Robotic Flexible Ureteroscopy for Renal Calculi: Initial Clinical Experience

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Purpose: We report what is to our knowledge the initial clinical experience with remote robotic ureterorenoscopy and laser lithotripsy for renal calculi using a novel flexible robotic system.

Materials and Methods: After institutional review board approval and informed consent 18 patients with renal calculi underwent flexible robotic ureteroscopy. Study inclusion criteria were 5 to 15 mm renal calculi. Patients with ureteral calculi or obstruction, uncontrolled infection, renal insufficiency or solitary kidney were excluded from analysis. The flexible robotic catheter system was manually introduced into the renal collecting system over a guidewire under fluoroscopic control. All intrarenal maneuvers, including stone relocation and fragmentation into 1 to 2 mm particles, were done exclusively from the remote robotic console.

Results: All procedures were technically successful without conversion to manual ureteroscopy. Mean stone size was 11.9 mm, mean robot docking time was 7.3 minutes, mean stone localization time was 8.7 minutes, mean total robot time was 41.4 minutes and mean total operative time was 91 minutes. The mean visual analog scale rating on a scale of 1—worst to 10—best was 8.5 for robotic control, 9.0 for stability and 9.2 for fragmentation ease. There were no intraoperative complications. Postoperative complications included transient fever in 2 cases and temporary limb paresis in 1. One patient required secondary percutaneous nephrolithotomy for residual stone. Based on computerized tomogram/excretory urogram the complete stone clearance rate at 2 and 3 months was 56% and 89%, respectively. At 3 months all patients had stable renal function and unobstructed drainage.

Conclusions: We present a novel flexible robotic platform for retrograde ureteroscopic treatment for intrarenal calculi. Initial experience is encouraging.

Key Words: kidney, kidney calculi, endoscopy, robotics, instrumentation

Abbreviations and Acronyms

CT = computerized tomography

IVP = excretory urography

KUB = plain x-ray of kidneys, ureters and bladder

MID = master input device

RCM = remote catheter manipulator

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Study received institutional review board approval.

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ONGOING refinements in flexible ureteroscope technology, accessories and Ho:YAG laser lithotripsy have led to a widespread increase in the use of flexible ureteroscopy to treat small to medium renal calculi.[1,2] The ability to directly visualize a stone and relocate it to a favorable site for adequate fragmentation and subsequent drainage is an attractive advantage of flexible ureteroscopic laser lithotripsy for renal calculi. Efforts are ongoing to further improve deflection, enhance maneuverability and improve optical performance of current actively deflectable flexible ureteroscopes.[3]

Recently the novel flexible Sensei® robotic catheter system was introduced for intracardiac applications. After making purpose specific software modifications we evaluated the technical feasibility and efficacy of this novel flexible robotic system for flexible ureterorenoscopy and Ho:YAG laser lithotripsy in the animal model.[4] We report the results of what is to our knowledge the first human technical feasibility trial using the flexible robotic system for ureteroscopic laser lithotripsy in 18 patients with renal calculi.

MATERIALS AND METHODS

After obtaining institutional review board approval 18 patients with renal calculi were enrolled for robotic flexible ureteroscopic laser lithotripsy for renal calculi. Patients with 5 to 15 mm renal stones were included in the study. Exclusion criteria included concomitant ipsilateral ureteral calculi, ipsilateral ureteral stricture or obstruction, documented active urinary tract infection, baseline renal insufficiency, a solitary kidney and anatomical renal anomalies. Although patients with bilateral renal calculi were included in analysis, only 1 side was treated using the robotic system. Contralateral calculi were treated as needed using conventional modalities at a separate session.

All patients underwent preoperative baseline hematology, serum biochemistry and urine culture sensitivity tests, noncontrast spiral CT and IVP. Positive urine cultures were adequately treated with appropriate antibiotics and all patients had a negative urine culture before surgery.

Mean patient age was 46 years (range 26 to 74) and mean body mass index was 25 kg/m^2 (range 19 to 32) (see table). There were 12 males and 8 procedures were done on the right side. All cases were prestented for 1 to 2 weeks preoperatively.

Demographic, operative and stone clearance data

Mean mm stone size (range)	11.8	(9–25)
No. stone site:		
Pelvis	4	
Upper calyx	1	
Middle calyx	1	
Lower calyx	9	
Multiple	3	
No. prior stone intervention (%)	68	(33)
Mean American Society of Anesthesiologists class	1	
Mean days prior stenting (range)	14.5	(5–30)
Mean mins (range):		
Total operative time	91.3	(60–130)
Robot docking	7.3	(4–18)
Stone localization	8.7	(1–36)
Total robot	41.4	(21–70)
No. stones relocated (%)	7	(38)
Fluid:		
Mean ml reabsorbed (range)	1,494.5	(3,783.33–2,288.88)
No. absorbed (pos ethanol test)	3	
Intraop complications	0	
Mean days hospital stay (range)	2.3	(2–7)
Mean wks duration of stenting (range)	4.2	(4–6)
No. postop complication:	1	
Paraparesis	2	
Febrile urinary tract infection		
No. stone clearance (%):		
Day 1 on KUB	8	(44)
Stent removal on KUB	12	(67)
2 Mos postop on CT	10	(56)
3 Mos postop on IVP	15	(89)
No. normal kidney function on IVP	18	
No. ancillary percutaneous nephrolithotomy	1	

Flexible Robotic System

The flexible robotic system consists essentially of 4 components, including 1) the surgeon console, including the liquid crystal display and MID, 2) the flexible catheter system, 3) the RCM and 4) the electronics rack. The surgeon console contains the MID, which is a 3-dimensional joystick that allows intuitive control of the tip of the steerable catheter. Robotic navigation can be performed in the endoscopic and fluoroscopic modes, which can be interchanged by a switch on the surgeon console. The liquid crystal displays on the console simultaneously show endoscopic and fluoroscopic views side by side. The system also has the capability of registering and showing preoperative imaging, such as CT, on the real-time display. The robotic flexible catheter system consists of an outer catheter sheath and an inner catheter guide with outer and inner diameters of 14Fr/12Fr and 12Fr/10Fr, respectively. A custom-built passive fiber-optic flexible ureteroscope with a 7.5Fr outer diameter and a 3.4Fr central working channel was inserted through the flexible robotic catheter system. Remote manipulation of the catheter system maneuvers the ureteroscope tip, which is glued in place to the inner guide. The space between the inner guide catheter and the flexible ureteroscope provides space for irrigation fluid inflow and the working channel provides space for irrigation fluid egress. The 14Fr/12Fr outer guide is essentially a stabilizing catheter with a tip that lies stationary at the ureteropelvic junction. The inner guide catheter is the catheter that navigates through the collecting system. The passive fiber-optic ureteroscope has a 7.5Fr tip diameter and protrudes just beyond the inner guide catheter. Thus, the tip of the active component of the robotic system is 7.5Fr with a 12Fr shaft outer diameter.

The guide catheter and ureteroscope have a maximum deflection of 270 degrees in all directions, which is not decreased by using accessories though the working channel. The robotic catheter manipulator is an arm that is attached to the operating table or floor mounted. It consists of 1 setup joint and mounts to attach the catheter sheath and guide. For flexible ureteroscopy an additional mount was created on the RCM to stabilize the ureteroscope in place. The electronic rack contains the computer hardware, power supplies and video distribution units.

Operative Procedure

All procedures were performed with the patient under general anesthesia. Initially cystoscopy was done and the preexisting Double-J® ureteral stent was exchanged for a 0.0035-inch hydrophilic wire. Using a dual lumen catheter a second safety wire was positioned in the renal collecting system. The robotic catheter system, consisting of the outer sheath and the inner guide, was manually inserted under fluoroscopic guidance, such that the tip of the outer sheath, marked by a radiopaque marker, was positioned at the ureteropelvic junction. Catheter guide system insertion was facilitated by a tapered obturator with a central channel for the wire. The sheath guide system was mounted on the RCM, which was positioned on a specially designed floor stand (fig. 1). After the sheath and guide were positioned the flexible ureteroscope was inserted through the inner guide and the external end of the ureteroscope was also mounted on the RCM.

After this point all operative steps were performed robotically from the console. Renal calculi were located using robotic manipulation of the ureteroscope tip using direct endoscopic visualization and intermittent fluoroscopy. Calculi at unfavorable sites, such as the lower pole calyx or calyces with a long narrow infundibulum, were entrapped in a nitinol stone basket and repositioned into a favorable upper pole calyx. Stones were systematically fragmented into 1 to 2 mm gravel with a 365 μ laser fiber using 10 W, 1 J and 10 Hz Ho:YAG laser energy. Contrast medium was injected through the sheath to confirm the integrity of the ureter and the renal collecting system. A Double-J ureteral stent was routinely inserted in all patients for 2 weeks.

All data were collected prospectively. Immediately upon the conclusion of the procedure the surgeon and assistant independently ranked the control rating, defined as the ability to maneuver the robotic system tip to the desired site, stone fragmentation ease and robotic system stability, defined as the ability to maintain the ureteroscope tip at a site location for an extended period, on a visual analog scale of 1—worst to 10—best. Intraoperative irrigation fluid absorption was measured by subtracting egress from inflow and by ethanol absorption testing.[5] All patients underwent KUB at stent extraction, noncontrast spiral CT at 2 months and IVP at 3 months.

Data are shown as the mean $\pm$ SD, the median and range for continuous variables, and the number and percent for categorical variables.

Figure 1. Operating room setup for robotic ureteroscopy. Surgeon sits on console and remotely controls flexible catheter using MID. Console screens provide simultaneous endoscopic and fluoroscopic views.

RESULTS

All 18 procedures were technically successful in achieving desired stone fragmentation without conversion to manual ureteroscopy or procedure abortion. The 14Fr flexible sheath guide system could be inserted in all 18 renal units without balloon dilation. Mean total operative time was 91 minutes (range 60 to 130), mean robot docking time was 7.3 minutes (range 4 to 18 minutes), time to stone localization was 8.7 minutes (range 1 to 36) and total robot time was 41.4 minutes (range 21 to 70) (see table). Stones were relocated with a basket in 7 patients (38%). There were no intraoperative complications and contrast injection confirmed absent perforation in all 18 patients. Postoperative complications included transient upper extremity paresis in 1 patient with severe kyphoscoliosis and febrile urinary tract infection in 2 that responded to antibiotics. Mean fluid absorption was 1,494 cc. In 15 patients there was no significant ethanol absorption while in 3 an increased breath ethanol level indicated fluid absorption, which normalized immediately after decreasing irrigation pressure. Thus, no patient experienced clinical sequelae due to fluid absorption.

There was no perinephric fluid collection in any patient on abdominal ultrasound on postoperative day 1 and no serum electrolyte change. Mean hospital stay was 2.3 days (range 2 to 7). The mean visual analog scale rating on a scale of 1—worst to 10—best was 8.5 for control rating, 9.0 for stability and 9.2 for fragmentation ease (fig. 2). Complete stone clearance was achieved in 10 patients (56%) at 2 months based on CT and in 15 (89%) at 3 months based in IVP (see table, and figs. 3 and 4). One patient required secondary percutaneous nephrolithotomy for a symptomatic residual fragment. There was stable renal function and unobstructed drainage with no ureteral stricture in all 18 patients on IVP at 3 months.

DISCUSSION

Flexible ureteroscopy is increasingly used as a diagnostic and therapeutic modality for various urological conditions.[1,2] The surge in flexible ureteroscopy use in the last few years has been largely due to significant technological advances in the ureteroscope and in ureteroscope accessory technology. Technological refinements of ureteroscopy have focused on scope miniaturization to improve the deflection range and enhance visual quality.[3] While experienced endourologists use current generation ureteroscopes facilely, there is still room for improvement. Manual ureteroscopy, similar to most flexible endoscope platforms, incorporates a deflecting mechanism at the tip to enable navigation in the

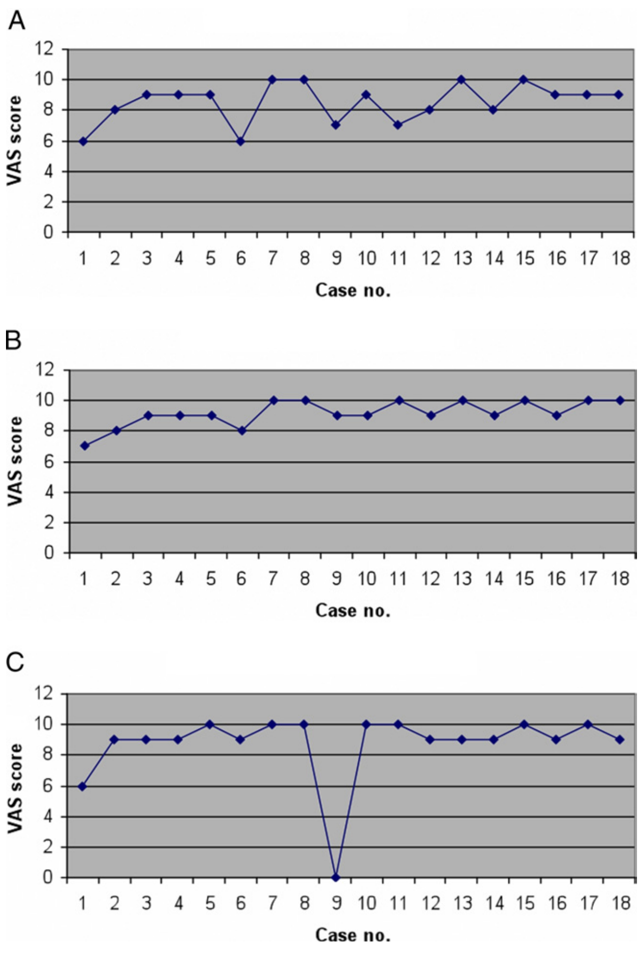

Figure 2. Flexible robotic system performance on visual analog scale (*VAS*) of 1—worst to 10—best for control rating (*A*), navigation stability (*B*) and ability to fragment stones (*C*).

intraluminal space. Apart from this active deflection all other movements, such as insertion and retraction, and torque, are applied by the endoscopist externally and transmitted to the endoscope tip. This in turn depends on the length and caliber of the ureteroscope, and the space and tortuosity of the luminal space to be traversed. While the experienced endoscopist generally overcomes these inherent limitations of the manual mechanical flexible endoscope platform, this presents an opportunity to potentially further enhance ureteroscope capabilities, specifically with respect to range of motion.

Robotic technology has been incorporated to enhance the precision and decrease the learning curve of various laparoscopic surgical procedures. The da Vinci® system provides EndoWrist® technology, which increases df compared to that of conventional rigid instruments. Also, high definition 3-dimensional vision, movement scaling and ergonomic superiority have led to increasing incorporation of robotics in laparoscopic surgery. Novel flexible robotic technology has been used to assist electrophysiological ablation for cardiac arrhythmia to enhance the accuracy, stability and precision of the radio frequency energy application.[6,7] We used 1 such flexible robotic catheter system and modified the length and driving software to enable its use for flexible ureteroscopy.

We initially tested this flexible robotic system for ureteroscopy in the swine model.[4] The robotic catheter system was used to perform ureteroscopy in 10 swine kidneys. The 14Fr catheter was easily inserted in 8 of 10 ureters but ureteral balloon dilation was required to facilitate insertion in 2. The robotic system navigated 83 of the 85 porcine calyces. With increasing experience and familiarity with the robotic device total navigation time decreased from 15 minutes in the initial cases to 45 seconds in the final cases. We also laser ablated renal papillae and fragmented implanted stones in a few kidneys. The major problem identified in the porcine experiments was significant extravasation of irrigation fluid, which was corrected by changing ureteroscope diameter, allowing adequate ingress and efflux.

Encouraged by our animal experience we designed this current prospective clinical trial in 18 patients. There were no technical issues with the robotic system in any case. After prestenting the 14Fr outer sheath could be inserted in all patients without ureteral balloon dilation. On visual analog scale assessment the system was rated favorably in stability, control and the ability to fragment stones. The robotic system had an obvious ergonomic advantage, in that the surgeon was conveniently seated at the console away from the radiation field. This also allowed the assistant on site to have unobstructed access to the working channel. The flexible robotic platform also allows the future potential to incorporate the guidewire and accessories (baskets/lasers) in the sheath, which could be controlled by the surgeon at the console along with irrigation and contrast injection to make the entire procedure more efficient.

Another advantage of the robotic system is the ability to scale motion. This provides a particular advantage during Ho laser lithotripsy, when the surgeon can increase the motion scaling as the stone is fragmented, such that fine scaling can be used for the small fragments. We used a basket to reposition stones to a more favorable collecting system site as necessary. Our preference even with conventional ureteroscopy is to fragment the stone in situ and allow spontaneous passage of the 1 to 2 mm gravel. However, if required, basket extraction can be done with the robotic system through the 14Fr outer sheath. In fact, a potential advantage is that the inner guide can be robotically retracted and repositioned to the exact calyx containing stone fragments.

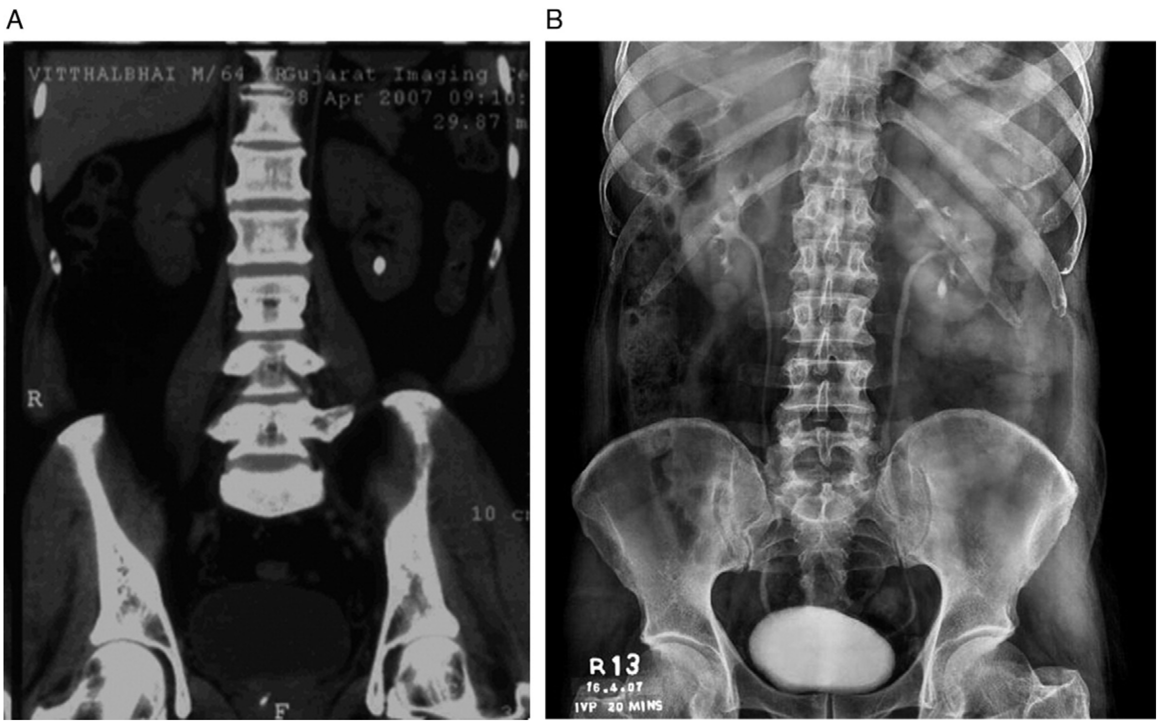

Figure 3. Preoperative CT (*A*) and IVP (*B*) show 1 cm lower pole calculus in acute angle infundibulum

The robotic system also has several limitations. The current diameter of the robotic catheter system may be too large. It should be decreased to less than 14Fr, especially if routine ureteral prestenting is to be avoided. Smaller diameter robotic catheter development is already well underway. We used a

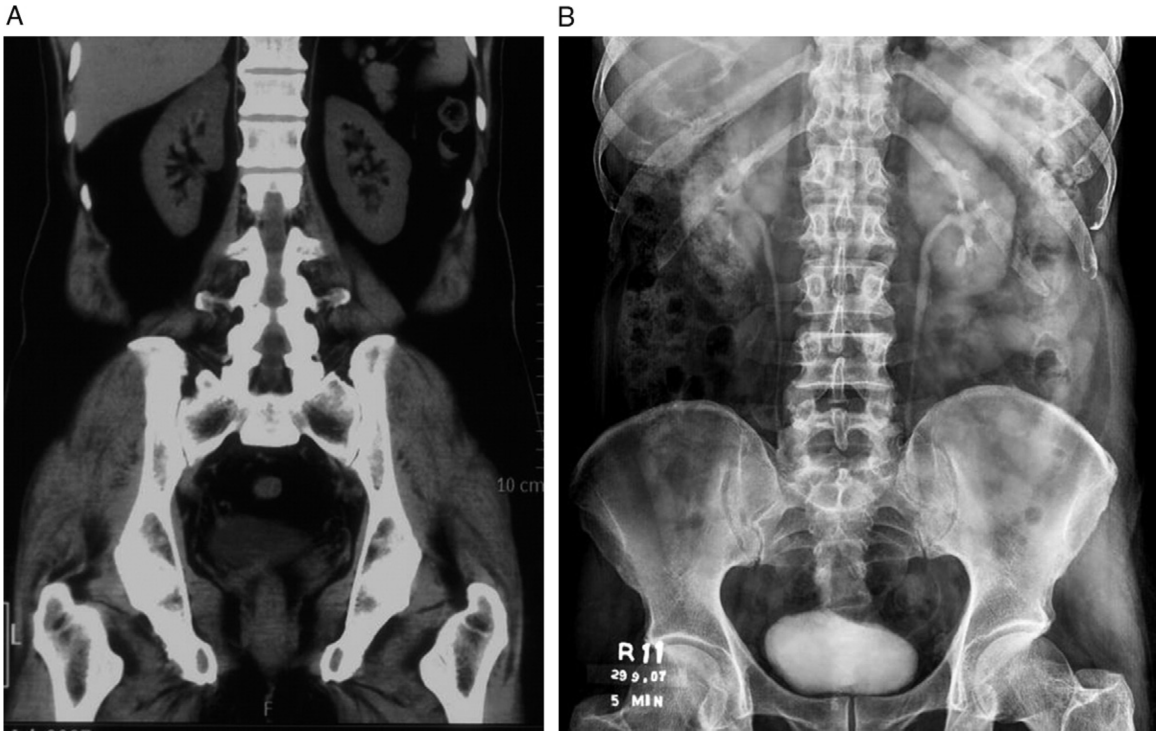

Figure 4. CT (*A*) 1 month and IVP (*B*) 3 months postoperatively in patient with lower pole calculus in acute angle infundibulum reveal complete calculous clearance, normal function and unobstructed drainage.

standard fiber-optic passive scope with visual resolution somewhat inferior to that of already commercially available digital ureteroscopes. Current excursion of the robotic system was somewhat limited and so did not allow full robotic manipulation from the lower to the upper tract. As such, robotic manipulation was limited to the area within the renal collecting system. However, at the time of this report these technical limitations were already being addressed and a system with extended range of excursion for use in the vascular space is being developed. This technological advance should allow complete robotic navigation from urethra to kidney if required.

Although we are encouraged by our feasibility study, we believe that ultimately comparative studies with manual ureteroscopy are required to see whether the potentially improved engineering platform that the robotic system provides translates into tangible clinical benefit. As such, a clinical advantage of the robotic approach must be determined to justify the potentially increased cost.

CONCLUSIONS

To our knowledge we report the first human technical feasibility study of remote robotic ureteroscopy for renal calculi. Our initial clinical experience with this novel flexible robotic system is encouraging. Ultimately comparative studies with standard manual ureteroscopy will determine its place in clinical practice. Ongoing refinements of flexible robotic technology are likely to extend its application across surgical disciplines.

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