

Stereotactic localisation system: a modified puncture technique for percutaneous nephrolithotomy

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Abstract The objective of the study was to establish and evaluate a modified puncture and dilation technique—“stereotaxic localisation” system—and the corresponding instruments for percutaneous nephrostomy. Four hundred patients were randomised to the intervention group (200 cases, stereotaxic location puncture and dilation procedures) and the traditional group (200 cases, traditional procedure) under X-ray guidance. In the modified intervention system, the distance and horizontal angle of the puncture pathway between the puncture point and the target site were calculated accurately. The time for punctures, time with X-ray exposure and operation, success rate of each puncture to access the target, number of patients requiring blood transfusion, stone clearance, drops of haemoglobin and days of hospital stay were compared between the two groups. In the traditional and intervention groups, the time for puncture was 17 and 7 min, respectively; the X-ray exposure time was 9.1 and 1.3 min; the cases requiring blood transfusion were 9 and 5; and the success rates for each puncture to access the

target were 42.9 and 88.0%, all with statistical difference ($p < 0.01$). The other outcomes and complications revealed similar trends. The stereotaxic localisation system for puncture is statistically better than the traditional procedure used in this study. The stereotaxic localisation system in this study is safer and more accurate, and provides easier access to the target with less bleeding and reduced exposure to X-ray compared to the traditional puncture and dilation procedures of percutaneous nephrostomy.

Keywords Stereotaxic localisation · Percutaneous nephrolithotomy · Puncture · Dilation · X-ray

Introduction

Percutaneous nephrolithotomy (PCNL) is one of the most preferred treatment modalities for renal calculi [1–3]. However, the currently used traditional procedures, such as puncture and tract dilation, are not practical because they: (1) require a lot of experience; (2) are difficult for a small renal dropsy or small stone; (3) carry relatively low accuracy for a target point; and (4) involve excessive exposure to X-ray [4, 5]. Therefore, more straight and accurate target access puncture and tract dilation techniques will be required.

Inspired by the locating principle of extracorporeal shock-wave lithotripsy (SWL) and by the stereotactic technique used in neurosurgery with three-dimensional coordinates for localisation [6, 7], we designed a modified “stereotactic localisation” system together with a series of accessory devices for the puncture. The aim of this study was to evaluate its advantages over the traditional procedures for PCNL.

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Methods

Stereotactic localisation system for stereotactic puncture procedure

The principle for this fluoroscopic “stereotactic localisation” puncture system for our self-designed devices was illustrated (Fig. 1). In this perspective diagram, the horizontal distance (a) between M and O as well as the vertical distance (b) between M and P–N level can be measured. The distance (c) between M and P can be calculated by the Pythagorean theorem ($a^2 + b^2 = c^2$), as a , b and c are the three sides of a right-angle triangle. The puncture angle (β), formed by the MO and MP lines, can be calculated as well. Therefore, the depth (c) and the angle (β) of the puncture can be determined, which will guide the puncture needle precisely towards the target for the PCNL.

Measuring rulers

To measure the distance of (a) and (b) as shown in Fig. 1, a measuring ruler was invented. This ruler consists of a horizontal ruler, a height ruler, an angle ruler and a level gauge with each bubble in the horizontal and the height ruler for maintaining their position (Fig. 2). Based on the principle of Fig. 1, with the horizontal ruler and the height ruler in the vertical position, the height ruler can be slid to adjust the horizontal and vertical distance. By shifting the horizontal and vertical arm to the corresponding positions of (a) and (b), the triangle ruler side (c) and angle (β) between the angle ruler and the zero line of the goniometer can be calculated. These measurement devices have been proven to be applicable and accurate tools in stereotactic puncture procedures and were awarded a National Patent (China patent No. ZL2005 23 0128984.8).

Angle indicator

Because of the curvature of the area between the scapular line and posterior axillary line on which the puncture point

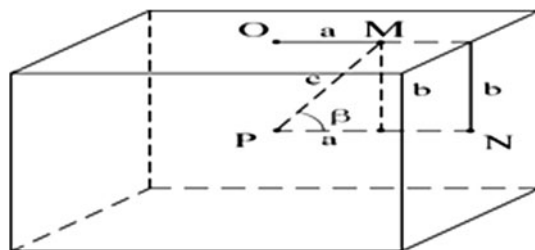


Fig. 1 Illustration of the puncture principle. M puncture point; P stone (or the target point); O vertical projection point of P by X-ray; N horizontal projection point of P by X-ray; a horizontal distance between M and O; b vertical distance between M and N; c straight distance between M and P; β angle between a and c (angle between the needle and the horizon)

was located, the angle between the needle and this curve did not exactly reflect the calculated angle (β). To deal with this problem, a self-made angle indicator was created (China patent No. ZL2005 23 0128986.7), which consists of a half goniometer with a track alongside the goniometer arc, two fixing rings and a gradienter with a direction line, with a bubble in the centre of the gradienter to maintain its horizontal position (Fig. 3). One fixing ring was mounted on the central point of the goniometer and the other on the track of the goniometer arc, which could slide along the track to adjust the angle of the puncture needle or dilator. The angle was set to (β). The gradienter was maintained horizontally with the direction line pointing towards O for the puncture and dilation.

Marking strips

The marking strip was specially designed for a quick and convenient attachment to reduce the time of radiation exposure (China patent No. ZL2005 23 0128985.2). This rectangular-shaped strip has X-ray opaque figures printed at equal intervals on one side and mucilage glue on the other (Fig. 4). One strip was attached to the back of the patient, parallel to the vertebral column for horizontal X-ray display. The other was attached vertically to the middle axillary line in the 11th intercostal region for vertical X-ray display. The projection point could be quickly marked by overlap of the stone image and the figures, reducing the radiation exposure. The three instruments described above are commercially available in China (Hua Te Medical Science & Technology Limited Company of Guilin).

Clinical trials

This randomised multicentre study of PCNL was approved by the Ethics Committee of the Third Military Medical University. All the patients had signed informed consents. From June 2008 to January 2010, a total of 400 patients [202 male and 198 female, aged from 8 to 78 years (average 40)] from two urological centres were recruited for this study. The patients with serious disease of respiratory or vascular systems were excluded. All patients who underwent KUB, IVU, ultrasonography or CT analysis and were confirmed to be with pelvis or staghorn stone (size from 1.5 cm \times 1.8 cm to 6 cm \times 7 cm) were completely randomised to the intervention group (punctures for PCNL access were performed by the stereotactic localisation approach, $n = 200$) and the traditional group (by the traditional approach, $n = 200$). All of the patients with urinary tract infection were pre-operationally treated with antibiotics. Urine leukocyte was controlled to be less than 20/high power. Patients with fungal infection were treated until no more mycete spores or bacterial filaments could be detected

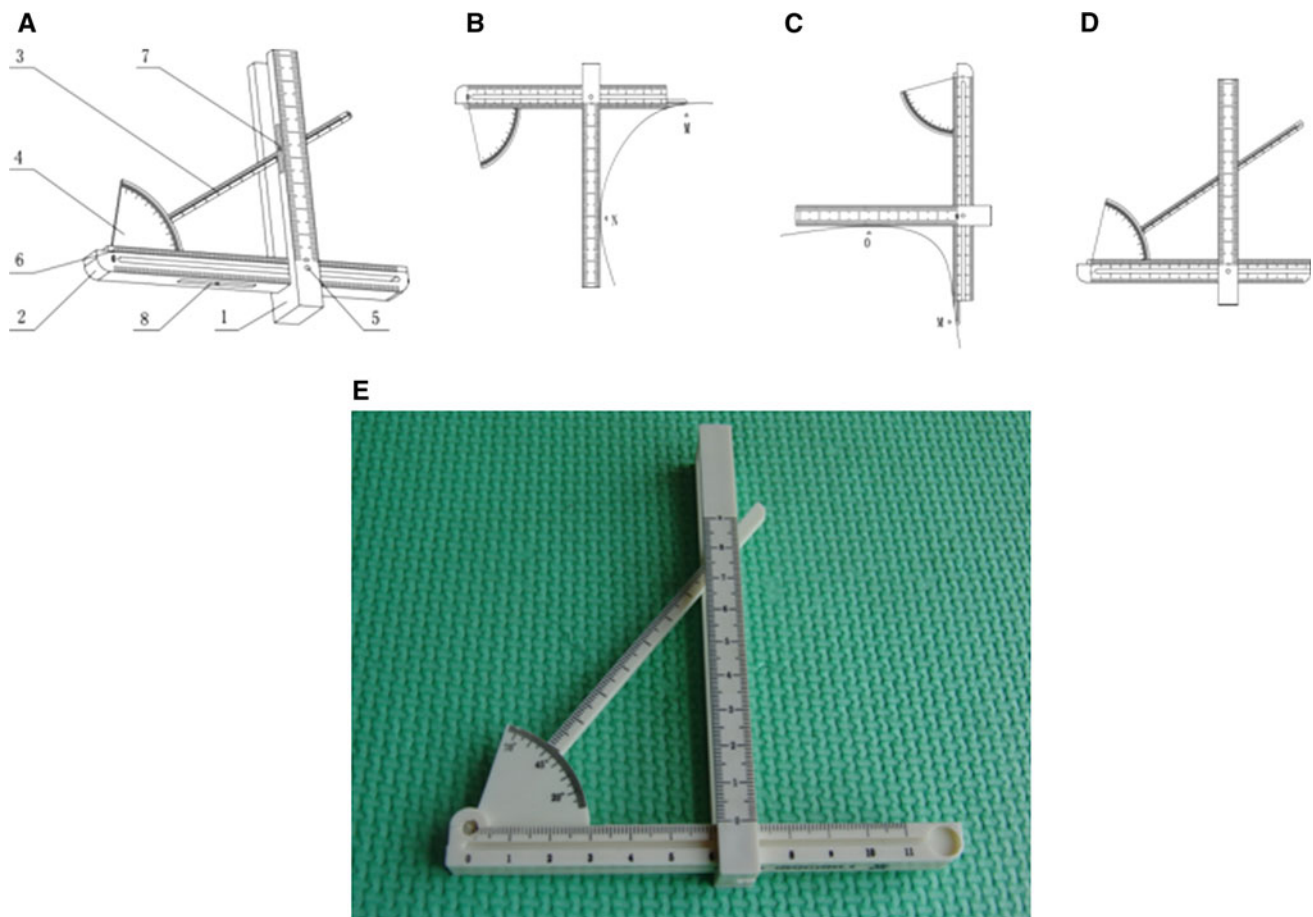
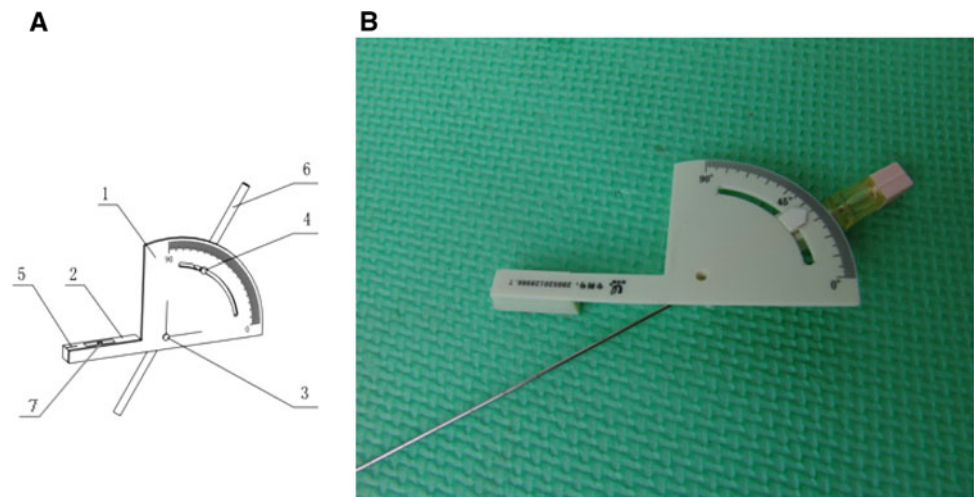


Fig. 2 Measuring rulers. **a** Illustrations (1 vertical ruler, 2 horizontal ruler, 3 angle ruler, 4 goniometer, 5 rotating axis A, 6 rotating axis B, 7 gradienter A with a bubble in its centre, 8 gradienter B with a bubble

in its centre) and photo of instrument (**e**); **b** horizontal measurement based on Fig. 1; **c** vertical measurement based on Fig. 1; **d** angle and invasion depth calculation

Fig. 3 Angle indicator.

a Illustration (1 goniometer, 2 gradienter with a bubble in its centre, 3 fixing ring A, 4 fixing ring B, 5 line of direction, 6 needle or dilator, 7 bubble for judgement of horizontal position); **b** photo of instrument (needle or dilator is able to rotate around the fixing ring)

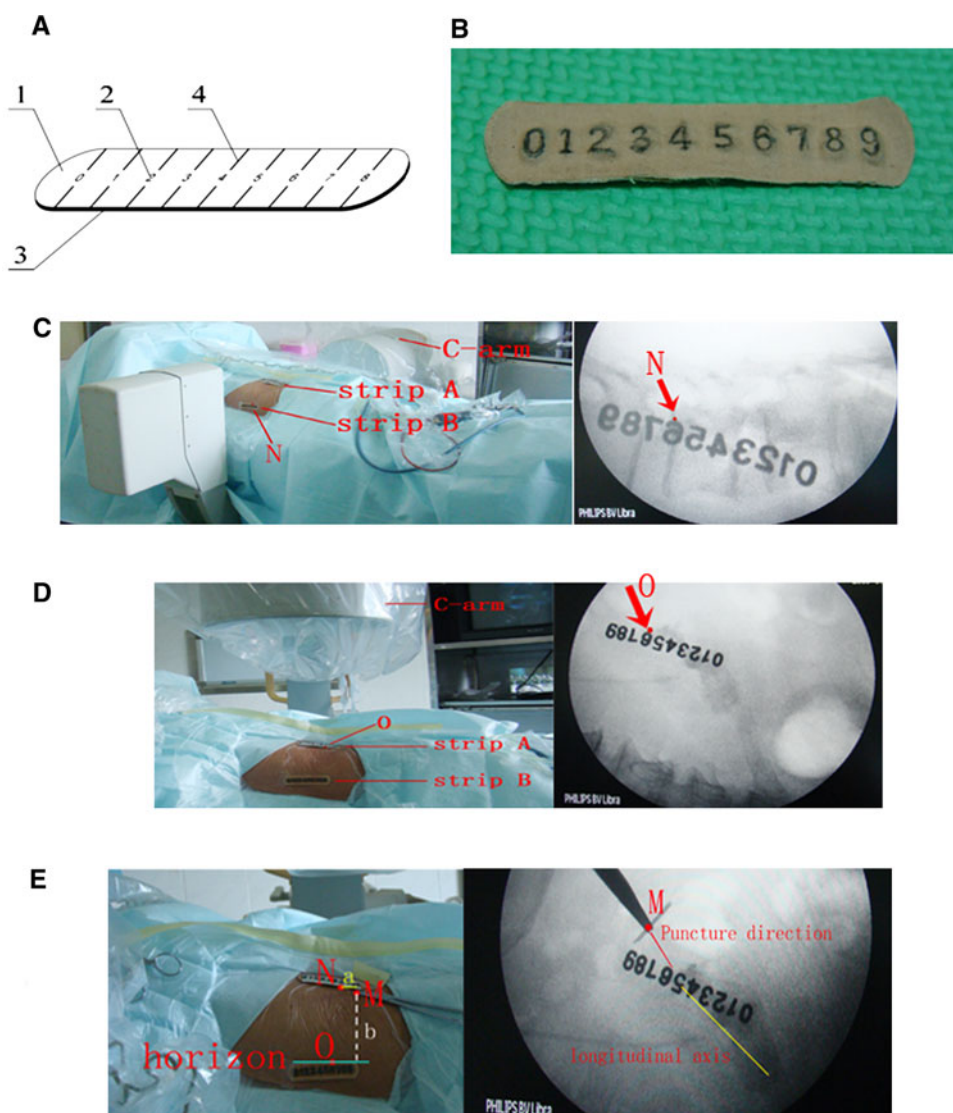


in the urine. Serum creatinine of patients with renal failure was controlled to be less than 400 $\mu\text{mol/L}$. The surgical procedures were carried out by several urologists with the same procedure and almost the same level of experiences with PCNL in this multicentre study.

Surgical procedures

All the patients were generally anaesthetised and received pre-operative ureteral catheterisation. All the punctures and dilations were accomplished with patients in the

Fig. 4 Stereotactic localisation with marking strip. **a** Illustration (1 strip, 2 X-ray opaque figures, 3 adhesive glue, 4 parallel X-ray opaque lines); **b** photo of instrument; **c** illustration for horizontal perspective (*N* the horizontal project of the stone on the strip at point 6); **d** illustration for vertical perspective. (*O* the vertical project of the stone on the strip at point 6); **e** mark of puncture point and direction



prone position. The procedures in the traditional group were performed according to the traditional protocol, under X-ray guidance [8]. In the intervention group, based on the view of pre-operative kidney–ureter–bladder (KUB) film, as shown in Fig. 4, one marking strip (A) was attached parallel to the vertebral column at the stone area (or alternatively, contrast agent was injected via the pre-operatively retrograde implanted ureteral catheter for the radiolucent calculus or hydronephrosis) or in the area 4 cm away from the spinal process for those with radiolucent calculus. Another strip (B) was attached vertically to the mid-axillary line at the apex of the 11th rib on the same side. The nearest or the best target calyx for stone clearance was usually selected as a target. If no stone was inside, contrast material was used. At the end of inspiration, the horizontal perspective point (*N*) of the stone on “strip B” was read, and a horizontal line was drawn through *N*. Under the guidance of the C-arm X-ray

machine (Philips-BV Libra), the vertical perspective and the perspective point (*O*) of the target calyx on “strip A” were determined at the end of inspiration. If the strips were out of the expected positions, markers were made on the patient’s back. The fluoroscopy time needed to set the strips was about 2 s. The measuring rulers and the angle indicator were fixed on the dilators, without any need to be set.

Puncture point *M* was picked to be near the area of the 12th rib between the scapular line and the posterior axillary line. Then, the horizontal distance between *M* and *O* (*a*) and the vertical distance of (*b*) between *M* and *N* were measured. The length (*c*) and the angle (β) of the puncture passage were determined using the measuring ruler (as in Fig. 2). The same procedure was used for the extra channels when necessary.

With the help of the contrast, which was injected through the retrograde ureteral catheter and localised by the

Table 1 Comparisons of outcome between the traditional and intervention groups

	Traditional group	Intervention group	<i>p</i> Value
Mean time for punctures (min)	17.0 ± 1.3	7.0 ± 1.2	0.005
Mean X-ray exposure time (min)	9.1 ± 1.1	1.3 ± 0.2	0.026
Min operative time (min)	65.0 ± 20.3	55.0 ± 18.3	0.005
Success rate per puncture to the target (%)	42.9 ± 8.7	88.0 ± 11.3	0.005
Bleeding requiring transfusion	9	5	0.008
Stone clearance cases	165	193	0.04
Hb drop (g/l)	15.5 ± 5.8	9.8 ± 5.2	0.005
Hospital stay (days)	9.5 ± 1.2	7.3 ± 0.9	0.03
Re-PCNL	10	4	0.005
Mean nephrostomy days	6.1 ± 1.2	5.8 ± 1.4	0.257
Gross haematuria	32	23	0.013
High fever, over 39°C	13	11	0.039
Secondary obstruction	18	14	0.027

stereotactic technique, a G18 needle followed by a Cook dilator was mounted to the angle indicator through the fixing rings. The angle was set at (β), whilst the gradienter was kept in the horizontal position, judged by the maintenance of the gradienter bubble at the centre. The puncture was set at M, whilst the direction line pointed to O. At the end of inspiration, the needle was inserted towards P following the direction and depth of (*c*). Successful puncture was verified by free passage of saline out of the internal cavity of the puncture needle when saline was continuously injected via the pre-operatively implanted ureteral catheter (if the stone was obvious, the position of the calyx or pelvis was judged according to its internal stone location without contrast). Then a F0.038 Zebra guidewire was introduced into the collecting system of the kidney through the needle. The tunnel F8 to F16 was stepwise dilated with a fascial dilator, and a peel-away plastic sheath was implanted. An example video of the technique has been linked to our home page: http://www.swhospital.com/XNYYFore/dnews_view.aspx?id=513. We also welcome anyone who is interested to contact the corresponding author for this video.

Statistical analysis

The comparisons of outcome between two groups were performed for time for puncture (timing from breaking into the skin to successfully reaching the target pelvis), X-ray exposure time, operative time, rate of success by the puncture in achieving target access, number of patients requiring blood transfusion, stone clearance, drops of haemoglobin (Hb) and days of hospital stay. The data were presented as mean ± SD. Student's *t* test was used for comparison (SPSS 13.0 software), with *p* < 0.05 considered significant.

Results

Using the traditional and three-dimensional coordinate so-called stereotactic localisation system, all of the patients in the two groups were successfully punctured and dilated. The mean time for punctures, mean X-ray exposure time, mean operative time and cases requiring blood transfusion were, respectively, 17.0 ± 1.3 min, 9.1 ± 1.1 min, 65.0 ± 20.3 min and nine cases in the traditional group, but only 7.0 ± 1.2 min, 1.3 ± 0.2 min, 55.0 ± 18.3 min and five cases in the intervention group (*p* < 0.01). The Hb drop was 15.5 ± 5.8 g/L in the traditional group and 9.8 ± 5.2 g/L in the intervention group (*p* < 0.05). All the targets were successfully reached; the success of each needle puncture in reaching the target and the stone clearance cases (rate) was 42.9% ± 8.7 and 165 (82.5%) cases in the traditional group. These values increased to 88.0% ± 11.3 (*p* < 0.01) and 193 (91.5%) (*p* < 0.05) cases in the intervention group. The hospital stay was 9.5 ± 1.2 days in the traditional group and 7.3 ± 0.9 days in the intervention group (*p* < 0.05). The outcomes and the complications in the two groups are shown in Table 1. The stereotactic localisation system for puncture was statistically better than the traditional procedure in this study.

Discussion

PCNL is a microinvasive procedure widely used for upper urinary tract calculi treatment. Clinical practice shows that the puncture technique is crucial for successful lithoclasty and satisfactory stone clearance [9]. With the improvement of skills and equipment, the puncture time

has been shortened, as have X-ray exposure time and operation time. Due to the increased safety of the operation, more complicated and higher risk cases would be able to receive the treatment. As more and more powerful stone-break machines have been used in lithoclast, a quick and safe technique for the puncture and PCNL manipulation would be required [10]. However, the puncture procedures used currently and the accessory equipment are somewhat unsatisfactory, and there is enormous potential for improvement through our clinical and experimental investigations. In comparison to the traditional procedures, the present study of a “stereotactic localisation” system for the puncture and dilation of PCNL presented higher efficiency, better stone clearance and lower morbidity for the patient with renal calculi, which presumably may be due to the greater accuracy of the puncture to reach the target point, the shorter time, less bleeding, easier multiple-channel PCNL and better general condition.

X-ray guidance for stone localisation is still favoured by some urologists. Therefore, it is crucial to improve the puncture technique to shorten the X-ray exposure time. In this study, we located the site of the target by X-ray from both vertical and horizontal perspective views. After measuring the distances between target stone and puncture point vertically and horizontally, the straight distance and angle between puncture point and target stone could be calculated and clarified. Therefore, the puncture was more straightforward and precise. For instance, in the cases of the traditional group, an instant X-ray inspection was routinely performed when the needle reached the thick cortex in case of kidney aberrance due to breathing. Whilst using the modified technique, the procedure was completely skipped because the puncture could be rapidly performed with the patient at the end of inspiration.

Accurate orientation of target access is essential for successful puncture and tract dilation [11]. The discordance of puncture access and tract dilation occurred occasionally under X-ray or ultrasound guidance with the traditional procedure, which could result in twisting or exodus of guidewires [12]. The problems did not occur in this intervention group, because our self-made angle indicator was able to guide both needle and tract dilator at the same angle. The puncture time, X-ray exposure time and total operation time were significantly shorter, and the failure rate for each puncture to gain access to the target, as well as the number of patients requiring blood transfusion, was drastically reduced, compared with the traditional group, suggesting that the modified procedure was safer and more efficient.

In cases of anterior calyceal calculus, the ureteroscope might be placed almost vertically to the horizon. The technique was not effective when the puncture angle was less than 30°, because the buttocks of the operator would be in the way when the ureteroscope moved from the anterior to

posterior renal calices. As the longitudinal axis of the kidney is 30°–50° in the horizontal plane [13], the puncture point for 45° is near the Brödel tangent at the posterior renal calices, which will cause the least bleeding and most convenience for surgery. In this study, we generally selected the puncture point with the same distance vertically and horizontally, which means at 45° from the skin to the stone, called the “45° principle”, to minimise injury to the pleura [14].

Although this is a multicentre study, all of the surgeons had experience with over 500 cases of punctures and dilations. Several advantages over the traditional procedures were revealed: increased accuracy and feasibility; reduced renal injury, bleeding and X-ray exposure; and a relatively shorter learning curve [15]. The modified puncture technique for PCNL has several advantages over the traditional procedure. This stereotactic localisation system and the accessory instruments should improve the clinical practice of PCNL.

Conclusion

The stereotactic localisation system and the accessory instruments were proven to clarify the distance and the angle to the target stone from any puncture point, which led to a nephrostomy that was more accurate and less invasive, with less bleeding and less exposure to X-ray. This method offers a novel approach to PCNL.

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Conflict of interest All the authors declare that all the devices and inventions included in the patents belong to Xuede Li, and there is no conflict of interest.

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