

Mammography in transition

Carestream Health, Inc., has a long history of delivering innovative medical imaging solutions including market-leading products for mammography. To highlight some of the trends in mammography (and available technologies) and provide insight on what's next, here are excerpts from a discussion with several members of the mammography team within Carestream Health, Inc.



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How has the technology for mammography been changing?

Byng: Since the mid-1990's the mammography community has been increasingly focused on digitization. Mammography has been one of the last areas in medical imaging to make the transition, due in part to the technical issues with making the high quality digital images to meet the challenging clinical task of breast cancer detection, the ability to effectively manage image handling and interpretation across all the steps of the mammographic examination, and the high cost of digital mammography systems. The majority of mammograms today are still made with traditional film systems – and this will continue to be an important component of mammography imaging for many years to come – but as digital systems mature, they are becoming a viable option within the mammography center. Digital mammography involves the capture, processing, presentation, printing, storage and transmission of mammographic images in digital form, but most of the early interest has been on digital capture.

What does Carestream Health offer for digital mammography?

Byng: We offer a broad portfolio of products and services for digital mammography that cover all aspects of the digital imaging chain. Services include transition planning and workflow optimization to achieve the highest value from a digital investment. Products include: image capture with state-of-the-art image processing,

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PACS, RIS and image management offerings; a multi-modality, multi-vendor workstation with mammography-specific features; digital mammography printing; and computer aided-detection (CAD).

Schmitz: Most of the interest in digital mammography has been on the capture of digital mammography images. The KODAK DIRECTVIEW CR Mammography Feature has been developed as an option to our popular portfolio of CR 850, CR 950 and CR 975 systems. The choice of single- or multi-cassette systems provides an affordable path to digital for sites with different workflows, varied patient throughput and budgets. Facilities benefit from the ability to perform general radiography and mammography on the same device. The CR Mammography Feature is designed to be available with new units, added as an option, or as an upgrade to an existing KODAK CR 850/950/975 system. Mammography images are scanned at high resolution (20 pixels per millimeter) and require specialized mammography CR screens designed for maximum resolution.

The CR Mammography Feature is widely used in Europe, Asia and Latin America and was recently approved by Health Canada. We have applied for regulatory approval from the FDA in order to begin selling the system in the U.S. The KODAK CR Mammography Feature was the winner of a 2006 Frost & Sullivan Award for excellence in technology in recognition of advancing the use of CR for breast cancer detection. In addition the KODAK DIRECTVIEW CR 975 System earned a prestigious 2006 “Best in KLAS” Award in the computed radiography market segment from KLAS Enterprises.

How are digital mammography systems compared?

Yorkston: There are many aspects to consider when comparing digital mammography systems including: technical performance, operational efficiency or workflow and ultimately clinical performance. Medical physicists tend to concentrate on the specific technical performance of the detector. In early development this is often the only way that we can evaluate system performance since we have no direct clinical experience. Physicists and system developers often characterize technical performance through metrics that can be measured in the lab. Care must be taken when interpreting the significance of differences between systems since each vendor’s laboratory has historically had their own measurement and analysis techniques. This can lead to an erroneous comparison of non-standardized values when comparing results. New, more rigorously defined standards are currently being developed by international organizations that will improve this situation in the near future. Metrics like DQE and MTF tell us about signal and noise transfer efficiencies in making the captured image, but do not directly tell us about the final processed image to be interpreted. And let’s not forget that these results are suggestive of performance, but have not been shown to be directly correlated with clinical performance.

How does the clinical performance compare?

Fletcher-Heath: While there are technical differences between film, CR and FFDM, the most important question is the clinical performance delivered by each platform.

To put clinical performance in context, consider the elements in the overall imaging chain: positioning, exposure, capture, processing, presentation and interpretation. Studies have shown that positioning and interpretation—not the digital capture platform—are the most significant factors in clinical performance, and can overwhelm the effect of other factors.

Studies with our CR product have tested it against the current standard of screen-film mammography as did the studies of other manufacturers of digital systems. Initial results indicate that radiologists prefer the CR images to screen-film images and that clinical performance is comparable. For the purposes of FDA and Health Canada approval we have submitted comparison data between our CR and screen-film systems for mammography. Our FDA application is under review.

Our CR system is intended to be operated at the same dose as screen-film systems. Our studies (as well as those of many other systems) matched the exposure techniques to screen-film. The clinical performance is believed to be comparable to film-screen at this dose level, implying a cost benefit trade-off due to radiation dose at least comparable to film.

Getting the most from your digital system requires outstanding image processing.

The most comprehensive evaluation of the clinical performance of digital mammography is the DMIST trial. In the New England Journal of Medicine article's summary of results, the DMIST investigators indicate that "...digital mammography also did not vary significantly from that for film mammography according to race, the risk of breast cancer, or the type of digital machine used." (N Engl J Med 2005; 353:1773-83)

Yorkston: To add to that, the systems used in the DMIST trial represented a wide range of measurable technical performance, but the authors did not report any measurable difference in clinical performance.

How does the dose compare?

Yorkston: Digital systems are capable of capturing images over a wider range of doses than screen-film systems. The ability to process the image adjusts the overall brightness and contrast regardless of the dose. Noise, however, will vary directly with the dose.

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It is possible to take digital images at much smaller doses than screen-film systems, but it is important to ensure that a corresponding increase in noise does not obscure clinically relevant detail. Some studies have begun to investigate how x-ray technique can be optimized and lower doses used, but the current dose operating point is well understood and accepted.

How does the workflow compare?

Schmitz: At first look CR has the workflow of traditional film imaging. It is a latent image captured in a cassette and needs to be transported to a scanner to reveal the image. Not all CR platforms are equal however. Carestream Health offers systems capable of handling one plate at a time as well as systems where multiple cassettes can be loaded for automated handling allowing a 'drop and go' workflow. Our single plate system can be located centrally, but is well suited for placement beside the x-ray stand to facilitate a rapid exam. Our multi-cassette system is ideally suited for centralized workflow. This system is designed with 8 in slots and 8 out slots, which permits two technologists to drop off cassettes at the same time in random order, without causing a bottleneck at the scanner. When the KODAK DIRECTVIEW Remote Operations Panel is used to associate a cassette with a patient and to position and validate image capture, even more efficiency can be achieved. These features and the ability to perform mammography and general radiography on the same scanner make CR a very cost-effective solution for digital mammography.

How should a facility choose a mammography technology?

Byng: Each technology— film, CR, and FFDM — has a role in mammography. Film is proven and well understood. Both CR and FFDM have been found to perform similar to film in terms of cancer detection (DMIST study). Both CR and FFDM provide a digital image. CR has the advantage of being able to use the existing analog x-ray stand and familiar film workflow to ease the transition to digital. CR systems may also be used for more than just mammography, which can extend the benefit of an existing CR or the benefit achieved with the investment in a new CR. Since FFDM systems can provide images for review almost immediately after acquisition, the volume of imaging studies captured in each exam room is increased. In addition this change in acquisition may enable new procedures such as tomosynthesis, but this is an area that's still under development.

We have already made several generations of improvements to our CR mammography feature including sharper screens, higher resolution scanning, enhanced image processing and easier workflow.

New technologies show promise in detecting the disease or the signals that accompany the disease, but we expect mammography, in both analog and digital forms, to continue to play a leading role in detection for many years to come.

Each customer should evaluate their needs and choose the technology that best fits their clinical need, budget, workflow, patient throughput, infrastructure, timing and goals. There is a considerable additional investment beyond the capture device, and ensuring that the systems integrate well and operate reliably requires a trusted partner.

Is Carestream Health considering offering FFDM capture?

Byng: Our goal is to provide a range of mammography capture solutions so that we can meet the specific needs of each mammography provider. Regarding image capture, film will continue to be an important part of mammography imaging, and we will continue to offer our leading film systems. For facilities that choose CR, our mammography feature has been widely adopted in parts of the world and we anticipate similar success in the U.S. when it becomes available. FFDM is a technology that will appeal to many mammography providers and we will share more details about our participation in that modality as our plans develop.

What's next?

Schmitz: We have already made several generations of improvements to our CR mammography feature including sharper screens, higher resolution scanning, enhanced image processing and easier workflow. We anticipate making further improvements in these areas as the technology improves and user experience develops.

Fletcher-Heath: Getting the most from your digital system requires outstanding image processing. We have excellent processing today based on our mammography experience and our enhanced visualization processing (EVP) software, but our future image processing platform promises to be even better.

Yorkston: As the use of digital mammography expands, the interest is shifting to advanced applications such as multi-modality integration, and 3-D imaging including tomosynthesis. There are lots of promising early results, but also considerable work still to be done to verify clinical efficacy. While it is attractive to think that an existing system could be upgraded to tomosynthesis, it is unlikely that this will be easily done from current systems.

Byng: Mammography is the best tool we have today for early detection of breast cancer but there is considerable room for improvement. New technologies show promise in detecting the disease or the signals that accompany the disease, but we expect mammography, in both analog and digital forms, to continue to play a leading role in detection for many years to come.

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