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# CLINICAL ARTICLE

# Posterior INFIX for Treating Unilateral Unstable Sacral Fractures

Haotian Qi, MM<sup>1</sup>, Xin Geng, MM<sup>2</sup>, Xiaokun Yu, MM<sup>3</sup>, Wenhuan Chen, MM<sup>4</sup>, Jian Jia, MD<sup>1</sup>, Wei Tian, MD<sup>1</sup>

Department of <sup>1</sup>Orthopaedic Trauma and <sup>2</sup>Radiology, Tianjin Hospital and <sup>3</sup>Department of Radiology, The Fifth Centre Hospital of Tianjin City, Tianjin and <sup>4</sup>Third Clinical Medical College of Guangzhou University of Chinese Medicine, Guangzhou, China

**Objective:** To evaluate the clinical outcomes of the treatment of unilateral unstable sacral fractures by fixation with the posterior INFIX (posterior pelvic ring screw-rod internal fxation).

**Methods:** Data of 60 patients with unilateral unstable sacral fractures who underwent surgery from March 2013 to March 2020 were retrospectively analyzed according to the selection criteria. All patients were associated with anterior pelvic ring injuries, and the operations were performed by the same team of surgeons. According to the different types of internal fixation, the patients were divided into two groups, which both included 30 patients: the posterior INFIX group and iliosacral screw fixation group. The demographic and clinical data of the two patient groups, such as age, sex, sacral fracture types based on the Denis classification, operation time, amount of intraoperative bleeding, intraoperative fluoros copy time, Majeed pelvic score at final follow-up, and quality of fracture reduction based on Mears and Velyvis's imaging classification criteria were collected by the same researcher and compared statistically.

**Results:** All patients were continuously followed up for  $23.17 \pm 3.34$  months (range, 12 to 46 months). All sacral fractures healed with an average healing time of  $9.3 \pm 2.24$  months (range, 6 to 18 months). None of the patients had re-displacement of the fracture or fixation failure. Compared to the iliosacral screw group, the posterior INFIX group patients had more intraoperative bleeding (t = 3.59, P < 0.001), shorter operation time (t = 4.49, P < 0.001), and shorter intraoperative fluoroscopy time (t = 6.26, P < 0.001). There were no statistical differences between the two groups in terms of age, sex, fracture type, Majeed score, and quality of fracture reduction (P > 0.05). In the posterior INFIX group, one patient had a superficial wound infection and one patient complained of discomfort due to a prominent fixation. In the iliosacral screw fixation group, one patient had intraoperative iatrogenic S1 nerve injury and vessel injury. The posterior INFIX fixation was a simpler manipulation with higher safety, shorter time of operation and intraoperative fluoroscopy, and similar clinical outcomes compared to iliosacral screw fixation.

**Conclusion:** For the treatment of unilateral unstable sacral fractures, the posterior INFIX fixation can be recommended in clinic application.

Key words: Sacrum; Bone fractures; Fracture internal fixation; Minimally invasive surgical procedures

#### Introduction

A mong all types of pelvic fractures, the proportion of sacral fracture is 10% to 45%<sup>1</sup>, and 17% to 30% of them are unstable sacral fractures<sup>2</sup>, which means these fractures are often associated with vertical, horizontal, and rotational deformities. Additionally, most sacral fractures of this type

are unilateral (Tile C1-3), which always result from high-energy injuries, have severe complications, and their treatment is considered to be very challenging due to the unsatisfactory prognosis. Currently, more and more surgeons advocate using the surgical treatment and internal fixation<sup>3,4</sup> for treating unilateral unstable sacral fracture to obtain anatomical reduction

Address for correspondence Wei Tian, MD, Department of Orthopaedic Trauma, Tianjin Hospital, Tianjin, China 300211 Tel: 0086-1382-0737-331; Email: 850225851@qq.com

All authors contributed equally to the work.

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and stable fixation in order to reconstruct the normal weightbearing load to ensure early ambulation and fracture healing.

Among the different types of internal fixation devices for the treatment of unstable sacral fractures, iliosacral screws have been widely used by surgeons due to its multiple advantages, including good biomechanical stability, minimally invasive procedure, and low infection rate<sup>5,6</sup>. However, upper sacral dysplasia can occur in 30%–50% of all sacrum<sup>7</sup>, which leads to a more narrow and oblique screw pathway in S1 than normal and makes screw placement difficult and significantly increases the risk of iatrogenic vessel and nerve injury<sup>8</sup>. Furthermore, the process of understanding changes from intraoperative fluoroscopy images to three-dimensional anatomical comprehension of the sacrum and becoming skillful in the manipulation of screw insertion is complicated and challenging for orthopaedic surgeons and the learning curve is long.

According to current perspectives, the unilateral stable sacral fracture can be fixed indirectly. The traditional internal fixation techniques include transsacral plate and lumbopelvic fixation. However, both of them have limitations. Transsacral plate has insufficient mechanical strength and has been shown to be less stable than the iliosacral screw, which increases the possibility of fixation failure<sup>9</sup>. The surgical procedure of lumbopelvic fixation usually requires a long incision in the lumbosacral region, which results in more bleeding and higher rate of infection than other minimally invasive fixation techniques<sup>10,11</sup>.

The technique of INFIX (internal fixator) consists of two LC II screws, which are implanted from the upper anterior inferior iliac spine (AIIS) to posterior superior iliac spine (PSIS) of both ilium and a subcutaneous connected rod. It has been widely used in the treatment of anterior pelvic ring fracture due to its advantages of being a minimally invasive procedure, having reasonable biomechanical model, providing enough fixing strength, and having satisfactory fracture healing rate<sup>12,13</sup>.

Recently, some surgeons reported a new application of INFIX asposterior pelvic ring internal fixation which was named "posterior INFIX". It involves the reverse implantation (from PSIS to AIIS) of two LC II screws and connection with a subcutaneous rod that is placed in backside. This fixation technique not only has the advantages of the original anterior pelvic ring INFIX procedure, but also is surgically safer and causes less radial damage than iliosacral screw placement, and has resulted in good outcomes in patients treated for unilateral unstable pelvic fractures<sup>14,15</sup>. However, these studies did not include a control group for comparison and the level of clinical evidence is relatively low.

In this study we retrospectively analyzed the data of patients who underwent a surgical procedure for "posterior INFIX"—posterior pelvic ring screw-rod internal fixation system—to treat unilateral unstable pelvic sacral fractures in the past 5 years and statistically compared the outcomes with those of the iliosacral screw fixation group. The main purposes were: (i) to evaluate the clinical outcomes of the posterior INFIX to treat the unilateral unstable sacral fractures, (ii) to discuss the

indications and contraindications of its application, and (iii) to introduce the keys of the surgical procedure.

# Methods

#### Inclusion and Exclusion Criteria

Inclusion criteria: (i) unilateral unstable sacral fractures, (ii) underwent the posterior INFIX fixation or iliosacral screw fixation, (iii) followed up continuously, (iv) no previous medical history or long-term medical records.

Exclusion criteria: (i) traumatic lumbosacral joint instability, (ii) sacral fractures associated with lumbar or sacral nerve injuries which required neurolysis surgery, (iii) open or osteoporotic sacral fractures.

#### General Data of the Patients

According to the inclusion and exclusion criteria, 60 consecutive patients who underwent surgery from March 2013 to March 2020 were included in the study, and medical records of the patients were retrospectively reviewed. According to the different types of fixation techniques, the patients were divided into two groups: the posterior INFIX fixation group and iliosacral screw fixation group, with 30 patients in each group. Among the 30 patients in the posterior INFIX fixation group there were 15 males and 15 females, with average age of  $45.13 \pm 18.79$  years (range, 18 to 78 years). 12 patients were injured in falls, 14 in traffic accidents, and four were injured by crushing. Fove patients had Denis type I fractures and 25 had type II sacral fractures. All patients had anterior pelvic ring injuries, of which 26 patients had pubic rami fractures and the other four had pubic symphysis dissociation. Eight patients had rib fractures and pleural effusion, seven had fractures of limbs; seven patients had sacral nerve injuries, of which six were grade II and one was grade III according to Gibbons classification. Among the 30 patients in the iliosacral screw fixation group, there were 18 males and 12 females, with average age of  $47.13 \pm 20.53$  years (range, 16-80 years). Ten patients were injured in falls, 16 in traffic accidents, and four were injured by crushing. Six patients had Denis type I fractures and 24 had type II sacral fractures. All patients had anterior pelvic ring injuries, of which 25 patients had pubic rami fractures and the other five had pubic symphysis dissociation. Ten patients had rib fractures and pleural effusion, eight had fractures of limbs, two had brain injuries (cerebral concussion) and one had spleen contusion; eight patients had sacral nerve injuries, of which seven were grade II and one was grade III according to Gibbons classification.

#### **Preoperative Treatment and Plan**

In the acute phase, the objective severity of the injuries of the patients was evaluated using Injury Severity Score (ISS). If the score of the patients was higher than 16, Damage Control Orthopaedics (DCO) principle was applied. Resuscitation and urgent surgical procedures which were necessary for saving lives were performed in emergency, then patients

were transferred to ICU to accept the further treatment. The definitive operations of sacral fracture were performed until the physiological conditions of patients were stable. The standard preoperative plan included a general physical examination. Three-dimensional reconstruction computed tomography (3D-CT) was applied necessarily in order to assess the degree of the deformity of the sacral fracture and determine whether the iliosacral screws could be safely implanted by imaging measurement preoperatively. Patients who had neural injury symptoms underwent magnetic resonance neurography (MRN) to assess the characteristics and degree of the nerve injury. Preoperative skeletal tractions were performed on all patients to correct the deformity as much as possible and nerve injury changes were observed to prejudge whether the decompression of the sacral plexus was necessary. All operations were performed by the same group of surgeons within a time period from 5 to 15 days after the primary injuries and the related clinical data involving ISS, time period from injury to operation, and operative data of sacral fracture such as operation time, amount of bleeding, and intraoperative fluoroscopy time were collected and recorded by the same researcher.

# **Operative Techniques**

#### Surgery of the Posterior INFIX Fixation

The patient was administered general anesthesia, after being placed in the prone position. Two longitudinal incisions of 3 cm were made on both distal parts of PSIS, then the gluteus maximus were dissociated to expose the PSIS.

One pair of 7.3-mm diameter pedicle screws were inserted 10 cm deep in the direction from PSIS to the ASIS and between the medial and lateral lamina of the iliac wing on each side with the monitor of the fluoroscopy. The image of lateral, iliac tangential position (inlet-obturator), and teardrop (outlet-obturator) position were necessary in this procedure. Then the bone around the ends of the Schantz screw were removed about 2 to 3 cm to avoid the prominence of internal fixation and a 7-mm diameter titanium connected rod was pre-contoured and implanted subcutaneously to connect the fixations on both sides.

The reduction of the fracture displacement was achieved with closed or limited open procedure. The vertical displacement of fracture was reduced with traction, and the horizontal and rotational displacement were corrected with an extra Schantz screw inserted to upper sacrum, which was lateral to the fracture line temporarily to manipulate the upper sacrum as a joystick. When the intraoperative fluoroscopy showed that the satisfied reduction was obtained, the end caps of the screw were screwed up tightly on both sides to fix the fracture indirectly (Fig. 1). Irrigation was applied and the wounds were closed.

#### Surgery for Iliosacral Screw Placement

After general anesthesia, the patient was placed in the prone position and displacement of sacral fracture was reduced with closed or limited open procedure. The intraoperative fluoroscopy of the anterior–posterior (AP), inlet, outlet, and lateral views was performed to evaluate the quality of the reduction and confirm the safe pathways of the screws. Then, a pair of 2-cm incisions were made and two 7.3-mm cannulated screws were correspondingly inserted percutaneously from the lateral cortex of the iliac border to the median line of  $S_1$  and  $S_2$ . During this procedure, consecutive fluoroscopy must be monitored to ensure the correct insertion of screws.

## Surgery of Anterior Pelvic Ring Fracture

The anterior pelvic ring injuries were all treated simultaneously with different operations. The modified ilioinguinal approach combined with reconstruction locking plate was applied to the patient who has pubic rami fractures, and the modified Pfannenstiel incision combined with plate or cannulated screw was applied to treat pubic symphysis dissociation.

# Postoperative Treatment

The antibiotic was regularly transfused 48 h postoperatively. Regular thromboprophylaxis therapy was administered 1 month postoperatively. Rehabilitation was planned and performed by a physical therapist as soon as the conditions allowed. Full weight-bearing was allowed 8–12 weeks postoperatively depending on the type of fractures and associated injuries.

#### Follow-Up and Clinical Outcome Evaluation

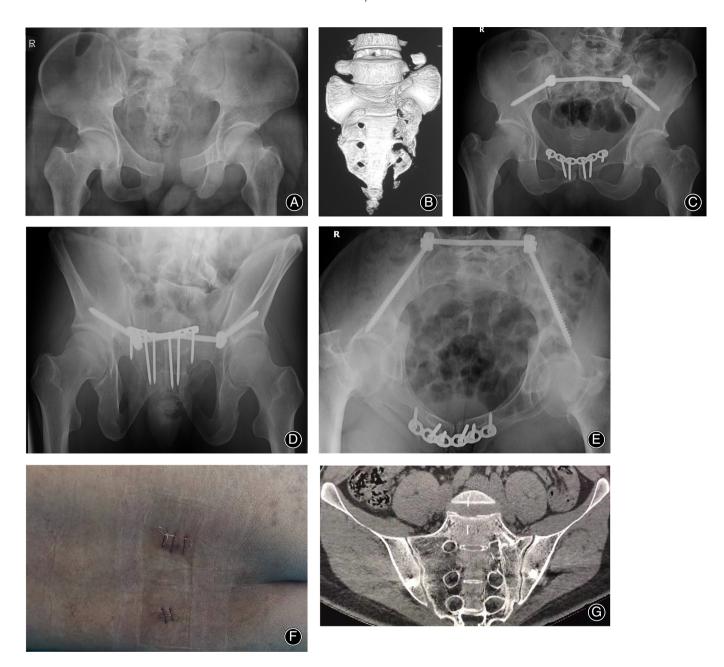
The follow-up visits were scheduled for 1 month, 2 months, 3 months, and every 3 months postoperatively. The imaging exams (CT scans) were performed to evaluate the degree of fracture healing, and the Mears and Velyvis's radiological classification criteria<sup>16</sup> were applied to evaluate the reduction quality of fractures. The clinical outcome of the fracture treatment was evaluated with the Majeed function assessment<sup>17</sup> and the Gibbons score was evaluated as the index of neurological deficiency<sup>18</sup> at the last follow-up.

#### Statistical Analysis

The statistical analysis of the data was performed using the SPSS 20.0 software (IBM Corporation, Armonk, NY, USA). The age of the patients, ISS, time period from injury to operation, operation time, amount of bleeding, and intraoperative fluoroscopy time were compared using the independent Student's *t*-test. The patient number of set, Gibbon grades, sacral fracture and anterior pelvic ring injury types, associated injury types, quality of fracture reduction and postoperative Majeed score were compared by the chi-square test. The confidence interval was set at 95%.

# Results

A ll patients were continuously followed up and the average time was  $23.17 \pm 3.34$  months (range, 12 to 46).



**Fig. 1** (A) Male, 30 years old, was injuried by falling. X-ray of AP showed left pelvis had vertical and rotational displacement associated with pubic synthesis dissociation. (B) Three-dimensional CT showed the left sacral fracture was unstable. (C–E) The patient accepted operation 4 days after injury. Closed reduction and posterior pelvic screw-rod fixation was applied to treat sacral fracture, and the pubic synthesis was treated with open reduction associated with reconstruction plate. (F) CT of 6 months postoperatively showed the sacral fracture had anatomic reduction and complete union.

# Comparison of General and Clinical Data

The average ISS score was  $14.73 \pm 9.26$  (range, 9 to 34) in the posterior INFIX fixation group and  $16.13 \pm 9.90$ (range, 9 to 43) in the iliosacral screw fixation group. The average time period from injury to surgery was  $7.13 \pm 2.64$  days (range, 5–15) in the posterior INFIX fixation group and  $7.53 \pm 2.80$  days (range, 5–14) in the iliosacral screw fixation group. There were no significant statistical difference in terms of age, ISS, time period from injury to surgery, sex, different causes of injury and associated injury types, Gibbon grade, sacral fracture and anterior pelvic ring injury types between the two groups of patients and they could be comparable (Table 1, P > 0.05).

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# Comparison of Operative Data

In the posterior INFIX fixation group, the average operation time was  $40.70 \pm 10.21$  min (range, 32 to 63 min), average amount of intraoperative bleeding was  $69.67 \pm 46.49$  mL (range, 30 to 100 mL), and the intraoperative fluoroscopy time was  $7.83 \pm 4.46$  s (range, 4 to 12 s). In the iliosacral screw fixation group, the average operation time was  $55.83 \pm 15.01$  min (range, 35 to 75 min), average amount of intraoperative bleeding was  $35.17 \pm 24.68$  mL (range, 20 to 100 mL), and the intraoperative fluoroscopy time was  $15.00 \pm 4.40$  s (range, 7 to 22 s).

There were significant differences in clinical data between the two groups. Compared to the iliosacral screw fixation group, the patients in the posterior INFIX fixation group had more intraoperative bleeding (t = 3.59, P < 0.001), shorter operation time(t = 4.49, P < 0.001), and less intraoperative fluoroscopy time (t = 6.26, P < 0.001, Table 2).

#### **Quality of the Fracture Reduction**

According to Mears and Velyvis's classification criteria, in the posterior INFIX group, anatomical reduction was achieved in 12 patients, satisfactory reduction was achieved POSTERIOR PELVIC RING INTERNAL FIXATOR (INFIX)

in 17 patients, and one patient had unsatisfactory reduction. Meanwhile, in the iliosacral screw fixation group, anatomical reduction was achieved in 10 patients, satisfactory reduction was achieved in 18 patients, and two patients had unsatisfactory reduction. There was no statistical difference in the quality of the fracture reduction between the two groups (P > 0.05; Table 3).

#### Majeed Score

At the last follow-up, the average Majeed score of the posterior INFIX fixation group was  $83.10 \pm 7.52$  (range, 75 to 90), while the average Majeed score was  $86.20 \pm 7.87$  (range, 75 to 90) in the iliosacral screw fixation group. There was no statistical difference in the average Majeed score between the two groups (P > 0.05, Fig. 2).

#### Neurological Improvement

In the posterior INFIX group, six of seven patients whose preoperative sacral nerve injuries were no less than grade II (Gibbons classification) changed to grade I. In the iliosacral screw fixation group, six of eight patients whose preoperative sacral nerve injuries were no less than grade II (Gibbons classification) changed to grade I.

TABLE 1 Comparison of general data between two groups							
Characteristics	Screw-rod fixation group ( $n = 30$ )	lliosacral screw fixation group ( $n = 30$ )	t or $\chi^2$ value	Р			
Sex (male: female)	15:15	18:12	0.61	0.44			
Age (years)	$\textbf{45.13} \pm \textbf{18.79}$	$\textbf{47.13} \pm \textbf{20.53}$	0.28	0.78			
ISS	$14.73\pm9.26$	$\textbf{16.13} \pm \textbf{9.90}$	0.4	0.69			
Time period (d, injury to op)	$\textbf{7.13} \pm \textbf{2.64}$	$7.53 \pm 2.80$	0.4	0.69			
Denis classification			0.11	0.74			
I	5	6					
II	25	24					
Cause of injury			0.32	0.85			
Fall	12	10					
Traffic accident	14	16					
Crush	4	4					
Anterior pelvic ring injury			0.13	0.72			
Pubic rami fracture	26	25					
Pubic symphysis dissociation	4	5					
Associated injury	15	21	2.35	0.50			
Rib fracture(pleural effusion)	8	10					
Limb fracture	7	8					
Brain injury	0	2					
Spleen contusion	0	1					
Sacral nerve injury	7	8	0.099	0.95			
Grade II	6	7					
Grade III	1	1					

TABLE 2 Comparison of operative data (mean $\pm$ SD)					
Operation	Operation time (min)	Intraoperative bleeding (mL)	Intraoperative fluoroscopy time (s)		
Posterior pelvic screw-rod ( $n = 30$ )	$40.70 \pm \textbf{10.21}$	$69.67\pm46.49$	$7.83\pm4.47$		
lliosacral screw ( $n = 30$ )	$55.83 \pm 15.01$	$\textbf{35.17} \pm \textbf{24.68}$	$\textbf{15.00} \pm \textbf{4.40}$		
t	4.49	3.59	6.26		
Р	0.000	0.001	0.000		

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TABLE 3 Comparison of the reduction quality and Majeed score									
Operation	Reduction quality of fracture								
	Anatomical	Satisfactory	Unsatisfactory	Majeed score					
Posterior pelvic screw-rod ( $n = 30$ )	12	17	1	$83.10\pm7.52$					
lliosacral screw ( $n = 30$ )	10	18	2	$86.20\pm7.87$					
X <sup>2</sup> or t value		0.54		1.56					
Р		0.76		0.12					



Fig. 2 Image of iliac tangent position fluoroscopy intraoperatively, which can display the pathway of iliac screw completely

#### Complications

All sacral fractures healed with an average healing time of  $9.3 \pm 2.24$  months (range, 6 to 18 months). None of the patients had re-displacement of fracture or fixation failure.

In the posterior pelvic ring screw-rod fixation group, one patient with a superficial wound infection healed after surgical debridement and treatment with oral antibiotics. One patient complained of discomfort due to prominent fixation, and the symptom disappeared after removing the fixation 1 year postoperatively as soon as the sacral fracture healed.

In the iliosacral screw fixation group, one patient had iatrogenic  $S_1$  nerve damage postoperatively and felt plantar

numbness, he accepted oral drug treatment and the symptom had disappeared at the last follow-up visit. Another patient had the screw cut out intraoperatively and suffered from anemia postoperatively. The vessel angiography showed that the anterior pelvic sacral plexus was broken and the patient was transferred to the vascular surgery department for treatment.

# Discussion

#### Advantages of the Posterior INFIX

Multiple studies have shown that the iliosacral screw obtains the most reliable stability among the different kinds of internal fixation which were used to treat posterior pelvic ring injury with minimum iatrogenic invasive damage<sup>19,20</sup>, thus it has become the preference of many surgeons. However, its limitation and deficiency are obvious: the influencing factors, such as intestinal gas and obesity will decrease the sharpness of the image intraoperatively, which leads to the bias of screw insertion; nearly half of the patients has morphological abnormality of uppersacrum, which leads to difficulty in safety of the screw insertion. In addition, Reilly et al.<sup>21</sup> reported that the screw pathway of S<sub>1</sub> would be decreased by 36% if the residual fracture displacement was 5 mm, which means that the safe pathway of the screw will be narrower, more dangerous, and difficult during the screw implantation procedure<sup>21,22</sup> even if minimal displacement of sacral fracture exists, which is hard to avoid in operation.

The posterior INFIX fixation can avoid those problems effectively and has the following clinical advantages: (i) this technique can fix the sacral fracture indirectly and the strength of fixation can be guaranteed, which make the operation easier and safer. In our study, the operation time in the posterior INFIX fixation group was less than that in the iliosacral screw fixation group, which supports our concept. Although the amount of intraoperative bleeding in the posterior INFIX fixation group was higher than that in the iliosacral screw fixation group, the confounding factors that can possibly mislead the outcome should be considered, such as intraosseous concealed bleeding during the insertion of the screw and the intracutaneous bleeding of soft tissue. Furthermore, the total amount of bleeding is so small that it hardly influences the safety of the surgical procedure; (ii) the iliac screws which were placed along almost the full length of both ilium combined with the thick connected rod can effectively embrace the posterior pelvic ring and

ensure the stability of the fracture fixation. The results of our study showed that the posterior INFIX fixation was as effective as the iliosacral screw fixation and can be reliable; (iii) the intraoperative fluoroscopy images of the iliac screw insertion can be more easily and clearly obtained than that of the iliosacral screw insertion<sup>23</sup>, indicating that the placement of posterior INFIX fixation has shorter operation time and less radiological exposure time to both surgeon and patient, as we demonstrated in our study, which leads to less iatrogenic damage and easier manipulation; (iv) the surgical procedure is minimally invasive, with minor iatrogenic damage and complications. In our study, the only complication that occurred in the posterior INFIX group was a superficial wound infection in one patient, which was less severe than the nerve and vessel damage that occurred in the iliosacral screw fixation group.

# **Contraindications of the Posterior INFIX**

Despite the obvious advantages of the posterior INFIX fixation, this surgical procedure is not suitable for all unilateral unstable pelvic fractures. We determined that the contraindications of this surgical procedure are as follows: (i) the sacral fracture which imaging exam showed obvious vertical displacement sustained preoperatively after high weight skeletal traction. These fractures cannot be treated with this minimally invasive surgical procedure and the open operation or lumbopelvic fixation should be considered to obtain satisfactory reduction; (ii) the procedure is contraindicated for the sacral fractures associated with lumbosacral conjunction instability which are higher than type IIB according to Isler classification because it is difficult to handle the lumbosacral joint through PSIS incision<sup>24</sup>; (iii) this procedure is also not recommended to treat the patients who have sacral fractures accompanied with nerve injuries which were found to have traumatic canal stenosis or sacral nerve compression caused by fragments of fracture by preoperative MRN and need to accept the open operation of neurological dissection and decompression.

# Key Points of the Surgical Procedure

i. The bone of the bilateral PSIS around the screw ends should be removed partly and the screws should be inserted deeply enough in order to avoid the associated complications caused by a prominent fixation, such as chronic pain and wound dehiscence, of which occurrence rate has been reported to be 44% in some studies<sup>25,26</sup>.

- ii. The posterior INFIX has limited effecton sacral fracture reduction. Therefore, the surgeon should perform the operation of anterior pelvic ring firstly to reduce the sacral fracture indirectly and minimize the displacement of posterior pelvic ring. Furthermore, the anterior and posterior pelvic ring injuries should be fixed simultaneously to enrich the mechanical strength of fixation, avoid the risk of re-displacement of the sacral fracture or fixation failure, which leads to non-union or mal-union of fracture<sup>24,27-29</sup>.
- iii. Besides the regular lateral and teardrop position intraoperative fluoroscopy images to confirm the correct direction of the iliac screws insertion, the iliac tangential position image is necessary. The image can be obtained when the tube of C-arm is tilted cephalad and ipsilaterally 30° to 45°, which is similar to the obturator-inlet position image. The fluoroscopy of this position can show the whole pathway of the iliac screw insertion clearly. The surgeon can judge whether the screw cuts out the medial or lateral cortex of the ilium accurately and correct the direction of the screw implantation effectively by using this image intraoperatively (Fig. 2).

# Limitations

Our study has some limitations, including that the clinical evidence generated by this study is not high-quality given that it is a retrospective study. In addition, the size of the sample is relatively small, and the follow-up time is not long, which may lead to the deviation of the results and affect the validity of conclusions.

# Conclusion

In summary, the posterior INFIX has similar clinical outcomes compared to the iliosacral screw fixation in the treatment of unilateral unstable sacral fractures. Furthermore, it has the advantages of easier manipulation, being safer, shorter operation time and intraoperative fluoroscopy time, and can be recommended for clinical application.

# **Conflict of Interest**

The authors declare that they have no conflict of interest.

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