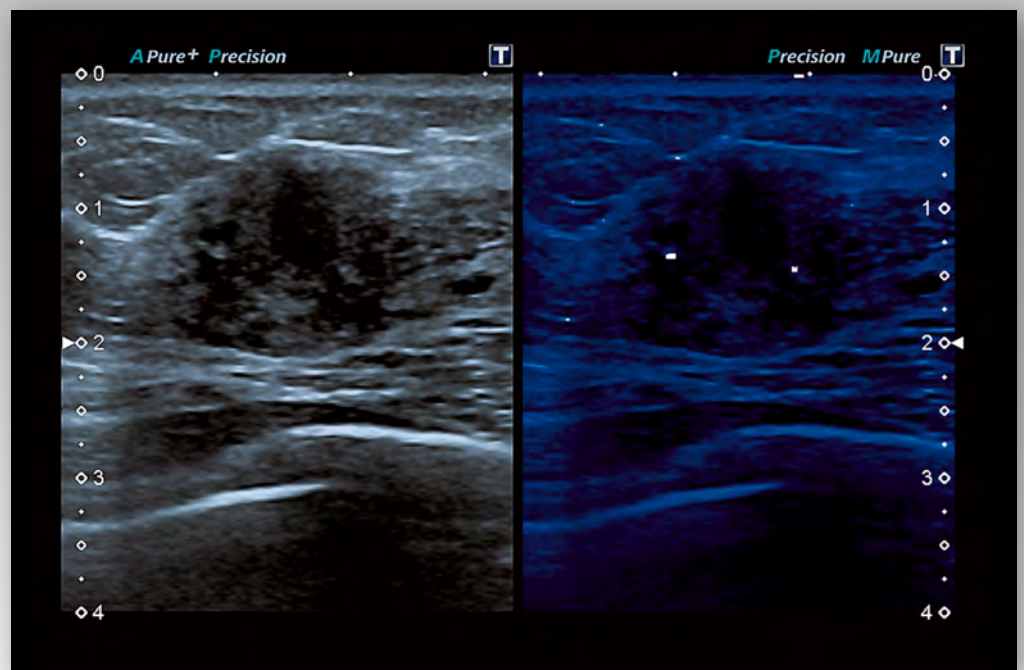


Easily Visualize Microcalcifications

Using Ultrasound



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While mammography is the gold standard in breast imaging, ultrasound can provide a supplemental advantage to aid in the diagnosis of breast lesions, especially for women with dense breasts. However, ultrasound has been an unreliable method for the identification and evaluation of breast microcalcifications. In an effort to advance the usefulness of breast sonography, Canon Medical Systems, Inc. has developed MicroPure, available on the Aplio™ 500 and 300 Platinum ultrasound systems, which is an image processing technique that extracts isolated points and allows for improved delineation of microcalcifications relative to the surrounding breast tissue.

Traditional B-mode imaging is unable to delineate most microcalcifications due to contrast limitations and the complicated structure of mammary glands.

Microcalcifications are often visible in association with a mass; however, independent of a lesion they are obscured by the breast parenchyma. MicroPure combats the contrast limitations of grayscale imaging by using a filtering technique called CFAR (for constant false alarm rate). By comparing the average brightness within a small area to that of the central pixel and calculating the difference, brighter areas representing microcalcific regions are prominently displayed as “white spots” that are superimposed on a blue background.

Our research team at Thomas Jefferson University has performed a comparative study to assess the efficacy of MicroPure for identifying breast microcalcifications visualized on mammography. The prospective clinical trial was approved by university’s Institutional Review Board (IRB) and conducted from June 2010 to October 2013 at the

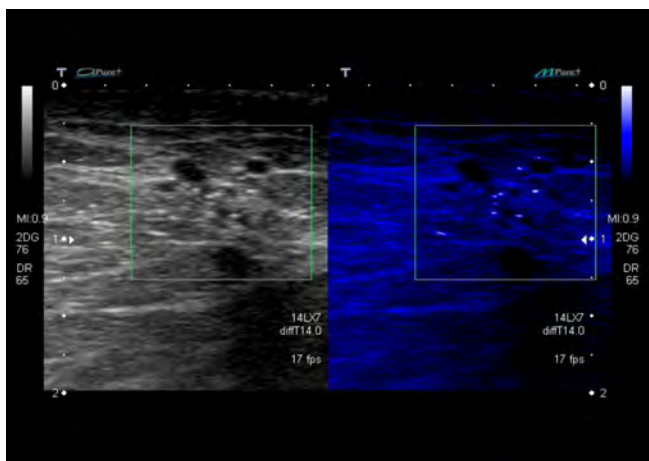


Figure 1: Images obtained from the specimen of an 80-year-old female. The patient had an unsuccessful stereotactic breast biopsy, and subsequently underwent surgery for the removal of suspicious breast calcifications. The patient’s specimen was imaged using MicroPure and the breast calcifications were prominently displayed.

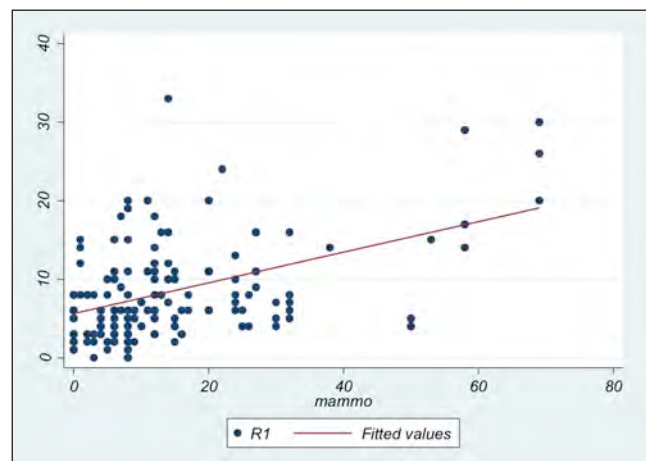


Figure 2: Number of microcalcifications seen with mammography and by Reader 1 (R1) along with the best linear fit.



Figure 3: Cooper’s ligaments artifacts. A. Several artifacts can be seen. B. Same area imaged with a change in transducer angle to eliminate Cooper’s Ligaments artifacts.

Thomas Jefferson University Breast Imaging Center. Eighty-one women were enrolled, 20 of which were scanned after their mammogram identified microcalcifications; 61 women were scheduled for surgical excision or image guided biopsy of microcalcific areas. The Aplio ultrasound system, with a 14 MHz broad-bandwidth liner array, was utilized to produce grayscale and MicroPure™ images. The dual screen TwinView™ option displays grayscale on the left and MicroPure enhancement on the right. Figure 1 demonstrates images obtained for the identification of microcalcifications.

Using each participant’s mammograms as a reference, target regions of interest were localized and scanned. All patients evaluated had confirmed scattered and/or diffuse microcalcifications. MicroPure cine loop and still images were evaluated for quality and the presence of artifacts. The number of identifiable microcalcifications was also determined and recorded. The mean number of microcalcifications visualized with MicroPure was 8.8 ± 7.4 (average range 5.8-14.2). The results from each reader are shown in Table 1. The results with MicroPure were generally a bit lower, but nonetheless in good agreement with the reference mammography images (mean number of microcalcifications: 14.7 ± 13.1); as shown in Figure 2. Reader 3, being the most experienced breast imager, had the highest rate of accuracy in identifying the presence of microcalcifications.

The sonographic pitfalls of MicroPure can be credited to Cooper’s ligaments, which potentially elevates the number of “white spots” visualized. By adjusting transducer angle and utilizing the Twin View display, Cooper’s ligament artifacts were easily differentiated from true microcalcifications as demonstrated in Figure 3.

MicroPure’s enhanced images display microcalcifications otherwise obscured within the surrounding breast tissue and has the potential to provide biopsy guidance based on microcalcification identification. Initial results in this application are encouraging. Four lesions that underwent ultrasound-guided biopsies using MicroPure had the same procedure times as regular ultrasound-guided biopsies using grayscale imaging, and the performing radiologist felt confident with the MicroPure images.

Figure 4 shows an ultrasound-guided breast biopsy using the benefit of MicroPure as a reference point for needle guidance. MicroPure-guided biopsies provide an attractive alternative to stereotactic biopsies. As an ultrasound-guided utility, MicroPure has the potential to provide a more comfortable procedure at a lower cost in comparison to stereotactic biopsy exams. MicroPure may be one solution that can help healthcare providers promote fiscal responsibility and improve patient satisfaction, a known factor that directly impacts Medicare payments.

As exemplified by the case presented in Figure 1, MicroPure has the potential to change patient management. This patient could have had a MicroPure-guided biopsy of her calcifications, but instead underwent a surgical excision due to a failed attempt at stereotactic biopsy. MicroPure could have provided a minimally invasive alternative to surgical excision, which would have offered significant benefits including a lower cost, lower risk of complications and better overall patient experience. MicroPure, therefore, presents a new strategy in patient management by potentially providing access to calcific areas that may otherwise be unobtainable by traditional methods.

Mean Number of Microcalcifications Observed	
READER	MICROPURE
1	8.5 ± 5.7
2	6.8 ± 5.4
3	14.2 ± 13
4	5.8 ± 5.6
Total	8.8 ± 7.4

Table 1

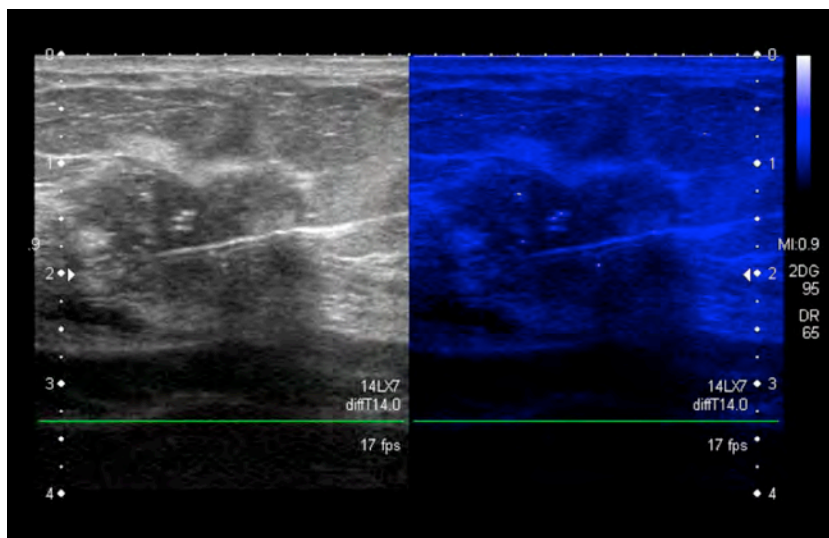


Figure 4: Ultrasound needle guidance enhanced with MicroPure

While mammography is still the most reliable tool for identification of breast calcifications, this pilot study has demonstrated that MicroPure markedly improves the visualization of microcalcifications compared to conventional grayscale ultrasound. Hence, a new tool for ultrasound breast imaging has been introduced into the clinical

armamentarium. More work is required to fully understand the capabilities of this new imaging mode, but our results to date indicate that MicroPure guided biopsies may be an important future clinical application with significant benefits in today's healthcare reform environment.

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