A novel device for image-guided interventional breast procedures using 3D access and geometry

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INTRODUCTION Magnetic Resonance Imaging (MRI) often provides visualization of breast lesions that escape detection with mammography or high frequency breast US.[1] MRI has superior capability for 3D imaging without sensitivity to breast density or volume. Thus, MRI can be an important tool in the early detection of breast lesions and may provide improved capability for imaging-guided interventions (IGI) and therapies (IGT). Novel MR-compatible devices for remote monitoring of breast IGI have been previously developed by various groups using a conventional 2D grid plate system[2,3]. A novel MR-compatible true 3D IGI/IGT device was developed to provide improved access to lesions for real-time MRI guided breast biopsies and treatment therapies such as cryoablation[4] using a 3D geometry. The purpose of this study was to evaluate the performance of this device and demonstrate sub-centimeter localization accuracy within a breast phantom.

METHODS The developed device provides 3D access through four degrees of freedom (see Figure 1). This configuration allows a path of least insertion depth to be achieved. A breast phantom with lesions embedded into a gel matrix (Gammex RMI, Madison, WI) was used to test the accuracy of the algorithm and device. The device is integrated into a commercial breast coil (Open Breast Phased Array 4-Channel; MRI Devices, Waukesha, USA). On each day of the 5 days of testing the breast phantom was placed in the right or left port of the coil. Using a 1.5T MRI system (GE EXCITE II Echo-speed, Waukesha, WI), a 3D SPGR MRI sequence (TR/TE/FA 7 ms/in-phase/30°) was used to create a 3D volume image for planning in a custom Graphical User Interface (GUI). Semi-automated localization was achieved through graphical placement of cursors on 4 fiducial markers: 3 on the rotating base and one on the target lesion. These positions were then automatically loaded into the planning algorithm resulting in an output of 3D cylindrical coordinates for the device positioning to achieve the most direct access to the lesion within the available range of motion of the device. The platform design of the coil restricted rotational motion within a range of 0 to 60 degrees. A 20-gauge E-Z-EM MRI Compatible Breast Lesion Marking System (E-Z-EM Corp., Westbury, NY) was used to perform the "biopsy" procedure. After needle insertion using the calculated coordinates, the needle tip position was verified using a FIESTA MRI sequence (TR/TE/FA 4 ms/1.0 ms/45°). A total of 21 lesions of varying size and position were targeted for needle localization and access over the 5 different days of testing. A hit was defined as needle contact with the lesion. The distance between needle tip and each targeted lesion center was measured and the lesion size and position within the phantom was noted.

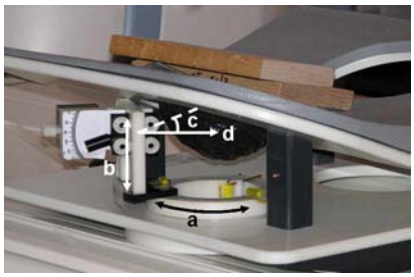

Figure 1. Breast phantom and device within the coil on the MRI scanner bed. Four mechanical movements describe the capability of the device. Letters a-d correspond to base rotation, height of needle guide, needle inclination, and insertion depth respectively.

RESULTS The mean diameter of targeted lesions was 4.5 mm (range 3-6 mm). The mean insertion depth of the needle was 141.0 mm (range 107.2-178.4 mm). Of the 21 lesions that were targeted, 17/21 (81%) lesions were contacted by the needle tip. One successful trial result is shown in Figure 2a. Of the 4 targeted lesions in which the needle tip did not result in contacting the lesion, 3 were located in the upper medial quadrant of the phantom (see Figure 2b). On average, the mean difference between the center of the lesion and the needle tip is about 1 mm more when targeting lesions in the medial quadrants (4.3 mm) than when targeting lesions in the lateral quadrants (3.2 mm). The varying lesion sizes did not appear to be as big a factor as the magnitude of insertion depth of the needle in the accuracy of the system. The average time/lesion for the procedure, defined as acquisition time, planning time, intervention, and verification of needle placement was 14.1 min±1.9 min.

DISCUSSION Feasibility for accurate and precise sampling and therapy of breast lesions using a 3D geometry is shown by this study. Accuracy was always better than 1 cm, and as low as 1.2 mm depending on lesion location. The majority of lesions missed were located in the upper medial quadrant of the breast phantom where needle insertion depth was greatest and needle inclination was needed. Needle depth is an important consideration for this design as conformal breast compression will be used to preserve breast shape and improve patient comfort. As a consequence needle insertion depths to target lesion will be larger than the more conventional 2D paddle compression. To alleviate these concerns and based on the results reported here, a new version of the device with a custom platform and RF-coil to allow medial access to the breast tissue was developed and is undergoing similar validation experiments. The same GUI and planning algorithm is used in the new design. It is anticipated that this new model will diminish the dependence on lesion location for lesion access accuracy.

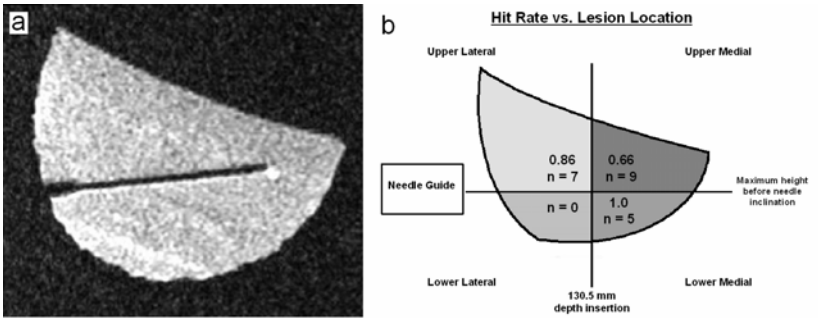

Figure 2. (a) Verification image of needle position with respect to target lesion. This trial resulted in a hit where the lesion was in the upper medial quadrant (178.4 mm insertion, 2.9° needle guide inclination). (b) For analysis, the breast phantom was divided into 4 quadrants. Upper and lower quadrants are differentiated by the need for needle inclination, and the medial and lateral quadrants are differentiated by the center axis of the device, located at a depth of 130.5 mm. Although possible, no targeted lesions were located in the lower lateral quadrant. The lowest hit rate occurred in the upper medial quadrant, where both high insertion depth and needle inclination were needed.

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