Using the Hologic Selenia™ Dimensions™ System

Introduction

Breast tomosynthesis is a method of acquiring and displaying three-dimensional (3D) mammograms that provide greater image clarity than conventional two-dimensional (2D) mammograms by reducing the confounding effects of superimposed parenchyma[1].

Selenia™ Dimensions™ Breast Tomosynthesis System

The Hologic Selenia™ Dimensions™ system* performs breast tomosynthesis in a platform optimized for both 3D and all conventional 2D imaging modes. A unique Fusion™ Imaging mode enables the acquisition and display of correlated 2D and 3D images from a single breast compression to enhance the detection and classification of subtle calcifications and lesions, and reduce false positives caused by tissue overlap.

System Description

X-ray Tube and Filters

The Selenia Dimensions x-ray generation system consists of a custom-designed high power (mA) tungsten (W) anode x-ray tube, and x-ray filters of rhodium (Rh), silver (Ag), and aluminum (Al). These different filters are used in 2D and 3D imaging and produce optimal x-ray spectra based on breast thickness/composition and imaging modes. This ensures that patient radiation exposure is minimized while maintaining image quality and keeping exposure times at a minimum.

Improved Image Receptor

The Selenia Dimensions image receptor is a 70-micron pixel pitch selenium direct-capture detector, which offers the same high quality 2D imaging as on the Hologic Selenia digital mammography system. Furthermore, the image receptor has high-speed, low-noise readout electronics for rapid imaging necessary for tomosynthesis, and improved Detective Quantum Efficiency (DQE) that allows 3D images to be acquired with low radiation dose to the breasts.

Similar to Selenia, the Selenia Dimensions image receptor employs an anti-scatter high transmission cellular (HTC®) grid in contact 2D imaging modes. The grid is automatically moved out of the field of view when 3D imaging mode is selected. The retracting grid allows rapid switching between the 2D and 3D imaging modes and enables the acquisition of images with one breast compression and hence the ability to fuse 2D and 3D images with perfect overlap and registration.

Summary of Advantages

The Selenia Dimensions system design allows very low dose imaging while maintaining image quality and short exposure times in both 2D and 3D imaging modes. This is achieved by the use of use of a tungsten anode x-ray tube, optimized filters, markedly higher x-ray tube current, and a fast selenium direct-capture detector. Because patient motion degrades the visibility of small objects in the breast, minimizing total scan time is important. The use of a W tube, faster read out image receptor, and optimized scan angle all help to minimize exposure time.

Imaging Modes

Digital Mammography (2D) Imaging

This imaging mode is the conventional imaging done by digital mammography. The system supports all the paddles and all the modes provided by the Selenia system.

Breast Tomosynthesis (3D) Imaging

In this mode, the x-ray tube will move over a 15 degree arc while the breast is compressed, taking a series of ultra low-dose mammograms, known as projections. The projections are then combined to create a full 3D image set of the breast, with 1 mm slices through the breast. The determination of optimal scan angle involves a complex optimization of scan time, reduction of out-of-plane objects, in-plane resolution, reconstructed slice separations, and patient concerns such as size of face shields and time breast under compression. We have performed clinical trials investigating these parameters

* The Selenia Dimensions system is available commercially in Europe and other countries and awaiting U.S. Food and Drug Administration (FDA) approval in the United States.

to arrive at our final product design of a 15 degree scan.

Unique Fusion Imaging Mode

The Selenia Dimensions system allows the automatic acquisition and fusing of the two independent 2D and 3D imaging modalities. This Fusion Imaging mode combines the best features of both 2D and 3D imaging: rapid review of calcifications and assessments of asymmetric densities using the 2D image, and better visibility of masses and spiculations through reduction of tissue overlap using the 3D image.

In Fusion Imaging mode, the system will perform both 2D and 3D acquisition in one breast compression, in just seconds. Furthermore, because both acquisitions are performed in one compression, the two separate images are co-registered. This allows the radiologist to toggle between these two image sets, and objects in one image set appear in the same location in the second image set. This is demonstrated in Fig 1, where objects found in the 2D image are at the same x,y location in the 3D image, and vice versa.

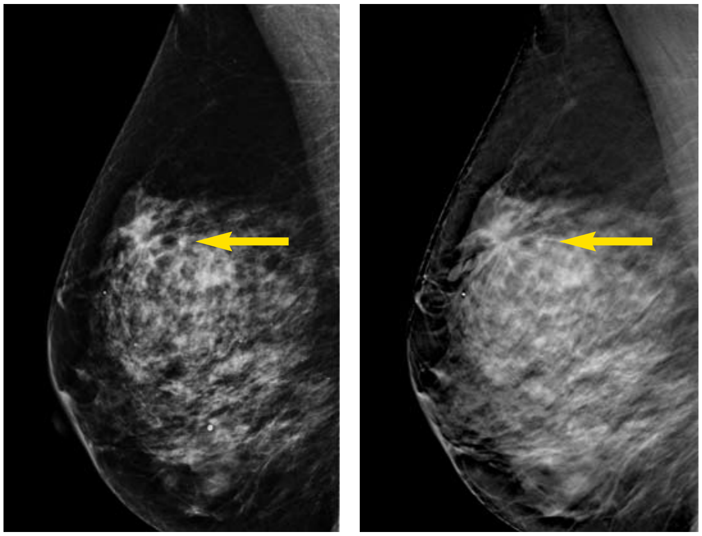

Figure 1 Image in 2D (left) and 3D (right) are perfectly registered relative to each other, when acquired in the Fusion Imaging mode

Fusion Imaging mode allows rapid and accurate correlation between objects seen in the 2D and the 3D images. For example, the presence of a subtle lesion suspected on the 2D image can be confirmed through analysis of the corresponding location in the 3D image, and a suspicious area seen in 2D due to tissue superimposition can be dismissed by using the 3D image.

Softcopy Display

The Hologic SecurView™ workstation is designed to work seamlessly with both 2D and 3D Selenia Dimensions images, and especially with the Fusion Imaging mode images. 3D images can be reviewed as part of a hanging protocol similarly to 2D images as with the Selenia system. When Fusion mode images are available, the user can toggle easily between the 2D and 3D image modes.

Introducing Tomosynthesis into Clinical Practice

Screening with Breast Tomosynthesis

Despite the proven success with mammography in reducing breast cancer mortality, conventional mammography, both digital and analog, shows some limitations as a screening modality. These limitations are that some cancers are missed in screening mammography, and mammography has a non-zero false positive rate, which results in recalls that are resolved through diagnostic tests. It is expected that breast tomosynthesis will improve both of these metrics through the reduction in superimposed tissue from obscuring the lesions[2,3,4,5].

We recommend the use of Fusion Imaging mode in screening. For screening, Fusion Imaging in both CC and MLO provides the maximal additional imaging information, avoids the potential problem of missing cancers if only 3D-MLO is performed, avoids the need to screen for micro calcifications in the large number of 3D slices, and avoids the potential problem of missing subtle microcalcifications if the 2D exam is skipped.

Diagnostic Workups with Tomosynthesis

The reduced variability in the performance of radiologists when using breast tomosynthesis suggests that it is easier to correctly characterize lesions when using tomosynthesis, compared to 2D alone. For this reason, we think that 3D imaging has a place in the diagnostic workup, although no large clinical trial results have yet been reported. Early reports indicate promise[8].

Transitioning Into Tomosynthesis

It is anticipated that there will be a transition period when radiologists use their experience in 2D imaging and explore the values of 3D imaging while preserving the quality of patient care. During this transition, it is expected that both 2D and 3D images will be desired. The 2D images will facilitate comparison to prior mammograms, help in the learning curve to interpret 3D images, and also speed up image assessment especially in regards to looking for asymmetric densities and in evaluation of calcification clusters.

The availability of the 2D image will also allow the use of computer aided detection (CAD), as true 3D CAD is not yet available. Fusion Imaging allows one to see if a suspicious region in a 3D image had a 2D CAD mark at the corresponding location.

Fusion Imaging is the Key for Breast Cancer Screening

Fusion Imaging is the best method to acquire and display both 2D and 3D images. In the Fusion Imaging mode, the 2D image quality is the same as a Mo-based Selenia image. The corresponding 3D images allow for much improved detection and characterization of subtle lesions which may be obscured by overlying breast tissues. Acquiring data in Fusion mode is preferred to acquisition using 2D or 3D alone, as it provides much more clinical information.

Breast Tomosynthesis Without 2D

On the Selenia Dimensions system, the 3D imaging mode alone may be used for diagnostic purposes, for example to evaluate masses and spiculations, but its performance has not yet been evaluated for breast cancer screening. With the dose efficiency afforded by the system design, both 2D and 3D imaging can be performed at doses similar to conventional mammography, so Fusion Imaging is the recommended mode.

What About Dose?

The introduction of the Selenia Dimensions system with its improved detector and tungsten anode x-ray tube and advanced filtration system allows a significant reduction in radiation dose. Several operating modes will be available with the system, and can allow Fusion Imaging with radiation doses comparable to the majority of digital mammography systems installed throughout the world. Different dose settings allow flexibility in managing the tradeoff between radiation exposure and image quality. Of key importance for the introduction of tomosynthesis is the availability of multiple dose levels in the Fusion Imaging modes. In the "Dose" mode, the total dose for obtaining both 2D and 3D images with Selenia Dimensions is comparable to the dose required on conventional digital mammography systems. The "Contrast" mode produces enhanced 3D image quality. All imaging modes provide 2D image quality identical to the standard Selenia image, critical for the detection of the faintest microcalcifications.

Typical Mammography Dose Levels

<table>
<tr><th>Description</th><th>Dose per view (mGy)*</th></tr>
<tr><td>Dimensions 2D
(W anode)</td><td>1.0-1.2</td></tr>
<tr><td>Selenia 2D
(Mo anode)</td><td rowspan="2">1.6-1.8</td></tr>
<tr><td>Dimensions 2D+3D Dose mode
(W anode)</td></tr>
<tr><td>Dimensions 2D+3D Contrast mode
(W anode)</td><td>2.4-2.6</td></tr>
</table>

* Doses are measured relative to the ACR accreditation phantom, which simulates a 4.2 cm comressed breast consisting of 50% glandular and 50% adipose tissue. Doses measured relative to 4.5 cm PMMA are approximately 20% higher.

Summary of Clinical Results

Clinical trials have been conducted to measure the performance of breast tomosynthesis[2]. A summary of the results is shown in Fig. 2. The curves indicate the Receiving Operating Characteristics (ROC) performance of conventional digital mammography imaging compared to the Fusion method of using breast, whereby every patient has a CC and MLO in Fusion Imaging mode.

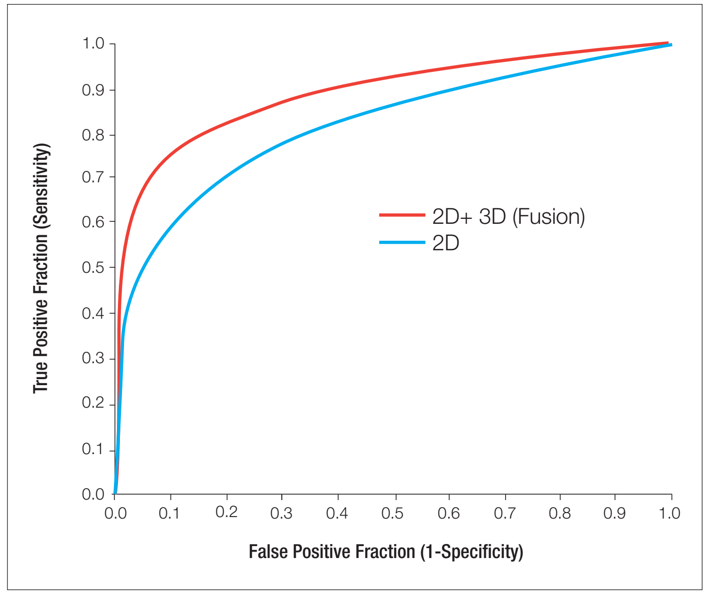

Figure 2 Performance of breast tomosynthesis compared to digital mammography

It can be seen that the addition of 3D breast tomosynthesis to the normal 2D exam significantly improves clinical performance. Rafferty et al[2] estimated both an increase in sensitivity and specificity by the Fusion Imaging method. These same performance improvements can be predicted through the ROC curves seen in Fig. 2. They predict that the use of 3D imaging, combined with 2D imaging, will show significantly improved cancer sensitivity without adversely affecting recall rates, or equivalently, maintaining sensitivity while reducing recall rates.

Why Take Both 2D + 3D Images?

The ROC curve is an accepted method of quantifying the performance of an imaging modality. It shows how the recall rate (False Positive Fraction) relate to the cancer detection rate (True Positive Fraction). It can be seen that the best clinical performance was obtained by acquiring both CC and MLO in Fusion mode. Poorer performance was obtained by 2D imaging alone.

Figure 3 shows the performance obtained when only one view, in this case MLO, was acquired using Fusion Imaging. The middle curve, labeled "2D+3D-MLO" consisted of acquiring a MLO in both 2D and 3D, and a CC in 2D alone. Including a partial 3D exam, 3D-MLO only, to the 2D exam gave performance somewhere between the two other imaging methods, as can be seen in the figure. This is consistent with the results of Rafferty et al[3], where 9% of cancers were not visualized in the 3D MLO view. It seems that 3D imaging in both CC and MLO, Fusion Imaging in both views, offers the best performance.

This point seems at first counter-intuitive, because one might think that a single 3D exposure would gather all the 3D information available. Breast tomosynthesis is a form of limited angle tomography. This yields a 3D image, but one

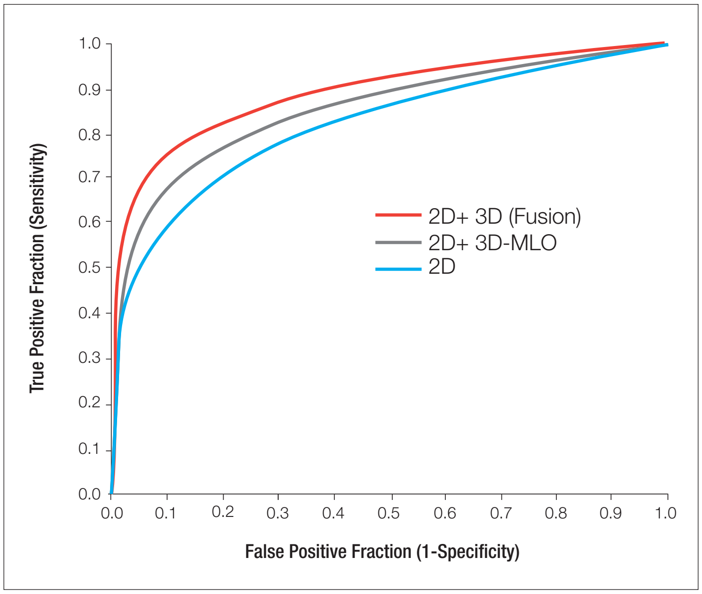

Figure 3 Performance of MLO-tomosynthesis compared to 2-view tomosynthesis and digital mammography

where the in-plane cross sectional slices have very high mammographic resolution, but relatively coarser resolution (~ mm) in the out-of-plane third direction. Therefore, one cannot just perform an oblique reconstruction to turn an MLO exam into a CC exam. If a cancer is non-spherical, there may well be a preferred orientation that optimizes its visibility. This has been postulated as a reason why cancers are sometimes better visualized in a CC tomosynthesis view as compared to an MLO view, or vice versa. Optimal sensitivity is expected when both views are acquired, consistent with the ROC results shown in the figure.

What About Dense Breasts?

Preliminary results[4] indicate that using Fusion Imaging for dense breasts improves the performance relative to 2D imaging alone, giving an ROC performance in dense breasts equivalent to digital mammography in fatty breasts.

Radiologist Variability

Several reports[5, 6] indicate that the inter-radiologist performance variability is reduced when using 3D imaging. This is not unreasonable, as the 3D exam reduces the confusing effects of superimposed parenchyma.

Why Bother with 2D Imaging?

As noted earlier, 2D imaging helps the radiologist transition to 3D imaging. Moreover, at this time, no multi-reader, multi-center trial has been reported that estimates the performance of 3D alone in a screening population. Until then, it is likely that the use of 2D in addition to 3D is the prudent course of action.

3D Imaging as a Function of Radiologist Experience

A recent study[7] investigated whether tomosynthesis imaging was more helpful for the less experienced or more experienced radiologist. The authors' conclusion was that the addition of 3D to the 2D exam helped all radiologists, independent of their experience level. 3D imaging is not only for the inexperienced.

Training

Breast tomosynthesis images are similar to digital mammography images, yet have subtleties that recommend that specialized training be conducted, even for experts in digital mammography. To this end, Hologic is conducting training lectures where tomosynthesis cases are reviewed and discussed. Hologic is also developing an online training course, which might be more convenient for some users, who are unable to travel to the live lectures.

References

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Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730 U.S.A.
T: 781.999.7629
www.hologic.com
womensimaging@hologic.com
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