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FOREWORD

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Digital Mammography: Preliminary Demonstration of Clinical Feasibility

Edward R. Boyle, M.D.

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INTRODUCTION

The objective of our protocol was to assess the clinical feasibility of digital mammography using the Prototype Arizona Slot Scanner has more recently been referred to by the manufacturer, (Fischer Imaging Corporation, Denver, Co.), as the SenoScan unit Prototype 1. Although we initially hoped to image up to 2,000 patients between 1 January 1996 and 30 September 1996 this proved to be impossible. Unanticipated delay in delivery of the unit by the manufacturer resulted in no patients being imaged prior to suspension of funding 30 September 1996. We, nevertheless, requested and received an amendment to MIPR 96MM6636 to extend the period of performance to 31 December 1997 with research ending 30 September 1997. This report concerns our experience with the digital mammographic unit since its installation at Brooke Army Medical Center (BAMC) in October 1996 with the first attempt at patient imaging 31 October 1996.

Background

Breast cancer is a major source of suffering and premature death among women. Mammography is the principal method of detecting breast cancer at a curable stage. The film-screen modality is the current standard for mammography.

Despite the many advantages of film-screen mammography, however, there are a number of inherent problems in the system that do not permit optimal mammography to be performed. These chiefly center on the multiple, sometimes conflicting functions required of a film based system which must act as an image acquisition detector, display device, and image archiver (1). By separating these functions an alternative system would permit optimization of each. The system ideally suited to accomplish this is digital mammography which was recognized in September 1991 at a workshop entitled "Breast Imaging: State-of-the-Art and Technologies of the Future" as the evolving technology with the greatest potential impact on management of breast cancer (2).

The Promise of Digital Mammography

There are many potential advantages of digital mammography that interrelate to one another (3,4). For convenience these can be organized under two broad categories: (1) improved detection of breast cancer, and (2) enhanced efficiency and lowered cost.

Improved Detection of Breast Cancer: Improved detection of breast cancer can reasonably be expected as the result of (1) improved image quality, (2) improved accessibility to centralized interpretation or consultation by expert mammographers, (3) improved availability of

high quality comparison studies, (4) computer aided diagnosis, and (5) facilitation of research using large integrated data bases.

Improved image quality can be expected as a result of improved detection and display of contrast, improved signal to noise ratio, digital image processing, and elimination of the need for film development.

Noise degrades all radiologic images. An ideal imaging system would be "quantum limited" meaning that x-ray quantum noise would be the dominant source of random fluctuation. This is not true in film-screen systems where the dominant noise is related to film granularity. Digital systems eliminate this source of noise and allow a closer approximation to the ideal. Reduction of noise will improve the signal to noise ratio and allow better detection of abnormalities.

Film processing is a potentially weak link in image production in film-screen mammography. Elimination of this step would avoid potential image degradation and artifacts related to film processors and would thus be an additional reason to expect improved image quality.

There is considerable range in the number of mammograms performed at various facilities and the experience and expertise of radiologists who interpret them. By use of a system linked with teleradiology interpretation of screening mammograms could be performed at a central site and second opinions readily obtained. This could particularly improve the quality of care for relatively underserved populations of women such as those in rural areas and Indian reservations.

The importance of comparison studies for optimal interpretation of mammograms and detection of developing densities and other subtle changes related to cancer is well recognized. Universal use of digital systems linked by telecommunication would allow perfect replicas of the original digital images to be readily accessible, thus permitting the ideal of comparison to prior studies to become more of a reality than it currently is. This, in turn, would permit both better detection of subtle developing signs of cancer and to the avoidance of unnecessary interventions for some of the mammographic abnormalities proved to be stable by comparison with older studies.

Computer aided diagnosis has been shown to have great promise for detecting signs of cancer. Images obtained with digital mammography would already be in a form suitable for computer aided analysis. Furthermore, there would be no loss of information such as occurs in digitization of film images and analysis could be performed on the raw data collected by digital acquisition systems rather than being limited to images displayed at windows pleasing to human perception.

One final way in which digital mammography would be likely to aid in the fight against breast cancer is by facilitating research. With digitized data and telecommunication multiple institutions could pool large numbers of cases for collaborative studies which would be especially useful for investigation of uncommon pathologic entities or atypical variants of more common conditions.

Enhanced Efficiency and Cost Reduction: Almost as important in today's environment of limited budgets is the potential for enhanced efficiency and lowered cost through replacement of film-screen mammography with an integrated digital system. In the short term this potential is unlikely to be realized due to new equipment purchases, adaptation of personnel to the systems, and the initial need to maintain the capability of film interpretation and storage. In the longer term, however, significant savings are likely.

Enhanced throughput of patients, elimination of time spent putting up and taking down films from view boxes, elimination of supplies consumed with film systems, elimination of costly film storage requiring large amounts of space and manpower, rapid retrieval and transfer of old digital studies, batch reading by centralized experts in mammography, and facilitated quality assurance both from within a facility and from outside supervising agencies such as the Food and Drug Administration may all be expected. Improved patient throughput should result from elimination of the need to process films and the virtual elimination of repeat images due to improper exposure. Interpretation should be facilitated since both current and prior images could be formatted to be displayed in a set pattern eliminating the shuffling of films and envelopes and the wait for films to be hung or taken down. Obtaining old studies for comparison can be a very time-consuming and frustrating chore not infrequently associated with loss of films, costly mailing and copying, and need for addenda to reports if prior studies are received after interpretation of a study. Much of this could be eliminated once a digital system were widespread.

Current Status of Digital Mammography

Several methods of direct digital acquisition of mammographic images have been proposed and a few are in various stages of implementation (4,5). The one with which we have worked is the slot scanner that utilizes a narrow beam of x-rays that sweeps across the object to be imaged synchronously with a narrow array of charge-coupled devices (CCD's) on a detector below the object. As the photons pass through the object, proportional electronic signals are transmitted from the detector, first, to an analog to digital converter and, then, to a computer that creates the image for display (3,4,6). A unique advantage of this system over others proposed for digital mammography is that it substantially reduces image degradation from scatter radiation (7,8).

In Europe digital mammography systems of lower performance standards than the SenoScan Prototype 1 have been used with patients, and at some institutions have replaced film-screen mammography (9,10,11). Even when images are derived from digitization of film-screen images there is evidence that there is virtually no loss of clinically relevant information (12).

BODY

Methods

Our initial intent was to invite all patients scheduling mammograms at BAMC between 1 January 1996 and 30 September 1996 to have a digital as well as a film-screen mammogram if they met certain criteria. Those consenting after review of the nature of the study and its risks were to be included in the study group. This could not be successfully accomplished due to the manufacturer's delayed installation of the prototype unit that occurred after the funded study period. Subsequently there were extensive technical problems resulting in erratic availability of the unit for imaging. Criteria used for inviting a patient to participate were that she: (1) be at least 40 years old, (2) not be pregnant, (3) have breasts of a size permitting adequate imaging using the most common cassette size (18 x 24 cm), and (4) have no disability or deformity that would interfere with satisfactory completion of the study by a single technologist.

Those patients being seen specifically for follow-up of a previously detected mammographic finding on a film-screen study had the diagnostic film-screen study performed before the digital study. For project purposes the radiologist made a tentative interpretation after the diagnostic film-screen images were completed. Following this, pertinent digital images were performed and reviewed by the same radiologist who made a final report and recommendation to the patient. Instances where digital images resulted in a change in interpretation and recommendation were noted. Interpretative assessments were made according to the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiology (ACR) which includes 6 categories: (0) incomplete assessment; (1) negative; (2) benign; (3) probably benign; (4) suspicious; and (5) malignant (13). In our protocol as originally written "normal or benign findings for which routine cancer screening is advised" equates to BI-RADS categories 1 and 2; categories 4 and 5 equate to "finding suspicious for malignancy for which biopsy is advised." The third diagnostic interpretative option which we had described in our initial protocol was "probably benign finding for which either ultrasound or directed mammographic follow-up in one year or less is advised." We found instances when this would not strictly apply and, therefore, made some minor modifications. When an assignment of 0 (incomplete assessment) was made, the radiologist noted which of the remaining five BI-RADS categories were still being considered and whether physical exam and/or ultrasound was to be performed before assignment to a single interpretative category. Following the physical exam and/or ultrasound a final selection among BI-RADS categories 1-5 was made. If an ultrasound was performed it was done after all mammographic images were obtained and assessed.

All other patients were randomly assigned to one of two imaging sequences: (1) digital followed by film-screen, or (2) film-screen followed by digital. Screening studies consisted of routine mediolateral oblique (MLO) and craniocaudal (CC) views of each breast. Diagnostic studies were tailored to the patient. The same radiologist assessed all images for a given patient and, for project purposes, recorded a management decision at the stage of screening of either: (1) no finding suspicious for potential malignancy, or (2) at least one finding suspicious for potential malignancy for which further diagnostic assessment is recommended. Diagnostic studies were interpreted in a fashion similar to that described for patients being seen for follow-up of a previously detected finding on a film-screen study. Although interpretative categories were recorded for project purposes at each stage of assessment for each modality, the final decision and report made for the patient's record was based on all images.

Observations included patient throughput, digital unit downtime, artifacts, ability to archive and retrieve data, and ability to display on hard copy laser printed images soft copy findings detected at the monitor. Ease of use and comfort of the digital unit were evaluated by technologists and patients.

Digital images were obtained using the SenoScan Prototype 1 which had a tungsten target and a set duration of exposure of 6.9 s. Selection of filter (molybdenum, rhodium, or cadmium), kVp, and mA were made on the basis of technique charts provided by the manufacturer based on the thickness of the compressed breast. For purposes of the more formal part of the study only images reviewed at a high resolution (2 x 2.5K) monitor (model DR-80, Dataray, Denver, CO) were used for interpretation and patient management decisions.

Film-screen images were obtained with a Senographe DMR (General Electric, Milwaukee, WI) using the Min-R 2000 film screen-combination (Kodak Corporation, Rochester, NY) and were processed in a Kodak X-Omat 5000 RA processor.

Results

From 31 October 1996 through 30 September 1997 there were 59 patients recruited for the study and 47 of these had successfully completed digital as well as film-screen mammograms. Twelve patients were unable to have complete digital studies due to technical factors and will not be discussed further in this section. Of the 47 patients in the study 20 were seen because of a finding on a film-screen study and had film-screen images before digital images; they are considered the "F" group. Four of these had unilateral and 16 had bilateral studies. Five patients were in a follow-up protocol: 15 were seen in recall from a screening mammogram. The remaining 27 patients in the study were considered part of the "R" group where the sequence used for mammographic imaging was randomized between the two potential sequences of (1) digital then film-screen and, (2) film-screen then digital. Of these, 5 had unilateral and 22 had bilateral studies; 3 had screening exams and 24 had diagnostic exams; 11 had the film-screen study before the digital and 16 had the digital study before the film-screen. Of the 3 patients in the "R" group who had screening mammograms all were felt to have no finding suspicious for potential malignancy.

The remaining 44 study patients in the "R" and "F" groups had diagnostic assessments after which they were assigned to interpretative categories as follows: 25 category 1 (negative); 14 category 2 (benign); 6 category 3 (probably benign); 1 category 4 (suspicious); and 1 category 5 (malignant). Thus, 2 had findings suspicious enough for malignancy so that biopsy was advised. Availability of the second imaging modality in the assigned sequence resulted in a change in overall diagnostic assessment only once. In this case digital imaging initially resulted in an interpretative assignment of category 2 (benign), whereas the subsequent film-screen study resulted in an assignment of either 2 (benign) or 3 (probably benign) and ultrasound was recommended. This patient had a palpable abnormality in one breast. Spot compression magnification film-screen views demonstrated nodular densities that contributed to a recommendation for an ultrasound that revealed simple cysts. Magnification views are not currently available with the digital unit.

Three patients underwent biopsy. One had a cluster of microcalcifications which on excisional biopsy proved to be related to benign fibrocystic changes. A second patient had a new mammographic mass with similar appearance on both digital and film-screen images that was palpable. It was categorized as probably benign after diagnostic breast imaging primarily because of a history and physical examination strongly suggesting a hematoma. Subsequently this patient had surgical excision guided by palpation. The pathology was benign and compatible with the suspected etiology. The third patient had a spiculated mass of similar appearance on both digital and film-screen studies which was palpable and found to be an invasive ductal carcinoma on subsequent excision.

Observations

Our objective was to determine the clinical feasibility of the slot scanning digital mammography unit. A number of observations were made which are of considerable importance to this objective although not related to the more formal aspect of the study described above.

There was considerable downtime related to either prototype malfunction or installation of upgrades. This involved more than half of the period between initial attempt at use Oct 31, 1996 and completion of study Sep 30, 1996.

Several different artifacts were encountered which have resulted in corrections by the manufacturer. Principal among these were: (1) "stitching" artifact which consisted of bright lines in the image in the direction of scanner sweep at the junctions of the component charge-coupled devices, (CCD's); (2) an "echo" artifact resulting in an appearance resembling a faint repeat version of at least a portion of the principal image displaced and superimposed over the principal image; (3) white columns in the direction of scanner sweep at least roughly equivalent to one or more of the CCD's; and (4) "wrap around" of the image where the information acquired for the anterior portion of the breast was displayed posterior to the information acquired for the posterior portion of the breast. The "stitching" artifact occurred where adjacent CCD's fed in overlapping data that included noise for which it was not possible to perfectly correct. A new detector without such an overlap has eliminated this artifact. The "echo" artifact was primarily related to electronic cross-talk between analog multiplexers associated with adjacent CCD's and was

corrected with an improved circuit-board layout and better signal shielding. The white columns were related to mechanical disruptions of surface mounted connectors which are less likely to occur in the future due to hardware improvements. The "wrap around" artifact was found to be related to a timing error in the communications interface and was eliminated by substituting an improved timing crystal.

Display of digital images for patient management was restricted to soft copy, i.e., on a high resolution (2.5 x 2K) monitor. Although satisfactory high resolution (4 x 5K) laser images have been printed using the Ektascan 2180 laser printer (Kodak Corporation, Rochester, NY), this took too long for reasonable patient throughput. Early attempts at printing took more than an hour per image when successful; more recent attempts after software upgrades have taken about 5 minutes per image not counting development. The optimal look up table (LUT) for printing has not yet been determined although more than one have produced what appear to be satisfactory images.

The format for soft copy display has generally been acceptable. Either a single image can be displayed at approximately one-fourth resolution or 4 images can be displayed at resolution that is further reduced. Use of either the "pan" or "zoom" function allows full resolution to be displayed. As the limited field for either the "pan" or "zoom" function is moved over an image there is frequent hesitation and delay as the image is updated. We developed the interpretative review habit of using the zoom function to look at the entirety of each image at fully displayed resolution and found this repetitive delay to be time-consuming and annoying. To facilitate review of an image at full resolution it might be preferable to have a function that could be selected where the single image could be broken into multiple images, e.g., four with the system we studied, where digital information would be displayed at full resolution and the component images could be reviewed sequentially. We also noted a delay of up to several seconds between selection of a display mode and actual display. Considering the huge amount of digital data being processed this is understandable. Nevertheless, it could limit acceptance of the system by radiologists. Whether soft copy or hard copy digital images will prove to be superior for purposes of interpretation is a question not yet settled.

Several analysis tools were initially available including one for measurement of lesion size. This was unavailable for much of the later portion of the study because of a software problem that has since been addressed.

Archiving has, to date, been limited to a redundant array of inexpensive disks (RAID). Retrieval of information has been relatively rapid and satisfactory. We have not yet had to use a longer term storage device.

Exposure factors were limited by a set time for scanner movement of 6.9 seconds. The kVp was set manually based on the compressed thickness of the breast. Early in our experience some of the settings chosen resulted in overexposure of the skin and superficial tissues so that the corresponding pixels were saturated. This resulted in uncertainty as to location of the skin border, a situation which we felt was unacceptable. Particularly if an algorithm for display of digital information on a single image is used, recognizable skin borders will be essential (14,15).

With regard to patient throughput, image acquisition was relatively rapid and, after an exposure, was typically available to the technologist for review at the acquisition station within one minute. Suboptimal positioning or substantial image degradation from artifact was recognized quickly and allowed for rapid repeat imaging when appropriate.

The technologists found the control panel and display monitor at the acquisition station relatively easy to use. They had more difficulty adapting to the new detector and compression device due to their configuration and the fact that the effective imaging field corresponded to only a portion of the surface of the detector housing. The 12 cm thickness of the housing resulted in some difficulty with incorporation of posterior tissues in patients with protuberant abdomens. The gentle curvature in the surface of the housing, as well as approximately 3 cm of dead space at the left and right aspects of the housing which were mainly required for acceleration and deceleration of the detector, made positioning for oblique and 90° views slightly more difficult. It was found that by using the palpable lateral border of the latissimus dorsi muscle to guide placement of the detector for mediolateral oblique views more posterior upper outer tissue could be imaged than when the lateral margin of the pectoralis muscle was used for guidance as is recommended in film-screen imaging (16).

Even with careful attention to the technique used for positioning, however, at least some posterior tissue is not effectively imaged with the detector of the slot scanner due to the mandatory gap between the edge of the moving detector and its housing. This gap, the thickness of the shell of the detector housing, and the absence of sensitive CCD elements at the extreme tip of the bar-like detector result in a dead space where imaging data is not acquired of about 9 mm. This is 5 mm greater than the dead space we measured with the film-screen unit. Since the amount of excluded tissue is small and, in this region of the breast, typically includes little to none of the fibroglandular tissues from which cancers arise, this might not prove to be a major limitation. Nevertheless, it was judged to be an undesirable feature of the system. It has been reduced by about 3 mm on the detector of the SenoScan Prototype 2.

A factor that proved to be less of a problem than we had initially expected was the effective size of the imaging field. We had expected it to approximate the smaller (24 x 18 cm) of the two standard cassette sizes and had, therefore, anticipated that roughly 20% of our patients would not be adequately imaged if only routine single images in craniocaudal and mediolateral oblique projections of each breast were obtained. For this reason we initially excluded women with large breasts from the study group. After initial experience with the unit, however, we dropped this restriction and found that single routine digital views were all that were required for the last 22 patients of whom 7 required the use of large (24 x 30 cm) film-screen cassettes. Undoubtedly some breasts are so large that more than one digital exposure would have been needed to satisfactorily image the breast in one of the standard projections, however, this would probably have been an uncommon circumstance with the unit that we studied.

In an attempt to understand why this proved to be the case, we measured the imaging platforms for both the SenoScan Prototype 1 and the smaller of the cassette platforms for the Senographe DMR, and assessed their effective fields on images. For the film-screen unit we

found that the platform measured 18.6 x 27.7 cm, the film measured 17.8 x 23.8 cm, and the actual interpretable exposed field free of identifying information measured only 15.4 x 23.4 cm. For the digital unit the dimension of the platform in the direction of scanning was 32.3 cm with 26.9 cm of the length relating to the effective imaging field. The measurement from the platform edge which would be placed against a patient's chest wall to the margin of the effective field was 20.2 cm with the 0.9 cm closest to a patient constituting dead space. There was no field loss related to identifying information. Thus, the effective imaging field for the SenoScan Prototype 1 was significantly larger than that of the standard small size film-screen system. The factor which seemed to make the greatest difference in allowing patients with relatively large breasts to be imaged with the digital unit was the perpendicular distance from platform edge abutting the chest wall to the distal edge of the effective imaging field which was 20.2 cm (19.3 cm effective field + 0.9 cm dead space) as compared with 15.8 cm for the film-screen unit (15.4 cm effective field + 0.4 cm dead space). The above observations do not apply to the SenoScan Prototype 2, the imaging field for which has been reduced in size.

Because of the relatively long exposure time required with the slot scanner (6.9 sec), concerns have been raised regarding the risks of increased patient discomfort and motion artifact (3,4,6). Based on comments by patients, many seemed to have had more discomfort with the digital unit than the film-screen unit, however, this was not judged to be severe and in no case resulted in a patient withdrawing from the study. We did not identify motion artifact on any of the digital studies. No patient was harmed as a result of participating in the study.

Discussion

As the title of our protocol indicates, this was a preliminary demonstration of clinical feasibility: unfortunately, it was more preliminary than we had hoped. Because of the small number of patients studied, we are not warranted in drawing firm conclusions with regard to the probability that digital mammography using a slot scanner is as sensitive or more sensitive than film-screen mammography in detection of breast cancer. Only one breast cancer was discovered and was readily apparent using each modality. Availability of the second modality resulted in an alteration in management in only one patient. This suggests basic agreement between the two modalities and should encourage those wishing to compare the two modalities in larger trials. In this one instance the alteration in management was primarily related to the availability of spot magnification views with the film-screen technique. Although a system for magnification is not yet available for the slot scanner it is in the process of being designed and tested. Magnification is a frequently used tool in diagnostic mammography and, until it is available, we do not feel that the digital system will be optimal for use in that setting.

A second patient who had her digital study performed after her film-screen study had a cluster of very subtle tiny microcalcifications assessed to be suspicious for malignancy after magnification views. Even in retrospect most of the calcifications cannot be identified on the digital images. We feel they would have been judged to be benign if only the digital images had been available. Although the pathology was benign, this case raised concern regarding the ability of the digital system to detect extremely fine calcifications. A new detector installed by the manufacturer after the end of the study period is capable of much finer resolution (about 11

lp/mm) than the original detector (about 6 lp/mm) so that this may not prove to be a significant problem in the future.

We have made a number of observations on equipment performance, artifacts, display, patient throughput, breast positioning, and detector platform design. Many of these have led to equipment and software improvements that are ongoing. Despite the problems encountered in use of the system during the study period we remain very optimistic that a successful and reliable digital slot scanning digital mammography unit will prove feasible.

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Digital Mammography: Preliminary Demonstration of Clinical Feasibility

Edward R. Boyle, M.D.

CONCLUSIONS

Our objective was to assess the clinical feasibility of digital mammography using a slot scanner system and to make comparisons to conventional film-screen mammograms performed on the same patients. Delay in installation of the unit and subsequent malfunctions made it impossible to conduct the study in the fashion originally planned. Of 59 patients recruited between 31 October 1996 and 30 September 1997, 47 had successfully completed studies using both modalities. Three of these had screening exams and 44 had diagnostic exams. Sixteen had their digital exam before their film-screen study; 31 had the opposite sequence. Interpretative decisions using the BI-RADS system were made for study purposes after each modality. In only one patient did the availability of the second modality result in a change in management. In this case, spot compression magnification views, (unavailable with the digital unit), of a region of palpable abnormality revealed nodular densities that on ultrasound were simple cysts. Only one patient had cancer; this was evident using both modalities.

A number of observations were made, several of which have led to modifications of the unit that are likely to enhance its performance in the clinical setting.

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APPENDIX A

No personnel received pay related to this MIPR.

No publications or meeting abstracts have yet resulted from this MIPR.