Digital Breast Tomosynthesis (DBT)

Several presentations at the ECR Breast Care Day, which traditionally takes place on the first day of the annual ECR meeting and is sponsored by Siemens Healthineers, in cooperation with Bayer Healthcare, were this year devoted to the current status and potential of DBT. More than 1300 radiologists were treated to detailed presentations given by specialists experienced in the tomosynthesies field. This article summarizes the presentations.

Clinicial perfomance of synthetic mammograms (Insight 2D) and its role in screening procedures.

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To set the scene, Dr Bernathova reminded the audience that synthetic mammograms are developed from the data acquired during DBT acquisition, so a synthetic mammogram is NOT a Full Field Digital Mammogram (FFDM), a difference which can be clearly seen just by looking at the images [Figure 1].

Since several studies of DBT (e.g. the Malmö Breast Tomosynthesis Screening Trial) have shown that 3D tomosynthesis increases the number of lesions detected, it has been proposed to use DBT as a simple "stand-alone" imaging modality. The problem with such a scenario comes when comparisons with previous 2D mammograms have to be carried out. Likewise comparison of the right and left breast and the detection of asymmetries, distortions and calcifications can be challenging if only 3D data are available.

Several studies (*e.g. Lotti et al., ECR 2015*) were carried out to examine the need for 2D images in DBT and have shown that the addition of a synthetic 2D image to DBT was overall rated beneficial and useful particularly in the assessment of distortions and asymmetries.

Expectations for synthetic 2D

However although the benefits of synthetic 2D mammography seem clear, the situation is complicated by the fact that different users have different expectations for synthetic 2D. For example, some users want synthetic 2D only as a guide to the breast density, others want to have the image quality of synthetic 2D to be equivalent to that of digital mammography. The result of this lack of clarity as to what the users want is that different vendors are adopting different approaches to the issue.

A priority is therefore to define exactly what the role of synthetic mammograms should be, in both screening and diagnostic settings. However it shouldn't be forgotten that the advantage of using SM + DBT is that there is a significant reduction in radiation dose compared to DM and DBT. Radiation reduction is always important but is particularly so in screening situations.

Evidence for usefulness of SM.

There is an increasing body of evidence regarding the usefulness of SM. One early study, the Tommy trial (*Gilbert et al*, 2015) compared three reading arms, namely (i) 2D alone; (ii) 2D + DBT and (iii) SM +DBT. The conclusions were:

• that the specificity of 2D or SM with DBT was improved compared to 2D alone;

•there was an improvement in sensitivity of 2D + DBT in women with dense breasts, but not for SM plus DBT in such women;

• 2D and SM with DBT had higher sensitivity for women with cancers greater than 1 cm

• The "problem child" remains calcifications, where SM with DBT had a lower sensitivity than that of 2D + DBT and 2D alone

In another small study (*Zuley et al 2014*) the performance of SM and FFDM alone were compared in terms of Area Under Curves (AUCs) of the Receiver Operating Curves (ROC) and found to be equivalent, while the combination of SM with DBT also showed very comparable performance compared to FFDM + DBT. Of course, the specificity of 2D or SM with DBT was improved compared to 2D alone. The overall conclusion of this trial was that "*the use of SM instead of FFDM, either alone or in combination with DBT does not result in any clinically meaningful differences in diagnostic accuracy and may eliminate the need for FFDM in routine clinical studies*". The fact that this study was relatively small means that it is however dangerous to extrapolate this clear message. Nevertheless, it shouldn't be forgotten

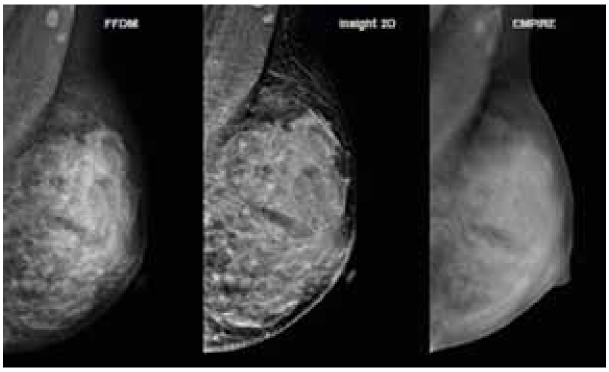

Figure 1. The appearance of the FFDM image (left panel) is different from that of the synthetic 2D image (Center panel) which is generated , in this case by the Siemens Insight 2D system, from 3D tomosynthesis data. Right Panel is the mage after processing by Siemens EMPIRE reconstruction algorithm.

2017 Breast Care Day Video recordings
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www.siemens.com/breastcareday

that DBT and SM are continually improving so it is very likely that in the future SM may actually provide better performance than FFDM.

The current evidence regarding SM — a summary:

- Its use allows reduction in radiation dose
- The performance of DM+ DBT is similar to that of SM + DBT
- When interpreting the evidence from such trials, it should always be remembered that differences in study designs, in the actual DBT systems used and the cases examined means that, sometimes conflicting results can be produced.

However the key, fundamentally important question is whether there is a danger of missing cancers if SM were to replace DM in combination with DBT for screening. Right now there is no absolutely definitive reply to this question, so in Austria it was recently decided to set up a study with the express purpose of evaluating the diagnostic accuracy of SM generated from data acquired in tomosynthesis compared to DM.

In this study, the Siemens Mammomat Inspiration system is used (the system has a wide, 50 degree angle), the DBT reconstruction is carried out using Siemens' EMPIRE algorithm and synthetic mammograms are generated by Siemens' Insight 2D system.

Secondary aims of the trial are to compare the diagnostic accuracy of DM versus 1 view S2D + DBT vs 1 view DM + DBT; to compare the image quality of S2D vs DM; and to compare the readers' confidence and reading times.

In this study 200 cases will be examined, with each examination involving DM, DBT and SM 2D for both breasts, in two views (CC and MLO). The cases are a mixture of histologically defined malignant (40%); benign (35%) and negative (25%), and cover all breast densities. Four readers blinded to the clinical history will read the images.

The study is still ongoing, so final results are not yet available, but already several individual cases show the usefulness of SM. It is planned to present more detailed results at RSNA

Conclusions

- The use of SM allows dose reduction and also means that, with SM, the transition to 3D is less abrupt than just 3D alone
- the role of SM in a diagnostic setting is still questionable since there are very few data available
- Since the appearance of SM images is different from that of DM, there is an inevitable learning curve needed for the interpretation of SM images
- Quality criteria are needed by which the quality of SM images can be evaluated

The overall take-home message is however that synthetic mammography is a significant advance and looks set to play an important future role, especially in screening applications.

Practical challenges in screening with digital breast tomosynthesis (DBT)

Prof. Chantal Van Ongeval

Just like other advances in the history of the evolution of mammography, the implementation of new technological advances is frequently accompanied with new challenges which have to be addressed. Thus, while digital breast tomosynthesis (DBT) in its current form (i.e. DBT + 2D Full Field Digital Mammography, FFDM) brings many advantages, there are also several disadvantages. These include increased acquisition time, increased radiation dose and increased reading time, which have been described in detail elsewhere. In addition, the use of DBT in practice is accompanied by other issues, e.g. comparison with prior 2D FFDM images; the comparison of DBT images generated by systems from different manufacturers; and the evaluation of morphology and the extent of microcalcifications.

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Comparison with prior images

As for the comparison of DBT with prior screening images from 2D FFDM, the synthetic mammogram (SM) generated from the DBT projections has a role to play, since, using this, there is no need for an additional FFDM. This means that overall there is only a slightly higher radiation dose and a slightly longer acquisition time. Exactly what the impact on the reading time still isn't clear — some people maintain that simply reading the synthetic mammogram (SM) is sufficient and that there is no need to look at the DBT images unless there is an indication from the SM to do so. This is short-sighted.

Quality of SM

Reporting on the quality of SM is all the more important in the context of DBT systems with different geometries and specifications from different manufacturers. One method for describing the quality of SM could simply be via measures of detection accuracy and characterization, but there is a case for the retention of a visual grading system based on contrast, sharpness and noise, which works well for FFDM [Figure 2]

A small two arm study was carried out at the University Hospital of Leuven on 29 women attending the clinic every year for follow-up after breast cancer. In one arm of the study, 4-view FFDM images taken in 2015 were compared with FFDM images taken in 2016. In the other arm of the study 2DFFDM images from 2015 were compared with SM 2D generated in DBT carried out in 2016. All images were acquired on the Siemens Inspiration System. The images were evaluated by three readers not only using BI-RADS categorization, density evaluation but also using visual grading parameters namely contrast, sharpness, noise, presentation of microcalcifications and masses and overall image quality.

The results showed that there was a low level of inter-reader agreement, especially as far as the SM images (Insight 2D) were concerned.

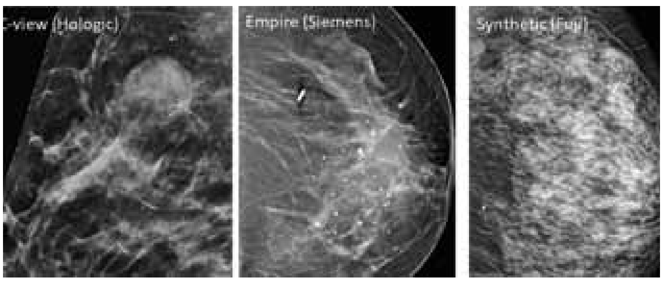

Figure 2. The need for a system to enable evaluation of the quality of SM images is illustrated in these images, which are SMs generated using the systems of three different vendors. It can be seen that the image from one system appears noisier, another system has bright microcalcifications and the third appears to be of lower contrast. Image quality could be determined by detection accuracy and characterization, but there is also a role for classical visual quality grading (which functions well for FFDM) using parameters such as contrast, sharpness and noise.

There were statistically significant differences in the classification of density between the FFDM and the SM (Insight 2D) image, with the density derived from the SM tending to be higher than that from the FFDM. As for BI-RADS lesion characterization there was no significant difference. Regarding the overall image quality scores, the FFDM was considered better.

These results are not surprising, since it must be remembered that the synthetic mammogram is derived ultimately from the individual projections of the DBT taken at a low dose, which also explains the fact that overall the SM image quality is lower compared to FFDM, especially in the presentation of microcalcifications. This latter conclusion regarding microcalcifications was confirmed by a recent study (*Peters et al., Invest Radiol, 2016*) carried out by medical physicists using anthropomorphic phantoms including simulated microcalcifications. It was found that FFDM was superior to SM in the detection of such microcalcifications.

Thus the overall conclusion from such studies is that synthetic mammograms should only be seen as an overview of the DBT and should not be used as stand-alone image for evaluation. In addition there is a requirement for additional training before SM can be used optimally and compared meaningfully with FFDM.

High quality displays can help a lot — the latest FDA-approved monitors can eliminate motion blur and increase luminance. It is necessary to be able to scroll all the images at a rapid frame rate, without skipping frames, through all the slices for all the views displayed on the large 5MO display required for mammography. Ideally this should be synchronized with same size contralateral and prior views.

Data Handling.

The large amount of data generated by DBT means that the data handling systems, e.g. PACS and storage must be fast and large enough to deal with the data. This is not limited to just exporting the data, e.g. during the night but also within each department. For example, the data exchange rate governing the transfer of data from the acquisition and reconstruction (tomo) modules to the PACS is more efficient at 1 Gb/sec than at the standard network rate of 100Mb/sec. Special PACS are required and should be compatible so that, for example, images generated by a screening department can also be read by a diagnostic department.

Radiographers

Currently there is discussion regarding the possibility of reducing compression force, but care should be taken regarding this since reduced compression can result in greater dose. The radiographer has an important role to play in this aspect. Regarding the positioning of the breast, it is important that the radiographer ensures that the whole breast is covered during the tomo process and that compression is maintained during the longer tomo synthesis acquisition time.

Conclusion

- In comparison to FFDM + DBT, the use of SM + DBT will lower acquisition time and radiation dose, but will only have a small impact on reading time.
- SM can only be used in combination with DBT
- The performance of SM regarding microcalcifications is still not clear.
- It should also be remembered that once an X-ray dose has been administered, the radiologist is legally responsible for all the images generated including those DBT projections of which many may not be looked at
- Monitor must be 5 MP
- Adequate training of radiographers and radiologists is necessary.

Technical aspects of breast tomosynthesis:

are all DBT systems the same?

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Dr Lemish explained that recently his practice in Melbourne Australia had expanded which meant that they had ended up with two breast tomosynthesis units, each from a different manufacturer, so this enabled comparison between the two systems. Both systems had of course regulatory approval and the results of clinical trials have shown that the use of each system enables the detection of an increased number of cancers.

One particular case showed however that the performance of the systems could differ. A 55 year old woman with a clear palpable lump on her left breast presented to the practice. The first tomosynthesis analysis did not show clear evidence of any lesion corresponding to the palpable lump, so it was decided to repeat the tomosynthesis scan, which this time happened to be carried out using the tomosynthesis system from the other manufacturer. A spiculated mass was seen, and was followed up by ultrasound which showed a lesion that was ultimately confirmed histologically as an invasive ductal carcinoma Grade II.

The significance of such differences in the performance of tomosynthesis systems from different manufacturers was the subject that Dr Lemish wanted to explore in more detail.

First of all he recapped on the various design factors which constrain the actual performance of tomosynthesis systems.

These include:

- Total radiation dose, which should be as low as possible and should in any case be in the realms of the dose involved in standard 2D mammography
- Detectors should have high quantum efficiency. Tomosynthesis involves multiple low dose exposures with each individual exposure only the fraction of the dose of a standard 2D mammogram so the detectors need to provide rapid read-out and no lag
- Movement of the X-ray tube (XRT). In tomosynthesis there is of course mechanical motion of the XRT which can be done continuously. However this method runs the risk of having focal spot blurring. The alternative is the "step and shoot" option which means the XRT moves to a defined position, stops and then takes an exposure. Overall, however this approach takes more time.
- Scan Time. This should of course be as short as possible. Even with standard 2D mammography there can be motion artefacts, and the risk of this is greater in tomosynthesis. In practice reducing motion artefacts depends greatly on the ability and experience of the radiographer in positioning the breast.
- Whole Breast. The systems need to be able to image the entire breast in one scan.

In designing systems to deal with such aspects there are many parameters involved, which frequently involve design trade-offs and compromises, but the two key factors are :

1) The number of projections. This is directly analogous to CT: the more projections, the fewer artifacts

2) The scan angle. Increasing the scan angle results in higher depth or z-axis resolution, so there is less tissue superimposition, less anatomical noise as well as the increased z-axis resolution [Figure 3]. All tomosynthesis manufacturers produce images with slices that are 1mm apart but this does not mean that all slices are actually 1 mm in thickness. In fact the thickness of the slice is poorly defined in the z direction. What is clear however is that the greater the scan angle, then effectively the thinner the slice. So, in theory, it would be ideal to have an increased number of projections and a wider scan angle for increased z-axis resolution. In practice this ideal is constrained by the detector performance, the need to limit radiation dose exposure and the scan time.

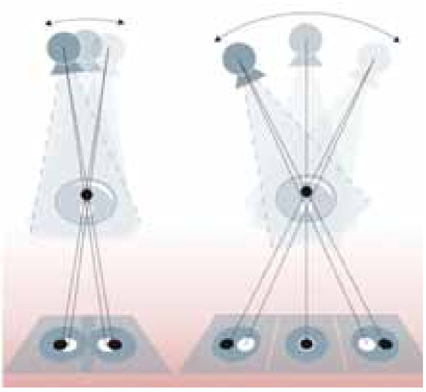

Figure 3. The effect of scan angle. An increased scan angle results in increasaed tissue separation, with less superimposition, less anatomical noise and increased z-axis resolution. This design can be constrained by the need to reduce radiation dose and scan time.

In view of all this, it is not surprising that different manufacturers have ended up with different combinations of design parameters, with consequent differences in image characteristics.

Take-home message

- A number of DBT systems from different manufacturers have regulatory approval.
- Manufacturers have used different combination of techniques and technologies
- The optimal combination of factors has not been determined
- Differences between systems could:

-potentially result in different clinical outcomes

-make comparison between clinical trials problematic

New tomo reconstruction algorithms: clinical experiences

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Dr Uhlenbrock started his presentation by pointing out that although digital breast tomosynthesis (DBT) is by now a validated and well-proven method there is still room for improvement, notably to overcome several current restrictions.

Tomosynthesis Angle

One of these is the question of the tomosynthesis angle. DBT systems developed by different manufacturers have different tomo angles, with the Siemens' system having the widest angle, (namely a total angle of 50°) and the largest number of projections (25).

Laboratory experiments can be used to examine the precise impact of the tomo angle. Thus, in experiments to study resolution using a PMMA phantom containing two steel balls of 1mm diameter situated 6mm apart, it is found that a wider scan angle can show separation of the steel balls, while a narrower angle cannot.

Iterative reconstruction

The Enhanced Multiple Parameter Iterative REconstruction (EMPIRE) is a new reconstruction algorithm introduced by Siemens for their tomo system. It operates in several steps:

• Artifact Suppression

There are several high attenuation structures which cause so-called artifacts, e.g. macrocalcifications; microcalcifications; dense tissue; and metal structures, such as clips or biopsy needles. In practice, the EMPIRE system uses outlier detection to eliminate an artefact. Normally with FBP the values of pixels are back projected to reconstruct the voxel, so if the pixel has a different value due to an artefact, this will be included in the back-projected voxel. The EMPIRE system uses statistically based machine learning algorithms to identify such a pixel as an outlier and thus enables suppression of the pixel by carrying out the back projection only with the remaining pixels.

• Super-resolution reconstruction.

Step 2 of the EMPIRE system involves artefact reduction using super-resolution reconstruction. In experiments using 1 mm thick slices the "normal" non-EMPIRE reconstruction results in "smearing" of microcalcification into the slices above and below a particular slice. Such smearing is retained in the voxel reconstruction and so the image quality is reduced, with the result that in the final images, the calcifications appear faded and details are lost.

With the new EMPIRE technology 0.2 mm slices are reconstructed and merged into 2 mm slices without smearing so that the contrast of calcifications is preserved in the 2 mm slice. The overall result is that the calcifications look brighter and details are retained.

• Iterative Noise Filtering.

In the third step of EMPIRE reconstruction, a system of iterative noise filtering is applied to every slice of the tomosynthesis volume. It preserves edges and microcalcifications as the algorithm has been manually optimized on clinical data sets.".

Take-home Message

The take-home message is that EMPIRE is an important advance in providing improved image quality, especially in terms of handling artefacts and in improvement of signal-to-noise ratio, [Figure 4].

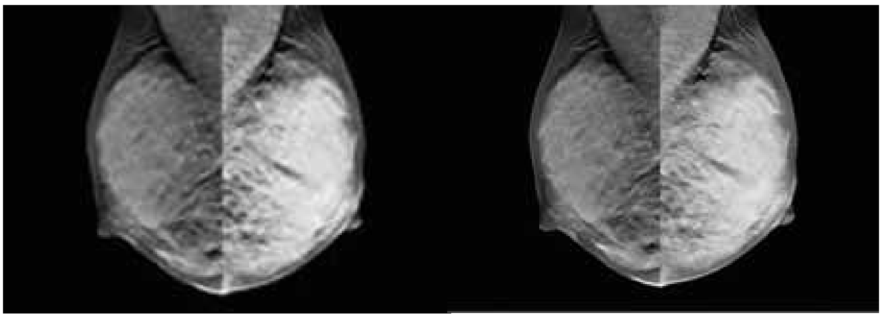

Figure 4. The effect of the new EMPIRE iterative reconstruction algorithm. Left Panel without EMPIRE. Right Panel with EMPIRE