Comparison of Soft-copy and Hard-copy Reading for Full-Field Digital Mammography[1]

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Purpose: To compare radiologists' performance in detecting breast cancer when reading full-field digital mammographic (FFDM) images either displayed on monitors or printed on film.

Materials and Methods: This study received investigational review board approval and was HIPAA compliant, with waiver of informed consent. A reader study was conducted in which 26 radiologists read screening FFDM images displayed on high-resolution monitors (soft-copy digital) and printed on film (hard-copy digital). Three hundred thirty-three cases were selected from the Digital Mammography Image Screening Trial screening study (n = 49 528). Of these, 117 were from patients who received a diagnosis of breast cancer within 15 months of undergoing screening mammography. The digital mammograms were displayed on mammographic workstations and printed on film according to the manufacturer's specifications. Readers read both hard-copy and soft-copy images 6 weeks apart. Each radiologist read a subset of the total images. Twenty-two readers were assigned to evaluate images from one of three FFDM systems, and four readers were assigned to evaluate images from two mammographic systems. Each radiologist assigned a malignancy score on the basis of overall impression by using a seven-point scale, where 1 = definitely not malignant and 7 = definitely malignant.

Results: There were no significant differences in the areas under the receiver operating characteristic curves (AUCs) for the primary comparison. The AUCs for soft-copy and hard-copy were 0.75 and 0.76, respectively (95% confidence interval: −0.04, 0.01; P = .36). Secondary analyses showed no significant differences in AUCs on the basis of manufacturer type, lesion type, or breast density.

Conclusion: Soft-copy reading does not provide an advantage in the interpretation of digital mammograms. However, the display formats were not optimized and display software remains an evolving process, particularly for soft-copy reading.

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Full-field digital mammography (FFDM) can improve the accuracy of mammography over screen-film mammography for pre- and perimenopausal women, women younger than age 50 years, and women with dense breasts (1). Compared with screen-film mammography, where the film both records and displays the image, FFDM decouples the two processes so that image acquisition and image display can be optimized separately (2). At present, however, it is unknown whether there is an advantage to viewing the images on a monitor (soft-copy) as compared with printing the digital images on film and viewing them on a view box (hard-copy).

Soft-copy viewing has the advantage of being able to optimize the display for each mammogram. Peripheral equalization algorithms can be used to reduce the dynamic range requirements of the display (3,4). This allows details in dense regions and regions near the skin edge to be visible simultaneously in a single image. Further, the image can be processed to highlight indications of cancer, such as masses and microcalcifications.

Soft-copy displays have the disadvantage of a less dynamic range than does film, making it more difficult to display the tissues near the skin edge and in dense regions of the breast simultaneously. Further, current displays are insufficient for viewing FFDM images that either have pixels smaller than 100 μm or, if the detector is large enough, have more than 2048 pixels in the smallest dimension. In such situations, the radiologist must zoom and pan the image to view all information recorded by the FFDM system. In addition, while image processing can be used to enhance lesions, the optimal image processing techniques are not as yet known. Finally, workstations still need much work to improve their functionality to enhance radiologists' productivity (5,6).

Our purpose was to compare radiologists' performance in detecting breast cancer when reading FFDM images either displayed on monitors or printed on film.

Table 1

Summary of Cases and Systems Used

Variable	Fischer	Fujifilm	GE Healthcare	All Systems
No. of readers	6	12	12	30
No. of cases	115	98	120	333
Cases negative for cancer	73	71	72	216
Lesion type				
No lesion	69 (94.5)	64 (90.1)	69 (95.8)	202 (93.5)
Mass	2 (2.7)	5 (7.0)	1 (1.4)	8 (3.7)
Calcification	2 (2.7)	2 (2.8)	0 (0.0)	4 (1.9)
Mass and calcification	0 (0.0)	0 (0.0)	2 (2.8)	2 (0.9)
Breast density*				
Not dense	40 (54.8)	43 (60.6)	36 (50.0)	119 (55.1)
Dense	33 (45.2)	28 (39.4)	36 (50.0)	97 (44.9)
Cases positive for cancer	42	27	48	117
Lesion type				
Occult lesion	16 (38.1)	6 (22.2)	16 (33.3)	38 (32.5)
Mass	7 (16.7)	14 (51.9)	18 (37.5)	39 (33.3)
Calc	17 (40.5)	6 (22.2)	11 (22.9)	34 (29.1)
Mass and calcification	2 (4.8)	1 (3.7)	3 (6.3)	6 (5.1)
Breast density*				
Not dense	16 (38.1)	18 (66.7)	25 (52.1)	59 (50.4)
Dense	26 (61.9)	9 (33.3)	23 (47.9)	58 (49.6)

Note.—Numbers in parentheses are percentages. Calcification refers to clustered calcifications.

* Breast density was determined with the Breast Imaging Reporting and Data System breast density scale by the clinical radiologist reading the digital mammograms: Not dense = score of 1 or 2, dense = score of 3 or 4.

Materials and Methods

This study received appropriate investigational review board approval from the participating institutions. This study was Health Insurance Portability and Accountability Act compliant; written informed consent was waived.

Five FFDM systems were used in the Digital Mammography Image Screening Trial (DMIST) study. However, cases in which two those systems were used were discarded (Digital Mammography System [$n = 6$] and

Advance in Knowledge

- In a large reader study, it was found that there was no advantage to soft-copy reading of full-field digital mammographic (FFMD) images over digitally printed images.

Implication for Patient Care

- FFDM images can be read printed digitally on film or displayed on soft-copy monitors without compromising breast cancer detection.

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Abbreviations:
AUC = area under the ROC
DMIST = Digital Mammography Image Screening Trial
FFDM = full-field digital mammography
ROC = receiver operating characteristic curve

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Selenia Full Field Digital Mammography System [n = 16]; Hologic, Bedford, Mass) systems. The Hologic Digital Mammography System is the original FFDM system developed by Hologic. The other three systems used by the DMIST study (SenoScan, Fischer Medical Technologies, Denver Colo; the Computed Radiography System for Mammography, FujiFilm Medical, Stamford, Conn; and Senographe 2000D, GE Healthcare, Waukesha, Wis) were included in this study. Table 1 shows the breakdown of the cases by using pathologic analysis, lesion type, breast density, and type of digital system used. Table 2 gives the number of cancers sorted by diagnosis type and the average size of invasive cancers sorted by manufacture type.

The digital soft-copy images were displayed on each manufacturer's review workstation (SenoAdvantage 3.2, GE Healthcare; MV V02, Fujifilm; and SenoScan Soft-copy Workstation 2.1, Fischer) capable of displaying the digital mammograms acquired during the DMIST study. The software was state of the art at the time of the study, but newer software is available on some of the systems (eg, Premium view, which is now available on GE Healthcare display systems, was not used in this study). Calibration of GE Healthcare and Fujifilm monitors were automatically performed by the respective soft-copy systems given the manufacturer's specifications. Manual adjustments were made when prompted by the systems to do so.

The monitors used for these studies were components of commercial review workstations provided by each manufacturer. All 5-megapixel monitors were calibrated to the Digital Imaging and Communications in Medicine standard. The GE Healthcare workstation was a three-monitor configuration: one color liquid crystal display and two high-resolution gray-scale (SenoAdvantage [2560 × 2048 display, 10 bit]) cathode-ray tube monitors. The Fischer workstation was a three-monitor configuration: one color liquid crystal display and two high-resolution gray-scale (Barco MGD 521 M [2560 × 2048, 10 bit]) cathode-ray tube monitors. The Fujifilm workstation was a two-monitor configuration: two high-resolution liquid crystal display (DOME C5i [2560 × 2048, 8 bit]) monitors.

Fujifilm also provided a printer for the printing of both GE Healthcare and Fujifilm hard-copy images (if hard-copy films were not provided by the enrolling site). All Fischer hard-copy films were provided by the enrolling site through Fischer Medical Technologies.

Table 2

Diagnosis and Average Size for Invasive Cancers

System Used	DCIS*	Invasive Cancer				All Cancers*
		Size Not Available*	Size Available*	Mean Tumor Size (cm)	Total*	
Fischer Imaging	18 (43, 43)	2 (5, 22)	22 (52, 33)	1.4	24 (57, 32)	42 (100, 36)
Fujifilm	9 (33, 21)	3 (11, 33)	15 (56, 23)	1.4	18 (67, 24)	27 (100, 23)
GE Healthcare	15 (31, 36)	4 (8, 44)	29 (60, 44)	1.3	33 (69, 44)	48 (100, 41)
All	42 (36, 100)	9 (8, 100)	66 (56, 100)	1.3	75 (64, 100)	117 (100, 100)

Note.—DCIS = ductal carcinoma in situ.

* Values are number of cancers; the first number in parentheses is the percentage of all cancers detected, and the second number is the percentage all cancers detected across all scanners.

Figure 1

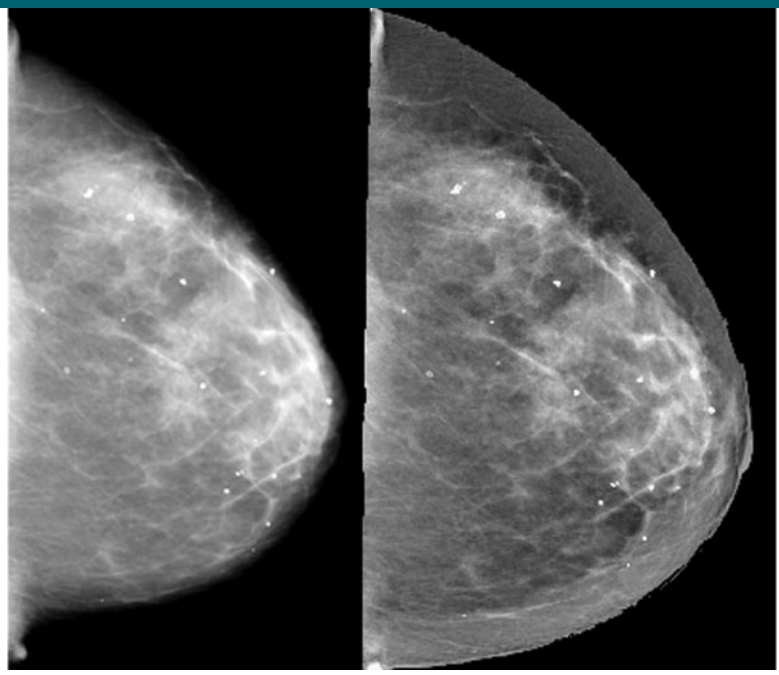

Figure 1: Mammographic image from 73-year-old patient, displayed on soft-copy monitor (left) and printed on film (right), was obtained with Fischer system. Interpretation of printed digital image at acquisition site was done with manufacturer's skin algorithm applied. Soft-copy image displayed here also includes algorithm.

Display Methods

The digital images selected for presentation for both soft-copy and hard-copy readings were printed on film suitable

for mammography by using laser printers to create hard-copy versions of the digital mammograms. The GE Healthcare digital images were printed at the University of North Carolina (Chapel Hill, NC), as were most of the Fujifilm digital images, on film (HI-HL; FujiFilm) by using a medical laser printer (Drypix FM-DPL; FujiFilm). For the Fischer cases, we used the images that were printed to film for the initial DMIST interpretations at the site where the mammograms were acquired. The type of film and printer were not specified in the study protocol, except that they were recommended by the manufacturer. The image processing applied depended on what each site had available at the time of printing but the resulting images would have matched the soft-copy images displayed. Examples of the soft-copy and hard-copy images for each manufacturer are shown in Figures 1–3.

Digital hard-copy images were displayed on a mammographic film viewer (RadX MammoView; S&S Technology, Houston, Tex). The readers had use of a ×2-magnification, 5-inch magnifying glass (Bausch & Lomb, Rochester, NY) for both conditions.

Description of Cases

The cases used in this study were selected from the 49 528 cases that were collected in the DMIST study (1), which had 335 patients with cancer and 49 193 without. The reader studies were designed and initiated before the end of the main study. The case set selected for this retrospective multireader study included all cancers known at the time of case selection (n = 117), along with a set of cases negative for cancer matched to the cases positive for cancer by using age and breast density. The case matching was done by the American College of Radiology Imaging Network Biostatistics Center (Brown University, Providence, RI) and used an algorithm specifically developed for this study. Roughly speaking, for every two cancer cases, three cancer-free controls were chosen, broadly matched by using age and breast density. The final composition of the reading set included 117 cases with cancer and 216 cases without. To establish a reference standard, subjects were classified as having a positive diagnosis for cancer if breast cancer was pathologically verified within 455 days after the initial study mammogram was performed; and having a negative diagnosis for cancer if their study records showed negative findings on a pathologic report of a biopsy specimen, if the follow-up mammogram (obtained 10–15 months after enrollment in the study) was normal, or if they were reported as cancer-free at the time of follow-up. All but one of the subjects without cancer underwent follow-up mammography.

As a result of time constraints, this reader study was started shortly after accrual to the main DMIST study ended. Therefore, follow-up data had been obtained for less than one-half of the subjects. Given this limitation, it was not possible to perfectly balance the distribution of lesion types across the different machine types.

The effect of breast density was examined. Breast density, as determined clinically by the radiologist who prospectively read the digital mammogram, was used in this study.

Description of Readers

Readers were recruited through a broadcast announcement to radiologists in the American College of Radiology Imaging Network. The readers were allowed to select the mammographic system for which they were interested in reading images from cases and they read all available images from cases in which that system was used, both hard-copy and soft-copy versions. If all available reading slots were taken for a specific manufacturer, the readers were asked if they would be interested in reading images from cases from another manufacturer. A total of 26 radiologists participated as readers. Four readers read images from cases from two manufacturers in this study. All radiologists except one self-reported breast imaging experience that

Figure 2

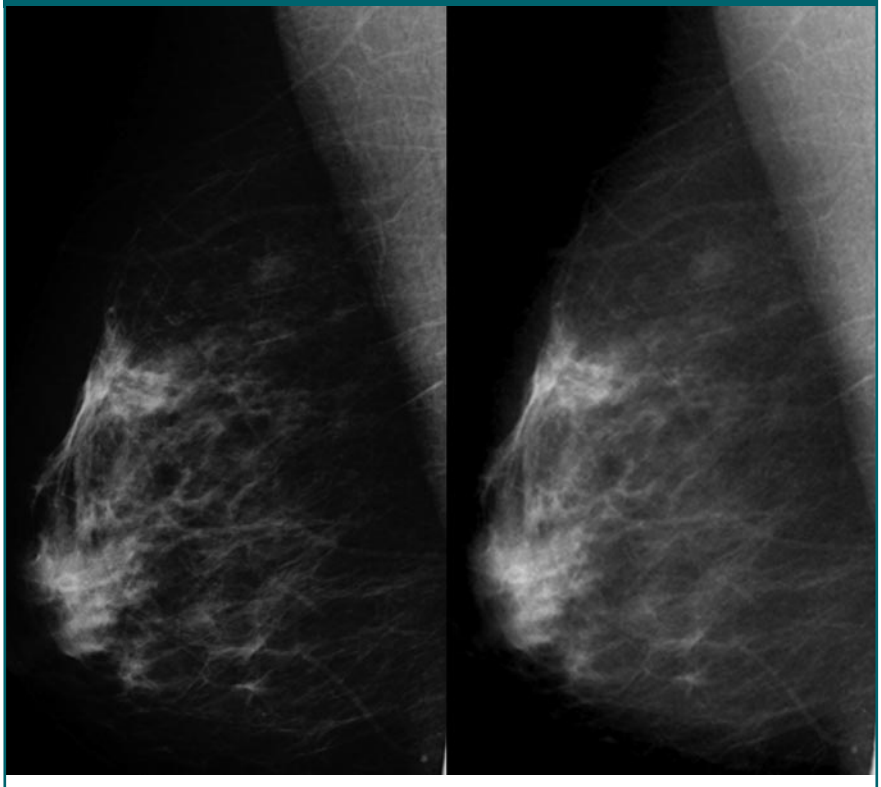

Figure 2: Mammographic image from 49-year-old patient, displayed on soft-copy monitor (left) and printed on film (right), was obtained with FujiFilm system. Image shows difference in adjustments to contrast and brightness that were, in some instances, made prior to printing digital mammograms to film. Readers in this experiment could adjust brightness and contrast of soft-copy images.

ranged from 1.5–33 years. They spent 10%–100% of their clinical duties dedicated to breast imaging, reading images from between 50 and 500 cases per week. All but two had prior digital mammographic experience (Table 3). Twenty-two radiologists were certified by the American Board of Radiology and were qualified under the Mammography Quality Standards Act, two had international certifications, and two had missing information. Ten of the readers were DMIST readers.

The target design of the reader studies was to include 50 patients with cancer and 75 without and 12 readers for each manufacturer. This would ensure 80% power to detect a difference of 0.06 in average receiver operating characteristic (ROC) curve areas among the results for each manufacturer (7). As outlined in Table 1, these targets were not met. As a consequence, the study design, as implemented, ensured 80% power to detect differences of 0.06 in average ROC curve areas for the GE Healthcare study set, 0.09 for the Fischer study set, and 0.08 for the Fujifilm study set.

For the GE Healthcare cases, 10 of 12 readers had prior digital mammographic experience on different systems (eight with GE Healthcare only and two with Fischer only) and two readers had none. Given the Forest plot, the performance of these two readers did not substantially differ from that of the readers with digital experience.

For the Fujifilm cases, all 12 readers had prior digital mammographic experience on different systems (seven with GE Healthcare only; one with Fujifilm only; two with GE Healthcare, Fischer, and Fujifilm; one with Fischer only; and one with Hologic only).

For the Fischer cases, all six readers had prior digital mammographic experience with different systems (two with Fischer only; two with Fischer, GE Healthcare, and Fujifilm; and two with GE Healthcare only). While this reduced the statistical power for finding differences among different acquisition systems, we do not believe that there are any trends in the data that suggest a larger number of readers would have led to finding significant differences among machine types. There were no trends in the data that suggested this unbalance had any effect on the conclusions of our study.

Figure 3

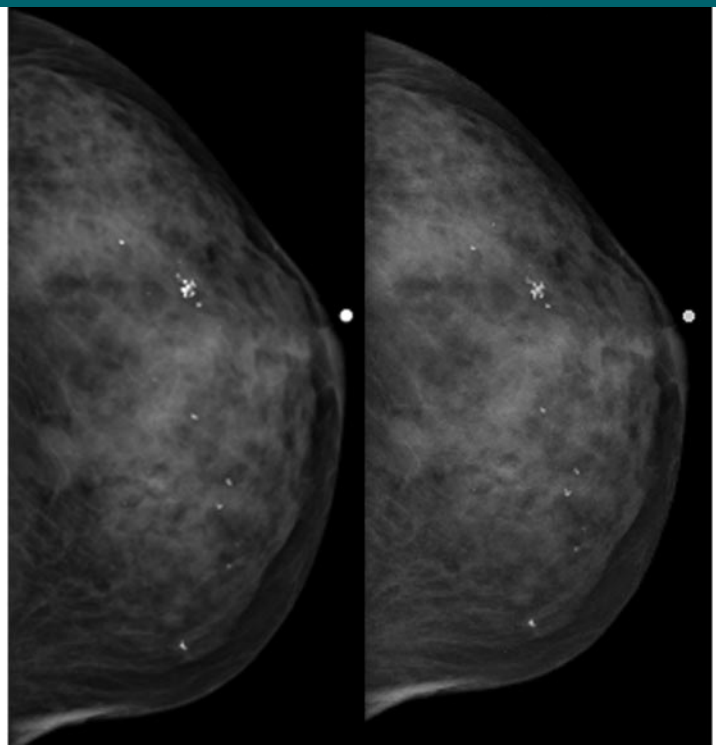

Figure 3: Mammographic image from 58-year-old patient, displayed on soft-copy monitor (left) and printed on film (right), was obtained with GE Healthcare system. For this image, soft-copy default was printed on film.

Table 3

Breakdown of Reader Experience

Years of Experience	GE Healthcare Images	Fujifilm Images	Fischer Images
No. of readers	12	12	6
Years of experience reading digital mammography			
Mean	2.38	3.67	3.83
Median	1.75	2	3
Range	1–12	1–10	2–10
Years of experience reading digital mammograms on softcopy display			
Mean	1.38	3.08	3.33
Median	1.25	2	2.5
Range	0–3	0–10	0–10

Note.—Three readers read both GE Healthcare and Fischer images; one reader read both FujiFilm and Fischer images.

Description of Observer Study

Each reader was instructed by a research assistant (E.B.C.) on the functional capabilities of the soft-copy review workstation: selecting cases, navigating through a case, and basic image processing features (window width and level, pan, zoom, magnify, and flip) at the beginning of the soft-copy reading session. This was done by using 10

training cases that were not included in the study.

Readers completed two 1-day reading sessions. A counterbalanced design was used, with images presented in a randomized order for each reader and condition. There was a minimum 6-week interval between each reader's sessions to minimize recall bias. For each case, the readers were asked to specify if there were any mammographically occult findings. If there were, the readers were asked if they would recall the patient for diagnostic work-up and/or biopsy and to specify the side. The readers were asked to provide their suspicion of malignancy rating for each breast by using the following seven-point scale for findings: 1 = definitely not malignant, 2 = almost certainly not malignant, 3 = probably not malignant, 4 = possibly malignant, 5 = probably malignant, 6 = almost certainly malignant, and 7 = definitely malignant.

Description of Statistical Analysis

We analyzed the data for differences in reader performance between soft-copy and hard-copy readings. The primary metric of diagnostic performance was the area under the ROC curve (AUC). ROC curves were constructed by using the seven-point malignancy scale. Sensitivity and specificity were secondary metrics that were also reported by using the seven-point scale, with scores of 1–3 considered as negative and 4–7 considered as positive. The primary aim was to compare the average AUC for soft-copy and hard-copy displays computed over all FFDM systems and readers. The secondary aims were to compare the average AUC computed for certain subsets of interest defined on the basis of lesion type and breast density. Comparisons were also made among the manufacturers.

Estimates of AUC were developed by using a parametric binormal model, as implemented in the ROCKIT software (8). Estimates of correlations for ROC areas needed for the mixed-model calculations were derived from paired analysis by using ROCKIT. Estimates of correlations for sensitivity and specificity terms were developed by using large-sample theory. The software OBUMRM *(http://www.bio.ri.ccf.org/html/obumrm.html)* and standard computing routines (SAS, version 9.1; SAS Institute, Cary, NC,) were also used for parts of the analyses. OBUMRM applied the protocol-specified mixed-model approach and treats cases and readers as random effects. We used ROCKIT to generate estimates of some input parameters for running OBUMRM. Graphs and plots were created with software (SPLUS, version 7; Insightful, Seattle, Wash).

AUC estimates were averaged across readers within a modality for each of the FFDM systems. Overall estimates of accuracy obtained by pooling data across the FFDM systems were recorded. A mixed-model approach was used to determine confidence intervals for averages and for the comparison of average AUC, sensitivity, and specificity (7,9–11). In each model, modality was entered as a fixed effect and reader was entered as a random effect. The mixed-model approach accounts for correlations from multiple readers interpreting the same image set for two modalities.

For each manufacturer, the above analysis was conducted first by using the ensemble of all images and then for subsets of images, defined on the basis of breast density computed from the digital display (and dichotomized as in the primary source [1]), and lesion features of interest (presence of masses and calcifications). In analysis of subsets, AUCs and correlations were estimated nonparametrically. We did not collect from the readers the type of lesion that they were marking. Therefore, we did not know what type of lesion the radiologist thought was present for false-positive detections; thus, specificity could not be calculated for lesion type. For true-positive detections we assumed that the type of lesion that was actually present on the image was the type of lesion that the radiologist detected, and thus, sensitivity could be calculated for each lesion type.

The number of years of experience or the reader was not significantly different by using the Kruskal-Wallis test for analysis across the three reported systems (Fischer, Fujifilm, and GE Healthcare) for both hard-copy (P = .13) and soft-copy (P = .16) experience.

The Bonferroni correction was ap-

Table 4

Comparison of Three Measures of Performance for Soft-copy and Hard-copy Display for Five Categories for All Machine Types

	AUC				Sensitivity				Specificity			
Category	Softcopy	Hardcopy	*P* Value	95% Confidence Interval	Softcopy	Hardcopy	*P* Value	95% Confidence Interval	Softcopy	Hardcopy	*P* Value	95% Confidence Interval
All lesions	0.75	0.76	.36	−0.04, 0.01	0.52	0.51	.97	−0.05, 0.05	0.83	0.83	.75	−0.03, 0.04
Mass lesion	0.72	0.71	.88	−0.07, 0.06	0.60	0.59	.98	−0.06, 0.07	NA	NA	NA	NA
Clustered microcalcification	0.58	0.59	.6	−0.12, 0.07	0.59	0.59	.79	−0.10, 0.08	NA	NA	NA	NA
BI-RADS density score												
1 and 2	0.76	0.77	.61	−0.03, 0.02	0.57	0.52	.27	−0.03, 0.09	0.83	0.84	.85	−0.04, 0.03
3 and 4	0.68	0.68	.8	−0.04, 0.03	0.43	0.46	.2	−0.12, 0.03	0.83	0.82	.36	−0.02, 0.06

Note.—Specificity was not calculated for different lesion types, because the type of lesion being marked by the radiologist was not recorded in our experiment. BI-RADS = Breast Imaging Reporting and Data System, NA = not available.

plied to adjust for multiple comparisons. The accounting included the AUC, sensitivity, and specificity comparisons within each FFDM system, as well as similar analyses restricted to subsets of interest defined by covariates such as breast density and lesion type. There were 24 comparisons in all, and a *P* value of less than .002 was considered to indicate a Bonferroni-corrected significant difference.

Results

The difference in AUCs between soft-copy and hard-copy readings was −0.01 (95% confidence interval: −0.04, 0.01. There were no significant differences between soft-copy and hard-copy readings in terms of AUC, sensitivity, or specificity (Table 4).

We found no significant difference in AUC, sensitivity, or specificity between soft-copy and hard-copy displays for either fatty or dense breasts (Breast Imaging Reporting and Data System breast density scores of 1 and 2 or 3 and 4, respectively). Analyses performed showed no significant difference between soft-copy and hard-copy for any of the three machine types for viewing images with either masses or clustered microcalcifications.

Overall, there were no significant differences in AUC, sensitivity, or specificity. All of the *P* values except one were nonsignificant at the 5% level, even without adjusting for multiple comparisons, except the Fischer system sensitivity difference between soft-copy and hard-copy readings for the detection of cancer in fatty breasts (Breast Imaging Reporting and Data System breast density scores of 1 and 2) was ($P = .04$). Adjusting for multiple comparisons, this difference was not significant. Figure 4 shows Forest plots of AUCs for each reader grouped for each machine type.

Discussion

The sensitivities in our study were lower than those reported in the literature. We believe that is because our study included a large number of cases

Figure 4

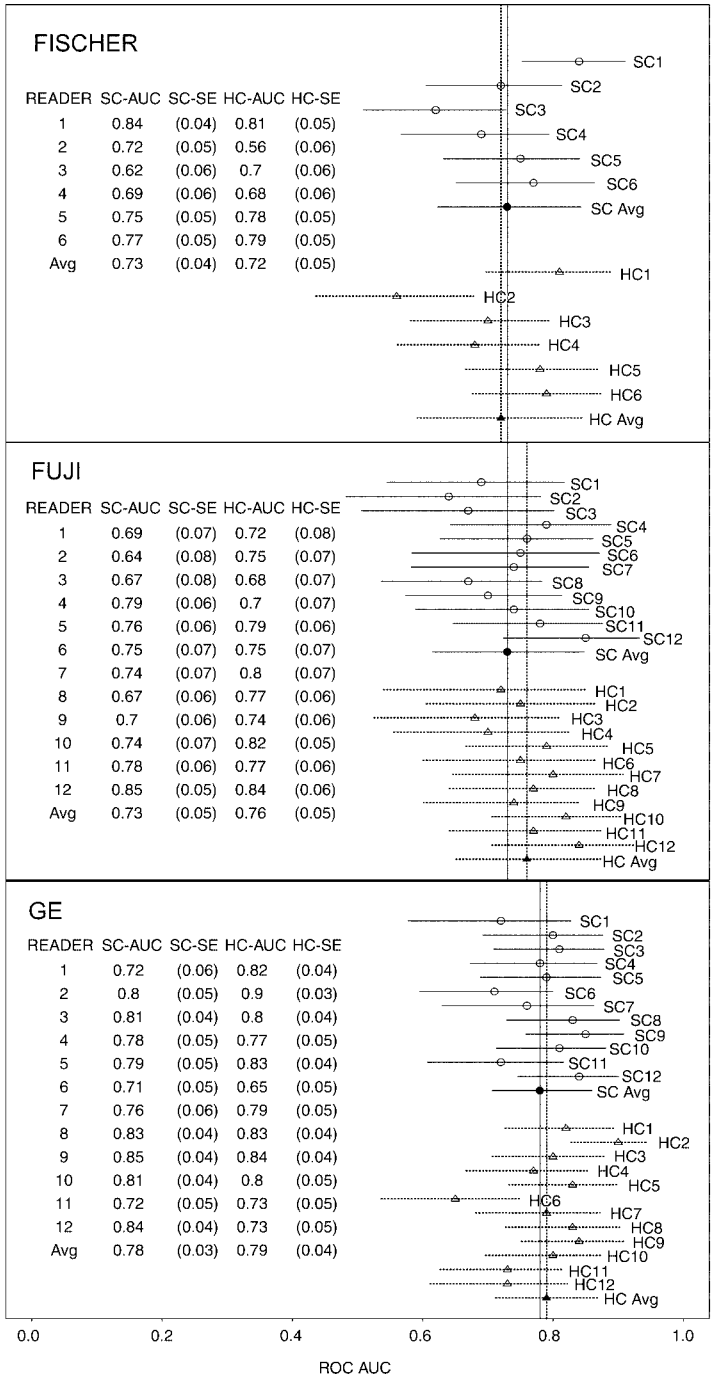

Figure 4: Forest plots of AUCs for machine types. Each plot shows soft-copy AUC (*SC-AUC*) and standard error of the mean (*SC-SE*) and hard-copy AUC (*HC-AUC*) and standard error (*HC-SE*) for each reader and average of all readers. Average AUC for hard-copy (△, dotted vertical line) and soft-copy (●, solid vertical line) images are shown.

in which findings were mammographically occult on the digital images because each woman underwent both digital and conventional mammography (and some cancers were detected only by using conventional mammography), and because we had a 15-month follow-up instead of the standard 12 months.

While there may be differences between sensitivity and specificity for different FFDM systems, no such direct comparison was done in this study. Given the relatively few cancer cases in the study for each machine type, a large variation in the conspicuity of the cancers among systems is highly probable. This variation in conspicuity can lead to a large source of variation in the experiment as a whole (12,13). Furthermore, and perhaps more important, different radiologists read images from the cases from each system and this could have led to a variation in the measured sensitivities and specificities among systems because there is a wide variation in radiologists' abilities (14,15).

The dynamic range of film is greater than that of soft-copy monitors, where the dynamic range is limited to less than 10 bits (3). However, window width and level adjustments allow the effective dynamic range of soft-copy reading to surpass that of hard-copy reading, which has a fixed display characteristic. Therefore, when imaging dense breasts, the dynamic range of film could be insufficient, conferring an advantage on soft-copy reading. However, all digital systems incorporated peripheral equalization (3,4), effectively reducing the required dynamic range by reducing the maximum pixel value needed to be displayed (Figs 1–3). We found no significant difference in AUC, sensitivity, or specificity between soft-copy and hard-copy displays for either fatty or dense breasts.

One limitation of soft-copy monitors was that the maximum image size that can be displayed at full spatial resolution is 5 megapixels. However, a digital mammogram recorded with 50-μm pixels has a full spatial resolution of at least 20 megapixels. Therefore, to view the image at full spatial resolution, each image must be viewed in at least four sections. This makes the process of reading the digital mammogram inefficient, which could lead to a decrease in performance. The Fischer Medical Technologies and FujiFilm systems recorded the image with 50-μm pixels and the GE Healthcare system used 100-μm pixels. Analyses for each manufacturer type showed no significant difference between soft-copy and hard-copy readings for any of the three machine types for cases with masses or clustered microcalcifications.

Another limitation of our study was that neither the hard-copy nor soft-copy display was optimized for viewing digital mammograms. In our study, the processing algorithms used to show the images were those integrated into the soft-copy display for each manufacturer. Default settings were established for initial viewing of the images for each soft-copy display system but the readers could adjust the brightness and contrast of the images. The readers also had the benefit of viewing images with secondary image processing integrated into the soft-copy display systems, which typically improved the visibility of the skin edge if not provided by the default setting. One of the advantages of digital mammography over conventional mammography is that digital mammograms can be processed to enhance the appearance of lesions. Unfortunately, the optimum processing techniques are as yet unknown, and it is possible that different processing algorithms will be used to enhance microcalcifications and masses in the future (16). With hard-copy film, unless multiple versions of the images are printed by using different types of processing—not practical or realistic clinically—then a compromise between enhancing microcalcifications and masses must be made. With soft-copy displays, it is both possible and practical to show two versions of each image: one for detecting microcalcifications and one for detecting masses. We did not take advantage of this feature for soft-copy reading and only a single compromised processed image was shown, as is done with film. With proper optimization, it is possible that soft-copy reading could be superior to hard-copy reading.

Finally, our study was conducted as an ROC study and did not take lesion localization into account. In theory, a reader could correctly identify the case as positive for cancer, but not localize the cancer correctly, which could change the measured sensitivity. However, we are more interested in looking at the differences between soft-copy and hard-copy readings. It is unlikely that if we accounted for lesion localization errors that the conclusions of our study would change because there is little difference in AUCs between soft-copy and hard-copy readings for any given reader.

In conclusion, we found that soft-copy reading does not provide an advantage over hard-copy reading for FFDM. Further, from the subset analyses, we concluded that soft-copy reading was no better than hard-copy reading in terms of sensitivity and specificity. However, the display formats were not optimized, and display software remains subject to an evolving process, particularly for soft-copy reading.

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