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Conformable Ultrasound Breast Patch - The Future of Breast Cancer Screening?

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ABSTRACT

Breast cancer is the most common cancer type among women worldwide with an average lifetime risk of 12.9%. Early detection and screening are the most important factors for improved prognosis and mammography remains the main screening tool for the average risk patients. Ultrasound (US) is used in women with elevated breast cancer risk, younger patients and patients with extremely dense breasts. Conventional US has certain limitations including operator dependence and reported low specificity. We designed a conformable US device (cUSBr-Patch) which offers large-area, deep tissue scanning and multi-angle, repeatable breast imaging. It is able to detect lesions as small as 1mm with excellent accuracy and reliability validated by *in vivo* comparison with conventional US. This is a user-friendly, innovating device designed to be used by patients with the potential to reshape our approach to breast cancer screening.

Keywords: Conformable ultrasound; elevated breast cancer risk screening; artificial intelligence, innovation in breast cancer

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Key Points

- Breast cancer screening is key to early detection.
- Breast ultrasound is a particularly helpful tool in screening and diagnostic work up of women with elevated breast cancer risk, the younger female population and patients with heterogeneously and extremely dense breasts.
- To eliminate the challenges of conventional ultrasonography, we designed a conformable ultrasound device (cUSBr-Patch) with an easily operable nature-inspired patch design, which offers large-area, deep tissue scanning and multi-angle, repeatable breast imaging.

Introduction

Breast cancer is the most common cancer type among women worldwide after skin cancers and remains the second leading cause of cancer deaths among the female population after lung cancer (1). Increasing awareness, early detection, efficient screening tools and strategies along with individualized systemic and locoregional treatments are all contributing to improved outcomes and overall prognosis. Early detection and screening are the most important factors, and mammography is considered the gold standard screening tool. Multiple studies have demonstrated reduction of breast cancer mortality and improved overall patient outcomes with implementation of mammography-based screening models (2). To overcome certain limitations of mammography, including decreased sensitivity with increased breast tissue density, supplemental screening with ultrasonography (US) and magnetic resonance imaging has been incorporated in breast cancer work up in women with elevated breast cancer risk (3-5). US is a particularly helpful tool in screening and diagnostic work up of this population and patients with heterogeneously and/or extremely dense breasts (6). Addition of a single screening US to mammography has been shown to increase sensitivity and diagnostic yield when compared to mammography alone (7, 8). The main limitations of US have been reported to be operator dependence, intra-observer and inter-observer variability and low specificity (9). The variability in size and shape of the breast is an additional challenge for conventional US since current transducers lack the ability to conform to curved body surfaces. Techniques such as automated breast ultrasound, which reduce operator-dependence by separating the moment of image acquisition from the moment of image interpretation have been developed and have successfully eliminated most of the limitations of conventional US. (10)

Another adjunct for breast cancer screening is artificial intelligence (AI) in the form of artificial neural networks (ANN), a powerful and

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useful tool with multiple applications in the field of medicine (11, 12). The use of AI in breast cancer care is evolving rapidly and the most popular potential applications are increased accuracy of diagnostic and predictive tests and reduced workload for health care providers. Retrospective and observational studies suggest at least similar if not superior cancer detection rates when comparing AI to regular radiologist assessment, even in low breast cancer prevalence cohorts (12, 13). Predictive models for breast cancer risk and mortality using ANN have been validated and shown to be more accurate compared to conventional clinical and statistical risk assessment models (14, 15). The use of ANN and deep learning algorithms expands beyond image reading with applications in pathology and lymphedema diagnosis, among others (16, 17).

To eliminate the challenges of conventional US, Dr. Dagdeviren and her team at Massachusetts Institute of Technology, Media Lab designed a conformable ultrasound device (cUSBr-Patch) with an easily operable, nature-inspired patch design, which offers large-area, deep tissue scanning and multi-angle, repeatable breast imaging (18). This nature-inspired breast patch has a honeycomb design and is composed of three main components including a soft bra as an intermediary layer, the honeycomb patch, which provides structure and guidance for the ultrasound array as an outer layer, and the tracker, which is responsible for handling and rotation of the ultrasound array. The patch and the arrays are held in place with magnets. At any given array position the tracker can rotate 360° and the views of each area are combined to form a comprehensive set of images that sufficiently covers the breast. *In vivo* comparison of the patch with a standard linear probe suggests that it can reliably identify lesions as small as 0.3 cm.

After studying the device on breast models, we studied this device on an actual patient. A female subject with a history of benign breast pathologies was imaged using the cUSBr-Patch, with results cross-validated by a conventional US linear probe. The cUSBr-Patch was applied to the left breast and scanned along multiple positions, revealing a 1 cm cyst at the 4:00 position. A smaller 0.3 cm cyst was also detected in the right breast. Cross-validation confirmed the presence of both cysts, demonstrating the cUSBr-Patch's precision in detecting even sub-centimeter lesions. The cUSBr-Patch provided similar imaging performance to the conventional US system, with a consistent field of view and stable results over time, suggesting its potential for early breast cancer detection.

This device has demonstrated great repeatability of array positioning which is a crucial component of a reliable breast screening tool. Compared to conventional US, it eliminates the operator bias and the need for an operator altogether. It has the ability to detect lesions as small as 0.1 cm and with application of the innovating rotating design at multiple array locations, it expands the lesion localizing ability beyond the standard four quadrant designated views. These technical characteristics make the cUSBr-Patch ideal for higher risk population including younger women with denser breast tissue, for which mammography has been shown to have inferior sensitivity to US (4).

As our understanding of factors influencing future breast cancer risk has expanded, breast cancer screening has also become more personalized. While yearly mammographic screening remains the gold standard for average-risk women, there exists a subgroup of patients who require more intensive screening. In addition, in certain cases, we may opt for short-interval follow-ups to monitor suspicious lesions in the breast. Normally, this process involves patients commuting back and forth to an imaging center. In addition to the commute, an US technician is necessary to capture the images and radiologist to interpret them. This device aims not only to reduce commuting between home and radiology facility but also offers long-term cost-effectiveness by removing the necessity for both an ultrasound technician and a radiologist. The user-friendly design and autonomic nature of the device offers patients at-will screening from the comfort of their home. Remote images will be collected and analyzed by a DL-based model which will limit traveling needs and expenses to only those necessary. This can be particularly useful for patients in remote areas, with poor access to healthcare or limited health awareness.

Finally, it is important to note that this device is not to be viewed as a substitute for traditional screening systems. Mammography is a well-studied modality with multiple cohorts establishing its efficacy. Conventional US is an overall inferior screening tool in patients within the typical screening age range and breast density. The cUSBr-Patch can detect small changes from baseline and select the patients who need to undergo conventional US or mammography outside of their standard timeframes which can be crucial, especially for patients with more aggressive subtypes of breast cancer. This device may be the "first guard" in detecting minor changes and abnormalities that would initiate an official and more comprehensive work up. We envision that our device will be utilized by imaging centers, hospitals and insurance companies to facilitate patients who need frequent follow-ups due to increased risk or a suspicious lesion. When our device detects any abnormalities, these patients will then be recalled to radiology facilities and breast centers for further work up and testing. Following the very promising early results, our device is now being tested in a large cohort. Pending confirmation of our preliminary findings, it could soon become commercially available as a portable, easily accessible and very cost-effective initial imaging tool for women with increased breast cancer risk or dense breast tissue.

Footnotes

Authorship Contributions: Concept: C.D., T.O.; Design: C.D., T.O.; Data Collection or Processing: C.D., T.O.; Analysis or Interpretation: T.O.; Literature Search: A.G.; Writing: A.G., T.O.

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