Breast Tomosynthesis

Considerations for routine clinical use

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This white paper serves to summarize the state of the art in the clinical use and performance of tomosynthesis.

Clinical Trial Results

Hologic conducted a large clinical trial, and two reader studies, in support of their submission to the U.S. Food and Drug Administration (FDA) to achieve approval for sale in the United States. The reader studies’ results are summarized briefly below and are in the FDA’s Summary of Safety and Effectiveness following approval of Hologic’s tomosynthesis product. Full details of the clinical trial and results are currently being submitted for publication.

The product was approved by the FDA for use in the same clinical indications as 2D mammography, and can be used for both screening and diagnosis of breast cancer. The purpose of the clinical trial was to compare the performance of 2D plus 3D imaging (also known as combo imaging) to that of 2D imaging alone. The trial revealed that adding tomosynthesis to the 2D reading significantly improved accuracy as demonstrated by an improved area under the Receiver Operating Characteristics (ROC) curve and a reduced non-cancer recall rate, for 2D plus 3D imaging compared to 2D alone.

Results from this trial were first presented by Rafferty at the RSNA. Images were acquired from 5 clinical centers in the U.S. under an IRB-approved protocol and informed patient consent. All subjects had bilateral 2-view mammograms (MLO and CC) in both 2D and 3D imaging modes. Two reader studies were conducted using images from this set. In the two reader studies conducted, the performance of 2D plus 3D was shown to be significantly superior to the performance of 2D alone. The fact that the ROC curve of 2D plus 3D is higher than the 2D curve illustrates that 2D plus 3D can offer either improved cancer detection rate, or superior recall rate, or both, compared to 2D alone. These are certainly very positive results, and are much stronger than the ACRIN DMIST study’s results which compared the performance of digital to film mammography, and found no average difference in performance between those two technologies.

The area under the ROC curves for both studies were significantly higher for 2D plus 3D compared to 2D alone, and are consistent with the results of an independent third study from the University of Pittsburgh which found a 7% improvement in the ROC curve area for 2D plus 3D compared to 2D alone.

Sensitivity of Tomosynthesis

In Hologic’s clinical studies reviewed by the FDA advisory panel radiologists reading in combo-mode (2D +3D breast tomosynthesis) compared to 2D mammography alone demonstrated improved sensitivity [the proportion of mammograms with cancer which were correctly diagnosed].

The sensitivity gain from using tomosynthesis in screening can be estimated from ROC curves, although the exact improvement in cancer detection will not be known until the technology is more widely implemented in routine screening practices. Figure 1 shows hypothetical examples of ROC curves from 2D and 2D plus 3D imaging. The diagonal arrow shows how one can improve both cancer detection and reduce recall rates using a technology that has a higher ROC curve. Because of the demonstrated improvement in ROC area using 2D plus 3D imaging, the expected sensitivity gain will be considerable, and will vary by site based on individual radiologist’s thresholds on detection and recall rate.

Figure 1  The use of 2D plus 3D imaging offers the possibility to both improve cancer detection and decrease recall rates.
Recall Rate Reduction

In three Selenia Dimensions 3D Breast Tomosynthesis studies reviewed by the FDA advisory panel, the radiologists reduced their recall rates using combo-mode (2D + 3D breast tomosynthesis) compared with 2D mammography alone.

The recall rate from the use of tomosynthesis in screening was studied in Hologic’s FDA study. A reduction of recall rate was reported for 2D plus 3D compared to 2D alone. Several studies have shown the potential to reduce the recall rate in screening. For example, the results from Gur suggest that the use of tomosynthesis during baseline screening mammography may reduce the recall rate by 28%.\(^5\) Rafferty in her 2007 RSNA presentation estimated the recall rate reduction to be over 40%.\(^1\)

Single View Tomosynthesis

Based on Hologic’s clinical studies, two-view tomosynthesis (CC and MLO) was superior to one-view tomosynthesis (MLO) in combo-mode (2D + 3D breast tomosynthesis) imaging.

The reader studies above used 2-view mammography in both 2D and 3D imaging. One of the reader studies also investigated a 3\(^{rd}\) arm: single-view tomosynthesis (3D-MLO) imaging in combination with 2-view (CC and MLO) 2D mammography. The performance of two-view mammography plus 3D-MLO showed that the 3D-MLO-only arm performed better than 2D but not as well as two-view 2D plus 3D. These results are consistent with several other studies, illustrating that MLO-only breast tomosynthesis is likely to be inferior to two-view tomosynthesis.

Summary of Clinical Trial Results

The Hologic reader studies showed the following conclusions regarding the use of 2D plus 3D imaging compared to 2D alone:

- 2D plus 3D is superior to 2D
- The screening recall rate of 2D plus 3D is lower than that of 2D
- The sensitivity of 2D plus 3D is higher than 2D
- Performance using both 3D CC and MLO views was greater than 3D MLO alone

Why do 2D plus 3D rather than 3D alone?

There are several reasons why acquiring both the 2D and 3D images together are useful, especially in screening. It is well known that comparison of current images with prior images is standard mammography practice and critical to perceive subtle changes which may be associated with a cancer. Obtaining a 2D exam along with the 3D exam allows direct comparison of current 2D images with prior 2D images.

The 2D exam is also useful for the rapid detection of calcifications and perception of their distribution. Segmental and clustered calcifications are more easily and quickly appreciated with 2D because they can traverse multiple slices in 3D.

The 3D portion of the 2D plus 3D exam is also critical in optimizing performance. The 3D image reduces structure overlap, minimizing recalls for overlapped structures and better demonstrates masses and architectural distortions. Thus we see that 2D and 3D are complementary and acquired together offers an advantage in clinical use.

There may be methods to eliminate the need to separately acquire the 2D exam, through mathematical algorithms that generate a synthesized 2D image reconstructed from the 3D dataset. This approach is discussed in the following section of this paper.

In conclusion, the 2D exam as part of a 2D plus 3D exam is valuable because:

- The 2D image is useful for comparison to priors
- The 2D image allows for quick reading of microcalcifications

Synthesized 2D

We have seen how 2D plus 3D imaging is superior to 2D alone. The question has been asked - Can a synthesized 2D image be created from a 3D data set for use in a tomosynthesis-only acquisition mode for screening? One value of such a synthesized 2D image would be reduced patient dose — approximately half the dose of a 2D plus 3D exam, and approximately the same as a 2D exam alone.

The algorithms to create such a synthesized image that approximate the necessary components of the true 2D, involve smart summing of the individual slices that make up the 3D exam. In clinical use, the synthesized 2D image will be reviewed together with the 3D image set.
There are technical challenges to creating a synthesized 2D image that is close in quality to that from a true 2D image, however much progress has been made recently in this area. Gur has studied the performance of an early version of synthesized 2D in a pilot study. He concluded that a minor improvement in the quality of a synthesized 2D image could lead to an acceptable diagnostic quality and eliminate the need for acquiring both a 2D and 3D dataset during tomosynthesis-based screening. This is certainly promising and offers the possibility of providing the improved performance gain of two-view breast tomosynthesis without increasing the dose beyond normal 2D mammography levels.

Hologic has also conducted a study to investigate the performance of synthesized 2D images. In this study, the performance of 3D (with synthesized 2D) was compared to 2D alone. As seen in the ROC performance of 3D was superior to 2D, and this was accomplished without requiring the dose of a separate 2D exposure. The ROC curves from this study are shown in Figure 2, and 3D with synthesized 2D shows improved ROC performance relative to 2D alone.

One-view Versus Two-View Tomosynthesis

Should one perform one- or two-view tomosynthesis imaging? Single view tomosynthesis (either CC or MLO) is a lower-dose procedure compared to two-view tomosynthesis, but it has been demonstrated to have poorer clinical performance.

The relative performance of one-view versus two-view 2D mammography is well understood. Screening using two views offers an increase in cancer detection and a reduction in recall rate compared to single-view mammography; the paper by Wald estimates the sensitivity gain is 24% and recall rate reduction is 15%. It is not unreasonable to ask if a similar effect is observed in the clinical implementation of tomosynthesis. Perhaps, not surprisingly, the use of single view tomosynthesis is associated with poorer performance compared to tomosynthesis using two views.

This phenomenon is no different with one-view vs. two-view tomosynthesis. There is mounting evidence that two-view tomosynthesis has increased sensitivity relative to one-view tomosynthesis. This has been illustrated in the Hologic clinical data, where the clinical performance of two-view 2D combined with a single MLO 3D view, as measured using ROC curve analysis, was inferior to the performance of two-view 2D combined with two-view 3D imaging.

Other data is consistent with this finding. Rafferty found that 12% of lesions were better seen on 3D MLO, 15% better seen on 3D CC and 9% of lesions were visible only on CC. Similar results were reported by Baker, who found 8% of lesions were visible only on the CC tomosynthesis view and 1.4% only on the MLO.

These results are also consistent with evaluations where studies comparing ROC performance of two 3D views demonstrate superior performance over two-view digital mammography (Michell), but studies comparing one 3D view to two-view digital mammography have poorer performance and do not show superiority (Gennaro, Wallis).
In addition to the likely loss of sensitivity that occurs if only one 3D view is taken, there are some clinical challenges that arise with single view tomosynthesis imaging. Neither the CC nor the MLO views capture all the breast tissue, so both views in some form are needed. Mixing up the technologies such as 3D MLO and 2D CC might address the tissue coverage but creates its own set of issues. It might be difficult, for example, to correlate a suspicious lesion seen in 2D CC with the same lesion in the 3D MLO, or vice versa. An even more challenging situation is when the exam consists of solely a 3D MLO. It could be difficult to see asymmetries with only one view, and comparison to 2D prior images would also be challenging. The best clinical performance will likely be seen in protocols that acquire both a CC and an MLO 3D image set.

Performing two views uses more radiation dose than one view and having two views may increase the reading time; however, these doses are well within the federally established limits and are commonly accepted in conventional mammography, where two-view mammography is performed so as to optimize the mammogram for cancer detection, with tolerable recall rates such as was found by Wald et al, 1995. Performing two-view tomosynthesis is associated with higher sensitivity along with reduction in recall rates, as compared to single view tomosynthesis where sensitivity will suffer.

Given that there is an established dose limit for mammographic imaging in the U.S., it would seem reasonable to maximize the use of the dose budget. An alternative approach to acquiring two tomosynthesis views, given a fixed radiation dose budget, would be to acquire only one tomosynthesis view, but double the dose for that view. This certainly would lower noise and may result in a superior image due to the increased photon statistics, however, based on the above results, it is better for a fixed 2x dose budget to split the dose into two views. The Gennaro (2009) study confirmed that the use of single-view 3D at 2x dose achieved inferior performance, compared to digital mammography, than did Michell (2010) who used two 3D views at approximately 1x dose each.\textsuperscript{11, 10}

**How well does tomosynthesis image calcifications and masses and distortions?**

The clinical trial data presented as part of Hologic's FDA submission has been analyzed by separating the image sets into cases that separately contained calcifications, or non-calcifications. Rafferty found that 2D plus 3D offered a very significant increase in performance relative to 2D imaging for cases involving masses and distortions. For the imaging of cases involving microcalcifications, there was a small improvement in the ROC performance with the addition of 3D, but that was not a significant improvement. Importantly, the use of 3D was not associated with a poorer microcalcification ROC performance compared to 2D alone.

Other studies have looked at calcifications and their visibility with tomosynthesis. Early investigations found that digital mammography was often superior to tomosynthesis for calcification visualization\textsuperscript{13}, however these early systems had long scan times (10-18 seconds) which can lead to patient motion. Scan times have been reduced significantly in some systems, and many papers give a positive outlook. For example, Kopans found that the characterization of calcifications in tomosynthesis was equal or superior to their characterization in conventional digital mammography in 92% of cases.\textsuperscript{14} If one acquires 2D plus 3D exam then one is assured that calcifications are always optimal in at least one image set.

**What is the performance of tomosynthesis in fatty and dense breasts?**

Tomosynthesis has been shown to improve the performance of mammography in both fatty and dense breasts. Researchers have performed an analysis on cases following their grouping into fatty breast and dense breast sub-groups. For this...
analysis, fatty breasts were defined as BI-RADS density 1 and 2 and dense breasts were defined as BI-RADS density 3 and 4.

In a study by Rafferty, she found that 2D plus 3D was significantly better than 2D alone in ROC performance for both fatty and dense breasts.\textsuperscript{15} The gain in area under the ROC curve was 2-3 times higher in dense breasts than it was in fatty breasts, with a gain in both breast density types. She also reported large recall rate reductions in both fatty and dense breast types.

In a separate study, Rafferty studied the performance of tomosynthesis in women with dense breasts and found an increase in the recall for cancer cases and a reduction in the recall rate for non-cancer cases.\textsuperscript{16}

These results are not unexpected. Fatty breasts may have sufficient parenchyma that tomosynthesis would be expected to offer some advantages, and the larger improvement in performance in denser breasts using tomosynthesis illustrates that tomosynthesis is doing what is expected from the physics principles – reducing superimposed parenchyma.

Is tomosynthesis finding invasive cancers or just more DCIS?

It is expected that the additional cancers found by tomosynthesis will be found to be an increase in mass lesions, and not calcification-only cancers. The reasoning for this is seen in the much greater improvement in the ROC curve performance for non-calcifications than for cases involving calcifications. We thus expect that the gain in sensitivity using tomosynthesis can be attributable to invasive cancers. A cancer found on the 3D image and not seen in the 2D image during routine screening would not have been found until a successive screening round had the 3D exam not been performed.

Tomosynthesis Computer-Aided Detection (CAD)

Just as in conventional 2D digital mammography, CAD may help find suspicious objects in a 3D dataset. However, there are differences in the use for CAD in tomosynthesis. Conventional 2D CAD helps find both masses and microcalcifications. In tomosynthesis, there may be less of a need for a mass-detection algorithm, because often the masses and distortions are found very quickly and easily by the human observer.

The situation is different in the case of microcalcifications. It can be time consuming to have to carefully search a large number of slices looking for subtle microcalcifications. An efficient and sensitive calcification CAD algorithm could help speed up the search by, for example, identifying suspicious calcification clusters on a scout image, and rapidly navigating to the appropriate slices of interest without the need to scan...
through the 3D dataset. Figure 3 shows an example of a CAD algorithm marking potentially suspicious microcalcifications on a single slice from a 3D study.

Figure 3  CAD marks identify areas of interest on a single 3D slice

Patient Dose and Risk/Benefit

The dose of both a 2D and a 3D exam are very small. Even taken together, as a combo acquisition, they are below the U.S. FDA/MQSA-determined safe level, and are not far from where mammography was historically.\textsuperscript{17}

We have seen how the clinical protocol of CC and MLO 2D plus CC and MLO 3D gives the best clinical accuracy for screening; however, there are many methods of performing the 2D and the 3D exam, and the patient dose will vary depending upon how many exposures are made, i.e. what combinations of CC and MLO and 2D and 3D images are taken, such as is the case in a diagnostic workup.

![Figure 4 Dose levels of 2D and 3D exams compared to natural background radiation](image)

The doses of a 2D and a 3D exam can be compared to the levels of background radiation that everyone receives from natural sources such as cosmic rays and the soil. These exposure levels are shown in Figure 4. A 2D, 3D, or combined 2D plus 3D study all have effective dose levels that are fractions of typical doses that people are annually exposed to in the U.S., Europe, and elsewhere in the world. There are normal variations in these levels, and higher altitude cities have higher background radiation levels that can give an occupant more radiation than on average, as seen in the background radiation in Colorado compared to the average in the U.S. Breast cancer mortality rates are lower in Colorado than on average in the U.S., which is an indication that radiation at these levels should not be a concern.\textsuperscript{18}

Indeed, the Health Physics Society issued a position statement on the very topic, stating that “Estimation of health risk associated with radiation doses that are of similar magnitude as those received from natural sources should be strictly qualitative and encompass a range of hypothetical health outcomes, including the possibility of no adverse health effects at such low levels.”\textsuperscript{19}

It is important to keep a perspective on the actual risks from the very low radiation doses delivered by modern mammography and tomosynthesis systems. Doses at current levels are low and risks are hypothetical.\textsuperscript{20} The benefits of screening mammography and early detection of cancer, on the contrary, are not hypothetical – they are proven. And tomosynthesis will be an improvement over conventional mammography, in improving sensitivity, and avoiding unnecessary workup of women without disease.

Tomosynthesis In the Evaluation of the Symptomatic Patient

The use of tomosynthesis in diagnostic assessment offers the opportunity for both improved performance and a reduction in the number of x-ray images and dose and time.

Zuley found comparable sensitivity and specificity in the use of two-view 3D imaging in place of the additional diagnostic 2D views typically taken.\textsuperscript{21} Because the number of diagnostic views in the evaluation of masses or focal asymmetries can average three or more, there is a clear opportunity to reduce radiation exposure through the use of 3D in diagnostic evaluations.\textsuperscript{22}

Other researchers such as Svahn have also shown that the combined diagnostic performance of digital mammography and tomosynthesis is superior to either digital mammography or tomosynthesis alone.\textsuperscript{23}
Several studies have shown that tomosynthesis is superior to 2D mammography in predicting tumor size, demonstrating margins, extents of lesions, and in staging.

Michell showed that tomosynthesis is superior to 2D mammography in predicting the histological tumor size, because tomosynthesis demonstrates the margins and extents of the mammographic lesions more clearly, and concluded that this is critical information for prospective treatment planning by the multi-disciplinary team. Michell showed that tomosynthesis is superior to 2D mammography in predicting the histological tumor size, because tomosynthesis demonstrates the margins and extents of the mammographic lesions more clearly, and concluded that this is critical information for prospective treatment planning by the multi-disciplinary team.24 Fornvik found breast tomosynthesis superior to digital mammography in the assessment of breast tumor size and stage.25 Meacock found that 3D was more accurate than 2D in tumor size measurement.26 Tagliafico found that tomosynthesis could replace spot compression views, lowering both radiation dose and the potential to reduce biopsies on non-malignant lesions.27

**Tomosynthesis Reading Time**

Reading tomosynthesis images involves the evaluation of more images than a 2D image, because one must view each slice from a 3D stack with an average of 50 or more slices. Typical slice thicknesses in tomosynthesis range from 0.5 to 1.0 mm thick, with more slices to review as the slice thickness is made thinner. Nonetheless, reading times for tomosynthesis are not unreasonable.28 The increase in the number of images reflects the increase in the information available to the radiologist, and is justified by the superior clinical performance.

**Tomosynthesis Compared to Ultrasound**

No studies have been published directly comparing the performance of tomosynthesis compared to ultrasound in a screening usage. Nonetheless, several observations may be made about this. Tomosynthesis, like ultrasound, has a superior performance in dense breasts relative to mammography. However, unlike ultrasound, where the recall rate of 2D and ultrasound was 4 times that of 2D alone as was seen in the ACRIN 6666 trial, tomosynthesis improves sensitivity without increasing the recall rate.29

**Contrast Enhanced Breast Imaging**

Contrast enhanced breast imaging is a procedure that images the distribution of an iodinated contrast agent using either 2D or 3D x-ray imaging technologies. This technology is in its early evaluation stage, but may offer some advantages relative to contrast breast MRI in terms of reduced cost and access for patients currently contraindicated for MRI. Contrast enhanced breast imaging combines functional information from the distribution of the contrast agent and morphological information from the x-ray images. Hologic is investigating this technology using a dual modality system, capable of imaging the functional 2D contrast uptake and the morphological 3D image in rapid sequence, and combining these two image sets into a single fused study. It is thought that the 3D tomosynthesis image can give additional morphological information not found in either a 2D or 3D contrast image or a standard 2D image.

**Implementation of Tomosynthesis In Clinical Practice**

Which patients should receive tomosynthesis imaging? How should one incorporate it into one's practice? This section will contain some examples from users that have adopted tomosynthesis.
Should I use tomosynthesis for screening or diagnostic imaging?

Tomosynthesis has shown value in a diagnostic evaluation of a symptomatic breast. It also can be used in screening to improve sensitivity and reduce recalls. Therefore, either or both indications are acceptable uses of tomosynthesis. Diagnostic procedures often take longer than screening examinations. With a limited number of tomosynthesis systems, more women per day can be accommodated in machines dedicated to screening use, so this might be a consideration for a clinic that cannot convert all systems to tomosynthesis.

Should I use tomosynthesis only on women with dense breasts?

Tomosynthesis showed value in both fatty and dense breasts, but had a greater impact on improving performance for women with dense breasts. Therefore, if a practice does not have enough systems to screen all women, it is reasonable to triage them and reserve tomosynthesis for the harder cases with denser breasts. However, as tomosynthesis offers a benefit in both fatty and dense breasts, the goal for screening should be to screen 100% of women with tomosynthesis.

How should I select which patients get tomosynthesis?

Tomosynthesis benefits all women, irrespective of breast type, and will find cancers not found using 2D mammography. Nonetheless, as discussed above, one could choose to image only women with dense breasts, creating a possible scheduling challenge. And remember, tomosynthesis does offer an advantage for women with fatty breasts, and these women would not have access to this technology in this model.

Some clinics offer tomosynthesis using the ‘next available free system’ model, where if the room with the tomosynthesis system is free, the next patient will be scanned on this system, regardless of their breast density. Some clinics also offer full access to a tomosynthesis system for any woman who requests the procedure. There can be special after-hours or otherwise scheduled blocks to give access to the system. Both these methods solve the dilemma of giving unequal care in a pre-defined and ecumenical way.

Different Implementation Scenarios

We have discussed a variety of different implementation scenarios. All of these are reasonable.

Example 1: Complete conversion of the clinic to tomosynthesis. All screening and diagnostic patients get the procedure.

Example 2: Partial conversion to tomosynthesis. Use for diagnostic patients only.

Example 3: Partial conversion to tomosynthesis. Use for some screening patients, selected populations subgroups such as women with dense breasts.

Example 4: Partial conversion to tomosynthesis. Use for some screening patients, as the tomosynthesis system(s) are free and available.

Handling Priors

Current mammography practice involves the comparison of current images to priors. The acquisition of a 2D plus 3D image exam gives the radiologist access to a 2D current for comparison to 2D priors. This 2D plus 3D image procedure also offers some advantages in the scenarios mentioned above where a patient this year might get a tomosynthesis study and in the next year receive only a 2D study because of scheduling constraints or equipment access. In such a situation, the radiologist reading the study in the following year would have access to the 2D exams from previous 2D plus 3D mode studies.

These types of scenarios are illustrated in Figure 5, and represent a hypothetical clinic that switches, in the current year, some but not all of their screening systems to tomosynthesis. In the prior year(s) the woman had 2D mammograms. In the current year she receives a combo image exam. The radiologist can diagnose from the 2D and 3D dataset, and uses the current year’s 2D to compare to prior years’ 2D images. Come next year, she might get a 2D exam or a 2D plus 3D exam, depending upon which system she is imaged on. If she gets a 2D plus 3D exam in the next year, the radiologist has both 2D and 3D currents and priors. If she gets a 2D exam in the next year, the radiologist has the next year’s 2D, and can compare that to the ‘current year’ 2D prior, and also the ‘current year’ 3D prior if desired.
**Radiologist Training**

Hologic learned from the tomosynthesis clinical trials the importance of proper training on how to interpret tomosynthesis images. To that end, Hologic has set up training classes around the world, taught by radiologists experienced in tomosynthesis, to aid in the education in tomosynthesis interpretation. These classes cover the appearance in tomosynthesis of different density parenchymal patterns, benign, and malignant lesions, and review clinical cases. Self-assessment practice cases are reviewed and discussed to give radiologists chances to test their learning.

The following is a link to Hologic’s tomosynthesis training page for radiologists: [www.hologic.com/radomo](http://www.hologic.com/radomo)

For radiologists in the U.S., the following is a link to the U.S. FDA’s website that covers the requirements for facilities and personnel using breast tomosynthesis: [http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm127739.htm](http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm127739.htm)

In the U.S., radiologists are required to have 8 hours of instruction prior to reading tomosynthesis clinically.

**Archiving and Display**

Tomosynthesis display and storage is covered by a DICOM standard. Nonetheless, at this time not all PACS vendors support either the storage or display of these images. Hologic has developed, as an interim solution, a storage method whereby the tomosynthesis images are stored in a secondary capture format, which allows the storage in PACS, but for display one must use a Hologic SecurView diagnostic workstation. It is expected that PACS companies will rapidly implement and support the viewing of tomosynthesis images, now that the systems are in widespread use in Europe and the U.S. following the FDA approval for Hologic’s tomosynthesis system.

In planning a site, careful consideration must be given to the size of the images. The images from a 3D study can be 5 times larger than the corresponding size of a 2D digital mammography dataset. Network speeds and PACS storage must be adequate for the increase data flow. These larger datasets are a natural result of tomosynthesis offering more information than digital mammograms.

**Conclusions**

Tomosynthesis is an exciting new technology that will likely revolutionize mammography, and will offer benefits to all women. It offers the potential for improvements in both screening and diagnostic evaluations. The improvements in clinical performance, compared to 2D, are significant.
REDUCED RECALL RATES: The 2D mammogram reveals a spiculated mass laterally in the right CC view. 3D tomosynthesis slices at 23, 33, and 43 mm above the breast platform show that this 2D finding was superimposed structures, resolved through the use of 3D imaging.

CONTRAST IMAGING: This study of 2D and 3D iodine contrast mammography was acquired under a single compression. The proven cancer in the lateral subareolar breast (horizontal arrow) is not visible on the unenhanced 2D mammogram (except for the clips placed at biopsy) but is easily seen on the 2D and 3D dual energy contrast images. Contrast imaging led to the detection of an additional enhancing cancer in the far medial breast (downward arrow). The 3D image shows the irregular shape of that lesion, greatly increasing its likelihood of malignancy.