

A Novel Patient-Specific Three-Dimensional Printing Template Based on External Fixation for Pelvic Screw Insertion

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Abstract

(1) Background: To investigate the clinical effect of the novel patient-specific 3D printing templates based on external fixation for pelvic screw insertion.

(2) Methods: We retrospectively studied 8 patients with pelvic fractures who were treated using this novel template from July 2017 to July 2018. During the operation, the screws were inserted with the aid of the template. The operative time per screw, radiation exposure time, and accuracy of the screw insertions as evaluated by post-operative CT scans were analyzed statistically and compared with previous outcomes using the fluoro-navigation technique.

(3) Results: In the template group, a total of 9 pubis screws and 6 sacroiliac screws were inserted. The mean surgical time was 11.3 min/screw and the mean X-ray exposure time was 11.8 ± 3.9 s/screw. The mean deviation distance and angle between the actual and planned screw position was 2.6 ± 0.2 mm and 2.0 ± 0.3 degrees, and blood loss during the surgery was 12.2 ml/screw. No superficial and deep infections and no patient sustained recognized neurologic, vascular, or urologic injury occurred in the template group. The surgical time and X-ray exposure time was less than that in the fluoro-navigation group ($P < 0.05$).

(4) Conclusions: The patient-specific template based on external fixation can guide the insertion of the pelvic screw accurately, safely and invasively and significantly reduce operation and radiation exposure time.

1. Background

Pelvic fracture accounts for 2–8% of all fractures [1]. Unstable pelvic ring fracture require fixation to restore stability [2]. As open reduction and internal fixation with plates may lead to secondary damage, excess intraoperative blood loss, and iatrogenic injury of the nerve and blood vessels, most practitioners [3, 4] recommend percutaneous screw fixation to treat the pelvic fractures when applicable because that technique provides adequate biomechanical stability in non-displaced or minimally displaced fractures [5, 6, 7]. However, specific patient factors such as obesity, intestinal gas, and a dysmorphic sacrum, can result in a screw malposition rate of 2–15%, which may lead to iatrogenic neurovascular injury [8]. C-arm fluoroscopy is often used to insert the screws more precisely, which increases the operation time and the X-ray exposure to the patients and surgical team. With the development of the fluoro-navigation system, the minimally invasive percutaneous screw technique has become a safe, more accurate, and fairly quick method to treat pelvic ring fracture [9]. However, the high cost and complexity of the setup of the navigation system have limited its widespread application in intermediate and primary care hospitals.

For unstable pelvic fractures (Tile type B and type C) with unstable hemodynamics, external fixation is commonly used for damage control and fracture site preliminary reduction [10, 11]. After the patient's vital signs become stable, final internal fixation can be performed. The external fixator pins, which are inserted deep into the iliac crest, combined with the connecting rod, could provide a simple geometric

surface and solid cornerstone for mounting an external template. In that case, we could use the patient-specific screw guide template based on frame of the external fixation with the help of the 3D printing technique in the final surgery(Fig. 1), instead of the navigation system, to aid in the minimally invasive percutaneous screw surgery(Utility model patent NO: ZL201720618195.5).

With the development of 3D printing technology, it became possible to design and print an excellent surgical template. Operation planning can be focused on the production of the 3D template. When this template is used, it only needs to contact the planned position before the operation to enable the surgeon to accurately guide the direction and depth of the screw trajectory, determine the distance and angle, and so on. It has the potential to improve the accuracy and safety of the operation, shorten the operation time, reduce the bleeding and side effects during the operation, make some traditional complex and difficult operations much easier, and reduce X-ray exposure and operative complications. The 3D printing template has effectively improved the quality of other orthopaedic surgical procedures [12]. The surgical guide template is based on the patient's individual data, as has been done for arthroplasty, and spine and osteotomy surgery [13, 14]. Traditionally, to obtain a good match, one would put the 3D printing template close to the bone surface, which would demand considerable dissection of the soft tissue [10, 11, 15]. However, the soft tissue in the pelvic area is thicker and adjacent to important vessels and nerves; thus, the traditional 3D printer template technique is largely unsuitable. To resolve this problem, we designed a patient-specific screw guide template based on the external fixation to insert the antegrade pubic rami screw and sacroiliac screw using the minimally invasive percutaneous technique without dissection of the soft tissue. The aim of this study was to describe the use of our novel template technique and to evaluate its accuracy and safety compared to the fluoro-navigation technique. We hypothesized that use of patient-specific 3D printing templates based on external fixation would deliver similar outcomes to the fluoro-navigation technique.

2. Methods

Patients

The template group consisted of 6 male and 2 female patients who were treated using this new type of screw guide template from July 2017 to July 2018. The inclusion criteria were as follows: (1)closed pelvic unstable fracture (Type B); (2) without severe internal

organ injury; (3)without obvious fracture displacement, or displacement can be reduced by pre-operative external fixation. The exclusion criteria were as follows: (1) severe open fracture; (2) fracture requiring open reduction and internal fixation. The average age was 52.3 years (range 23–78 years). The mean body mass index (BMI) was 22.7 (rang 20.5–26.3). According to the Tile classification, there were two type B1, four type B2.1, and two type B3 fractures. The average injury severity score (ISS) was 15.2(range 11–27). 3 patients only had unstable pelvic fractures, 3 patients combined with multiple rib fractures and pleural effusion, 1 patient combined with subarachnoid hemorrhage, and 1 patient combined with multiple lumbar fractures and bilateral femoral fractures. All patients underwent external fixation to achieve

damage control and a closed reduction at the same time in the emergency room during the first stage (Figs. 1 and 2). The external fixation (Trauson, China) was performed with a Carefix composite scaffold, which consists of 6-mm diameter stainless steel spicules, an 8-mm diameter aluminum alloy bar material, and an 8-mm diameter carbon fiber/PEEK unilateral connecting rod. When the vital signs of the patients became stable, we evaluated the fracture site, if the fracture was non-displaced or minimally displaced and did not need to reset during the operation, we used our 3D template for screw placement. The mean surgical waiting time to insert the pelvic screw was 4.2 days (rang 3–8 days). This study got approval from the ethics review committee of the Qingpu branch of Zhongshan Hospital of Fudan University and written informed consent was obtained from each patient.

In the fluoro-navigation group, there were 10 patients, including 7 men and 3 female. The mean age was 45.2 years (range 28–58). According to the Tile classification, there were three type B1, four type B2.1, and three type B3 fractures. The fracture sites also did not need to be resetted during the operation. The surgical technique was described in our previous paper[9].

Template design and printing

Before the final operation, patients with external fixation were examined with a 64-slice spiral computed tomography (CT) scanner (GE, Boston, MA, USA), with 5-mm slice thickness. The images were stored in DICOM format and analyzed with Mimics 10.01 software (Materialise, Louvain, Belgium). The trajectory and the depth of the screws were designed in 3D format. We adopted 6.5 mm as the optimal diameter of the screw. The direction was adjusted until the optimal screw path was found using a reverse engineering technique to make sure that the virtual cylindrical implant was totally in the bony structure and did not penetrate the acetabulum, the pubis rim cortex, or the sacral foramen. In addition, 2D images of the pelvis in transverse, coronal, and sagittal planes were observed to confirm that the virtual cylindrical implant was intraosseous. We also measured the length of the cylindrical implant. After the screw entry point and the tip of the screw were determined, the data were saved in STL format(Fig. 3D).

The above data were input into the Geomagic studio 2012 software (3D Systems, Morrisville, NC, USA). Next, the patient-specific screw guide template was designed (Fig. 2D, 3E). Following that design, the patient-specific template was subsequently manufactured using a 3D printing system (Liantai RS6000) with photosensitive resin material (Fig. 2E, Fig. 3F).

The cost for the design and printing of the template is about 200 US dollars. We needed about 2 hours to design the template and about 8 hours to print it, after which it was sterilized with ethylene oxide.

Surgical technique

After general anesthesia, the patient was placed in the supine position and the assistant connected the 3D printing template to the external fixation. A 1.5 cm incision was made according to the direction of the guide hole on the template. The assistant used one hand to stabilize the template and external fixation. The surgeon drilled 2.5 mm relatively rigid K-wires along the guide hole to the pubic rim or S1 body. When

the screws were inserted into the pubic rim, there was a slope due to the irregular shape of the iliac wing. In order to reduce sliding of the K-wire, we also used a sleeve of our own design to guide the insertion of the K-wire (Fig. 4). The C-arm was used to confirm the position of the K-wire during the insertion process. When the K-wire was in the right position, the template was removed and the length of the screw was measured. Appropriate 6.5 mm cannulated screws (AO, Synthes, Stratec Medical, Oberdorf, Switzerland) were inserted along the K-wires, which were of similar length as in the preoperative plan. The C-arm was used again to assure the position and length of the screw. Finally, the K-wire was removed and the incision was sutured (Figs. 2,3)

Measurement and analysis

The amount of time required for screw insertion and radiation were recorded for analysis. Radiographic imaging in the form of X-rays and CT scan was repeated after surgery and used to check for fracture reduction and hardware placement. We also calculated the screw deviation from the planned trajectory. Quantitative data are presented as the mean \pm standard deviation. Between-group differences were evaluated using independent sample Student's t-test, the chi-squared test, and Fisher's exact test, as appropriate for the data type and distribution. All analyses were performed using SPSS (version 17.0; Chicago, IL, USA).

3. Results

Surgery

A total of 9 pubic screws and 6 sacroiliac screws were inserted in the template group. The average surgical time was 11.3 min/screw and the average time of X-ray exposure was 11.8 ± 3.9 s/screw. The mean deviation distance and angle between the actual and planned screw position was 2.60 ± 0.2 mm and 2 ± 0.3 °. Blood loss during the surgery was 12.2 ml/screw. In the fluoro-navigation group, the average surgical time was 23.3 min/screw ($P < 0.05$) and time of X-ray exposure was 19.1 ± 2.5 s/screw ($P < 0.05$), the average deviated distance was 3.11 ± 0.3 mm ($P > 0.05$) and the average trajectory angle difference was 2.81 ± 0.2 ° ($P > 0.05$). Blood loss during the operation was 12.3 ml/screw ($P > 0.05$). None of the screws deviated out of the fracture site during the operation in the template group, whereas one screw (3.1%) did deviate out of the fracture site during the operation in the fluoro-navigation group. No superficial or deep infections developed and no patient sustained any recognized neurologic, vascular, or urologic injury in either group (Table 1)

Table 1
Surgery and follow-up details

	Template group	fluoro-navigation group	P value
Screw number	15	22	
Surgical time	11.3 min/screw	23.3 min/screw	P < 0.05
Time of X-ray exposure	11.8 ± 3.9 s/screw	19.1 ± 2.5 s/screw	P < 0.05
Deviation distance	2.6 ± 0.2 mm	3.11 ± 0.3 mm	P > 0.05
Deviation angle	2.0 ± 0.3°	2.8 ± 0.2°	P > 0.05
Blood loss	12.2 ml/screw	12.3 ml/screw	P > 0.05
Bone union time	12.4 weeks	12.6 weeks	P > 0.05
Full weight-bearing time	12.9 weeks	13.0 weeks	P > 0.05
SMFA			
Dysfunction index	62.44	64.26	P > 0.05
Annoyance index	63.18	65.83	P > 0.05

Follow-up

In the template group, the mean follow-up time was 13.25 months (6–18 months). The mean radiographic bony union time was 12.4 weeks (10–15 weeks) and the mean full weight-bearing time was 12.9 weeks (12–15 weeks). Each patient was evaluated with the Short Musculoskeletal Function Assessment Questionnaire (SMFA) at the last follow-up. Mean scores were 62.44 (58.466–84.34) points for dysfunction index and 63.18(52.34–100) points for annoyance index,. Compare with the fluoro-navigation group, there is no significant difference in bone union time, full weight-bearing time and the SMFA score(Table 1).

4. Discussion

In this study, we found that the use of patient-specific 3D printing templates based on external fixation was a novel and safe technique for the percutaneous insertion of the pelvic screws and provided high accuracy. Compared with the fluoro-navigation technique, the surgical time and radiation exposure was lower.

All traditional techniques of open reduction and internal fixation require extensive surgical exposure of the deep structures of the pelvis, which can slow or prevent wound healing, damage major vessels or nerves and increased the incidence of infection up to 25% [16, 17]. Some surgeons suggested using a subcutaneous internal anterior screw-rod fixation to avoid the disadvantages of the external fixation with low rates of wound infections[18]. However, that was associated with new complications, such as injury

of the femoral lateral cutaneous nerve and femoral nerve or heterotopic ossifications [19]. Currently, percutaneous screw fixation is a popular method to deal with the non-displaced or minimally-displaced pelvic fracture and provides adequate biomechanical stability [1, 20, 21, 22, 23]. However, percutaneous screw fixation is a demanding procedure and requires the surgeon to have detailed anatomic knowledge and extensive surgical experience. Much more fluoroscopic time is required to avoid damage to vessels and nerves as well as penetration of the acetabulum, ensuring that the screw is in the ideal position [24, 25, 26]. With the introduction of navigation technology into surgery, the percutaneous screw technique became safe, more accurate and reasonably quick. However, we have to insert a titanium tracker preoperatively for registering with a small incision [27, 28] and need to take another fluoro-image to plan the screw trajectory during the surgery. Accordingly, in this comparative study the surgical time and X-ray exposure time are shorter in the template group than in the fluoro-navigation group, because we have designed the screw trajectory by computer beforehand, and can simply insert the screw according to the template, reducing fluoroscopic time. The accuracy is similar in template group and fluoro-navigation group.

The patient-specific screw guide template is based on the patient's individual CT data, computational software, reverse engineering, and the 3D printing technique. Hu and Li have succeeded using the template assisted percutaneous vertebroplasty [29, 30]. Yang described a external template to insert iliosacral screws in 2018[31]. The template can guide us to the entry point and show the direction of the guide pin and screw, making the operation much more accurate, convenient and safe. On the other hand, the normal template requires that the bone surfaces engage each other, and we must still dissect the soft tissue and expose the bone surface during the operation. Some surgeons have used this method to insert the screw to treat pelvic fracture, but the dissection of soft tissue lacks the advantage of minimally invasive percutaneous screw technique [32, 33]. Our specific template is based on the external fixation. The advantage is that the screw guide template is engaged with the external fixation rather than the bone surface, in consequence of which dissection of the soft tissue is unnecessary. Just as in fluoro-navigation surgery, the skin incision was about 1 cm and the bleeding was minimal (12.2 ml/screw). The novel template technique thus truly achieves minimally invasive surgery.

Although the newly designed template offers satisfactory accuracy and safety, there was nonetheless a deviation of 2.6 ± 0.2 mm and $2.0 \pm 0.3^\circ$ in trajectory compared to the preoperative plan; these values are quite similar to those in the fluoro-navigation group. This deviation may be caused by any of a number of factors, including CT slice thickness, data conversion due to slight differences between the software model and the actual pelvic bone, the method used to deal with the CT data of the external fixation, the template size, the print material, the stability of the template in the operation, and the elastic modulus of the template.

We summarize our recommendations for use the novel template as follows. (1) To reduce the distortion of the data conversion and 3D reconstruction model, the thickness of the CT scan slices should not exceed 1 cm. (2) The soft tissue thickness should be considered according to the CT 3D reconstruction because the template is close to the skin instead of close to the bone surface. (3) We should choose a

larger elastic modulus material to print the template, which is also resistant to high temperature and deformation, and easy to disinfect and operate. (4) The connection rod should contact at least two of the rods of the external fixation. The two template rods are preferably not parallel, so there is only one location to place the template. (5) The inner diameter of the guide hole must be slightly larger than the diameter of the K-wire in order to pass the K-wire through easily. (6) We do not compress the template, because the consequent deformation would reduce the accuracy. (7) When the K-wire is drilled through the guide hole, we should drill the K-wire along the guide hole gently. To improve stability, we designed a special sleeve to insert the K-wire (Fig. 4).

A few shortcomings to this new technique remain. First, the patient needs the external fixation to aid to design the template. Second, we are thus far limited to non-displaced or minimally-displaced pelvic fractures. If the fracture needs reduction during the operation, the original guide template cannot be used because the required trajectory of the screw will be completely changed. These technical shortcomings will be further explored and improved.

5. Conclusions

Patient-specific screw guide templates based on external fixation can be used to accurately and safely insert the screw with a very small incision. This technique can significantly reduce the operation time and radiation exposure to the patient and surgeon team. The patient-specific screw guide template also can help residents with less experience insert the percutaneous screw more effectively to yield a good preparation. With the further maturation of this technology and clinical verification, many more orthopedic surgeons in intermediate and primary care hospital will be able to choose it to treat their patients. The application of this technique will thus play an important role in clinical practice in the future.

Abbreviations: None

Declarations:

- **-Ethics approval consent to participate:** This study got approval from the ethics review committee of the Qingpu branch of Zhongshan Hospital of Fudan University and written informed consent was obtained from each patient.
- **-Consent to publish:** We had got consent to publish participants' information. The proof of consent to publish from study participants can be requested at any time.
- **-Availability of data and materials:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.
- **-Competing interests:** The authors declare that they have no competing interests.
- **-Funding:** This study was financially supported by the program of the Qingpu district health committee, Shanghai, China: W2019-40.
- **-Authors' contributions:** KZ conceived the study. KZ and XT and CL participated in its design and coordination. KZ, HY and FP analyzed the data and drafted the manuscript. All authors interpreted

the data and participated in drafting the text and tables. All authors read and approved the final manuscript.

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- **-Availability of data and materials:**The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.
- **-Competing interests:**The authors declare that they have no competing interests.
- **-Funding:** This study was financially supported by the program of the Qingpu district health committee, Shanghai, China: W2019-40.
- **-Authors' contributions:**KZ conceived the study. KZ and XT and CL participated in its design and coordination. KZ, HY and FP analyzed the data and drafted the manuscript. All authors interpreted the data and participated in drafting the text and tables. All authors read and approved the final manuscript.
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Figures

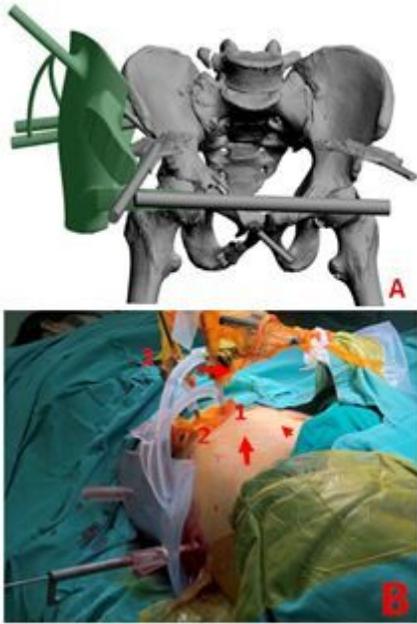


Figure 1

A. the patient-specific screw guide template was based on frame of the external fixation. B. The template contacted the external fixation by at least three sites

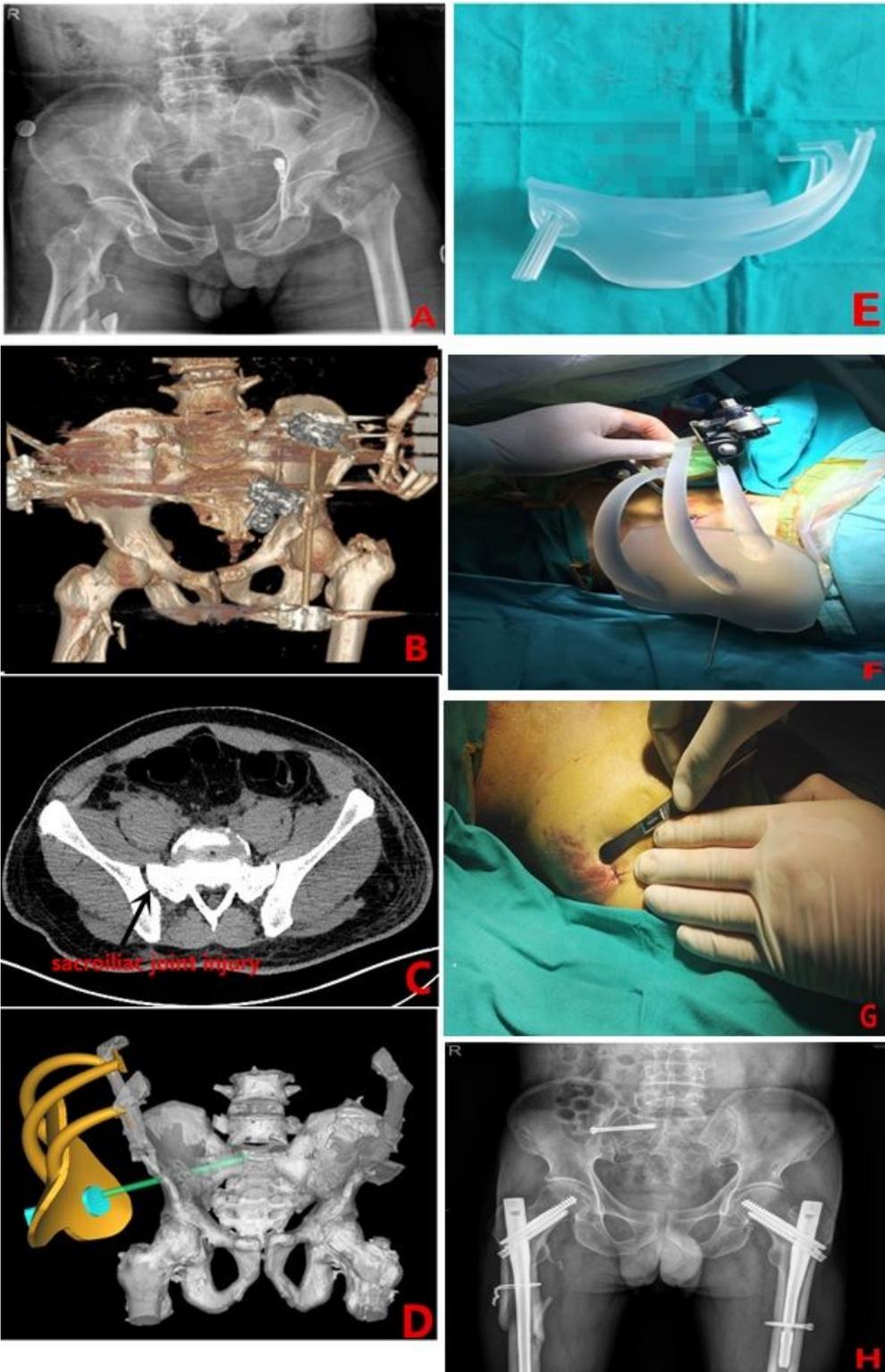


Figure 2

a 50 year-old male patient with heavy crush injury (Tile B1, Symphysis pubis separation, bilateral femoral fracture and lumbar 1 and 3 fractures, traumatic shock). A. X-ray. B. CT 3D reconstruction after damage control , pubic symphysis separation was corrected by closed reduction. C. CT transverse view indicate sacroiliac joint injury and unstable fracture ring. D. A virtual cylindrical implant with a diameter of 6.5mm was placed in the axis of the S1 body and the patient-specific screw guide template was designed. E.the

patient special template. F. one cannulated screws were inserted to the sacroiliac joint according to the Patient-specific screw guide template. The template was connected to the external fixation. G. The incision is small about 1.5cm. H. Postoperative X-ray: A-P view



Figure 3

a 45 year-old male patient hit by a car with pelvic fracture (Tile B2.1, right sacral fracture and right pubis rim fracture), traumatic shock. A. X-ray. B. CT 3D reconstruction. C. X-ray after external fixation. D. A virtual cylindrical implant with a diameter of 6.5mm was placed in the axis of the pubic rim and S1 body. E. the patient-specific screw guide template was designed. F. the patient special template. (G-J). three

cannulated screws were inserted according to the Patient-specific screw guide template meanwhile. G.the patient operation position H. the template was connected to the external fixation. I,J. The incision is about 2cm.K.Intraoperative X-ray. L. Postoperative X-ray

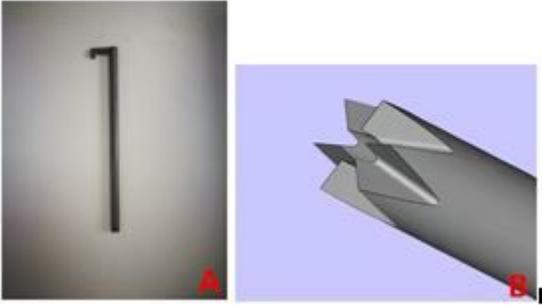


Figure 4

Self-design sleeve with special head detation design which can Fix on the bone surface, reduce sliding and improve the accuracy of the K-wire