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ORIGINAL ARTICLE

Novel laser positioning navigation to aid puncture during percutaneous nephrolithotomy: a preliminary report

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Abstract

Purpose Accurate puncture of the renal collecting system is crucial to the success of percutaneous nephrolithotomy and presents a technical challenge for urologists. Here, we introduced the Surgical Approach Visualization and Navigation (SAVN) system, a novel navigation system to assist puncture and reduce intraoperative radiation.

Materials and methods Twenty kidneys of 10 cadavers were randomly divided into two groups for renal calyx puncture. In the control group, traditional fluoroscopy was used for guidance, while SAVN system was used in the experimental group. Puncture duration, number of puncture attempts, total number of intraoperative fluoroscopies, and number of fluoroscopies during the puncture procedure were recorded.

Results The puncture duration was 14.2 ± 2.5 s in SAVN group and 48.3 ± 7.1 s in conventional group ($P < 0.05$). One puncture attempt was needed for successful puncture in SAVN group, while more than one in conventional group ($P = 0.28$). The total number of intraoperative fluoroscopies was 3.3 ± 1.0 in SAVN group and 14.5 ± 3.1 in control group ($P < 0.05$),while the number of fluoroscopies during the puncture procedure was 0 and 11.2 ± 2.4, respectively ($P < 0.05$).

Conclusions The novel SAVN system has a simplified structure and is easy to use. It can be used to successfully assist with puncture of the renal calyx, thus reducing puncture duration and radiation dose.

Keywords Kidney stones · Percutaneous nephrolithotomy · Puncture · Navigation

Introduction

Since its introduction in 1976, percutaneous nephrolithotomy (PCNL) has become the gold standard for the treatment of kidney stones larger than 20 mm in diameter [1], as it is minimally invasive and associated with few complications.

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This procedure has been embraced by most urologists and largely accepted by patients [2]. The establishment of a safe and reliable percutaneous tract to the renal collecting system is critical during the PCNL procedure as this often affects the outcome of the treatment [3, 4]. Currently, percutaneous puncture under fluoroscopic C-arm guidance is one of the safest and most accurate ways to establish a tract. However, distinguishing three-dimensional renal anatomy on two-dimensional X-ray film is a problem when using any of the current fluoroscopic guidance methods [5, 6]. This results in a greater number of fluoroscopies needed for an accurate puncture, increasing harmful radiation exposure for both surgeons and patients. Therefore, establishing percutaneous tracts safely and accurately, while reducing radiation exposure is a research goal for many surgeons.

Here, we describe a method for establishing percutaneous tracts using a novel surgical navigation named the Surgical Approach Visualization and Navigation (SAVN) system. The SAVN system is designed to determine the optimal surgical path to a target site and has previously been used to locate foreign objects accurate for surgical removal [7–9]. The SAVN system has the potential to quickly and accurately establish PCNL percutaneous tracts. The current study was designed as a randomized, controlled experiment using cadavers to investigate, if the SAVN system improved puncture efficiency and reduced radiation exposure compared with conventional fluoroscopic guidance techniques.

Materials and methods

The navigation: description of the apparatus

The specific technique applied to the SAVN system (Santa Medical Technology Limited Company, Hangzhou, China) used in this study is based on the theory of “X-ray Trajectory Visualization during Target Imaging” [7, 8]. The SAVN system is compatible with multiple models of C-arm devices from multiple manufacturers. In our study, the SAVN system was installed on our C-arm machine (JZ06-C, Jizhi Medical Devices Technology Limited Company, Xi’an, China) and the main components of the SAVN system are the laser driver device and the data processing module (Fig. 1). The laser driver device is installed at the image intensifier of the C-arm machine to generate a visible laser beam to indicate the optimal path. The data processing module is connected to an image signal output cable of the C-arm machine to receive the target image acquired by the C-arm machine, process and utilize the data. The working principle is as follows (Fig. 2): The X-rays produced by the C-arm machine form a conical structure and the central axis of the cone is the Z-axis, while the image intensifier is in the X–Y plane, together establishing a three-dimensional coordinate system. When an X-ray emitted by the bulb tube of the C-arm machine passes through point A in the body and body surface point A_1, it is imaged as point A_2 on the image intensifier. The image acquired by the intensifier is input to the data processing module via the data cable and subsequently processed to calculate the coordinates $(x, y, 0)$ of point A_2. Using the coordinates of point A_2 and point O $(0, 0, -h)$, where h is the distance from point O to the X–Y plane calculated by the navigation and calibration, an equation based on

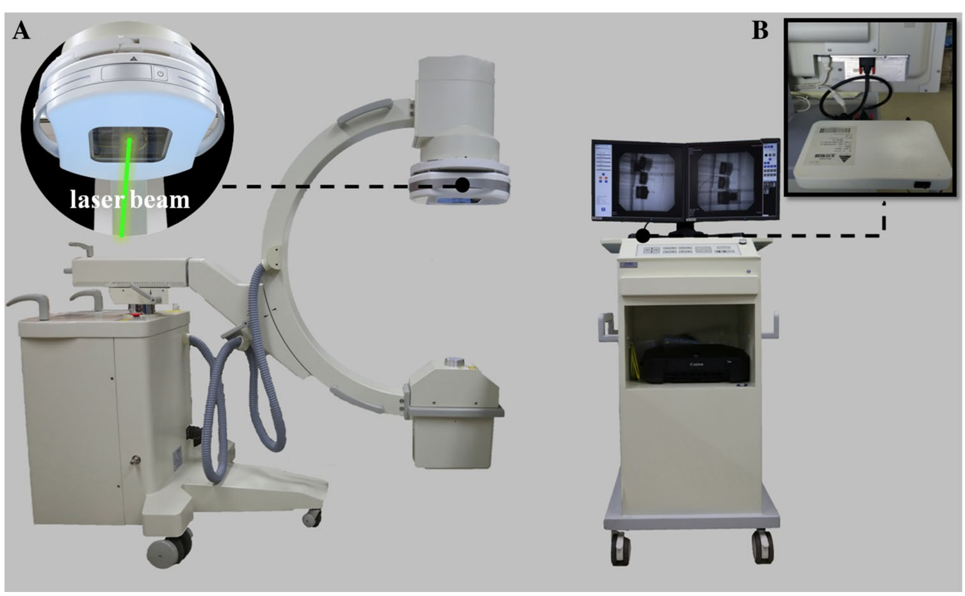

Fig. 1 Components of navigation equipment: **a** the laser driver device, and **b** the data processing module

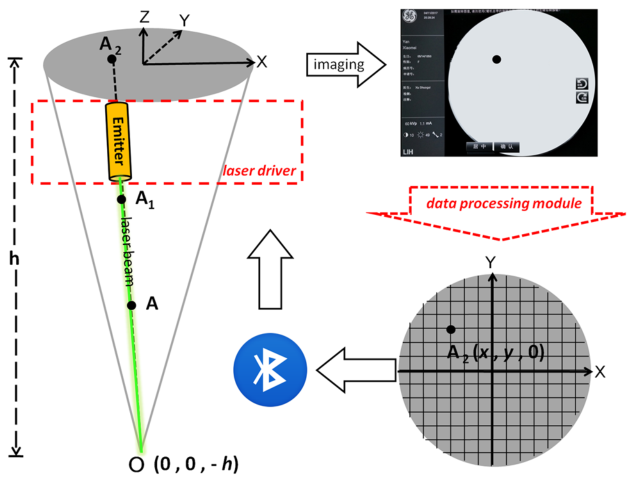

Fig. 2 Navigation principle

the X-ray which passes through point A and A_1 and imaged at point A_2 can be calculated. The data processing module then passes the equation to the laser driver device through the wireless device. The laser driver device automatically adjusts the position and direction of the built-in laser-emitting tube. The X-rays are then simulated by a visible laser beam to visualize it. The positions of the body surface point A_1 and the pass to point A (OA_2) are then able to be determined along the position and direction indicated by the laser beam.

Experimental setup

Ten cadavers, without history of urinary tract disease, were used in this experiment. Twenty kidneys were randomly assigned to a conventional group or an SAVN group ($n = 10$ each group). The posterior calyxes of all the kidneys were regarded as the desired renal calyxes. All surgical procedures were performed alternately between groups by the same urology trainee who had little previous PCNL experience. All puncture procedures were performed using 18-gauge, 15-cm-length, diamond-tipped needles.

Retrograde pyelography was performed prior to the experiment. An approximately 10-cm incision above the symphysis pubis was made layer-by-layer until the bladder was exposed. The anterior bladder wall was then excised using tissue scissors to expose the vesical trigone. Two 5 Fr or 6 Fr ureteral catheters were slowly inserted into each of the ureters (Fig. 3a). Catheters were inserted as deep as possible, but advancement was stopped immediately in cases where resistance was felt, as formalin-fixed ureters lose elasticity and are easily perforated. Iohexol Injection, 350 mg I/ml, was diluted to a ratio of 1:3 and slowly infused along the ureteral catheter as a contrast agent. Special care was taken to prevent extravasation of the contrast agent.

Surgical procedure (conventional group)

The cadavers were placed prone and the C-arm machine was placed perpendicular to the specimen at the location of the target kidney. An image was taken and the position of the C-arm was adjusted such that the kidney was approximated to the center of the visual field, near the operator's side. The C-arm was rotated 30° from a perpendicular position toward the operator and fluoroscopy was performed to acquire the cup-opening image of the desired renal calyx (Fig. 3b). The operator was wearing a radiation-proof lead coat. The puncture needle was held using a needle holder and the direction and position of the needle was adjusted under fluoroscopy, such that the two ends of the puncture needle and the desired renal calyx were superimposed on the fluoroscopic screen, showing a "bull's eye" sign [5]. Once the puncture needle was in the correct position and orientation, it was inserted. Repeated fluoroscopy was needed during the insertion of the needle to monitor the position and direction of the needle such that when deviations occurred, the needle could be adjusted quickly. When the needle reached a depth of 4–6 cm (at the level of the renal capsule), gentle suction was applied to the attached syringe, while the needle was advanced further. The puncture was successful if urine was withdrawn successfully [5]. If the direction for needle advancement could not be adjusted or the puncture failed, the needle was pulled out and the puncture repeated. This was recorded as a puncture attempt.

Surgical procedure (SAVN group)

The acquisition method for the cup-opening image of the desired renal calyx was the same in the SAVN and conventional groups (Fig. 3). After successful acquisition, fluoroscopy was not needed for subsequent steps. The center point of the desired renal calyx cup-opening was easily selected with a mouse cursor on the screen of the C-arm machine equipped with SAVN system, and the data processing module of the SAVN system then calculated the coordinate information at the point. The equation of the X-ray beam through the desired renal calyx was calculated by combining the coordinates O (0, 0, h) of the bulb tube of C-arm machine. This equation was then passed via Bluetooth to the laser driver device at the end of the image intensifier. The laser driver device subsequently adjusted the position and direction of the built-in laser tube such that the X-ray could be simulated with a visible laser beam (Fig. 4a). Then, the puncture needle was placed on the laser-indicated projection point of the body surface (Fig. 4b). The tail of the puncture needle was adjusted such that the direction for needle advancement was superimposed with the laser beam (Fig. 4c). After successfully adjusting the position and direction, the needle puncture

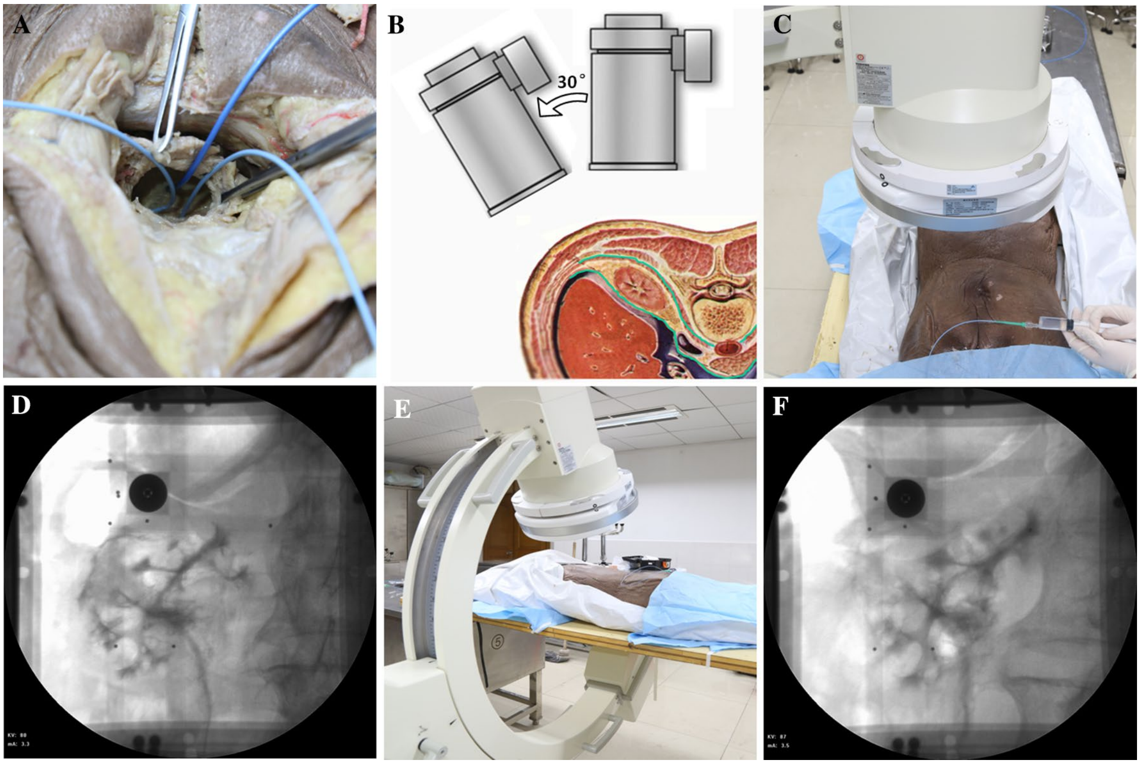

Fig. 3 **a** The ureteral catheter was inserted from the opening of both ureters at the urinary bladder and retrograde pyelography was performed. **b** A schematic diagram of the method for obtaining a cup-opening image of desired renal calyx. **c** C-arm machine is perpendicular to the specimen and obtained the anteroposterior image. **d** The anteroposterior fluoroscopy of the renal collecting system. **e** The C-arm machine rotated 30° towards the operator and took radiographs. **f** The fluoroscopic image of the posterior renal calyx taken by the C-arm machine, which rotated 30°

was made in the direction indicated by the laser. Similar to the conventional procedure, when the needle reached a certain depth (4–6 cm), suction was gently applied to the attached syringe as the needle was advanced further and if urine was successfully withdrawn, the puncture was considered to be successful (Fig. 4d). If the puncture was not successful, the operator relocated the needle and the puncture was repeated. This was recorded as a puncture attempt.

As the surgical procedures after the puncture are identical in both groups, the goal of the current study was to determine whether the novel SAVN system could assist with puncture of the renal calyx and reduce radiation dose. Thus, puncture duration (that is, the time from the successful acquisition of the cup-opening image of the desired renal calyx on the fluoroscopic screen to the successful puncture), the number of puncture attempts, the total number of intraoperative fluoroscopies, and the number of fluoroscopies during the puncture procedure were recorded. The time of a single fluoroscopy exposure was 2 s. The data were analyzed with SPSS 23.0 (SPSS Inc., an IBM company, Chicago, Illinois, USA) and $P < 0.05$ was considered statistically significant.

Results

Retrograde pyelography was successful in all renal collecting systems of 20 kidneys. No abnormalities or lesions were found. The desired renal calyx puncture was successful in both groups (all 20 cases). The puncture duration was significantly shorter in the SAVN group (14.2 ± 2.5 s) compared to the conventional group (48.3 ± 7.1 s, $P < 0.05$). The frequency of puncture attempts was 1 in 10 kidney specimens (100%) in the SAVN group with all punctures successful on the first attempt. The frequency of puncture attempts was 1 in 7 kidney specimens (70%), 2 in 2 kidney specimens (20%), and 3 in 1 kidney specimen (10%) in the conventional group. The SAVN system reduced the frequency of puncture attempts, but this was not statistically significant ($P = 0.28$). There was no significant difference in the success rate of the first puncture was between the two groups (70%, 100%, $P = 0.211$). Fluoroscopy was performed during surgery 3.3 ± 1.0 times in the SAVN group and 14.5 ± 3.1 times in the conventional group ($P < 0.05$). The number of fluoroscopies performed during the puncture procedure was 0 in the SAVN group and 11.2 ± 2.4 in the conventional group ($P < 0.05$, Fig. 5).

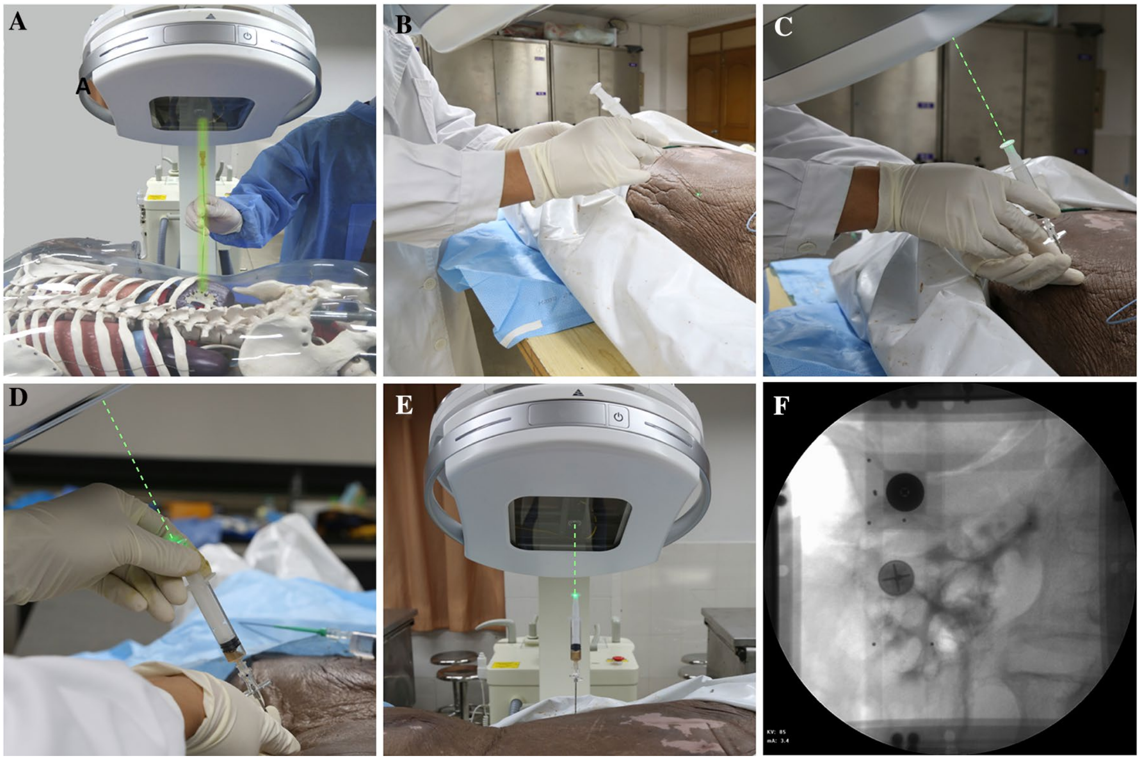

Fig. 4 **a** Renal calyx puncture diagram. **b** The tip of the puncture needle superimposed with the laser beam-indicated point on the body surface. **c** The tail of the puncture needle was adjusted so that the puncture needle was in line with the laser beam. **d** The puncture was considered to be successful if urine was successfully withdrawn when suction was applied to the attached syringe. **e** Successful puncture was verified on the fluoroscopic screen. **f** The fluoroscopic image showed that the tip, hub of the puncture needle and the desired renal calyx were shown on the Bull's eye sign

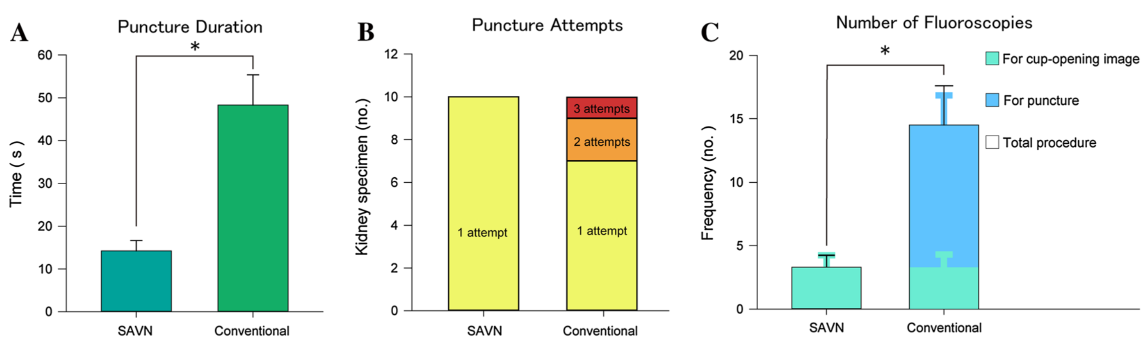

Fig. 5 Comparison between SAVN group and conventional group: **a** puncture duration. **b** Number of puncture attempts. **c** Number of fluoroscopies. *Significant differences, $P < 0.05$

Discussion

Successful percutaneous access is crucial to PCNL [3, 4], as improper puncture can lead to bleeding, perforation of the collecting system, urinary tract infection, injury to adjacent structures, and other complications, of which intraoperative and postoperative renal bleeding is the most troublesome [10]. In an ideal puncture, the needle enters the skin and passes through the papilla directly to the desired renal calyx [11]. Therefore, successfully guiding the puncture needle into the renal calyx accurately becomes an issue of concern for all urologists.

Fluoroscopy was first used to guide calyx puncture and is now a commonly used guiding technique in clinical practice [12]. At present, there are two main fluoroscopic guidance technologies in use: the triangulation technique [13–15] and the "bull's eye" puncture technique [3]. Since the triangulation technique can only monitor the direction of the puncture needle in one plane at a time, it is difficult to ensure that puncture needle does not change directions in the medial–lateral or cephalo-caudal plane. Therefore, this technique requires strong spatial imagination capacity, and often requires more fluoroscopies and additional puncture attempts. Also, the triangulation technique has a lengthy learning curve compared to the "bull's eye" technique [16]. In the "bull's eye" technique, it is only necessary to show the renal calyx cup-opening in the axial direction of the desired renal calyx. The puncture can then be achieved by adjusting the position and advancement direction of the puncture needle on the fluoroscopic screen. This technique reduces the puncture difficulty to some extent, improves the puncture success rate, and reduces radiation exposure. However, the "bull's eye" puncture technique directly exposes the surgeon's hands to radiation. Wearing gloves to protect against radiation or holding the puncture needle with hemostatic forceps negatively affects the visual field of the puncture [5]. Recently, researchers have attempted to solve this problem. Chowdhury et al. [17] produced a simple apparatus with a radiolucent cap and two aligned tubes [17]. This apparatus was used to adjust the direction and position of the puncture needle under intermittent fluoroscopy to obtain the bull's eye sign. This apparatus is simple, convenient, cheap, and effective and also allows the surgeon to adjust the puncture needle using intermittent fluoroscopy, reducing radiation exposure [17]. Lazarus et al. [18] also designed an assisted puncture locator shown to be more stable and reliable [18]. Although these devices effectively reduce the radiation exposure of the surgeon, radiation exposure to the patient is not significantly reduced. Despite the lack of studies reporting malignancies or adverse effects associated with the radiologic exposure from PCNL [19], the effects of cumulative ionizing radiation over a long period of time are of great concern to both patients and doctors [20]. Therefore, further reduction of radiation exposure in patients and surgeons is necessary.

Many doctors choose to use ultrasonic guidance for percutaneous puncture. Although this can greatly reduce the radiation dose, ultrasound does not provide adequate image quality in patients with non-distended renal collecting systems or in obese patients [21]. Furthermore, the learning curve is longer with ultrasound, as it is difficult for beginners and requires much practice [22]. In most cases, ultrasound is only used for the puncture procedure. The remaining procedures, including tract dilation, still need to be performed under fluoroscopic guidance [23]. This requires changing equipment during surgery, which may lead to a longer surgical duration and increases the chances of contaminating the sterile surgical area.

Therefore, these problems could be addressed with a safe, and more effective method for needle puncture guidance. In the current study, a new puncture technique was designed based on the SAVN working principle of in vivo target location. Our data suggest that the SAVN method is an improvement over the traditional "bull's eye" puncture technique. Only 3.3 ± 1.0 fluoroscopies were needed during the entire surgical procedure in the SAVN group and these were only used to obtain an image of the cup-opening of the target renal calyx. Once the image of the cup-opening was successfully acquired, the center of the cup-opening was selected using a mouse cursor and the visible laser beam was used to guide the surgical path through this point. The surgeon then reached the desired renal calyx by puncturing in the direction of the laser guide without any additional fluoroscopy. Comparatively, the conventional group required nearly five times the number of fluoroscopies over the entire surgical duration. The number of fluoroscopies for the acquisition of the image of the cup-opening of the desired renal calyx in this group was 3.3 ± 1.1; similar to the number in the SAVN group ($P > 0.05$). There was no statistical difference between the two groups in this step. During the subsequent puncturing procedure, the conventional group needed 11.2 ± 2.4 fluoroscopies to adjust the position and advancing direction of the puncture needle, while the SAVN group did not require any more fluoroscopy. These data indicate that the SAVN system effectively reduced the radiation dose received by the patients and surgeons. All punctures in SAVN group were successful on the first puncture attempt, with a success rate of 100% on the first attempt. However, in many cases, more than one puncture attempt was needed for successful puncture in the conventional group with a success rate on only 70% on the first puncture attempt. However, there was no significant difference in the first puncture success rate ($P = 0.211$) or the number of puncture attempts between the two groups ($P = 0.28$), which may be related to the small sample size in this study. Other studies have shown that an increase in the number of puncture attempts is related to an increased risk of complications, such as massive bleeding and renal parenchymal injury [24]. The SAVN system can direct the puncture path in real time through a visible laser, thereby avoiding multiple puncture attempts and likely reducing the occurrence of various complications. In addition, studies have confirmed that prolonged tract establishment leads to increased blood loss [25]. The results of this study also show a significant reduction in puncture duration in the SAVN group compared with the conventional group (14.2 ± 2.5 s versus 48.3 ± 7.1 s, $P < 0.05$). Unlike other surgical procedures used for percutaneous renal calyx puncture requiring complicated equipment and cumbersome procedures [26, 27], the SAVN system is simple in structure, easy to operate, does not require additional steps, and only requires one to click on the target point to complete the path navigation. In this study, all surgical procedures were performed by the same urologic trainee who did not have previous PCNL experience. The trainee mastered the SAVN technique quickly and all the renal calyx punctures were successful on the first attempt. Compared to other expensive surgical navigations, the price of SAVN system is approximately RMB 900,000. No additional consumables are needed during the operation, keeping the patient's surgery costs lower.

There are certain limitations to this study. We confirmed the success of the puncture by pulling out the urine instead of using the gold standard such as endoscopy. When operating on a patient, kidneys will inevitably move in three directions (sagittal, coronal, and transverse planes) when they breathe or when a puncture needle is inserted [28]. This movement may result in failure of the puncture, but cadavers cannot simulate this movement. In addition, none of the cadaver specimens had significant renal collecting system stones, and, thus, puncture in the presence of stones was not simulated. In the other hand, this method is an improvement over the traditional "bull's eye" puncture technique, and so it cannot guarantee that adjacent organs are not damaged in real time, like can be seen in ultrasound. In spite of limitations of cadavers-based studies, these results have important implications to improving patient and surgeon safety during guided puncture.

Conclusions

SAVN system assists in the establishment of percutaneous access in PCNL. This method reduces the radiation exposure of patients and surgeons throughout the puncture process, and reduces puncture duration. Furthermore, this technology is very simple and convenient, and can be mastered quickly by beginners. This study suggests that the SAVN method would be clinically useful when establishing percutaneous tracts in PCNL. However, clinical trials are needed to further evaluate the safety and effectiveness of this technique in live patients.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical statement The manuscript does not involve humans, or human data, or animals.

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