Pilot Study of a Novel Fusion Algorithm for MRI-guided TRUS Prostate Biopsy

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Introduction and objective: Prostate cancer (PCa) is the second leading cause of cancer-related death in men in the U.S. Pathologic evaluation of biopsy samples remains the current clinical standard for diagnosing PCa. State-of-the-art image fusion-guided biopsy approaches that combine pre-biopsy diagnostic multi-parametric magnetic resonance (MR) imaging (mpMRI) with intra-procedure imaging, such as trans-rectal ultrasound (TRUS), has helped to improve detection of clinically significant PCa [1]. Here, we demonstrate an evaluation of a novel fusion methodology within the clinical environment and present quantitative and qualitative results.

Specific aims: The goal of this study is to prospectively evaluate the clinical impact of an updated fusion model to improve the accuracy of targeted prostate biopsy. We have developed an improved model for prostate motion during biopsy based on retrospectively collected data. In this study, we will attach an additional research laptop to the normal clinical system, and compare the results between the research and clinical devices prospectively.

Rationale and background: Deformable fusion methods are necessary to compensate for prostate shape changes caused by variations in patient orientation, changes in bladder volume or rectal filling, and the deformation caused by the TRUS probe. Current methods for fusion-guided biopsy rely upon accurate segmentations of the prostate gland in both the MR and the TRUS images. However, gland segmentation is a challenging task subject to high inter-rater variability. Therefore, robust and accurate fusion methods are necessary. We previously developed a novel fusion methodology for reliable, robust, and consistent fusion by learning a statistical model of intra-procedural deformation derived from retrospective clinical training data [2]. Synthetic experiments showed our statistical deformation model (SDM) was robust to segmentation errors.

Methods and materials: We performed a real-time prospective evaluation of our SDM fusion approach with a clinical Artemis (Eigen, Grass Valley, CA) biopsy system at our Institution. We integrated the SDM fusion into the current standard-of-care without altering the patient experience. First, targeted biopsy of the mpMRI-identified lesion regions of interest (ROIs) was performed using the standard Artemis fusion approach. Then, on a separate laptop, we ran our SDM fusion algorithm and visualized the ROI results on the Artemis display by transferring data across a shared network drive. Finally, 12-core systematic template biopsy was performed.

Results: We obtained consent from N=23 patients (Yale IRB-approved HIC #2000020925) with heterogeneous gland size (mean$\pm$SD) 52$\pm$29 cc and MR identified lesions with PI-RADS$\geq$3 scoring. A total of 34 lesion ROIs were identified with 15, 5, and 3 patients having 1, 2, and 3 lesions, respectively. We quantified the difference between the Artemis and SDM fusion approaches (Fig. 1) by calculating the centroid of each ROI and measuring the difference magnitude. The ROI difference between the two fusion methods (mean$\pm$SD) was 3.3$\pm$2.5 mm with minimum and maximum values 0.6 and 10.4 mm, respectively. Using relative change in gland volume between MR and TRUS segmentation as a surrogate for segmentation inaccuracy, we found weak correlation between percentage volume change and ROI centroid difference, $r = 0.16$. Qualitatively, the urologist noted that visual ROI agreement between the methods provided a level of confidence in the biopsy localization.

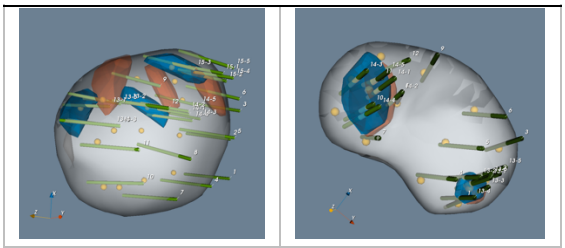

Figure 1. Fusion methodology visualization examples showing estimated lesion ROI locations from the Artemis system (blue) and from the proposed SDM method (orange) with recorded biopsy sample locations (green) and virtual targets (yellow). We show results with both poor (left) and good (right) fusion agreement.

Discussion and conclusion: In this prospective study without access to quantitative landmark ground-truth, e.g. cysts visible in MR and TRUS, both the Artemis our SDM fusion methods may be considered as two different fusion estimates. In this scenario, having more than one fusion estimate gave the urologist performing the biopsy a level of confidence in the fusion result. In the future, incorporating the pathology results and biopsy core locations for this dataset may elucidate quantitative fusion performance. Additionally, we aim to develop an optimal biopsy sampling strategy that incorporates fusion uncertainty.

References

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[2] J. A. Onofrey *et al.*, "Learning Non-rigid Deformations for Robust, Constrained Point-based Registration in Image-Guided MR-TRUS Prostate Intervention," *Med. Image Anal.*, vol. 39, pp. 29–43, Jul. 2017.