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Ethical Approval

Not applicable as publicly available data were investigated.

Data Availability Statement

The datasets used during the current study are available to bona fide researchers from the corresponding author on reasonable request.

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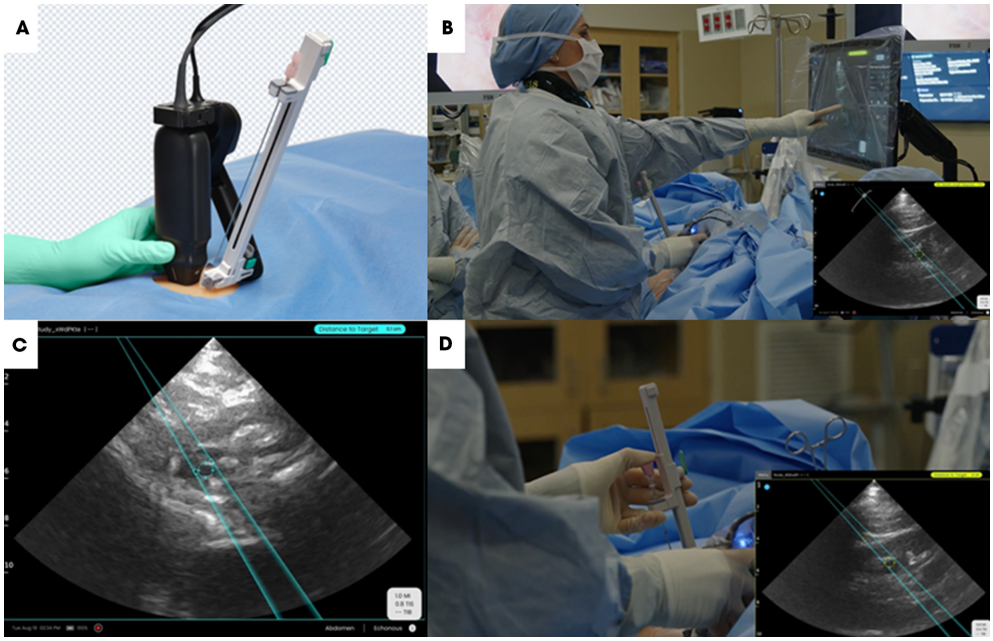
Robot-assisted ultrasound-guided PCNL: initial experience in 10 consecutive cases

Percutaneous nephrolithotomy (PCNL) remains the 'gold standard' for the management of large and complex renal calculi, with renal access representing the most technically demanding and morbidity-defining step of the procedure [1,2]. Although fluoroscopy has traditionally guided access, ultrasound offers advantages including real-time visualisation of the collecting system and adjacent structures while avoiding ionising radiation [3,4]. Despite these benefits, adoption of ultrasound-guided access has been limited by technical challenges, a steep learning curve, and variability in operator experience [5]. We report the first clinical experience worldwide using a robot-assisted ultrasound platform to facilitate percutaneous renal access during PCNL.

This prospective observational study included 10 consecutive patients undergoing PCNL with attempted robot-assisted ultrasound-guided access at a single academic centre between August and September 2025. Patients were not selectively chosen for device use. Institutional Review Board approval was obtained, and the study was deemed exempt. All cases were supervised by a fellowship-trained endourologist, with renal access performed by attendings, fellows, or chief residents following structured simulation-based training on the platform.

The Focalist™ system (Mendaera, Inc., San Mateo, CA, USA), a robot-assisted, handheld ultrasound device, is a novel platform designed to facilitate urologist-performed ultrasound-guided access. The system consists of a bedside, handheld robotic arm that attaches to a phased-array ultrasound probe and interfaces with a touchscreen console. The software allows on-screen target selection, automated needle alignment, and real-time needle-tip tracking within the ultrasound plane. After sterile setup and mapping scans to identify the target calyx and adjacent at-risk structures, an 18-G access needle was advanced manually under continuous

Fig. 1 Robot-assisted ultrasound-guided percutaneous renal access workflow. **(A)** Probe-mounted robotic arm stabilising and aligning the access needle. **(B)** Target calyx or papilla selected on the touchscreen interface with the probe stabilised at the flank. **(C)** Manual needle advancement under continuous ultrasound guidance with real-time needle-tip and trajectory tracking displayed on the console. **(D)** Collecting-system entry confirmed by direct ureteroscopic visualisation using an endoscopic combined approach.



ultrasound visualisation. Once collecting system entry was confirmed, standard wire placement, tract dilatation, and stone treatment were performed without deviation from institutional PCNL technique. The robot-assisted ultrasound-guided access workflow is shown in Fig. 1.

The 10 renal accesses were analysed, including one bilateral case. The mean (range) patient body mass index was 29.9 (17.5–44.6) kg/m^2. Stone locations included renal pelvis (three), lower pole (two), upper pole (two), and complete staghorn calculi (two). All procedures were performed prone. Eight cases used standard 24-F tracts and two were mini-PCNLs with 18-F tracts.

Device-assisted renal access was successful in eight of 10 renal units (80%). First-attempt success occurred in six cases, with a mean of 1.6 needle passes. Papillary access was achieved in seven of 10 renal units overall and in seven of eight cases where device-assisted access was successful. The mean (SD) time from final target selection to needle entry into the collecting system was 19 (17) s, with a mean (SD) needle insertion time of 14 (19) s. The mean (SD) total operative time was 64.0 (19.2) min.

Two cases required abandonment of the robotic platform. In one patient with complex anatomy and no hydronephrosis, access could not be achieved using either robot-assisted or conventional ultrasound and was completed fluoroscopically onto a radiopaque calculus. In another patient with a high-riding, malrotated kidney, a safe needle trajectory could not be established while simultaneously visualising adjacent structures, prompting conversion to standard ultrasound guidance.

Radiation exposure was minimal across the cohort, with a mean (SD) fluoroscopy time of 15.5 (23.7) s and mean (SD) cumulative air kerma of 5.5 (11.3) mGy, consistent with prior reports demonstrating reduced radiation with ultrasound-guided access [3,4]. No device-related complications occurred, and there were no intraoperative or immediate postoperative adverse events. Postoperative CT was available in six renal units, five of which were stone-free.

Usability surveys completed by operating room personnel demonstrated favourable acceptance. The mean Likert scores (1–5) were 5.0 for ease of setup, 4.1 for ease of use, and 4.6 for confidence in needle placement. Operators reported smooth workflow integration without delays, with particular value placed on continuous needle-tip tracking and the ability to make real-time trajectory adjustments without probe repositioning. Preservation of tactile feedback during collecting system entry was felt to be beneficial, particularly for trainee education.

This study demonstrates the first-in-world clinical experience demonstrates that robot-assisted ultrasound-guided renal

access during PCNL is feasible and safe in a real-world training environment. Consecutive, non-hand-selected patients were included, and access was successfully achieved by surgeons across varying levels of experience, addressing known barriers to urologist-directed access [5,6]. Although the success rate reflects an early learning phase, performance metrics, minimal radiation exposure, and absence of complications are encouraging.

Several limitations were identified. The phased-array probe's restricted field of view occasionally limited simultaneous visualisation of adjacent structures during needle descent, particularly for high intercostal or upper-pole access. Image quality was variably affected by rib attenuation, and system-suggested needle trajectories were not always optimal for tract geometry, underscoring the continued importance of operator judgement. These factors contributed to the two unsuccessful device-assisted cases and represent areas for future software and hardware refinement.

In summary, robot-assisted ultrasound-guided renal access using this platform was successfully performed in the majority of cases, with minimal radiation exposure and no observed complications. These preliminary findings support further evaluation in larger comparative studies to define safety, efficacy, learning curves, and cost-effectiveness.

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Disclosure of Interests

The authors declare no conflicts of interest related to this study.

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Abbreviation: PCNL, percutaneous nephrolithotomy.

Deep early tumour shrinkage in metastatic upper tract urothelial carcinoma treated with enfortumab vedotin plus pembrolizumab

For decades, tumour response to systemic therapy has been evaluated using the Response Evaluation Criteria in Solid Tumours (RECIST), later adapted to RECIST version 1.1 (RECIST 1.1), which were originally developed and validated in cohorts primarily treated with conventional chemotherapy [1,2]. With the advent of immunotherapy, these criteria were adapted to iRECIST to account for phenomena such as pseudo-progression [3].

However, in metastatic urothelial carcinoma (UC) systemic therapy has evolved beyond chemotherapy and immune checkpoint inhibition in recent years. The current standard of care combines the antibody–drug conjugate enfortumab vedotin with the immune checkpoint inhibitor pembrolizumab (EV + P) [4], a regimen that profoundly alters treatment dynamics.