

Digital Mammography: An Update

Summary

- ✓ **Digital mammography can improve breast-image quality and storage through the digital capture of x-ray images.**
- ✓ **Large comparative studies indicate that the overall accuracy of full-field digital mammography (FFDM) is similar to that of conventional film-screen mammography (FSM).**
- ✓ **Recent evidence suggests that FFDM is more accurate than FSM for diagnosing cancer in women younger than 50 years, those with dense breasts, and pre- or peri-menopausal women.**
- ✓ **The costs of FFDM are higher than those for FSM.**
- ✓ **The quality control of FFDM systems offers advantages compared to that of FSM, but it is more complex, and it is associated with a long learning curve.**

The Technology

Breast cancer, which is the most common cancer to affect women, is the second leading cause of death due to cancer in Canadian women, after lung cancer. In 2006, there will be an estimated 22,300 new cases of breast cancer in Canada, and 5,300 deaths from this malignancy.¹ Conventional film-screen mammography (FSM), in which x-ray images of the breast are captured on film, has been shown to provide a significant contribution to the detection of breast cancer. Decreases in death rates from breast cancer are believed to be the result, in part, of earlier detection and improved treatment.²

In digital mammography, the x-ray image of the breast is captured digitally, and can be viewed on a workstation screen (soft copy), or sent to a laser printer to generate a hard copy image. In full-field digital mammography (FFDM), solid-state detectors convert x-rays into electrical signals, to produce an image of the breast. In computed radiography (CR) systems, the image is recorded on a reusable plate that is scanned using a laser reader, to produce the digital image. Digital mammography improves image storage and transmission, because images can be stored and sent electronically. Computer aided detection

(CAD) systems have been used with both types of mammography to help interpret the images.

This bulletin provides an update of the literature published since an assessment was done by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), in 2002.³

Regulatory Status

FFDM systems that are licensed by Health Canada include the Selenia mammography system (Hologic Inc.); Mammomat Novation (Siemens AG); and Senographe DS mammography system main unit, and Senographe 2000D mammography system (GE Healthcare). A CR system, the FCR PROPECT CS (Fuji), has also been licensed by Health Canada.⁴

Patient Group

Like conventional mammography, digital mammography is intended for use in the screening and diagnostic examination of women who are considered to be at risk for breast cancer.

Current Practice

Mammography is a more effective screening technique than either breast self examination or professional palpation.⁵ FSM continues to dominate the market. The uptake of FFDM has been limited.

In diagnostic applications, ultrasound is used as a targeted diagnostic examination that focuses on areas of specific concern.⁵

The Evidence

The 2002 CCOHTA report³ found that the available literature, which included a large study by Lewin *et al.* on FFDM in breast cancer screening,⁶ indicated that FFDM and FSM had a similar sensitivity and specificity, but that FFDM might be associated with a lower recall rate after a screening examination. Details about the investigation by Lewin *et al.* and major studies published since the 2002 report are shown in Table 1.

Table 1: Major comparative studies of FFDM and FSM

Study, Country	Number of Women Examined	Number of Cancers Detected			Recall Rate
		Digital and Film	Digital Only	Film Only	
Lewin, US ⁶	4,489 (FFDM and FSM)	18	9	15	FFDM 11.8%, FSM 14.9%
Oslo I, Norway ⁷	3,683 (FFDM and FSM)	20	3	8	FFDM 4.6%, FSM 3.5%
Oslo I (2 year follow-up), Norway ⁸	3,683 (FFDM and FSM)	20	7	11	unreported
Oslo II, Norway ⁹	FFDM 6,997 FSM 17,911 (randomized)	N/A	41 (0.59%)	73 (0.41%)	FFDM 3.8%, FSM 2.7%
DMIST, US ¹⁰	42,760 (FFDM and FSM)	122	63	52	FFDM and FSM 8.4%

N/A=not applicable

In the Norwegian Oslo I study, all women had FSM and FFDM. There was no statistically significant difference in cancer detection rates between FSM and FFDM on initial diagnosis or after two years of follow-up.^{7,8} Women in the Oslo II study were randomized to undergo FSM or FFDM.⁹ FFDM provided a higher cancer detection rate than FSM in the group aged 50 to 69 years, though the difference did not reach statistical significance ($p=0.053$). Detection rates for the group aged 45 to 49 years were similar for each method.

Women in the North American DMIST study underwent both types of mammography.¹⁰ For the entire population, FFDM and FSM had similar accuracy [difference in areas under the receiving operator characteristic (ROC) curves 0.03, CI -0.02 to 0.08; $p=0.18$]. The accuracy of FFDM was found to be significantly higher among women <50 years ($p=0.002$), those with dense breasts on mammography ($p=0.003$), and pre- or peri-menopausal women ($p=0.002$). The data suggest that in women >49 years, post-menopausal women, and women with less dense breasts, more cancers were found with FSM than with FFDM, though the difference was not statistically significant.¹¹

In the Norwegian studies,^{7,9} the recall rates were higher for FFDM than for FSM, in contrast to the earlier findings by Lewin *et al.*⁶ In the Oslo II study, the difference in recall rates was statistically significant for women aged 50 to 69 years, but not for the group aged 45 to 49 years.⁹ In the DMIST study, recall rates were the same for each type of mammography.¹⁰

Two small studies from Germany with 200 and 55 women respectively found that FFDM was more sensitive than FSM in the detection of microcalcifications.^{12,13}

A Japanese study that included 480 women in a screening program, found no significant difference between FFDM and FSM in recall rates, positive predictive values, and detection of microcalcifications.¹⁴

Two studies that compared FSM with CR, both with 100 participants, concluded that the diagnostic performance of the two approaches was equivalent.^{15,16}

Adverse Effects

There seem to be no adverse effects that are specific to FFDM or CR. As with any x-ray technique, there are risks to the patient through exposure to ionizing radiation. FFDM offers the prospect of a reduced radiation dose, compared with that of FSM.^{3,17} The clinical significance of a reduction in radiation dose is unknown, and the health benefit is not expected to be large.³

Administration and Cost

Digital mammography systems are often 1½ to four times as expensive as film mammography systems.^{2,11} Also, annual service contracts for FFDM will be more expensive than those for FSM.¹⁷

The CCOHTA report concluded that total annualized capital and operating costs for a FFDM system were 38% (C\$137,000) more than those for FSM. The costs of CR were found to be equivalent to those of FSM. The equipment purchase costs of FFDM were higher (C\$1.1 million versus C\$180,000 for FSM or CR). It was assumed in the analysis that all FFDM images would be interpreted as soft copy on a workstation.³

Examples of digital mammography system costs in Canada are C\$250,000 for the Fuji CR FCR PROTECT system, C\$600,000 for the Hologic Selenia (Ward Baird, Christie Group, Edmonton: personal communication, 2006 Sep 14), and C\$550,000 for the Siemens Mammomat Novation system (Bert Stadler, Siemens Canada, Edmonton: personal communication, 2006 Sep 5).

A UK report estimated that the cost of screening 10,000 women would be £157,623 with FFDM and without hard-copy imaging, compared with £113,700 with FSM (38.6% higher).¹⁸ If throughput increased and led to a 20% reduction in equipment requirements, the total cost for FFDM would fall to £128,345 per 10,000 women screened (12.8% higher than the cost of FSM). These estimates were based on indicative prices, because the true costs of equipment and maintenance contracts were unknown. Also, a full analysis of the additional cost of related electronic information systems was not undertaken.

Concurrent Development

The US Food and Drug Administration (FDA) has approved magnetic resonance imaging (MRI), ultrasound, scintimammography, thermography, and electrical impedance imaging for the diagnosis of breast cancer, but not for screening.⁵ MRI may have higher sensitivity but lower specificity than mammography in selected women at high risk of developing breast cancer. MRI has not been studied in the general population as a screening tool.^{5,19} Ultrasound as an adjunct to mammography in women with radiologically dense breasts detects additional cancers and results in additional false positives.¹⁹ Research is continuing on the application of near-infrared technology to provide optical mammography.²⁰

Contrast-enhanced mammography and tomosynthesis can improve the accuracy of FFDM, but are not yet in clinical use.²¹ A recent health technology assessment noted that two CAD systems have received pre-market application approval by the FDA for use with FFDM.²² It concluded that the available data from well-conducted studies are insufficient to determine whether adding CAD to FFDM

leads to diagnoses that are as or more accurate than reading the FFDM images alone.

Rate of Technology Diffusion

FFDM's rate of diffusion has been slow. In the US, approximately 8% of breast imaging units provide FFDM.² The use of CR systems in North America has been minimal, because of delays in regulatory approval, though they have been widely used in Europe and Japan. Fuji announced in July 2006 that it had received approval from the FDA to market its CR system in the US.²³

Implementation Issues

The evidence suggests that FFDM systems provide an accuracy that is similar to that of FSM, but at a higher cost, when all women who are to be screened for breast cancer are considered. Results from the DMIST study indicate that women in some groups would benefit from undergoing FFDM instead of FSM.¹⁰

A variety of designs for digital systems using different technologies are available. How the differences in design affect the ability to detect mammographic abnormalities is unknown.²¹

The quality control for FFDM, when compared to that for FSM, is more difficult, time consuming, and expensive. The advantages of FFDM quality control include greater precision, independent evaluation of individual components, and elimination of wet processors. The disadvantages include a slow learning curve, longer time commitment, and possible interference with clinical workflow.²⁴ Operators of digital mammography systems may also have to address problems with image display.²¹ Alternative quality control tests that draw on the experience of the DMIST trial have been proposed with a view to reducing time and costs.²⁵

References

1. Canadian Cancer Society, et al. *Canadian cancer statistics 2006*. Toronto: The Society; 2006. Available: http://www.ncic.cancer.ca/vgn/images/portal/cit_86751114/31/23/935505938cw_2006stats_en.pdf.pdf.
2. Digital vs film mammography in the Digital Mammographic Imaging Screening Trial (DMIST): questions and answers. In: *News* [website]. Bethesda (MD): National Cancer Institute; 2005. Available: <http://www.cancer.gov/newscenter/press-releases/DMISTQandA>.

3. Ho C, et al. *Digital mammography versus film-screen mammography: technical, clinical and economic assessments* [Technology report no. 30]. Ottawa: Canadian Coordinating Office for Health Technology Assessment; 2002. Available: http://www.cadth.ca/media/pdf/131_digital_mammography_tr_e.pdf.
4. *Medical devices active license listing* [database online]. Ottawa: Medical Devices Bureau, Therapeutic Products Directorate, Health Canada; 2006. Available: <http://www.mdall.ca/>.
5. Elmore JG, et al. *JAMA* 2005;293(10):1245-56.
6. Lewin JM, et al. *AJR Am J Roentgenol* 2002;179(3):671-7.
7. Skaane P, et al. *Radiology* 2003;229(3):877-84.
8. Skaane P, et al. *Acta Radiol* 2005;46(7):679-89.
9. Skaane P, et al. *Radiology* 2004;232(1):197-204.
10. Pisano ED, et al. *N Engl J Med* 2005;353(17):1773-83.
11. Dershaw DD. *N Engl J Med* 2005;353(17):1846-7.
12. Fischmann A, et al. *Br J Radiol* 2005;78(928):312-5.
13. Fischer U, et al. *Eur Radiol* 2002;12(11):2679-83.
14. Yamada T, et al. *Radiat Med* 2004;22(6):408-12.
15. Bonardi R, et al. *Eur J Radiol* 2005;55(2):258-63.
16. Van Ongeval C, et al. *Eur Radiol* 2006;16(6):1360-6.
17. *Full-field digital mammography for breast cancer screening*. [Target report 206]. Plymouth Meeting (PA): ECRI; 2006.
18. Legood R, et al. *A cost comparison of full field digital mammography (FFDM) with film-screen mammography in breast cancer screening* [NHSBSP Equipment report 0403]. Sheffield (UK): NHS Cancer Screening Programmes; 2004. Available: <http://www.cancerscreening.nhs.uk/breastscreen/publications/er0403.pdf>.
19. Irwig L, et al. *Br J Cancer* 2004;90(11):2118-22.
20. Intes X. *Acad Radiol* 2005;12(8):934-47.
21. Dershaw DD. *Breast J* 2006;12(2):99-102.
22. Technology Evaluation Center. *Computer-aided detection with full-field digital mammography* [Assessment program vol. 21 no. 3] BlueCross BlueShield Association; 2006. Available: http://www.bcbs.com/tec/vol21/21_03.pdf.
23. Fuji CR mammography receives FDA approval, July 11 2006. In: *Fuji news* [web site]. Stamford (CT): Fujifilm Medical Systems USA; 2006. Available: http://www.fujimed.com/company-info/press-room/doc/press_fda-approval.asp?location=3&area=25&id=0&subid=0.
24. Parikh J, et al. *J Am Coll Radiol* 2004;1(11):854-60.
25. Yaffe MJ, et al. *Med Phys* 2006;33(3):737-52.

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CADTH appreciates comments from its reviewers.

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Dr. Yaffe has been involved in research collaboration with GE Healthcare, and is on the Scientific Advisory Board of Xcounter (Stockholm).

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