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Clinical Study

Development of a Custom 7-Degrees of Freedom Robotic Prostate Fusion Biopsy System Using 3-Point Volumetric Coregistration: Technical Description and Initial Clinical Feasibility

Aykut Recep Aktas MD [a], Mustafa Cetin MD [c], Ali Erhan Eren MD [d], Burak Yangoz MD [c], Atakan Aktas CE [b], Bugrahan Musa Ayvali CE [e], Murat Savas MD [d] Show more

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Abstract

Purpose

To introduce a 7-Degrees of Freedom (DOFDOF) robotic prostate biopsy system utilizing a "3-point volumetric fusion" algorithm and evaluate its clinical feasibility and comparative diagnostic yield against standard systematic biopsy.

Materials and Methods

A prospective analysis was conducted on 48 biopsy-naïve patients with mpMRI lesions (Prostate Imaging Reporting and Data System ≥3) biopsied using a proprietary 7-DOF robotic system. The software integrates pre-operative MRI with real-time transrectal ultrasound (TRUS) using three internal anatomical landmarks to compensate for organ deformation. Patients underwent Robotic Targeted Biopsy (TB) followed by a 12-core Systematic Biopsy (SB) performed via the robot's joystick control. Primary outcomes were Overall Cancer Detection Rate (CDR) and quantitative tumor burden.

Results

Prostate cancer was detected in 23 (47.9%) of 48 patients (mean age 64.5 years, PSA 7.2 ng/mL). The cancer detection rate was 47.9% for TB and 43.8% for SB, with a *P*-value of .48, indicating no statistically significant difference. In cancer-positive cases, the mean tumor involvement in Robotic TB cores was 68.5%, which was significantly greater than the 31.4% observed in Systematic SB cores ($P < .01$). Cancer was detected exclusively by Robotic TB in two biopsy-naive patients (8.7%) harboring anterior lesions.

Conclusions

The 7-DOF robotic system demonstrated high safety and clinical feasibility. Consistent with the established advantages of image guidance, the targeted approach yielded substantially higher tumor volume samples than systematic biopsy.

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Abstract

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Abbreviations

DOF, degree of freedom; IRB, institutional review board; ISUP, International Society of Urological Pathology; MR, magnetic resonance; PI-RADS, Prostate Imaging Reporting and Data System; PSA, prostate-specific antigen; SB, systematic biopsy; STARD, Standards for Reporting of Diagnostic Accuracy; TB, targeted biopsy; US, ultrasound

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Study Design and Population

This prospective, single-center, exploratory feasibility study was conducted between April 2025 and January 2026, following institutional review board (IRB) approval. The study was structured and reported in accordance with the Standards for Reporting of Diagnostic Accuracy (STARD) guidelines. A total of 52 patients were initially screened. Patients were indicated for biopsy based on elevated prostate-specific antigen (PSA) levels or abnormal digital rectal examination, followed by an mpMRI …

Clinical Characteristics

The final cohort consisted of 48 patients. A STARD flowchart detailing patient selection is provided in Figure 3. The mean age was 64.5 ± 8.2 years. The mean serum PSA was 7.2 ± 4.5 ng/mL, and the mean prostate volume was 53.5 ± 18.2 cc. Patients diagnosed with cancer had significantly higher PSA density (0.23 vs 0.12 ng/mL/cc, $P < .001$) and smaller prostate volumes (48.0 vs 62.0 cc, $P = .048$) compared to the benign group (Table 1). The difference in patient age (66.0 vs 63.1, $P = .220$) and …

Discussion

The evolution of prostate cancer diagnosis relies heavily on accurate spatial registration. While software fusion improves cancer detection, transrectal approaches remain limited by non-linear organ deformation and the geometric constraints of the anal sphincter. This exploratory study evaluated the clinical feasibility of a l 7-DOF robotic platform utilizing 3-point volumetric co-registration, assessing the comparative diagnostic yield of targeted versus systematic sampling intent executed via …

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None of the authors have identified a conflict of interest.

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