Whitepaper

Automated Breast Volume Scanning

Visualization of Mammographically Occult Breast Cancer - Two Cases

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With growing awareness of genetics and other factors that increase a women's risk for developing breast cancer, there is even greater demand for advanced breast imaging methods to supplement mammography. Automated breast volume scanning is a potentially practical adjunct to mammography, which is the cornerstone of breast cancer early diagnosis, for both detection, as well as evaluation, of the extent of breast cancer in high risk patients. This whitepaper will illustrate the role that the ACUSON S2000™ Automated Breast Volume Scanner (ABVS) could play in this developing clinical area.

It is unfortunately common in clinical breast imaging practice that malignant masses, which can be palpated, are not detectable by mammography, especially in women with dense breast tissue. Likewise, mammographically occult cancers are frequently visualized by contrast-enhanced breast MR imaging. Yet, in both cases, the tumors are often apparent on directed (second-look) hand held ultrasound (US) exams.

A key shortcoming in conventional breast US is that it is usually used to evaluate a small area surrounding a palpable mass or a specific mammographic finding. Systematic whole breast US is infrequently used in the ipsilateral breast, and even less often is the other contralateral breast fully examined. Because US is operator-dependent, time consuming, non-reproducible and poorly reimbursed, hand held is seldom used at its full capacity in breast cancer evaluations.

Equipment/technique

The following exams were done under the supervision of the Swedish Medical Center Institutional Review Board. Informed consent was obtained from all participants in this pre-clinical evaluation. The ACUSON S2000 Automated Breast Volume Scanner (ABVS) used for these exams has subsequently been granted FDA 510(k) clearance for clinical use.

Automated breast ultrasound was performed using an ACUSON S2000™ ultrasound system with the Automated Breast Volume Scanner attachment. The ACUSON S2000 ABVS features an adjustable scanner arm and automated one-button pressure and locking mechanism to improve workflow by simplifying and expediting volume acquisition for consistent results.

Workflow is streamlined by providing image presets that are optimized to the patient's cup size. The system automatically adjusts depth, frequency, focal zone placement and overall gain.

A complete breast ultrasound imaging system, the ACUSON S2000 ABVS also provides high-resolution hand held imaging with innovative applications such as fatty tissue imaging, eSie Touch™ elasticity imaging, and allows biopsy procedures with US guidance.

A typical exam is comprised of three automated 65 second scans of each breast in the Anterior-posterior (AP) and both oblique positions. Occasional additional views are required for larger breasts, with scans centered on a palpable abnormality or axillary lymph nodes. The large footprint wide frequency bandwidth transducer utilizes a high center frequency. This 14L5BV transducer captures a volume of up to 15.4 cm x 16.8 cm x 6 cm by acquiring a series of 320 high resolution axial 2D images at slice intervals of 0.5 mm. Real-time Advanced SieClear™ spatial compounding is employed in combination with Dynamic TCE™ tissue contrast enhancement technology during the scanning process. After the acquisition is finished, proprietary post-processing algorithms are applied based on the nipple location to maximize the quality of the diagnostic information:

- A Reverberation Removal algorithm processes the 3D data and determines where tissue contact is present and where it is not. The data corresponding to the area with no tissue contact is removed. This suppresses the reverberation artifacts from the non-contact area.
- An adaptive Nipple Shadow reduction tool analyzes data on a case-by-case basis and enhances structures in the retroareolar area to improve visualization of this challenging region.
- A Gain Correction algorithm analyzes the 3D data and adjusts for the brightness variation artifacts caused by transducer channel-to-channel variations.

After acquisition, the axial image series is automatically sent from the ACUSON S2000 ABVS to, a dedicated breast ultrasound review workstation. The workstation presents images through multiplanar reconstruction (MPR) and reconstructs secondary images from the acquisition volume in any plane, such as sagittal, coronal, radial and anti-radial views.

The workstation is used for comprehensive analysis, interpretation and manipulation of the acquired 2D and 3D data. It includes semi-automated reporting features and comprehensive BI-RADS® Ultrasound reporting capabilities. These capabilities further enhance the clinical workflow of this breast volume US solution.

Method

Exams for this pre-clinical release project were somewhat longer than expected for clinical applications. However, typical exam times are anticipated to be approximately 10-15 minutes in routine clinical practice. Interpretation times are estimated at five minutes, depending on the patient population. Both patients in this study had known breast malignancies and a recent contrast-enhanced breast MR (Siemens MAGNETOM™ Avanto or Harmony).

Case 1 Images

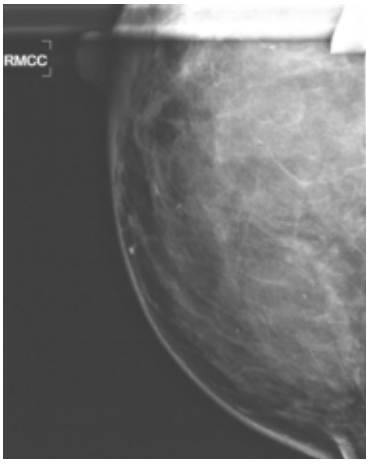

Figure 1A: Mammogram

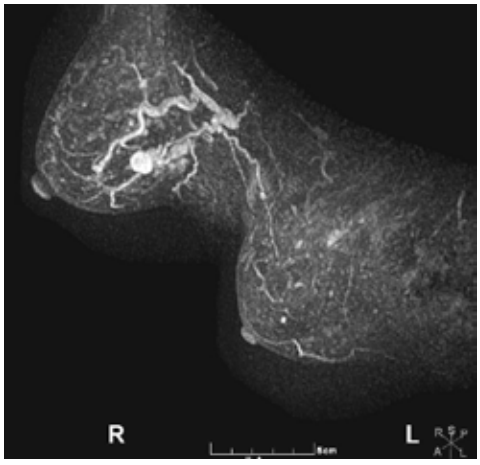

Figure 1B: MR

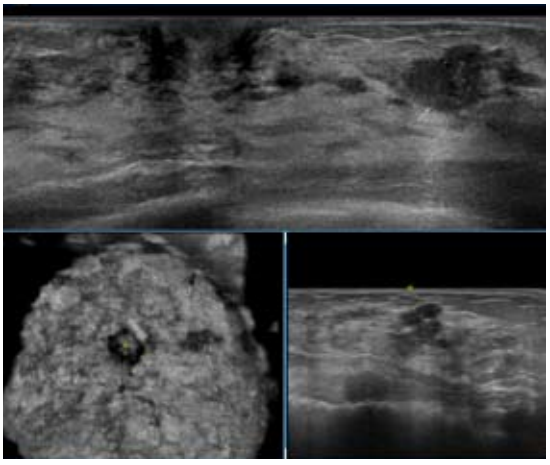

Figure 1C: ABVS

Figure 1A Mammogram: *Right coned compression CC mammogram: dense with no malignant-type calcifications, masses or architectural changes. The left mammogram was similarly negative and unremarkable.*

Figure 1B MR: *Right oblique Maximal Intensity Projection (MIP) MR image shows a suspicious right upper inner quadrant enhancing mass. Note the large asymmetric draining vein. The left breast is normal with scattered physiological foci on MR.*

Figure 1C ABVS: *Three orthogonal planes (axial, coronal, sagittal) of the medial right breast. An irregular, spiculated, hypoechoic mass is present at 3 o'clock medial to the nipple (arrow). An intraductal carcinoma is seen extending to the subareolar space. Punctuate micro-calcifications can be seen within the mass in the axilla. This is 1 of 8 serial images through a 4 mm area (i.e. a 1.0 mm slice interval). High-resolution, thin slices allow high quality multiplanar image reconstructions.*

Case 1

A palpable left breast lump and strong family history of breast cancer brought this 49-year-old woman to a highly-qualified mammographic facility where mammography revealed dense breast parenchyma with no malignant findings in either breast **(Figure 1A)**. Hand held US of the area of concern in the left breast was also unrevealing and normal. Because of her high risk status, she was referred to our facility for a breast MR, which detected a suspicious lesion in the upper inner quadrant of the opposite, right, breast **(Figure 1B)**. A directed hand held US confirmed a malignant-appearing mass at 2 o'clock in the upper inner quadrant, which was core biopsied under US guidance. The pathology report indicated high-grade infiltrating ductal carcinoma with associated in situ carcinoma.

The patient then had an ABVS exam and the tumor was apparent even to her during image acquisition. On post-processing workstation evaluation, the location, size, extent, and associated in situ intraductal component were well seen in the Axial (acquisition) plane **(Figure 1C upper image)**, as well on the reconstructed Coronal and Sagittal images **(Figure1C bottom images)**. Images can be reconstructed in radial and anti-radial projections, if desired. Although this cancer was clearly evident in real-time during image acquisition, interpretation is best done on the ABVS Workplace which facilitates rapid multiplanar review of the large numbers of images produced by automated scanning **(Figure 1D)**. This capability brings US interpretation into the realm of routine 3D

Case 1 Images (cont.)

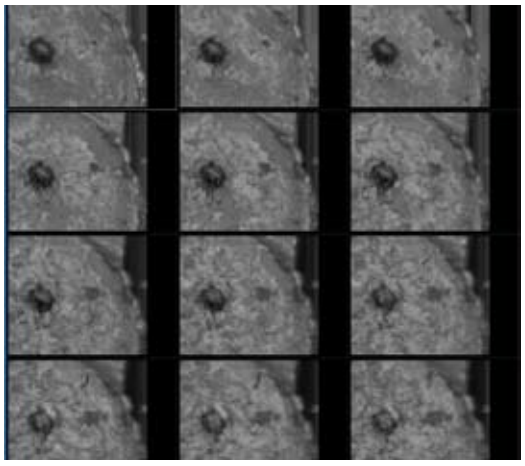

Figure 1D: ABVS

Case 2 Images

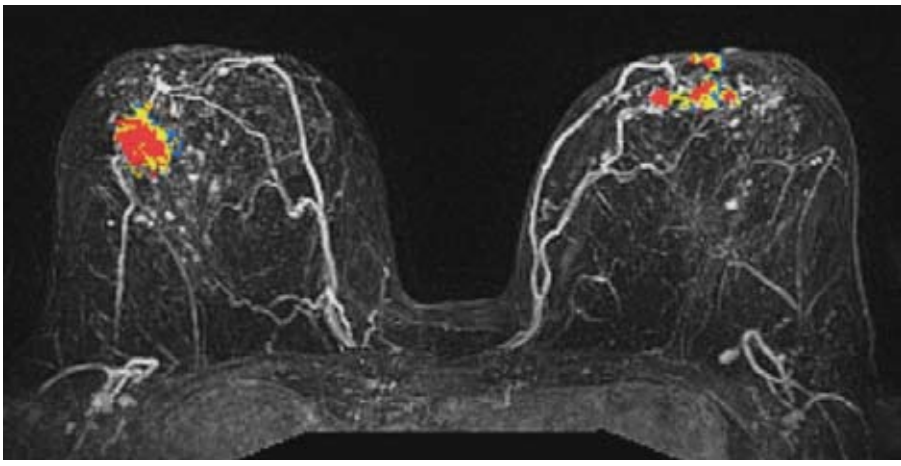

Figure 2A: MR

Figure 1A ABVS: *MultiSlice display of coronal reconstruction at 0.5 mm slice intervals showing the tumor progressing throughout the depth.*

Figure 2A MR: *Transverse post-contrast MIP subtraction MR with CAD color overlay shows multiple enhancing physiological foci due to hormone effect bilaterally, but also detects multi-focal and unexpected malignant lesions in the left breast as well as a clinically unsuspected suspicious enhancing mass in the right breast.*

evaluation, as done with CT and MR. The coronal plane has not been available on US until the recent development of the automated systems with their 3D capabilities. The coronal view provides a more understandable representation of the breast's global anatomy and architecture; in particular, the segmental organization of the ductal system is more apparent. Tissue retraction and architectural distortion are often particularly well seen in this unique plane.

The patient elected bilateral mastectomy. She has done well post-operatively and was well served by multi-modality advanced breast imaging, which detected her potentially life-threatening cancer earlier than conventional breast screening. Although the tumor was detected with MR in this pre-clinical evaluation, it is clear that in this particular case, the physician would have been able to make the diagnosis entirely with ABVS, without MR.

Case 2

Screening mammography detected suspicious peri-areolar calcifications in the left breast at 9 o'clock in a healthy and vigorous 72-year-old woman currently on exogenous hormone replacement, which she was taking despite a prior biopsy diagnosis of a typical ductal hyperplasia. An outside US was used to evaluate the area in question on the mammogram and showed a suspicious mass. Biopsy yielded invasive ductal carcinoma. The right breast was heterogeneously dense, but since no mammographic abnormality was present, it was not evaluated by US. This represents the usual and standard radiological practice. Because she was considered to be at elevated risk based on dense breasts, prior biopsy results and family history of breast cancer, she was referred for breast MR. MR revealed multiple additional suspicious lesions in the left breast **(Figure 2A)** as well as an unsuspected, malignant-appearing mass in the upper outer quadrant of the right breast. She was then scheduled for high-resolution US of both breasts with biopsy of any malignant US findings, with particular attention to the finding in the right breast.

Case 2 Images (cont.)

Figure 2B: 2D US

Figure 2C: 2D US

Figure 2B 2D US: *Radial hand held US, right breast, at 10 o'clock, 3 cm from the nipple confirms the suspicion of malignancy. A 2.3 cm irregular, poorly marginated, hypoechoic mass with a hyperechoic halo is demonstrated – all typical features of an US BI-RADS category 5, extremely suspicious lesion.*

Figure 2C 2D US: *Core biopsy under US guidance was performed on the right breast mass in real-time.*

The full US breast imaging and interventional capabilities of the ACUSON S2000 ABVS are well illustrated by this case. In the right breast, at 10 o'clock, a very malignant-appearing hypoechoic 2.3 cm mass, was identified **(Figure 2B)**. Core biopsy **(Figure 2C)** was performed, with placement of a stainless steel marker clip. This also proved to be an invasive ductal carcinoma.

Hand held grayscale imaging US of the left breast revealed the known lesion at 9 o'clock, as well as an additional mass at 10 o'clock, **(Figure 2D)**. This had multiple malignant features as well as abnormal US elasticity **(Figure 2E)**. Figures 2F and 2G compare high frequency grayscale and tissue harmonic imaging (THI). The latter provides substantially higher contrast, but anatomic detail is appreciably lower, as expected. With THI, hypoechogenicity is significantly increased and therefore more difficult to use as a diagnostic feature. A separate area of lower suspicion in the lower outer quadrant, remote from the above two lesions, was selected for core biopsy which yielded atypia without malignancy.

The patient then had the ABVS exam **(Figures 2H and 2I)**, which she found comfortable and interesting. She subsequently elected bilateral mastectomies with breast reconstruction. The pathology exam of the left mastectomy specimen confirmed multi-focal infiltrating ductal cancer; and positive axillary lymph nodes were found in the left axillary dissection. The mammographically occult right breast tumor was a mixed ductal-lobular carcinoma also with multiple tumor containing axillary lymph nodes.

Case 2 Images (cont.)

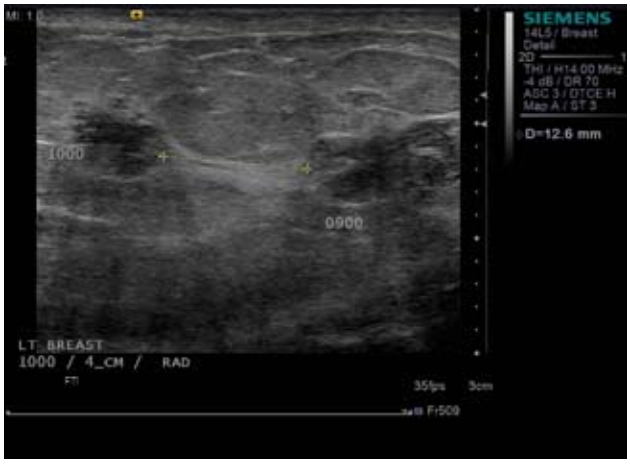

Figure 2D: 2D US

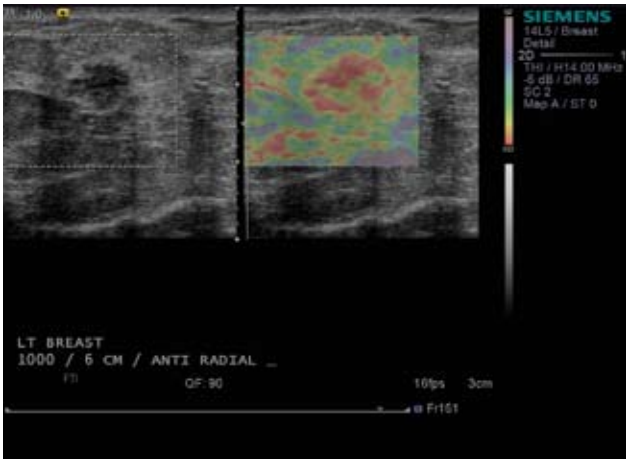

Figure 2E: 2D US

Figure 2D 2D US: *Multi-focal cancer is confirmed in the left breast on high-resolution ultrasound imaging. The lesions are separated by 1.3 cm.*

Figure 2E 2D US: *Gray scale and elasticity image with a color overlay of the left breast document abnormal stiffness of the biopsy-proven malignant mass also at 10 o'clock.*

Figure 2F: 2D US

Figure 2G: 2D US

Figure 2F 2D US: *High-resolution grayscale images of the left breast 10 o'clock, 6 cm from the nipple using a broadband 14-5 MHz transducer shows the malignant second mass with high spatial resolution and detail.*

Figure 2G 2D US: *At the same location, tissue harmonic imaging provides higher tissue contrast, but lower anatomic detail.*

Case 2 Images (cont.)

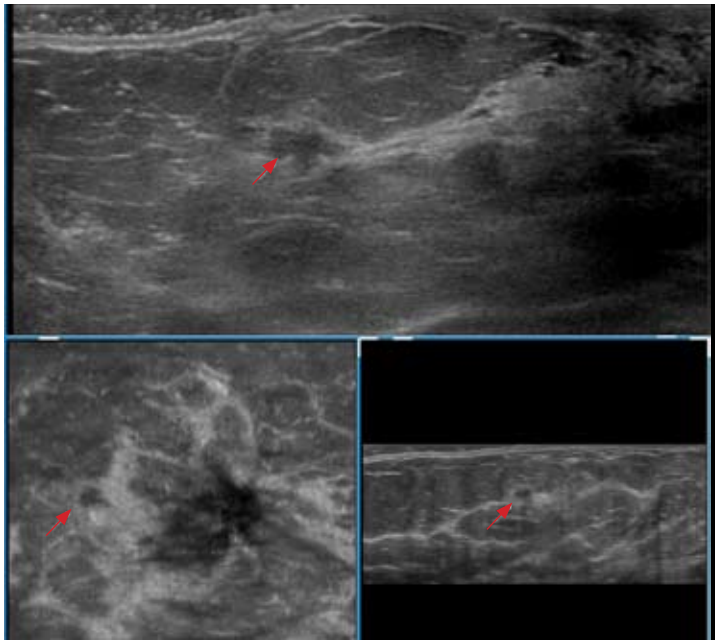

Figure 2H: ABVS

Figure 2H ABVS: *Three orthogonal views of the left breast. Axial ABVS images at slice intervals of 0.5 mm at 10 o'clock have similar resolution to the hand held 14-5 MHz image in Figure 2F, but cover 15 cm transversely. These high-resolution axial source images provide the 3D data for multiplanar image reconstruction.*

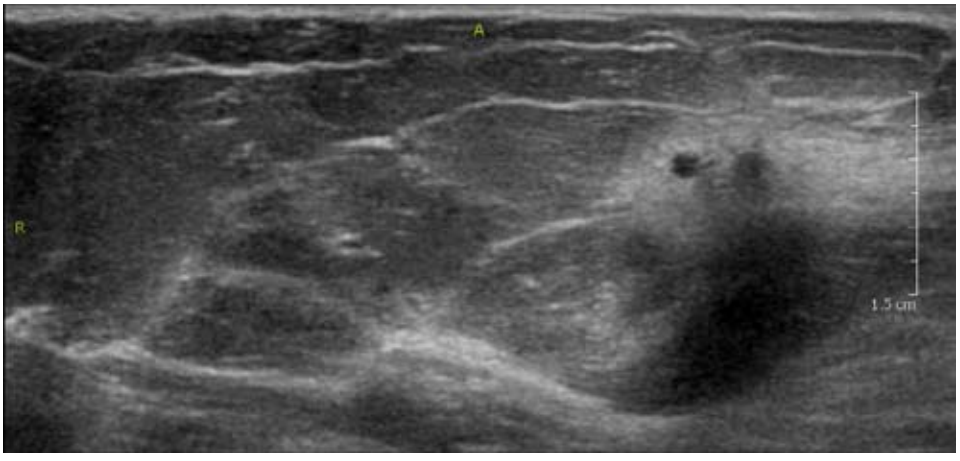

Figure 2I: ABVS

Figure 2I ABVS: *Two small (< 4 – 5 mm) hypochoic lesions are clearly demonstrated on the ABVS at the cranial margin of the tumor.*

Discussion

These cases illustrate the diagnostic imaging capabilities of an automated breast volume ultrasound system with advanced technologies such as eSie Touch elasticity imaging and fatty tissue imaging.

Although these patients had known, MR detected cancers, it is apparent that in these two specific cases the physician would have readily detected all of the additional lesions with the ABVS exam which were seen on MR that were not suspected on mammography or conventional US exams performed elsewhere at experienced facilities. This illustrates a key advantage of an automated breast ultrasound system – standardized, reproducible bilateral whole breast imaging, with 3D capability and retrospective multiplanar image review. Patients have the benefit of a fast exam time, no breath holding, no ionizing radiation (important for young or pregnant patients), no contrast agents and minimal compression. These systems are now commercially available and will soon move into more routine clinical evaluation.

Imaging methodology evaluations and validation studies for automated breast US are underway and necessary. Appropriate clinical indications for this exam are also under development as are optimization of image acquisition techniques and patient positioning. Refinements on image algorithms, as well as user interface and workstation efficiency are also underway. These improvements promise to further enhance an already impressive new clinical tool that has significant promise as an adjunct to mammography for earlier diagnosis of breast cancer in selected patients. This exam will be appropriate for consideration in patients with mammographically dense breasts and documented risk factors for breast cancer as well as potential for better pre-operative assessment of patients with known breast malignancy.

References

1. *Boyd NF, Guo H, Martin LJ, Sun L, Stone J, Fishell E, et al. Mammographic density and the risk and detection of breast cancer. N Engl J Med. 2007;356(3):227-36. [Increased risk is 4.7 times greater in women with a mammographic density of 75% (dense breast tissue) as compared to women with a mammographic density of 10%.]*
2. *Kolb TM, Lichy J, Newhouse JH. Comparison of the performance of screening mammography, physical examination, and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. Radiology. 2002;225(1): 165-75.*
3. *Berg WA, Blume JD, Cormack JB, Mendelson EB, Lehrer D, Bohm-Velez M, et al. Combined screening with ultrasound and mammography vs. mammography alone in women.*
4. *Mendelson EB, Baum JK, Berg WA, Merritt CB, Rubin E. Breast Imaging Reporting and Data System BI-RADS: Ultrasound, 1st edition. Reston, Va: American College of Radiology; 2003.*
5. *American Cancer Society – Global Cancer Facts and Figures, 2007-08.*
6. *Breast Ultrasound by A. Thomas Stavros Coronal Ultrasound: A New Way of Looking at Breast Lesions. László Tabár, MD, PhD.*
7. *Breast Ultrasound. by A. Thomas Stavros, Cynthia L. Rapp, Steve H. Parker Contributor Cynthia L. Rapp, Steve H. Parker Edition: 2, illustrated Published by Lippincott Williams & Wilkins, 2004.*
8. *Coronal Ultrasound: A New Way of Looking at Breast Lesions. László Tabár, MD, PhD. Abstracts Presented at the 18th Annual National Interdisciplinary Conference of the National Consortium of Breast Centers: The Convergence of Art, Passion and Science. American Journal of Clinical Oncology: October 2008 - Volume 31 - Issue 5 - ppg 507.*

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