Visually navigated, ultrasound-guided, freehand percutaneous calyceal puncture – preclinical evaluation of a novel device to simplify a complex surgical task

Authors

Gamal Anton Wakileh[1], Manuel Hohmann[2], Marie Claire Rassweiler-Seyfried[3], Jan Thorsten Klein[1, 4]

Affiliations

1 Urology, University Ulm Medical Centre, Ulm, Germany

2 Urology, University Hospital Ulm, Ulm, Germany

3 Department of Urology and Urological Surgery, University Medical Center Mannheim, University of Heidelberg, Mannheim, Germany

4 Urology, Spital Thurgau AG, Kantonsspital Münsterlingen, Münsterlingen, Switzerland

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70469 Stuttgart, Germany

Correspondence

Dr. Jan Thorsten Klein
Urology, University Ulm Medical Centre
Albert Einstein Allee 23
89070 Ulm
Germany
jan-thorsten.klein@uniklinik-ulm.de

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ABSTRACT

Purpose Freehand sonographic percutaneous puncture techniques for the renal calyceal system are on the rise. Much time and practice are required to master this technique. Navigation-supported puncture aids could help make percutaneous access easier and faster. The aim of this study was to determine whether navigated puncture is feasible, and whether it is easier and faster compared to the conventional sonographic procedure.

Materials & Methods We performed prospective free-hand percutaneous puncture on a porcine kidney model embedded in gelatin using the Xperius ultrasound system in combination with needle tracking with a Stimuplex Onvision hollow needle, compared to the conventional freehand ultrasound puncture technique. Punctures were performed by 25 participants using the ultrasound machine with or without needle tracking mode.

Results Compared to the conventional approach, the navigated approach reduced the number of puncture procedures by 0.2 attempts(8 %) in the experienced group. The time to calyx access was reduced by 15 seconds (26 %). In the novice group, navigated puncture required 1.2 fewer attempts (36 %) and the time to access was 70 seconds faster (61 %).

Conclusion Puncture using the novel device is feasible. The number of punctures and the time needed for successful access of the calyceal system was reduced by use of navigation in both groups, although the trend was significant only in the novice group. Navigation using needle tracking seems to help beginners perform sonographic percutaneous puncture at a level similar to experienced users. For a more precise analysis and validation, further studies are needed.

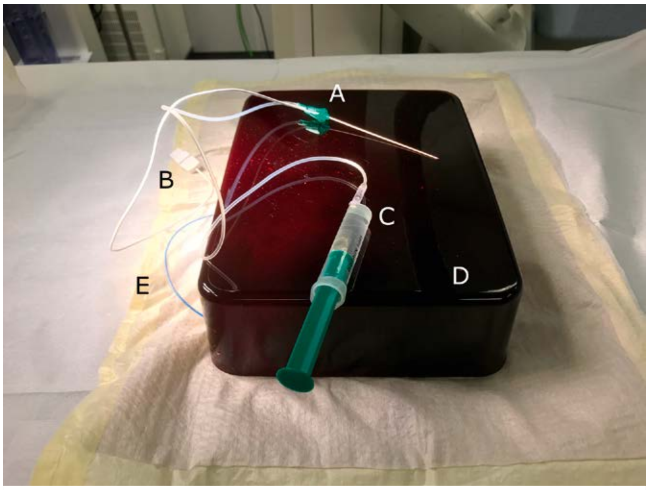
Introduction

Percutaneous puncture of the renal pelvicalyceal system is a well-established and widely used urological technique. The technique was first described in 1955 by Goodwin and colleagues [1]. In addition to ensuring reliable urine drainage in obstructed urinary diversion pathways, it serves as an access route for percutaneous nephrolitholapaxy (PCNL) in cases of distinctive nephrolithiasis. Despite widespread and frequent use, it takes a lot of time and practice to correctly perform this technique to puncture the renal pelvicalyceal system. Important factors that influence the successful puncture are body mass index (BMI) [2], the hydronephrosis grade, patient positioning technique, and, in case of a PCNL, the stone location and size and the selected access route to the renal pelvicalyceal system [3–5]. One of the main factors is the surgeon's experience, as it has been proven that a novice surgeon requires an average of 60 punctures before being able to perform them adequately and reliably [6]. The most common puncture techniques for percutaneous renal access are the “bullseye” and “triangulation” techniques [7]. Both techniques require fluoroscopy. To simplify the procedure, puncture aids [8, 9] as well as new supportive systems such as CT- [10, 11], iPad- [12], MRI- [13, 14] and robot-assisted [15] puncture and electromagnetic guided PCNL [16] were developed. New techniques are being implemented to further optimize the training process of the puncture technique itself using virtual reality (VR) simulators [17]. A disadvantage of these systems, however, is that additional instruments, devices, or even access routes [18, 19] are needed, creating additional acquisition and operating costs. In addition, new working techniques and work steps must be learned and practiced by the user. The future trend of percutaneous renal access is evolving away from fluoroscopically assisted puncture, to reduce radiation exposure [20]. This could reduce the harmful long-term effects of radiation exposure and make the use of PCNL in pediatric urology [21] safer. The purpose of this study is to find out if the novel ultrasound-guided renal puncture method used in a prevalidated pig kidney animal bench-top model [22] is feasible, safe, radiation-free, and easy to learn in comparison to traditional freehand percutaneous renal puncture. The novel ultrasound-guided needle tip tracking technology used for renal puncture in the study was first invented for peripheral nerve block procedures in the field of anesthesiology and was described previously [23].

Materials & Methods

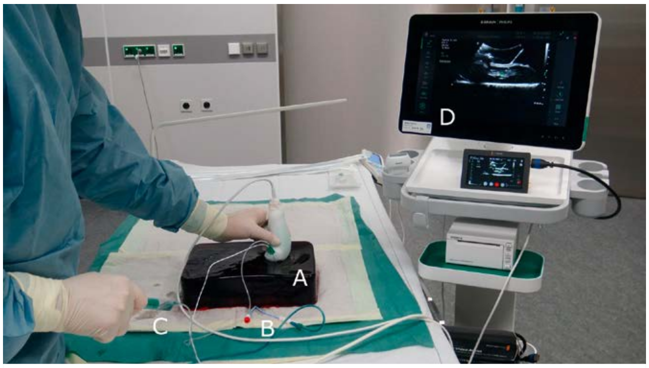
We prospectively performed freehand percutaneous renal access in a previously described animal bench-top model using the novel ultrasound-guided technique compared to the conventional ultrasound technique. The freehand punctures were performed for both techniques by 25 participants utilizing the Xperius ultrasound system (Philips Medical Systems International BV, Eindhoven, The Netherlands).

For this study we recruited 10 urologists, 7 residents of the urology department, and 8 medical students. The participants were divided into 2 groups – the 10 urologists formed the experienced group, and the other 15 participants were defined as the novice group. Despite the wide range of available training options and models, there is currently no established standardized training curriculum for puncturing the renal pelvicalyceal system. The typical training of beginners essentially consists of supervised use in the operating room. It is therefore difficult to clearly define the term expert. In this study the definition of the “experienced” group was based on the number of ultrasound-guided organ punctures performed by the surgeon to date (e. g.: percutaneous nephrostomies, lymphoceles, and abscesses). The minimum number of punctures per surgeon was > 75. As already mentioned, studies have shown that a safe and adequate puncture procedure can be assumed if the number of punctures is at least 60 [6]. Participants in the “beginner” group, meanwhile, had never previously performed an ultrasound-guided puncture. It was randomized by lot which participant should use which puncture technique (navigated vs. conventional). The kidney model (▶ **Fig. 1**) consists of an *en bloc* specimen (a pair of pig kidneys connected to the big vessels and the ureter) embedded in ballistic gelatin. The feasibility of this animal bench-top model was validated with respect to face, construct, and content validity in a previous study [22]. We placed a standard 5F ureteral catheter in the ureter to fill the calyceal system with a sodium chloride solution combined with indigo carmine amino dye to mimic an obstructive calyceal system and as a tool for verifying the correct puncture of the calyceal system (▶ **Fig. 2**). The puncture was rated successful if the blue fluid could be aspirated via the puncture needle (▶ **Fig. 3**). Fluoroscopy was not needed to verify the correct placement of the needle. The ultrasound machine (Xperius ultrasound system, Philips Medical Systems International BV, Eindhoven, The Netherlands) consists of a 100mm Stimuplex Onvision hollow needle (“Luer version”, 30 °, 20G, 100mm, B. Braun Melsungen AG, Melsungen, Germany) with a piezoelectric sensor integrated at the tip of the needle (▶ **Fig. 2**) and an integrated electronic console that processes computerized signals [23]. The Xperius ultrasound system used in this study, including the Stimuplex hollow needle, is a fully commercially available system.



▶ **Fig. 1** Overview of the gel model. (**a**) Stimuplex Onvision hollow needle (“Luer version”, 30 °, 20G, 100mm) with needle sensor in the needle tip and connecting cable (**b**) to the ultrasound device. (**c**) 10ml syringe, Braun company, connected by tube to the Stimuplex Onvision needle to inject or aspirate fluids. (**d**) Gel model, containing a real pair of porcine kidneys with one ureter per each kidney that are intubated by 5 french ureteral catheters (**e**).

The correct position of the needle tip within the ultrasound beam is indicated by a green circle projected around the needle tip on the ultrasound screen (▶ **Fig. 4**). Once the needle tip is positioned slightly outside the ultrasound beam, but is still visible for the surgeon, the green circle turns into a red circle and an additional blue circle appears around the red circle (▶ **Fig. 5**). As the needle

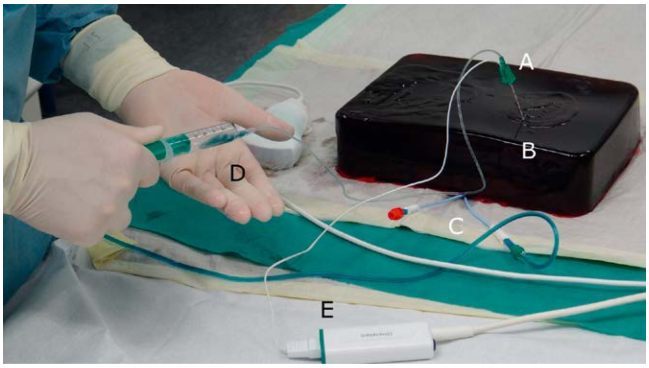


▶ **Fig. 2** Experimental setup with successful puncture of the gel model (**a**), the renal pelvis is filled with blue fluid via the inserted ureteral catheter (**b**). The blue fluid as a control of successful puncture, was aspirated with a 10ml syringe (**c**), via a tube of the hollow needle. (**d**) Xperius ultrasound system with the guided needle tip (green circle) of the Stimuplex Onvision hollow needle ("Luer version", 30°, 20G, 100mm; B. Braun Melsungen AG, Melsungen, Germany) with a piezoelectric sensor which is integrated in the needle tip, on the ultrasound image of the pig kidney. Needle navigation is switched on. The correct position of the needle tip within the ultrasound beam is indicated by a green circle projected around the needle tip on the ultrasound screen (D).

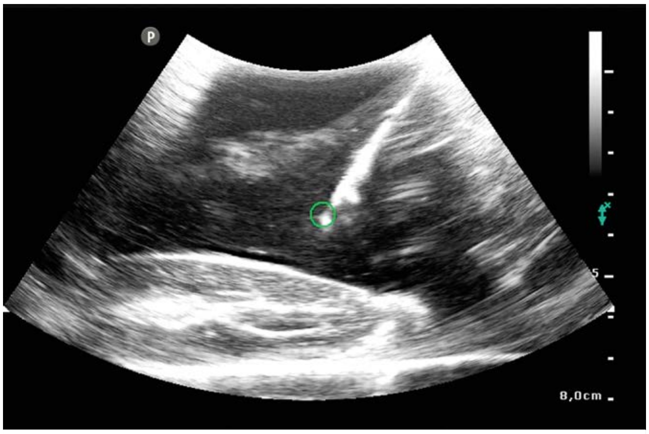
tip moves further away from the ultrasound beam, the diameter of the blue circle increases (▶ **Fig. 6**). The maximum size of the blue circle can become twice the size of the red circle. Afterwards, it disappears.

To standardize the procedure, all participants went through a defined 15-minute introduction. First, the participants were shown a video clip that demonstrated the technique and technology of visualizing the needle tip. To adapt to the anatomy of the puncture model and to get used to the handling of the ultrasound transducer, a short exercise sequence was performed on the model under qualified supervision. Thereafter, the attendees were randomized per lot into two puncture groups, one with a visually guided needle tip and one without (conventional). Each participant had to puncture successively first the lower, then the middle, and lastly the upper pole of the calyceal system of the model. The primary endpoint was successful access to the calyceal system. Needle correction during the puncture was allowed, but if the participant removed the needle completely, he had to restart with a new puncture attempt. The puncture time in seconds and the number of puncture attempts were measured.

Due to the prospective nature of the feasibility study with a sample size of 25 subjects (N = 25), the focus of this study was on providing a detailed description of the collected data. For descriptive statistics, medians, minimum and maximum values, ranges and the 25 %, 50 %, and 75 % percentiles were determined separately for each of the two puncture methods. The descriptive evaluation was carried out once for the entire group of test subjects and separately according to the two degrees of experience of the surgeons: "experienced" and "novice".



▶ **Fig. 3** Close-up view of the successful puncture. (**a**) Stimuplex hollow needle. (**b**) Gel model. (**c**) Inserted ureteral catheter with blue dyed water, to fill the renal pelvic calyceal system. The blue fluid as a control of successful puncture was aspirated with a 10ml syringe (**d**), via a tube of the hollow needle (**a**). (**e**) Connecting cable of the sensor (which is wrapped around the needle tip) with the ultrasound device.

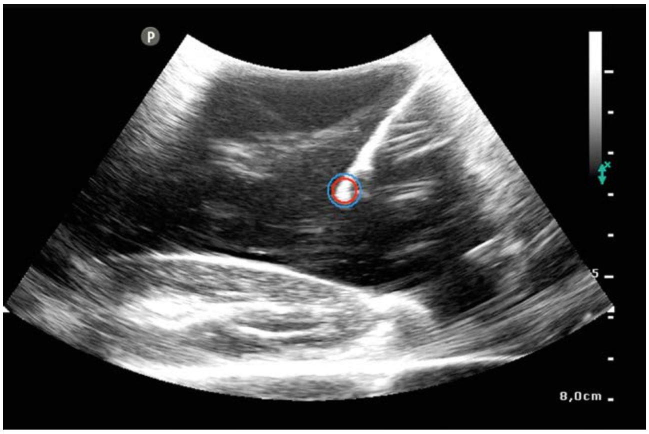


▶ **Fig. 4** Ultrasound image of the kidney model. Needle navigation is switched on. The correct position of the needle tip within the ultrasound beam is indicated by a green circle projected around the needle tip on the ultrasound screen

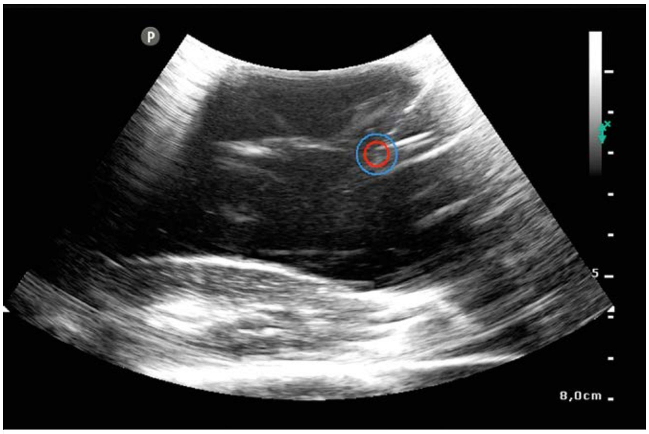
Statistical analysis was performed with SPSS Statistics 26 (IBM Corporation, Armonk, New York, USA) using the unpaired t test. Results with $p \leq 0.05$ were considered significant.

Results

The results are summarized in ▶ **Table 1** and shown graphically in ▶ **Fig. 7**. Navigated access for experienced participants reduced the number of punctures by 0.2 attempts (8 %) and the time to calyceal access by 15 seconds (26 %). These results were not significant (puncture attempts (PA) $p = 0.42$; time to access (TTA) $p = 0.19$; see ▶ **Table 1**). The novice group using navigated puncture required 1.2 fewer attempts (36 %) and 70 seconds less (61 %) in comparison to the conventional puncture technique. These results were significant (PA $p = 0.037$; TTA $p = 0.042$; see ▶ **Table 1**).



▶ **Fig. 5** Ultrasound image of the kidney model. Needle navigation is switched on. The needle tip is positioned slightly outside the ultrasound beam but is still visible. An inner red circle and an outer blue circle appear at the tip of the needle. This indicates that the needle tip is not on track. The direction must be corrected.



▶ **Fig. 6** Ultrasound image of the kidney model. Needle navigation is switched on. The blue circle becomes larger the further the needle tip deviates from the sound plane. The direction must be corrected.

▶ **Table 1** Puncture attempts and puncture times of the different puncture groups.

Group (N = 25)	Average number of puncture attempts (PA) (median* (range))	Average puncture time in seconds time to access time to access (TTA) (median** (range))
1 (n = 5) Experienced/conventional	2.5 (±1.5)	57 (±36)
2 (n = 5) Experienced/navigated	2.3 (±0.5)	42 (±8)
3 (n = 9) Novice/conventional	3.3 (±1.5)	114 (±87)
4 (n = 6) Novice/navigated	2.1 (±0.6)	44 (±28)

*Median of the mean values of puncture attempts needed for calyceal access.**Median of the mean values of puncture time needed to calyceal access in seconds.

Discussion

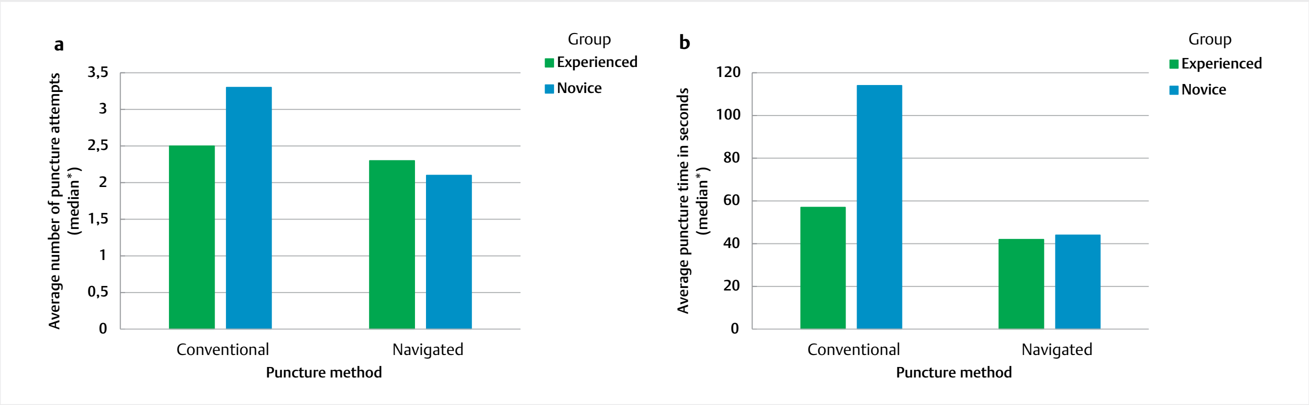
Our data show that use of the navigational system did not make a significant difference in the number of puncture attempts, or the time required for successful access to the renal pelvicalyceal system for well-trained urologists. In contrast, for participants in the novice group, use of the navigational system significantly reduced both the number of puncture attempts and the time needed for successful access. Furthermore, the results of the beginner group using the navigation system are comparable to the results of experienced users with or without navigation. These findings suggest that use of navigation, particularly for trainees, provides safer and easier handling of the percutaneous puncture technique and would theoretically be associated with increased patient safety. Fewer puncture attempts would reduce the risk of intra- and postoperative complications. While severe and life-threatening complications like intestinal perforation, sepsis, uncontrolled hemorrhage requiring an explorative laparotomy and potential nephrectomy, cardiac arrest, or death are rare, occurring with a frequency of 0–4 % [24–27]. The most frequent complications described in the literature, including pain, postoperative fever, transient hematuria, urinary tract infections, and tube dislodgment or occlusion, occur with an average rate of 4–38 % [24, 25, 27, 28] and cause significant stress and additional expense.

Of course, the results must be viewed critically, since they are limited by the small cohort number and the model construction. As this is a bench-top model, the punctures were performed under near-optimal and highly repeatable experimental conditions. The use of real pig kidneys, which are very similar in morphology to those of humans, offers an excellent training model with a low cost-benefit factor [29], and could be enhanced by the use of dyed liquid for confirmation of successful puncture. Natural disruptive factors present in real-life percutaneous puncture, such as resistance of the abdominal wall layers, excess patient weight, respiratory movement, poor positioning of the patient, higher degrees of congestion, such as II-III ° hydronephrosis of the calyceal system, all would be expected to increase the complexity in real procedures.

Due to the designed approach of a feasibility study based on a gel model and under near optimal puncture conditions, possible complications occurring under real conditions could not be detected. The only thing that stood out, which can be transferred to the real world, is that with frequent punctures (> 7) per kidney, there was leakage of fluid from the kidney. This would be an indication of urinoma formation or possibly postoperative hemorrhage. This occurred in a total of 3 subjects only from the beginner group, who performed a conventional puncture without a needle tracking system.

An important advantage of sonographically guided puncture is the complete lack of X-rays, which significantly increases the safety for the patient and the surgeon in terms of radiation exposure.

A limitation of the commercially available system used here is mainly the size of the available Onvision Stimuplex hollow needle. The needle is 100mm in length and 20G in width. In the gel model used here, the length was adequate to achieve sufficient organ



▶ **Fig. 7** Graphical illustration of the number of puncture attempts and time to successful puncture of the two groups studied. The green graph represents the experienced participants and the blue graph represents the novices. (**a**) Average number of puncture attempts according to the puncture method and level of experience. *Shown is the median of the averaged number of punctures (mean values from puncture 1, 2, and 3) needed for calyceal access, grouped according to the puncture method and level of experience. (**b**) Average puncture time according to the puncture method and level of experience *Shown is the median of the mean puncture time (mean values from puncture 1, 2, and 3 in seconds), grouped according to the puncture method and the level of experience. Navigated access for experienced participants reduced the number of punctures by 0.2 attempts (8 %) and time to calyceal access by 15 seconds (26 %). These results were not significant (puncture attempts (PA) p = 0.42; time to access (TTA) p = 0.19; see ▶ **Table 1**). The novice group using navigated puncture required 1.2 fewer attempts (36 %) and 70 seconds less (61 %) in comparison to the conventional puncture technique. These results were significant (PA p = 0.037; TTA p = 0.042; see ▶ **Table 1**).

puncture. Under real circumstances, it would be too short, especially in patients with obesity. Needles up to 150mm in length are available but were not able to be obtained at the time of the study. These, too, might be too short under real-world conditions. In addition, a slightly thicker needle, e. g., 18G, would be advantageous for placing common wires.

To simplify the puncture procedure, increase patient safety, and reduce surgical complications, new techniques have already been developed. Various puncture aids and additional imaging techniques such as CT- [10], MRI- [13], or iPad- supported [12] percutaneous puncture have been successfully tested (see **supplementary table 1**). For example, in 2015, Ritter et al. [10] demonstrated a new and safe puncture technique for complex punctures in PCNL, biopsy, or drainage tube insertion, using the Uro-Dyna CT scan and 3D reconstruction of organ structures. However, this also required special training with regard to using the technique. In 2008, Kariniemi et al. [13] also demonstrated MRI-assisted complication-free and radiation-free nephrostomy in 8 patients in a feasibility study. In this case, however, puncture was performed by radiologists and an average puncture time of 26 minutes was demonstrated. In addition, a special MRI-capable puncture set was required. Puncture robots such as the AcuBot system were also developed, but are not yet well established [15]. The advantages of puncture combined with sectional imaging are the ability to determine the exact location of the puncture needle as well as targeted puncture in the desired organ area. This also allows puncture of smaller or sonographically difficult-to-access target structures such as small masses and abscesses or complex punctures with a pronounced stone load in the kidney and reduces the risk of complications such as injury to surrounding structures and multiple puncture attempts. One disadvantage is the additional time needed for imaging. In Germany, the puncture procedure and a CT or MRI examination must be performed in a radiology department and require additional personnel to operate the equipment. In addition, the use of CT entails radiation exposure. For iPad-navigated puncture, a CT examination is required in advance. Furthermore, real-time imaging during iPad-navigated puncture is not possible, so that fluoroscopy is also required. In summary, the visually combined procedures result in an increase in time, are cost-intensive, require spatial and personnel expenditure, and, depending on the procedure, require additional radiological radiation exposure. Sonographically guided renal puncture is firmly established as an alternative. Freehand puncture without the use of puncture aids also provides the surgeon with more degrees of freedom and puncture angles. However, sonographically assisted puncture is technically more demanding of the surgeon because the puncture needle is very difficult to track on ultrasound. Thus, a certain discrepancy between the needle seen on ultrasound and the actual needle position in the desired target area can be assumed. In addition, the needle has to be corrected as soon as it is lost from the ultrasound field. This leads to trauma in the target tissue, which can lead to complications such as severe secondary bleeding and hematoma. Studies show that at least 60 punctures are necessary to master sonographically supported puncture [6]. There have been various approaches to simplify sonographically supported percutaneous renal puncture, while avoiding radiation exposure. Already in 2011, Huber et al. published an experimental study on electromagnetically supported, ultrasound-guided percutaneous renal puncture [30]. More recently, in a single-center study by Chau et al. in 2016, percutaneous nephrolithotomy was successfully performed on 18 patients without X-ray radiation. In this study, sonographic puncture was supported by a magnetic field for better visualization of the needle position [20].

Conclusion

Navigated freehand puncture of the calyceal system utilizing the Xperius ultrasound system, in combination with needle tracking using the Stimuplex Onvision hollow needle in an ex vivo pig-kidney model embedded in gel is feasible and allows novice users to perform like experienced users in terms of puncture time and number of attempts. The major technical drawback is the limited length and diameter of the available needle. The small cohort of participants is a limitation of our study. Because of the constraints of the bench-top model that was used, the transferability of the results to real-world scenarios must be verified using an *in vivo* clinical study.

Parts of this work were previously published as a dissertation by M. Hohmann [31].

Conflict of Interest

The authors declare that they have no conflict of interest.

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