Initial Clinical Experience with Stationary Digital Breast Tomosynthesis

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Abbreviations

BIRADS

Breast Imaging Reporting and Data System

DBT

digital breast tomosynthesis

sDBT

stationary digital breast tomosynthesis

ROC

receiver operating characteristic

AUC

area under the receiver operating characteristic curve

Rationale and Objectives: A linear array of carbon nanotube-enabled x-ray sources allows for *stationary* digital breast tomosynthesis (sDBT), during which projection views are collected without the need to move the x-ray tube. This work presents our initial clinical experience with a first-generation sDBT device.

Materials and Methods: Following informed consent, women with a “suspicious abnormality” (Breast Imaging Reporting and Data System 4), discovered by digital mammography and awaiting biopsy, were also imaged by the first generation sDBT. Four radiologists participated in this paired-image study, completing questionnaires while interpreting the mammograms and sDBT image stacks. Areas under the receiver operating characteristic curve were used to measure reader performance (likelihood of correctly identifying malignancy based on pathology as ground truth), while a multivariate analysis assessed preference, as readers compared one modality to the next when interpreting diagnostically important image features.

Results: Findings from 43 women were available for analysis, in whom 12 cases of malignancy were identified by pathology. The mean areas under the receiver operating characteristic curve was significantly higher ($p < 0.05$) for sDBT than mammography for all breast density categories and breast thicknesses. Additionally, readers preferred sDBT over mammography when evaluating mass margins and shape, architectural distortion, and asymmetry, but preferred mammography when characterizing microcalcifications.

Conclusion: Readers preferred sDBT over mammography when interpreting soft-tissue breast features and were diagnostically more accurate using images generated by sDBT in a Breast Imaging Reporting and Data System 4 population. However, the findings also demonstrated the need to improve microcalcification conspicuity, which is guiding both technological and image-processing design changes in future sDBT devices.

Key Words: Stationary digital breast tomosynthesis; Digital mammography; 3D mammography; Breast cancer imaging.

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INTRODUCTION

On average, a woman in the United States has a greater than 10% lifetime risk of being diagnosed with breast cancer (1). Early detection of breast cancer through mammography screening reduces breast cancer mortality by 40% (2), since women with screen-detected cancers benefit more from therapy than do women with cancers detected clinically (3). However, since standard mammography collapses the 3D anatomy into a 2D image, overlapping features can hide diagnostic clues or mimic concerning patterns. This is especially true in “dense” breast tissue, which is associated with a higher risk of cancer presence (4). As such,

the false negative rate of the mammogram averages 20% (5), resulting in missed and delayed diagnosis, while the cumulative probability for a false positive finding ranges from 30% to 70% (6), largely dependent on breast density, resulting in call-backs for additional testing.

Digital breast tomosynthesis (DBT) was approved as a screening tool in 2011 for combined use with standard 2D mammography (7,8). All commercially available DBT devices work by moving a single x-ray tube to collect a series of projection views at multiple angles relative to the compressed breast. Computer algorithms then mathematically reconstruct a quasi-3D image, which allows readers to visualize structures through depth, thereby reducing the problem of superposition with 2D mammography. By 2014, approximately 30% of breast imaging clinics in the United States offered DBT, growing to 65% by 2016 (9). In 2016, about one-third of all screening evaluations included DBT, at which time a standard mammogram was also obtained in most cases (9). However, since combined imaging doubles the radiation dose and increases cost, work continues to improve DBT, with a goal of eliminating the need to collect a standard mammogram at the same time. Both technological and image processing advances are being made. For example, synthetic mammography uses forward-projection algorithms to integrate the information in the 3D image stack into a single 2D image, potentially replacing the standard mammogram. Additionally, technological innovations seek to minimize the limitations imposed by the need to move the standard x-ray source through space to collect the projection views. For example, continuous source motion introduces focal spot blurring, limiting the translational speed of the x-ray source and thus the achievable angle-span, while step-and-shoot takes longer, increasing the chance of patient motion. Motion during acquisition degrades image resolution (10–12). *Stationary* DBT (sDBT) is a novel imaging approach in which the single moving x-ray source has been replaced by a fixed array of multiple sources made possible by carbon nanotube (CNT) technology (13).

Standard x-ray tubes generate the electrons needed for x-ray production by heating a metal filament. In contrast, CNT cathodes release electrons at room temperature in response to an applied voltage, allowing for a fast and easily coordinated x-ray production by multiple individual sources. As such, arrays of CNT-enabled sources can be used to collect projection views over a wide-angle span quickly and without motion. Although sDBT is still considered experimental, CNT-enabled medical imaging devices have now been operational for years in human studies across a broad range of applications (14,15).

This study provides the first quantitative assessment of sDBT in humans, comparing its performance to digital mammography in women with known breast lesions of concern. The findings with this first-generation device will guide continued software and hardware development, as future studies seek to contextualize the potential screening and diagnostic value of sDBT compared to conventional DBT.

MATERIALS AND METHODS

Subject Selection and Demographics

This IRB-approved and HIPAA-compliant prospective study (ClinicalTrials.gov [NCT01773850](https://clinicaltrials.gov/ct2/show/study/NCT01773850)) recruited adult women discovered to have a “suspicious abnormality” (Breast Imaging Reporting and Data System [BIRADS] 4) (16) by standard screening digital mammography at our Breast Imaging Clinic between May 2014 and February 2016.

Image Acquisition

The sDBT device was a modified Selenia Dimensions DBT system (Hologic Inc., Marlborough, Massachusetts) in which the standard single x-ray source was replaced by a fixed array of CNT-enabled x-ray sources (Fig 1) (13). The sDBT device has nominal focal spot sizes of 0.6 IEC. The total exposure was divided equally between 15 sources, providing an angular

Figure 1. Stationary digital breast tomosynthesis (sDBT). (A) Schematic representation of sDBT. Conventional DBT systems move a single standard x-ray tube through space to collect the projection views for reconstruction. In contrast, sDBT uses a distributed array of fixed carbon nanotube (CNT)-enabled x-ray sources to collect the projection views without any source motion. (B) The sDBT device in the University of North Carolina Cancer Hospital. (Color version of figure is available online.)

span of 28° with a magnification factor of 1.08×. No changes were made to the compression plates or digital detector, which is operated without binning (pixel size: 70 μm). An electronic control system directed exposures up to 90 mAs over a range of 29–39 kVp, based on breast thickness, with 1 mm aluminum filtration. These exposures were set to match the exposures used by the “parent” Selenia Dimensions DBT system, from which the sDBT device was constructed. A radiation safety inspection assured dose compliance with the Mammography Quality Standards Act during the collection of craniocaudal and mediolateral oblique views by sDBT. The scan time for each view was less than 5 seconds, and only the breast containing the “suspicious abnormality” was imaged by sDBT. The sDBT images were compared to the mammogram images that had identified the lesions of concern.

The mammograms that identified women appropriate for the study were acquired using Senographe Essential (GE Healthcare, Milwaukee, Wisconsin) devices operated in standard automatic optimization of parameters mode with Premium View processing. The Senographe Essential has a nominal focal spot size of 0.3 IEC. Table 1 summarizes key differences between the mammography and sDBT systems used in this study.

Given the differences in these two imaging devices, the radiation doses delivered by each during the study were compared. Since the entrance dose provides a comparison that can be directly measured at each breast thickness on the novel sDBT system, doses are reported as the incident air kerma (mGy). These measurements were obtained using a Radcal Accu-Pro (9096) dosimeter and 10 × 6–6M mammography ion chamber (Radcal, Monrovia, California). The entrance dose was obtained from the DICOM header of each mammogram, and although the accuracy of the DICOM information was not directly verified for this study, the Senographe Essential mammography devices are subject to the standard Quality Assurance testing by our Department of Radiology.

TABLE 1. Comparison of the Senographe Essential Mammography and Stationary Digital Breast Tomosynthesis (sDBT) Systems and Operational Settings Used in this Study

Attribute	Senographe Essential	sDBT
kVp Range	26–31	29–39
mA Range	60–130	25.8
Nominal focal spot size (IEC)	0.3	0.6
Target/Filter	Mo/Mo, Mo/Rh, Rh/Rh	W/AI
Detector composition	a-Si flat panel CsI (TI) scintillator (indirect)	a-Se (direct)
Pixel size (mm ²)	0.1 × 0.1	0.07 × 0.07
Scatter-rejection grid	Present	Absent

Image Processing, Reconstruction, and Display

The 15 projection images collected by sDBT were corrected for offset and gain nonuniformities, providing the information for reconstruction using a customized filtered backprojection approach (Piccolo 4.0.5, Real Time Tomography LCC, Villanova, Pennsylvania). The image slices were reconstructed at a thin depth increment of 0.5 mm to ensure that small features, such as microcalcifications, were displayed sharply. All images were presented to the readers on Mammography Quality Standards Act-qualified 5-megapixel gray-scale display monitors equipped with conventional DICOM viewing software tools.

Readers and image evaluation

Four fellowship-trained breast imaging radiologists participated in this multireader, multicase, and paired-image study. The readers averaged 15.3 ± 6.8 years (10–25) of experience with mammography and 3.8 ± 2.5 years (0–5) of experience with DBT. Only one reader had zero years of experience with DBT. Each reader was first presented with either the mammogram or sDBT image stack for a particular patient. Readers answered a questionnaire, rating the likelihood of malignancy (0–100% in increments of 10%), the density of breast tissue (BIRADS A–D classification) (15), and confidence in their overall impression (1–10 scale). Images of the same patient by the other modality were then immediately presented, and readers used a 7-point scale (–3 to +3) to rate a preference compared to the initially-presented modality when assessing diagnostically important image features using accepted descriptors of mass margin and shape, architectural distortion, asymmetry, and microcalcification morphology/distribution (15). The order of cases and the modality presented first were random. After a wash-out period of at least 4 weeks, the image pairs were presented to the same readers. The patient order was again randomized, but the modality viewed first was reversed. The questionnaire was again completed. This study design reduced the bias associated with viewing a particular imaging modality first, since the reader determined the likelihood of malignancy for each modality before interpreting images from the other modality. Readers were not provided with any clinical information and were unaware of the pathology results.

Statistical Analysis

Reader performance was quantified as the area under the receiver operating characteristic (ROC) curve (AUC). In this study, ROC curves for sDBT and mammography were generated for each reader using the reader's reported likelihood of malignancy during image interpretation. The likelihood of malignancy cutoffs (0–100%, in 10% increments) provided thresholds around which sensitivity and specificity were calculated based on the actual presence of malignancy, as determined by pathology. Given the relatively small number of

cases, Tukey's pseudovalue estimation with jackknife resampling was used to correct for bias at each threshold (R 3.4.0, R Foundation for Statistical Computing, Vienna, Austria and RStudio 1.1.456, RStudio, Inc., Boston, Massachusetts). Plotting the true positive rate (sensitivity) as a function of the false positive rate (1-specificity) for each threshold defined a relationship through which the ROC curve was fit using logistic regression analysis (MATLAB R2018a, The MathWorks, Inc., Natick, Massachusetts).

Inter-reader agreement was quantified using the Fleiss kappa (κ) statistic for mammography and sDBT. This calculation involves selecting a threshold for the readers' reported likelihood of malignancy in order to categorize each interpretation as malignant or benign. Agreement was calculated at thresholds of 0.5 and 0.8. Likelihood of malignancy values greater than the threshold were considered to be a malignant finding, while values less than or equal to the threshold were considered benign. κ values were interpreted using the guidelines described by Landis and Koch (17). Intra-reader agreement could not be assessed, as readers rated a likelihood of malignancy for each case using each modality only once.

In order to compare the aggregate reader performance with respect to each modality and assess the influence of breast tissue density and compressed breast thickness on performance, a multivariate analysis was performed by fitting a linear mixed-effect model (SAS 9.4, SAS Institute, Inc., Cary, North Carolina). The fixed effects were the difference between the two modalities and density of the breast tissue, and random-effects were used to account for within-patient and within-reader correlations. An *F* test compared the mean AUCs between mammography and sDBT.

A similar multivariate analysis was used to assess reader preference when interpreting diagnostically important image features: mass margin and shape, architectural distortion, asymmetry, and microcalcification morphology/distribution. Scores significantly greater than zero indicate a preference for sDBT while scores significantly less than zero indicate a preference for mammography. Means are reported with their confidence interval, with *p* values less than 0.05 defining statistical significance.

Average reader confidence in overall interpretation using mammography and sDBT was compared by Student's *t* test with *p* values less than 0.05 defining statistical significance.

RESULTS

Patient Demographics

Following informed consent, a total of 55 women were recruited for the study. Of this group, four underwent biopsy before the sDBT was obtained and were excluded. The sDBT images were unavailable in another eight due to an issue coordinating the detector and source array. Therefore, images from 43 women were available for analysis. The average age of the participants completing the study was 56.7 ± 12.7 years (35–83), of whom 64% were considered to have

dense breast tissue (BIRADS density categories C or D) (16). Average compressed breast thickness for mammography was 4.6 ± 1.1 cm (1.9–6.7) and 4.7 ± 1.3 cm (2.2–7.5) for sDBT. Of the 43 subjects included in the final analysis, 12 cases of malignancy (28% of the study population) were identified by pathology on specimens obtained by ultrasound-guided core needle biopsy, stereotactic biopsy, or a surgical excision following needle localization. The final pathologic diagnoses included six infiltrating ductal carcinomas, five intraductal carcinomas, and one invasive lobular carcinoma.

Radiation Dose

Figure 2 compares the entrance doses (incident air kerma) as a function of breast thickness for the Senographe Essential mammography system and sDBT. Differences in the dose for a given thickness reflect differences in the approaches used by each system to select its operational settings. sDBT uses only the breast thickness to select the technique (kVp and mAs). In addition to breast thickness, the Senographe Essential incorporates a scout view and automatic exposure control to account for the breast composition and select the operational settings, including the target and filter. As a result, the Senographe Essential can produce variable doses for a given breast thickness, as seen in Figure 2.

Reader Performance

Reader performance can be appreciated by analyzing ROC curves (Fig 3A–C). The area under the ROC curve (AUC) provides a measure of diagnostic accuracy and was calculated for each reader and each modality using a mixed-effect model (Fig 3D). In this study, three of the four readers performed better using sDBT. Only Reader 2 performed better using mammography and interestingly had the most experience with mammography at 25 years. Reader 4 had the least experience with sDBT and demonstrated a performance that

Figure 2. Entrance dose as a function of breast thickness for the Senographe Essential mammography system (gray diamonds) and the stationary digital breast tomosynthesis (sDBT) system (black line). Doses are reported as the incident air kerma (mGy) and were measured using a mammography ion chamber dosimeter for sDBT. For each mammogram, doses were obtained from the DICOM header.

Figure 3. Overall reader performance. The receiver operating characteristic (ROC) curves for Readers 1–4 when interpreting mammograms (A) and stationary digital breast tomosynthesis (sDBT) images (B). Sensitivity and specificity were calculated from the reported likelihood of malignancy at the time of interpretation and the actual presence of malignancy as determined by biopsy. The area under the ROC curve (AUC) provided a measure of diagnostic accuracy, and the mean AUC for sDBT was significantly higher than the mean AUC for mammography (C). AUCs were also calculated for each reader and each modality using a mixed-effect model (D). * represents $p < 0.0001$.

differed the most from the other readers when interpreting sDBT images (Fig 3B), as reflected by the ROC curve shape. Overall, the mean AUC for sDBT was significantly ($p < 0.0001$) higher than the mean AUC for mammography (Fig 3C), demonstrating that on average, readers were more likely to identify malignancy correctly when interpreting the sDBT images.

The higher diagnostic accuracy using sDBT held true for each breast density category (BIRADS A–D) (16) and breast thickness range, as reflected by statistically higher ($p < 0.05$) mean AUCs for sDBT compared to mammography (Fig 4). The breast thickness ranges were selected to ensure an adequate number of samples within each interval for statistical analysis. There was no statistically significant relationship between the mean AUCs and breast density or breast thickness for either modality ($p > 0.05$).

Reader Agreement

Using a likelihood of malignancy threshold of 0.5, the overall agreement between readers for the presence of malignancy was fair ($\kappa = 0.35$) with mammography and slight ($\kappa = 0.18$) with sDBT. Increasing the likelihood of malignancy threshold to 0.8 resulted in moderate agreement ($\kappa = 0.59$) between

readers when using mammography and substantial agreement ($\kappa = 0.67$) between readers when using sDBT.

Reader Confidence

On average, readers had similar confidence in their interpretation of the mammograms and sDBT images (Fig 5A). Although the readers were not given any clinical information and were unaware of the biopsy results, they were significantly more confident ($p < 0.05$) in their final impression when interpreting images that actually contained malignant lesions compared to their final impression when interpreting images that were determined to be benign by biopsy (Fig 5B). This higher confidence when viewing images of malignant as opposed to benign lesions was similar for both mammography and sDBT.

Reader Preference When Interpreting Image Features

Figure 6 summarizes reader preference when using sDBT and mammography to interpret diagnostically important image features. As reflected by average preference scores greater than zero, readers preferred sDBT over mammography when interpreting soft-tissue features, including mass shape and

A				B			
BIRADS Breast Density	Mammography Mean AUC	sDBT Mean AUC	p-value	Compressed Breast Thickness (cm)	Mammography Mean AUC	sDBT Mean AUC	p-value
A	0.6831	0.7156	0.0030	≤ 3.4	0.6883	0.7145	0.001
B	0.6811	0.7106	< 0.0001	3.5 – 4.4	0.6765	0.7064	< 0.0001
C	0.6858	0.7007	0.0120	4.5 – 5.4	0.6890	0.7129	< 0.0001
D	0.6777	0.7126	< 0.0001	≥ 5.5	0.6801	0.7025	0.006

Figure 4. Average reader performance as a function of breast density (A) and compressed breast thickness (B). The area under the receiver operator characteristic curve (AUC) provided a measure of diagnostic accuracy. Readers were more likely to make a correct diagnosis using stationary digital breast tomosynthesis (sDBT) compared to mammography for each breast density category (BIRADS A–D) (16) and breast thickness range, as reflected by statistically higher ($p < 0.05$) mean AUCs.

margins (Fig 7), architectural distortion, and asymmetry ($p < 0.05$ in all cases). However, mammography was preferred over sDBT when characterizing microcalcifications ($p < 0.05$).

DISCUSSION

Although DBT use continues to increase (9), as experience has demonstrated an overall improvement in diagnostic accuracy when combined with mammography (18), DBT has yet to replace standard mammography. Software and hardware advances are being made, with technological innovations directed at minimizing the limitations in spatial and temporal resolution imposed by the need to move the x-ray source to collect projection views (11). For example, one DBT system uses continuous source motion to cover a larger angular span but rotates the detector during each projection to compensate for source blur (19). Enabled by CNT technology, sDBT uses a fixed and distributed source architecture, allowing for a fast and motion-free collection of projection views across a wide-angle span.

This report summarizes our initial clinical experience with this first-generation sDBT system. The study was designed to gain insight into the performance of this novel technology, with a goal of directing continued development. As such, comparison was made to digital mammography, which is still

considered the reference standard for breast imaging. Additionally, the study focused on a BIRADS 4 population, thereby ensuring pathology using a relatively small number of participants while also presenting readers with a diagnostically challenging image set. Across its full spectrum (A–C), the BIRADS 4 designation implies a predictor of malignancy ranging from 2% to 95% (16). Finally, readers with a wide range of DBT experience (0–5 years) were selected.

Although this study design did provide an assessment of sDBT performance across a broad range of pathology and reader experience, it was also associated with limitations that affect the findings. First, the compared images were collected by devices that differed in terms of focal spot size, anode target composition and beam filtration, and selected technique (exposure and kVp) for a given breast thickness. As a result, there are differences in the dose and beam quality between these two systems. Additionally, the mammography system utilized a scatter-rejection grid and a detector with a different pixel size and detection method compared to the sDBT system. All of these have an effect on contrast and resolution and thus the visibility of image features. As such, it is not possible to draw specific conclusions about the benefits offered by an isolated component of the sDBT device, such as the stationary source array. Rather, this study offers an assessment of the sDBT system as a whole, referenced against a standard breast imaging tool. Second, the sDBT images displayed to

Figure 5. Reader confidence. (A) Average reader confidence in the overall impression when interpreting mammograms (gray) and stationary digital breast tomosynthesis (sDBT) images (black). (B) Readers were significantly more confident in their interpretation of images containing malignant lesions (darker shade) compared to their interpretation of images with benign lesions (lighter shade), with malignant and benign determined by pathology (* represents $p < 0.05$, with bars representing the standard error of each group). This finding was similar for both mammography and sDBT.

Figure 6. Reader preference. Bar graphs summarizing aggregate reader preference when interpreting diagnostically important image features as displayed in the mammogram and stationary digital breast tomosynthesis (sDBT) image stack. Readers preferred sDBT over the mammogram when interpreting soft-tissue features (mass margins and shape, architectural distortion, and asymmetry) but preferred mammography when characterizing microcalcifications ($p < 0.05$ in all cases, with error bars representing the 95% confidence interval of each grand mean estimate). Positive scores represent a preference for sDBT, and negative scores represent a preference for mammography.

the readers were a stack of reconstructed image slices. Choices made in the reconstruction algorithms that produce these images also affect the visibility of image features. For example, in this study, the image slices were reconstructed at a thin increment of 0.5 mm to ensure that small features, such as microcalcifications, were displayed sharply. However, presenting a larger stack of thinner slices may contribute to reader fatigue, as there are more images to review. Also, the tomographic nature of the displayed sDBT image stack can make the assessment of microcalcification clustering more difficult, since the calcifications can be distributed through multiple slices. Appreciating the spatial association of microcalcifications may therefore be more problematic as the slice thickness decreases. This study was unable to tease out this issue, as readers were asked to rate a preference on microcalcification morphology and clustering collectively. Future studies are planned to investigate the effects of slice thickness on the visibility of microcalcification clusters with sDBT, as work continues to develop the algorithms incorporating a slab and synthetic mammography capability into sDBT. Given these limitations, the findings of this study cannot be extrapolated to define a specific screening or diagnostic role for sDBT.

Nevertheless, the findings do suggest that although experimental, sDBT should prove to be a viable clinical tool. Overall, readers were equally confident interpreting the sDBT images and mammograms. Also, the inter-reader agreement increased with both modalities when a higher threshold was used to categorize the readers' reported likelihood of malignancy, suggesting that the readers tended to agree on which lesions they considered most concerning. This agreement is supported by the finding that readers reported significantly higher confidence scores when viewing images from both mammography and sDBT that contained malignant lesions. Also, similar to DBT experience in general (20–22), readers preferred sDBT over mammography when interpreting soft-tissue features, including mass shape and margins, architectural distortion, and asymmetry. Finally, as reflected by a statistically higher mean AUC, the readers were diagnostically more accurate with sDBT compared to mammography for all breast densities and compressed breast thicknesses.

Previous studies have compared the diagnostic accuracy of readers interpreting mammograms and conventional DBT image stacks. Several studies have demonstrated single-view DBT to be noninferior to standard mammography (23,24), while Svahn et al. reported a significantly higher diagnostic

Figure 7. Example mammogram (A) and image slice from the reconstructed stationary digital breast tomosynthesis (sDBT) image stack (B). Based on pathology, the site of concern (expanded view) was benign. Readers were more likely to characterize this lesion accurately and were more confident in their assessment when interpreting sDBT, given the fact that the margins of the mass were more difficult to characterize on the mammogram. For this example, readers scored an average likelihood of malignancy of 50% when interpreting the mammogram and 25% when interpreting the sDBT images. The difference in microcalcification image intensity between the sDBT image slice and mammogram reflects the differences in the processing and display of each image. Window/level settings were selected to optimize feature display in the image overall.

accuracy using single-view DBT compared to mammography (25). However, as the authors of that study noted, the majority of the breast lesions were discovered by ultrasonography and were difficult to see in the mammograms. As such, the study was quite different from ours, in which the concerning lesions that identified patients as study candidates were found by mammography alone. When comparing two-view DBT with standard mammography, Wallis et al. demonstrated a significantly higher diagnostic accuracy with DBT, reporting a difference of 0.110 between the mean AUCs for each modality (26). In our study, although significant, the mean AUC difference between sDBT and standard mammography was lower at 0.028. Interestingly, this difference may in part be related to reader experience. Wallis et al. noted a loss in the statistical difference in performance when readers had more than 10 years of breast imaging experience (26). All of the readers in our study had at least 10 years of experience with mammography and differing levels of experience with DBT, ranging from no experience to 5 years. Indeed, it would be interesting to measure changes in reader performance with sDBT as a function of experience and training, which could include the opportunity to study image features in light of known pathology. Measuring the relationship between experience and performance will be considered in future studies, as we continue to explore sDBT at the clinical level, imaging more patients and involving more readers.

Although readers were on average more accurate interpreting sDBT images compared to mammograms, it is important to note that readers preferred mammography over sDBT when characterizing microcalcifications. Indeed, concern

over the ability to adequately assess microcalcification morphology and distribution using DBT has been a significant obstacle to DBT replacing standard 2D mammography (27,28). Visualizing individual microcalcifications requires a high in-plane resolution, which must be balanced against the depth resolution of the system. Wider projection-view angle spans improve depth resolution and favor the display of soft-tissue masses, while narrower angle spans improve the visibility of microcalcifications. In this study, the sDBT device collected projection views over an angle span of 28° , which falls within the range (15° – 50°) of currently available DBT devices (29). The first-generation sDBT device used in this study contains focal spots that are larger than those used in standard mammography. Therefore, the image resolution is expected to be lower. Design changes in future CNT-enabled sources will aim to reduce the anode focal spot size using electronic focusing of the CNT cathode-generated electron beam (30). This improvement should allow us to take advantage of the opportunities offered by the stationary source array, including the ability to alter the transmission geometry for task-specific imaging (31) as well as achieve a wider angle-span without compromising in-plane resolution (32), both of which are problematic with conventional, moving-source DBT (11). Finally, as noted previously, the tomographic display of DBT images as a stack of thin-slice reconstructions can make it difficult to assess the spatial relationship between microcalcifications. Generating a synthetic slab or full mammogram from the reconstructed image stack provides the opportunity to (1) enhance selected image features, such as microcalcifications and (2) display their

distribution in a single 2D image (33). Given its high resolution, the sDBT system may prove to be a valuable tool for generating synthetic mammograms optimized for the detection of microcalcifications, and work is underway to develop the forward projection and feature-enhancement algorithms to incorporate slab and synthetic mammography capability into sDBT. It is anticipated that these advances will improve microcalcification presentation, and future human studies comparing sDBT not only to standard 2D mammography but also conventional DBT are planned.

CONCLUSION

This initial clinical experience with this prototype sDBT system is encouraging, as readers preferred sDBT over mammography when interpreting soft-tissue breast features and were more likely to identify malignancy correctly using images generated by sDBT. These findings align with DBT performance in general and demonstrate the potential of sDBT as a viable clinical tool. However, reader preference for mammography when characterizing microcalcifications highlights the need for additional work to take full advantage of the unique benefits offered by the sDBT technology. As hardware and software optimization of the sDBT system continues, future studies will compare its performance to standard 2D mammography and available DBT systems to contextualize its clinical utility in the breast imaging arena.

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AUTHOR DECLARATION

The authors certify that this original work has not received prior publication and is not under consideration for publication elsewhere.

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