, but in opposite direction to the physical motion of the detector. The bundles of charges are integrated, collected and read out corresponding to x-ray transmission on the detector for each x-ray path through the breast (Pisano et al., 2004). This is known as time-delay integration.

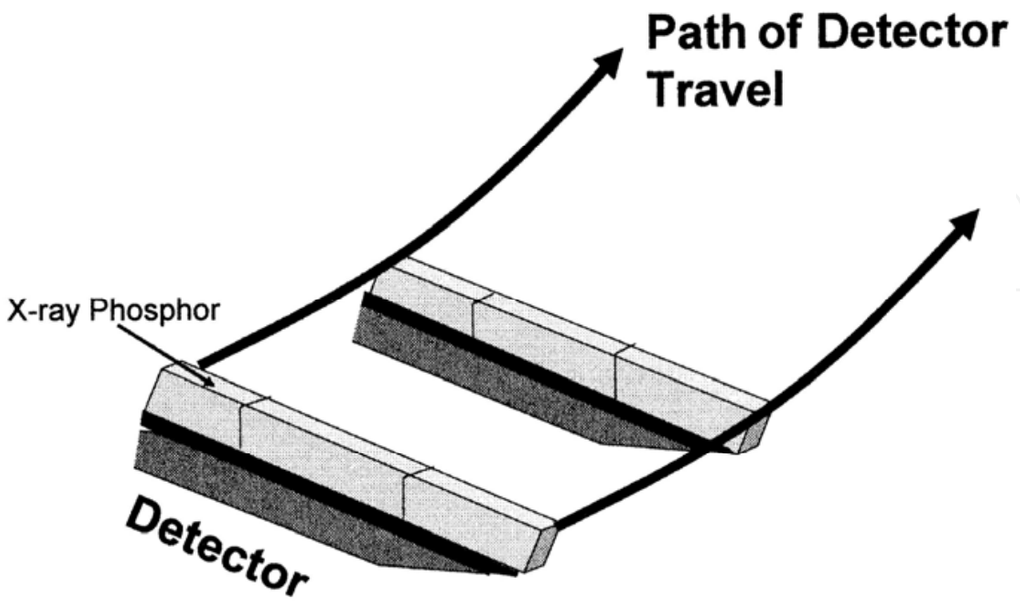


Fig. 10. Schematic of the path of detector travel in a scanned-slot detector system.

A major advantage of this scanned-slot system is the result of the x-ray beam being collimated and only part of the breast being imaged at a time. Consequently, the transmitted x-rays are not lost (scatter-to-primary ratio is reduced), resulting in a grid no longer being needed. Therefore, the dose should be reduced. A limitation of this type of system is that it requires a longer image acquisition time.

A commercial unit like this was originally marketed by Fischer Imaging Inc (Denver, CO) as seen in Figure 8. It has dels of 54 µm with digitization performed at 12 bits. Of interest, over a small area of the detector, data could be read out at 27 µm to provide a high-resolution mode.

3.3.3 Selenium Flat Panel

A selenium detector utilizes a thin layer (100-200 µm) of amorphous selenium for x-ray absorption. When an x-ray is absorbed by this material, it causes some electrons in the selenium to be liberated. The now "freed electron" and its corresponding "hole" from its departure create an electron-hole pair. This electron-hole pair creates the signal (Pisano et al., 2004). When electrodes are placed above and below the selenium and an electric field is applied, this causes the charges to move toward the electrodes. The signal is collected by one of the electrodes that are composed of a large matrix of dels. The dels act as capacitors to store the charge. At the corner of each del is a TFT switch. The readout of the charge is performed in the same manner as for the phosphor flat panel detector.

A detector of this kind is produced by Hologic (Danbury, CT). The Hologic detector dels are 70 µm with 14-bit digitization. Anrad (St Laurent Quebec, Canada) produces another selenium flat-panel system with 85 µm dels. To increase the geometric efficiency of this type of detector and to have a del of 50 µm, Fujifilm Medical has developed an amorphous selenium detector that has two separate layers of selenium as seen in Figure 11. In the Fuji system, the upper layer of selenium absorbs the x-rays and produces the electron-hole pairs. The charge is then stored in each del. The lower selenium layer will transfer the stored charge to a set of readout lines and then it will be transferred to an amplifier and digitized (Yaffe, in Bick & Diekmann, 2010). The information from one del will be used to create the information corresponding to a pixel of the image. This system has a bit depth of 14.

3.3.4 X-ray (Photon) Quantum Counting

The x-ray quantum counting detector is another example of a direct radiography mammography system. However, unlike the other detectors described above, it functions on the principle that each individual x-ray quantum is counted regardless of its energy. The unique design and concept of this detector allows each del to produce an electronic pulse every time an x-ray interacts with it (Pisano et al., 2004). The pulses are then counted and will create the signal for that pixel. Advantages of this type of detector are that no noise is associated with energy conversion and no analog-to-digital converter is needed.

Two quantum-counting systems have been developed. The detector in the Phillips Medical (Germany) [previously Sectra] system uses crystalline silicon in its multiple detectors. The detector and collimated x-ray beam move in synchrony across the breast. The x-rays are absorbed by the crystalline silicon. The electron-hole pairs are collected in an electric field and shaped into a pulse and counted (Aslund et al., 2007) as seen in Figure 12. The Phillips

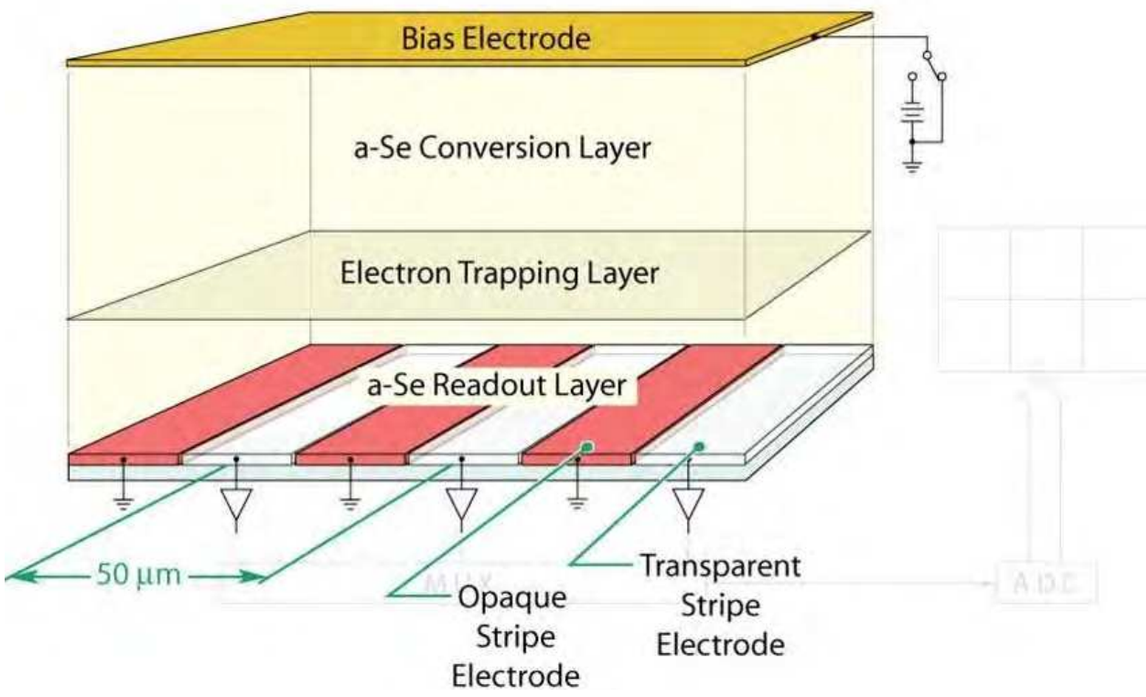


Fig. 11. An illustration of the Fuji FFDM system that uses two layers of selenium. (Courtesy of Fujifilm Medical, Stamford, CT).

system has a del size of 50 µm and a bit depth of 16. In the system by XCounter (Stockholm, Sweden), it uses a set of multiple linear detectors and scans across the breast in synchrony with a collimated x-ray beam similar to the Sectra system. However, it uses a pressurized gas as the x-ray absorber. The pulses of ions generated by the gas form the signal (Thunberg, in Antonuk & Yaffe, 2002). The XCounter system has the same del size and bit depth as the Sectra. Neither system uses a grid.

3.3.5 Photostimulable Phosphor (PSP) System

The last detector to be discussed is the PSP system which is a computed radiography (CR) system. CR systems have been in use in general radiography for many years and are based on the principle of photostimulable luminescence. More recently they have been developed and used in mammography. The CR mammography systems utilize a phosphor screen. Energy from x-ray absorption causes electrons in the phosphor crystal to be liberated from the matrix and captured and stored in "traps" in the crystal lattice (Pisano et al., 2004), as seen in Figure 13. The number of traps filled is proportional to the amount of absorbed x-ray signal.

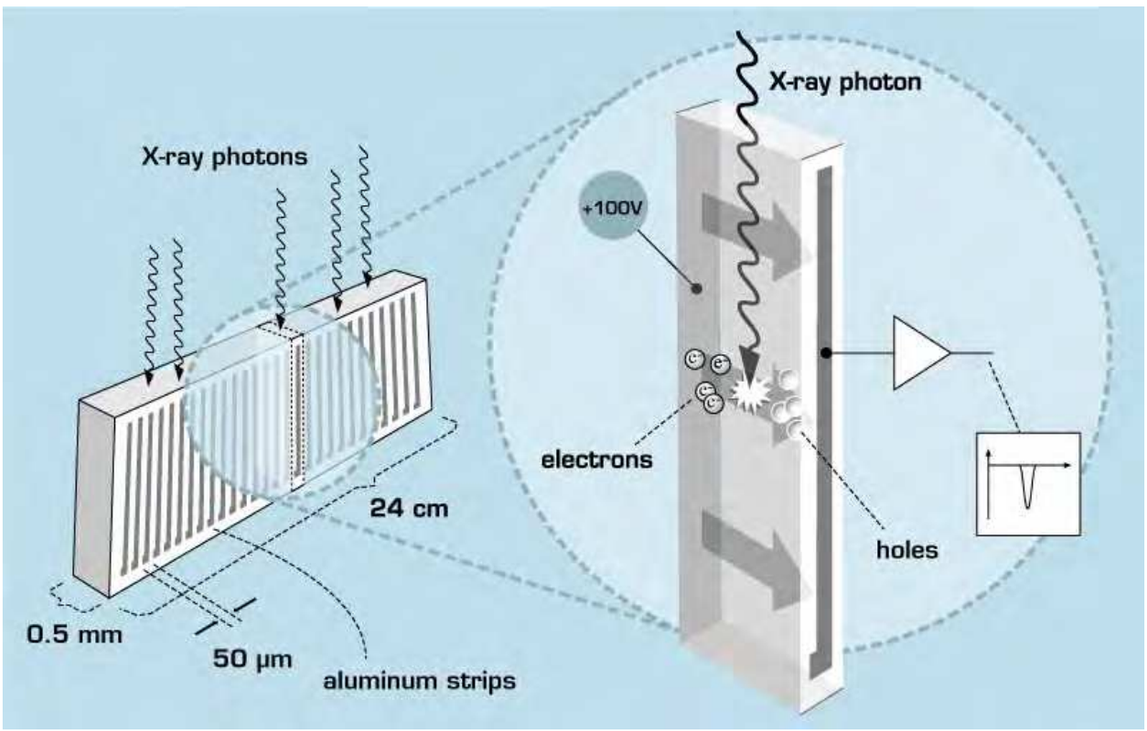


Fig. 12. X-ray (Photon) quantum counting detector. Schematic of a silicon based photon counting detector. (Courtesy of Phillips Medical, Germany)

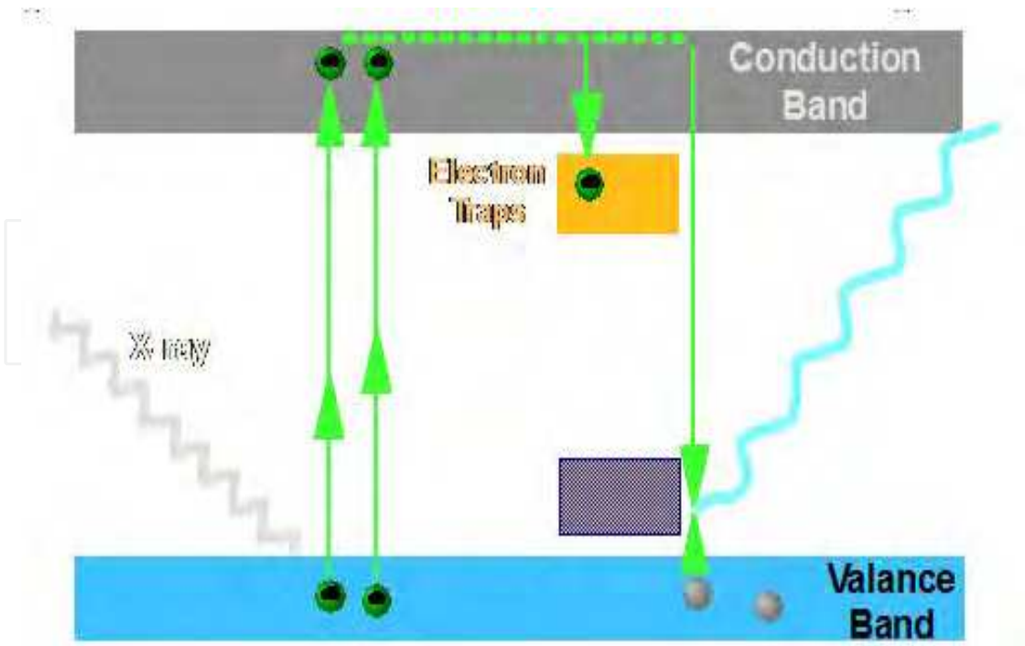


Fig. 13. Schematic demonstrating energy from x-ray absorption liberates electrons from the phosphor crystal and are captured and stored in "traps" in the crystal.

The CR image, which is analog, is then read out by placing the screen in a reading device. The reading device will scan it with a red laser beam in one dimension as it moves through the reader in the orthogonal direction. The red laser beam will free the electrons from the traps and cause them to return to their original resting state in the crystal lattice. As they return to their original state, the electrons will pass between energy levels created in the crystal with certain materials. The selected materials incorporated into the crystal typically emit blue light that is proportional to the x-ray energy absorbed by the phosphor (Yaffe, in Bick & Diekmann, 2010). The emitted blue light is measured with a light-collecting system composed of a photomultiplier tube, selected optical filter to eliminate the red light from interfering with the measurement, and a photomultiplier tube. Because the PSP is not composed of physical dels, spatial resolution of the system is the result of the size of the laser spot (del size) and the distance between sampling measurement (pitch) (Pisano et al., 2004). To decrease scan time while increasing light collection efficiency, SNR and sensitivity, some PSP vendors utilize a double-sided (read from the top and bottom surface of the PSP) reading device as seen in Figure 14.

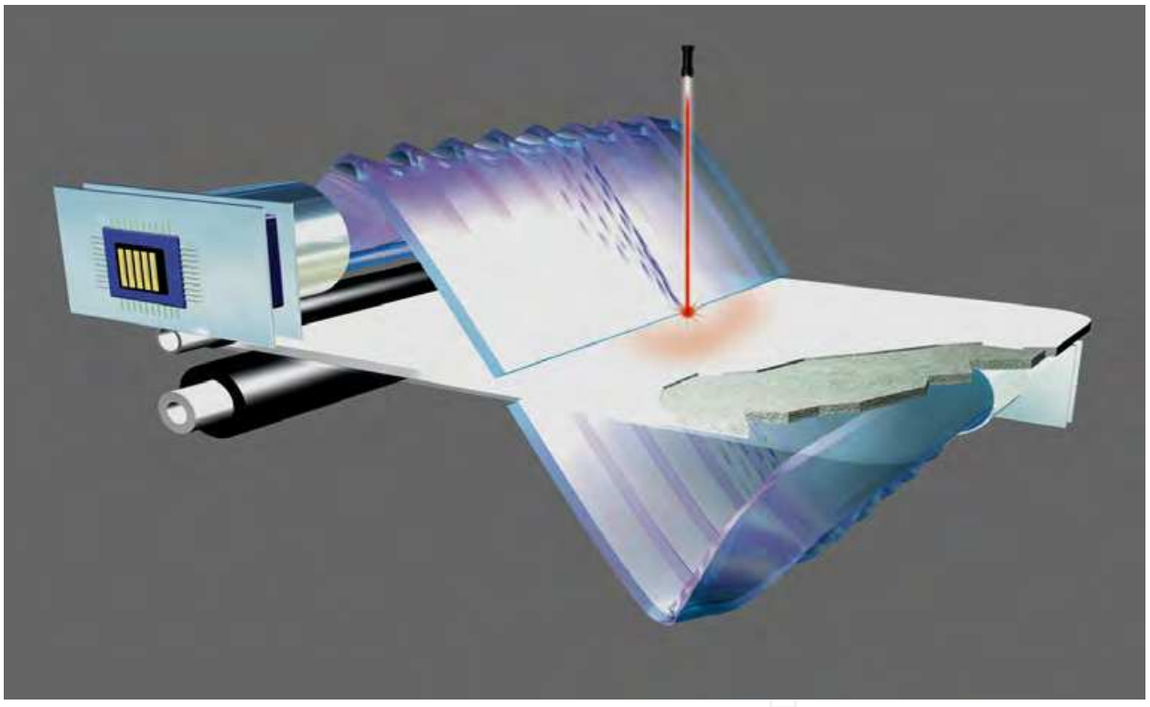


Fig. 14. CR mammography dual optical collection system scanned with a red laser beam. (Courtesy of Fujifilm Medical, Stamford, CT)

A system of this type was developed by Fujifilm Medical Systems (Stamford, CT). Its del size is 50 μm and has a bit depth of 12. There are other PSP systems developed and used throughout the world that have similar del and bit depths.

Unlike the DR systems, the CR system uses removable cassettes that are placed into a bucky tray. This system can be a cost saver to some institutions since they may be able to convert their current SFM machine to CR. For work-flow, there may be little change in daily routine

for technologists. For some mammography technologists, CR systems have a similar "feel" as SFM. Cassettes with the PSP are still placed into the bucky tray, the patient is positioned and imaged the same, and then the plate is placed into a reading device without having to go into a darkroom. The mammographic image obtained can be printed to hard copy or displayed on softcopy just like the DR systems.

3.4 Quality Control (QC)

Mammography must be of high image quality in order for radiologists to detect the subtle changes of breast cancer. This can be difficult since breast cancer can present as a mass of the same density as normal breast parenchyma or be obscured by it. To ensure optimal performance from a system, the equipment must be properly set up and maintained. In the United States, the Mammography Quality Standards Act (MQSA) was established in 1992 to establish a federal mandated quality control program for screen film mammography. It now includes digital mammography. In Europe, as countries began to develop a breast cancer screening program, each began to develop their own national program. To standardize quality assurance and quality control, the European Commission published guidelines in 2006. Now in its 4th edition, the published guidelines include digital mammography (Perry et al., 2006). However, there is no single international source on QC procedures. In the United States, it is required that users follow the manufacturers' QC procedures for their systems.

Digital imaging allows the decoupling of acquisition, processing and display. In order to have meaningful QC of a digital system, each of the components must be evaluated separately. To evaluate acquisition (detector, beam, scatter, and radiation dose), quantitative measures are performed on the "raw" or unprocessed images. The QC for image processing is still in its early stages. To evaluate image display, electronic test patterns are used.

Image quality for mammography has been based on a test phantom, with objects imbedded within it. This test is subjective and prone to observer error. In the future, automated software may be useful for solving this problem (Young et al., 2008). Instead of a phantom, a more reliable measurement for verifying the consistency of image contrast in a digital system is the contrast-to-noise ratio (CNR). It is sensitive to changes in dose, object contrast and beam quality for each digital machine (Young, in Bick & Diekmann, 2010). The CNR object imaged is made of different materials that simulate the attenuation coefficient of breast tissue.

As with SFM, digital mammography can have artifacts. The artifacts may arise from detector non-uniformities. Over time, there can be degradation of the homogeneity of the detector leading to image degradation. To correct for this, an algorithm can be applied to all the images. The procedure is called "flat-field" or "gain correction" and is based on the principle that the detector responds linearly to radiation exposure. The first step in this test is to record the receptor response for the same amount of time of an image, but without any x-ray exposure. The values from this "dark" image are stored in the dels. In a subsequent image acquired using x-rays, the values stored are subtracted from the measurement from each corresponding del resulting in an image where it appears that the dark signals from all dels are zero (Yaffe, in Bick & Diekmann, 2010). Figure 15 is an example of flat-field correction.

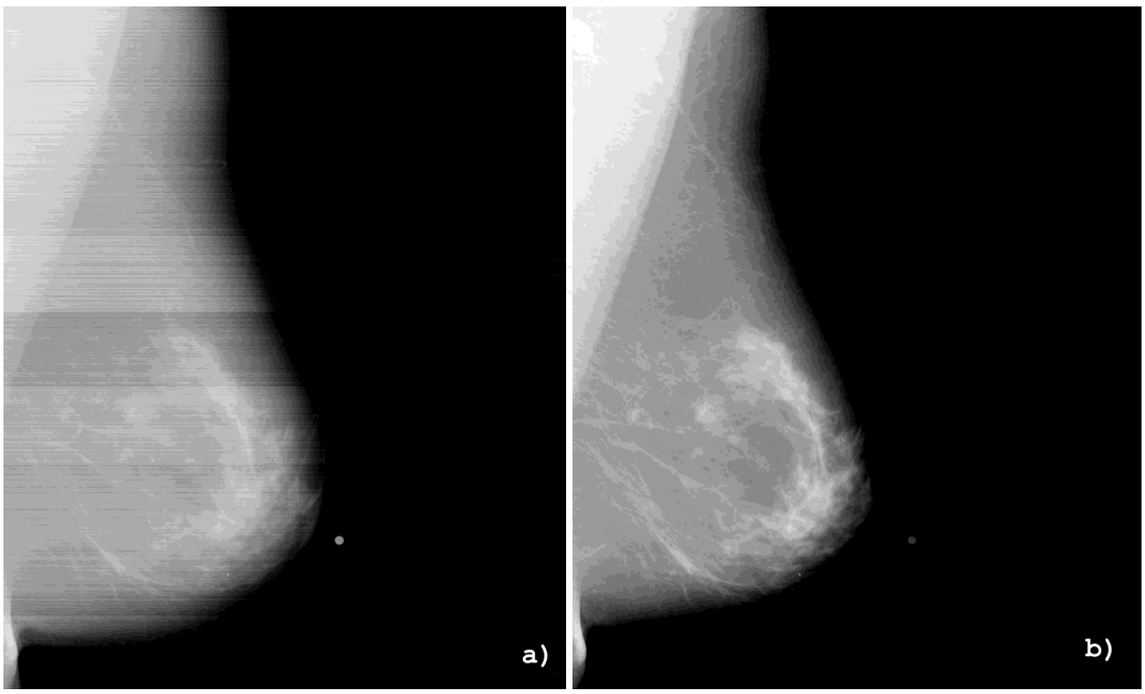


Fig. 15. Digital mammogram a) before and b) after flat-filed correction. Courtesy of Martin Yaffe, PhD; Sunnybrook Health Sciences Centre, Toronto, Canada. (from Digital Mammography, eds. ED Pisano, MJ Yaffe, CM Kuzmiak. Lippincott, Williams & Wilkins, a Walters Kluwer Company, 2004. With permission.)

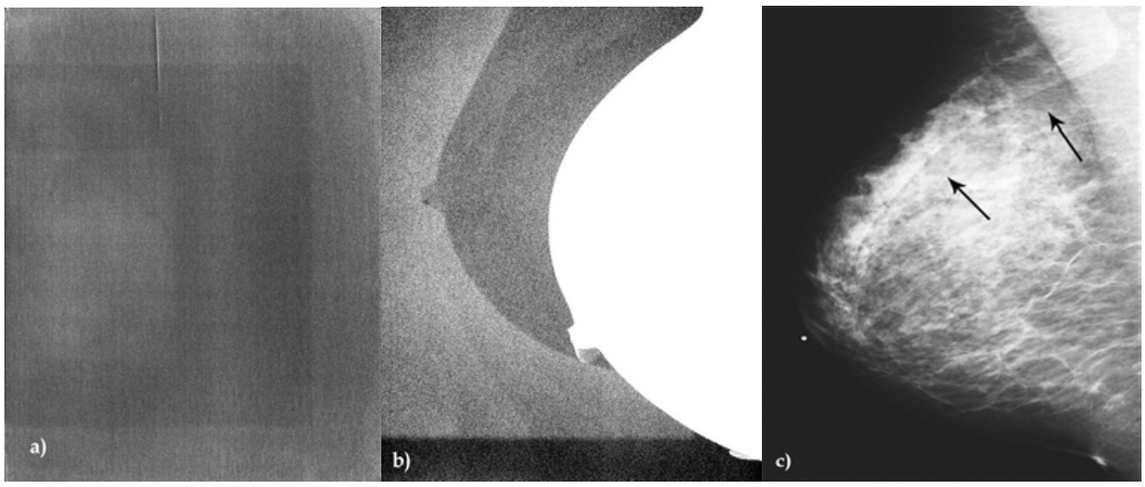


Fig. 16. Ghost or lag artifact. a) Artifact seen on a detector. b) Another example of ghosting. c) Clinical image with the appearance of a second breast (arrows). (Images **b** & **c** are courtesy of Elizabeth Franklin of Carolinas Medical Center, Charlotte, North Carolina, USA)

Other digital artifacts can be attributed to the digital detector. A single non-functioning pixel may not be noticed or even affect clinical images, but if the numbers of non-functioning pixels are too many it will impact clinical images. The non-functioning pixel can appear as a white dot and may simulate calcifications. If a pixel discharges too early it may result in a

bloom artifact, a white spot with a black halo secondary to the increase in charge of the neighboring dels (Van Ongeval, in Bick & Diekmann, 2010). If there is crystallization of the selenium of the detector, the images may become blurred over time (Marshall, 2006). Figure 16 are examples of ghost or lag artifact and are the result of incorrect electron clearing. Electronic interference can result in a zigzag artifact as seen in this CR image, Figure 17. Artifacts can be the result of image processing in which there is significant edge artifact between dense and fatty tissue, Figure 18. Also, artifacts can be related to the patient, i.e. chin, nose, finger, or hair artifact as seen in Figure 19.

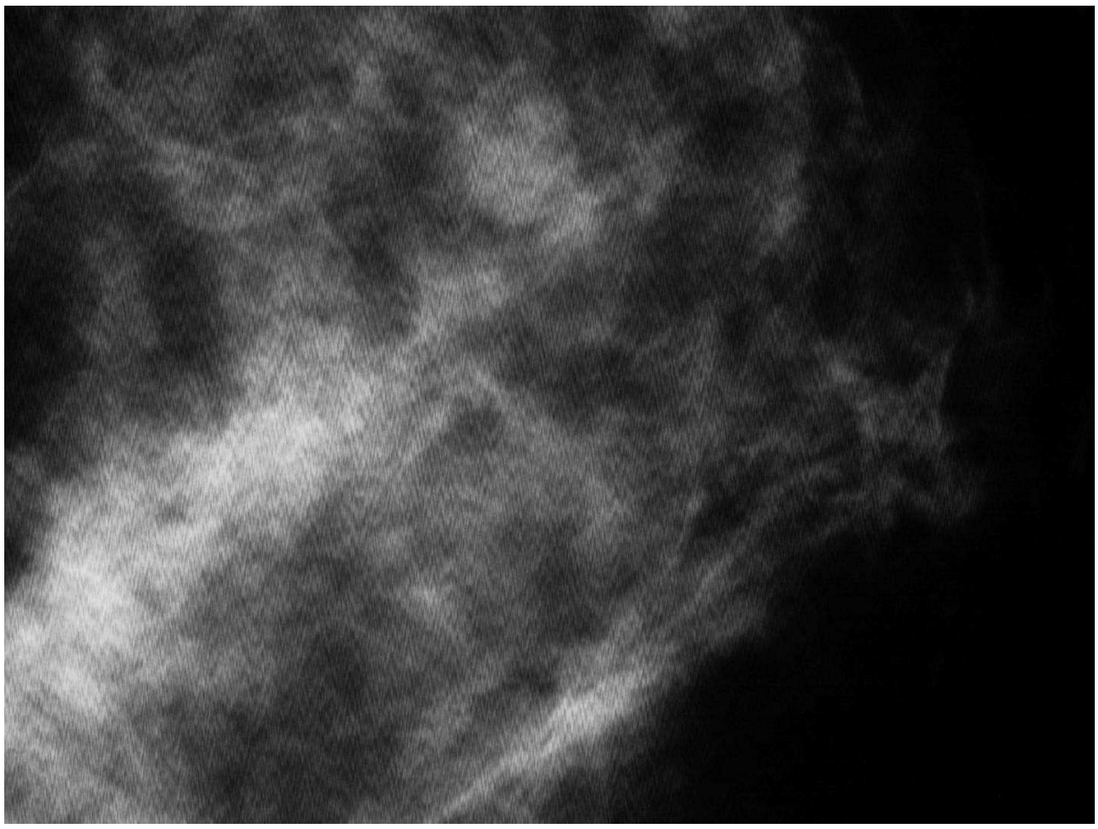


Fig. 17. Electronic interference in a CR system resulting in a "zigzag" black line artifact.

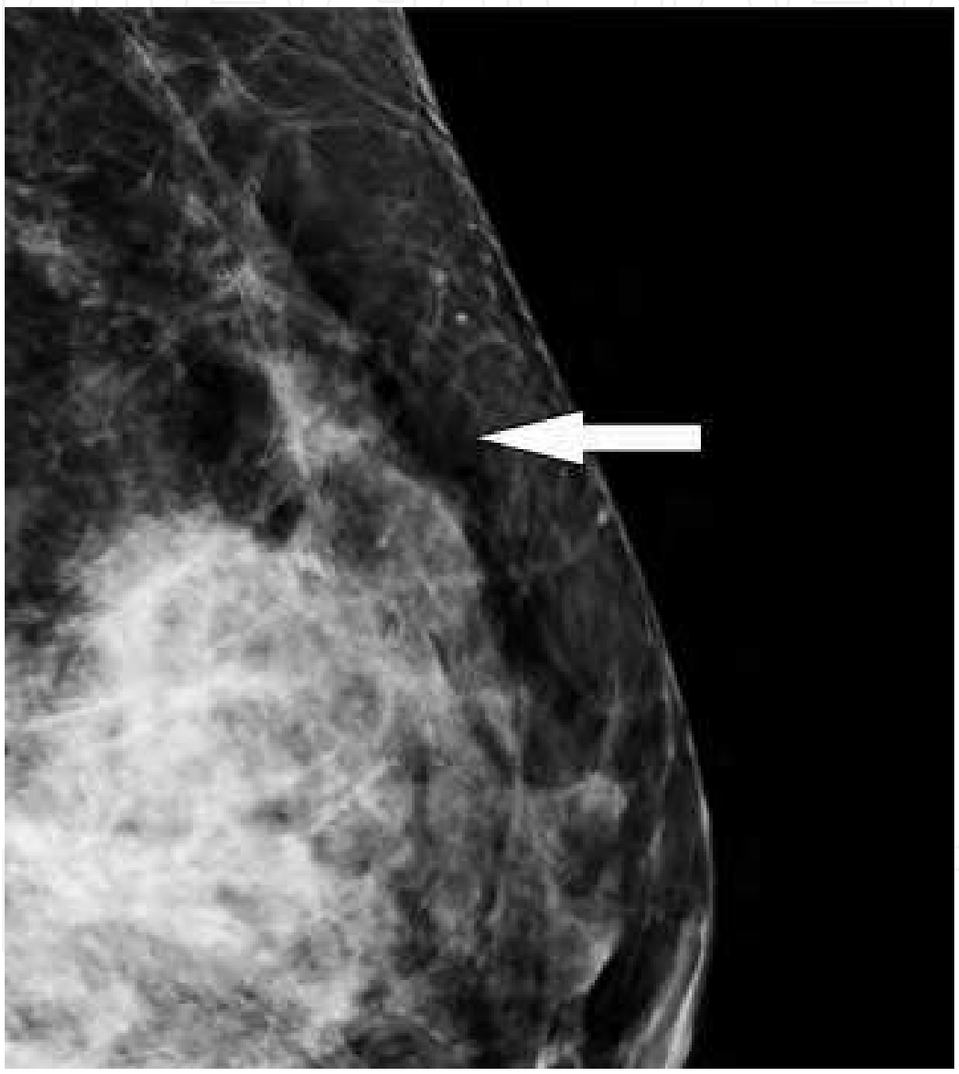


Fig. 18. Processing artifact. Significant edge enhancement between the white breast tissue and black fat. This results in significant "blackness" of the image adjacent to the black white interface (arrow).

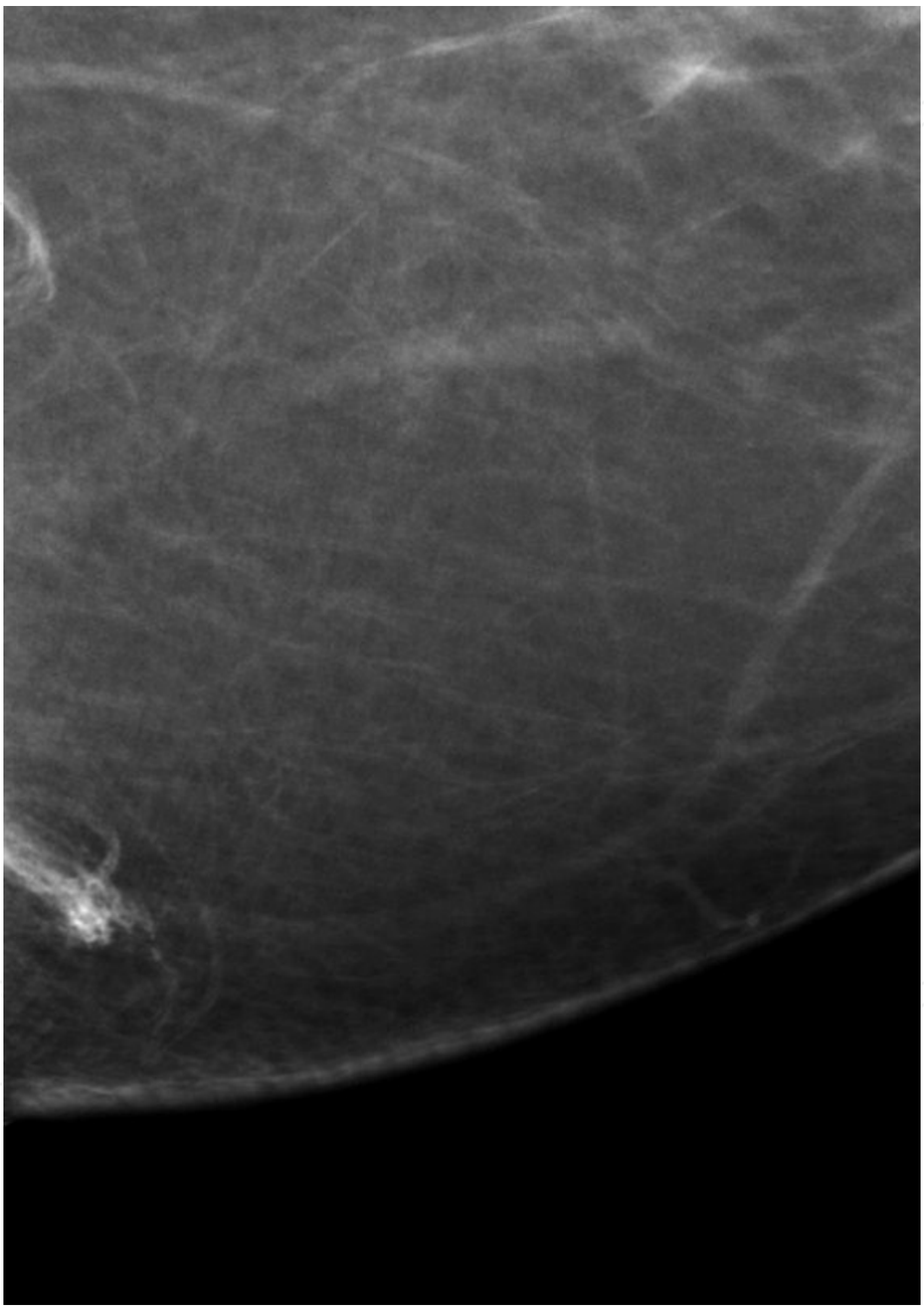


Fig. 19. Hair artifact. White swirling lines representing the patient's hair are seen projecting over the medial portion of the breast.

4. Clinical trials

4.1 United States

In 1996 in the United States, the Federal Food and Drug Administration (FDA) published the *Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems* (Food and Drug Administration, 1996; Pisano, 2004). For manufacturers of digital mammography equipment seeking FDA-approval through 510(k) or Premarket Approval, the document required that each manufacturer demonstrate through a designed clinical trial that digital mammography equipment was equivalent to SFM. However, this was not without some challenges. The original FDA guidelines required manufacturers to demonstrate a higher rate of inter-reader agreement with FFDM than was obtainable between readers of SFM when SFM was compared to itself (Beam, 1996; Elmore, 1992; Howard, 1993). There was no requirement that manufacturers determine the truth about the presence or absence of breast cancer, only that the mammogram interpretations agree.

After an Advisory Panel met to discuss the "flawed" guidelines, the FDA released its revised guidelines on February 8, 1999. The guidelines now required approval trials to be based on breast cancer status truth. Consequently, sensitivity and specificity as measured by a Receiver Operating Characteristic (ROC) analysis was to be used with the goal of the studies to demonstrate that the difference in the areas under the ROC curve between digital and film was no greater than 0.1 (Pisano et al., 2004). This was now the FDA's standard for proving "substantial equivalence" of the two technologies.

Several minor clinical trials studies have been published in the US comparing digital mammography versus SFM, and these demonstrated promising results for digital mammography (Cole, 2001; Hendrick 2001; Pisano, 2004). One of the first major published clinical trials was the Colorado-Massachusetts Screening Trial (Lewin et al., 2001, 2002). The goal of this two-site study was to prospectively compare full-field digital mammography (FFDM) and SFM for cancer detection in a screening population. The design of the study was simple. All women at least 40 years old presenting for a screening mammogram were eligible to undergo both a SFM and a FFDM. A FFDM prototype system made by General Electric Medical (Milwaukee, WI) with a 18 cm x 23 cm amorphous silicon detector with a CsI crystal and a commercial SFM unit (DMR: General Electric Medical Systems, Milwaukee, WI) were used for imaging. A prototype softcopy display workstation was also used.

Final results by Lewin et al. were published in 2002 (Lewin et al., 2002). A total of 6,736 paired exams were performed on 4,521 women over a 30-month period. In these patients, 2,048 findings were detected in 1,467 of the studies with film, digital, or both imaging modalities. Additional work-up of the findings led to 183 biopsies and 42 were positive for cancer. The cancer detection rate was not statistically significant ($p > 0.1$). The difference between the ROC area for digital (0.74) and SFM (0.80) were not significant ($p > 0.1$). FFDM had fewer recalls than SFM ($p < 0.001$); however, the positive predictive values of both modalities were similar (3.3% SFM, 3.4% FFDM) (Lewin et al., 2002). Although FFDM did not lead to a higher cancer detection rate, it did lead to fewer recalls with a study that used a prototype unit and display workstation. This study becomes the foundation for the next major screening clinical trial, Digital Mammography Imaging Screen Trial.

The Digital Mammography Imaging Screening Trial (DMIST) was sponsored by the American College of Radiology Imaging Network (ACRIN) and the National Cancer Institute (NCI) (Pisano et al., 2005). It was a cooperative venture by 33 sites in two counties led by Dr. Etta Pisano. A total of 49,528 asymptomatic women presenting for a screening mammogram underwent both a digital mammogram and SFM in a random order by the same technologist on the same day. A total of five digital systems were used: Senographe 2000D (General Electric), SenoScan (Fischer Medical), Selenium Full-Field Digital Mammography System (Hologic), Digital Mammography System (Hologic) and Computed Radiography System for Mammography (Fuji Medical). The images were read independently by radiologists, one radiologist for each exam. The radiologist scored each study on a 7-point malignancy scale for ROC analysis and a BIRADS (American College of Radiology, 2003) final impression to guide clinical work-up. The patient was recalled for additional diagnostic imaging whether the film, digital and/or both screening modalities demonstrated an abnormality. Standard work-up at each institution was performed that may have led to a biopsy. Breast cancer status was based on a breast biopsy within 15 months of study entry or a follow-up mammogram acquired at least 10 months after study entry.

Of the total patients recruited to DMIST over its 2-year accrual period, data was complete for 42,760 (86.3%) patients. A total of 335 breast cancers were diagnosed. Of these, 254 (75.8%) were diagnosed within 365 days and 81 (24.2%) were diagnosed between 366 and 455 days after study entry. The results demonstrate that for the entire population, the diagnostic accuracy of digital and film mammography was similar with a mean AUC of 0.78+/-0.02 for digital and 0.74+/-0.02 for film (difference in AUC, 0.03; 95 percent confidence interval, -0.02 to 0.08; P = 0.18). However, for certain subgroups, the accuracy of digital mammography was significantly higher than that of film mammography. The subgroups include women under the age of 50, women with heterogeneously dense or dense breasts, and premenopausal or perimenopausal women (P values of P =0.002, P = 0.003, P =0.002, respectively) (Pisano et al., 2005). Although the overall diagnostic accuracy of digital was similar to film, this large prospective, multicenter center study showed advantages for younger women with dense breasts.

4.2 European clinical trials

The first prospective digital screening study in Europe was performed in Norway in 2000 (Skaane et al., 2003, 2005). The Oslo I trial was a prospective study to compare SFM and FFDM with soft-copy reading in a population-based screening program. By invitation from the Norwegian Breast Cancer Screening Program (NBCSP), women aged 50-69 years of age were invited to participate. The women who agreed to participate in the study underwent two standard views of each breast with each modality (similar to the US studies). The FFDM studies were performed with Senographe 2000D (General Electric Healthcare, Buc, France) and interpreted on a GE softcopy display system with 2K x 2.5K monitors. Eight radiologists performed independent double readings for both modalities and used a 5-point malignancy scale. All images deemed positive (score of 2 or higher) were reviewed in a consensus meeting for each technique used. It was the consensus conference that decided whether the patient should be called back for additional imaging or scheduled for follow-up screening in 2 years.

The Oslo I study resulted in 3,683 women participating and a total of 31 cancers detected (detection rate 0.84%). Twenty-eight cancers were seen with SFM (detection rate 0.76%) and 23 by FFDM (detection rate 0.62%). The cancer detection rates were not significant (P= 0.23). The PPV for SFM was 46% and FFDM 39%. The recall rate after the consensus meeting was 3.5% (128 cases) for SFM and 4.6% (168 cases) for FFDM (Skaane et al., 2005). The recall rate was not significant. The authors concluded that there was no statistically significant difference in cancer detection rate; cancer conspicuity was equal between the modalities and soft-copy reading is comparable to SFM in a population based screening (Skaane et al., 2005).

Other data to come out of the Oslo I study was a retrospective review of the cancers (Skaane et al., 2003). In this retrospective review, a side-by-side feature analysis of conspicuity of the cancers was performed and there was no difference between the modalities. In 2005, Skaane et al. published follow-up information on the missed FFDM cancers from the Oslo I study (Skaane et al., 2005). They concluded that inexperience of the readers with softcopy, improper viewing conditions and rapid interpretations might have contributed to the lower detection rate.

Within a few months after completion of the Oslo I trial, patient enrollment for the Oslo II screening trial began. The aims of this study were to prospectively compare cancer detection rates, recall rates and positive predictive values of SFM versus FFDM in a screening program in Norway (Skaane & Skjennald, 2004). Women 50-69 years old were invited to the NBCS and women 45-49 years old were invited to the Oslo screening program. The patients were randomized for age and residence to undergo SFM or FFDM. Due to the physical location of the mammography equipment, the study investigators decided to have 70% of the patients undergo SFM and the other 30% to undergo FFDM (Skaane & Skjennald, 2004). The same radiologists who participated in the Oslo I trial participated. All images were again independently double-read (now with appropriate viewing conditions in the room) and scored using a 5-point malignancy scale. The potential "call back" cases were again reviewed at a consensus conference.

Results of the Oslo II study demonstrated a total of 64 cancers (cancer detection rate 0.38%) detected in 16,985 women who underwent SFM and 41 cancers (cancer detection rate 0.59%) in 6, 944 women who underwent FFDM (Skaane et al., 2007). The difference was in support of FFDM and was statistically significant (p = 0.03). The sensitivity was 77.4% for FFDM and 61.5% for SFM (P =0.07). The specificity was 96.5% and 97.9% respectively for the imaging modalities (P<0.005). The PPV was 15.1% for SFM and 13.9% for FFDM and this difference was not significant. The recall rate for SFM was 2.5% and 4.2% for FFDM (P < 0.001) (Skaane et al., 2007). The higher recall rate of this study confirmed the higher recall rate in the Oslo I trial. However, it is important to know that recall was based on a consensus conference, and it was only at the conference where comparison mammograms were made available for review. The study concluded that FFDM with softcopy interpretation is well suited for breast cancer screening programs.

Unlike the prior studies, the Swedish Helsingborg Study by Heddson et al. was a retrospective study that compared SFM, photon counting DR (PC-DR), and CR mammography from January 2000 to February 2005 (Heddson, et al., 2007). The goals were to evaluate cancer detection rates, recall rates, and PPV values in a screening population. A total of 52,172 screening mammograms were performed on 24,875 women during the study.

Fifty percent of the studies were performed with SFM, 19% with photon counting DR system (Sectra, Sweden), and 31% with a CR system (Fujifilm, Japan). The age range of the patients was 46-74 years of age. Forty percent of the SFM cases and 65% of the FFDM cases were double read by two radiologists. Recall of the patient was based by consensus of the radiologists.

Results of Helsingborg study demonstrated a statistically significant difference in the cancer detection rate for PC-DR versus SFM (P= 0.01) (Heddson et al., 2007). The cancer detection rates were 0.31% (81/25,901) for SFM, 0.49% (48/9841) for PC-DR, and 0.38% (63/16,430) for CR. In contrast to the Oslo studies, this study demonstrated a significantly higher recall rate for SFM than digital. The recall rate was for SFM, PC-DR, and CR were 1.4%, 1.0%, and 1.0%. As a result of the higher cancer detection rate and lower recall rate, the PPV for digital was higher than film [(P< 0.001): PC-DR = 47%, CR = 39% and film = 22%] (Heddson et al., 2007).

In addition to the above results, the Helsingborg Study demonstrated that digital mammography provided a dose reduction compared to film mammography as expected by its linear response to x-ray (Heddson et al., 2007). PC-DR provided a 75% dose reduction and CR a 16% dose reduction. The average glandular dose was 0.28 mGy, 0.92 mGy, 1.1 mGy, for PC-DR, CR, and SFM, respectively. The authors concluded that given the advantages of digital mammography, it is a valid alternative to screen film mammography.

Study	Study Design	SFM Exams	FFDM Exams	Recall Rate (%) SFM	Recall Rate (%) FFDM	Cancer Detection Rate (%) SFM	Cancer Detection Rate (%) FFDM	PPV (%) SFM	PPV (%) FFDM
Oslo I	Prospective, paired	3,683	3,683	3.5	4.6	0.71	0.54	20.2	11.8
Oslo II	Prospective, randomized	16,985	6,944	2.5	4.2	0.38	0.59	15.1	13.9
Helsingborg	Retro-spective	25,901	9,841	1.4	1.0	0.31	0.49	21.8	47.1
Florence	Retro-spective	14,385	14,385	3.5	4.3	0.58	0.72	14.7	15.9
Vestfold	Retro-spective	324,763	18,239	4.2	4.1	0.65	0.77	15.1	18.5
CELBSS	Retro-spective	31,720	8,478	4.4	4.8	0.65	0.68	14.6	14.3
Barcelona	Retro-spective	12,958	6,074	5.5	4.2	0.42	0.41	7.5	9.7

CELBSS = Central East London Breast Screening Service Study.

Table 1. Published European studies comparing screen film mammography (SFM) and full field digital mammography (FFDM) for recall rate, cancer detection rate, and positive predictive value.

Three of the European studies have been discussed above to give examples of designs and results. In total, there have been seven published European population-based screening studies comparing SFM and FFDM (Del Turco, 2007; Heddson, 2007; Sala, 2009; Skaane, 2005, 2007; Vigeland, 2008; Vinnicombe, 2009). Table 1 compares the results. It is important to keep in mind when reviewing the data that each of the studies is of different design. Only the Oslo studies were prospective studies. The Oslo I was a paired-designed as were the US studies. Double reading was performed in the European studies followed by consensus or arbitration meetings for positive studies. In the US studies, each modality was interpreted using an independent reader blinded to the results of the other modality. The Colorado-Massachusetts Screening Trial by Lewin et al. used a consensus conference, DMIST did not. In DMIST, if a single reader, regardless of modality, noted an abnormality then the patient was recalled. The recall rates reports vary in the studies; four of the European studies show a higher recall rate with digital (Del Turco, 2007; Skaane, 2005, 2007; Vinnicombe, 2009). In five of the studies, the cancer detection rate was greater for digital (Del Turco, 2007; Heddson, 2007; Skaane, 2007; Vigeland, 2008; Vinnicombe, 2009). Two were statistically significant: Oslo II and Helsingborg Study (Skaane, 2007; Heddson, 2007). From these results, the utilization of digital screening mammography in the Western European Countries and the United States continues to increase.

5. Image processing

Image processing is the application of applying mathematical operations to the "raw" digital image with the aim to visualize subtle abnormalities so that they can be perceived by the radiologist as seen in Figure 20. Image processing should be robust and reproducible. The need for extra manipulation of the images should be none or very minimal for the radiologist. In addition, the radiologist should feel confident in reviewing the images. The unique property of digital is that each component of the system can be optimized. A few of the basic methods used will be discussed.

Intensity windowing algorithms are based on the principle that each acts on individual pixels in the image. A small portion of the full intensity range of the image is selected and then remapped to the full intensity range of the display (Pisano et al., 2000). With this process, it allows for the selection of specific intensity values of interest. Consequently, dense normal tissue and abnormal tissue values are exaggerated to accommodate for their small differences. This may result in increased lesion conspicuity.

Manual Intensity Windowing (MIW) is one of the versions of intensity windowing. It is operator dependent. The radiologist manually windows and levels the images on a display system. Several examples are demonstrated in Figure 21. This can be quite variable depending on the radiologist's image reading preference and experience. Another version is histogram-based. In this version, it allows the system to select a window to allow the full range of contrast across the part of the histogram representing any fatty, mixed, or dense portion. The advantage of HIW is that it can adapt to individual breast types. The third version is Mixture-Model Intensity Windowing (MMIW). It provides region-specific window settings: background, compressed and non-compressed fat, dense tissue, and muscle (Pisano et al., 2000). Examples of these are demonstrated in Figure 22.

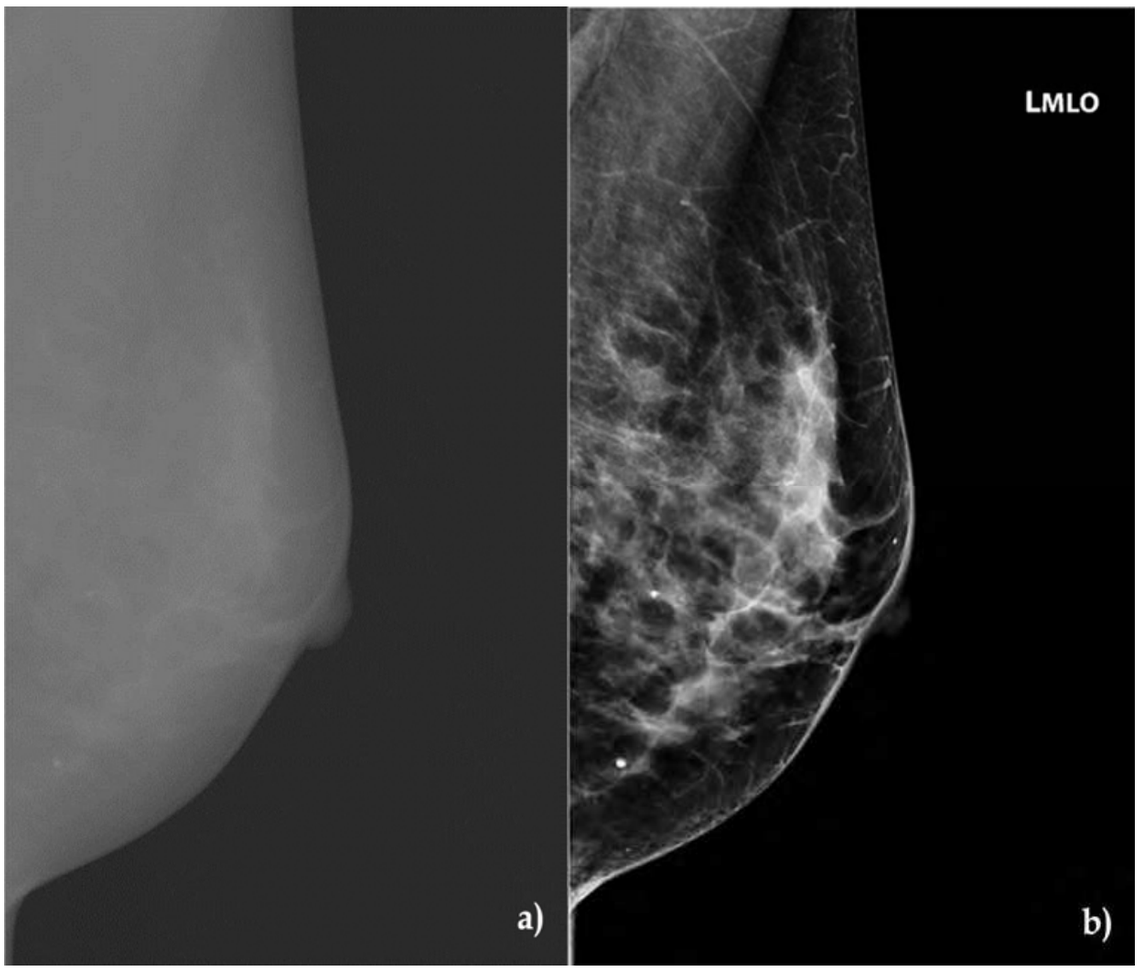


Fig. 20. Digital mammogram. a) Raw image. b) Processed image. (Courtesy of Fujifilm Medical, Stamford, CT)

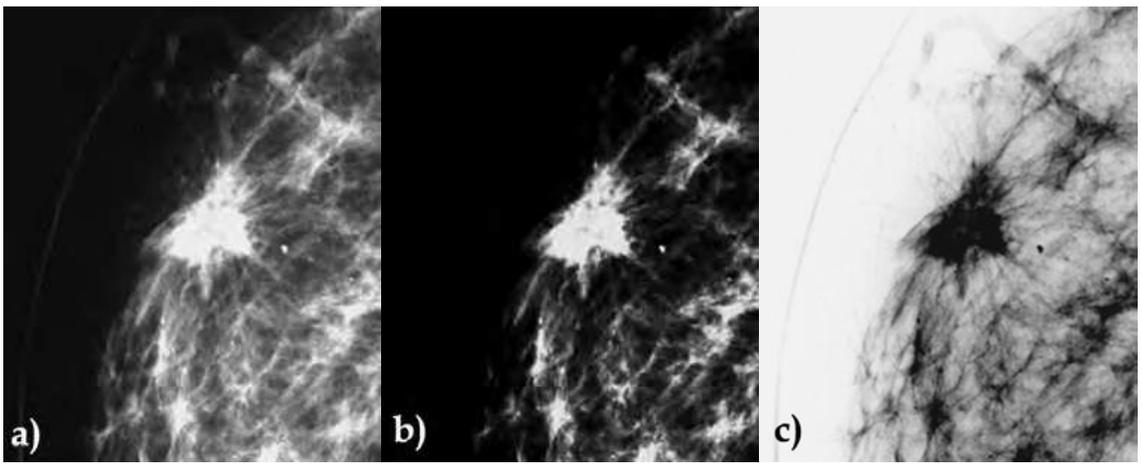


Fig. 21. Examples of different manual windowing and leveling of a digital mammogram that contains a spiculated mass. a) Initial. b) Manipulated image. c) Inverted image.

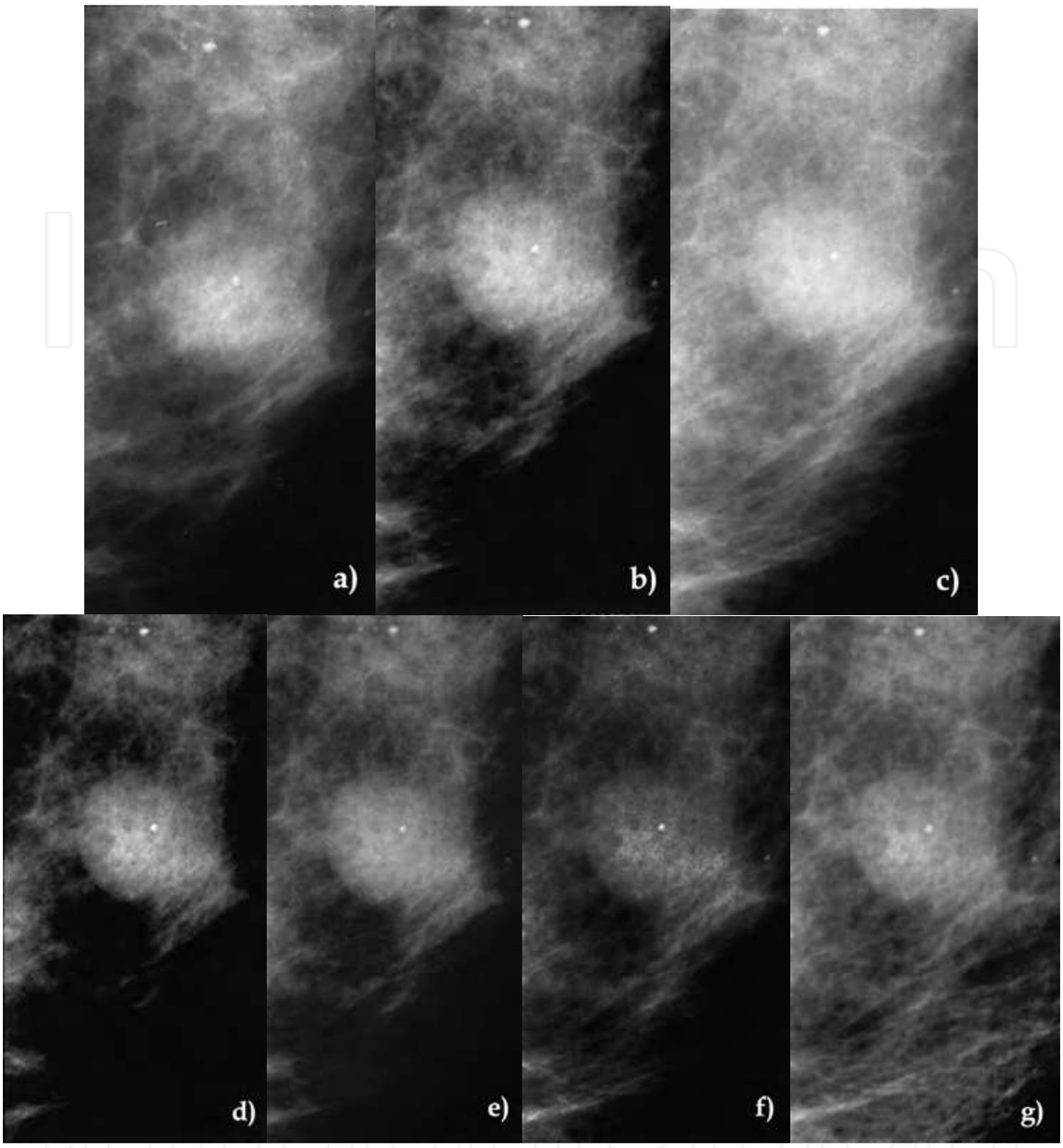


Fig. 22. Different post-processing algorithms (a) SFM of a cyst. (b-g) Photographic magnifications of a digital mammogram process with MIW (b), HIW (c), MMIW (d), CLAHE (e), unsharp masking (f), and peripheral equalization (g) (from *RadioGraphics*. Pisano et al. 2005. With permission).

Adaptive Histogram Equalization (AHE) is a spatial enhancement method that changes pixel value based on spatial content. When applied to an image, there is enhancement of each pixel in relation to its local area. In doing so, all the gray values occur at an equal frequency in the image and consequently, the contrast of the background may be enhanced at the loss of contrast in the breast tissue (Karssemeijer, in Bick & Diekmann, 2010). In addition to the tissue contrast being increased in the image, so is noise. To limit noise, Contrast-Limited Adaptive Histogram Equalization (CLAHE) was developed. It limits the

maximum contrast adjustments by clipping and renormalizing the histogram (Pisano, 2000; Karssemeijer, 2010).

Unsharp Masking (UM) is a post-processing technique that is created by subtracting a low-pass filtered version of the original image from the original image (Chan et al., 1987). This process enhances high frequencies in the image such as calcifications and mass edges. A disadvantage of UM is that it also adds noise to the images. Also, it may falsely enhance a margin of a mass (i.e. an indistinct mass may appear more circumscribed and lead to inappropriate classification and follow-up of a mass instead of the need for a biopsy) (Pisano et al., 2000).

Peripheral Equalization or Peripheral Enhancement (PE) is a post-processing technique developed to improve the visualization of the less compressed (and over penetrated) outer edges of the breast. A filter is used to obtain a blurred version of the mammogram representing tissue thickness. This blurred image "mask" is scaled from 0 to 1, and the mammogram is divided by means of the mask values on a pixel-by-pixel bases (Byng et al., 1997). The applied algorithm acts on the pixels in the breast and where there is a thickness change. The result is that the pixels near the periphery are changed so the image becomes "flatter" across the mammogram and the periphery appears less black.

Image processing is a vital component of digital mammography. We may find that it may take more than one algorithm and not necessarily "film-like display" to evaluate for masses, distortion and calcifications. Image processing algorithms are currently not assessed as part of QA protocols. However, they should be to ensure the image chain is working optimally. Automated systems may be of great importance for efficient use of technologist and physicist time in QA and QC. There is a great need to continue to develop and evaluate this area of digital mammography.

6. Image display

Image display of digital images can be performed with a laser printer onto hard copy "film-like" medium or viewed on high-resolution computer monitors. Regardless of display type, it is important to know how the image is being seen relative to its full spatial resolution. Commercial laser printers for digital mammography can support spatial resolutions, grey scale and optical density similar to mammographic film. If the images are printed with a laser printer, it may be done with 8, 10, or 12 bits per pixel displayed. If a digital mammography system uses larger bits than the printer, there will be loss of the dynamic range of digital image and the contrast scale will be compressed (Pisano et al., 2004). Consequently, not all the shades of grey can be displayed. If more than one version of the image is needed to display a finding, another image may need to be printed and this is a disadvantage. However, an advantage of laser-printed film is that it allows radiologists to use the same reading and workflow protocols as SFM.

Softcopy display is performed with high-resolution mammography monitors that allow the flexibility of image display and contrast. An early study by Pisano et al. compared the speed and accuracy of the interpretation of Fischer digital mammograms on softcopy versus those on laser-printed film (Pisano et al., 2002). In the study, 8 radiologists interpreted 63 digital mammograms both on a prototype softcopy display system and on laser-printed film per the manufacturer's recommendation. All studies had comparisons for review. All

radiologists read both conditions with at least one month between reads. Six cancers, 13 biopsy-proven benign lesions, 23 probably benign findings and 20 normal cases were included. The results demonstrated that softcopy display interpretations tended to be faster than film: mean time 34 seconds versus 40.5 seconds. In contrast, the ROC curve and sensitivity favored film (0.67:0.71 for film and 0.65:0.69 for softcopy). Specificity was slightly higher with softcopy (0.563 versus 0. 528), but not significant (Pisano et al., 2002).

With specificity of softcopy as a concern, a retrospective study comparing the specificity for calcifications in digital mammograms using softcopy versus film was performed by Kim et al. in 2006 (Kim et al., 2006). Eight radiologists reviewed 130 biopsy-proven cases of calcifications on softcopy and screen film. For each condition, the radiologists were asked to rate the probability of malignancy on a 5-point scale. For film, the radiologists could use a magnifying glass for further evaluation of the images, and for softcopy they could "roam and zoom" to manually window for contrast. The study concluded that there was no statistically significant difference in specificity achievable using softcopy digital versus screen-film mammography.

For radiologists using softcopy display for interpretations, appropriate room ergonomics and viewing conditions are absolutely necessary to minimize radiologist distractions and fatigue. Vendors need to continue developing hanging protocols and other tools that allow the radiologists to view all digital images with little manipulation of buttons or clicks of the mouse.

7. Digital imaging and clinical workflow

7.1 Clinical workflow

Digital mammography has transformed our everyday working environment. For many, gone are the days of darkrooms with wet chemical processing and the challenges associated with them. Film screen mammography view boxes are being used less each day as softcopy display becomes more familiar to the radiologist. Digital mammography images can be viewed from anywhere, and the trend for comparisons to be on softcopy is becoming apparent. Also, with prior studies being in digital format, the number of lost or missing priors has decreased. Files rooms with overcrowded shelves and stacks of folders piled on the floor are starting to disappear as picture archiving systems (PACS) with electronic storage are used.

Digital mammography has also had a large impact on patient throughput. Technologist image acquisition and processing time with direct radiography (DR) digital mammography has been significantly decreased in both screening and diagnostic mammography (Berns, 2006; Kuzmiak, 2010). In the DR FFDM digital screening study by Berns et al., they studied the timed comparison of 183 hard-copy SFM cases and 181 FFDM softcopy display cases. Their results demonstrated a 7.5 min/case (35%) time savings over SFM (Berns et al., 2006).

Results were similar in the diagnostic timed mammography study by Kuzmiak et al. (Kuzmiak et al., 2010). This prospective study consisted of 3 phases: 1st Phase, 100 patients imaged with SFM; 2nd Phase, 100 patients imaged on DR FFDM and interpreted on a recently installed softcopy display mammography system; 3rd Phase, same as 2nd Phase but 3-months after installation of the softcopy display system. Their results showed the

diagnostic mammographic acquisition times with processing were 13.02 min/case for SFM (Phase 1), 8.16 min/case for digital (Phase 2), and 10.66 min/case for digital (Phase 3). All phases also included the measured time for additional imaging that was requested by the interpreting study radiologists. Compared to SFM, acquisition time for Phase 2 and 3 digital were significantly less ($P < .001$ and $P < .0001$, respectively). For Phase 2 & 3 digital, there was a 4.86 min/case (37.3%) and 2.36 min/case (18.1%) time savings compared to SFM (Kuzmiak et al., 2010).

Regardless of reason for the mammogram, the main reason for the time savings is the elimination of processing time with DR mammography. The technologist no longer has to leave the exam room with SF cassettes to develop. With SFM, each film takes approximately 90 seconds to develop. This time is now saved. The technologist now can review the images on a 1-megapixal monitor after exposure while the patient is still in the room. After initial review by the technologist for positioning and technique, the images are sent to PACS with a push of a button or touch of a screen.

As part of the clinical workflow, there has been the concern of radiologist interpretation time with digital mammography. Berns et al. published average interpretation times, interpreted by seven radiologists, for their screening study of 1.2 minutes for SFM and 2.0 minutes for DR FFDM (Berns et al., 2006). Study results by Haygood et al. showed similar results in longer interpretation times with digital (Haygood et al., 2009). Haygood's study included 4 radiologists who were timed in clinical interpretation of 457 screening mammograms consisting of 189 SFM and 268 digital mammograms. They reported increased interpretation times for digital ranging from 1.27 to 3.37 minutes. The average interpretation time for all readers for SFM was 2.12 minutes and 4.0 minutes for digital (Haygood et al., 2009).

In contrast to the above screening studies, Kuzmiak et al. found the radiologist interpretation time for digital mammography on softcopy display was not significantly different from that for film mammography in a diagnostic mammography setting ($P = .2853$ and $P = .2893$, respectively) (Kuzmiak et al., 2010). The mean interpretation times were 3.75 min/case for screen film (Phase 1), 2.14 min/case for digital (Phase 2), and 2.26 min/case for digital (Phase 3). The results provide support to radiologists for conversion to direct radiographic digital mammography for clinical use and that radiologists planning on using softcopy display systems must have appropriate training to optimize throughput. In addition, softcopy display manufacturers should continue to improve the functionality and ergonomics of their products to make softcopy interpretation more efficient.

7.2 Electronically generated report

With softcopy display systems an electronically generated reporting system can be integrated with it. Numerous vendors are available and each has different functions depending on radiologist preference. With these systems, mammograms and other imaging reports can be dictated (generated) and electronically signed off. Thus, it decreases the time from the initiation of the patient's exam to the exchange of information to the patient's referring physician.

8. Conclusion

Digital mammography decouples the process of image acquisition, processing and display so that each component can be optimized. The digital format has allowed the development of additional software to aid the radiologist in lesion detection – computed aided detection. We are now able to view mammography images and interpret them from other clinical sites in different parts of the city, state, or country through televideo. Other emerging technologies such as three dimensional tomosynthesis are now entering clinical use. Digital technology has changed mammography over the last decade, and it will continue to change it for decades to come. It will be interesting to see what the future holds for our patients and us.

9. Acknowledgement

Dr. Kuzmiak is grateful for the inspiration and guidance provided over the years by her friend and colleague, Etta Pisano, MD. She would like to express her gratitude to Martin Yaffe, PhD, and Elodia Cole, MS, for their clinical insights and outstanding work. Finally, she would also like to thank Shiela Kuzmiak for the many hours of support during this project.

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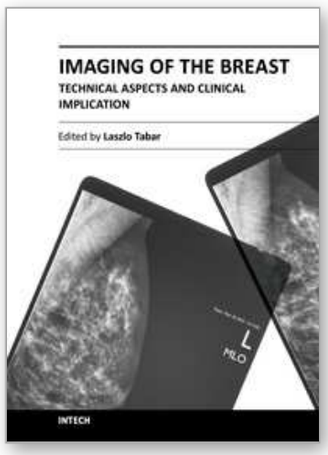

Imaging of the Breast - Technical Aspects and Clinical Implication
Edited by Dr. Laszlo Tabar

ISBN 978-953-51-0284-7
Hard cover, 224 pages
Publisher InTech
Published online 16, March, 2012
Published in print edition March, 2012

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How to reference
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Cherie M. Kuzmiak (2012). Digital Mammography, Imaging of the Breast - Technical Aspects and Clinical Implication, Dr. Laszlo Tabar (Ed.), ISBN: 978-953-51-0284-7, InTech, Available from: http://www.intechopen.com/books/imaging-of-the-breast-technical-aspects-and-clinical-implication/digital-mammography-chapter

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