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3D breast tomosynthesis – intelligent technology for clear clinical benefits

White Paper

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3D breast tomosynthesis – intelligent technology for clear clinical benefits

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1. Introduction

One of 10 women will develop breast cancer at some point in her life and 15-20% will die within 5 years following the diagnosis. Despite the improvements in different therapy modalities, the earlier the tumor is detected the higher are the chances of complete cure and a longer relapse-free survival time. Thus, mammography screening programs have been implemented in many western countries and have contributed to a significant decrease in the mortality of women affected by this illness. This has been proven in controlled randomized clinical trials. Digital Mammography (DM) is currently the state-of-the-art technology. However, mammography suffers from limited sensitivity and specificity particularly in dense tissue: it renders a two dimensional image of the breast with superimposed tissue that is sometimes difficult to interpret, leads to unnecessary recalls and does not enable a visualization of malignancies in an early stadium.

Siemens, with its long-standing experience in Computed Tomography (CT) and 3D imaging, has developed a 3D breast tomosynthesis* (BT) system, which improves diagnosis by minimizing tissue superimposition and enables recognition of micro-calcifications and malignancies in an early status.

1.1 Historical background

The original idea of generating 3D information out of 2D x-ray images is not new. The earlier practical systems and theoretical groundwork date from the 1930s and relied on the relative movement of the x-ray tube, the image receptor, and the patient. The history of tomography has been well described by S. Webb (Webb, 1990).

In 1922, A.E.M. Bocage (Bocage, 1922) invented the first selective slice representation with the planography system. Ziedes des Plantes (Ziedes des Plantes, 1931) published his first theoretical work and practical experience on planography in 1931. Based on this work, the Siemens-Reiniger Werke built the first "planigraph" for scientific purposes.

Since then, many different methods with different detectors (from photographic films to x-ray image intensifiers to digital detectors) and different types of relative movement (linear and circular, elliptical a.o.) have been tested and have evolved into conventional tomography. A major drawback of conventional tomography is that only one plane can be imaged sharply: the focal plane containing the fulcrum (pivoting point) for the mechanical motion of the tube relative to the object. The consequence is that for each plane to be imaged, an acquisition sweep has to be carried out which increases the radiation dose tremendously. Driven by the development of digital detectors and fast computers, a similar technique evolved, called digital tomosynthesis. This technology allows reconstructing retrospectively virtually any slice through the object from the stored projection images. The advantage is obvious: with the radiation dose of one acquisition sweep, a complete set of slices and thus 3D information can be obtained.

Siemens has designed a 3D tomosynthesis system for breast imaging that requires a similar radiation dose as a normal digital mammography (DM) and improves diagnostic power.

1.2 Expected clinical benefits of tomosynthesis

The main clinical benefit that can be expected from BT results from the removal of overlaying tissue in the breast (Niklason, 1997). By the superimposition of different tissue types and features, a lesion might not become visible because the tissue above or underneath may mask it. Vice versa, the superimposition of normal structures in the breast may mimic a lesion. Thus, BT can be expected

* Tomosynthesis is not commercially available in all countries. Due to regulatory reasons its future availability cannot be guaranteed. Please contact your local Siemens organization for further details.

to decrease the superimposition effect, thus increasing the detection rate and reducing the recall rate.

Since BT is still in development as a clinical tool, it is currently used mainly for diagnosing women with an abnormal screening mammogram or clinical symptoms. Several early studies have demonstrated that BT may reduce the false positive rate significantly by 30% or more when used in combination with mammography (Baker et al., 2011).

However, the long-term vision is to apply tomosynthesis also in the screening setting. In a first study (Andersson et al., 2008) an international team compared the visibility or detectability of breast cancers with BT and DM, demonstrating that the clinical performance of detecting breast cancers with BT is significantly better than that of DM, thereby making it a candidate for a screening method.

Ongoing large-scale studies that integrate BT as a screening procedure will still be needed to demonstrate the benefits of BT.

In summary, the expected clinical benefits of BT may be: earlier detection of smaller cancers, meaning an increase of sensitivity, a reduction of screening recall rates and improved specificity.

Furthermore, a reduction of breast compression during the procedure may be envisioned, since tomosynthesis provides slice images and the image quality does not rely on flattening the breast as in DM (Förnvik et al., 2010).

2. Theory of Tomosynthesis

2.1 Principles and limitations

A thorough description of the mathematical tools and techniques that make 3D tomosynthesis an excellent diagnostic tool is naturally beyond the scope of this paper. We will focus on the principles that enable a 3D reconstruction of an object from multiple projection images.

A digital x-ray image of any part of the body is a projection on one plane of the x-ray absorption across the tissue it encounters on its passage. It will not include any information whatsoever about where (in relation to the x-ray direction or z-axis) the most more or less opaque masses were encountered (Figure 2.1).

If the same object is projected again after rotating the x-ray tube, the single absorption images will be different and will thus provide extra information on the spatial location of the various opaque masses in the object (Figure 2.2).

A mathematical technique called shift-and-add gives an idea as to how the masses are spatially distributed (Figure 2.3) and slices parallel to the detector plane can be generated. By shifting the single projection views according to the height of a certain feature, the information of that feature is summed up, whereas the information of features from other heights are spread out or smeared as in conventional tomography.

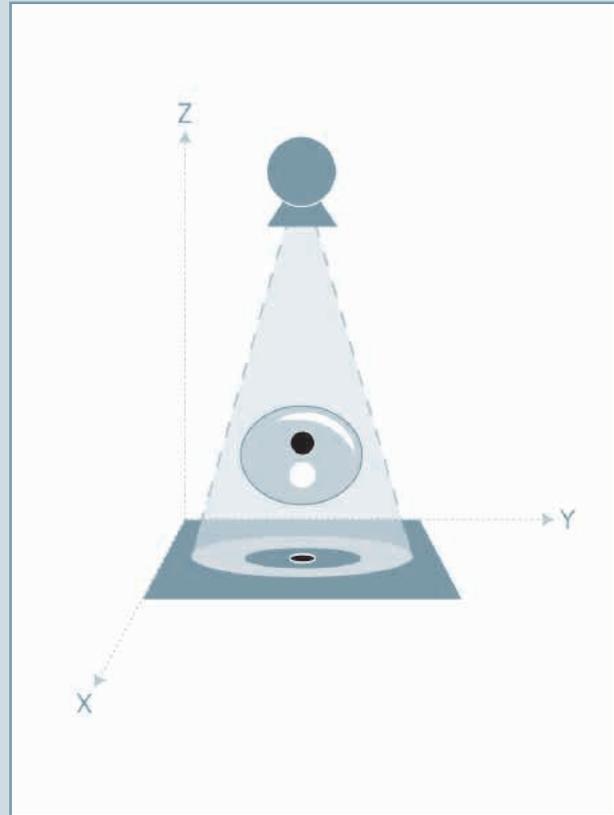


Figure 2.1: A single projection will not include any spatial information in the x-ray direction (z-axis).

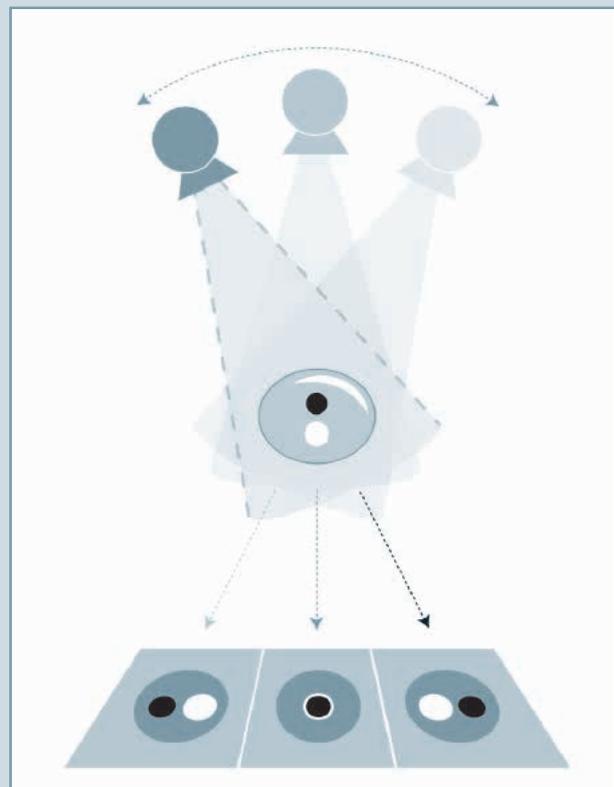


Figure 2.2: The two masses will appear more or less shifted according to the position of the x-ray source.

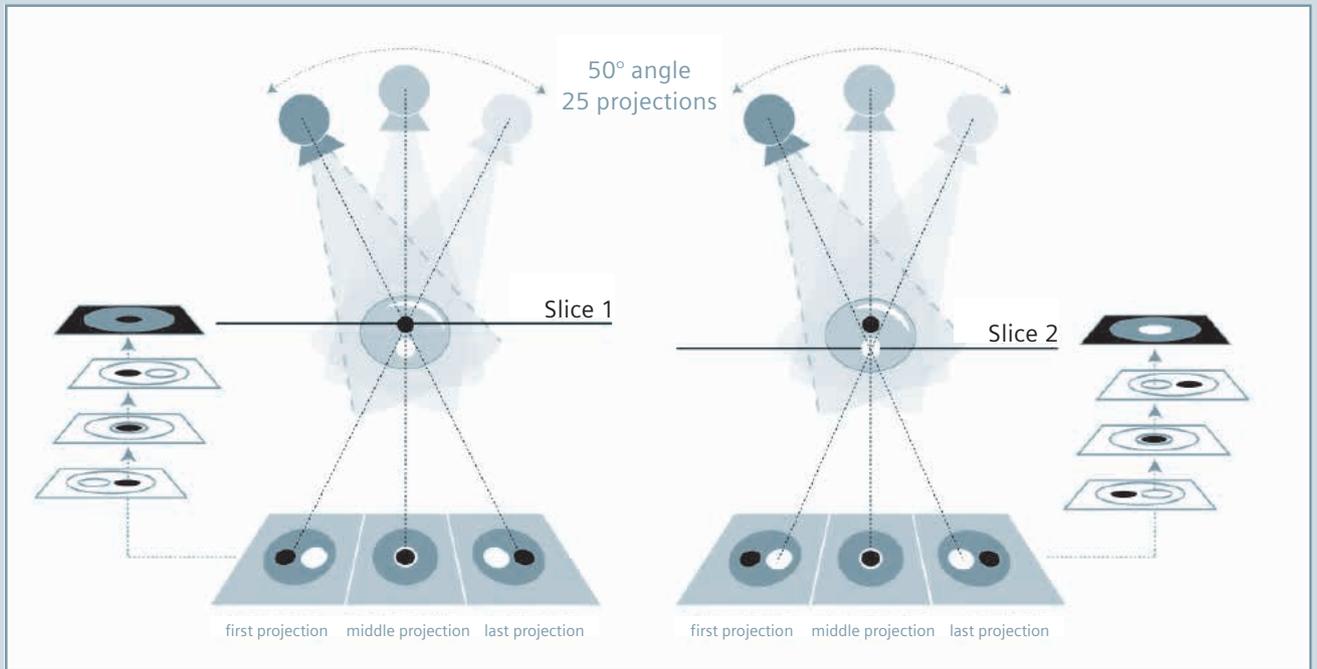


Figure 2.3: In this example, the shifting and adding of the 3 images enables the location of the two masses on the z-axis. Slices perpendicular to the z-axis can be reconstructed, each with accurate spatial information. On the left and right side you see how the images must be shifted to get the corresponding planes.

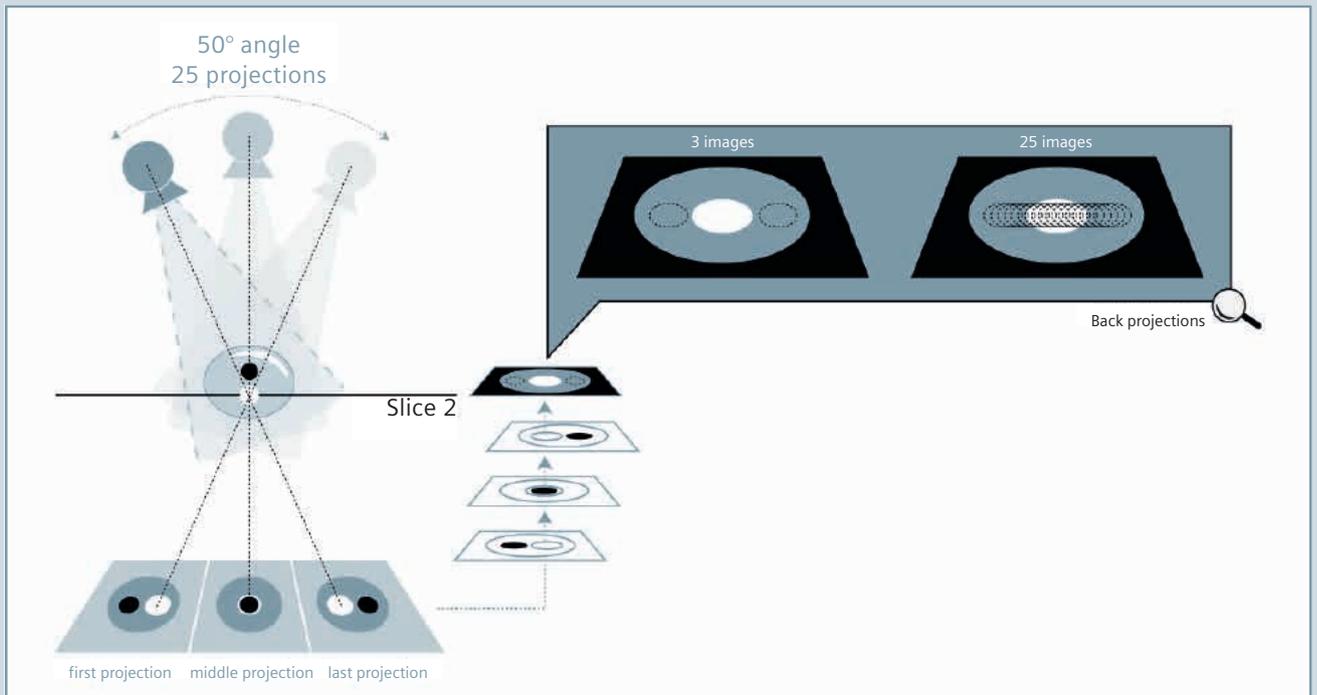


Figure 2.4a: The back projection of 3 images generates two out-of-plane artifacts as indicated in the first set of back-projected slices. 25 back projected images result in spread out-of-plane artifacts as shown in the second set of reconstructed slices.

A mathematical analysis shows that the shift-and-add procedure is equivalent to a back projection process as all rays are accumulated in the volume element (voxel) the rays contribute to. Reconstructing not only one slice but also many others, yields a 3D image of the studied object. In the case of CT, many projections are acquired over 360° around the object providing a huge amount of information. The commonly used reconstruction algorithm employed in CT is a version of back projection, in particular filtered back projection, which excels by minimal distortion and high accuracy. However, this type of imaging technique with a 360° scan (CT) implies a considerable radiation dose for the breast and does currently not provide the necessary resolution for visualizing micro-calcifications. Other practical issues for routine use of dedicated breast CT include patient positioning, or tissue coverage at the chest wall and axilla, and are in a very early research phase.

Siemens' 3D breast tomosynthesis (BT) system is based on similar principles and uses image reconstruction algorithms derived from CT technology. The 3D images are reconstructed from a limited number of projections (25) resulting in less radiation exposure than a conventional CT scan necessitates. However, this also results in a more complicated method of 3D reconstruction. Particularly, the out-of-plane (Figure 2.4a and Figure 2.4b) and streak artifacts (Figure 2.5) that are an inherent feature of the limited number of projections pose a special image reconstruction challenge.

The severity of out-of-plane artifacts depends on the size of the feature/lesion. For small calcifications the vertical range (in z-direction) is rather limited. The larger the feature, the larger the range of the artifacts will be.

The filtering of the reconstruction causes another type of artifacts prior to back projection. If the filtering processes extend beyond the border of the sampled region in frequency space, overshoot artifacts are introduced (see Figure 2.6). However, the smaller the feature, the weaker the appearance of the artifact will be.

On the one hand, tomosynthesis shows some artifacts caused by the missing data. On the other hand, these artifacts are well known and can even be used in the reading process. For example, all objects being blurred in one slice are located out of this slice and not in focus. The overshoot artifact emphasizes small objects and thus facilitates detection.

2.2 Technical requirements for high quality images

The main challenge in the design of BT is to achieve an image quality that will render maximum clinical benefits with a limited radiation dose, i.e. that will provide an improvement to mammography at the same or even lower dose to the patient.

The parameters and techniques that affect image quality are: quality of each projection, number of projections, angular range of the projections, and, last but not least, the image reconstruction algorithm.

The quality of each projection is determined by the radiation dose and the detector used. High detective quantum efficiency (DQE) detectors that can deliver images with a

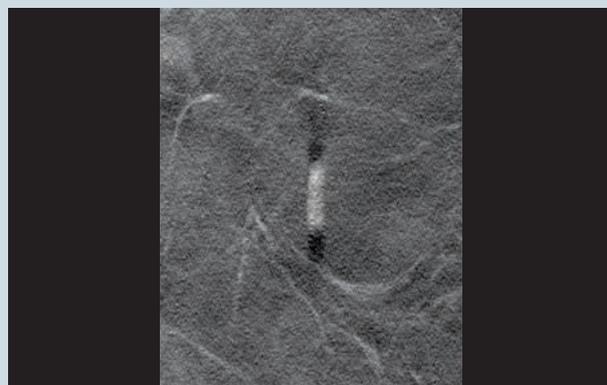


Figure 2.4b: Example of the clinical effect of the out-of-plane artifacts caused by a calcification in a different plane.

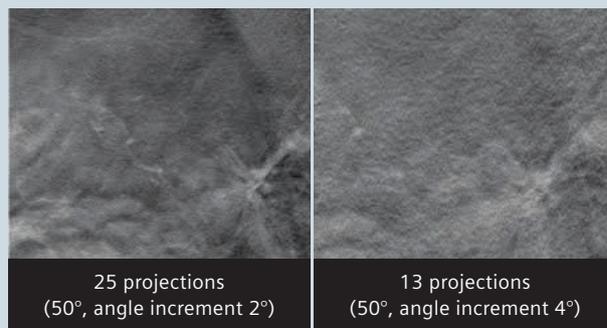


Figure 2.5: Streak artifacts: the left image with 25 projections shows less streak artifacts than the right one with only 13 projections. The lesion can be easier detected in the left image.

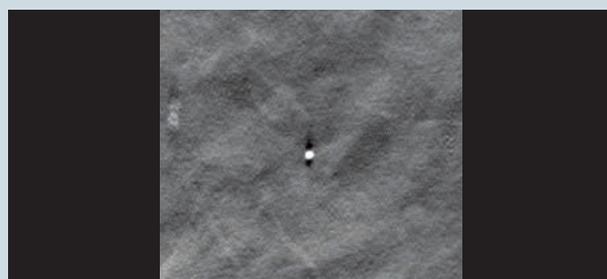


Figure 2.6: Overshooting artifact: high contrast features such as microcalcifications exhibit black rims in scan direction.

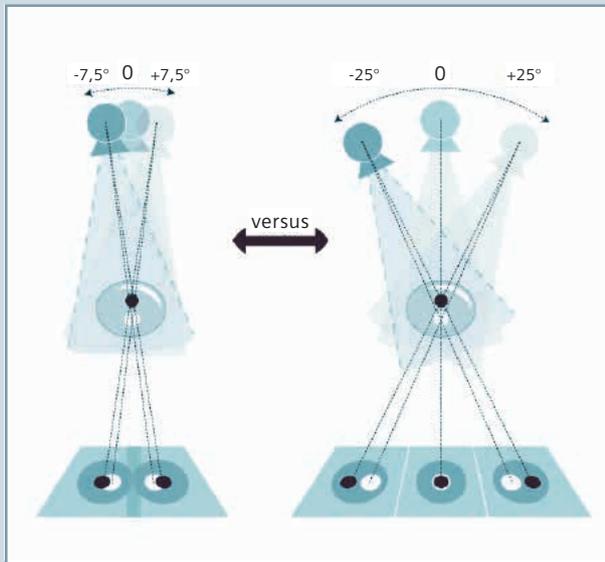


Figure 2.7: The angular range of the tomosynthesis system will directly affect the depth resolution. Two projections at $\pm 7,5^\circ$ will not be able to separate the two spheres. Two projections at $\pm 25^\circ$ can separate the two spheres due to an adequate depth resolution.

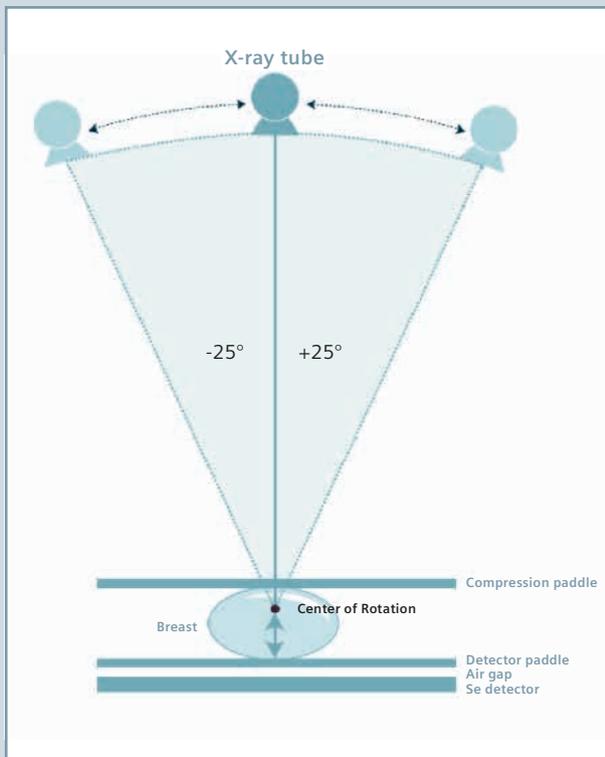


Figure 3.1: Twenty-five (25) projection images are acquired by the detector as the x-ray source rotates from $+25^\circ$ to -25° angle degrees and saved as DICOM MG objects for further processing.

high signal-to-noise ratio (SNR) despite the very low x-ray exposure are required. The detector's low noise feature is key, since the total exposure has to be split into many single projections. But also the x-ray spectrum, i.e. the anode/filter combination and the tube voltage has to be chosen deliberately.

With respect to the number of projections, fewer projection views will render less information to reconstruct the real 3D volume. A larger angular range will directly affect the depth resolution of the system as shown in Figure 2.7 since objects in different depths can be better separated. In other words, the physical slice width decreases with a larger angular range and tissue overlap is reduced. In addition, out-of-plane artifacts are reduced as they are spread over a wider range in the plane considered. Most importantly, as there is more information available, relatively large but subtle lesions can be imaged with a higher contrast.

On the other hand, a larger angular range may reduce the accessible volume that can be imaged using a stationary detector. The goal is to optimize to gather sufficient information of the larger volume and a good image quality even if some parts might not be covered by all projections.

The number of projection views at a given angular range is another important design parameter. An angular increment which is too large will introduce streak artifacts as known from CT. However, the number of projections is limited by the performance of the detector, supposing the dose applied to the patient has to be limited. Also the scan duration will be longer with increasing number of projections.

Multiple combinations of the parameters and methods mentioned above are being tested by several groups in various prototypes such as: a 40° angular range with only 11 projections and variable x-ray intensity per projection with an iterative reconstruction algorithm; 15° angular range, 15 projections, a constant x-ray intensity and a filtered back projection algorithm among others.

Siemens has developed a BT system and a filtered back projection algorithm optimized to comply with the needs of the radiologist: a clear 3D analysis of calcifications and lesions' distribution together with adequate contrast enhancement of tissue characteristics and masses.

3. Siemens' 3D breast tomosynthesis

3.1 Image acquisition

The setting for the BT procedure is similar to that of a DM. The breast is compressed on the object table containing a full-field DM detector with the following characteristics: high DQE direct-converting amorphous selenium (a-Se) flat panel with an array of 2816×3584 pixels, a $85 \mu\text{m}$ pixel pitch rendering an active area of $23.9 \text{ cm} \times 30.5 \text{ cm}$ and high-speed, low-noise digital images. The read time of the detector is optimized for BT imaging and the 25 projections over an angular range of 50° can be acquired with full detector resolution within approximately 20 seconds

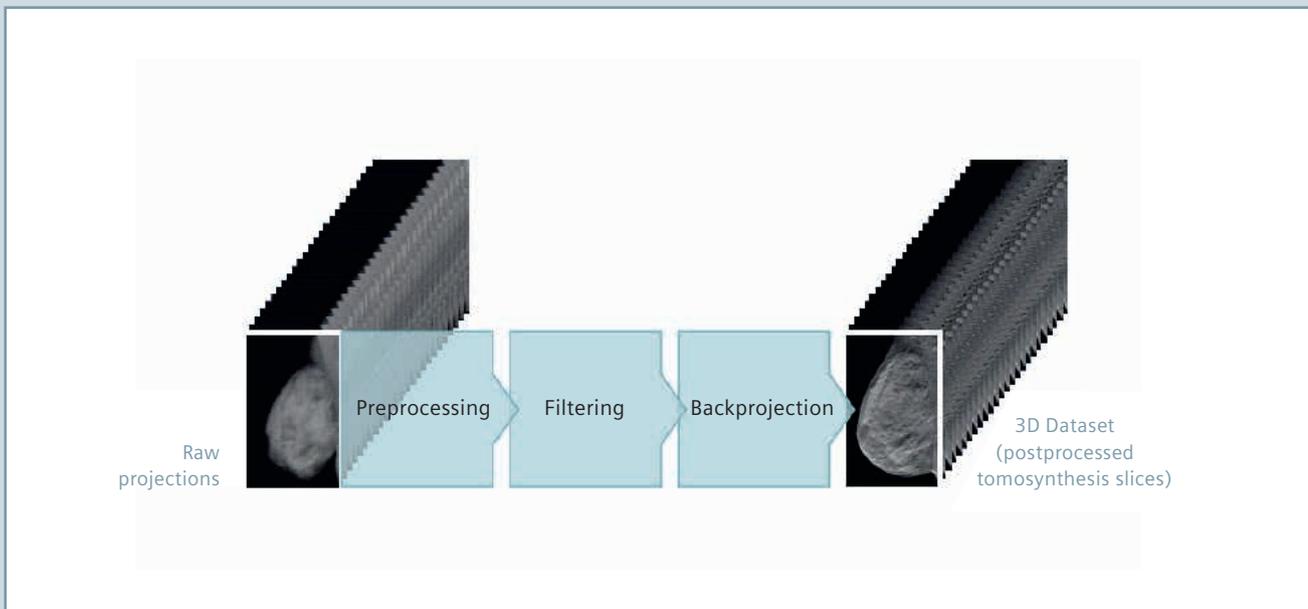


Figure 3.2: Schematic diagram of the FBP algorithm with the different filtering and processing steps.

in the current version. The tungsten/rhodium spectrum of the high-power x-ray tube employed in the Siemens system ensures high quality of the projection images at low patient dose.

To optimize the set of parameters and minimize the impact of the constraints discussed in section 2.2, Siemens' BT acquires 25 images as short pulses during a continuous* scan of $\pm 25^\circ$ relative to the 0° position with a 2° angle increment per image and a stationary detector. The exact angle of each projection is measured on-line during the scan to make usage of the exact geometry for the 3D reconstruction which is essential in the back projection step. The rotation center is at 4.7 cm above the detector surface. The distance between the x-ray source and the detector surface is approximately 66 cm as in normal screening mammography (see Figure 3.1).

These image acquisition parameters are the result of a thorough analysis and provide the optimal compromise between image quality, dose, and field-of-view. They have been analyzed in detail and reinforced by the following authors:

Bissonnette et al., presented the system for the first time and investigated the impact of the number of projections

on image quality and artifacts. Using a sponge phantom, the authors demonstrated that the streak artifacts seen with 13 projections were largely reduced if 25 projections were used. The authors also describe the first tests of the system in human subjects, which showed promising results (Bissonnette et al., 2005).

Mertelmeier et al. studied the relationship between angular range and number of projections with a phantom consisting of two 1 mm diameter metal balls and with a clinical data set consisting of 25 projections over 45° . The authors showed that the two balls of the phantom could be visually separated with a $\pm 20^\circ$ scan but not with a scan angle of $\pm 10^\circ$. The influence of the number of projections and streak artifacts was shown using the clinical data set: the less projections were used, the more pronounced were the streak artifacts. The authors also explain why the image quality of large, low contrast objects could also be improved despite the higher background noise for a wider scan (Mertelmeier et al., 2008).

Zhao et al. investigated the dependence of image quality on angular range and detector operational mode. They found that increasing the angular range from 20° to 40° improved the detection of large-area, low-contrast masses in the phantom used (Zhao et al., 2009).

There are several more studies on the subject of optimizing the tomosynthesis angle. Using a mathematical observer model, Chawla et al. found in a study with simulated 3 mm masses embedded in real mastectomy images that the

* A continuous scan avoids mechanical instabilities when compared to the "step and shoot" mode.

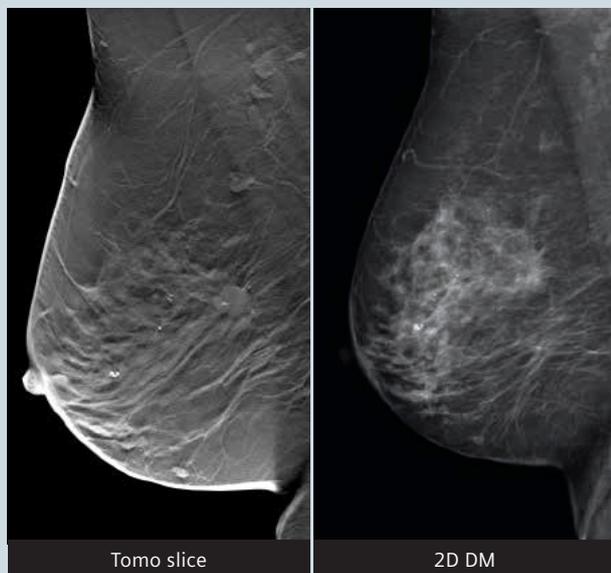


Figure 3.4a: 68-year-old woman, 1.5 cm invasively growing carcinoma, mixed with 2 cm DCIS. The lesion and its delineation are better visible with tomosynthesis. The fact that microcalcifications are positioned in the neighbourhood of the tumour suggests a DCIS component. (With courtesy of KU Leuven, Belgium, Prof. van Ongeval and Dr. van Steen).



Figure 3.4b: 76-year-old woman, 0.9 mm intraductal invasively growing carcinoma, BIRADS 5, density ACR 2. Tumor evaluation is better with tomosynthesis than with DM. (With courtesy of MVZ Prof. Dr. Uhlenbrock & Partner, Prof. Dr. Detlev Uhlenbrock)

performance improved with an increase in the angular span (Chawla et al., 2009). The best performance was obtained for 15–17 projections spanning an angular arc of approx. 45° which is close to the Siemens design. This study is in good agreement with the investigation of Van de Sompel which proved, under isostudy dose conditions, an increase of mass detection performance with the angular range, practically independent of the reconstruction algorithms (Van de Sompel et al., 2011). In another simulation study it was concluded that increasing the angle up to 60° (maximum angle in that study) increases the vertical resolution (Sechopoulos et al., 2009). Task-based detection for different sampling modes was studied by Reiser and Nishikawa, 2010. They found that the detection of signals from lesions larger than 0.5 mm improved with increasing scan angle, independent of the noise level. However, for small-scale signals as well as for high quantum noise the scan angle has little influence: The sampling density has to be sufficiently high with an angular increment of smaller than 3° (Reiser and Nishikawa, 2010).

As a result of these investigations, Siemens has set the parameters to 25 projections over a relatively large scan angle of 50°.

3.2 3D Image reconstruction

As mentioned before, moving the x-ray tube over an arc of $\pm 25^\circ$ generates the data for reconstruction. The set of 25 images are then filtered and back projected. However, this limited number of projections (25) that is available for the 3D reconstruction results in artifacts inherent to the method as discussed previously (see Figures chapter 2.2). These can be reduced by adjusting and tuning the reconstruction algorithm to the inverse problem with incomplete data.

Based on Siemens' extensive experience in CT reconstruction algorithms as well as intense research, a dedicated filtered back projection (FBP) reconstruction algorithm has been designed (Figure 3.2). Particularly important are the filters that reduce the artifacts and noise mentioned above.

The complete filtering process is an optimal combination of 3 filters that includes a ramp type filter, a spectral filter and a so-called "slice-thickness filter". The ramp-type filter compensates for the blurring introduced by the back projection. The spectral filter reduces high-frequency noise. Both these filters are similar to those used in standard CT reconstruction. The third filter, called "slice thickness filter" as introduced by Lauritsch and Haerer, ensures a constant depth resolution to a certain degree (Lauritsch and Haerer, 1998). It controls the spatial slice sensitivity profile and suppresses the out-of-plane artifacts typical for BT.

This dedicated FBP algorithm is particularly apt to provide a pronounced appearance of (spiculated) masses and architectural distortions and is very well suited for visualizing breast tissue. The filter parameter can be tuned for the specific imaging task. The Siemens BT system enables the user to select between several parameter settings, for example emphasizing soft tissue lesions or enhancing calcifications.

Mertelmeier et al. applied these filters to simulated data to analyze the effects of the different filtering steps on the images, and to clinical data sets acquired with a research BT system. They demonstrated that the slice thickness could be kept approximately constant throughout the relevant sampled range and that the artifacts due to incomplete sampling could be suppressed (Mertelmeier et al., 2006).

Zhao et al. found that a slice thickness filter as described for linear BT in Mertelmeier 2006 reduces the reconstruction noise and improves the contrast-to-noise ratio in the slices (Zhao et al., 2009).

The results of the optimal combination of these filters and the complete back projection algorithm are shown in Figure 3.4a and Figure 3.4b.

3.3 Image display and reading

Siemens' BT is based on the MAMMOMAT Inspiration DM unit. Breast positioning and system operation is the same as for the DM system, making it easy to use for technicians and radiological professionals accustomed to use the MAMMOMAT Inspiration system.

The results of the BT processing are displayed on the reading and reporting workstation. It is important to follow DICOM standards so that BT images can be viewed on any PACS workstation which is able to read the standard. Siemens tomosynthesis slices are stored as DICOM CT images, so that most of the known workstations are able to display the images correctly. To optimize the reading a dedicated workstation is favorable, such as the *syngo* MammoReport. The so-called TomoViewer is specifically designed for the fast loading of the tomosynthesis data sets and fast stepping through the slices. The reading physician can easily scroll through slices that have been reconstructed and review the whole depth of the breast, no matter how big the breast is (bigger breasts will result in more slices than smaller breasts). All routine applications such as magnifying glass, measurement tools, configurable hangings, correct sizing are available to support easy and fast reading. Since the image processing has been adapted particularly for breast tissue, it renders excellent image quality which enables the physician to easily identify important markers such as: spiculated masses, microcalcifications, etc.

For dedicated questions specific display algorithms such as maximum intensity projection (MIP) or average projection can be applied to support an easier evaluation of the tissue.

4. Review of Clinical Studies

The field of breast tomosynthesis is in its early stage and the list of clinical studies presented here cannot be exhaustive.

There is general agreement that BT in combination with mammography has a positive effect on recalls. In a relatively large study (Rafferty et al., 2007, Smith et al., 2008),

radiologists could reduce the false positive recall rate by 43% without compromising sensitivity.

Similar results for the reduction of recall rates with a combined use of full-field DM and BT was reported by several other authors (Poplack et al., 2007, Gur et al., 2009) and in countries in which recall rates are high, such as in the USA.

Using BT as an additional diagnostic tool to reduce recall rates would spare many women an invasive diagnostic procedure (e.g. excision or aspiration biopsy) and the related anxiety.

Even though there is still some controversy as to whether BT is more sensitive and specific than full-field DM, investigators have found that BT improves the detection of cancerous tissue and enables a better classification of lesions. Particularly masses, and architectural distortions are visualized more easily (Baker and Lo, 2011). Other authors have found that 3/4 of the detected cancers were more visible with BT and 50% of these were upgraded in the BI-RADS classification (Andersson et al., 2008), which is an indication for a possibly increased sensitivity. The same group published the comparison of the diagnostic performance of single-view (MLO only) tomosynthesis with dual-view digital mammography. In the statistical evaluation, BT proved to be superior to DM (Svahn et al., 2010). One author (Teerstra et al., 2010) found the sensitivity of BT in combination with mammography to be 93% with a specificity of 84% in cancers with BI-RADS 4 and 5 – these values being similar to those of DM. However, if BI-RADS 3 cases were considered negative in that study, the sensitivity of tomosynthesis in combination with mammography turned out to be 80% vs. 73% of mammography alone, with basically the same specificity for both modalities (96% vs. 97%).

All studies published to date have been conducted in women with pathologic or unclear findings in the DM images or in enriched (with cancer cases) screening populations. In order to fully evaluate the potential of BT to detect tumors in earlier stages that have not been detected with DM, screening studies comparing both methods are necessary. Two of those screening studies are currently ongoing, one in Oslo, and one in Malmö (Tingberg et al., 2011).

BT seems to have some advantages also for imaging prior to surgery. In the study by Förnvik et al., it was found that tumor sizes could thus be more accurately assessed than with digital mammography or sonography (Förnvik et al., 2010a).

A further beneficial aspect for women could be the lower compression pressure. A DM procedure is painful for many women due to the required breast compression. Without compressing the breast, the overlapping of the different breast areas would render a useless DM image. It is assumed that a certain percentage of women do not participate in mammographic screening programs due to the anxiety generated by the procedure. Including BT as an alternative to DM in screening programs could prove useful in this case. One study confirmed the theoretical results of Saun-

ders et al. that the image quality remains the same with 12% to 50% less compression force to the breast (Förnvik et al., 2010, Saunders et al., 2009).

To summarize: the clinical benefits for the patients and physicians include a more comfortable procedure, more confidence in the diagnostic results, as well as less recalls and biopsies.

5. Future perspectives

5.1 Tomosynthesis as a screening tool

The BT procedure itself and the reading of the multiple 3D slices that the method delivers make it difficult to use BT in a screening setting where a high throughput is required. It is still to be investigated if BT should be offered as a diagnostic tool for only those women that have very dense breast tissue or are high-risk candidates according to previous findings or family history. Eventually, with the implementation of faster reporting workstations and the training of radiologists, 50 BT reads per hour may be achieved, as is the goal of an ongoing screening study in Malmö, Sweden.

5.2 Further technological developments

Future improved BT systems could provide an easy to read 3D model of the breast with the same processing time as for a normal full-field DM, or even automatic recognition of abnormal tissue that would render feasible an integration of the BT in a screening set up (Singh, 2008). Future BT systems may even have alternative reconstruction algorithms or better filters particularly designed to depict microcalcifications and abnormal tissue. Eventually, different sets of 3D images processed with different slice depths could be provided. This could enable a faster view of the whole breast and a detailed analysis of those regions that look suspicious.

6. Conclusion

BT is a young technology based on theoretical and scientific visions of the last century. The practical implementation of this imaging modality became possible with the development of flat-panel detectors and digital-image processing techniques on fast computers. The longstanding experience in CT imaging and the intensive research in tomosynthesis system design and reconstruction algorithms that Siemens invested in in the last decade, have resulted in a user-friendly BT system with a high specificity and sensitivity level. Siemens' BT has already been adopted as an accurate and valuable tool in the diagnosis of breast cancer and is already being tested as a screening tool. Further developments will make it even more invaluable in the diagnostic field and in a routine screening setting.

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