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

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ABSTRACT

Purpose: To investigate the clinical effect of novel patient-specific 3D printing templates based on external fixation for pelvic screw insertion compared with the fluoro-navigation technique.

Materials and methods: We retrospectively studied 18 pelvic fracture patients from July 2017 to July 2018. For analysis, patients were divided into two groups: the template group (15 screws in 8 patients) and the fluoro-navigation group (22 screws in 10 patients). The screw insertion time, radiation exposure time, and accuracy of the screw insertion as evaluated by postoperative CT scans were analyzed.

Results: In the template group, the average screw insertion time (11.5 ± 2.3 min/screw) was significantly 50.6% less than that in the fluoro-navigation group (23.3 ± 3.1 min/screw; P < 0.05). The average time of X-ray exposure in the template group (11.5 ± 3.9 s/screw) was also significantly 39.8% less than in the fluoro-navigation group (19.1 ± 2.5 s/screw; P < 0.05). In the template group, the mean deviation distance and angle between the actual and planned screw position was 2.6 ± 0.2 mm and 2 ± 0.3°.

Conclusions: The patient-specific template based on external fixation can guide the insertion of the pelvic screw accurately and safely while significantly reducing operation and radiation exposure time.

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1. Introduction

Pelvic fracture accounts for 2–8% of all fractures [1]. Unstable pelvic ring fracture requires 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 nerves and blood vessels, some surgeons [3,4] recommend percutaneous screw fixation to treat the pelvic fractures. Percutaneous screw fixation can provide adequate biomechanical stability in non-displaced or minimally displaced fractures [5–7]. However, specific patient factors such as obesity, intestinal gas, and a dysmorphic sacrum may lead to fluoroscopy problems that can result in screw malposition accompanied by nerve and vessel injuries [8]. In order to insert the screws more precisely during the surgery, we should use fluoroscopic guidance, which increases the operation time and the X-ray exposure to the patients and the 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.

The surgical template is based on the patient’s individual data, as has been done for arthroplasty and spine and osteotomy surgery [10,11]. For unstable pelvic fractures (Tile types B and C) with unstable hemodynamics, external fixation is commonly used for damage control and fracture site preliminary reduction [12,13]. With the development of 3D printing technology, we can combine external fixation with the 3D printing technique to design and print an excellent surgical template. We do not need to strip the soft tissue much to attach the template to the bone surface [12–14]. The external fixation pins, which are inserted deep into the iliac crest, combined with the connecting rod, could provide a simple geometric surface and a solid cornerstone for mounting an external template. So, we designed a patient-specific screw guide template based on external fixation to insert the antegrade pubic rami screw and sacroiliac screw using a minimally invasive percutaneous technique without dissection of the soft tissue (Utility model patent NO: ZL201720618195.5).

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 the clinical outcome using patient-specific
3D printing templates based on the external fixator technique would not be inferior to the fluoro-navigation technique.

2. Materials and methods

This study got approval from the ethics review committee of our hospital. We performed a retrospective study of 18 patients who underwent closed reduction and percutaneous screw fixation of pelvic fracture by the template or the fluoro-navigation method in our hospital between July 2017 and July 2018. The radiographs and medical records of these patients were retrospectively analyzed. 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 the displacement can be reduced by preoperative external fixation. The exclusion criteria were as follows: (1) severe open fracture; (2) fracture requiring open reduction and internal fixation.

2.1 Marker pin insertion and data collection in the template group

Two 6-mm diameter stainless steel pins (inserted into the iliac crest for emergent fixation at the time of admission), an 8-mm diameter aluminum alloy bar material, and an 8-mm diameter carbon fiber/PEEK unilateral connecting rod (Trousion, China) were used as marker pins, as well as preoperative external fixation. The data were saved in STL format (Figure 1D). The above data were then input into Geomagic Studio 2012 software (3D Systems, Morrisville, NC, USA). A virtual template was designed using the trim and curve software to connect the marker pins. The STL format of the template design was processed using 3-matic software (Materialise, Leuven, Belgium) to complete the virtual template through Boolean calculation (Figure 1E). The data from the 3-matic software were imported into the 3D printing system (Liantai RS6000) to subsequently manufacture the patient-specific template with photosensitive resin material (Figure 1F).

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

2.2 Template design and printing

The images of the pelvis and skin (DICOM format) were imported and analyzed with 10.01 software (Materialise, Louvain, Belgium). In the 3D model of the pelvis, 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 ensure that the virtual cylindrical implant was completely in the bony structure and did not penetrate the acetabulum, the pubis rim cortex, or the sacral foramen. Usually, the trajectory of each sacroiliac screw was planned to place the virtual screw into the S1 vertebra along the midline of the osseous corridor, and the pubic screws were all in the medullary cavity of the pubic branch. 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 estimated the length of screws, which was the distance between the corresponding cortex of the two ends of the cylindrical implant. After the screw entry point and the tip of the screw were determined, the data were saved in STL format (Figure 1D). The above data were then input into Geomagic Studio 2012 software (3D Systems, Morrisville, NC, USA). A virtual template was designed using the trim and curve software to connect the marker pins. The STL format of the template design was processed using 3-matic software (Materialise, Leuven, Belgium) to complete the virtual template through Boolean calculation (Figure 1E). The data from the 3-matic software were imported into the 3D printing system (Liantai RS6000) to subsequently manufacture the patient-specific template with photosensitive resin material (Figure 1F).

The surgical procedure in the fluoro-navigation group was the same as described in our previous paper [9].

Surgical waiting time, defined as the time from the injury to the final surgery, was recorded. During the surgery, the amount of time required for screw insertion, radiation and blood loss were also recorded. The blood loss is calculated by the following formula: \( \text{Blood loss (ml)} = \left( \frac{\text{wet weight of dressing (g)} - \text{dry weight of dressing (g)}}{1.05} \right) \). Radiographic imaging in the form of a CT scan was reviewed immediately after surgery to compare the planned screw trajectory and postoperative CT images in the template group. The deviation distance and angle were recorded. The patients were followed up until the X-ray showed fracture union. The follow-up time, fracture union time, and postoperative complications were also recorded (Figure 1K).

Each patient was evaluated with the Short Musculoskeletal Function Assessment Questionnaire (SMFA) at the last follow-up [15].
Figure 1 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 6.5 mm 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. Intraoperative X-ray. J. The incision is about 2 cm. K. Postoperative X-ray.
2.4. Statistical analysis

SPSS (version 23.0; Chicago, IL, USA) statistical software was used to analyze the data. Quantitative data are presented as the mean ± 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. Differences are considered to be statistically significant when \( P < 0.05 \).

3. Results

During the study period, 18 patients were enrolled. All 18 patients had undergone external fixation of the pelvic fracture in the emergency department at the time of admission for damage control. In the template group, there were 8 patients, including 6 men and 2 women, 52.5 ± 16.9 years of age (range, 23–78 years). In the fluoro-navigation group, there were 10 patients, including 7 men and 3 women, 45.2 ± 9.9 years of age (range, 28–58 years). The cause of fractures in the template group was motor vehicle accident, 3 (37.5%); high-energy fall, 3 (37.5%); and machinery injury, 2 (25%). The cause of fractures in the fluoro-navigation group was motor vehicle accident, 4 (40%); high-energy fall, 3 (30%); and machinery injury, 3 (30%). There was no statistically significant difference between the demographic characteristics of the two groups. The demographic characteristics are listed in Table 1.

We inserted a total of 37 screws in 18 patients: 15 screws in the template group, 22 screws in the fluoro-navigation group. The total average screw insertion time was 11.5 ± 2.3 min/screw for the template group, which was significantly 50.6% less than the 23.3 ± 3.1 min/screw for the fluoro-navigation group \( (P < 0.05) \). The average pubic screw insertion time was 12.8 ± 2.5 min/screw for the template group, which was significantly 46.3% less than the 23.83 ± 2.6 min/screw \( (P < 0.05) \). In both groups, the average screw insertion time of pubic screws was longer than that of the sacroiliac screws (12.8 ± 2.5 vs 9.2 ± 1.7 min/screw in the template group \( (P < 0.05) \), 23.83 ± 2.6 vs

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**Table 1. Demographic characteristics of patients.**

|                        | Template group (n = 8) | Fluoro-navigation group (n = 10) | \( P \) value |
|------------------------|------------------------|---------------------------------|--------------|
| Sex                    | Men 6, women 2         | Men 7, women 3                  | 0.618*       |
| Age (years)            | 52.5 ± 16.9            | 45.2 ± 9.9                      | 0.269*       |
| Surgical waiting time (days) | 4.5 ± 0.8             | 4.3 ± 0.8                       | 0.599*       |
| Cause of injury        |                        |                                 | 0.914**      |
| Motor vehicle accident | 3                      | 4                               |              |
| High-energy fall       | 3                      | 3                               |              |
| Machinery injury       | 2                      | 3                               |              |
| Tile classification    |                        |                                 | 0.914**      |
| B1                     | 2                      | 3                               |              |
| B2.1                   | 4                      | 4                               |              |
| B3                     | 2                      | 3                               |              |
| Injury severity score (ISS) | 15.5 ± 3.7            | 15.9 ± 3.4                      | 0.784*       |
22.7 ± 2.5 min/screw in the fluoro-navigation group (P > 0.05). The total average time of X-ray exposure in the template group (11.5 ± 3.9 s/screw) was also significantly 39.8% less than in the fluoro-navigation group (19.1 ± 2.5 s/screw; P < 0.05). The average pubic screw X-ray exposure time was 14.8 ± 1.4 s/screw for the template group, which was significantly 29.9% less than the 21.1 ± 1.2 s/screw for the fluoro-navigation group (P < 0.05). The average sacroiliac screw X-ray exposure time was 7.5 ± 0.5 s/screw for the template group, which was significantly 55.4% less than the 16.8 ± 1.6 s/screw in the fluoro-navigation group (P < 0.05).

In both groups, the average X-ray exposure of pubic screws was also longer than that of the sacroiliac screws (14.8 ± 1.4 vs 7.5 ± 0.5 s/screw in the template group (P < 0.05), 21.1 ± 1.2 vs 16.8 ± 1.6 s/screw in the fluoro-navigation group (P < 0.05)). The blood loss was 12.5 ± 1.3 ml/screw in the template group, which was similar in the fluoro-navigation group (12.3 ± 1.7 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. In the template group, the mean deviation distance and angle between the actual and planned screw position was 2.6 ± 0.2 mm and 2 ± 0.3°. No superficial or deep infections developed, and no patient sustained any recognized neurologic, vascular, or urologic injury in either group.

In the template group, the mean follow-up time was 13.25 months (6–18 months). The mean radiographic bony union time was 12.5 ± 0.8 weeks (10–15 weeks). Mean SFMA Questionnaire scores were 62.4 ± 5.8 (58.46–84.34) points for dysfunction index and 63.2 ± 4.7 (52.34–100) points for annoyance index. There was no significant difference in bone union time or SMFA Questionnaire score between the template and fluoro-navigation groups.

The clinical outcomes of patients are presented in Tables 2 and 3.

### 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 were 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 increase the incidence of infection up to 25% [16,17]. Some surgeons suggest using a subcutaneous internal anterior screw-rod......
fixation to avoid the disadvantages of 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 still a popular method to deal with the nondisplaced or minimally-displaced pelvic fracture and provides adequate biomechanical stability [1,20–23]. However, the traditional percutaneous screw fixation technique requires more fluoroscopic time to avoid damage to vessels and nerves as well as penetration of the acetabulum, ensuring that the screw is in the ideal position [24–26]. With the introduction of navigation technology into surgery, the percutaneous screw technique became safer, more accurate, and reasonably quick. However, we still have to preoperatively insert a titanium tracker for registration through a small incision [27,28] and need to take another fluoroo-image to plan the screw trajectory during the surgery. So, in this study, we found the screw insertion time and X-ray exposure time were shorter in the template group than in the fluoro-navigation group because we designed the screw trajectory by computer beforehand and could thus simply insert the screw according to the template. The intraoperative planning time and part of fluoroscopy time were reduced, but the accuracy was not affected. The results also showed that the production of the template did not prolong the surgical waiting time because we designed and printed the template at the same time during the treatment period of the patients, so there was no time delay.

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 in using the template-assisted percutaneous vertebroplasty [29,30]. Yang described a type of template to insert iliosacral screws in 2018 [31]. The template can guide the surgeons to the entry point and show the direction of the K-wire and screw, making the operation much more accurate, convenient, and safe. However, this type of template requires that the bone surfaces and the template engage each other and thus that the soft tissue be dissected to expose the bone surface during the operation, which loses the advantage of minimally invasive percutaneous screw technique [32,33]. Our specific template is based on external fixation. The advantage is that the screw guide template is connected with the external fixation rather than the bone surface, in consequence of which dissection of the soft tissue is unnecessary. The skin incision was only about 2 cm, and the bleeding was minimal, which was similar to that of the fluoro-navigation group. 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 $2.6 \pm 0.2 \text{ mm}$ and $2.0 \pm 0.3^\circ$ in trajectory compared to the preoperative plan. However, the deviation distance and angle of the screw in the template group was similar to the intraoperative fluoro-navigation technique in our previous paper [9]. The 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.

Based on our experience thus far, we developed the following tips for 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 5 mm. (2) The soft tissue thickness should be considered 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, to ensure 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 improved the traditional special sleeve to insert the K-wire much more easily (Figure 2).

A few shortcomings to this new technique remain. First, the patient needs external fixation to aid in the design of the template. Second, we are thus far limited to nondisplaced 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 significantly reduce the operation time and radiation exposure to the patient and surgeon team, which can also 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, this technique will thus play an important role in clinical practice in the future.

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 patients’ 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.

Disclosure statement
No potential conflict of interest was reported by the author(s).

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