Konica Minolta Healthcare Americas, Inc.

Exa™ Mammo

A Solution that Overcomes the Challenges of Implementing Digital Breast Tomosynthesis

A WHITEPAPER

KONICA MINOLTA

INTRODUCTION

Numerous published studies have shown that digital breast tomosynthesis (DBT), also referred to as 3D mammography, can overcome limitations of traditional 2D mammography, enhance lesion conspicuity, and improve sensitivity and specificity.[1-4] Other studies report that adding 3D mammography or ultrasound to regular screening mammograms can detect more cancers in dense breasts.[5,6] In the US, nearly 50% of women in their 40s have dense breasts.[7]

A 2014 study reported a 41% increase in the detection of invasive breast cancers and a 29% increase in the detection of all breast cancers with DBT compared to 2D mammography.[8] Another study found that the rate of recalls was nearly 37% lower among women who had DBT compared to women who only had conventional mammography (2D). The benefits of DBT were further reported in a 2016 study, including a 50% increase in invasive cancer detection in women with heterogeneously dense breasts.[9]

With evidence supporting the clinical benefits of DBT, new guidelines from the National Comprehensive Cancer Network (NCCN) recommending that physicians consider tomosynthesis as an option for their patients' annual breast cancer screenings and three new CPT codes for screening and diagnostic DBT, along with Centers for Medicare and Medicaid (CMS) reimbursement of DBT for screening in conjunction with 2D mammography, the market for DBT is expected to continue growing. By 2018, DBT units will exceed 2D mammography systems in the US and by 2020 the DBT market value will reach $521B.

While DBT delivers clinical advantages over 2D mammography, there are workflow and infrastructure challenges to implementing the technology. Exa™ Mammo from Konica Minolta Healthcare Americas is designed to overcome the challenges associated with viewing, reading and reporting DBT exams.

Implementation challenges

One of the most significant impediments to implementing DBT is the large files size generated by the modality. On average, a DBT study (450MB) is approximately 10times the size of a conventional 2D mammography exam (45MB) and can sometimes be significantly larger (up to 3GB).[10,11] This large file size places an immediate strain on the network and IT infrastructure, resulting in lag time that can directly impact a physician's reading capabilities, productivity and potentially the facility's financial bottom line. As a result of this large file size for DBT studies, many facilities will need to invest in upgrading network capabilities and infrastructure.

In mammography/breast imaging, radiologists review the current exam and compare it to the patient's prior exams, which are typically pre-fetched from a server and downloaded onto the workstation. The importance of reviewing multiple prior mammograms with the current exam is underscored by a published study that found a significant decrease in recall rates in a retrospective analysis of 46,288 consecutive screening mammograms. Mammograms interpreted without comparison to prior mammograms led to a recall rate of 16.6%. When at least one prior mammogram was compared to the current mammogram, the recall rate dropped to 7.8%, while comparison of two or more prior mammograms further dropped the recall rate to 6.3%.[12]

However, downloading prior and current studies requires more local storage and can consume network bandwidth, slowing down the transfer of the DBT study and other tasks being performed by radiologists and technologists. If the prior study is not pre-fetched, it can take several minutes to load, further straining the network speed and bandwidth.

Radiologists reading remotely will also be impacted by network bandwidth and speed. Further, not all third-party mammography viewers have the capability to display DBT images, which may require installation of a dedicated DBT workstation at the imaging facility. As a result, facilities are resorting to deploying radiologists at each remote DBT facility. This conflicts with the main principle of teleradiology and can dramatically increase labor costs.

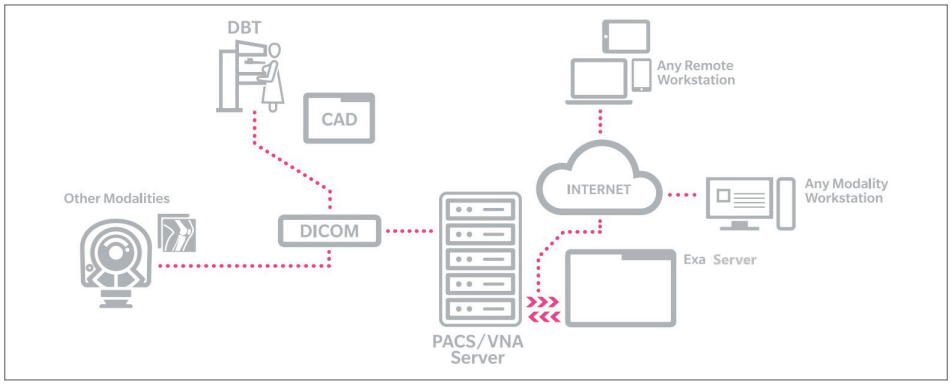

Figure 1. Exa Mammo from Konica Minolta Healthcare is designed to overcome the challenges associated with viewing, reading and reporting DBT exams.

Cybersecurity

Downloading and pre-fetching patient studies onto a workstation may introduce additional cybersecurity vulnerabilities. A June 2017 report by the US Department of Health and Human Services, Health Care Industry Cybersecurity Task Force, warned that US healthcare cybersecurity is in critical condition, citing a "severe lack of security talent" in the majority of health delivery organizations. The report also noted that Meaningful Use requirements may have led to "hyper-connectivity without secure design and implementation."[13]

Twenty-one cybersecurity experts helped compile the report, which also found that the healthcare industry experienced more breaches due to cybersecurity than any other industry.[11] An increase in ransomware has only exacerbated this issue, as is evident by the recent attack on National Health Service (NHS) hospitals in the United Kingdom that shut down medical care in 16 hospitals and impacted nearly 40 NHS organizations.[14,15]

Cost and ROI of DBT

The cost of a DBT system can vary from just under $400,000 for a basic system configuration to just over $550,000 for a fully configured solution that may include computer-aided detection (CAD), a dedicated workstation, contrast-enhanced spectral mammography and upright biopsy equipment. By comparison, the average cost of a FFDM unit is around $275,000.[16]

Interest in DBT has fueled an increase in the price of digital mammography systems, which can often be upgraded to DBT. According to the latest public data available from the Modern Healthcare/ECRI Institute Technology Price Index, digital mammography (likely with a tomosynthesis option) was one of the top 10 most expensive capital items reported by ECRI Institute members in November 2016.[17] The index also reported a 4.1% increase in the cost of digital mammography over a 12-month period (November 2015-November 2016).

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In 2015, CMS adopted new CPT coding for DBT when used in conjunction with screening and diagnostic mammography. Coding changes for DBT were implemented in 2017 to simplify mammography codes that were previously separate for FFDM, film mammography, CAD and DBT.[18]

For both screening and diagnostic DBT, the Medicare reimbursement component is $30.86 for professional (physician) and $25.48 for technical (facility), or $56.34 for both. An imaging site would recover its initial investment in a basic system configuration ($400,000) after billing for 2,219 DBT exams or in a fully configured system ($550,000) after billing for 4,881 DBT exams.

DBT with Exa Mammo

Considering the cost of DBT and the volume required to recoup the initial investment before generating income, facilities may seek solutions that reduce overall expense yet enable remote reading without requiring extensive upgrades to networks and infrastructure.

Exa Mammo is a first-of-its-kind Konica Minolta solution that preserves an existing investment in imaging and information technology while enhancing radiologists' efficiency and productivity. The platform enables the viewing of images from any modality, including DBT and digital 2D mammograms, from any workstation* with instant access and zero lag time.

Two key features make Exa Mammo one of a kind. First, with 100% Diagnostic Zero Footprint (ZFP) technology, the user/facility never has to install a viewer. It functions on any operating system or browser, and it is a true diagnostic viewer for any modality, including DBT. Second, Server-Side Rendering (SSR) allows immediate access to even the largest file sizes, such as DBT, as well as priors. SSR eliminates the need to download images or files, which can reduce radiology-related network traffic by up to 60%. Further, SSR significantly increases exam opening speed, as all rendering and processing occurs on the server, not the workstation, and removes the need to pre-fetch or plan ahead with routing rules. For cybersecurity, Exa minimizes unwanted exposure to patient data with no data transferred to or stored on workstations.

By implementing Exa Mammo, facilities can avoid the additional expense and maintenance of a separate mammography workstation. It works as a stand-alone solution or supplements an existing PACS or VNA and enables radiologists to read remotely from any location. Exa Mammo also offers a customizable

mammography workflow engine and optional voice recognition and report-creation technologies.

With SSR and ZFP, Exa Mammo is exceedingly simple to deploy and use on existing workstations. It integrates with other interfaces and saves facilities from expensive IT upgrades when deploying DBT, while enhancing security of patient data by never downloading images or information onto an individual workstation. For all required (MQSA) mammography tracking and reporting, Exa Mammo integrates with third-party software, such as Penrad, MRS and Ikonopedia. Through this software, tracking items such as Bi-Rads assessment and recommendations, breast density, calcification and geometry selection, and biopsy protocol selection are all presented to the radiologist during reading and dictation. Each third-party software meets MQSA standards put forth by the American College of Radiology.

Conclusion

DBT is an evolution in digital mammography systems, with initial clinical evidence indicating a higher cancer detection rate, particularly in women with dense breasts, and a lower false-positive recall rate. However, the large file size of DBT exams presents implementation challenges and can place a strain on existing networks and IT infrastructure. The equipment's high cost can further impede a facility's economic ability to provide this potentially life-saving technology to patients.

Exa Mammo from Konica Minolta can help overcome these limitations with a cost-effective solution that does not require any image downloads, dedicated tomosynthesis workstation or expensive

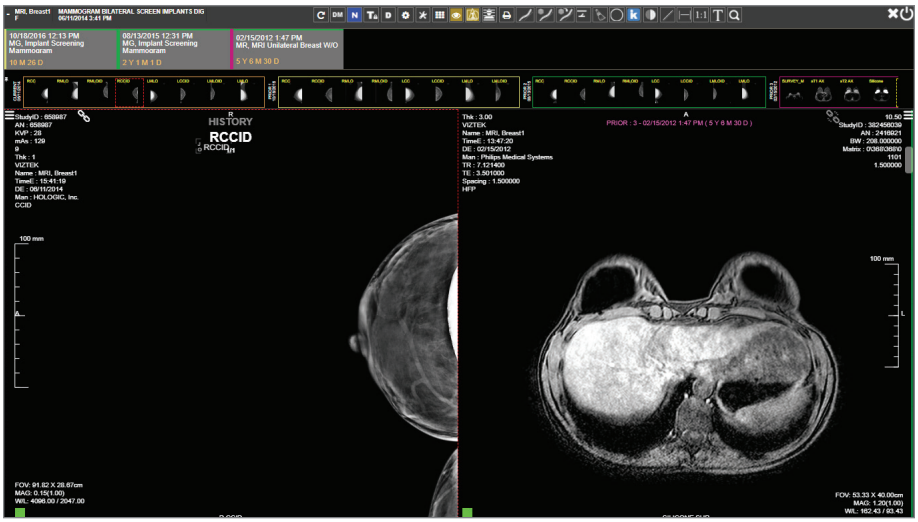

Figure 2. Exa Mammo is a true multi-modality breast imaging workstation that can be used for reviewing MRI exams in addition to mammography, DBT and ultrasound.

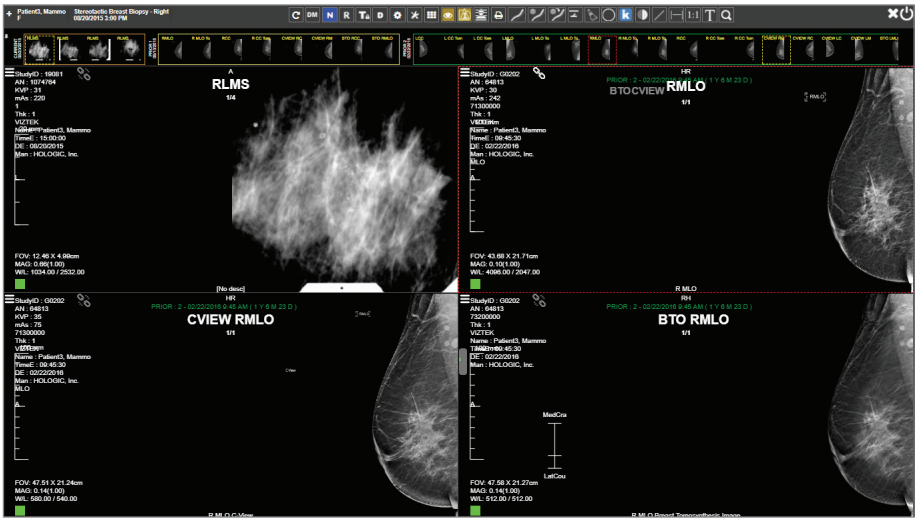

Figure 3. Exa Mammo integrates with third-party software to help track items such as Bi-Rads assessment and recommendations, breast density, calcification and geometry selection, and biopsy protocol selection.

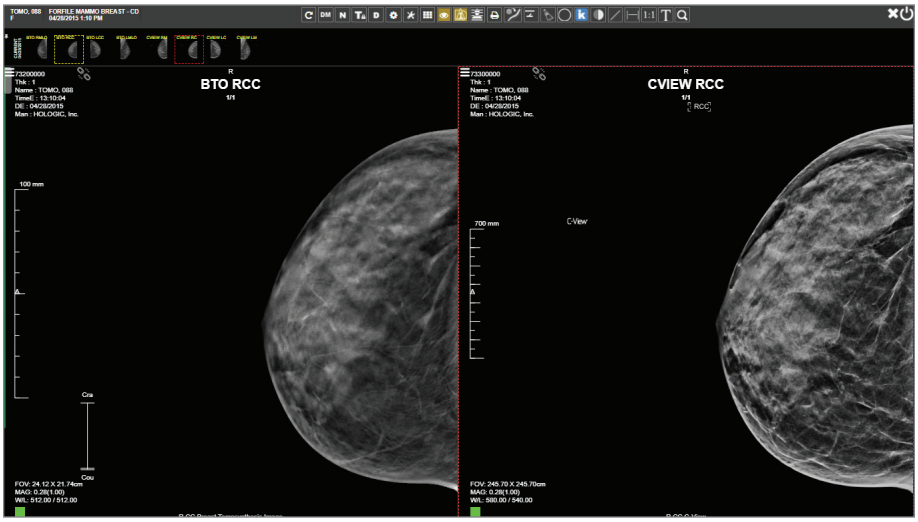

Figure 4. With Server Side Rendering and Diagnostic Zero Footprint technologies, Exa Mammo is exceedingly simple to deploy and use on existing workstations.

IT upgrades. It delivers fast access to images and prior studies with zero lag time, minimizes unwanted exposure to patient data, and can be deployed on existing workstations. With ZFP and SSR technologies, facilities can embrace remote reading/teleradiology for a more cost-effective and productive workflow.

With Exa Mammo, breast imaging facilities have a cost-effective and efficient workflow solution for DBT.

**For digital mammography, a 5MP monitor is required per MQSA guidelines.*

"DBT IS AN EVOLUTION IN DIGITAL MAMMOGRAPHY SYSTEMS, WITH INITIAL CLINICAL EVIDENCE INDICATING A HIGHER CANCER DETECTION RATE, PARTICULARLY IN WOMEN WITH DENSE BREASTS, AND A LOWER FALSE-POSITIVE RECALL RATE."

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