

Electromagnetic Planning, Guidance and Feedback System Retrofitted to Prostate Biopsy Equipment and Validation

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Abstract— Objective: Design refinement and validation with simulated physical prostates of a planning, guidance, and feedback system for visualizing prostate biopsy in 3D perspective. **Methods:** A visualized prostate biopsy system (vPBx) using electromagnetic tracking of a transrectal ultrasound (TRUS) probe, a biopsy device, and a urinary catheter placed inside the patient’s prostate was refined and integrated as a reversible retrofit to a Flex Focus 400 ultrasound machine (BK Medical). The system was verified using simulated physical prostates with 12 0.065 ml (2.5 mm radius) spheres, arranged in a double sextant template, registered to a virtual model of the prostate and used to distinguish hits and misses. Systematic prostate biopsy (sPBx) was performed on simulated prostates using the vPBx as a retrofit to the TRUS machine. **Results:** The vPBx system enabled an inexperienced user to sample the sPBx template locations with a template deviation below 2.5 mm. **Conclusion:** An electromagnetic guidance system was refined, retrofitted with a Flex Focus 400 machine and a side-cut biopsy device (Max-Core Disposable Core Biopsy Instrument; Bard) and successfully validated with simulated physical prostates. **Significance:** If validated with patients, the vPBx system has the potential to reduce prostate biopsy false negatives, which may lead to earlier diagnosis of clinically significant prostate cancer and improved 10-year mortality in high risk prostate cancer patients.

Index Terms—3D perspective visualization, 6DOF electromagnetic tracking, biopsy, mixed reality.

I. INTRODUCTION

PROSTATE biopsy false negatives (PBxFN) occur when prostate cancer that is present is not sampled during prostate biopsy and the patient is incorrectly informed that he does not have prostate cancer. The incidence was reported as 21%-47% in a 2012 study [1] and likely remains high today. During COVID, a study to determine what cancer treatments can be safely delayed found that high-risk prostate cancer patients who waited 4-6 months before initiating treatment had a 4.6% increase in 10-year mortality compared to expeditious initiation of treatment [6]. In the US, a repeat prostate biopsy occurs at least 6 months after a negative prostate biopsy. If the initial

prostate biopsy was a false negative, initiation of treatment (assuming the repeat prostate biopsy does sample the lesion) will have been delayed by at least 6 months, with potential impact on 10-year mortality.

To improve the odds of sampling a suspected prostate cancer lesion when its location is unknown, a systemic prostate biopsy (sPBx) can be performed. An sPBx improves the odds of sampling a lesion by sampling 12 or more biopsy cores, evenly distributed within the prostate according to a template. These suggested biopsy locations are called template locations. The shortest distance, in millimeters, of the center of a biopsy core from its intended template location is the deviation, and the average of the deviations for all template locations is the template deviation [2]. When template deviation is high (>5 mm), the biopsy cores are unevenly distributed [3] and the risk of a prostate biopsy false negative increases. Current sPBx practice mainly uses the 2D information in the transrectal ultrasound (TRUS) screen without guidance to the template locations. This requires the operator to mentally perform complex spatial and psychomotor tasks such as mentally reconstructing the 3D prostate volume, estimating where the template locations are situated, orienting the TRUS probe to place the intended template location within the insonation plane, and determining how far to advance the biopsy needle tip before firing to place the biopsy core close to the intended template location.

It has been shown that sPBx is highly operator dependent and results in nonuniform distributions of cores. In one study, template deviation was 9 mm, leading to uneven distribution of cores [3]. We propose that lack of real-time guidance and feedback in terms of spatial positioning and core placement contribute to this problem. To facilitate sPBx, we refined a conceptual visualized prostate biopsy (vPBx) system [5] and retrofitted it to real prostate biopsy equipment. The vPBx integrates 6 degrees of freedom (6DOF) electromagnetic (EM) tracking of the TRUS probe, biopsy device, and prostate with an intuitive 3D-perspective visualization and user interface. The vPBx displays the template locations and uses cognitive aids to assist the user in accurately placing biopsy cores close

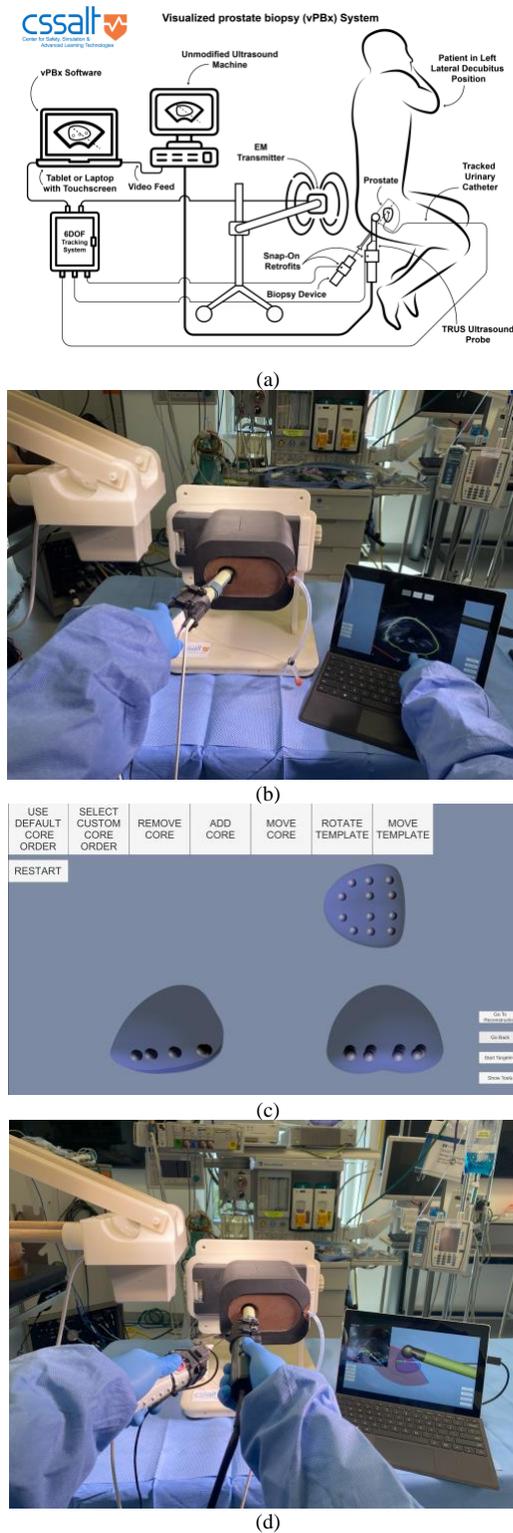


Fig. 1. (a) Schematic of vPBx system components, layout, and setup. An EM transmitter tracks 3 EM sensors: one in the probe, one in the biopsy device, and one in a urinary catheter inserted in the urethra. The vPBx software receives a live video feed from an unmodified BK FlexFocus 400. (b) User performing a reconstruction by tracing the prostate contour. (c) Template editing screen with 3 orthogonal views of the coarse segmented prostate. (d) User performing sPBx assisted by 3D perspective visualization and cognitive aids.

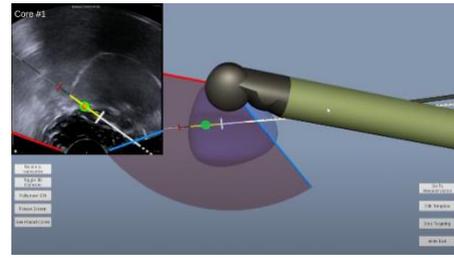


Fig. 2. Guidance screen of the vPBx software. The TRUS probe and insonation plane and the prostate are displayed in a 3D perspective visualization, with a duplicated 2D TRUS image. The cognitive aids can be seen in both: the 3D visualization and the duplicated 2D TRUS image.

to their intended template locations. After integration, we validated the accuracy of the vPBx retrofitted to actual prostate biopsy equipment by performing sPBx on physically simulated prostates and measuring template deviation physically and electromagnetically.

II. MATERIALS AND METHODS

A. Setup, Operation, and Function

Hardware was built for interfacing the vPBx to actual prostate biopsy equipment. A holder and supports for the EM transmitter (Mid-Range Transmitter; Northern Digital Inc) were designed and 3D printed. These were affixed to a mobile stand to allow placement of the transmitter facing the lower back of a patient in left lateral decubitus position. A side-cut biopsy device (Max-Core Disposable Core Biopsy Instrument; Bard) and a Prostate Triplane 8818 ultrasound probe (BK Medical) were fitted with removable, cleanable, reusable 3D-printed clamps which house 6DOF EM tracking sensors (Model 800 Sensor; Northern Digital Inc). An EM sensor was embedded in a urinary catheter (18 Fr dual balloon; Poiesis Medical), inserted through the simulated urethra, and lodged at the base of the prostate to track prostate position and movement. The vPBx set-up is shown in Fig. 1.

In anticipation of eventually using the vPBx system in clinical settings, we tested if ferromagnetic or metallic materials present during clinical prostate biopsy interfere with EM tracking accuracy. A clinical chair (Ritter 230 Procedure Chair; Midmark) and bed (Operon B810 Operating Table; Berchtold) introduced significant EM tracking offsets while the sensor was placed on the bed. With the sensor >65 mm above the bed and a transmitter-to-sensor distance of 140 mm, the offset due to EM interference was below the quoted accuracy of the EM tracking system (0.2 mm). For transrectal prostate biopsy, patients lay in the left lateral decubitus position, which elevates the procedure-relevant anatomy. These results indicate that, for a patient laying in left lateral decubitus position (Fig 1a), placing the transmitter at the small of the back will enable accurate tracking of the tracked biopsy equipment in the clinical setting. For other patient positions, we recommend using a nonmetallic MRI bed instead of a regular procedural bed.

Software for vPBx was developed in Unity and was based on two independent pre-existing components: a conceptual vPBx system and a tool to edit locations in sPBx templates [5]. A simplified version of the conceptual vPBx software was developed, replacing the simulated TRUS with a live video feed

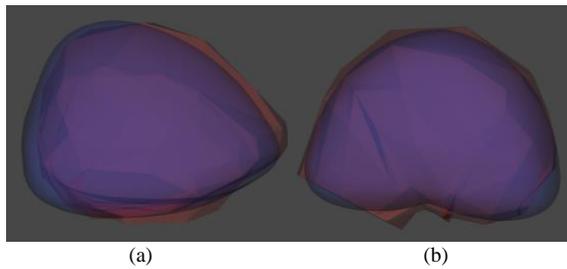


Fig. 3. Reconstruction (red) and ground-truth CAD model (blue). (a) Side view. (b) View of prostate base.

from an actual ultrasound machine (FlexFocus 400; BK Medical) at our urology clinic via a VGA cable and a video interface (AV.io HD; Epiphan Video) to a touchscreen laptop (Surface Pro 7; Microsoft). The template editing tool was integrated into the new software.

The operation of the vPBx system consists of 3 stages: reconstruction, template creation and editing, and guidance and feedback (Fig. 1).

After setting up the equipment and preparing the patient, the user first uses the sagittal or transverse plane to outline the contour of the prostate at different roll angles or TRUS probe depths respectively. This tracing and segmentation functionality was adapted from the vPBx simulator software [4], allowing the user to outline the prostate perimeter from the TRUS image for real-time segmentation. The collection of 2D contours is then compiled into a coarse, but usable, reconstructed 3D model of the prostate using a simple triangulation algorithm. The resulting reconstruction, as compared to the ground truth, can be observed in Fig. 3. If a region of interest (e.g., a shadow that might be a lesion) is visible in the TRUS image, it can also be segmented into a 3D object and will appear inside the segmented 3D prostate. An equivalent procedure can be used to reconstruct the urethra.

The coarse 3D model of the prostate is used to arrange the template locations inside it. Preset 6, 10, 12, or 14-core sPBx templates can be selected and modified by the attending clinician as needed. This includes moving, adding, deleting, and sequencing (order in which cores are taken) of the template locations, to optimize it to the patient anatomy, as well as placing one or more sampling locations in ROIs reconstructed in the previous step.

Once all the template and sampling locations have been arranged, the guidance mode can be activated and the software will display the sampling locations, one by one, in the prescribed sequence in the 3D visualization (Fig. 2). If the insonation plane intersects the intended template location, the template location will also be overlaid in the TRUS view as an external green sphere (5 mm diameter) with a concentric internal red sphere (4.5 mm diameter). The software provides cognitive aids to assist with guidance, displaying the needle with a stop line at its tip, the needle tip's maximum excursion line, and the predicted biopsy core location if the biopsy device is fired. These are displayed in the 3D visualization as well as an overlay in the live 2D TRUS video feed. To aim at the template location, the insonation plane should be aligned with the template location in the 3D visualization, and then the template location should be moved to be on the needle path

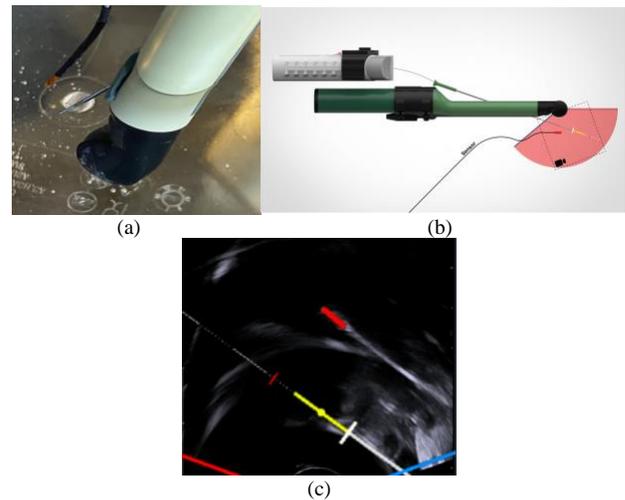


Fig. 4. Alignment of the insonation camera with respect to the real insonation plane. (a) Real ultrasound probe with needle inserted in guide and alignment sensor. (b) Diagram displaying the configuration and the positioning of the virtual insonation camera with respect to the ultrasound insonation plane. (c) Ultrasound image after insonation camera was aligned so that the virtual imaged objects align with their ultrasound images; virtual sensor in red can be seen aligned with its physical ultrasound image.

(dotted line) in the replicated TRUS screen. The insonation plane should cut through the center of the template location, and the smaller concentric red sphere aids the user in performing that operation. Once the probe is appropriately positioned, it should remain stationary while the needle is introduced until the yellow projected biopsy core is superimposed with the red core overlay, at which point the biopsy device may be fired.

B. Alignment

A virtual insonation plane is used to display the virtual needle and cognitive aids as an overlay to the live TRUS video feed. The TRUS video feed is generated by the physical insonation plane in the real ultrasound. In order for the cognitive aids and virtual needle to properly overlay to the live video feed, the virtual insonation plane needs to be aligned or collocated with the real, physical insonation plane.

To align the planes, the TRUS probe was placed in water to obtain a clear image (Fig. 4). An EM sensor was placed in the water so that it was in view of the physical and the virtual insonation planes. The physical sensor was viewable in the live ultrasound video feed, while the virtual sensor was viewable in the overlay. The virtual insonation camera was repositioned to make the overlay match the ultrasound image of the sensor, achieving alignment of the insonation plane.

Once the insonation plane was aligned, the virtual needle was aligned by a similar procedure. When the long flexible needle bends, as usually happens in clinical practice, the position of the needle tip can no longer be extrapolated from the EM sensor position at the biopsy device handle. To address this, we approximated the bent needle curve as 2 line segments, one from the biopsy device to the needle guide entrance and the other from the needle guide entrance to the needle tip.

To validate this approximation, the needle was introduced into the guide while the probe was kept in the water container, and an alignment EM sensor placed on the needle tip. It was visually observed that whenever the needle tip was beyond the

needle guide exit (i.e., the clinically relevant range), the TRUS image (1080 pixels \times 1080 pixels, 6.79 cm \times 6.79 cm) of the needle matched the virtual image.

This alignment process was done at development time and does not need to be repeated as long as the probe model, biopsy device model, or clamps housing the EM sensors are not changed.

C. Testing

A ground-truth anatomical representation was built, including an anus, a rectum, and a 25 ml prostate with a 12-core template embedded in a ballistic gel block. Molds to create prostates with embedded spherical (5 mm diameter) template locations were designed (Rhinoceros 3D) and 3D printed with a Mark Two printer (Markforged) using Onyx (Markforged), a micro carbon fiber, and nylon composite. The spherical template locations were separately cast as ballistics gel with a red color to physically differentiate a successful or accurate acquisition of the template location from a miss (Fig. 5). For testing, the assembled anatomical representation was affixed to a stand (Fig. 1c). The transmitter was placed near where the lower back of the patient would be.

The CAD model for the ballistic gel prostate and template locations was tracked by the EM sensor in the urinary catheter. The CAD model was used instead of the reconstructed prostate because, as opposed to a real patient, the ballistic gel prostate had materially distinct, predetermined template locations that needed to be sampled. In a real patient, template locations would be set by the clinician based on the reconstructed geometry, size and visible ROIs. Using the 3D visualization and cognitive aids, the template locations were biopsied. The deviation reported by the software as well as whether red gel was present in the sample was recorded.

III. RESULTS

During initial tests, not all cores had red gel. This was partly due to improper initial alignment of the CAD model with respect to the urinary catheter sensor and the sensor slipping within the urethra during the course of the procedure. This was addressed by an improved alignment using an alignment EM sensor and by firmly anchoring the sensor to the prostate and avoiding pushing, pulling or twisting the urinary catheter.

Once these factors were accounted for, the vPBx system allowed an inexperienced, nonclinical user to successfully perform a double-sextant (12-core) sPBx with a template deviation of 0.59 mm and a standard deviation of 0.23 mm, with a maximum deviation of 1.11 mm. A total of 14 biopsies were taken, 12 of which contained red gel indicating a hit on the spherical template location. The 2 misses had EM-reported deviations below 2.5 mm. One contained no core due to needle failure, while the other contained a white (no red) core. Fig. 5 displays the needle trajectories through the 12 template locations.

The technique was adjusted throughout the course of experimentation to minimize sources of error. General guidelines were developed to avoid needle bending and deviation and operator variability. The main technique considerations were as follows:

- 1) The bevel of the needle tip should face towards the rectal wall to avoid slipping, and that tip orientation should be maintained from needle insertion in tissue to when the biopsy device is fired.
- 2) The needle trajectory should be minimized to avoid excessive bevel-induced deviations.
- 3) After aligning the template location with the insonation plane, push or pull the TRUS probe to align the template location to the needle path (dotted line in TRUS image), with the needle tip inside but not protruding from the needle guide of the TRUS probe. Only introduce the needle tip into the prostate once the TRUS probe can be kept stationary.
- 4) Compensate for recoil before firing by manually bracing the biopsy device so it does not kick backwards.

IV. DISCUSSION

The results presented here, if replicated clinically, represent a significant improvement over the current standard practice. Accurately performing sPBx allows for more uniform distribution of cores within the prostate, and should reduce the rate of PBxFN by avoiding clustering of cores and undersampling of some prostate regions.

The 2 observed misses can be explained by artifacts of the anatomical model. The biopsy needle is not designed to biopsy ballistic gel and hence can sometimes fail to do so. The white sample had a deviation of 1.11 mm and, upon inspection of the needle trajectory, it was determined that the needle hit and pushed down the separate red template location, away from the notch in the side-cut biopsy needle. Since the template locations in a real patient are not materially distinct or separated from the surrounding tissue, that is not expected to happen in a clinical application of the vPBx system.

The main limitation of the vPBx system is that it is dependent on an environment with minimal EM interference if an MRI-compatible bed is not used. Additionally, the test results are

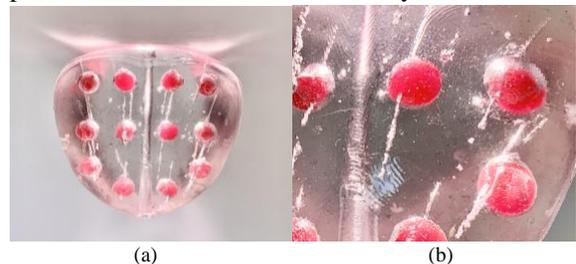


Fig. 5. (a) Needle trajectories through all 12 red template locations. (b) Close-up view of needle trajectories.

constrained by the accuracy of the anatomical model. In a clinical implementation of the device, an additional error would be incurred by the 3D reconstruction of the prostate, both in terms of geometric match and colocation with the physical anatomy.

V. CONCLUSION

A system for visualized PBx was refined, retrofitted to actual prostate biopsy equipment, and validated, facilitating accurate sPBx in simulated physical prostates. In clinical practice, this

system is expected to significantly reduce PBxFN and hence 10-year mortality rate in high risk prostate cancer patients [6].

We plan to apply for funding to use the vPBx retrofitted to prostate biopsy equipment in a clinical trial in consenting patients. We expect this clinical trial will help determine the clinical safety and efficacy of the vPBx.

Additional avenues for exploration include generalizing this technology to targeted prostate biopsy and transperineal prostate biopsy as well as other biopsies and procedures, by incorporating EM tracking, 3D visualizations and cognitive aid on top of the relevant imaging modalities.

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