FFDM – AN EMERGING TECHNOLOGY

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With improvements in recall rates, reimbursement, and the potential for improved archiving and film savings, the future points squarely at full-field digital mammography.

The technical mandates of mammography are more complex than in any other area of imaging. These include excellent spatial resolution at the lowest possible dose, optimal contrast without significant loss of latitude, imaging of a broad spectrum of tissue types, visualization of adjacent structures with only slight contrast differences, and the ability to compensate for tissue-thickness differences from the chest wall to the nipple.

Where these requirements are concerned, film-screen mammography has reached its peak capability. It has narrow exposure latitude (good image contrast, but susceptibility to underexposure or overexposure); it is subject to film and screen noise that can reduce the ability to visualize high frequency structures adequately; and chemical processing is often the weak link in the optimal conversion of the latent image. Film use is also beset by inefficiencies in its handling, storage and retrieval requiring huge amounts of space and staff time.1 Post-processing of hard copy images is not possible and thus there is no ability to enhance the image after the exposure.

For film-screen mammography, although spatial resolution potential is 15 to 20 line pairs (lp)/mm this is seldom achieved due to the previously described inherent weaknesses. Under the Mammography Quality Standards Act (MQSA), the minimum required spatial resolution is 13 lp/mm to the parallel and 11 lp/mm to the perpendicular; and film-screen mammography systems now in use meet or exceed these specifications.

DIGITAL MAMMOGRAPHY

The US Food and Drug Administration does not require digital mammography systems to prove that they are superior to film-screen mammography systems. Instead, the FDA requires manufacturers to prove that their equipment performs at least as well as film-screen mammography. In full-field digital mammography (FFDM), spatial resolution requirements are not mandated, but to detect microcalcifications FFDM technology requires a minimum spatial resolution of 5 to 10 lp/mm. FFDM systems now in use meet this criterion.

In FFDM, however, spatial resolution is not the final indicator of quality. Detective quantum efficiency (DQE) and modulation transfer function (MTF) are terms often used to describe FFDM resolution capabilities. In simplistic terms DQE indicates how much of the information that was originally contained in the object is converted by the imaging medium, resulting in the acquired image. Film has a conversion factor of about 25%, while FFDM has been described as being capable of at least 60%. MTF is the ability of the system to display high-frequency structures (such as microcalcifications) without

losing them in the noise of the system. This is affected by spatial frequency (the amount of signal emitted and the resultant frequency needed to display it), by the signal-to-noise ratio, and by dynamic range, which is the contrast capability of the system. Therefore, while spatial resolution is no better than that of film mammography (and may even be worse) digital mammography offers the benefits of decreased noise, and improves contrast resolution by the windowing functions that optimize the available contrast. These features help counteract the lower spatial resolution of digital systems.2

INTERPRETATION

Criticism of FFDM is usually directed not toward the digital technology itself, which continues to advance, but toward the associated workstation applications. Full resolution at 10 lp/mm requires display capabilities of 4000x5000 pixels but commercially available workstations limit the display to 5 lp/mm at full resolution. The enhanced contrast resolution of FFDM also depends on the imaging display. A 14-bit image displayed on an 8-bit or 10-bit monitor has its contrast capability reduced accordingly.3 As R. James Brenner, MD, JD notes, “For a busy diagnostic breast center, workstations can become a real bottleneck. The workstations aren’t designed to accommodate multiple image views at full resolution. Moreover, workstations lack a windowing feature whereby a radiologist can switch between two or more patient studies easily. Vendors are aware of the problem and are working on solving it.”4

Reading soft copy has its own challenges. A facility may be performing 50 exams per day using an FFDM system without a problem. This is probably typical of what happens in the technical arena, but the efficiency gained can be reversed during interpretation, at least initially while they gain experience in reading and manipulating digital images. Radiologists continue to be frustrated by the difficulty of comparing the current soft copy study with prior hard copy images. Even though they like the digital images, they may not want to read soft copy as comparison is difficult. Some institutions are still printing hard-copy images off of the FFDM units because of this problem. There are also the associated lighting and ergonomic issues for the radiologists in reading both hard copy and soft copy images. A PACS reading room may have three types of workstations available: fully digital stations, film-based stations, and hybrid (combination) stations. All of these will probably be needed for some time.5

DATA AND STORAGE

Despite the availability of image compression and web-based image distribution in other areas of radiology, mammography providers must consider the large size of the data files associated with FFDM and the bandwidth required to move the images swiftly and effectively without creating network havoc. Such traffic would overwhelm the bandwidth available to many PACS networks in existence today. For example, a 4 view FFDM study obtained using a large detector with a 70 micron pixel (Hologic) equates to 110MB. Vendors continue to develop improved approaches to data storage and retrieval, and the cost of archiving is declining steadily. Among the newer archive models in use are fully online systems that make mechanical disk jukeboxes unnecessary.6 A current feasibility study by the US National Institutes of Health to establish a central facility to store digital images is intended to demonstrate the workability and value of centralized storage and

retrieval. 7

Compounding storage issues, facilities must still meet MQSA image retention mandates and some state laws may be even more stringent. For MQSA, images must be maintained for 10 years after the patient's most recent examination at a given facility. For patients that return to a facility regularly (every 1 to 2 years), prior images must be kept for 5 years. Even when a facility provides only digital exams, image storage and retrieval methods must be able to cope with both hard-copy storage and soft-copy archive issues. For the foreseeable future, facilities that provide FFDM will also need to consider hard copy when images need to be transferred to facilities and health care providers outside the facility's image-distribution network, as well as to patients and their attorneys.

ACQUISITION TIMING

Television and magazine advertising that promotes digital mammography is, meanwhile, generating a level of requests that can be overwhelming. With so much demand, it seems logical to hasten acquisition of FFDM and place the system in service as quickly as possible. The soundness of this investment must be investigated, however.

The Michigan Cancer Consortium (MCC) and its accomplishments have been hailed by the US Centers for Disease Control and Prevention, Atlanta, as a model for the nation. MCC has concluded that study data from the last few years has not proved the superiority of FFDM when compared with standard film-screen mammography. This resulted in the MCC position statement that FFDM costs still outweigh its benefits, 3. This statement buys time for health systems that are weighing whether to spend up to six times as much for a digital system (along with service and software upgrade expenses) as for a conventional mammography unit while they await results of a national study comparing film-screen and digital mammography (see sidebar, page [# [DMIST]]).

Despite the MCC position statement, Dr. Max Wicha, University of Michigan Comprehensive Cancer Center director, who co-chaired the consortium's digital mammography statement still stated "All of us believe that, in the future, digital mammography will prove to be better. We will all acknowledge that it is not there yet. Everyone agrees that we should practice evidence-based medicine, and we should not jump on the bandwagon to tout digital mammography as better when we don't have the proof." However, Murray Rebner, MD, chief of breast imaging at William Beaumont Hospital , Royal Oak, Michigan, states, "I personally feel that the image quality is superior with digital." In 2002, the facility invested $2 million to buy four new digital units.

CURRENT DIGITAL ADVANTAGES

Although one study (2) concluded that there was no difference in cancer detection rates, digital mammography had a significantly lower recall rate due to the ability to manipulate the image. This study demonstrated a 10% decrease in the need for repeat imaging where digital mammography was used. Since image contrast can be adjusted on the workstation, there is the ability to reduce the overall radiation dose to the patient which may aid in increased tube life for the unit. Digital mammograms can also be archived in various

ways, are easily retrieved, and can be copied exactly. FFDM also encourages the use of off-line interpretation and expert consultation via telemammography. Digital mammograms are an ideal online teaching aid, as well.2

Another major advantage is in film savings which can immediately impact the bottom-line. Upon conversion to FFDM, one institution experienced a 35% decrease in film costs during the first year and another projected a $30,000 per year savings.

Due to enhanced throughput a facility was able to reduce the number of mammography units needed from four to three. (Figure 1). Using the digital system vs. the analog system they perform approximately twice as many exams in the same amount of time. In the analog room, the facility books one patient every 15 minutes for screening mammography. In the digital room, it books two patients per 15-minute slot, having screened as many as 57 patients in an 8-hour work day.8

Clearly, the income potential is there to support FFDM for some facilities. Fixed costs for FFDM are high, so spreading those costs over more studies decreases the fixed cost per mammogram and allows return on investment to be achieved more quickly. The investment in digital mammography will be most effective for larger centers performing at least 15,000 mammograms per year. An imaging center that serves a small population will, for this reason, will find it difficult to justify the acquisition of FFDM financially.

The Breast Center at Houston Northwest Medical Center (HNMC) with 25,000 patients per year, reports that it justified FFDM acquisition on the basis that full return on investment (ROI) would be achieved in less than 3 years. 8 Another high volume center indicated the unit paid for itself within 2.5 years. With a lower patient volume (6500 patients per year) and the addition of computer-aided detection (CAD), one facility determined ROI within 3 years due to the increased reimbursement of mammography if combined with CAD. According to National Consortium of Breast Centers (NCBC), CAD is also a good marketing tool, although it requires approximately 5 additional minutes of the technologist's time per examination to input the films into the CAD system. Direct to digital CAD integration with FFDM is now available eliminating this concern increasing the viability of adding the CAD.

PREPARING FOR DEMAND

There is no doubt that demand for mammography services is increasing (Figure 2) driving additional procedural volume. The population over age 40 is expected to increase from 66 million in 2002 to 76 million in 2010, and this will also increase mammography demand. The procedural volume for mammography continues to grow at a rate of approximately 7% per year.

There are 9,600 certified mammography facilities in the United States, but the FDA recorded the closing of 160 centers during the first quarter of 2003. As an example of the local impact of this trend, four free-standing breast centers have closed this year in Jacksonville, Fla, alone. Breast imaging centers at two major hospitals there have also discontinued services. The reasons are poor reimbursement and medical malpractice issues. With these closings, delays of three months are now common for screening, as

well as diagnostic, examinations. The number of breast imagers is decreasing, and very few are willing to enter the field. FFDM has the potential to obviate these concerns by imaging of up to two times the number of patients as analog units. Mobile vans can meet the needs of rural communities that cannot afford a digital unit locally. Centralized reading rooms can compensate for the rising population demands and decreased breast imagers.

CONCLUSION

Many women are already enthusiastic advocates of FFDM. They see digital mammography as better technology than what has been available. They want screening with the best tool available, and that, in their thinking, is now FFDM.9 Due to marketing of FFDM they believe that it also does not require compression. In digital mammography the procedure itself is essentially the same and breast tissue is still compressed in the same way. The obvious difference for the patient is that the technologist does not leave the room to run the films. Women need to know with film-screen mammography they are receiving just as good a mammogram as with FFDM. Conventional mammography remains a viable method of choice for breast-cancer screening until studies prove that FFDM is superior and eventually it will happen.

Technological advances in FFDM will outpace those in film-screen mammography - it is only a matter of time. When it becomes public knowledge that the digital system is better than analog systems, women will have a right to demand it. Being prepared for FFDM means considering the future direction of mammography at your facility now. Early detection is the best protection for the woman – planning ahead is the best protection for any institution that will continue to provide mammography services since the future points squarely at FFDM.

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