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Step-by-Step

Robot-assisted MRI/US fusion transperineal prostate biopsy using the Biobot system: a single-centre experience

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Keywords

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Introduction

Treatment decisions for prostate cancer (PCa) still rely on histological confirmation from a biopsy [1]. In today's precision medicine era, cutting-edge technologies are revolutionising clinical practice. Although the potential of robotic surgery in urology is widely acknowledged, the possibility of robot-assisted prostate biopsies (RA-PBx) remains largely unexplored [2].

Newly available RA-PBx systems, such as the Biobot Mona Lisa (Biobot Surgical, Singapore), combine robotic precision with the transperineal approach, offering accurate PCa mapping, efficient site storage, and potential benefits for focal treatments [3,4]. Moreover, they promise lower complication and infective rates, as well as improved patient comfort by enabling a minimally invasive sampling process that requires only two puncture sites [5–7].

This study aims to demonstrate the RA-PBx process using the Biobot platform and to evaluate its feasibility and safety.

Material and Methods

Patient Population

Between July 2023 and July 2024, 44 consecutive patients with suspected PCa underwent a transperineal RA-PBx using the second generation of the Biobot MRI/TRUS fusion system.

If clinically feasible, multiparametric MRI (mpMRI) was performed on patients prior to the biopsy. mpMRI was conducted and analysed according to the Prostate Imaging Reporting and Data System (PI-RADS)-v2 classification system [8].

Biobot Robotic Platform

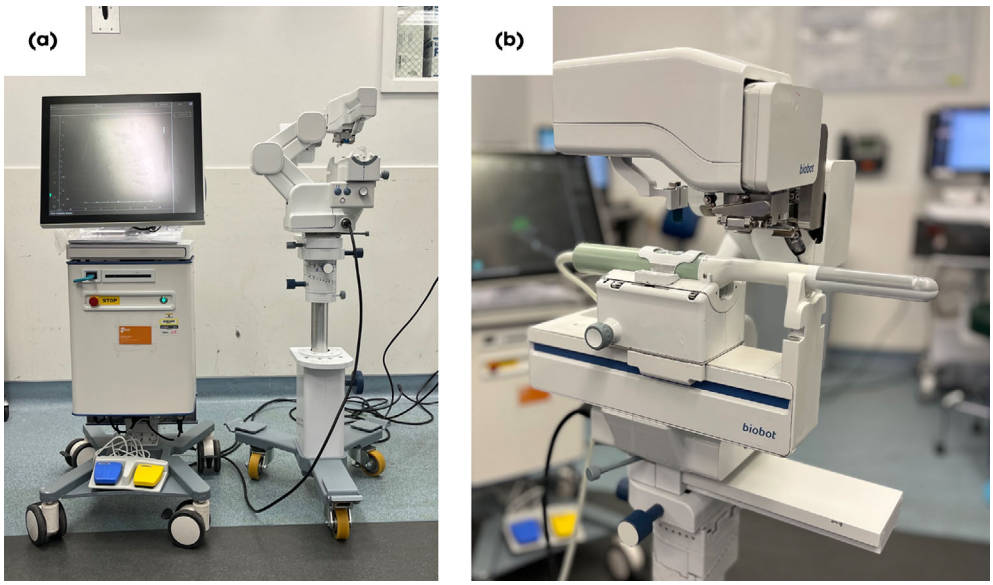
Before RA-PBx, both the prostate and the target lesions identified on MRI are segmented in the Biobot software. On the day of the biopsy, the patient is placed in the lithotomy position under sedation or general anaesthesia with laryngeal mask and receives antimicrobial prophylaxis. The Biobot system is then set up. This system requires an external ultrasound device; in this study, the BK 5000 ultrasound system with the 9048 high-resolution biplane transducer (BK Medical, Burlington, MA, USA) was used.

The Biobot system consists of two main components: the control system and the robotic arm. The control system, operated via a touch-screen monitor, allows for biopsy planning and continuous monitoring of the procedure. The software-controlled robotic arm, with its multiple joints, first facilitates manual positioning of the ultrasound probe in the patient's rectum to achieve an optimal view of the prostate, followed by RA-PBx execution (Fig. 1).

The software guides the surgeon through several steps, starting with setting the prostate's apical and base limits. It then scans the prostate every 0.5 mm to generate a three-dimensional ultrasound visualisation. After segmentation, the surgeon can refine the model by adjusting the segmentation markers.

Once the ultrasound segmentation is complete, the software generates an elastic fusion between the ultrasound-segmented prostate and the MRI-segmented prostate, displaying the target lesion on the ultrasound images. The biopsy planning process allows for the definition of three different levels of cores:

Fig. 1 The Mona Lisa system. (**a**) The control system with a touch screen and pedals on the left side, and the robotic arm mounted on its support on the right side. (**b**) Close-up of the robotic arm with the ultrasound probe positioned.



- Target cores (T). The system automatically samples the target area with the appropriate number of cores.
- Systematic cores (C). These cores are used to sample the perilesional area and must be manually placed in the appropriate location.
- Saturation cores (S). A variable number of cores are placed to randomly sample the prostate. The system adjusts the number and depth of biopsy cores based on prostate size to ensure comprehensive sampling from the apex, mid-prostate, and base.

Once biopsy planning is complete, the system positions the device to align the biopsy needle track with the target area specified in the software, using the skin as the centre of rotation. The clinician manually inserts the biopsy needle (Bard Max Core, Tempe, AZ, USA) to the required depth defined by the system without requiring any needle or sheath and acquires the biopsy sample. The system autonomously adjusts the needle's angle and depth to ensure precise and reproducible biopsies. Unlike techniques that use a coaxial needle, this system punctures the skin for each biopsy sample. However, the procedure is still completed with only two perineal access points, one per hemigland (see accompanying Video S1).

Biopsy Review and Pathological Correlation

When the pathological results become available, a dedicated software platform facilitates the review of the biopsy findings. By selecting the positive tumour cores, the system visually displays these cores within the prostate (Fig. 2). This enhances understanding of the tumour's location, which can be valuable for planning future focal treatments if clinically indicated.

Data Collection and Statistical Analysis

Data were retrospectively collected. For each patient, demographic information, urological history, MRI data, biopsy details, peri-operative complications, and treatment actions were recorded. Data are presented as medians with interquartile ranges for continuous variables and as relative frequencies for categorical variables.

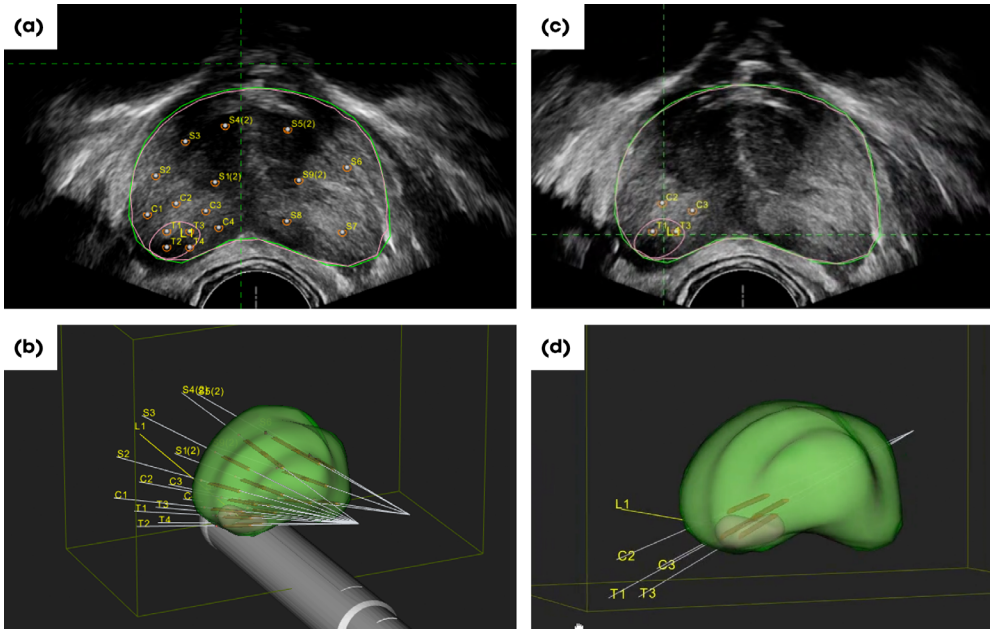
Results

The study included 44 patients with a median (IQR) age of 64.5 (58.7–70) years and a median (IQR) PSA level of 8.35 (5.57–10.97) ng/mL. Of these, 22 patients were biopsy-naïve, six underwent biopsy due to persistent clinical suspicion, nine had confirmatory biopsies following previous random sampling and seven were biopsied within an active surveillance setting.

Preoperative mpMRI indicated suspicious areas in 37 patients, was negative in four patients and was not conducted in three patients due to the presence of MRI-incompatible implants.

Targeted biopsies diagnosed PCa in 21 patients. Additionally, PCa was identified in five patients with initially negative targeted biopsies through randomised core biopsies. Of these five patients, four had International Society of Urological Pathology (ISUP) grade 1 PCa with less than 20% core involvement, and one had ISUP grade 2 tumours with 30%

Fig. 2 Biopsy planning and revision. (**a**) Transrectal ultrasound scan of the prostate, showing the segmentation and definition of the cores' positions. (**b**) Three-dimensional (3D) visualisation of the prostate with the planned cores. The elastic fusion system can be assessed by comparing the ultrasound segmentation (pink) with the MRI segmentation (green). The target lesion is indicated in red on the right side of the prostate. (**c**, **d**) Ultrasound and 3D visualisation of the cores with prostate cancer. Core nomenclature: T = target cores; C = perilesional cores; S = systematic cores.



core involvement. In the seven patients who underwent systematic biopsy only, three cases of ISUP grade 1 and two cases of ISUP grade 2 were detected.

Pathology revealed normal prostatic tissue in 10 patients and high-grade prostatic intraepithelial neoplasia in three patients. PCa was found in 31 patients, with most cases being ISUP grade 1 (12/31) and ISUP grade 2 (9/31).

The median procedure time per patient was 31 min, including 3 min for ultrasound prostate scanning, 5 min for prostate modelling on the ultrasound scan, 7 min for biopsy planning and 16 min for biopsy execution. Procedure time progressively decreased with increased experience. No technical issues were encountered during the 44 procedures.

No intra-operative complications were recorded, but one postoperative case of acute urinary retention associated with a UTI was observed. This Clavien–Dindo grade 2 complication was successfully treated with catheterisation and antibiotic therapy.

Discussion

This study has several limitations. First, the sample size was small, and the lack of a control group limits direct comparisons with other biopsy techniques. Second, while the Biobot system demonstrated high reliability and effectiveness in this preliminary study, its performance relative to state-of-the-art non-robotic MRI fusion platforms remains to be fully evaluated.

Concerns may arise regarding the cost implications and time efficiency of the procedure compared to standard techniques. Although the median procedure time was 31 min, future studies should assess whether the learning curve and robotic assistance justify potential additional costs.

It is also worth noting that the system currently lacks the capability for automatic prostate segmentation, and any patient movement requires manual repositioning of the device.

In conclusion, although preliminary, these data highlight the effectiveness and safety of the Biobot robotic system in assisting urologists with prostate biopsies. The system's high detection rate for clinically significant PCa and the absence of major technical issues underscores its reliability. Additionally, the precise PCa mapping and the ability to store and quickly revisit biopsied sites suggest potential benefits for focal treatments. Further research is warranted to compare this biopsy technique to more established ones and to better define its role in the current prostate biopsy armamentarium.

Disclosure of Interests

Srinivas Vourganti has received a training grant from Biobot Surgical, which supports educational or research activities related to training in the use of their technology. Additionally, he is a consultant for the development of the

Biobot system for use in focal therapy procedures. There are no conflicts of interest for any of the other authors.

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Abbreviations: ISUP, International Society of Urological Pathology; PCa, prostate cancer; RA-PBx, robot-assisted prostate biopsy.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. Step-by-step biopsy execution and preliminary results.

