Stereotactic Mechanical Percutaneous Renal Access

JEFFREY A. CADEDDU, M.D.,* DAN STOIANOVICI, Ph.D.,*‡ ROLAND N. CHEN, M.D.,* ROBERT G. MOORE, M.D.,* and LOUIS R. KAVOUSSI, M.D.*

ABSTRACT

Obtaining accurate percutaneous renal access when treating intrarenal disease requires substantial skill. Robotic devices have been used in a variety of surgical applications and have been successful in facilitating percutaneous puncture while improving accuracy. Laboratory models of robotic devices for percutaneous renal access have also been developed. However, several technical hurdles need to be addressed. One relates to the device–patient interface. As a first step in creating a complete robotic system, a mechanical arm (PAKY) with active translational motion for percutaneous renal access has been developed and clinically assessed. The PKY consists of a passive mechanical arm mounted on the operating table and a radiolucent needle driver that uses a novel active translational mechanism for needle advancement. The system utilizes real-time fluoroscopic images provided by a C-arm to align and monitor active needle placement. In vitro experiments to test needle placement accuracy were conducted using a porcine kidney suspended in agarose gel. Seven copper balls 3 to 12.5 mm diameter were placed in the collecting system as targets, and successful access was confirmed by electrical contact with the ball. The PKY was then used clinically in nine patients. The number of attempts, target calix location, calix size, and time elapsed were evaluated. In the in vitro study, successful needle–ball contact occurred the first time in all 70 attempts, including 10 attempts at the 3-mm balls. Clinically, percutaneous access to the desired calix was attained on the first attempt in each case. The mean target calix diameter was 14.7 mm (range 7–40 mm). The mean time elapsed while attempting access was 8.2 minutes. No perioperative complications attributable to needle access occurred. Early experience indicates that the PKY provides a steady needle holder and an effective and safe end-effector for percutaneous renal access. This device may provide the mechanical platform for the development of a complete robotic system capable of creating percutaneous renal access.

INTRODUCTION

Compared with open techniques, percutaneous renal surgery for select pathology has significantly reduced patient morbidity and recovery time. At many institutions, antegrade access is created as a separate procedure by an interventional radiologist using fluoroscopy, ultrasonography, or CT for guidance. However, several clinical situations require the urologist to perform the percutaneous puncture in the operating room utilizing C-arm fluoroscopic control. Unfortunately, many urologists have limited experience with obtaining access, and in cases where the collecting system is not dilated, accurate introduction of the access needle can be challenging even for experienced physicians. Inaccurate needle placement not only risks potential trauma to the kidney and adjacent organs but can markedly impede the subsequent procedure and affect the clinical outcome.

The task of obtaining intrarenal access in the operating room requires substantial skill because of the lack of simultaneous three-dimensional (3D) information provided by the C-arm fluoroscope. The procedure requires several cognitive and technical maneuvers by the surgeon. Primarily, needle alignment (trajectory) and the depth of insertion need to be considered simultaneously and adjusted continuously as the surgeon advances the needle. Moreover, needle insertion must be achieved with sufficient force and control to assure entry into the desired calix and prevent past-pointing. The surgeon must also compensate for tissue deformability and ventilatory motion.
Two groups have attempted to circumvent this clinical problem by employing a robotic system for percutaneous renal access. Investigators at the Imperial College in London were the first, utilizing a passive (manually positioned) manipulator that was guided by a C-arm.\textsuperscript{2-3} The computer system displayed the anticipated needle trajectory on the X-ray image, allowing the surgeon to adjust the robotic arm and choose an appropriate path. This process required 3D mapping (registration) of the fluoroscope’s and robot’s spatial relations. Using a similar image-guided approach, Bzostek et al\textsuperscript{4} developed an active robot (each joint is moved by an electric motor) to fully automate the task of image-guided percutaneous renal access. Although these systems have been tested in laboratory models, significant technical limitations were noted, and to date, neither has progressed to clinical evaluation. Nevertheless, the experience of these two groups has identified several developmental steps that are required for the creation of a complete robotic percutaneous access system, such as producing an active needle driver, creating a mechanism for needle and target registration, and compensating for organ motion as well as tissue deformability.

In order to address one issue in the development of a clinically applicable robotic system, we have developed a simple device, PAKY (percutaneous access to the kidney), which is a mechanical stereotactic frame and actuated needle system that can be used as a platform for needle placement. To determine the utility of this platform in creating a complete robotic system, we reviewed our initial clinical experience with the device.

**MATERIAL AND METHODS**

**PAKY Device**

The PAKY mechanical device consists of a unique needle driver attached to a passive mechanical arm (Fig. 1). The device is mounted on a custom-designed rigid siderail, which attaches to the operating room table to provide a sturdy base. This siderail is critical for maintaining a steady needle trajectory under the force produced by needle insertion through tissue. The mechanical arm has seven degrees of freedom (DOF), which refers to the sum of all possible motions at each joint in the device. Each DOF can be either translational or rotational, depending on the type of motion. With PAKY, all seven DOF are rotational and are locked simultaneously by depressing a single lever.

The needle driver end-effector is a one-DOF translational stage constructed of acrylic plastic, making it sterilizable and radiolucent (Fig. 2).\textsuperscript{5} Needle insertion is actuated (driven) by a variable-speed DC motor that is battery powered and controlled with a joystick. The driver mechanism grasps the barrel of the

**FIG. 1.** Robotic device for percutaneous access to kidney (PAKY). A. Schematic. B. PAKY mounted on operating table.

**FIG. 2.** Close-up view of needle driver end-effector. Black casing houses DC motor.
needle near the skin entry point, which significantly reduces any lateral deflection or bowing of the unsupported length of the needle during insertion. Actual needle advancement utilizes an axial-loaded rotational-to-translational friction transmission principle, which is unique to this device (Fig. 3).6

In Vitro Experiment

Prior to the clinical trial, the accuracy of the device’s needle placement was evaluated using a porcine kidney (10 cm long) suspended in agarose gel. A copper ball soldered to a wire was placed in a calix (upper, middle, or lower) in a retrograde fashion. The needle was also attached to a wire, and both wires were connected to a voltmeter. The PAKY device was mounted on the operating room table, and the kidney was placed on the table within its working envelope. A standard access needle, an 18-gauge, 20-cm-long, two-part trocar type (Cook Urological Inc., Spencer, IN), was attached to the needle driver. A C-arm fluoroscope was then positioned over the kidney, and the copper ball and agarose gel insertion site were identified. These two points, which define the access needle’s line of insertion (trajectory), were superimposed in the fluoroscopic image to align the C-arm with the insertion line. The PAKY device was then positioned between the C-arm and the kidney such that the needle tip was at the gel entry point and oriented along this line. This maneuver was accomplished by superimposing the needle, the gel entry point, and the target ball as a single point on the fluoroscopic image (superimposed registration). This method of needle alignment was possible because the needle driver end-effector is radiolucent, providing unimpeded fluoroscopic visibility.

Once the needle axis was aligned, the entire device was mechanically locked. In this way, the insertion line was stereotactically fixed by the manipulator, enabling the user to rotate the C-arm confidently to obtain a lateral view. The needle was then advanced to the target (ball) by depressing the joystick and monitoring its advance fluoroscopically from the lateral view. Accurate needle placement was confirmed by completion of the electrical circuit on needle-ball contact. Seven balls 3 to 12.5 mm in diameter were used, and the experiment was repeated ten times for each. Between attempts, either the ball was moved to a different calix or the kidney position was changed.

Operative Technique

The operative technique was similar to that employed in the in vitro experiments. After the induction of general anesthesia, patients were positioned prone with the head, arms, and legs cushioned. The PAKY device was mounted on the operating table on the side intended for access and covered with a sterile bag. A standard access needle was attached to the needle driver.

As with the conventional manual access technique, the C-arm was positioned over the collecting system and the target calix and skin insertion site chosen. These two points were superimposed in the fluoroscopic image (defining needle trajectory), after which the PAKY was manipulated so that the needle was positioned at the entry point and oriented along this line. This maneuver was accomplished utilizing the superimposed registration technique described above. To minimize the normal motion of the kidney, the anesthesiologist held ventilation at a fixed point for each patient during image and needle registration.

Once the needle axis was aligned, the entire device was mechanically locked, fixing the insertion line. This enabled the surgeon to rotate the C-arm confidently to obtain a lateral view. Ventilation was again held while the surgeon advanced the needle by depressing the joystick and monitoring its advance fluoroscopically. Because needle alignment was fixed, the insertion depth and intracaliceal needle placement were observed continuously without necessitating any movement of the C-arm. Caliceal access (success) was confirmed by observing for the leakage of urine through the needle and then passage of a flexible wire into the collecting system.

Once access was secured, the needle and end-effector were removed over the wire, and the PAKY was moved away from the operative field. The remaining steps in the procedure were then performed in a standard fashion.

Clinical Evaluation

The records of nine patients who underwent intraoperative renal access with the PAKY device were reviewed. Each puncture preceded a percutaneous nephrolithotomy. In each case, target calix location and size were recorded. Access time, defined as the time from when the device was first grasped by the surgeon and the needle loaded to when access to the collecting system was confirmed by urine leakage from the needle, was also recorded. The total number of access attempts (needle passes) was documented, as well as any complications secondary to the procedure.

RESULTS

In the in vitro model, the device inserted the needle and made contact with each target ball in all 70 attempts (100% success).
No malfunctions of the mechanical or electrical components were encountered.

In the clinical series, each patient underwent successful percutaneous renal access with the PAKY device. Specifically, the calix chosen by the surgeon to provide the easiest and safest approach to the renal stone was entered on the first attempt in each case, although in one patient, the needle was initially advanced through the calix and had to be withdrawn a few millimeters. Demographic data, as well as target location, target size, and time required to gain access, are presented in Table 1. Any increase in operating room set-up time was negligible, as the PAKY was mounted and covered with the sterile bag during patient positioning and sterile preparation. In every case, stone extraction was successful, and the percutaneous nephrostomy tube was removed when a nephrostogram confirmed stone-free status and absence of perinephric extravasation. There were no perioperative complications attributable to the use of the PAKY device.

DISCUSSION

The use of robotic devices as surgical aids was first investigated in the 1980s. The initial applications were in neurosurgery and orthopedic surgery, where the target organ provides fixed landmarks as reference points. Success in these fields led to the exploration of robotic applications in other surgical specialties. In urology, robotic-assisted laparoscopic surgery has been reported by investigators at Johns Hopkins. The possibility of a robot performing a transurethral prostatectomy has been explored by a group at the Imperial College in London.

Stereotactic mechanical devices that facilitate percutaneous procedures and localization have been utilized for more than a decade in neurosurgery. These have evolved from manual stereotactic frames to image-guided robotic systems. However, unlike the brain, the kidney is mobile within the retroperitoneum and, because of several tissue interfaces, is variably deformable. Nevertheless, there is impetus to develop a stereotactic device to assist with percutaneous renal access. First, the procedure requires a significant level of skill. This problem is compounded by the fact that urologic training and experience in percutaneous access are diminishing because of the increasing dependence on radiologists to perform the procedure. Moreover, the steps in the procedure are limited and repetitive, and as such, amenable to mechanization. Finally, this procedure requires accuracy, particularly when accessing a nondilated collecting system.

Potamianos et al at the Imperial College first developed a passive robotic system for percutaneous renal access that was guided by a C-arm fluoroscopic unit. This system displayed the access needle’s trajectory, which was held by the robotic arm, on a pair of registered radiographic images, allowing the surgeon to plan a suitable path for needle insertion. The passive manipulator had five DOF and was mounted on the operating room table while a personal computer performed the registration between the robotic arm and the fluoroscope (image) coordinate systems. Because all video fluoroscopic systems have considerable image distortion, which does not permit an accurate projection of an end-effector’s line of action or of the target’s position, computer software that corrected for image distortion was also required. The actual position and orientation of the manipulator were recorded by sensing instruments on the device, and once manually placed in the desired position, the device and needle trajectory were locked with electromagnetic brakes.

Recently, Bzostek et al utilized an active robot in a fully automated image-guided system for percutaneous renal access. Similar to the Imperial College system, computerized image calibration and robot registration methods were required. This system employed a robot to position, orient, and drive the access needle while X-ray images were acquired from a biplanar fluoroscope.

Although both of these systems have demonstrated that robotic percutaneous access is feasible, neither has been evaluated clinically. However, initial testing did identify some hurdles that need to be overcome prior to the development of a clinically useful and completely automated robotic device. First, the design of the user-device and device-patient interfaces is crucial. Unlike the cumbersome systems previously developed, the user-device interface must be “transparent” while not increasing procedure time. The design of the device-patient interface must ensure patient safety and replace human surgical

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Age/Sex</th>
<th>Target Calix</th>
<th>Target Calix Diameter (mm)</th>
<th>Access Time* (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>65 M</td>
<td>Lower</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>45 M</td>
<td>Lower</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>29 F</td>
<td>Lower</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>71 M</td>
<td>Lower</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>31 F</td>
<td>Lower</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>68 M</td>
<td>Middle</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>7</td>
<td>50 M</td>
<td>Middle</td>
<td>40</td>
<td>6</td>
</tr>
<tr>
<td>8</td>
<td>46 F</td>
<td>Lower</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>44 F</td>
<td>Lower</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Mean</td>
<td>49.8</td>
<td></td>
<td></td>
<td>14.7, 8.2</td>
</tr>
</tbody>
</table>

*Time required to position the device manually, advance the needle, and confirm intracalceal placement.

Needle was advanced through calix (past-point) but withdrawn a few millimeters into the collecting system.
skills. The integration of an imaging system to guide a robotic device is another technical challenge that needs refining. In particular, as demonstrated by Bzostek et al and the Imperial College group, quick computer algorithms to correct fluoroscopic image distortion are still needed.1,2,3 Another hurdle for a completely automated system that has not been addressed is the development of sophisticated software that would allow the system to track the target calix and adjust the needle trajectory if the calix's position changes (i.e., ventilation or tissue deformation). Finally, prior to clinical use, system cost and safety issues are critical and must be confronted.

We have designed and constructed a simple robotic device to address one of these hurdles as an initial step in developing a clinically useful and cost-efficient automated system capable of obtaining renal access. The focus in developing the PAKY device was a user–device interface and device–patient interface that could be assessed in the clinical setting. The user–device interface was designed to mimic the urologist's standard technique and is essentially transparent. In particular, by employing a proven radiologic needle alignment procedure (superimposed registration) that does not require a computer-based imaging and targeting system, PAKY is intuitively easy to use. This advantage was reflected in the 100% success rate in the in vitro experiments and, in the clinical setting, the minimal time required to gain access to the collecting system (mean 8.2 minutes). Because of a learning curve in operating the device, reflected in longer access times in the first three or four cases, the access time will likely decrease with additional experience.

Early clinical experience has also demonstrated that percutaneous renal access is facilitated by the device (device–patient interface) while procedure morbidity is unchanged. In every case, the device gained access on the first attempt at the target calix with no complications. The ability to fix the needle trajectory stereotactically and thereby watch the entire procedure from a lateral view also allowed the surgeon to monitor kidney position and deflection, which should reduce the likelihood of missing the target and also avoid injury. The concept of organ deflection and soft-tissue deformation under external forces is an important challenge for any robotic system developed for soft-tissue surgery.

Finally, the PAKY system incorporates several safety features to protect the surgeon and patient from any device-induced injury. First, as with the Imperial College device, the passive manipulator eliminates unwanted autonomous motion of the arm. To eliminate the risk of exposure to an electrical power surge and high voltages, the system is powered by batteries. Malfunction of the electrical components, potentially causing unintentional needle movement, is prevented by a dual-action pushbutton switch and joystick. Thus, three circuits (joystick and pushbutton switch [2 in Fig. 3]) would have to fail to result in inadvertent needle movement. The variable-speed drive of the motor also allows precise velocity control of needle insertion, while the rotational-to-translational friction transmission design allows the surgeon to limit the needle insertion force. By dialing a knob on the radiolucent driver (increasing friction), the surgeon can adjust the maximum deliverable force. When the tissue resisting force exceeds this loading force, the needle will slip and no longer advance. Grasping the needle barrel has another advantage in that the depth of insertion can be physically limited by choosing the initial point at which the needle is grasped.

**CONCLUSION**

The task of intraoperative percutaneous renal access may be simplified by the use of technical advances and medical robotics. Early experience with a mechanical device (PAKY) demonstrates that, in a clinical setting, a mechanical interface can obtain access effectively and safely. A larger series evaluating the efficacy of this device is required, while the addition of an image-guided computer interface will be necessary to develop a completely automated system for percutaneous access.

**REFERENCES**


Address reprint requests to: Jeffrey A. Cadeddu, M.D.}

James Buchanan Brady Urological Institute
Johns Hopkins Bayview Medical Center
4940 Eastern Avenue
Baltimore, MD 21224