Breast Monitoring via Time-Domain Microwave Radar: Early Clinical Trial Study

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***Abstract*— This work describes early results from our first-stage clinical trial involving the monitoring of healthy volunteers with our time-domain microwave breast screening system. The system is composed of a 16-sensor multistatic array that records the electromagnetic energy scattered off of the breast tissue. All measurements are performed in the time-domain. We present here the system setup, patient-interface considerations, volunteer criteria and initial results from breast monitoring.**

I. Introduction

In this work, we examine the application of our microwave breast screening system to the monitoring of healthy volunteers. Microwave methods for breast cancer screening, detection, and diagnosis have been comprehensively investigated as a possible complementary technology to the current standard of x-ray mammography. Such methods show promise for monitoring applications, as they do not use the ionizing radiation that mammography does and thus are safe for frequent repeated scans.

Several microwave breast cancer detection systems have been proposed in the literature however, only a few of them have undergone clinical trials [1] – [4]. None of these systems use the time-domain radar method, which has possible advantages including: more cost-effective than frequency-domain measurements, faster scan times, and less computational complexity [5]. The safe repeatability and cost-effectiveness facilitate breast monitoring through regular breast scans that in turn allow for collection of a large number of data sets. By comparing the resulting data we can hope to improve the chances of detecting abnormalities growing within the breast tissue.

Our most recent work, [6], presented our first experiences with volunteer trials of our breast screening system. In [6], we examined the effect of volunteer movement in between scans on the ability for the scans to be compared. The scans were performed on the same day, and it was found that although movement did affect the reconstructed breast images, it did not hinder interpretation of them. In this work, we advance on that study by demonstrating the use of the breast screening system for a monitoring application.

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II. Clinical Trial Description

A. System Overview

Our breast monitoring system is composed of a pulse generator, pulse shaping circuitry, a switching network that selects the transmitting and receiving antennas, and a picoscope that records the data. The pulse used has a duration of approximately 100 ps before pulse shaping, which concentrates the frequency spectrum in the 2 – 4 GHz range. The switching network, which is automated, selects each of 16 receivers in turn for each of the possible 16 transmitters. This leads to a total of 240 bistatic collected signals. An overview of the system operation is shown in Fig. 1. Further description of the experimental system, and each of the components of the system, is provided in [7].

The antenna array is held in place along the exterior of a dielectric radome. The radome is bowl-shaped, allowing the breast under test to be placed inside it. The antennas have broadband radiation over the ultrawideband range, and are designed specifically for bio-sensing. More details regarding the antenna type and characteristics can be found in [8].

The imaging system is integrated into an examination table for ease of use with human subjects. As in [6], the radome is embedded into a padded-top table. The volunteer lies in the prone position on the table with their breast in the radome. All equipment is located below the table (except for the control computer). In this way, the volunteer is isolated from the system except at the radome/breast interface. Two photographs of this patient interface are provided in Fig. 2, one with the experimental system showing and one with a volunteer lying in position.

B. Volunteer Criteria

In early stage clinical trials we scan only healthy volunteers. Once the feasibility of this method is confirmed and the system is optimized, we can then proceed to clinical trials with patients for the purpose of cancer detection. This study was approved by McGill University's Research Ethics Office.

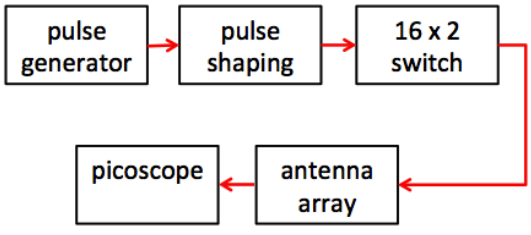

Figure 1. An overview schematic of the measurement system.

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Figure 2. Photographs of the experimental system embedded into the patient interface (left), and of a volunteer lying on the same exam table (right).

As in [6], we apply specific exclusion and inclusion criteria to select potential participants in the clinical trial. The criteria used to select volunteers are as follows: volunteers must be female, of legal age, and have bra cup size in the A to D range (a limitation of our initial prototype is that it has a fixed size and was designed only for the typical breast volume). Volunteers must also be free of breast implants or piercings, as we have not yet studied the safety of the device under these conditions. For the same reason, anyone with a pacemaker is also ineligible. Further, the volunteer must not have had breast cancer or any breast surgeries.

C. Breast Scan Procedure

In this series of breast scans, the volunteer's breast is placed in the radome with a layer of ultrasound gel filling any space in between the radome walls and the skin. This is necessary because the breast and radome may not conform perfectly and any air gaps can negatively affect the signals collected from the breast scan. Ultrasound gel, in particular, is chosen for its advantageous mechanical properties, its high loss (so it attenuates multiple reflections between the radome/ultrasound gel and ultrasound gel/breast surface), and the fact that it is already approved for medical use and therefore widely available [7].

Each volunteer has a breast scan done approximately once a month over several months. (At the time of writing this, the volunteers have visited up to 3 times – the study is in progress.) The setup and parameters for each breast scan are identical. In this way, we collect multiple scans from the same breast over time. This allows us to compare the monthly scans and monitor any changes in breast tissue composition.

III. METHODOLOGY

In this work, we examine the data from two volunteers. Volunteer 1 was age 23 at the beginning of the study, and has cup size B. Volunteer 2 is 44 with cup size of C. Both volunteers were screened to ensure they meet the study criteria. Each volunteer was scanned once per month for three months. Thus we have 4 breast scans that are each repeated three times for a total of 12 different scans. The breast scans were taken around the same time each month so as to minimize the effect of regular fluctuations in breast tissue along with the menstrual cycle.

For each breast scan, 240 received signals are obtained (one for each transmit-receive antenna pair). Each signal is recorded with 1024 samples, at a rate of 40 GSa/s. The picoscope performs 32 hardware averages on each signal to reduce the affect of random noise. Each full scan takes just over two minutes.

The scan data is preprocessed before being input into an image reconstruction algorithm. More specifically, all received signals are automatically windowed, low-pass filtered, and time-aligned. We then apply the Delay-Multiply-and-Sum (DMAS) imaging algorithm [9] in order to reconstruct images of the breast.

The pixel size of the reconstructed images is set to 2mm x 2mm x 2mm, in order to optimize the tradeoff between the image quality and the computational solving time. Within the results for each volunteer, images are normalized to the maximum over the entire set of 3-D images. In other words, the factor of normalization varies between volunteers, but is constant within images from the same volunteer.

We form two types of images: direct and difference. Direct images are generated from one data set corresponding to one breast scan. Difference images are obtained by comparing direct images of scans from the same breast on different occasions. Difference images are useful for monitoring applications as they allow visualization of any changes in breast tissue composition that have occurred between breast scans.

IV. RESULTS

The images presented in this section are 2-D coronal slices of a reconstructed 3-D breast. The slices are numbered from the chest wall (x = 0 mm) towards the nipple. The images represent the electromagnetic energy scattered from the breast tissue, where dark red indicates regions of strong electromagnetic scattering and dark blue suggests weak scattering locations.

In Fig. 3, we show sample slices of reconstructed (direct) images for both volunteers. For each volunteer, the same slice is extracted from one breast for each of the monthly breast scans: the first column corresponds to the first scan, the 2nd column corresponds to the scan taken during the 2nd month of the study, and the 3rd column corresponds to the scan from the 3rd month. Comparing the three scans from the same breast, we see that although there are small differences in the images, the overall images are consistent with each other and the changes are insignificant to data interpretation (they portray the same information related to the magnitude and location of scattering objects). Further, the images indicate that Volunteer 1 has a cluster of glandular tissue concentrated near the centre of the breast, whereas Volunteer 2's breast consists mostly of adipose tissue (at least for the slice shown).

In order to determine how much the breast tissue composition has changed in the month(s) between scans, we next examine difference images. Three difference images are generated for each volunteer breast: {scan 2, scan 1} which is the comparison between the scan from month 2 and month 1, and, similarly, {scan 3, scan 1}, and {scan 3, scan 2}. Ideally, the breast composition should not change significantly between months (as we have only healthy volunteers and no tumors are developing), so the difference images should show no regions of high scattering.

In Fig. 4 two such difference images are presented, for the same slice depth as the corresponding direct images in Fig. 3. The image on the top is from Volunteer 1 (left breast) and

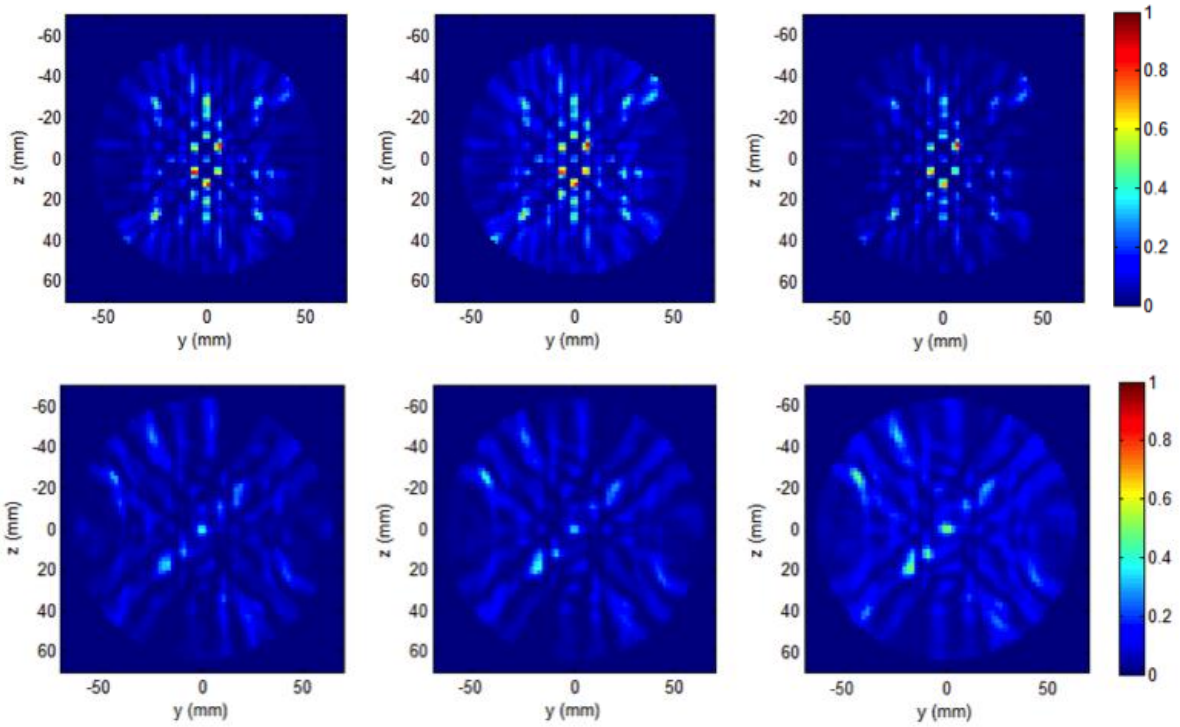

Figure 3. Reconstructed slices: images generated from Volunteer 1 (left breast) in the top row; images from Volunteer 2 (left breast) are shown in the bottom row. Column 1 presents the scan from month 1, column 2 the scan from month 2, and column 3 from month 3. For Volunteer 1 the slices are taken at a depth x = 21 mm; for Volunteer 2 the depth is x = 15 mm.

shows the difference between {scan 3, scan 1}. As a second example, the bottom image shows the difference between same for Volunteer 2 (left breast). Note that {scan 3, scan 1}is chosen because if a tumor was developing, the difference between the third month scan and the first month scan would be maximum whereas the difference between month 2 and month 1, and month 3 and month 2, should be somewhat less. Both difference images seen in Fig. 4 are significantly dark blue, indicating that any changes between the two scans are minimal. Note that the scale for the difference images and the direct images are the same. The remaining possible difference images that can be generated based on this scan data have also been analyzed and were found to look quite similar to the representative examples in Fig. 4.

There are multiple factors that can contribute to the small changes in the images reconstructed from scans on different dates. These include: possible changes in the breast tissues as part of the regular monthly cycle [10], [11], discrepancies in breast positioning in the radome between scans, inconsistent volume/layout of ultrasound gel around the breast between scans, as well as sources of measurement noise. Any discrepancies not due to actual changes in breast tissue are undesirable. Thus, research into each of these areas is currently underway to determine how much each affects the reconstructed images, and how we can mitigate any negative effects related to controllable system issues such as noise and breast positioning.

Finally, we show a quantitative summary of results in Table I. For each breast of Volunteer 1, the peak difference between each of the scans (for the slice at x = 21 mm, to be consistent with what is shown in the images) is listed in decibels. For instance, for the right breast, the peak difference between the 3rd month's scan and the 1st month's scan, {scan 3, scan 1} corresponds to -12.6 dB. For all of these investigated scenarios, the peak difference is at most -12.0 dB, a value that falls into the background clutter level as seen in the images. Also, for the right breast, for example, the mean values (not shown in the table) of the 3-D difference images are much lower at -28.5, -27.4 and -26.2 dB, respectively, for {scan 2, scan 1}, {scan 3, scan 2}, and {scan 3, scan 1}. This further confirms that the monthly scans do not have significant differences between them.

Given all of the possible factors that can influence the reconstructed breast images, the results shown here lend credence to the idea of a monitoring application by confirming that, with healthy volunteers, the scan results over several months do not change significantly. If, on the other hand, we were monitoring breast health of a patient who at some point during the monthly scans began to develop a breast tumor, it is expected that the difference images would show significant changes (i.e., regions of bright yellow or red that increase over time). This has yet to be tested with actual volunteers as it represents a challenging test scenario wherein one may have to track many women over many years before identifying one developing breast cancer. However, future work does involve monitoring of patients who have already been diagnosed or are at high risk. The study presented here is ongoing and will eventually cover many more volunteers followed over the course of time periods longer than three months.

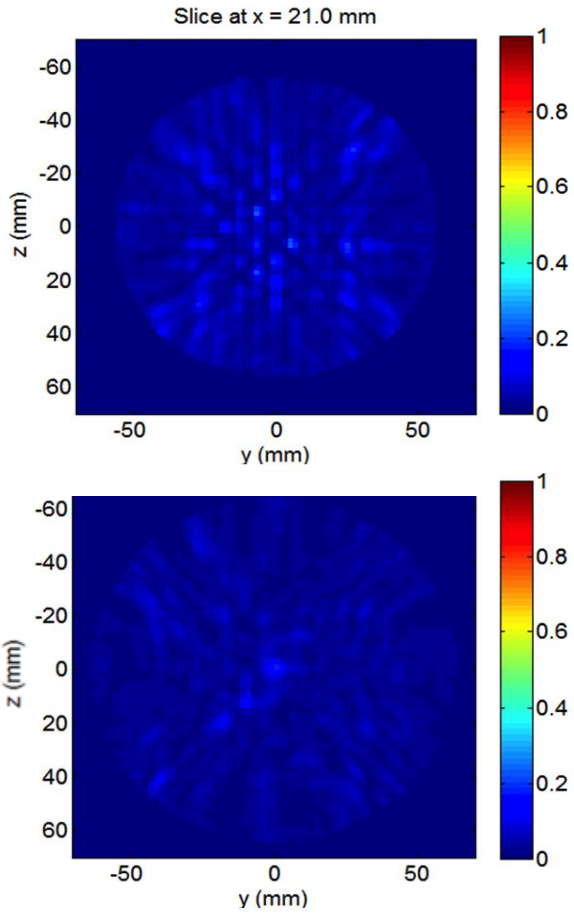

Figure 4. Sample difference images: from the left breast of Volunteer 1 (top) and the left breast of Volunteer 2 (bottom). Both difference images are {scan 3, scan 1}, i.e., the difference from images from the third monthly scan and the first, and correspond to the same slice as shown in Fig. 3.

TABLE I. PEAK DIFFERENCE (DB) BETWEEN THE VARIOUS MONTHLY SCAN SLICES FOR BOTH BREASTS OF VOLUNTEER 1.

	Left Breast	**Right Breast**
{scan 2, scan 1}	-16.4 dB	-12.6 dB
{scan 3, scan 1}	-12.6 dB	-12.0 dB
{scan 3, scan 2}	-12.8 dB	-14.9 dB

V. CONCLUSION

In this work we have presented the first clinical trial results of our microwave time-domain screening system being applied to breast monitoring. For two healthy volunteers, we performed scans over a period of three months. We confirmed that the breast scans were consistent over time and that small discrepancies between scans did not change the results significantly. We also show how scans can be compared, allowing for determination of the presence of irregular breast tissue growth. Future work includes a larger clinical trial and monitoring of patients who are at risk for developing breast tumors or who have already been diagnosed (to monitoring the treatment progress).

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