

**Conclusions:** 3D US and VOCAL is a highly repeatable method to measure volume. Positioning the focus at the same depth as an object and keeping object depth constant among serial US examinations by using same transducer position and acoustic window are essential for reliable volume assessment and comparison.

### 32711

#### Mechanical imaging of the breast: A pilot trial

Helvie MA,<sup>1</sup> Carson PL,<sup>\*1</sup> Sarvazyan A,<sup>2</sup> Thorson N,<sup>1</sup> Egorov V,<sup>2</sup> Roubidoux MA,<sup>1</sup> I. Radiology, University of Michigan, Ann Arbor, MI, and 2. Artann Laboratories, Inc., North Brunswick, NJ

**Objective:** The aim of this study was to describe initial results of a novel imaging device used to detect and discriminate breast masses via semi-quantitative noninvasive evaluation of tissue hardness.

**Methods:** A mechanical imaging (MI) device was developed to respond to tissue structure and viscoelastic properties using a rectangular array of force sensors. Women with breast masses by clinical examination, mammography, or ultrasound and other volunteers were recruited to undergo MI. Outcomes were established by use of pathologic and clinical records. Three iterations of the prototype device were used, with the final MI head similar to an ultrasound scan head (5 cm long, 192 sensors). The sensor head was pressed against the breast in four quadrants and the retroareolar area utilizing light hand pressure. Color-coded hardness images were produced after non-blinded computer processing from recorded pressure patterns related to the 3-D distribution of tissue elastic modulus. An empiric threshold of normalized peak pressure units was used to distinguish benign from malignant and palpable abnormality from nonpalpable area. IRB approval and prospective written informed patient consent were obtained.

**Results:** Studied were 34 cases (31 women). Of the 31 cases with uncorrupted data, 12 were cancer (all palpable, mean size 1.8 cm), 19 were benign (14 of 19, 74%, palpable). Sensitivity of MI for cancer detection was 92% (11/12), specificity 79% (15/19). False positives were related to cysts and fibrocystic change. MI sensitivity and specificity for detection of clinically palpable masses were 80% and 75%. A majority of patients considered scanning at least as comfortable as physical examination.

**Conclusions:** Mechanical imaging of the breast is feasible and well tolerated by patients. High sensitivity was achieved for these palpable cancers. Future studies should include blinded, real-time reconstruction of the images and, eventually, screening of asymptomatic women for nonpalpable breast cancer. This mechanical stress imaging should be quite complementary to ultrasound strain imaging; mechanical sensors could easily be added to the ultrasonic probe. (This work was supported in part by USPHS Grant # R44CA069175.)

### 31849

#### Development and validation of an in vivo analysis tool to identify changes in carotid plaque tissue types in serial three-dimensional ultrasound scans

Coleman D,<sup>\*</sup> Rakebrandt F, Neil P, Woodcock J, Medical Physics and Clinical Engineering, University Hospital of Wales, Cardiff, South Glamorgan, United Kingdom

**Objective:** The aim of this study was to develop a system to identify changes in plaque tissue type using 3D B-mode ultrasound for use in patients undergoing lipid lowering drug treatments.

**Methods:** A series of 3D ultrasound scans were captured on a Toshiba 6000 Powervision machine. This was achieved by a mechanical device driving a 7.5-MHz probe forward at a constant speed. The ultrasound machine captured a set of images and then used specialized software

(TomTec) to construct a 3D representation of the data. The 3D data were transferred onto a PC (Mertec), and software programs (Matlab) allowed the data to be displayed and regions of interest (ROI) selected. A set of first- and second-order statistical methods was applied to analyse tone and texture for each valid 9×9 pixel (kernel) region within the selected image data. An artificial neural network classified each kernel into one of five classes representing five tissue types identified by histology (Rakebrandt, UMB, 2000). The results were displayed as parametric images and the total number and percentage values calculated for each class. Interobserver variability studies were completed to determine the level of agreement in selecting the ROIs. Intraobserver variability studies were completed to estimate the test precision to determine whether an observed difference in results in the serial scans reflects a true change in tissue type.

**Results:** Three different observers analysed ten plaques, and an overall interobserver 95% coefficient of agreement of 8% was calculated. One observer analysed ten plaques ten times, and an overall intraobserver coefficient of repeatability of <2% was calculated.

**Conclusions:** These results show that the technique is subjective in the selection of the ROI but is reproducible and may be useful in identifying changes of >2% in tissue type. Future work involves comparison with plaque histology post endarterectomy to identify the different tissue types and comparing serial scans of patients on statin and LDL apheresis drug treatments.

### 32812

#### Threshold damage induced during thermal therapy with focused ultrasound: Histological investigation in the normal rabbit brain

Vykhodtseva NI,<sup>\*</sup> McDannold NJ, Hynynen K, Radiology, Harvard Medical School/Brigham and Women's Hospital, Boston, MA

**Objective:** The aims of this study were to investigate histological effects in the brain after ultrasound-induced heating where the thermal dose was near the threshold for tissue damage; and to establish safety limits for thermal therapy in the brain.

**Methods:** Multiple 30-s sonications at different powers were delivered to 2–4 locations in 24 rabbit brains through a craniotomy. MRI temperature measurements were used as feedback to ensure that the accumulated thermal dose was near the threshold for tissue damage. A 16-channel sector vortex phased array (D/ROC=10/8 cm, f=1.63 MHz) generated the ultrasound. The acoustic power ranged from 1–20 W. At different time points after the experiments (2 h–5 d), the animals were sacrificed, and the brains removed, sectioned, and stained using H&E to detect tissue damage and TUNEL staining to detect apoptosis.

**Results:** Tissue damage was observed in 36/59 locations. The threshold lesions appeared as small (< 1 mm in diameter) vacuolated (spongy) areas. In most cases, there was mild vascular congestion, cellular shrinkage with nuclear pyknosis, and vacuolation at the margin at 4 h. These changes were further enhanced at 12–24 h. At 48–72 h, the treated areas showed coagulation necrosis with nuclear pyknosis and mild infiltration of polymorphonuclear leukocytes. Apoptotic cells were found in all affected regions. Marked infiltration of macrophages, necrosis, and vascular hyperplasia were observed at 5 d. In general, extravasation within the treated area was not significant. However, two lesions showed areas with large concentrations of erythrocytes, which appeared as amorphous masses at 4 h. Similar masses were also observed inside the dilated blood vessels. In five cases at 48 h, multiple hemorrhages and vascular necrosis within the central necrotic area were observed.

**Conclusions:** Our results indicate that near the threshold for thermal damage the vasculature may be affected first. In all cases, the damage resulted in necrosis, indicating the need for careful temperature monitoring of even near threshold level heating during thermal therapy.