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Collecting system percutaneous access using real-time tracking sensors: first pig model in vivo experience

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Title Page

Title: Collecting system percutaneous access using real-time tracking sensors: first pig model in vivo experience

Running Head: Percutaneous puncture using real-time **sensors** tracking

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Abstract (249 words)

Purpose: Precise needle puncture of the renal collecting system is a challenging and essential step for successful percutaneous nephrolithotomy (PCNL). This work aims to evaluate the efficiency of a new real-time electromagnetic tracking (EMT) system for *in vivo* kidney puncture.

Materials and Methods: Six anesthetized female pigs underwent ureterorenoscopies in order to place a catheter with an EMT sensor into the desired puncture site and to ascertain the success of puncture. Subsequently, a tracked needle with a similar EMT sensor was navigated into the sensor inside the catheter. Four punctures were performed by two surgeons in each pig: one in the kidney and one in the middle ureter, on both right and left pig sides. Number of attempts and time needed to evaluate the virtual trajectory and to perform the percutaneous puncture were outcomes measurements.

Results: Overall 24 punctures were easily performed without any complications. Surgeons required more time to evaluate the trajectory during ureteral puncture than kidney (median 15 versus 13 seconds, range 14 to 18 and 11 to 16 seconds, respectively; $p=0.1$). The median renal and ureteral puncture time were 19 and 51 seconds respectively (range 14 to 45 and 45 to 67; $p=0.003$). Two attempts were needed to achieve a successful ureteral puncture. The presented technique demands presence of renal stone for testing.

Conclusions: The proposed EMT solution for renal collecting system puncture proved to be highly accurate, simple and quicker. **This method might represent a paradigm shift in percutaneous kidney access techniques.**

(Main Text: 2567 words)

1. Introduction

The prevalence of nephrolithiasis has risen over the past 30 years¹. Today, percutaneous nephrolithotomy (PCNL) is the established treatment for staghorn kidney stone removal and usually comprises three main steps: a) insertion of a ureteral catheter to perform a retrograde study; b) puncture of the kidney to establish a percutaneous path; and, c) disintegration with removal of stone fragments²⁻⁶. The puncture step remains the most challenging task for surgeons, since treatment outcomes are highly dependent on the accuracy of needle puncture in the desired calix^{2, 7, 8}.

The ideal renal access is one that **allows an optimal working angle for complete stone removal while minimizing the risk of bleeding**. An inaccurate needle puncture can cause some complications such as injuries in the kidney and contiguous organs, difficulty in handling surgical instruments and eventually, prejudice the overall surgical procedure and patient outcome⁸.

Although fluoroscopy and ultrasounds are the most popular approaches², modifying surgery^{9, 10} and patient position¹¹⁻¹³, use of computed tomography¹⁴, robotic devices^{15, 16}, and navigation systems¹⁷⁻¹⁹ have been proposed to improve and ease the renal puncture during PCNL. However, most of these tools and techniques only assure 2D images, do not provide **real-time** 3D information, demand preprocessing steps to register all the anatomical structures, are not tested in vivo and may also be affected by operator skill, patient breath movement, and needle deflection^{2, 17, 20}.

In an attempt to solve the above limitations **we** tested the efficiency of a new 3D real-time EMT system to perform in vivo percutaneous renal collecting system access.

2. Material and Methods

The study was performed at University of Minho, Braga (Portugal) in six female pigs (*Sus scrofa domestica*), with weight ranging from 25 to 35 kg, according to the internal ethical protocol for animal studies. The animals were fed with liquids for 3 days and then restrained from food (24 hours) and water (6 hours) before the surgical tests.

All procedures were carried out with the pigs under general anesthesia, with 5.0 mm endotracheal intubation and mechanical ventilation. Pre-anesthesia medication consisted of an intramuscular injection of 32 mg/mL azaperone, reconstituted with 1 mg/mL midazolam with a dose range of 0.15-0.20 mL/kg. The venous access was obtained through an intravenous line placed at the marginal ear vein. The anesthesia was induced with 3 µg/kg fentanyl, 10 mg/kg thiopental sodium, and 1 mg/kg vecuronium. It was maintained with 1.5% to 2.0% of sevoflurane and a perfusion of 1 mg/kg per hour of vecuronium. All pigs received an intramuscular injection of 1 g ceftriaxone before the tests beginning.

2.1. 3-D real-time navigation system

The commercially available Aurora EMT system (Northern Digital Inc., Waterloo, Canada) was used to track the catheter and needle tip inside the ureteral and kidney calyx. In addition, the navigation system is also composed by the following components:

- 1) One planar low-intensity and varying electromagnetic field generator (Fig. 1), that establishes a tracking volume (working space in Fig. 1-b);
- 2) Two Aurora sensor interface units (SIU in Fig. 1), working as an analog-to-digital converter and amplifier of the electrical signals from the sensors to an Aurora system control unit (SCU in Fig. 1). The SIU unities decrease the possibility of electromagnetic

interferences in the operating room. The SCU transmits the spatial data, using a serial port connector, to a computer for subsequent processing and navigation using the software described below;

3) One needle 18G/180 mm Chiba (Fig. 1–d) and one ureteral catheter (Fig. 1–c) with 1.1 mm diameter and 2 m length. Both integrate an Aurora EMT sensor with five degrees of freedom at its tip;

4) An uretero-reno-fiberscope Flex-X™ (Fig. 1) from Karl Storz with video support and an active deflection tip of 270 degrees (Fig. 1–f) in either direction for complex navigation maneuvers;

5) A software for surgical guidance developed specifically for this work, resorting to C++ and VTK (The Visualization ToolKit), entitled *3DPuncture (EMT Kidney and Ureter Percutaneous Access Software)*, working as a control station (Fig. 1) by gathering and processing information from different equipment needed for the PCNL puncturing: video from the Flex-X™, orientation and position of the needle and catheter EMT sensors. It allows the surgeon to choose in real-time the correct needle orientation and path by visual and audio support (bip sound which frequency increases when the needle tip is close to the catheter tip).

2.2. Surgical procedure description.

The pigs were **placed in** supine position and a rigid cystoscope was used to identify the ureteral orifices of both kidneys. Then, ureterorenoscopies were performed bilaterally using the Flex-X™. The 1.2 mm Flex-X™ working channel allowed to put the ureteral catheter into the desired puncture site (Fig. 1–f). The EMT sensor located at the catheter tip operates as a GPS (global position system) for the puncture site.

After positioning the Flex-X™ tip at the puncture target, **resorting to the direct view from its camera**, the surgeon inserted the needle **into the calyceal fornix. To this**

extent, a virtual trajectory determined by the relative orientation and position information retrieved in real-time by both needle and catheter EMT sensors was used.

This virtual trajectory was displayed in the *3DPuncture* software (Fig. 2–D and E) to the surgeon, **who must confirm that the catheter and needle are parallel aligned. If necessary, the surgeon can redefine the catheter orientation, and a new virtual trajectory will be calculated. This procedure provides constant real-time positioning feedback (bip sound and 3D representation) to the surgeon, allowing him to accomplish a perfect orientation of the needle at all times, even in the presence of anatomical changes, such as tract dilatation, respiratory movements and needle deflections, among others.**

The percutaneous punctures were performed for each pig at the ureter half way between the kidney and the urinary bladder and in renal calyces in order to evaluate the puncture location influence.

2.3. Outcomes measurement.

The following surgical parameters were evaluated during renal and ureteral punctures, in order to ascertain if the proposed tracking solution confers any advantage to the surgeon performing PCNL:

- a) Planning time: time needed by the surgeon to evaluate the virtual trajectory displayed at the *3DPuncture* software and orient the needle at skin surface;
- c) Number of attempts: number of tries to reach the puncture site;
- b) Puncture time: time needed to perform a successful renal puncture from the skin surface to the puncture target. This was also confirmed by the ureteroscope Flex-X™ camera view;

The surgical procedures were performed by an expert surgeon and a resident in order to avoid a supposed bias related to surgeon ability. Furthermore the puncture location was also analyzed as a variable influencing the above outcomes.

2.4. Statistical analysis.

The Mann-Whitney test was used, under SPSS Windows version 17.0 software, for statistical analysis, and p values lower than 0.05 were accepted as significant - data is presented by median and range.

3. Results

Overall 24 punctures were successfully performed without any complications: 12 in middle ureter and 12 in the kidney calyx (**lower, middle or upper kidney calyx**).

Table 1 summarizes measured outcomes. Planning time was longer for the ureter case than the kidney (median 15 versus 13 seconds, range 14–18 versus 11–16; $p=0.1$).

Likewise, time to achieve ureteral puncture was significantly longer than kidney puncture, requiring 51 (range 45–67) and 19 (range 14–45) seconds ($p=0.003$), respectively. Two attempts were needed to carry out the ureteral puncture, contrasting with a single attempt for the kidney ($p=0.01$). **Non-significant differences were found between puncture time, planning time and number of attempts ($p=0.9$, $p=0.51$, $p=0.62$, respectively) regarding different kidney calyx.**

Finally, non-significant difference was found between the two surgeons – with different skills – regarding surgical outcomes (Table 2). Both physicians carried out the test with comparable performance regarding the puncture stage.

4. Discussion

PCNL is a minimal invasive surgery with many associated benefits, such as small patient incisions and improving postoperative recovery, complications may still arise^{3, 16, 17}. In what concerns PCNL puncture in particular, the most relevant contributions have been provided by the application of medical imaging techniques. Although surgeon's preferences determine the imaging method choice, fluoroscopy and ultrasounds are the most common imaging technologies for puncture guidance and planning^{2, 21}. X-ray exposure, 2D image, difficult visualization of small calculi, operator dependence and requirement of skill has been reported as the main limitations associated with these imaging techniques^{2, 7, 8, 22}.

Medical imaging assistance to puncture commonly requires approximately 10 min^{7, 23-26}, which is significantly greater than the times obtained in this work. Li *et al.*²³ designed a modified "stereotactic localization" system for PCNL inspired by the locating principle of extracorporeal shock-wave lithotripsy and by stereotactic techniques. Although they decreased the puncture time from 17 to 7 min, they still continue using X-Ray imaging with an exposure time higher than 2 min and success rates lower than 90%.

A locator apparatus that stabilizes the needle during the puncture was tested by Lazarus *et al.*²⁶. The authors achieved a mean puncture time of 225 seconds in vitro with no target or respiration movements limitations that can cause difficulties during the puncture procedure.

Comparing the related work results with the outcomes of the proposed technique, one has achieved a puncture time improvement between 75 and 85% (Table 1), without any radiation exposure.

Aside from medical imaging, several approaches have been reported in order to easily track and guide the needle tip inside the kidney, in particular the exploration of different patient positions^{12, 13, 24}, robotic assisted surgeries¹⁵, navigation systems¹⁷⁻¹⁹ and electronically instrumented needles^{2, 19}.

Robotic assisted in actual PCNL surgeries is limited due to non-biocompatible and non-sterilizable materials, complex control, manipulation and setups. Moreover, these systems are expensive, work slower than the surgeon and still need medical imaging support¹⁵.

Finally, optical navigation systems, in contrast with the proposed solution, require pre-operative computed tomography image, acquired with the patient lying in the same position of the surgical procedure and a line of view to the optical references that can limit its use in procedures inside the human body^{17, 21, 27}.

The proposed methodology makes use of small EMT sensors that can be embedded in surgical instruments for tracking inside the body²⁸. The ureteral catheter and needle, both integrating an Aurora EMT sensor at its tip, were able to retrieve in **real-time** the position and orientation. The catheter remained associated to the puncture target (worked as a 3D real-time locator) and was permanently monitored by the EMT sensor and the Flex-XTM camera, during the whole surgical procedure. Therefore it followed in real-time all the anatomic tissues deformations and movements – originated by the respiratory cycle and also by those induced to the patient. Regarding puncture, the surgeon inserted the needle guided by the virtual puncture path displayed in the *3DPuncture* software.

The described puncture procedure only demands endoscopic imaging and the information regarding the position and orientation of the 3D sensors located at the needle and ureteral catheter tips.

An important proof-of-concept step was also achieved by succeeding in performing a direct ureteral puncture, even though the procedure took significantly more time, due to the ureteral movements, ureter small diameter and soft consistence, which made the needle glide on its surface. Even though this preliminary results provide prospective paths for other applications (e.g. Percutaneous Ureteral Lithotripsy), the main objective was to further corroborate the efficiency of the purposed puncture method in a small target cavity.

Interesting of note, no difference in operator skill was found in performing the puncture. Whereby, it is reasonable to speculate that this tracking solution may reduce the number of cases needed to perform an appropriate collecting system access and make it easier. Specific literature reports that the learning curve completion for PCNL surgical competence around 60 cases⁷. Considering the kidney access one of the most challenges phases, in this study a resident achieved the same skill level of an expert surgeon with only twelve cases.

Even though the purposed puncture orientation methodology was proven suitable, and achieved a very positive performance *in vivo*, the presented technique certainly demands further evaluation regarding its human applicability, such as presence of renal stone, patient position.

The safety efficacy of different surgical positions for accessing the collecting system has been a controversial issue, with currently no established best practice consensus. The use of a real-time 3D trajectory proposed in this work to guide the surgeon throughout the puncture path may broad the use of supine position for the whole PCNL procedure. In this case, the surgeon does not need to reposition the patient (decreasing surgery time in about 30-40 minutes) and may improve levels of comfort for both patient and surgeon as described in literature¹². On the other

hand, when the patient is repositioned, there is a reduced risk of access dislodging, since the catheter remains permanently monitored by the EMT sensor and the Flex-XTM camera, allowing the surgeon to perform small adjustments and complex navigation maneuvers – considering the Flex-XTM active deflection tip of 270 degrees in every direction.

This study does not consider kidneys with renal stones, which prevents us from providing solutions to specific situations with a fair degree of certainty, such as staghorn calculi or obstructive uropathy, where a physical obstruction may hinder the positioning of the ureteral sensor inside the desired calyx. Nevertheless, this is a very relevant aspect which the authors are aware of and intend to develop further research to study ways of overcoming such situations.

Although Yaniv *et al.*²⁸ reported that electromagnetic systems may be susceptible to environment interferences in the operating room, we did not experience any kind of interferences that could tamper the tracking information, provided that the SIU from Aurora is stationary and positioned in an acrylic base.

Hereupon, the proposed solution may be the simple and easy system to choose and follow the correct puncture path and the helpful tool to acquire the so important required skill for PCNL, regardless of calculi location, presence of large or multiple renal calculi and in cases of ectopic or malformed kidneys.

5. Conclusion

This paper purposes a novel procedure for kidney puncture in PCNL using EMT sensors. The procedure was preliminary tested in vivo, and the obtained results show that it may be a promising and helpful device for this kind of surgery. Using this system neither X-ray or pre-operative imaging studies are needed. Moreover,

it was not subject to be influenced by physician skill and expertise and proved to be highly accurate, simple and quicker.

However, this experience needs to be confirmed in a large comparative human study in order to have stronger evidence on its utility and security.

Once the entire procedure is certified for human trials, an interesting topic for future work would be to compare the entire costs involved in two different groups of patients, one treated with the traditional PCNL technique and the other with the proposed system. Other topics for future work entail the application of this technique (with the necessary adaptations) to similar procedures, in particular for Gastrostomy, Endopielolitotoly, Endoscopic resection and treatment of upper urinary tract urothelial tumors, Calyceal diverticuli treatment, Diagnostic indications such as antegrade pyelography and pressure/perfusion studies.

Finally, we strongly believe that this method has the potential to become the new puncture standard in PCNL, comprising the elimination of radiation, broad the use of PCNL to surgeons less familiarized with minimal invasive surgeries and reducing surgical costs and time.

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Table 1. Surgical outcomes according to puncture location

<i>Median (minimum and maximum)</i>	Puncture Site		<i>p</i> [*]
	Kidney calyx	Ureteral	
Puncture Time (seconds)	19 (14–45)	51 (45–67)	0.003
Planning Time (seconds)	13 (11–16)	15 (14–18)	0.1
Number of Attempts	1 (1–2)	2 (2–4)	0.01

* Mann-Whitney Test

Table 2. Measured outcomes related to surgeon skill and puncture location

<i>Median (minimum–maximum)</i>	Experience	Resident	p[*]
Puncture Time (seconds)	24 (14–50)	47 (15–67)	0.20
Planning Time (seconds)	13 (10–15)	15 (13–18)	0.03
Number of Attempts	1 (1–2)	1 (1–4)	0.69

* Mann-Whitney test

Figures

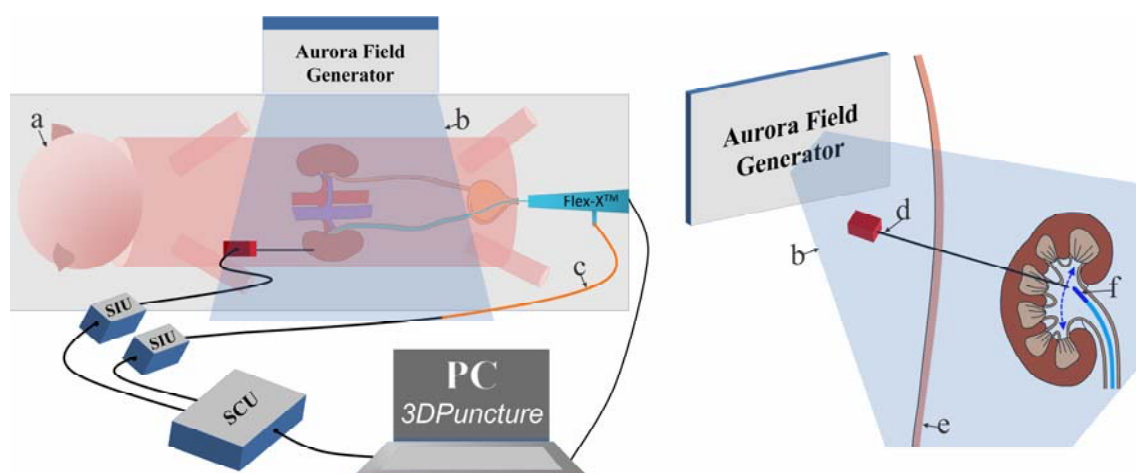


Fig. 1 – Overview of the pig experience setup for percutaneous collecting system access in vivo model (a) using the Aurora EMT system (composed by the Aurora field generator, SCU and SIU); this system establish an electromagnetic working space (b). The ureteral catheter with an ETM sensor (c) at its tip linked to the SIU was placed inside the Flex-X™ with a flexible tip (f). The equipment is linked to a processing PC. (d) represents the surgical needle with an EMT sensor at its tip, guided from the skin surface (e) towards the catheter sensor position.

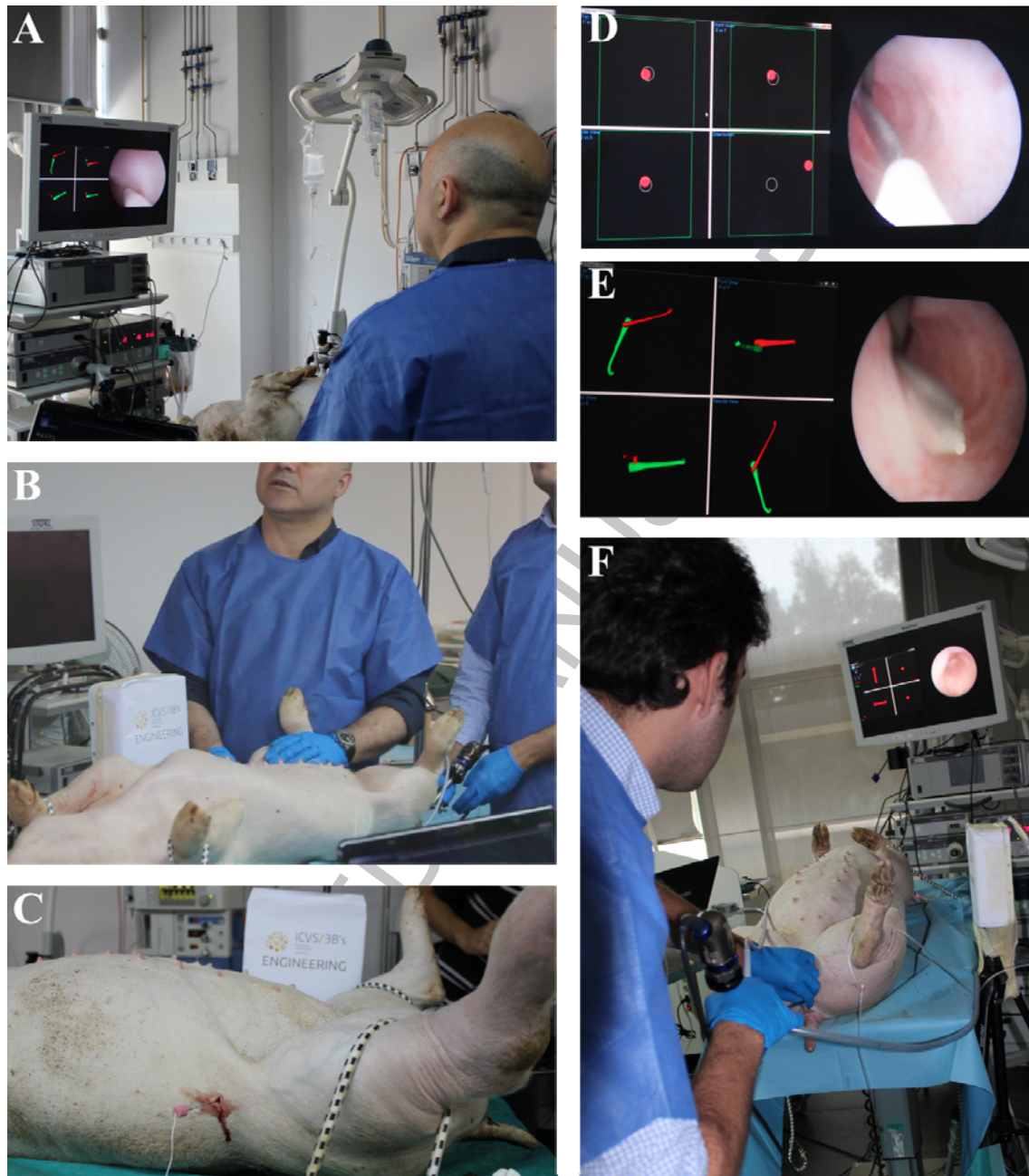


Fig. 2 – Clinical experience: A) and B) shows the surgeon performing the puncture stage guided by the *3DPuncture* software with 2D and 3D Views (D and E respectively); D and E on right shows the camera view from Flex-XTM, displaying the needle tip at the puncture site indicating puncture success (C); F) shows the resident performing the retrograde study.