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● *Technical Note*

PRELIMINARY CLINICAL EXPERIENCE WITH A COMBINED AUTOMATED BREAST ULTRASOUND AND DIGITAL BREAST TOMOSYNTHESIS SYSTEM

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Abstract—We analyzed the performance of a mammographically configured, automated breast ultrasound (McABUS) scanner combined with a digital breast tomosynthesis (DBT) system. The GE Invenia ultrasound system was modified for integration with GE DBT systems. Ultrasound and DBT imaging were performed in the same mammographic compression. Our small preliminary study included 13 cases, six of whom had contained invasive cancers. From analysis of these cases, current limitations and corresponding potential improvements of the system were determined. A registration analysis was performed to compare the ease of McABUS to DBT registration for this system with that of two systems designed previously. It was observed that in comparison to data from an earlier study, the McABUS-to-DBT registration alignment errors for both this system and a previously built combined system were smaller than those for a previously built standalone McABUS system. (E-mail: ericlar@umich.edu)

Key Words: **Automated breast ultrasound, Digital breast tomosynthesis, Mammography, 3-D imaging, Compression, Combined system.**

INTRODUCTION

Several studies (Berg et al. 2008; Giger et al. 2016; Weigert and Steenbergen 2015; Wilczek et al. 2016) have reported significant increases in cancer detection rates with the addition of ultrasound (US) screening to mammography in dense breasts. Digital breast tomosynthesis (DBT) is more sensitive to breast cancer masses in dense breasts than digital mammography (Sharpe et al. 2016). One recent study (Tagliafico et al. 2016) compared DBT with US for screening in mammographically negative dense breasts, and found that US detected almost double the number of cancers as DBT, and had a comparable rate of false-positive recall for biopsy. Conventional breast ultrasound screening is highly dependent on the skill and experience of the operator, and requires skillful probe manipulation. It is typically performed freehand in an uncompressed supine geometry. A significant source of the uncertainty, and hence recalls, in the reading of hand-held ultrasound or automated breast ultrasound (ABUS) images is the difficulty in translating supine imaging to the upright compressed imaging of DBT or mammography (Brem and Gatewood 1992; Conway et al. 1991). ABUS-to-DBT registration is easier if the ABUS is instead performed in same geometry as the DBT imaging. We refer to this as mammographically configured ABUS (McABUS).

To explore the potential of McABUS, two systems were previously designed to provide proof-of-concept for (i) combined McABUS–DBT (Padilla et al. 2013) and (ii) standalone dual-sided McABUS (Carson et al. 2011; Larson et al. 2016). These two systems are here referred to as the first-generation combined system and the standalone system, respectively. Both systems used GE LOGIQ 9 ultrasound scanners with M12 L transducers (GE Healthcare, Milwaukee, WI, USA). A third system, referred to as the second-generation combined system, is the focus of this study. This system is a prototype combined McABUS–DBT system in which our non-Food and Drug Administration (FDA)-approved, prototype research DBT unit was combined with the FDA-approved supine screening ABUS system, the Invenia (GE Healthcare, Sunnyvale, CA, USA). Although all the equipment mentioned above was made by or in cooperation with GE, we note that this is not the only company to have made such equipment.

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Our purpose was to examine the mass detection of the system to determine limitations and potential improvements and to compare the ease of McABUS-to-DBT registration for this system with that of the two previously designed systems. Comparable data are not available on other systems for automated breast ultrasound in the mammographic geometry (Dines et al. 2005; Leproux et al. 2010; Richter et al. 1997; Smith 2014; Vaughan et al. 2016).

METHODS

The transducer transport and compression frame of the Invenia was modified and integrated into a mammography compression paddle that could be inserted into the prototype DBT system at the University of Michigan (Eberhard et al. 2006; Goodsitt et al. 2014) or on an FDA-approved commercial DBT system, the SenoClaire (GE Healthcare, Chicago, IL, USA). In this system, referred to as the second-generation combined system, the Invenia automatically scans the breast using a large (15.4 cm), 6- to 15-MHz bandwidth linear-array transducer at 10-MHz center frequency and produces a 3-D B-scan ultrasound image volume measuring $15 \times 10 \times 5$ cm. The probe's unique concave shape gives it improved contact to the breast and better patient comfort. The Invenia was modified in several ways for this study, and the configuration used for this study is not FDA approved. The Invenia was given a new operator interface, and the transducer was mounted on a hinge that allowed it to be lifted up and out of the way of the X-ray beam path. The Invenia transducer is illustrated mounted on the prototype DBT and on the SenoClaire in Figure 1a and b, respectively.

The prototype DBT system was used as part of the second-generation combined system for the cases presented here because the image quality from the prototype is equivalent to that of the SenoClaire, and we encountered scheduling logistical issues with the SenoClaire system. That prototype DBT used the same detector design and the same X-ray tube as the Senographe Essential (GE Healthcare, Chicago, Il, USA). For the prototype DBT, multiple scanning modes are possible. For this study, nine X-ray projections were acquired from an angular range of 24°, to match the SenoClaire system, which acquires nine projections from an angular range of 25°. A Simultaneous Algebraic Reconstruction Technique (SART) algorithm (Zhang et al. 2006) was used to compute the DBT images, which are typically presented as a set of slices parallel to the detector. The resolution of these slices was 0.1×0.1 mm, and the spacing between each slice was 1 mm.

The curved dual-modality curved compression paddle in Figure 1a was specially designed to match the curved Invenia transducer. That paddle is composed of the same polyester chiffon material, with sub-millimeter-size filaments and spacing, as that used in the inserts for the standard Invenia ABUS system. The mesh is clear enough to allow visual inspection of the breast position through the material and porous enough to allow ultrasound coupling lotion through the weave, eliminating most air bubbles between the transducer and the breast tissue. The mesh was tightly stretched across a thin, composite material frame and glued. The mesh and composite material paddle were then inserted into an aluminum frame that matches the exact dimensions of a standard tomosynthesis compression paddle for the SenoClaire system. The 15.4-cm Invenia transducer and the 3.8-cm GE M12 L transducer used in the first-generation combined system are compared in Figure 2.

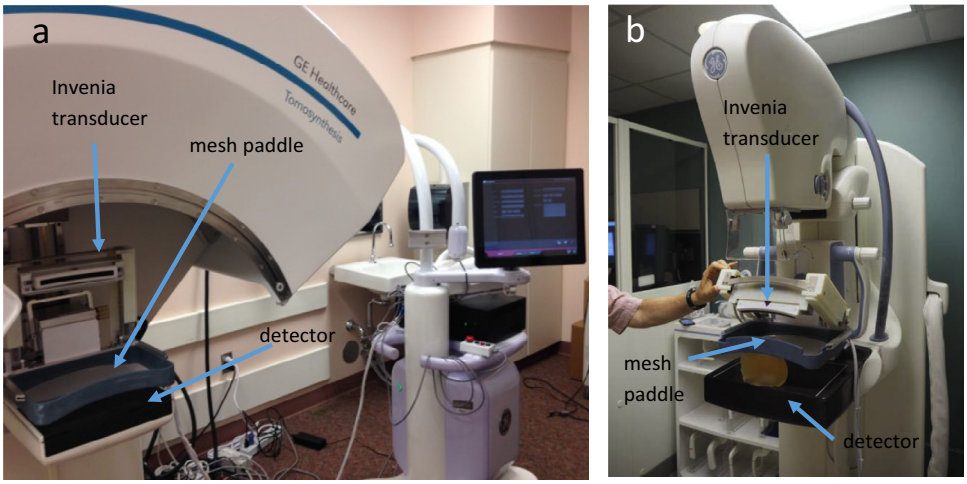

Fig. 1. Modification of the Invenia for mammographic geometry. (a) Second-generation combined system of prototype digital breast tomosynthesis system and Invenia, using custom Invenia-compatible compression paddle. (b) GE SenoClaire breast tomosynthesis system with Invenia transducer and Invenia-compatible compression paddle.