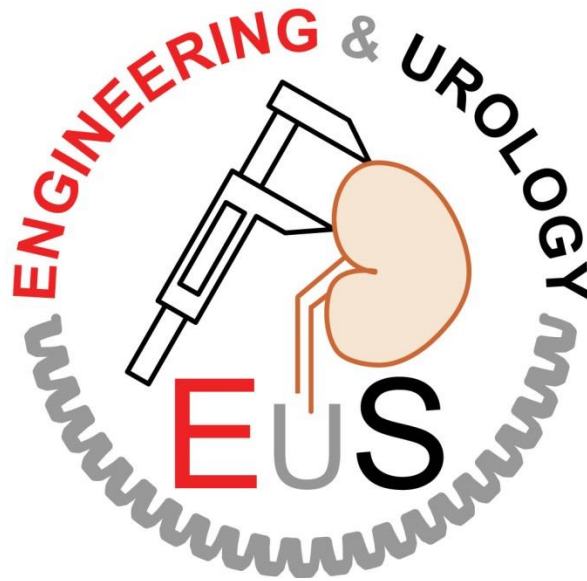


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PROSTATE BIOPSY PLAN PERSONALIZATION

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Introduction: Prostate cancer (PCa) diagnosis is made based on pathology results from core needle biopsy acquired under transrectal ultrasound guidance. Classic biopsy methods use a systematic biopsy (SB) approach with a 12-core template plan. More recent biopsy methods incorporated the fusion of ultrasound with MRI to target the biopsy (TB) based on MRI findings [[EUS2019](#), Abs.13]. In addition to TB, we have developed technology that personalizes the SB plan for the patient and executes the TB+SB plan digitally with a robot that handles the transrectal ultrasound (TRUS) probe. A Phase I clinical trial has commenced to 1) gain early evidence on the effectiveness of the TRUS-Robot in detecting PCa and 2) further optimize [[EUS2018](#) Abs.43] the biopsy plans based on the clinical data from the trial.

Methods: The robot is a hands-free TRUS probe manipulator, TRUS-Robot, that moves the probe with the same 4 degrees-of-freedom that are used manually [[EUS2017](#) Abs.34, [PMC30624210](#)]. However, it provides uniform 3D ultrasound scanning and accurate needle targeting based on the 3D ultrasound and fused MRI. The needle is guided on target by the robot and biopsy is performed manually, as usual. After the biopsy procedure, we perform offline SB simulations with various plans on data acquired from the robot cases. A SB optimization method and algorithm described in [[PMC27760001](#)] is used. In short, a “Capsule” (cylindrical shape with semispherical ends) is the prostatic volume-unit that a biopsy core samples the smallest clinically significant (csPCa) lesion (5cm³). To increase the probability of csPCa detection, the algorithm attempts to distribute the SB capsules so that together with the TB capsules they optimally fill the gland (like in a sphere packing algorithm), thus generating an optimized SB plan.

Results: Two biopsy plans optimized for the same patient are shown in Figure 1. Figure 1a shows the real TB+SB biopsy plan for this patient with 12 SB (blue) cores and 3 TB cores (red), for a total of 15 cores. Figure 1b shows a simulated plan with 16 SB cores, without TB. This includes the original 12 SB cores (blue) plus 4 additional (red) SB cores. The figures show that in this patient SB alone capsules could overlap TB locations by using just one additional core. In this example, however, the prostate volume was relatively small (35cm³).

Conclusion: Personalizing the SB plan for individual patients is feasible. It may also be feasible to make recommendations on the type of plan to be used. Once data from the trial accumulates, the results could be compiled in nomograms to make recommendations for the type of biopsy and number of biopsy cores in individual patients. We will also investigate how often optimized SB cores overlap TB locations and determine the lowest number of simulated personalized SB cores to yield noninferiority to the real TB+SB cores as a function of the prostate volume. If that number is less than or equal to the number of real SB+TB cores, personalized SB alone may be recommended. We plan to study whether SB alone could be offered more confidently to select patients, reducing the need for MRI, healthcare burden and expenses. Results would apply to transrectal as well as transperineal biopsy.

Disclosure: Authors DS, DP, MH and Johns Hopkins have a financial or other interest in this study. The results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins’ policies.

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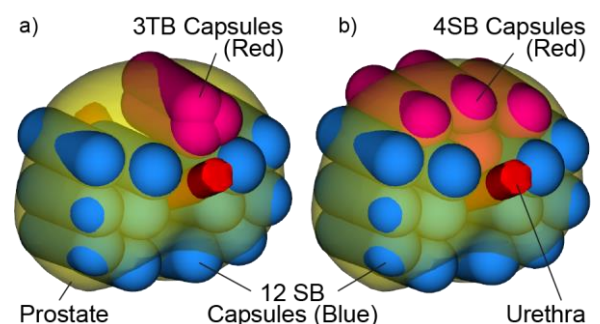


Figure 1: Biopsy plans:
a) 3TB and 12SB b) 12+4SB cores