Digital Mammography: Coming of Age

Andrew D.A. Maidment, PhD

According to the U.S. Food and Drug Administration [1], as of May 1, 2005, 7.2% (640 of 8911) of certified facilities in the United States had at least one digital mammography system, and 6.4% (874 of 13,621) of accredited mammography units were digital. These numbers are changing rapidly; in the period from March 1 to April 30, 2005, there was a net increase of 45 accredited digital units in the United States, while in the same time period, the number of accredited screen-film mammography units declined by 71. Has digital mammography come of age?

The motivation for adopting digital mammography has changed over the years. In the early days of digital mammography (the mid-1980s to the mid-1990s), the most common reason cited in favor of digital mammography was the technical superiority of digital imaging technology [2–4]. A screen-film mammography system is necessarily a product of compromise; it is the detector, the display device, and the storage medium. The use of digital mammography allows for the separation of these tasks into specialized detectors, display devices, and picture archiving and communication systems, each of which can be individually optimized. The digital format also simplifies the implementation of computer-aided detection (CAD) and other image-processing schemes, because the image data are intrinsically digital, and thus film digitization is eliminated. In early work, the superiority of digital detectors over film was repeatedly emphasized. Digital detectors have a larger dynamic range and a potentially superior signal-to-noise ratio (for a given detector dose), providing the potential for superior image quality at the same dose or similar image quality to film at a reduced dose [3]. Although these arguments are true, it is generally recognized today that the most important limitation in mammography (film or digital) is the projective geometry, which is discussed below.

Today, the primary motivation for switching to digital mammography is not necessarily the superiority of detector technology but rather the intrinsic value of the digital image format. Today, a large number of facilities are completely digital with the sole exception of mammography. The continued support of a film storage facility and staff members for mammography is not economical. In larger facilities, the absence of mammography images from picture archiving and communication systems and the absence of these images from patients' electronic records (visible in clinicians' offices and consultation and operating rooms) are clear deficits. In addition, the continued use of film makes the adoption of CAD more costly and time consuming.

The initial capital experience of digital mammography systems is high. However, digital mammography offers monetary incentives above and beyond the savings achieved in the file room and through the efficiencies of improved throughput. The average Medicare technical component and ambulatory patient classification fees for digital screening mammography for 2005 are $98.91, compared with $49.27 for screen-film mammography; the professional component of $36.38 is the same for both types of studies [5]. The average Medicare technical component and ambulatory patient classification fees for diagnostic digital mammography are $97.40, compared with $52.30 for screen-film mammography; again, the professional component of $45.10 is the same for both types of studies. The inclusion of CAD (whether for screening or diagnostic, digital or screen-film mammography) adds on average a total of $19.71 to Medicare reimbursement. Assuming that all insurers reimburse at a similar level and that this differential will be maintained, most facilities could recover their capital costs in 2 to 3 years.

There is reasonable evidence that digital mammography is comparable with screen-film mammography in terms of specificity, sensitivity, and observer performance. In the trial of Lewin *et al* [6], involving 4945 screening mammograms of women aged 40 years and older, digital mammography and film had comparable sensitivities and receiver operating characteristic observer performance. However, digital mammography had a statistically significantly reduced recall rate and a superior (but not significant) positive predictive value at biopsy. Clinical trials in Europe have shown similar results. Currently, we await the results of the ACR Imaging Network's Digital Mammographic Screening Trial study. This clinical trial, begun in October 2001, was designed to measure any potential benefit of digital mammography in screening. Approximately 49,500 women have participated in this trial at 31 sites in the United States and Canada. The results of this trial are anxiously awaited and are likely to be

0091-2182/05/$30.00 • DOI 10.1016/j.jacr.2005.06.008

published about the same time as this column. It is highly unlikely that digital mammography will be found to be statistically significantly inferior to screen-film mammography; any other outcome will likely accelerate the transition to digital mammography.

Although it is clear that the current detectors in digital mammography are adequate to the task, many new innovations are on the horizon. Each of the major detector manufacturers is in the process of developing or releasing the next generation of digital detectors. These improvements address a number of areas, including the development of larger detectors (covering approximately 24 × 30 cm) to address the need to image all breast sizes, as well as reductions in image readout time and detector noise (both needed for advanced applications). There are a number of technologies available, including cassette-based photostimulable phosphors, indirect and direct flat-panel detectors, scanning charge-coupled device technology, and 2 different scanning photon-counting detectors. In all of these systems, there is a continued effort to reduce the amount of tissue lost at the chest wall and at the edges of the detector (ie, corresponding to areas that image the axilla in mediolateral oblique projections). Furthermore, there continues to be debate on the most appropriate pixel size in digital mammography. There is no clearly correct answer. Most research now indicates that a pixel size of between 50 and 100 μm is acceptable. Such factors as the intrinsic spatial resolution of a detector (ie, the modulation transfer function), the noise of the detector compared with the x-ray quantum noise (usually quantified in terms of the detective quantum efficiency), and the image processing applied to the images all affect the detectability and conspicuity of fine details such as fibrils and calcifications; those features most closely associated with concerns of pixel size. Suffice it to say that all of the commercially available systems are adequate for these tasks.

An area of relative weakness today is the issue of display workstations. At the time of writing, there is only one manufacturer with a picture archiving and communication system display system approved for reading all of the various manufacturers' digital mammography images. All other manufacturers today produce workstations that are approved only for reading images produced with their own digital mammography systems. Although this situation is likely to change very quickly, the fact remains that many manufacturers' workstations offer special processing and display options that are proprietary and not available to users if the images are read on any other vendors' workstations. Furthermore, the processing that is offered is often not reversible, so that it may be difficult or even impossible to accurately compare images of the same woman acquired on different digital mammography systems, particularly if quantitative measures (such as breast glandularity) are of interest. Although an attempt at providing sufficient flexibility was incorporated into the initial Digital Imaging and Communications in Medicine standard of the mammogram image object definition, with the inclusion of "for processing" and "for presentation," the implementation and use of these features has generally been poor and subject to error (David Clunie, personal communication, May 23, 2005). This is a current subject of discussion for the ACR/National Electrical Manufacturers Association Digital Imaging and Communications in Medicine Working Group 15.

There has been an interesting advance in the archive of digital mammography images. As a result of an early National Library of Medicine grant [7], there have been tremendous advances in the development of permanent breast health records online. Several companies now offer breast imaging centers the ability to archive their digital mammograms in one of a number of centralized Web archives. Such a service offers breast imaging centers excellent long-term image storage and disaster management, as well as a number of value-added services, such as CAD and offline image printing. The result is that many centers (especially smaller, standalone breast imaging centers) can avoid certain capital expenses (e.g., large archives and high-quality film printers) in exchange for an ongoing operating expense. Such services also offer many advantages to consumers, because patients will now have the ability to maintain their own digital mammography records, so that images can be readily viewed by physicians across the country (or world) with appropriate permission. This is a clear improvement over the use of duplicated film mammograms, which have intrinsically poor image quality and are easily lost.

Finally, digital mammography facilitates many advanced acquisition and processing methods. The two most widely touted methods today are breast tomosynthesis and contrast-enhanced mammography (CEM). Both methods are based on the realization that mammography is not limited by the number of x-rays being used to image the breast but rather the superimposition of the anatomic structures of the breast upon themselves, thus making the task of finding a cancer much like finding

one specific tree in a large forest. Breast tomosynthesis attempts to address this problem by imaging the breast tomographically. Contrast-enhanced mammography attempts to address this problem by differentially increasing the subject contrast of breast cancers through the uptake of iodinated contrast agents (similar to the method of breast magnetic resonance imaging).

Tomosynthesis is a term coined by Grant [8], for synthetic tomography, in which a discrete version of continuous linear tomography was proposed. Today, it is recognized that tomosynthesis is in fact a special case of computed tomography in which a limited number of projections is used, leading to the alternate names of limited-view (or limited-angle) computed tomography. Tomosynthesis is being pursued by many research groups and most mammography manufacturers [9–13], while Boone *et al* [14,15], Tornai *et al* [16], Ning *et al* [17], and others are pursuing fully three-dimensional computed tomography of the breast. Rafferty [18], in a pilot study of 60 patients, has shown that with tomosynthesis, the callback rate was reduced by 83%, while providing a 93% detection rate for actual cancers. These initial results seem to indicate that breast tomography has a very bright future; some have proposed that it will replace mammography. However, there will need to be a large, multicenter clinical trial to prove the value of breast tomosynthesis. Furthermore, it is not clear whether tomosynthesis should be used for screening, diagnosis, or both.

Finally, there has been significant work in the area of CEM. Skarpathiotakis *et al* [19] and Jong *et al* [20] used temporal subtraction of mammograms acquired before and after injection of an iodinated contrast agent to produce CEM images. Lewin *et al* [21] investigated the use of dual-energy subtraction CEM. Contrast-enhanced mammography seeks to derive functional information about breast lesions, much like magnetic resonance imaging of the breast. Contrast-enhanced mammography provides an alternate method of overcoming the superposition limitation of mammography. Contrast-enhanced mammography adds new information, because more than morphology is being imaged. Moreover, CEM can be combined with tomosynthesis to produce images with the appearance and features of contrast-enhance magnetic resonance breast images. In an ongoing clinical trial of multimodality breast imaging, we have imaged 8 patients with contrast-enhanced tomosynthesis; the initial results are encouraging. Finally, several groups, including researchers at the University of Pennsylvania, are now examining mammographic imaging agents that specifically bind to tumors.

In summary, digital mammography has come a long way, from the development of the first generation of imaging detectors in the 1980s to the ongoing assessment of large clinical trials and the development of new and innovative means of radiographically imaging the breast. There are many compelling reasons to switch to digital, and given recent statistics from the Food and Drug Administration, it seems that digital mammography is beginning to supplant screen-film mammography.

REFERENCES

1. U.S. Food and Drug Administration. MQSA facility scorecard. Available at: http://www.fda.gov/cdrh/mammography/scorecard-statistics.html. Accessed March 18 and June 7, 2005.
2. Pisano ED, Yaffe MJ, Hemminger BM, et al. Current status of full-field digital mammography. Acad Radiol 2000;7(4):266-80.
3. Yaffe MJ, Rowlands JA. X-ray detectors for digital radiography. Phys Med Biol 1997; 42(1):1-39.
4. Maidment AD, Yaffe MJ. Scanned-slot digital mammography. Proc SPIE 1990;1231: 316-26.
5. Dakins DR. Breast centers tune up for peak performance. Diagn Imaging. 2005;27(5): 24-32.
6. Lewin JM, Hendrick RE, D'Orsi CJ, et al. Comparison of full-field digital mammography with screen-film mammography for cancer detection: results of 4,945 paired examinations. Radiology 2001;218(3):873-80.
7. National Library of Medicine. High-technology medical awards announced. Available at: http://www.nlm.nih.gov/archive/20040831/news/press_releases/nextgen.html. Accessed June 7, 2005.
8. Grant DG. Tomosynthesis: a three-dimensional radiographic imaging technique. IEEE Trans Biomed Eng 1972;19(1):20-8.
9. Maidment ADA, Albert M, Thunberg S, et al. Evaluation of a photon-counting breast tomosynthesis imaging system. Paper presented at: Medical Imaging 2005: Physics of Medical Imaging; 2005; San Diego, Calif.
10. Bissonnette M, Hansroul M, Masson E, et al. Digital breast tomosynthesis using an amorphous selenium flat panel detector. Paper presented at: Medical Imaging 2005: Physics of Medical Imaging; 2005; San Diego, Calif.
11. Ren B, Ruth C, Stein J, Smith A, Shaw I, Jing Z. Design and performance of the prototype full field breast tomosynthesis system with selenium based flat panel detector. Paper presented at: Medical Imaging 2005: Physics of Medical Imaging; 2005; San Diego, Calif.
12. Wu T, Moore RH, Rafferty EA, Kopans DA. A comparison of reconstruction algorithms for breast tomosynthesis. Med Phys 2004;31(9):2636-47.
13. Wu T, Stewart A, Stanton M, et al. Tomographic mammography using a limited number of low-dose cone-beam projection images. Med Phys 2003;30(3):365-80.
14. Boone JM, Nelson TR, Lindfors KK, Seibert JA. Dedicated breast CT: radiation dose and image quality evaluation. Radiology 2001;221(3):657-67.
15. Boone JM, Kwan ALC, Nelson TR, et al. Performance assessment of a pendant-geometry CT scanner for breast cancer detection. Paper presented at: Medical Imaging 2005: Physics of Medical Imaging; 2005; San Diego, Calif.
16. Tornai MP, Bowsher JE, Jaszczak RJ, et al. Mammotomography with pinhole incom-

plete circular orbit SPECT. J Nucl Med 2003;44(4):583-93.

17. Ning R, Tang X, Conover D, Yu R. Flat panel detector-based cone beam computed tomography with a circle-plus-two-arcs data acquisition orbit: preliminary phantom study. Med Phys 2003;30(7):1694-705.
18. Rafferty E. Tomosynthesis: new weapon in breast cancer fight. Decis Imaging Econ 2004; 17(4). Available at: http://www.imagingeconomics.com/library/200404-12.asp.
19. Skarpathiotakis M, Yaffe MJ, Bloomquist AK, et al. Development of contrast digital mammography. Med Phys 2002;29(10): 2419-26.
20. Jong RA, Yaffe MJ, Skarpathiotakis M, et al. Contrast-enhanced digital mammography: initial clinical experience. Radiology 2003; 228(3):842-50.
21. Lewin JM, Isaacs PK, Vance V, Larke FJ. Dual-energy contrast-enhanced digital subtraction mammography: feasibility. Radiology 2003;229(1):261-8.

Andrew D. A. Maidment, PhD, University of Pennsylvania, Department of Radiology, 3400 Spruce Street, 1 Silverstein, Philadelphia, PA 19104; e-mail: andrew.maidment@uphs.upenn.edu