2025 CMBEC47/ACCES26
Fredericton, NB
May 27-29, 2025
CMBES/SCGB

A Mechatronic Needle Guidance System for Prostate-Specific Positron Emission Tomography and 3D Transrectal Ultrasound-Guided Trans-perineal Prostate Biopsy

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Abstract—**Prostate cancer (PCa) is the most frequent cancer in men in Canada which the underlines importance of the development of new methods for diagnosis. The current study presents a mechatronic needle guidance system which is to be used in conjunction with a prostate specific PET (P-PET) system and 3D transrectal ultrasound (TRUS) for trans-perineal prostate biopsy. The system consists of a motorized 3D TRUS system for the generation of volumetric images, a tracking arm for targeting and a needle guidance device for needle placement and repositioning. The mechatronic needle guidance system includes a needle template which is capable of two-dimensional manual translation, and it helps in the alignment of the needle with the P-PET defined lesions in real time with the help of TRUS. To coordinate the biopsy, a functional and anatomic imaging from P-PET and 3D TRUS were co-registered with the help of a landmark-based registration method. The system was assessed using a phantom which was designed to simulate the prostate gland with artificial lesions and the outcomes indicated that the needle path planning and placement was accurate with a mean guidance error of 0.85 ± 0.22 mm. This innovation incorporates the 3D TRUS imaging technology and the P-PET functional information and the mechatronic needle guidance system for accurate and efficient needle placement. This paper aims at overcoming the challenges that are associated with 2D TRUS-guided techniques; hence it reduces false negative rates, the rates of repeat procedures, and improves the identification of the early stage and high-grade PCa. Further research will concentrate interoperability, on the enhancement of the needle system's guidance system to achieve better accuracy and the assessment of the system in clinical trials as a diagnostic and therapeutic tool in prostate cancer.**

Keywords— **transrectal ultrasound, prostate biopsy, positron emission tomography, needle guidance template, prostate cancer**

INTRODUCTION

Prostate cancer (PCa) is the most diagnosed cancer among men in Canada. While early-stage PCa has significantly higher survival rate compared to lung cancer at the early stage, early and accurate detection is crucial for expanding treatment options and improving outcomes, emphasizing the need for reliable diagnostic methods [1]. Image-guided prostate biopsy is crucial for PCa diagnosis, staging, and treatment planning, required highly sensitive and specific imaging for lesion detection and precise needle placement. Currently, 2D transrectal ultrasound (TRUS)-guided biopsy is the gold standard but has a high false-negative rate of 21–47% due to its inability to directly visualize cancer, leading to frequent repeat biopsies [2]. Additionally, transrectal biopsy carries infection risks, including sepsis, from rectal flora penetration. In contrast, trans-perineal biopsy reduces infection rates and improves access to anterior prostate zones, enhancing detection in hard-to-reach areas [3].

Advancements in imaging modalities like magnetic resonance imaging (MRI) and positron emission tomography (PET) offer promising solutions for improving diagnostic precision in PCa [4-5]. Specifically, PET is an effective functional imaging modality for detecting lesions and staging PCa, but its use for target localization in the prostate is limited to whole-body imaging, lacking the spatial resolution and anatomical guidance needed for accurate local staging and targeted biopsy, while often delivering higher radiation doses than ideal [6]. To address these challenges, the prostate-specific PET (P-PET) system (*Fig. 1*), developed by Radialis Medical Inc. and Lakehead University, integrates high-resolution imaging components tailored for prostate imaging, positioning detectors closer to the radiation source [7]. Its organ-specific design reduces radiation doses compared to standard PET/CT or PET/MRI systems while enhancing sensitivity and resolution, enabling detection of small, early-stage prostate tumors often missed by conventional PET. However, P-PET still lacks integrated anatomical reference and real-time visualization for precise needle guidance. To overcome these limitations, we propose integrating it with 3D TRUS-guided trans-perineal prostate biopsy. Unlike 2D TRUS, which captures only planar images and relies on operator-dependent mental reconstruction, 3D TRUS provides detailed volumetric imaging of the prostate [8]. Combining the anatomical imaging of ultrasound with the functional power of PET, this integration enables precise needle targeting by directly visualizing lesions in three dimensions. This study focuses on developing a novel mechatronic needle guidance system for P-PET and 3D TRUS-guided prostate biopsy. The system features a motorized 3D TRUS mechanism for volumetric imaging, a mechatronic needle guidance template for precise targeting, and integrated software for real-time image fusion and needle tracking. It validates the system's components and demonstrates their potential to enhance detection, guidance, and sampling accuracy for prostate cancer.

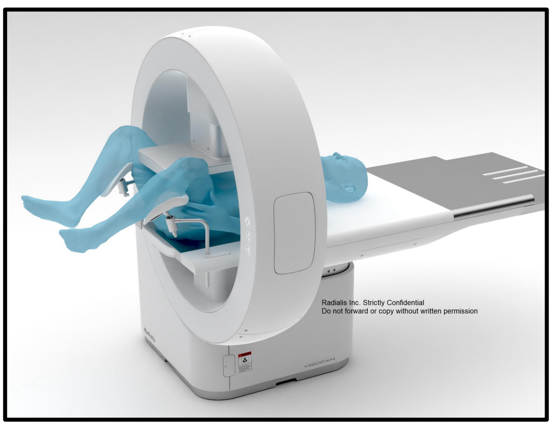

Figure 1: The proposed P-PET system model with patient positioning for prostate biopsy (Funded by CIHR grant-Reznik & Fenster).

METHODS

<u>System Description</u>

Our goal is to develop and integrate a P-PET with a 3D TRUS-guided prostate biopsy system featuring advanced robotic technologies, including a motorized 3D TRUS mechanism, a tracking arm, and a mechatronic needle guidance system. To achieve this, we adapted a motorized 3D TRUS mechanism, based on our previously developed MRI fusion prostate biopsy and gynecological brachytherapy systems *(Fig. 2A)*, for integration with the P-PET system *(Fig. 1)* [9-10]. The system is mounted on a motorized 3D TRUS mechanism for relative motion and integrated with a patient bed equipped with a computer and monitor to software interface. The system is specifically designed for trans-perineal access to the prostate, with the P-PET detector plates positioned for precise image-guided prostate biopsy. While the system is adaptable to any commercial ultrasound system, for preliminary testing, a ultrasound system (B-K Medical, MA, USA) with a side-firing US probe (5–7.5 MHz) was used. The motorized 3D TRUS mechanism includes a counter-balanced stabilizer with electromechanical (EM) brakes for precise control during biopsy. A motorized unit, or mover, rotates the TRUS probe around its long axis to collect 2D images, which are reconstructed into a 3D image in real-time. This allows complete viewing of the 3D TRUS image upon scan completion. The mechanical needle guidance system, carrying the motorized side-firing TRUS probe, is mounted against the perineum and designed for manual 2D movement and tracking, like prostate brachytherapy procedures.

The mechatronic needle guidance system prototype *(Fig. 2B)* also incorporates a tracking arm to ensure alignment and integration with the motorized 3D TRUS mechanism. The tracking arm is supported by a counterbalanced stabilizer for precise and controlled motion. A multi-jointed tracking arm facilitates image registration between the 3D TRUS and P-PET systems, ensuring alignment of coordinate systems and precise integration of functional and anatomical imaging. Each joint of the tracking arm is equipped with angle-sensing rotary encoders for real-time tracking of three-dimensional positions and orientations, along with EM brakes to lock the arm in place during prostate biopsy procedures. The mechatronic needle guidance system, designed to integrate with the motorized 3D TRUS mechanism, is mounted on the mover and counterbalanced arms, allowing six degrees of freedom for precise positioning and alignment during trans-perineal prostate biopsy. This system includes a needle template with multiple holes for accurate biopsy needle guidance. The template allows manual movement in two dimensions, enabling precise targeting and alignment under real-time 3D TRUS guidance. By combining these features, the system ensures accurate needle alignment with P-PET-detected target lesions, supported by 3D TRUS anatomical imaging and real-time tracking. This approach minimizes risks to surrounding structures, improves biopsy targeting accuracy, and significantly enhances diagnostic precision for prostate cancer.

The system's software modules, adapted from a previously developed 3D TRUS biopsy platform, were tested using phantoms prior to integration with the P-PET/3D TRUS software. These modules include 3D TRUS acquisition and scanning control, real-time 3D reconstruction, deep learning-based prostate and needle segmentation, 3D US display, and guidance software.

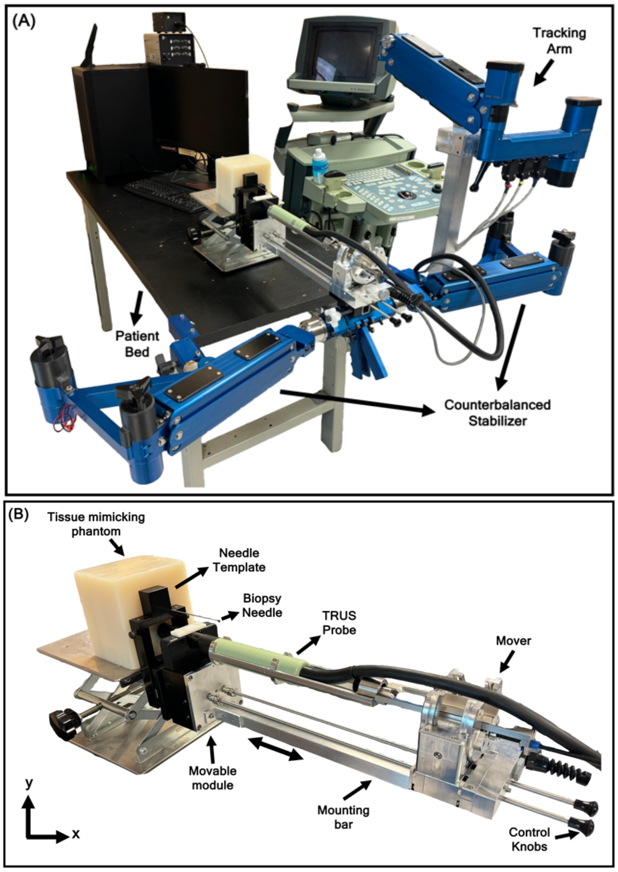

Figure 2: (A) Fully assembled 3D TRUS-guided biopsy system with needle guidance template, showing the patient bed, counterbalanced stabilizer, and tracking arm. (B) Mechatronic needle guidance system demonstrating movement capabilities. The double arrows indicate the 2D movement of the movable module along the X and Y axes and sliding back and forward on the mounting bar.

Integration of Coordinate Systems and System Workflow

The tracking arm is guided into removable calibration blocks mounted on the P-PET detector plate and the mover of the 3D TRUS mechanism. Using a landmark-based registration method, the coordinate systems of the P-PET and 3D TRUS are aligned to ensure precise integration of functional and anatomical imaging. The biopsy workflow, demonstrated with a tissue-mimicking phantom, begins with the insertion of the TRUS probe into the prostate phantom and the acquisition of a 3D TRUS image. Simultaneously, a 3D P-PET image is acquired, and the two modalities are overlaid during the P-PET acquisition to identify the target lesion. The system tracks the TRUS probe's position in real-time, ensuring alignment between the probe, the target lesion, and the needle guidance template. The TRUS probe is automatically rotated to align the 2D ultrasound image with the simulated lesion, while the needle template is manually translated in two dimension to position one of its holes over the target lesion. Finally, a biopsy needle is inserted through the aligned template hole, and the system fires the needle into the prostate phantom to collect a tissue sample.

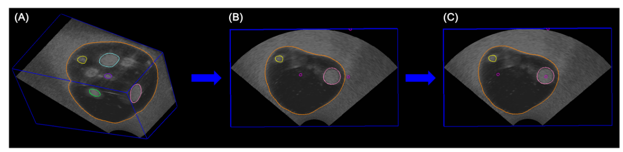

Figure 3: (A-B) Targeting workflow using the 3D TRUS-guided biopsy system. (A) 3D US image of the tissue-mimicking phantom with simulated tumor inclusions. (B) Front view of virtual needle template holes in the home position, with the light pink circle indicating the target and small pink circles showing template holes. (C) Virtual template hole aligned with the targeted inclusion.

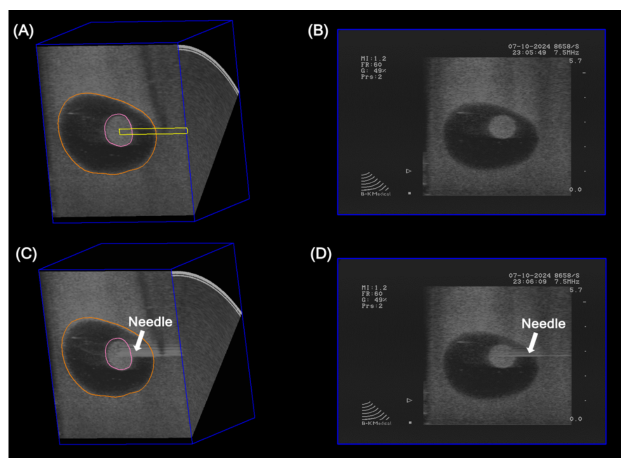

Figure 4: (A-B) Pre-needle placement 3D and 2D US images. (A) 3D US image showing the virtual needle path (yellow) aligned with the target through the template hole. (B) Corresponding 2D US image. (C-D) Post-needle placement 3D and 2D US images. (C) 3D US image showing the needle in the target area. (D) Corresponding 2D US image confirming needle placement.

Phantom Validation

The hardware and software of the 3D TRUS-guided prostate biopsy system were tested using a custom-designed prostate phantom mimicking tumor lesions embedded in tissue.

An agar-based tissue-mimicking phantom of a prostate model was fabricated that contained simulated tumor inclusions embedded in a surrounding agar background to provide texture. The inclusions in the prostate model and background were constructed by adding 7% by mass of glycerol solution with agar powder to produce a like that of human tissue is constructed similarly from a formulation published by Rickey et al [11].

RESULTS

First, the coordinate system calibration was conducted using in-house software, segmenting the prostate and inclusions *(Fig. 3A)* and the virtual needle template holes before needle insertion *(Fig. 3B-3C)*. Next, a software tool was developed showing the needle path through the aligned template hole targeting the inclusion, and the path was superimposed on the 3D US image. The target and insertion points were selected using the software interface. The created needle path in the 3D US image is shown in *Fig. 4A*. Finally, the biopsy needle was inserted through the selected template hole to the target point and tracked live on the 2D US image during the insertion. *Figure 4C* illustrates that the inserted needle is in the selected target in the 3D US image. The biopsy needle guidance error, defined as the distance between the needle track in the image and its planned position, was evaluated for five inclusions (r = 5mm), resulting in a mean guidance error of 0.85 ± 0.22 mm.

CONCLUSION

We successfully developed and tested a 3D TRUS-guided prostate biopsy system with a newly designed mechatronic needle guidance system using a tissue-mimicking phantom and in-house software. Once completed, this system, integrated with a P-PET system, is expected to reduce false-negative rates, minimize repeat procedures, and improve the detection and targeting of early-stage, high-grade PCa. This study introduces the world's first 3D TRUS-guided prostate biopsy system integrated with a P-PET system, advancing PCa diagnostic capabilities beyond traditional 2D TRUS techniques by combining advanced PET imaging with precise 3D US technology and robotic needle guidance. Additionally, the system offers a cost-effective and accessible diagnostic tool compared to traditional PET/CT and PET/MRI systems, potentially making a significant impact on the healthcare system. The next steps include registering the 3D TRUS-guided biopsy system with the P-PET system, performing needle segmentation from ultrasound images, and co-registering them with the P-PET images using custom software. Tissue-mimicking phantoms will be used to quantify the error in guiding needles to P-PET-identified targets. Ultimately, the goal is to validate the system's effectiveness in a clinical trial involving patients.

ACKNOWLEDGEMENTS

This study was funded by Western University, the Ontario Institute for Cancer Research (OICR), the Canadian Institutes of Health Research (CIHR), and the Natural Sciences and Engineering Research Council of Canada (NSERC). This work has not been submitted for publication elsewhere.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

REFERENCES

[1] Brenner DR, et al. "Projected estimates of cancer in Canada in 2022." *CMAJ*. 2022;194(17):E601-E607.

[2] Downs TM, et al. "Transrectal Ultrasound-Guided Prostate Biopsy." *Image-Guided Diagnosis and Treatment of Cancer. Humana Press*; 2003:3-33.

[3] Taira AV, et al. "Performance of transperineal template-guided mapping biopsy in detecting prostate cancer." *Prostate Cancer Prostatic Dis*. 2010;13(1):71-77.

[4] Ceci F, Fanti S. "PSMA-PET/CT imaging in prostate cancer: why and when." *Clin Transl Imaging*. 2019;7:1-3.

[5] Barbosa FG, et al. "Clinical perspectives of PSMA PET/MRI for prostate cancer." *Clinics.* 2018;73,suppl 1:e586s.

[6] Liu, Chen, et al. "68Ga-PSMA PET/CT combined with PET/ultrasound-guided prostate biopsy can diagnose clinically significant prostate cancer in men with previous negative biopsy results." *Journal of Nuclear Medicine* 61.9 (2020): 1314-1319.

[7] Stiles, Justin, et al. "Evaluation of a high-sensitivity organ-targeted PET camera." *Sensors* 22.13 (2022): 4678.

[8] Fenster, Aaron, Donal B. Downey, and H. Neale Cardinal. "Three-dimensional ultrasound imaging." *Physics in medicine & biology* 46.5 (2001): R67.

[9] Rodgers J, et al. "A semiautomatic segmentation method for interstitial needles in intraoperative 3D transvaginal ultrasound images for high-dose-rate gynecologic brachytherapy." *Brachytherapy.* 2020;19(5):659-668

[10] Cool DW, et al. "Comparison of prostate MRI-3D transrectal ultrasound fusion biopsy for first-time and repeat biopsy patients." *Can Urol Assoc J.* 2016;10(9-10):342-348.

[11] D.W. Rickey, P.A. Picot, D.A. Christopher, and A. Fenster, "A Wall-less Vessel Phantom for Doppler Ultrasound Studies," *Ultrasound in Med. & Biol* 21(9), pp.1163-1176, 1995.