Diagnostic quality of 50 and 100 µm computed radiography compared with screen–film mammography in operative breast specimens

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Objective: To compare reader ratings of the clinical diagnostic quality of 50 and 100 µm computed radiography (CR) systems with screen–film mammography (SFM) in operative specimens.

Methods: Mammograms of 57 fresh operative breast specimens were analysed by 10 readers. Exposures were made with identical position and compression with three mammographic systems (Fuji 100CR, 50CR and SFM). Images were anonymised and readers blinded to the CR system used. A five-point comparative scoring system (–2 to +2) was used to assess seven quality criteria and overall diagnostic value. Statistical analysis was subsequently performed of reader ratings ($n=16\,925$).

Results: For most quality criteria, both CR systems were rated as equivalent to or better than SFM. The CR systems were significantly better at demonstrating skin edge and background tissue ($p<1\times10^{-5}$). Microcalcification was best demonstrated on the CR50 system ($p<1\times10^{-5}$). The overall diagnostic value of both CR systems was rated as being as good as or better than SFM ($p<1\times10^{-5}$).

Conclusion: In this clinical setting, the overall diagnostic performance of both CR systems was as good as or better than SFM, with the CR50 system performing better than the CR100.

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There are currently three technologies widely available for diagnostic mammography: screen–film mammography (SFM) and two forms of large-field digital mammography [1]. The use of the term full-field digital mammography (FFDM) varies in the published literature and has been applied to both computed radiography (CR) and direct digital radiography (DR). Small-field digital mammography (SFDM) is mainly used for imaging during stereotactic biopsy [2].

The advantages of digital mammography over SFM include: improved sensitivity in dense breast tissue, reduced radiation dose, the ability to manipulate images for review, and digital storage and retrieval methods [3]. CR was the earliest digital system in use. Imaging cassettes contain a re-useable photostimulable phosphor, replacing the traditional screen–film cassettes, and are then transferred to a laser reader. DR has an in-built detector and reader. Digital mammography has a lower spatial resolution than SFM, but has a very high contrast resolution. This allows the overall resolution of digital mammography to be at least equivalent to SFM [4–8], even when viewing calcification smaller than the pixel size [9]. Some CR systems have not met the quality standards of a number of governing bodies for mammography, including the European Network of Reference

Assessment Centres (EUREF) and the NHS Breast Screening Programme (NHSBSP) [10, 11]. This is related to the resolution achievable with 100 µm cassettes [12]. It is now known that CR systems using 50 µm cassettes can provide improved resolution, at an acceptable mean glandular dose, and have been approved for screening by the NHSBSP [13–15].

Phantom studies indicate that the resolution and performance of DR are greater than those of CR [16, 17], but have limitations. Although there are many clinical studies comparing the performance of DR and SFM [4–7, 9, 18–26], there are fewer that compare CR with SFM or DR [8, 25, 27–32]. We sought a method to compare the clinical diagnostic quality of two types of CR technology with that of SFM. We chose to study surgical specimens of breast tissue, which, although not absolutely comparable to *in vivo* mammography, allows realistic testing of image quality. In addition, multiple exposures can be obtained in reproducible conditions without irradiating the patient.

Methods and materials

Study design

The local research ethics committee gave approval for the study. All patients signed consent forms pre-operatively, agreeing to use of tissue for research and

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teaching. Radiographs were taken of fresh operative specimens from the majority of breast surgical lists over a 5 month period. A helper collected each fresh specimen (in a thin, radiolucent bag) from theatre, which was then taken immediately to radiology, radiographed and then taken directly to pathology.

A total of 57 specimens from 49 patients (48 female, 1 male) were analysed (Table 1). The mean patient age was 58 years (range 33–88 years).

Imaging and processing

An Instrumentarium alpha RT mammography machine was used (Instrumentarium Corporation, Tuusula, Finland) with a molybdenum filter. Automatic exposure control was used for all images at 28 kV. Three sequential exposures were taken for each specimen using screen–film (MIN-R2 cassettes with EV 150 screens and MIN-R EV film; Kodak), 50CR and 100CR [Fujifilm, Fuji IP cassette (D) and Fuji IP cassette type C; Fuji Photo Film Company Ltd, Tokyo, Japan] cassettes. Exposures were made of the specimens in a thin, radiolucent bag, with identical position and compression for all three imaging systems, thereby providing absolutely reproducible conditions. CR cassettes were placed in a dual-sided laser reader (PCR CosimaX Image Reader; Philips Healthcare UK, Guildford, UK). The resulting digital images were then transferred to the hospital PACS system (EasyVision; Philips Sectra, Milton Keynes, UK). Hard-copy images were obtained from screen–film exposures, using a Kodak 480RA film processor (Carestream Health UK Ltd, Hemel Hempstead, UK).

Image interpretation

10 readers with varying experience analysed the images. The group comprised seven mammographic film readers with between 2 and 20 years' experience in screening mammography (five consultant radiologists, one radiographic specialist practitioner and one research fellow in breast imaging) and three specialist registrars in radiology. Images were anonymised and readers were blinded to the CR system. Readers carried out the evaluation over one or two sessions (in total between 3 and 4 h). Screen–film images were viewed on a light box with a bright light if required and a magnifying glass was available. CR images were viewed via a Phillips Sectra PACS on high-resolution 5 megapixel monitors (Bracco UK Ltd, High Wycombe, UK). The luminance of the reading room and viewing box met the standards for

mammographic interpretation as defined by the NHSBSP. Images were presented in the same order to all readers. Line diagrams of the specimen radiographs indicating the area of interest, skin edge and type of abnormality (if present) were available to all film readers during the analysis. For each specimen radiograph, comparisons were made between the CR100 and screen–film, the CR50 and screen–film, and the CR100 and CR50. CR images were viewed using a standard format on both fit to screen and maximum zoom. Fit to screen displayed a whole image at 100% size, whereas maximum zoom displayed a partial image at full resolution. The window settings could be altered manually with the mouse, and the "pan" function used on maximum zoom images. Masses were present in 29 of the specimen radiographs (14 specimens had irregular, 13 spiculate and 2 lobulated masses). Microcalcification was present in 27 specimens and, of these, 16 specimens contained both masses and calcification. 14 specimens were mammographically normal. A skin edge was present in 23 specimens. 14 wide local excision specimens had a localisation wire *in situ*. Readers evaluated eight parameters: mass conspicuity, mass detail, calcification conspicuity, calcification detail, number of calcifications visible, background tissue visibility, skin edge visibility (where applicable) and, finally, overall diagnostic value. The last was defined as the confidence of the reader to make a diagnosis from the information available. Preference scores were obtained for each parameter studied, using a subjective five-point system, where 0 is equivalent, 1 is slightly better, 2 is significantly better, –1 is slightly worse and –2 is significantly worse.

Statistical analysis

Preference scores for each parameter were cross-tabulated with each of the three pairwise imaging comparisons. The sums of the minus counts (worse than), 0 counts (no difference) and of the plus counts (better than) were analysed using the two-tailed *t*-test with Bonferroni correction for a binomial distribution (minimum number of tests, 229; maximum, 570), where a *p*-value <0.05 was statistically significant.

Results

Background tissue density

Specimen radiographs were scored for mammographic density, using the three-point scale (fatty, mixed

Table 1. Specimen type compared with final pathology

Specimen type	Normal	Benign	Lobular carcinoma <i>in situ</i>	<i>In situ</i> carcinoma	Invasive carcinoma	Totals
Mastectomy	2	0	1	6	13	22
Wide local excision	0	0	0	2	17	19
Surgical margins	0	0	0	0	1	1
Diagnostic excisions	0	3	1	2	0	6
Benign lumpectomy	1	2	0	0	0	3
Breast reductions	4	2	0	0	0	6
Totals	7	7	2	10	31	57

Figure 1. Reader scores of specimen density. CR, computed radiography; SFM, screen-film mammography.

or dense) described by the Royal College of Radiologists Breast Group (Figure 1).

Overall number of reader ratings

There were a total of 125 extra readings (0.7%) from an expected number of 16 800. This was because, for each comparison of CR with SFM, readers perceived and scored 2 more skin edges (0.9% of 230) and 4 fewer masses, but only 3 fewer on maximum zoom (1.4% and 1.03% of 290). 11 more lesions than expected were perceived to contain calcification (4.1% of 270).

Computed radiography compared with screen-film

Skin edge was significantly better visualised on both CR systems than on SFM (the CR50 was preferred to SFM on 193 occasions from 232 scores, $p < 1 \times 10^{-5}$). There was no difference between either CR system (Figure 2). Both CR systems were rated as equivalent to or better than SFM for background tissue visibility [the CR50 was equivalent to SFM on 312 (55%) and better than SFM on 234 (41%) occasions, from a total of 570 scores, $p < 1 \times 10^{-5}$].

For analysis of calcification (conspicuity, detail and relative numbers), all comparisons were rated as equivalent to or better than SFM (CR50 $p < 1 \times 10^{-5}$; CR100 $p < 0.048$), except for calcification detail on the CR100 (maximum zoom) compared with SFM, which was equivalent. Mass detail was equivalent to or better on the CR50 than on SFM ($p < 0.002$), but was equivalent on the CR100 and SFM.

Mass conspicuity was the only feature in which both CR systems were rated as either equivalent to or worse than SFM, on both image sizes (Table 2).

Comparisons between computed radiography systems

The CR50 was equivalent to or better than the CR100 ($p < 0.0001$) for all features relating to calcification (Figure 3), which was more marked on zoom. There was no difference between the CR systems for background tissue visibility and mass detail on fit to screen images. On maximum zoom, however, background tissue visibility and mass detail was rated as equivalent to or better on the CR50 ($p < 0.013$, $p < 0.0002$) than on the CR100.

Figure 2. (a) Film-screen and (b) 50µm computed radiography mammograms of a mastectomy specimen (normal pathology) showing superior skin edge visibility on computed radiography.

Table 2. Mass conspicuity

Image preference score	CR100 vs SF	CR50 vs SF	CR50 vs CR100	CR100 vs SF (zoom)	CR50 vs SF (zoom)	CR50 vs CR100 (zoom)
Worse	57	56	10	51	49	6
Equivalent	199	201	269	207	210	271
Better	30	29	8	28	27	10
Total readings	286	286	287	286	286	287
<i>p</i> -value	0.005	0.0045	0.81	0.013	0.015	0.45

CR50, 50 µm computed radiography; CR100, 100 µm computed radiography; SF, screen film.
Significant *p*-values shown in bold type.

Overall diagnostic value

The overall diagnostic value was found to be equivalent to or better with both CR systems than with SFM ($p < 1 \times 10^{-5}$). The CR50 was equivalent to or better than the CR100 (Figure 4) on both image sizes.

Results summary

Both CR systems were rated overall as equivalent to or better than SFM for most quality criteria. The CR systems were particularly good at demonstrating skin edge and background tissue. For visualisation of calcification, the CR50 was rated as equivalent to or better than both the CR100 and SFM, which was more marked on maximum zoom. Mass conspicuity, however, was overall equivalent to or worse on CR than on SFM. The overall diagnostic value of CR was as good as or better than SFM.

Discussion

Mammography is often the only remaining analogue technology within a radiology service. Conversion to digital mammography (DR and CR) brings a number

of benefits [1, 3]. An extended dynamic range (or latitude), together with post-processing image manipulation, improves the sensitivity for cancer detection in females with dense breast tissue [15, 16]. Computer-aided detection software can be added to both CR and DR.

The performance of mammographic systems can be tested with phantom-based or clinical studies. Phantom evaluations use a series of standard commercial test objects to look at performance indicators, including resolution *vs* dose [12, 17, 33]. Such physical studies can only give an indication of clinical performance, and it is difficult to exactly quantify the contribution made by soft-tissue structures [17].

Comparative *in vivo* clinical studies can be designed in a number of ways. An extra radiation dose to the patient can be involved, as in paired study designs. Double-exposure techniques can reduce variability from altered position and compression between image acquisitions. Smaller clinical studies that avoid additional radiation include comparison of screening mammograms with images in females who are recalled to assessment clinics. Alternatively, different mammography systems can be used for each breast. Post-operative specimens can be imaged and compared on different systems. Larger clinical studies avoiding further irradiation include

Figure 3. (a) 100 µm computed radiography and (b) 50 µm computed radiography (CR50) mammograms of a wide local excision specimen. The pathology was a Grade 3 invasive ductal carcinoma with high-grade, comedo and solid ductal carcinoma *in situ*. The fine detail of central calcification is better on the CR50 image.

Figure 4. Overall diagnostic value of computed radiography (CR) vs screen-film mammography (SFM).

prospective randomised trials or retrospective comparisons from screening populations.

Early clinical trials of digital mammography showed SFM to be superior or equivalent [18–20]. More recent trials have shown that CR and DR perform as well as or better than SFM [22–25, 27–31], with improved detection of ductal carcinoma *in situ* presenting as clustered microcalcification in younger females and in those with dense breasts [21].

CR systems have improved since early evaluations. Many now have dual-sided imaging plates and readers, tuned to high resolution and low noise [33], with a smaller laser spot size of 50 μ m or less [34]. Newer developments include needle crystal technology to reduce light spread and improve image sharpness [35], which is already used in general radiography.

In light of these recent improvements in CR technology, we compared two CR systems with SFM. Post-operative specimens were imaged because real breast tissue is evaluated, position and compression are absolutely reproducible and further patient irradiation is avoided. While acknowledging that *ex vivo* post-operative specimen imaging is not directly comparable to *in vivo* mammography, this approach simulates real-time conditions and overcomes some of the limitations of breast phantom imaging and the variation inherent in some *in vivo* study designs.

In our hospital, specimen radiographs are routinely taken of post-operative breast localisation specimens to confirm whether palpable lesions such as microcalcifications have been removed. Selected others may be imaged when the mammographic abnormality was not obvious to the pathologist. For this study, all post-operative specimens were imaged. Some of the wide local excision specimens in the study had a localisation wire *in situ*, which can reduce image quality around the wire tip; however, despite this, there was improved visualisation of calcification on the CR50 compared with the CR100 and SFM. 7 of the 10 readers were experienced in mammography. The three specialist registrars with less experience were familiar with CR used for general radiography.

We obtained a large number of readings in our study ($n=16\,925$), from 10 readers analysing 8 parameters in 59 specimens, which allowed statistical analysis for each

comparison. Readers' comments included that some analogue images were over- or underexposed. Several commented that the calcification within one carcinoma was seen on CR and not seen on analogue.

There are relatively few clinical studies comparing CR with SFM [25, 27–30]. The Digital Mammography in Screening Trial (DMIST) is the largest prospective clinical study which compared SFM with both CR and DR [25]. 5 FFDM systems were used in this paired multicentre screening trial, which enrolled 49 528 females. One of these was a CR system, which contributed 8957 (21%) of the total 42 760 evaluable cases and detected 17.9% of the cancers [26]. The overall sensitivity and specificity for cancer detection of CR and DR systems has been shown to be similar in other large-scale studies and as good as or better than SFM [29, 30].

The NHSBSP has so far published three clinical evaluations of CR mammography systems [13–15] that meet minimum requirements [10, 11], with other evaluations ongoing [36]. Both DR and CR systems are now, at some centres, being used as part of the NHSBSP. CR systems are closer in cost to SFM. An economic report concluded that CR was the most cost-effective technology for screening sites, by a small margin. The costing of DR was dependent on having a sufficiently large workload. The total capital cost of installing a DR system (£273 479) was approximately double that of CR (£129 729). DR remained more costly than CR, by the same margin, over a 7-year cycle and assuming an annual workload of 15 000 females [37].

Radiographic throughput is similar for CR and SFM and is greater with DR, which has reduced processing and handling steps. A Health Technology Assessment report estimated that, assuming a 30% annual increase in throughput for breast screening, the cost to replace standard mammography units would be twice that for DR compared with CR [38].

Conclusion

In our study of operative breast specimens, reader ratings of diagnostic performance of the Fuji CR50 system matched or exceeded those of SFM and of the CR100 system for most parameters, and significantly improved visualisation of calcification. Although this small study has limitations in that it is not directly comparable to formal breast imaging, the findings are consistent with larger *in vivo* studies, which have shown that CR is at least equivalent to or better than SFM with improved visualisation of microcalcification.

CR systems do not have the same potential for further developments (e.g. tomography) and are not currently able to match the spatial resolution of the newest DR systems at a low mean glandular dose. CR may be an attractive digital mammographic technology in certain situations. At low-volume screening and at symptomatic sites, CR can also be a cost-effective interim technology, bringing many of the benefits of digital mammography.

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