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Case report

Three-dimensional printing the navigation template for precise percutaneous renal puncture to treat pyonephrosis on a porcine model and a patient : a case report

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A R T I C L E I N F O

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A B S T R A C T

Objective: Percutaneous nephrolithotomy (PCNL) is the main method for pyonephrosis or lithotripsy in urology. However, it often comes with high risk, as the inaccurate puncture inevitably causes bleeding, intra- and post-operative complications. So, a new inter-disciplinary approach is needed to perform the puncture more accurately.

Methods: 3 signs made of lead were marked onto the skin of the posterior side of the waist of a domestic pig or a patient, which was scanned by computed tomography (CT). Based on the CT images, the computer design and the 3D printing, a navigation template made of the transparent resin material is constructed. They were attached onto the surgical area on pig or patient according to the signs. During the PCNL, with this template, the puncture position, angle and depth were optimized in order to precisely enter the targeted renal pelvis or calices.

Results: With the 3D navigation templates, 18G puncture needles were used to enter the renal pelvis upon performing the PCNL on a porcine model and a patient. On the porcine model, the urine outflow was observed with minimal complication. Post-operative CT scans revealed that the needle was located in the renal pelvis. For the patient case, the puncture point was designed to target the calix with stone. No obvious bleeding and complication was found in renal puncture with template.

Conclusions: The navigation template was made with the combination of 3D printing, CT images and computer design. This template allows for accurate puncture of the renal pelvis or calix. Surgical improvement in kidney stones and pyonephrosis was observed in porcine model and patient case. In the future, prospective, trandomized, controlled clinical trials are needed to further confirm its advantage.

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1. Introduction

For large and complex calculi, percutaneous nephrolithotomy (PCNL) remains to be the mainstream and efficient lithotripsy method in urology. However, this surgical method may have a variety of intra-operative and post-operative complications, such as bleeding, infection, residual stones [1]. A few issues are listed as below. Hemorrhage is the most common one due to the misplaced renal puncture, missing the actual passage by inexperienced surgeons often leads to the injury of vascular-rich areas [2]. In particular, the residual stones are also related to the location of renal calices. So, the accurate selection of renal calix is important to reduce the renal parenchyma tear [3]. In clinical practice, the PCNL is often performed under the guidance of X-ray or ultrasound [4,5]. The ideal target of renal calix requires an exact papillary puncture [6,7].

Before entering the required renal calix, the initial puncture on the body surface of the channel and the calix neck should avoid important organs. While X-ray guidance is applied to help position the needle, it is still unable to distinguish the needle from the surrounding tissues of the kidney [8], not to mention the immediate radiation to the medical staff and patients. Furthermore, despite that the ultrasound-guided PCNL is non-radiative, but the learning curve is steep to most surgeons. Also, the needle passage is liable to be lost during the operation. So, all the realities cause the high rate of puncture failure with serious bleeding, among other issues [9–11]. A better approach is called for.

Three-dimensional (3D) printing is a new technology that combines computed 3D digital imaging with multi-level continuous printing [12]. It can generate a 3D solid model by adding materials layer by layer through layered processing and superposition molding of human tomography data [13]. So, it has attracted a lot of attention in the medical field, and the application in urologic calculi treatment will be useful but still scarce. For example, one application of 3D printing in urology is to print out the 3D models of the kidneys and calculous for pre-operative case discussion and teaching [14], to help patients and doctors understand the anatomical structure of kidneys and perirenal to appreciate the key points of the PCNL surgery. The disadvantage is that the reference materials used for operation are not very significant [15,16].

In this study, we design a 3D printing navigation template which is based on kidney unenhanced computed tomography (CT), and apply it to the renal puncture experiment in a porcine model and a patient. Such a new way allows operation of the precise puncture leading to the good surgical performance.

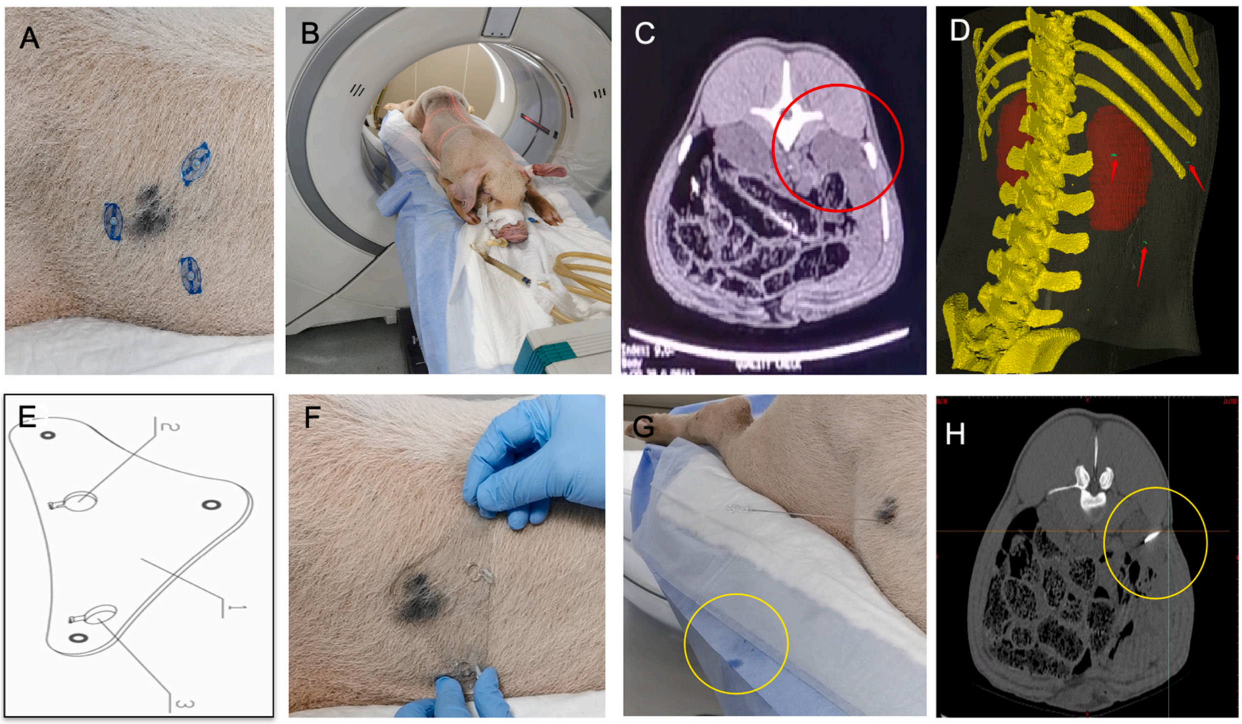

Fig. 1. A: 3 signs in blue in a red circle onto a domestic pig; B: CT scan on the pig with a focus on the red circle area; C: CT image of the kidney in the red circle; D: 3D reconstructed kidney; 3 signs are the red arrows; E: Drawing of the 2D puncture navigation template: 1. Panel of the puncture template. 2. Penetration toward middle calix puncture point. 3. Penetration toward upper calix puncture point; F: Marking points on pig body surface; G: Puncture of the pig kidney by attaching the puncture navigation template onto the pig; After puncture, the urine was observed, which is the wet area inside the yellow circle; H: CT scan to reveal the puncture needle in the renal pelvis.

2. Methods

1. Location of puncture position before experiment

The animal experiments were conducted according to the established animal welfare guidelines of Shanghai sixth people's hospital. Fig. 1 shows the steps. First, a 100 kg male, one year old pig lies in a computerized transactional scanning CT bed, where the right flank of the waist around the kidney puncture area is marked with 3 signs of lead (2 mm in diameter) (Fig. 1A). Then, the pig was scanned to obtain the CT images with the focus on the kidney (Fig. 1B). The DICOM format image was then imported into the image analysis software (Mimics, USA) to obtain the exact positions of the kidney and 3 signs for reconstruction.

2. Construction of the puncture navigation template

A 2D navigation template was first simulated in computer. The three holes in the template must match the 3 signs marked on the pig as obtained in the scanned CT image. Two possible puncture positions for upper and middle calix puncture points are then chosen and constructed in the template. With the pixel accuracy of the CT image, the positions of renal pelvis and renal calix are determined, and the central extension line of the target renal calix is extended to the skin as the puncture point.

Using a commercial resin 3D printer, the computer designed 3D printing puncture navigation template was imported into the 3D printer for layer-by-layer printing. The printing materials can be polylactic acid, brown or transparent resin; in this study, they are transparent resin. After 3.5 hours of printing with a 3D printer, a percutaneous renal puncture navigation template - based on the high resolution CT scan images - was obtained, which is made of the transparent resin material.

3. Puncture practice of the navigation template in a porcine model

The navigation template was attached onto the pig and the 3 holes in the template match the three blue signs as marked before. Then, the puncture was operated using a conventional 18G needle following the puncture position (position 2), angle and the depth from the 3D CT images model. The position 3 in the template is alternative, not used here. The criteria for judging the success of the puncture are: 1. urine flow out of the puncture needle; 2. the tip of the puncture needle in the renal calices or pelvis; 3. no obvious

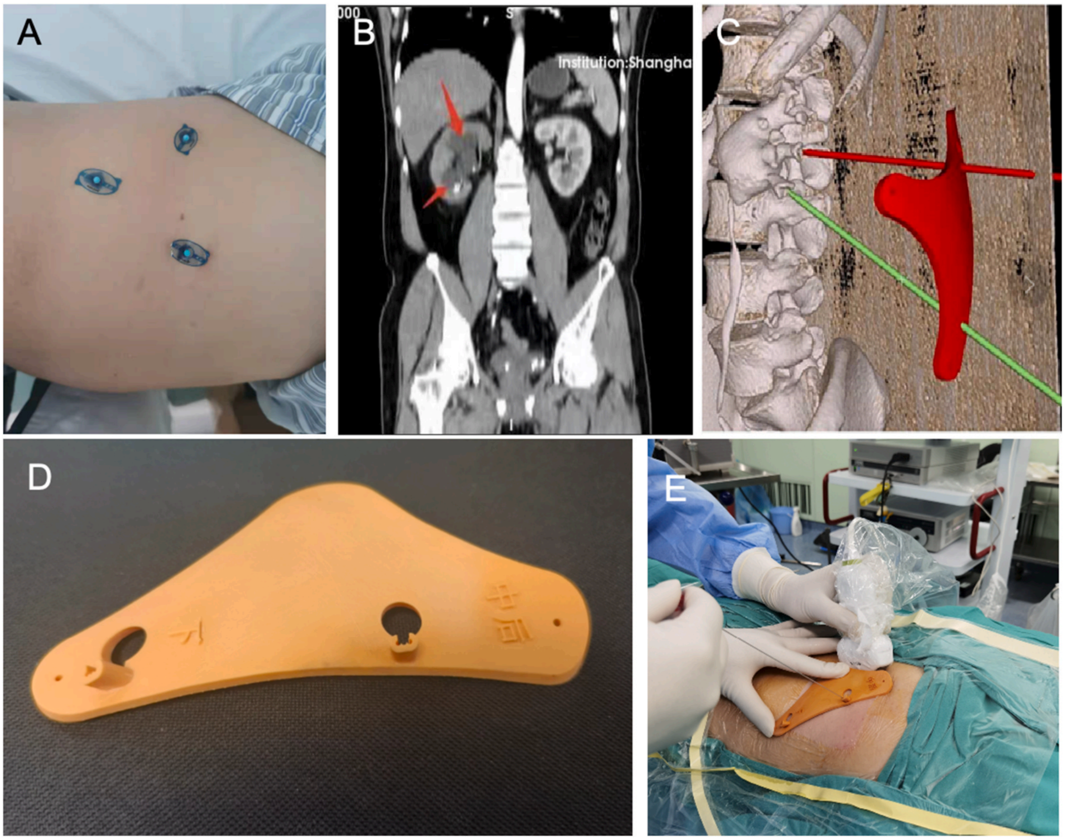

Fig. 2. A：3 signs marked on the skin; B: CT scan of puncture location (Red arrow indicates position); C: Position and angle of the puncture via the navigation template toward the kidney calices; D: The template with penetration point; E: The process of surgery with using the template.

complications, e.g., bleeding.

4. Puncture practice of the navigation template on a patient

The informed consent was first obtained from the patient for the publication of all images, clinical data and other data. The ethical approval was 2018-KY-072(K). The patient was 56 years old, male; a lower renal calix calculus was 21 mm in diameter. The method for making the template is similar with that in porcine model. Fig. 2 shows the steps. Three blue signs were stuck on the skin near the area of kidney. The area surrounded by the 3 points will decide how big the template is. Then, CT scanning of patient with supine position was performed to obtain the DICOM data. Then, the signs could be removed, but the position needs to be marked by marking pen. In the surgery, the 3 holes on the template will align the 3 markers to locate the template. The images were used to construct the kidney and the puncture point, and a 3D navigation template was printed. During the surgery, regular preparation was performed. The template with high temperature autoclave sterilization was placed onto the skin to match the markers. The puncture point was directed to the lower renal calix.

3. Results

From Fig. 1C, the pig kidney is in the anterolateral side of the psoas muscle. There is no muscle puncture point between the lowest rib and the erector spinae. From Fig. 1D, the kidneys, 3 signs, and the surrounding ribs and spine, are clear. Then, the puncture navigation template was designed to include the puncture entry point and the projection extension line of the renal calices (Fig. 1E). Due to the anatomical characteristics of the pig kidneys, there is no obvious hydronephrosis in the renal pelvis. In this animal study, we choose the clearer middle calix for needle insertion.

The 3D printed navigation template were then attached with its 3 holes to match exactly the previously marked 3 signs (Fig. 1F). The 18G puncture needle was performed to smoothly penetrate the skin, subcutaneous tissue and renal papillary from the simulated angle. At a depth of 5.5 cm also from the simulation, the urine outflow was observed suggesting the entering of the calix (Fig. 1G). The CT scanning showed that the needle passed through the lower edge of the erector spinae with the tip in the renal pelvis (Fig. 1H).

For the patient case, the three skin signs near the kidney area (Fig. 2A) were used to position the navigation template, and the CT image shows the stone and enlarged calices in the kidney (Fig. 2B). With the computer design, a 3D model allows the precision puncture (Fig. 2C), e.g. the position, angle and depth. The real object is printed out with a 3D printer (Fig. 2D). The surgery was performed with the help of template and untrasound (Fig. 2E). The stone was cleared with no obvious bleeding and complication. The time of puncture procedure was 25 minutes.

4. Discussion

PCNL is a high-risk operation in urology. The bleeding complication mainly comes from the difficulty in puncture operation and steep learning curve [17]. Plus, the commonly used X-ray and ultrasound have the inherent shortcomings. Therefore, it is important to find better measures to improve the puncture operation, with the aim to reduce intra-operative and post-operative complications and also be easy to learn [18].

Recent progress has been made to overcome the above known issues. For example, Xu et al. used the GPS navigation ultrasound, which can clearly observe the path and position of the puncture needle, to provide doctors with a more accurate puncture basis [19]. Li et al. reported a 3D reconstruction of the renal stones which accurately represented the inter-relationships between the intrarenal arteries and veins, collecting system, stones and adjacent anatomical structures [20]; PCNL was completed successfully in all 15 patients with this navigation in computer. Akand et al. described a 3D and augmented reality (AR) technology for access during PCNL and reported two preliminary results in two different ex-vivo models [21]. All the promising studies were based on a cognitive 3D images in computer, but they lack of the incarnate tool.

3D printing is more intuitive for surgeons, and has played an important role in the diagnosis and treatment of stones in the past, e.g. printing kidney models for teaching and preoperative planning. MertZL et al. used 3D printing to see the location of kidney stones and kidney tumors, shortening the operation time and improving the success rate of surgery [22]. Tang Run et al. used 3D printing to clearly map the kidney shape, cortex, renal artery and vein, collection system, location and size of stones, which can be used as teaching aids and preoperative planning [23]. In addition, a variety of materials used in 3D printing have high temperature resistance, deformation resistance and antibacterial properties, which can meet the requirements of aseptic operation in clinical operations. We find that the transparent resin material is most suitable for constructing the 3D printing templates. The transparency is important to observe the skin and the needle tip. During the operation, the ultrasound probe can also be used to correct the puncture depth and angle, which are critical to the accuracy of puncture.

Our method does not require multiple CT scanning or X-ray before or intra operation. It only needs to combine the first CT image of the patient to make the navigation template and then position it after general anesthesia in the operating room. The pyramid-shaped 3D model is established with the renal calices at the central position. In application, we find some factors that affect the performance of the template. The first is the respiratory effect. Different from the application in sacral nerve regulation, the position of the kidney will change due to the upper and lower positions of the respiratory muscle, so it is necessary to reduce the tidal volume in anesthesia to reduce the fluctuation in actual kidney position. In the real human experiment, the patient will be asked to inhale and exhale deeply. CT scanning is then performed twice, so that the range of the puncture point on the surface projection is obtained to estimate the exact depth. Combined with ultrasound, the puncture point can be further optimized. In addition, patients should be asked to take a prone position as much as possible in the initial CT scanning, which is helpful to simulate the exact position of kidney during operation.

In short, one of the purposes in this study is to make a device or tool, which is simple in structure, easy to operate and cheap in cost. Compared with the previous bone positioning [24], choice of the skin area can be done in a similar way. With 3D printers, we determine before surgery the high precision entry point, angle and depth of the puncture. The demonstration on the pig and patient shows our approach is promising as it is safe, accurate and comfortable, as also to flatten the PCNL learning curve, improve the puncture accuracy and reduce the complications.

One limitation of the study is as the technique has been tested only in one animal and in one patient. Obtaining CT data from a supine position is encouraged to simulate the puncture in surgery. However, it still has some variation which may influence the puncture operation. Thus, direct simulation of patients on the surgery bed will further improve the consistency between CT scanning information at pre-surgery and reality at surgery.

5. Conclusion

A renal navigation template is constructed with 3 skin signs, CT scanning, computer design and 3D printing. The entry position and angle of the needle are determined from the template pre-operatively. The CT image allows determination of the penetration depth of the needle. With this method, successful puncture experiments on a pig and a patient were performed to show good performance with no obvious bleeding and complication. In the future, prospective, trandomized, controlled clinical trials are needed to further confirm its advantage.

Ethics statement

This study was reviewed and approved by [Department of Urology, Affiliated Sixth People's Hospital, Shanghai Jiao tong University school of medicine, Shanghai, China], with the approval number: [2018-KY-072(K)].

All patients provided informed consent to participate in the study.

All patients provided informed consent for the publication of their anonymised case details and images.

Animal studies

This study was approved by the Department of Urology, Affiliated Sixth People's Hospital, Shanghai Jiao tong University school of medicine, Shanghai, China (Approval number; No: 2020-0073).

CRediT authorship contribution statement

Zhang Kaile: Resources, Formal analysis, Data curation. **Liu Jiafu:** Software. **Li Wenyao:** Writing – original draft, Supervision. **Yang Xi:** Resources, Project administration. **Li Ding:** Writing – review & editing. **Chen Rong:** Methodology. **Fu Qiang:** Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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