

# Moving into the digital era: a novel experience with the first full-field digital mammography system in Malaysia

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## ABSTRACT

**Introduction:** Breast cancer is the commonest cancer in women and represents a significant problem from the clinical and public health perspectives. The aim of this paper is to report our experience of transitioning from screen-film mammography (SFM) to computed radiography mammography (CRM), and finally to full-field digital mammography (FFDM), and to evaluate the performance of these three different types of mammographic systems.

**Methods:** A total of 2,734 mammograms using the three different systems were carried out at the University of Malaya Medical Centre. These examinations were evaluated based on time from start of examination to reporting, image quality, archiving, reject and repeat rates and overall diagnostic accuracy for SFM, CRM and FFDM.

**Results:** The time taken from the start of the examination to the radiologist interpretation and reporting were faster in both FFDM and CRM, compared to SFM. Image contrast with better contrast detail was almost equivocal for both CRM and FFDM, but lower for SFM. Easier image storage and archiving were available for CRM and FFDM in the form of magnetic optical discs, rather than hard copy storage as in SFM. The reject rate for FFDM was zero percent, compared to CRM and SFM which were two percent and two percent, respectively. The repeat rate for FFDM, CRM and SFM was zero percent, 0.1 percent and 1.5 percent, respectively. Overall diagnostic accuracy of FFDM, CRM and SFM were comparable as no cancers were missed on all three systems as double blinded reporting was done.

**Conclusion:** FFDM does improve quality of mammography service by providing better workflow time and archiving system, with good diagnostic accuracy.

**Keywords:** computed radiography, full-field digital mammography, mammography, screen-film mammography

*Singapore Med J 2007; 48(9):804–807*

## INTRODUCTION

Breast cancer is the commonest cancer in women and in Malaysia. It accounted for 31% of newly-diagnosed female cancer cases in 2003.<sup>(1)</sup> Early detection is the key as breast cancer can be cured with a five-year survival rate of almost 95%. Due to this, there are many modalities being touted as early breast cancer screening tools, which range from thermal imaging to bioimpedance imaging. Of these, mammography is still considered as the gold standard for screening of breast diseases, especially in women after the age of 40 years. Full-field digital mammography (FFDM) is a growing new technology for imaging the breast and initial reports show that this modality improves image quality, increases throughput and reduces radiation dose. FFDM has been in the market since 2000, after the approval of the first full-field system by the US Food and Drug Administration. Since its approval, it has rapidly displaced conventional screen-film mammography (SFM) in many developed countries and is even making waves on the shores of developing countries.

Although SFM remains popular for imaging of the breast, there are studies suggesting that the use of FFDM improves diagnostic outcomes.<sup>(2-4)</sup> The implementation of FFDM in a breast imaging practice or centre is not just a replacement of a conventional SFM system to a digital system, but rather the incorporation of a technology that will alter workflow at every level, from acquisition of images, through the interpretation and rendering of report to the archiving of examinations.<sup>(5-7)</sup> This paper is aimed at reporting our experience of transitioning from a screen-film system to a full-field digital system.

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## METHODS

From August 2004 to July 2005, a total of 2,734 mammograms were performed on patients referred for mammography, either for screening or from the breast clinic due to a specific problem, and out of these, 200 patients had their mammograms performed on the FFDM unit (Novation DR, Siemens, Erlangen, Germany). The rest of the patients had their mammograms performed on a computed radiography mammography (CRM) system (Nova 3000, Siemens, Erlangen, Germany). The patients were randomly selected to undergo the mammographic examination either using the FFDM system or the CRM system.

The SFM was performed using a conventional system (Senographe DMR, GE, France). The SFM analysis was retrospective as it was hardly used since the availability of computed radiography (CR) and digital radiography from 2001. Patients comprised the three major races in Malaysia, and ages ranged from 40 to 70 years. Some of these patients were on hormone replacement therapy (HRT). Breast density ranged from dense breast parenchyma to breasts with parenchymal involution (fatty background pattern).

Exposures on all three systems were done using automatic exposure control. All examinations were reviewed by two radiologists independent of each other and blinded to the other's report. The FFDM and CRM images were reviewed on a Sienet Workstation with Magic View 1000 Reporting Station. The CRM images were acquired using imaging plates (Fuji, Japan), which were processed by the CR reader (Fuji film FCR 5000MA plus, Kanagawa, Japan). The SFM images were viewed on a dedicated mammography view box (Planilux X-ray film viewer series DXHM) with a luminance of 3,000 candela/m<sup>2</sup>. Periodic quality control was performed on the view box and it complied with the American College of Radiology (ACR) standards. The patient's previous examinations were viewed as hard copy images as the hospital did not have a picture archiving and communication system (PACS) then.

The three systems were then assessed and compared in terms of:

1. Time to report: The time taken to perform the mammography examination (positioning and exposure) until the interpretation and reporting of images.
2. Image quality: Image quality was assessed using the

ACR accreditation phantom (RMI 156, Middleton, WI, USA).

3. Archiving of images: the method of storing and retrieving data.

4. Reject and repeat rates: The number of films deemed not diagnostic, due to technical faults and were therefore rejected, were analysed. The number of repeat examinations was also assessed.

## RESULTS

This is an initial one-year experience, hence the number of patients imaged by the FFDM were low, as there was a delay in adaptation by the radiographers to the new system after being familiar and comfortable with the CRM and SFM systems. There was a decrease in the time taken to perform the examination to the interpretation and reporting of the films. Differences were noted during soft copy reporting compared to the reporting of films, especially where SFM was concerned, and this was especially so in patients with dense breasts, as there was an ability to alter contrast and magnification details during soft copy reporting, eventually decreasing the number of recall and repeat examinations. (Fig. 1 and Table I).

Archiving of images was convenient as examinations done were stored in a magnetic optical disc leading to reduction in the loss of films (Table II). As for the repeat and reject analysis, there was no reject or repeat cases with the FFDM. However, the rejects from the CRM were due more to technical errors than to the examination or

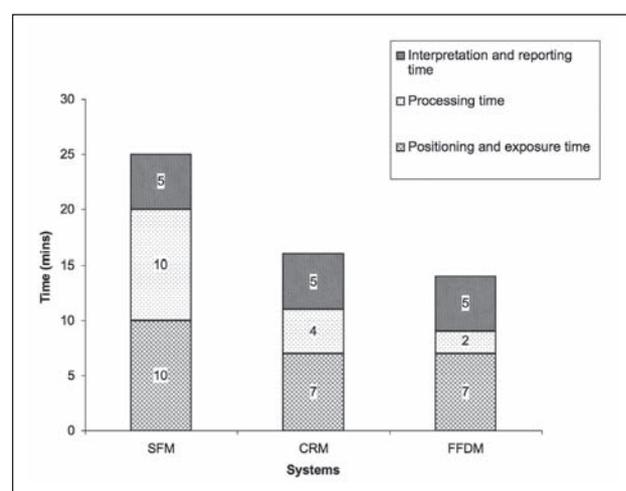


Fig. 1 Workflow of different mammography systems.

Table I. Image details and ability to alter contrast for different systems.

Mammography systems	Image contrast and details	Ability to alter contrast
SFM	Good, but difficult to interpret dense breasts	No
CRM	Good, easier to interpret dense breasts	Yes
FFDM	Good, easier to interpret dense breasts	Yes

the images themselves. The repeat examinations were due to artefacts from improper positioning rather than to inadequate exposure or processing conditions (Table III).

## DISCUSSION

The Radiology Department at the University of Malaya Medical Centre was the first centre in Malaysia to acquire a FFDM system. Converting from a screen-film based to a CRM and FFDM facility has introduced many changes to the quality of service provided by our centre. The primary change that affected both patients and radiology staff alike was in the workflow, namely an increase in throughput. The time taken for processing of films was also reduced. Workflow using SFM required additional hands to send exposed cassettes to the dark room and the time taken for the processing of the film itself. This has resulted in a vicious cycle that increased patients' waiting time. There were delays especially for patients who were scheduled to be reviewed by the clinicians in the clinic on the same day. Eventually, patients were given appointments to have the examination done on one day and reviewed by the clinicians on another day, leading to unnecessary trips to the hospital. This situation was improved greatly by the use of CRM and FFDM. We found that the time spent in soft-copy reporting was shortened by at least 40% using CRM and an even further 50% reduction using FFDM. Extra time was only taken for additional views or in cases where an ultrasound examination was warranted.

Once SFM images were obtained, there is no provision for contrast to be altered. If the diagnostic quality of an examination is degraded by a poor exposure setting, then a repeat examination is necessary, resulting in an extra radiation dose to the patient. Films were also subjected to artefacts during processing due to improper handling. There have been many studies which show that FFDM provides an improvement in imaging of dense breasts, with the ability to optimise and manipulate the image, create digital magnification views, and use the post-processing capabilities to increase cancer detection.<sup>(5)</sup> Studies done by Visweswaran et al also showed that there were also limitations in SFM as far as cancer detection were concerned in dense breasts.<sup>(8)</sup>

Using CRM and FFDM, digital acquisition and soft-copy reading allows the use of post-processing tools, such as windowing, magnification, panning and zooming to alter and enhance the appearance of images.<sup>(9)</sup> However, there were initial studies that claimed interpretive time for FFDM was approximately 2.5 times more than that for film-screen studies. This was partly due to radiologists taking time to adjust contrast and level to obtain the "best view" of the examination, as most radiologists were not trained to view and report soft-copy images.<sup>(10)</sup> This did not present as a problem in our centre as our radiologists were well-versed in soft-copy reporting, having had the

**Table II. Archiving of images for the different systems.**

Mammography systems	Archiving
SFM	Hard copy
CRM	Hard copy and magnetic optical discs
FFDM	Hard copy and magnetic optical discs

**Table III. Reject and repeat rates for the different systems.**

Mammography systems	Reject rate (%)	Repeat rate (%)
SFM	2.00	1.50
CRM	1.98	0.13
FFDM	0	0

advantage of using a CRM system for the past three years. However, for first-time users, acquiring soft-copy reporting skills would be necessary. After appropriate training, it was found that there was no difference in the speed of interpretation of images either on hard copy or soft copy, as was confirmed by the radiologist's reporting time for all three systems.<sup>(10)</sup>

Another limitation to SFM is that films serve as the image receptor as well as the display and storage medium. Factors, such as decreased exposure or processing conditions which are not optimal, lead to eventual loss of contrast details, especially over the years. This can cause a lot of problems in future comparisons with other examinations, as mentioned by Lewin et al in their study in 2001.<sup>(2)</sup> Furthermore, the films become the only 'proof-of-examination' with no other medium used to save the raw data. Human errors such as misplaced films, can result in missing examination material.

We experienced similar situations in our set-up. Films of patients, who had examinations performed before 2002, showed definite loss of contrast details when compared to recent examinations. This was because films were not stored in ideal conditions and image degradation was further hastened by the warm and humid environment. This problem was eliminated with the change to CRM and FFDM. Although we still file hard-copy images on films, the raw data of these images are stored in magnetic optical discs. Human errors were also minimised by this method of storing and archiving, as we can now retrieve images done previously that would otherwise have been lost forever using the SFM system.

Recall and reject rates are lower for FFDM compared to SFM, and with the advantage of changing of contrast and window details, the repeat rates are also lower.<sup>(2,10)</sup> An important advantage of FFDM over SFM is the standardised default settings, which needs no manipulation of data prior to printing. This produces a consistent quality of images and is important in

mammography because it allows subtle changes in parenchyma tissue, such as the scattered appearance or increased clusters of microcalcifications to be detected over time, especially in follow-up patients. This reduces repeat examinations, which in turn leads to reduced costs and also minimises stress for the patients. In addition, the images are reproducible and comparable, even over long periods due to archiving capabilities incorporated into the FFDM.<sup>(11)</sup>

The main drawback of FFDM is the cost. Although FFDM offers many advantages, healthcare providers have to be cautious in introducing such technology to replace the conventional SFM. For developing countries in particular, health technology assessment must be carried out to weigh the pros and cons for adopting this new technology, especially when the total cost of FFDM is approximately three times higher than the cost of the screen-film system. In conclusion, we find the use of FFDM to be advantageous as it decreases waiting time, simplifies workflow and most importantly, decreases repeat and reject rates. Furthermore, it has paved the way for easier storage and reduced missing images. Incorporating computer-aided diagnosis and detection software would also be easier in the future. Although Malaysia has not yet adopted a policy for screening mammography, when it does, the use of FFDM would definitely be useful.

#### ACKNOWLEDGEMENTS

We thank the medical physicists and radiographers who

helped with the quality assurance programme of the mammography systems.

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