Assessing cancer risk in 29 MHz micro-ultrasound images of the prostate: Creation of the PRI-MUS™ (prostate risk identification using micro-ultrasound) protocol

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Introduction & Objectives
A novel 29 MHz high resolution micro-ultrasound system (ExactVu™) has been developed enabling ~300% higher resolution than conventional TRUS systems for prostate imaging
• First clinical use of this platform is the detection of PCs during TRUS to guide prostate biopsies in real-time
• This study uses data from the first half of a randomized clinical trial1 to establish a newly developed protocol (PRI-MUS) for analyzing prostate micro-ultrasound images to better detect and grade cancer

Material & Methods
Cine loops of transrectal micro-ultrasound-guided (TRUS) biopsies were examined from an ongoing multicenter clinical trial1 of high-resolution TRUS vs standard TRUS for detection of clinically significant prostate cancer using the 29 MHz Exact Imaging system. Subjects underwent TRUS biopsy for suspicion of cancer due to PSA elevation and/or abnormal DRE. Features were identified and used to create the risk table (shown below). 3 of the 5 investigators who performed the blinded validation were familiar with the Exact Imaging system but naïve to the PRI-MUS protocol and received only 1 hour of PRI-MUS training.

Results
Ten sonographic features, confirmed by pathology to be malignant or benign tissue were identified during initial review. 6 features were significant when tested on the blinded data set. These features were incorporated into a 5-level PRI-MUS risk scale ranging from “Very low” (mean relative risk 0.28) to “Very High” (1.99) risk for clinically significant prostate cancer.

Validation results showed an AUC of 0.60 ± 0.02 over 5 independent reviewers. Each reviewer’s ability to detect clinically significant cancer using PRIMUS was significant at the p<0.01 level, and overall with p=0.0001.

Conclusions
• The resolution of micro-ultrasound, paired with the PRI-MUS protocol, shows significant promise in aiding real-time visualization of prostate cancer
• More significant disease (higher Gleason Scores) associated with higher PRI-MUS Risk Scores
• This first implementation of PRI-MUS will undergo ongoing refinement, including expansion to a multi-parametric micro-ultrasound approach incorporating functional scans for optimal diagnostic accuracy and a more direct comparison with MRI-based PI-RADS

References
1. Multi-Center Trial of High-resolution Transrectal Ultrasound (HITS) Standard Low-resolution Transrectal Ultrasound for the Identification of Clinically Significant Prostate Cancer, clinicaltrials.gov ID NCT02790252

* Please note that ExactVu micro-ultrasound system has not yet received FDA or CE approval, and is so is not yet available for commercial release.