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13. ABSTRACT (Maximum 200) Because of inefficient utilization of current mammography teaching facilities and existing deficiencies in training resources for radiologists, there is a need to supplement or replace the traditional film-based method of training. The purpose of this research is to develop a digital breast imaging teaching file (DBITF) as an interactive training tool for learning and continuing education for radiologists. Two hypotheses were investigated: (1) a comprehensive DBITF can be designed and implemented using current technology, and (2) this DBITF's interactive response-driven type of instruction is more effective than the traditional "show and tell" type of instruction used with film-based teaching files. To test these hypotheses, our current film-based breast imaging teaching file, which contains over 1,000 pathologically proved state-of-the-art imaging cases, was converted to digital format. Current technologies in high resolution film digitization, high resolution soft-copy image display, relational database architecture, and computer-aided instruction models were used to create a DBITF containing these cases. We have demonstrated that the effectiveness of using our DBITF to teach breast imaging interpretation is superior to that of traditional passive film-based teaching; it is also much more user-friendly. As a result of this research, we have developed a comprehensive DBITF as a national resource.				
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FOREWORD

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_____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Edward A. Sickles 10/6/97
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INTRODUCTION

Breast cancer is the fourth most common cause of death among women in the United States [1]. There is no known means of preventing the disease, and available therapy has been of very limited success in reducing the national mortality rate over the past 60 years. Current attempts at controlling breast cancer concentrate on early detection by means of mass screening, using clinical breast examination and periodic mammography, because ample evidence is now available to indicate that such screening indeed can be effective in lowering the death rate [2-13]. Cases judged abnormal at screening are further evaluated with breast ultrasonography, percutaneous-needle and/or needle-localization biopsy, and on an experimental basis with breast CT and breast MRI.

Extensive mammography quality assurance procedures have been developed over the past several years, and now are mandated by the U.S. Mammography Quality Standards Act. However, these procedures for the most part cover mammography equipment, imaging parameters, and image processing. They have not yet addressed the issue of image interpretation in a meaningful way.

Breast imaging interpretation is taught using a variety of approaches. During radiology residency and fellowship one-on-one instruction is used widely, but this is not feasible for post-graduate training (required for all radiologists practicing mammography), due to the overwhelming mismatch in numbers of teachers and students. As a result, continuing education primarily involves group instruction, using medical journals, books, lectures, workshops, and videotapes. A particularly effective teaching approach for both residency and post-graduate training involves individual review of selected case material, including original radiographs, sonograms, and supporting text material that indicates eventual clinical diagnosis. This material is traditionally presented in the format of film-based teaching files.

However, current teaching files, because they involve conventional film images, can be viewed by no more than a few users at a time. Because it is impossible to present the imaging work-up of each case on an image-by-image basis (one cannot anticipate all the work-up options that might be selected by an individual user), the display of film cases is limited to sequential descriptions of imaging findings, interpretations, and pathologic diagnoses.

Digitally stored and displayed teaching file images, on the other hand, can be viewed by large numbers of users simultaneously, at different workstations (even at distant sites), in the precise sequence in which the images were obtained. With carefully structured questions, each user can be prompted to respond by making his/her own observations, assessments, and work-up decisions just as if the patient were being examined at that time. This effectively replaces a "show and tell" teaching experience with the interactive, response-driven type of instruction that currently must be taught in person.

Additional advantages of a digitally-based teaching file are: (1) the user does not have to sort through all the films in each case in order to view them in the proper sequence; (2) the user is not burdened with the request to replace film images in the same sequence in which they were presented; (3) images and supporting text material cannot be misfiled, damaged, lost, or stolen; (4) digital images are much more amenable to

post-acquisition enhancement (enlargement, contrast and density windowing, filtering techniques [edge enhancement, unsharp masking, etc]) than are film images (enlargement by use of a magnifying lens); (5) digital images can be duplicated easily and relatively inexpensively without loss of image quality; (6) digital images can be viewed in various user-selected sequences (organized by mammographic finding, organized by pathologic diagnosis, organized by degree of difficulty of interpretation, organized by complexity of work-up, organized by use of specific work-up examinations); (7) user progress through the teaching file can be linked to providing correct answers for key questions; and (8) user progress through the teaching file can be documented by these correct answers, thereby permitting Category I credit for continuing medical education to be awarded automatically on an hour-for-hour basis.

This funded research is designed to investigate the effectiveness of an interactive computer-based digital breast imaging teaching file (DBITF) compared to that of an established and widely used conventional-film teaching file (CFTF) in providing initial and continuing medical education in breast imaging. Two hypotheses will be investigated: (1) A totally digital-based breast imaging teaching file can be designed and implemented with current technology; and (2) This DBITF's interactive response-driven type of instruction is a more effective teaching approach than the traditional passive "show and tell" type of instruction used with the CFTF. We believe that the DBITF will succeed primarily because it has the advantage of more closely approximating the real-life work-up of patients, since the user is presented with images in the sequence originally obtained and then is prompted to respond to his/her own observations and arrive at work-up decisions as if the patient were being examined at that time.

BODY

Six tasks were outlined in the Statement of Work within our grant proposal. Almost all of the Year 1 tasks were accomplished as initially planned. However, two minor modifications in our original plan were made during Year 1. (1) We undertook an initial pilot study evaluation of the DBITF in Year 1 rather than waiting until Year 3, to provide an early indication of effectiveness and user acceptance of the DBITF. This also permitted us to incorporate user suggestions for improved DBITF performance earlier in the process of DBITF creation. (2) We chose not to restrict case selection to those already entered into the CFTF as of the end of Year 1. This permitted us to include in the DBITF even more current case material and discussion of then unrealized concepts and advances in breast imaging. As a result, during Year 1 we selected only a representative sample of CFTF cases for inclusion into the DBITF, rather than all 1,000 cases planned for ultimate inclusion. The minor modifications we made in our original plan were affirmed, insofar as our Year 1 annual report was judged "acceptable as written".

The tasks for Year 2 outlined in the Statement of Work within our grant proposal were accomplished exactly as initially submitted. In our Year 2 annual report, we suggested a single modification to the evaluation (effectiveness and user acceptance analysis) task planned for Year 3. Specifically, we judged it impractical to divide our 1,000 DBITF cases into two 500-case sets for testing on radiology residents and practicing radiologists,

as initially planned, simply because such massive case sets would have taken many days (probably more than a week) for each individual to complete. Realistically, we would have been able to recruit few if any volunteers to spend this much time on the formal evaluation of DBITF versus CFTF. We therefore planned to select representative rather than comprehensive case material for testing, so as to limit the evaluation made by each individual to no more than 1 day. This minor modification was affirmed, insofar as our Year 2 annual report was judged "acceptable as written".

The tasks for Year 3 outlined in the Statement of Work within our grant proposal were accomplished exactly as initially submitted, except for the minor modification (described above) in our Year 2 annual report.

Task 1. Select cases from the current CFTF for inclusion into the DBITF. By the end of Year 2, we completed the selection of all 1,000 planned cases, based on inclusion of the full spectrum of mammographic findings, work-up approaches, and disease entities now encountered in breast imaging practice. Case selection includes the choice of images, collection of medical-related data, and formulation of questions/answers for interactive response-based instruction. Since many selected cases represent variations in appearance of similar mammographic findings, and since the work-up approaches for some mammographic findings are limited to relatively few choices, many of the DBITF test questions have similar (at times identical) wording.

Task 2. Convert the CFTF to digital format. In Year 2 we completed the digitization of selected film mammograms and other breast images (sonograms, needle localization images, ductograms, specimen radiographs, etc), so as to be compatible with our DBITF format. Related medical data (text) also was incorporated into the DBITF format that we described in our initial grant proposal. As we continued to accrue new (current) cases in our CFTF during Year 3, we incorporated the best of these into the DBITF, thereby replacing older cases already entered into the DBITF. We did not include cases involving breast CT and MRI, since the clinical roles of these modalities are still in flux.

Task 3. Image display. We have completed the development of a two-monitor 2K digital image display workstation (hardware and software), and have tested its use on a variety of subjects [14]. Refinements in software were based primarily on the suggestions of our initial test subjects, in order to maximize ease of use.

A Sun 4/470 platform is used, running SunOS 4.1.3. The workstation has 64 MB of system memory. Attached to the workstation is a parallel transfer disk, capable of storing 7-22 GB of digitized mammograms, and restoring these graphic files to be displayed very rapidly. Indeed, the four standard views of an initial mammography examination (MLO + CC views of right and left breast) are recalled from disk and displayed on paired monitors in less than 5 seconds. Using an average image size of 7.5 MB, this indicates a combined transfer-display rate of at least 5 MB/sec. The two gray-scale monitors used in the system have a display resolution of 2048 pixels by 2560 scan lines in portrait mode on their 21-inch (diagonal) screens, with 10-bit resolution.

Image processing is performed by dedicated hardware (Pixar, Inc), enabling an extensive library of image processing routines to be called upon for region of interest (ROI) investigations. Specifically, these include filtered edge detection, contrast enhancement, highlighted calcifications, and relief map simulation. In addition, images can easily be manipulated on the screen using real-time window and level controls and ROI magnification.

The only major limitation we have encountered so far in our digital image display system is a reduced ability to demonstrate at standard resolution (two paired images per monitor) the most subtle mammographic microcalcifications seen on conventional film mammograms. We encountered this limitation when digitizing film mammograms scanned with either 50-micron or 100-micron sampling pitch (using the specially designed Abe Sekkei laser film scanner described in our grant proposal). This has caused us to exclude cases involving extremely subtle microcalcifications as the sole mammographic finding on initial four-view examination (fewer than 1% of the cases included in our CFTF; fewer than 0.1% of cases encountered in clinical practice). During Year 2, we moved the DBITF workstation from its previous location in the UCSF Informatics Laboratory to the UCSF Mammography Reading Room, where residents, fellows, visiting radiologists, and UCSF staff radiologists do their daily work. These various physicians have been using the DBITF workstation ever since, on a regular basis, without any difficulty.

Task 4. Database design and implementation. During Year 1, we completed preliminary work on designing the architecture of the teaching file database system and the computer-aided instruction model, exactly as outlined in our grant proposal. In this format, we assembled a series of 20 DBITF cases, including 125 images and 155 interactive query-and-instruction questions. The bulk of this work, aided by feedback from initial test subjects, involved the development of a fast, robust, reliable, and user-friendly interface. The 20 cases also formed the basis for the pilot study of DBITF effectiveness described below.

During Year 2 we completed the remaining elements of database design and execution that had not been accomplished by the end of Year 1. Specifically, we successfully implemented our proposed design requiring the user to place a cursor over each lesion to be identified (pointing and clicking with a trackball), an important aspect of response-driven instruction, since only in this manner can the DBITF reliably test the user's ability to perceive abnormalities.

Task 5. Evaluation. Although our initial grant proposal called for this activity to begin in Year 3, for reasons stated previously we completed a pilot test of DBITF effectiveness and user acceptance.

This pilot study involved 18 of the 20 cases fully integrated into the DBITF, with test subjects using both DBITF and CFTF materials [15]. We studied 24 test subjects (radiology residents, fellows, and general diagnostic radiologists from UCSF and a neighbor institution), who were randomly assigned to start with either the DBITF or the CFTF. Each subject was given a pre-test and post-test, involving questions about breast imaging and breast cancer pertinent to the case material. Subjects then completed the

other teaching file, to serve as a comparison. The time required to complete each teaching file was recorded. A questionnaire was then administered asking subjects to rate on a scale of 1 to 10 the ease of use, level of enjoyment, and value as a learning tool for both the DBITF and CFTF. Subjects also were asked to indicate whether they would be more willing to use the DBITF or CFTF in the future, and which teaching file they would recommend to a colleague.

The mean time to complete the 18 cases in each teaching file was 1.5 hours. The group taking the post-test after completing the DBITF demonstrated a higher mean improvement (from pre-test) in scores, compared to the group that initially evaluated the CFTF, but results were not statistically significant. However, significantly higher ratings ($p < .01$) for the DBITF were recorded regarding ease of use, enjoyment, and value as a learning tool. 22 of 24 (92%) subjects favored using the DBITF over the CFTF in the future, and 23 of 24 (96%) subjects favored recommending the DBITF to a colleague.

Although not included in our original grant proposal, during Year 3 a fully functional DBITF workstation was displayed as a scientific exhibit at the week-long annual meeting of the Radiological Society of North America, a meeting attended by more than 50,000 registrants [16]. There was not sufficient time for such a large number of individuals to formally evaluate the DBITF workstation, but many hundreds of radiologists used it and provided us with suggestions for improvements. These assessments gave us additional guidance in further revising the numerous interactive response-driven test questions that we had already developed, and that we continued to develop, in order to maximize the teaching effectiveness of our case material.

The bulk of our evaluation took place in Year 3 of the project, as initially proposed. In order to recruit a sufficient number of volunteers to formally evaluate the DBITF versus the CFTF, we had to limit the number of studied cases so that each subject could complete his/her evaluation within one day. We selected 50-case DBITF and CFTF modules for study, on the basis of experience gained during Year 2 indicating that the average user could readily complete two such modules during one day. Each 50-case module involved cases of comparable degrees of variety, subtlety, and difficulty. We recruited 40 volunteer radiology residents, fellows, and general diagnostic radiologists to serve as test subjects in evaluating the DBITF in comparison with the CFTF. Subjects were randomly assigned to start with either the DBITF or the CFTF. Each subject was given a 50-question pre-test and post-test, involving questions about breast imaging and breast cancer pertinent to the case material. Subjects then completed the other teaching file, to serve as a comparison. The time required to complete each teaching file was recorded. A questionnaire was then administered asking subjects to rate on a scale of 1 to 10 the ease of use, level of enjoyment, and value as a learning tool for both the DBITF and CFTF. Subjects also were asked to indicate whether they would be more willing to use the DBITF or CFTF in the future, and which teaching file they would recommend to a colleague.

The mean time to complete the 50 cases in the DBITF and CFTF was 3.9 hours and 4.4 hours, respectively. The group taking the post-test after completing the DBITF demonstrated a significantly higher mean improvement (from pre-test) in scores, compared to the group that initially evaluated the CFTF ($p < .01$). Much more significantly higher subjective ratings for the DBITF were recorded, regarding ease of

use, enjoyment, and value as a learning tool ($p < .001$). 49 of 50 (98%) subjects favored using the DBITF over the CFTF in the future, and all 50 subjects favored recommending the DBITF over the CFTF to a colleague.

These results suggest that the DBITF is an effective approach to teach breast imaging interpretation, and that it is more readily accepted by radiologists than conventional film-based teaching files.

Task 6. Dissemination of the DBITF. During Year 2, the DBITF was made available to all radiology residents, fellows, staff radiologists, and visiting radiologists as an optional means to acquire continuing medical education at UCSF. At the start of Year 3, use of the DBITF became a mandatory part of the breast imaging instruction provided at UCSF; indeed, during this year it was used at UCSF by more than 300 radiologists from all over the United States. Also during Year 3, we disseminated our research findings to the general community of practicing radiologists in the form of an article published in the electronic journal of the Radiological Society of North America [17]. This is now available on the World Wide Web (http://ej.rsna.org/EJ_0_96/0037-97.fin/mammo.html). It contains a full description of DBITF design and implementation, as well as on-line demonstration of a DBITF case. We also published an article describing in detail the digital workstation used in the DBITF [18]. Finally, we will present our research findings later this year in Washington, DC, at the Department of Defense Breast Cancer Research Program's Era of Hope meeting, not only as a (required) poster presentation but also as an (invited) platform presentation.

The Breast Imaging Section at UCSF will maintain the DBITF after completion of the funded research project. Teaching file cases will be updated periodically by replacing older with newer case material (images, question and answer sets). When the availability of sophisticated digital breast imaging workstations, such as that which we have created at UCSF, becomes more widespread (including the necessary computer hardware and high-resolution display monitors), we plan to distribute the DBITF throughout the United States.

CONCLUSIONS

This project has been completed successfully, according to the description provided in our Statement of Work. We have indeed developed a functional, user-friendly, full-featured, comprehensive, interactive DBITF. This is now available, at UCSF, as a national resource for the teaching of breast imaging interpretation. We will make it available throughout the United States as soon as the availability of (required) digital breast imaging workstations becomes more widespread.

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PERSONNEL

This is a listing of all personnel receiving pay from this funded research effort.

Edward A. Sickles. M.D., principal investigator

H. K. Huang, D.Sc., co-investigator

Fei Cao, Ph.D., research fellow

Jianguo Zhang, Ph.D., research fellow

Tianro Zhang, B.S., research assistant

Helena Faye D'Alessio, data input technologist

RECOMMENDATION

Although we plan to disseminate the DBITF throughout the United States when the availability of high-resolution digital workstations becomes more widespread, this may take several years. In the meanwhile, the Department of Defense Breast Cancer Research Program should consider supporting the continuation of funding for maintenance of the hardware used in this project (a service contract for repair and replacement of all appropriate equipment costs approximately \$9000 per year).