CLINICAL ARTICLE

Minimally Invasive Percutaneous TightRope® System Fixation for an Unstable Posterior Pelvic Ring: Clinical Follow-up and Biomechanical Studies

Feng Gu, MD, Jiting Zhang, MS, Zhenjiang Sui, MS, Ke Zhang, MS, Xiaoping Xie, MS [iD], Tiecheng Yu, MD [iD]

Department of Orthopaedics, First Hospital of Jilin University, Changchun, China

Objective: To evaluate the mechanical stability and clinical efficacy of minimally invasive percutaneous TightRope® systems applied *via* gun-shaped reduction forceps for unstable posterior pelvic ring fractures.

Materials and methods: This study consists of two parts: a clinical retrospective study and a randomized controlled biomechanical test. For the clinical study, a retrospective analysis of posterior pelvic ring fractures was performed between June 2015 and May 2020. Eighteen patients underwent surgery using two TightRope® systems to fix a broken posterior pelvic ring because of unstable AO type C1 and C2 pelvic ring fractures. The patients were followed up for at least 2 years, and all patients were evaluated using the Majeed scoring system and vertical displacement. In the biomechanical tests, six embalmed adult pelvic specimens were used. The fractures were subjected to TightRope®, IS screw, and TBP fixation in a randomized block design. The specimens were placed in a biomechanical testing machine in a standing neutral posture. A cyclic vertical load of up to 500 N was applied, and the displacement of the specimens was recorded by the testing machine. The ultimate load in each group of specimens was recorded. The displacement and ultimate load were compared and analyzed by statistical methods.

Results: At a mean follow-up of 38.89 ± 8.72 months, the functional Majeed score was excellent in 14 patients and good in four patients. The final radiological examinations showed that the outcome was excellent in 14 patients and good in four patients. In these patients, no serious clinical complications were found. Weight-bearing was delayed in four patients. In biomechanical tests, the displacement of the specimens fixed with TightRope® was significantly lower than that of the specimens fixed with TBP ($P < 0.05$) when the load ranged from 300 to 500 N. The displacement in the IS screw group was significantly lower than that in either the TBP or TightRope® group ($P < 0.05$) when the load ranged from 0 to 500 N. The ultimate load in the IS screw group (1798 ± 83.53 N) was significantly greater than that in the TBP group (1352 ± 74.41 N) ($t = 9.78$, $P < 0.0001$) and the TightRope® group (1347 ± 54.28 N) ($t = 11.11$, $P < 0.0001$). However, no significant difference was observed between the TightRope® and TBP groups ($t = 0.13$, $P = 0.90$).

Conclusion: Percutaneous posterior TightRope® system shows strong stability in mechanical experiments and shows good results in clinical follow-up while this system has certain advantages in lower surgical requirements and lower risk of related nerve and vascular structural damage.

Key words: Biomechanics; Clinical study; Percutaneous; TightRope® system; Unstable pelvic fracture

Introduction

Pelvic ring injury, especially posterior pelvic ring injury, is a high-energy injury, with a fatality rate of 8% to 15% reported in the literature.[1] The most common cause of pelvic fractures is high-energy trauma, including traffic accidents and falls from a height.[2] Many pelvic ring fractures have

long-term complications, including gait disturbance, chronic pain, and arthritis.[2] Unstable posterior pelvic ring fractures are characterized by severe structural disruption of the sacrum, sacroiliac joint, and/or ilium resulting from a vertical shear force with high energy and severe vertical displacement of the sacroiliac posterior portion. The aim of treatment for posterior pelvic ring fractures is to rigidly stabilize the fracture, restore the integrity of the posterior pelvic ring, and decompress the nerves. The posterior pelvic ring bears approximately 70% of body weight, and fractures of the ring are very challenging to treat. It has been reported that the fracture malunion rate in fixation for the treatment of posterior pelvic injuries is approximately 7%, the failure rate of internal fixation is 5%, and the postoperative infection rate is 6%.[3]

The nonoperative management of severe unstable pelvic ring traumatic injuries is associated with numerous long-term complications, including lower back pain, gait abnormalities, and sitting imbalance.[4] Some posterior fixation methods have been introduced, such as an open approach with tension band plates (TBPs) or rods, which is accompanied by a risk of infectious complications, as well as a minimally invasive percutaneous approach with iliosacral (IS) screws.[5–13] Among them, the most commonly used methods for posterior pelvic ring fixation are those involving IS screws and TBPs.[6–13] However, both TBPs and IS screws have some limitations regarding treatment.[14–21] IS screw fixation is currently the mainstream method for the treatment of posterior ring injuries, but this kind of surgical technique is demanding with respect to surgical experience and skills. Conversely, high-quality fluoroscopy is required during the operation, and the operation risk is high for IS screw fixation. For patients with vertical instability, especially those with sacral fractures or fractures near the insertion point of the iliac bone, the efficacy of fixation is uncertain, and this fixation method cannot be used in patients with anatomical variations.[8] The use of TBPs to treat posterior ring injuries also has limitations and shortcomings. Some scholars believe that in addition to being stable, simple, and associated with little damage, they do not require repeated fluoroscopy, which reduces radiation exposure during surgery. However, the biomechanical strength of TBPs is still unclear, it is difficult to shape them during surgery, and a longer incision may be required to remove the steel plate.[22] The screw-rod system has also been reported in a previous study for the treatment of posterior pelvic ring fractures, but it is not widely used clinically and has limited indications.[23] At present, there is still controversy about the best treatment plan for posterior pelvic ring fractures, and there are still no biomechanical studies concerning the TightRope® system for the treatment of posterior pelvic ring fractures. Therefore, research on the treatment of unstable posterior ring fractures is of great significance for guiding clinical treatment, reducing the complications of this type of injury, and improving patient function.

The TightRope® system is an adjustable-loop length suspensory fixation device that comprises a pair of metal buttons, with one being ovoid and the other circular in shape. A No. 5 FiberWire (Arthrex) loop joins these buttons together. Recently, outcomes with TightRope® system fixation have been shown to be comparable to those of traditional rigid internal fixation while preserving normal physiological motion.[24–26] Feng et al.[27] have described TightRope® system fixation of the pubic symphysis with an external fixator to treat pelvic fracture. Other studies have shown that TightRope® system fixation (a kind of suture button) of the pubic symphysis is biomechanically similar to plate fixation in the management of partially stable pelvic ring injuries.[28] Compared with open TBP fixation for posterior pelvic ring fractures, TightRope® system fixation has a shorter operation, less intraoperative bleeding, and less soft tissue injury.[14,21,29–31] Percutaneous IS screw fixation has helped to reduce the operative duration, intraoperative bleeding,[21,29,32] and soft tissue injury but has a notable vascular and neurological risk. Because the anatomical structure around the sacroiliac joint is complicated, it is difficult to insert screws, and the operator skill requirements are high. Gory et al.[33] measured the distance between the screw placed in the S1 vertebra and the gluteal nerve vascular bundle after percutaneous iliac screw fixation in 58 pelvic specimens, and 18% of the screws injured the gluteal nerve and vascular bundle. There was a 4° deviation in the sacroiliac screw insertion, which could enter the S1 intervertebral foramen or penetrate the anterior cortex of the sacrum. The tip of the punctured screw may damage the iliac vessels and the phrenic nerve. Nerves can also be seriously damaged if the position of screws is inaccurate. Therefore, we assume that the TightRope® system will allow semirigid transfixation of the sacroiliac joint and provide a good fixation effect. In addition, when the TightRope® system is inserted into the posterior superior iliac spine, no relevant nerve structures are endangered. For this reason, a biomechanical analysis was performed of six embalmed adult male cadaveric pelvic specimens to analyze the stability of the TightRope® system, TBP, and IS screw fixation. The aims of this research were as follows: (i) to evaluate the clinical efficacy of the TightRope® system applied *via* a new coracoclavicular guider for the treatment of unstable posterior pelvic ring fractures; (ii) to evaluate the mechanical stability of the TightRope® system for the treatment of unstable posterior pelvic ring fractures; and (iii) to clarify the technical characters for minimally invasive surgery with the TightRope® system.

Materials and Methods

Clinical Research

Patients

This study was carried out in accordance with the guidelines for the care of human subjects adopted by the First Hospital of Jilin University; the study protocol was approved by the Research Ethics Committee of the First Hospital of Jilin University (ref. no. 2020–635); and written informed consent was obtained from all participants. The study was performed

following the principles of the Declaration of Helsinki (as revised in Brazil in 2013).

A retrospective analysis of posterior pelvic ring fractures was performed in this study between June 2015 and May 2020 in our department. The inclusion criteria were based on the following patient/intervention/comparator/outcome/study design (PICOS) criteria[34]: (i) "patients" with an unstable posterior pelvic ring fracture; (ii) an unstable posterior pelvic ring fracture due to a sacral fracture and/or sacroiliac joint dislocation; (iii) AO/OTA classification type C1 and C2; (iv) hemodynamic stability; (v) clear consciousness; (vi) the absence of severe medical conditions; (vii) complete or fundamental repositioning of the fracture after preoperative traction; (viii) complete follow-up data; (ix) "intervention" involving TightRope® system fixation surgery; (x) no "comparator" relevant to this study; (xi) "outcomes", including the Majeed score for functional evaluation and the results of radiological evaluation.

The exclusion criteria were as follows: (i) open fracture with a contaminated wound; (ii) unstable posterior pelvic ring fracture due to an iliac fracture; (iii) sciatic nerve injury or lower sacral nerve injury; (iv) severe osteoporosis.

Between June 2015 and May 2020, a total of 18 patients met these criteria and were enrolled. The causes of injury were traffic accidents in 13 patients and falls from a height in five patients. There were 61 OTA type C1 pelvic fractures in four patients and 14 OTA type C2 pelvic fractures in 14 patients. Radiological examinations of the anteroposterior, inlet, and outlet views of the pelvis were performed in all patients preoperatively. Before the surgery, to better evaluate the fracture dislocation condition and pelvic fracture stability, computed tomography (CT) scanning followed by three-dimensional (3D) reconstruction was performed.

Surgical Technique
Surgical Position and Incision. After general anesthesia, the patient lay prone on the full transparent surgery bed. Since the posterior superior iliac spine protruded from the body surface and there was no surrounding muscle tissue, it was easy to touch. After the bilateral posterior superior iliac spine was determined, longitudinal incisions approximately 2 cm long were made 1.5 cm lateral to the bilateral posterior superior iliac spine, and layers of subcutaneous tissue and fascia were bluntly dissected to separate them until the lateral side of the bilateral posterior superior iliac spine was touched.

Reduction and Internal Fixation. Since posterior pelvic ring fractures are usually accompanied by anterior pelvic ring fractures, to restore stability and integrity in the treatment of unstable pelvic ring fractures, anterior pelvic ring fractures should also be taken into account. If there was a vertical displacement of the pelvic fracture and the displacement was more than 2 cm, the affected extremity was subjected to traction to correct the vertical displacement. After the vertical dislocation was corrected under fluoroscopy, the operator palpated both posterior superior iliac spines. A gun-shape reduction forceps (Yutong Medical Technology Co., Ltd., Tianjin, China) was used in this process. The two ends of the guider (the stop side and the guide-wire entrance) (Figure 1) were inserted vertically between the two cortices of the bilateral posterior superior iliac spine from the two 2-cm surgical incisions (Figure 2). The operator had to ensure that the tips of the two ends of the guider were 1 cm below the tip point of the bilateral posterior superior iliac spine and tightly touched the cortices of the bilateral posterior superior iliac spines. Then, 2.5-mm guide pins were drilled to advance along the guidewire entrance of the guider (Figure 2). Insertion into the second guidewire was performed using the same technique. The operator ensured that the distance between the two guide pins was 1 cm. The cannulated drill was driven along the guidewire, leaving the hollow drill bit, and the two guidewires were removed (Figure 2). A suture-passing wire was advanced down through the cannulated drill bit, and then the cannulated drill bit was removed. The round button of a TightRope® system (Arthrex, Naples, Florida, USA) was then threaded through the bony holes along the suture-passing wire (Figure 2). Both tape ends of the TightRope® system were pulled back through the osseous channel with the tape consequently spanning between both iliac spines. The TightRope® system was then tightened, and both tape ends were manually surgically tied (Figure 2). Consequently, both metal buttons of the TightRope® system were placed on the lateral sides of the osseous channels on each iliac spine. A second TightRope® system was fixed with the same method. As shown in yellow in Figure 3A, the TightRope® system can be placed in these two positions to avoid the spinous process and vertebral body. Finally, the incisions were sutured.

Postoperative Treatment. Postoperatively, the patients were not allowed to bear weight on the fractured side for 8 weeks and gradually performed functional exercise according to their recovery. Patients were followed up for at least 2 years after surgery; follow-up included functional scores and radiological evaluations.

Outcome Measures
Majeed Scoring System. Functional outcomes were measured using the Majeed scoring system,[35] which is based on clinical physical examinations. Four criteria were chosen for functional assessment after major pelvic fractures: pain, standing, sitting, and sexual intercourse. Pain was given a score of 30 points, allocated according to six grades. Standing was given a score of 36 points in three main categories (aids, gait, and walking ability), each of which had six grades. Sitting was given 10 points in four grades. Sexual intercourse was given 4 points. Each of these clinical parameters was scored, with a maximum of 80 points for patients who were not working before the injury. The outcome was graded by total points, as follows: excellent, 70–80 points; good, 55–69 points; fair, 45–54 points; and poor, less than 45 points.
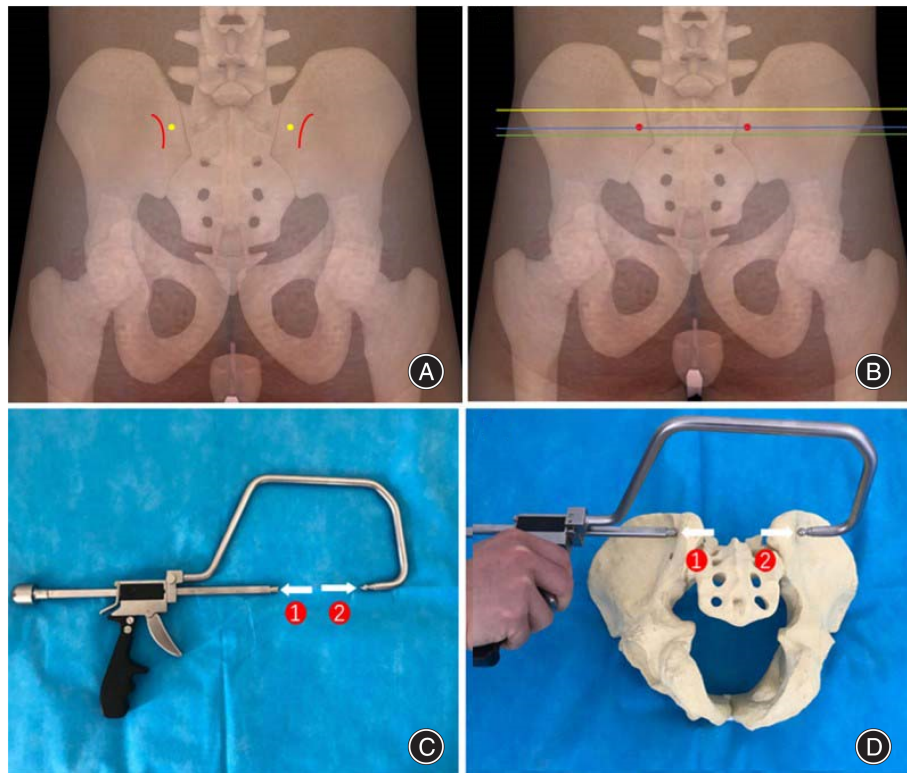
TightRope for Unstable Posterior Pelvic Fracture

Fig. 1 The guides for TightRope® system fixation. (A) Since the posterior superior iliac spine protruded from the body surface and there was no surrounding muscle tissue, it was easy to touch (marked in yellow dots). After the bilateral posterior superior iliac spine was determined, longitudinal incisions approximately 2 cm long were made 1.5 cm lateral to the bilateral posterior superior iliac spine (red arcs), and layers of subcutaneous tissue and fascia were bluntly dissected to separate them until the lateral side of the bilateral posterior superior iliac spine was touched. (B) ① The posterior superior iliac spines are marked with red dots, with a blue horizontal line between them. ② The horizontal position of the first TightRope® system is approximately 1.5 cm above the horizontal line between the posterior superior iliac spines, which is shown by the yellow line. ③ The horizontal position of the second TightRope® system is approximately 2 cm below the horizontal yellow line, which is shown by the green line. (C). ① The guide-wire entrance of the guider. The tip, to which the left arrow points, tightly touches the cortices of the lateral posterior superior iliac spine during the operation. ② The top side of the guider. The tip, which is indicated by the arrow, tightly touches the cortices of the lateral posterior superior iliac spine during the operation. (D) The guidewire entrance of the guider was used to retain tight contact with the cortices of the lateral posterior superior iliac spine during the operation

Vertical Displacement on Anteroposterior Radiograph. Vertical displacement in the injured pelvic ring was measured using anteroposterior (AP) radiographs of the pelvis. Vertical displacement was measured as the difference in height of the superior aspect of the sacrum from a line perpendicular to the long axis of the sacrum on the AP radiograph[36] (Figure 3B). Radiographs were obtained before the primary treatment, after reduction and internal fixation, and at the final follow-up. The radiographic results were graded by the maximal residual displacement of the pelvic ring based on Matta[36] and Lindahl[37] evaluation standards as follows: excellent, 0–5 mm; good, 6–10 mm; fair, 11–15 mm; and poor, more than 15 mm.[37]

Intraoperative Results. According to our experience, anatomical landmarks on the body's surface can be easily located during the operation. A good perspective and correct posture are essential for surgical procedures. It is necessary to verify good reduction before fixation, and good intraoperative fluoroscopy can ensure good reduction and accurate placement of the TightRope® system. For patients with anterior ring fractures, the surgical sequence and fixation methods need to be determined according to the specific situation. In general, the operation of the TightRope® system is relatively simple, and it can often achieve better results after the surgeon masters the operation.

Biomechanics Research

Preparation and Preservation of Specimens
This study was conducted in accordance with the Declaration of Helsinki. This study was approved by the Research
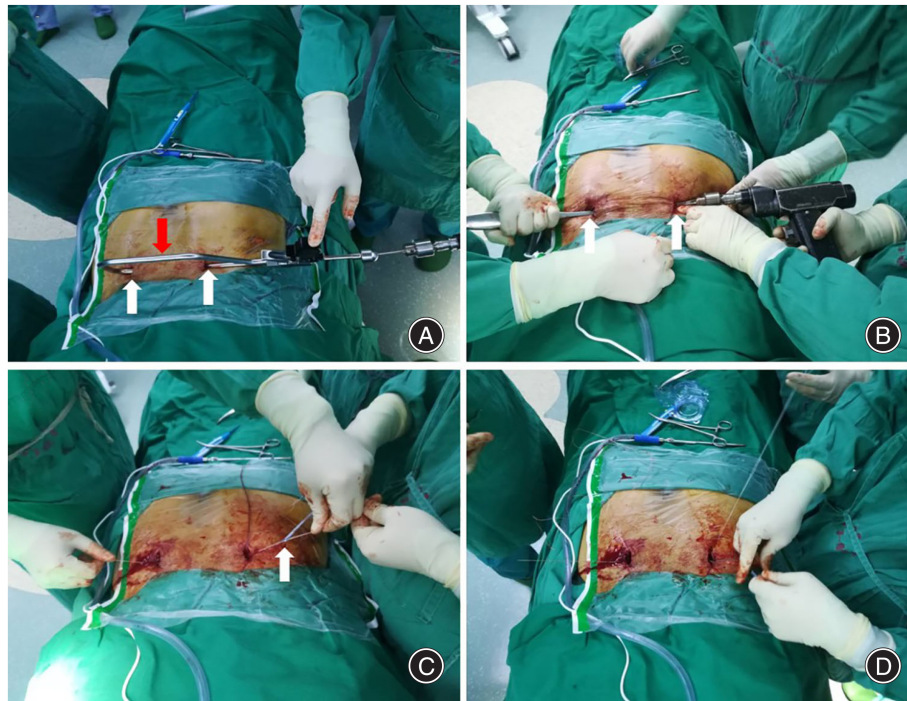
Fig. 2 Key surgical procedures for TightRope® system fixation. (A) The two ends of gun-shape reduction forceps (Yutong Medical Technology Co., Ltd.) were inserted vertically between the two cortices of the bilateral posterior superior iliac spine from the 2 cm surgical incisions (white arrows). The operator must ensure that the tips of the two ends of the guider are 1 cm below the tip point of the bilateral posterior superior iliac spine and retain tight contact with the cortices of the bilateral posterior superior iliac spine. Then, the operator inserts a 2.5-mm guide pin into the guide-wire entrance of the guider (the red arrow) and advances the guide pin along the guide-wire entrance and through the cortices of both posterior superior iliac spines using a power drill. (B) The operator places the 4-mm-diameter cannulated drill bit over the guide pin and then advances the drill bit along the pin and through the cortices of both posterior superior iliac spines using a power drill. The surgical incisions are indicated by white arrows. (C). A suture-passing wire (white arrows) of TightRope® system (Arthrex) is advanced down through the cannulated drill bit. (D). The round button of the TightRope® system is then threaded through the bony holes along the suture-passing wire
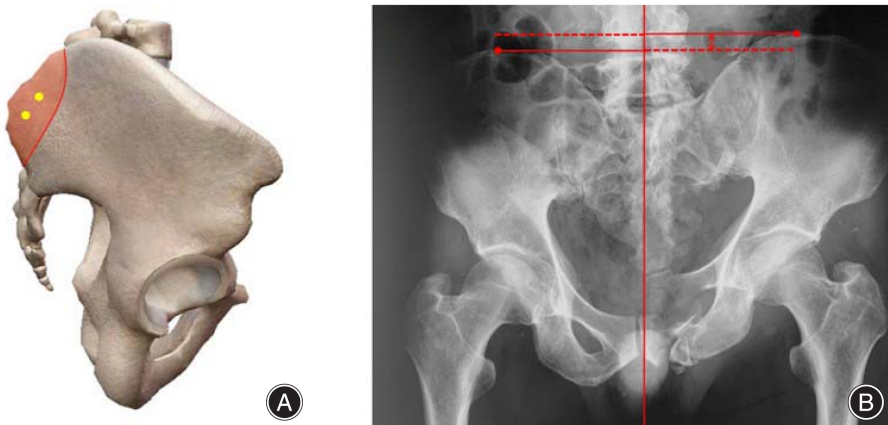
Fig. 3 The position of the pelvis marked in the anteroposterior and lateral views. (A) The TightRope® system can be placed in two positions to avoid the spinous process and vertebral body. The entry points with the drilled holes are marked in yellow. (B) Vertical displacement was measured as the difference in height of the superior aspect of the sacrum from a line perpendicular to the long axis of the sacrum on the AP radiograph. The red horizontal lines indicate the vertical displacement

Ethics Committee of the First Hospital of Jilin University (Changchun, Jilin, China). Written informed consent was obtained from all participants.

Six embalmed adult male cadaveric pelvic specimens (provided by the Department of Anatomy of Jilin University) were used for biomechanical investigations. The average age of the specimens was 45.5 years (range: 35 to 57 years). X-ray films of the pelvis were routinely taken for all specimens, and the absence of cancer, abnormalities, osteoporosis, and other abnormalities was confirmed. From the upper edge

of the fourth lumbar vertebra to the upper and middle femur, the soft tissue was removed, and the ligaments (anterior iliac ligament, posterior iliac ligament, intersacral ligament, pubic symphysis ligament, sacrospinous ligament, and iliolumbar ligament) were retained.

Modeling of Posterior Pelvic Ring Injury and Fixation of Specimens

The pelvic specimens were cut from the midpoint of the sacroiliac joint and sacral foramen (Figure 4). To exclude the influence of anterior pelvic ring fractures, the anterior ring was kept intact to simulate a simple posterior ring unstable fracture model. Three types of fixation were used in this study as follows: (i) TBP group: The fracture was fixed and stabilized with a TBP (Shandong Weigao Medical Co., Ltd., Shandong, China), and suitable screws were inserted into the external surface of the ilium (Figure 5A); (ii) TightRope® group: A Kirschner wire was used at the horizontal plane of the posterior superior iliac spine to create a tunnel, and the fracture was fixed with the TightRope® system through this tunnel (Figure 5B); (iii) IS screw group: Two 2.0-mm Kirschner wires were inserted through the ipsilateral external surface of the ilium and into the first sacral vertebral body, and two 7.3-mm cannulated, partially threaded, and cancellous IS screws (Shandong Weigao Medical Co., Ltd., Shandong, China) were inserted into the first sacral vertebral body with Kirschner wires (Figure 5C). X-ray examination was used to confirm appropriate screw placement.

The bilateral distal femur of the specimens was fixed using type II denture-based self-curing denture acrylic (Shanghai Medical Instrument Company, Ltd., Shanghai, China). The lower end of the femur was fixed in the clamp platform, and the upper end of the lumbar vertebra was fixed

in the steel plate platform. The pelvic specimens were placed in the Electroforce CSS-44110 biomechanical testing machine (Changchun Testing Machine Institute, Changchun, China) in a standing neutral position, and both anterior superior iliac spines and the ventral surface of the pubic symphysis were covered by the same plane.

This loading mode is based on that used in previous studies.[38] The purpose of this loading method is to eliminate errors caused by other effects and simulate the real force of the human body as much as possible. A vertical load of 200 N was applied to eliminate creep. The vertical cyclic load was between 0 and 500 N and increased at a rate of 10 N/s. The cyclic load was applied in 20 cycles. In the last three cycles, the displacement of the specimens was recorded at vertical loads of 100, 200, 300, 400, and 500 N by the testing machine. The ultimate load in each group of specimens was recorded.

Outcome Measures

Displacement Under Vertical Loading. Displacement of the fracture was measured under vertical loading. At the horizontal line of the first sacral vertebral body, two special Kirschner wires were inserted into each side of the fracture gap for marking, and the two Kirschner wires were stable and oriented in parallel. A fixed-position digital camera, which was vertically positioned on the front of the specimen, was used while facing the positioning mark to take pictures before loading. The above operation was repeated after loading. After the experiment, the image was transferred to a computer, the distance between the Kirschner wires before and after loading was measured using AutoCAD 2019 (AutoDesk, California, USA), and each distance was measured three times. The difference before and after loading to

Fig. 4 Posterior pelvic ring fracture models and the testing machine used in this study. (A) Six embalmed adult male cadaveric pelvises (viewed from the front) were cut from the midpoint of the sacroiliac joint and sacral foramen to create posterior pelvic ring fracture models. The fracture line is indicated by the red arrow. (B) The pelvic specimens viewed from behind. The fracture line is indicated by the red arrow. (C) The pelvic specimens were placed in the biomechanical testing machine

Fig. 5 X-rays of fractures treated with three types of fixation. (A) Fracture of the posterior ring treated using a TBP. (B) Fracture of the posterior ring treated using the TightRope® system. (C) Fracture of the posterior ring treated using IS screws

TABLE 1 Characteristics of the patients, their accidents, and their associated injuries				
Patient	Sex	Age (years)	Mechanism of injury	Associated injuries
1	F	33	Defenestration	Abdomen, urethra, and vagina
2	M	35	MVA	Abdomen, urethra, and vagina
3	M	59	Defenestration	Abdomen
4	F	41	MVA	Abdomen
5	M	48	MVA	Abdomen
6	F	38	MVA	Spine, ribs, and abdomen
7	F	21	Defenestration	Abdomen, ribs, and femur
8	F	63	MVA	Abdomen, ribs, and ulnar
9	M	58	MVA	Abdomen, femur, and radius
10	F	52	MVA	Femur
11	F	38	MVA	Abdomen, femur, and ribs
12	M	41	MVA	Abdomen
13	M	50	MVA	Abdomen and urethra
14	F	33	Defenestration	Abdomen and ankle
15	M	42	MVA	Abdomen
16	M	40	MVA	Abdomen
17	F	57	Defenestration	Abdomen, radius, and ulna
18	M	42	MVA	Clavicle

Abbreviation: MVA, motor vehicle accident.

obtain the displacement of the pubic symphysis was calculated and the average was taken. The relative positions of the camera and specimen remained unchanged throughout the whole recording process (Figure 5C).

Ultimate Load. The ultimate load in each group was measured. The following conditions were used as a sign of the ultimate load: (i) the fracture displacement exceeded 5 mm; (ii) the deformation increased without increasing or even decreasing the load; and (iii) the internal fixation failed or broke in the test. All of the pelvic fracture models were constructed and fixed by the same surgeon. Designing the location and direction of the internal fixation prior to implantation and using X-ray fluoroscopy after the procedure made it possible to reduce the influence of subsequent fixation.

Statistical Analysis
Statistical comparisons of displacement and the ultimate load were performed using paired t tests. All statistical analyses were conducted using SPSS 18.0 (IBM Corp., Somers, NY, USA) software. $p < 0.05$ was considered to indicate statistical significance ($\alpha = 0.05$).

Results

Clinical Results
Follow-Up. All patients were followed up for 38.89 ± 8.72 months, including at 1 month, 6 months, 1 year, and the last follow-up, and all patients were evaluated using the Majeed scoring system and vertical displacement. A total of 18 patients (mean age: 43.94 ± 10.94 years) with AO type

TABLE 2 Clinical follow-up outcomes

Patient	AO	Surgery time after the injury (days)	Fixation method for APF	Fixation method for PPF	Time (minutes)	BL (ml)	Last follow-up time (months)	WB (weeks)
1	C2.2	7	EF	TS	35	25	55	12
2	C2.2	3	SP	TS	30	30	53	8
3	C1.3	5	EF	TS	25	25	53	8
4	C1.3	5	SP	TS	35	40	45	8
5	C1.3	5	EF	TS	40	30	43	8
6	C1.2	5	EF	TS	35	25	41	8
7	C2.3	7	SP	TS	25	30	39	12
8	C1.2	5	EF	TS	35	40	37	8
9	C1.2	4	SP	TS	30	25	35	8
10	C1.3	5	SP	TS	30	40	31	8
11	C1.2	4	EF	TS	30	25	26	8
12	C1.2	3	EF	TS	25	25	28	8
13	C1.3	4	SP	TS	30	40	32	8
14	C1.3	6	SP	TS	35	35	41	12
15	C1.2	3	EF	TS	40	30	43	8
16	C2.1	3	EF	TS	30	25	29	8
17	C1.2	5	EF	TS	35	30	33	10
18	C1.3	3	EF	TS	30	25	36	8

Abbreviations: AO, AO classification; APF, Anterior pelvic fracture; BL, Blood loss during fixing the TightRope® system; EF, External fixator; PPF, Posterior pelvic fracture; SP, Screw plate; Time, Time needed to fix the TightRope® system; TS, TightRope® system; WB, Weight-bearing time after surgery.
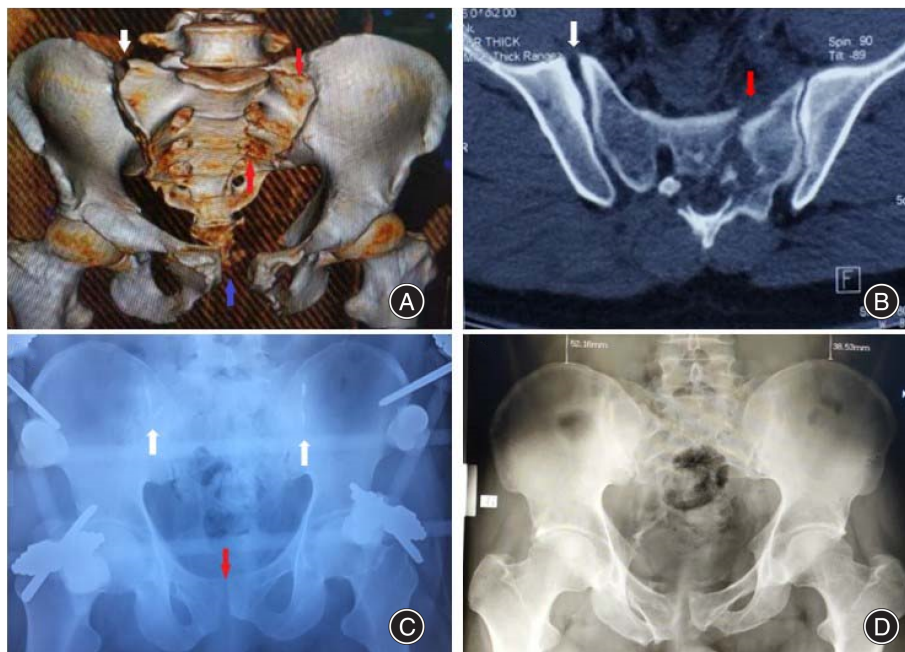

Fig. 6 A 35-year-old man who was hit by a car from the front and his pelvis was crushed against a wall, causing a pelvic fracture (AO classification, C2.2). Four days after the injury, the unstable posterior pelvic ring fracture was reduced and fixed with two TightRope® systems, and then the unstable anterior pelvic ring fracture was fixed with external fixation. Fifteen months later, the functional and radiological evaluation was excellent. (A) AP view of the 3D CT reconstruction of the patient's pelvis before surgery. The patient had a dislocation of the right sacroiliac joint (indicated by the white arrow), a fracture line was visible on the left metatarsal bone, and the fracture line passed through the metatarsal foramen (indicated by the red arrow). The patient's pubic symphysis was separated and displaced (indicated by the blue arrow). (B) CT obtained before surgery. The patient had a dislocation of the right sacroiliac joint (indicated by the white arrow). A displaced fracture was visible on the left metatarsal bone (indicated by the red arrow). (C) AP X-ray obtained 1 week after surgery. The displacement of the pubic symphysis was stably reduced and fixed by an external fixator (indicated by the red arrow), and posterior pelvic ring fracture was reduced and fixed with two TightRope® systems (indicated by white arrows). (D) AP X-ray obtained 15 months after the TightRope® systems and external fixator were removed
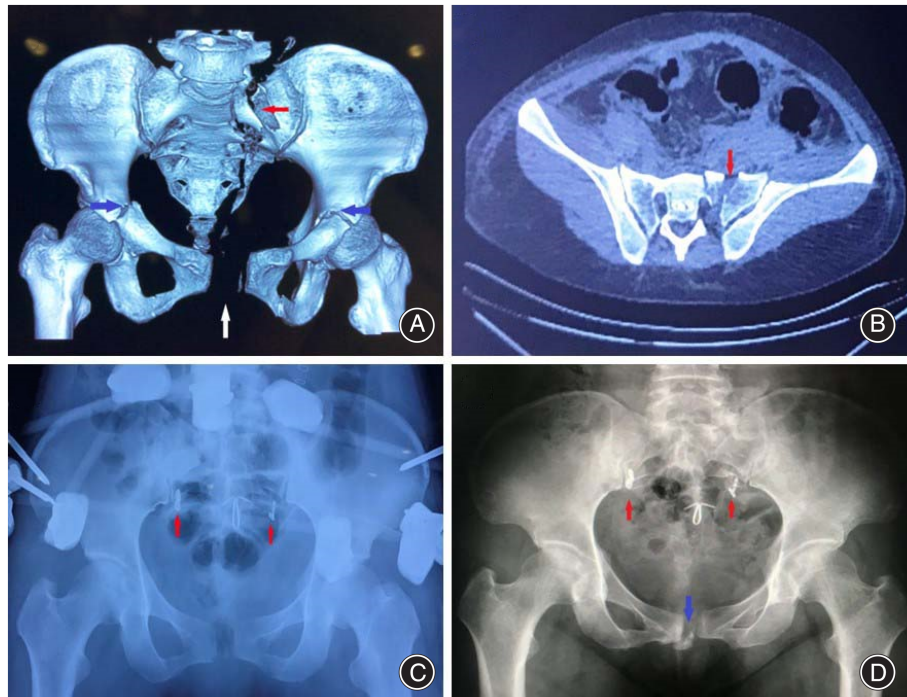
Fig. 7 A 41-year-old woman whose pelvis was injured by more than 200 kilograms of weight was diagnosed with a pelvic fracture (AO classification, C1.3). Five days after the injury, the unstable posterior pelvic ring fracture was first reduced and fixed with two TightRope® systems, and then the unstable anterior pelvic ring fracture was fixed with an external fixator. The external fixator was removed 3 months postoperatively when the fracture had healed. Forty-five months later, the functional and radiological evaluations yielded excellent results. (A) AP view of the 3D CT reconstruction of the patient's pelvis before surgery. A displaced fracture was visible on the left metatarsal bone (indicated by the red arrow). The fracture of the bilateral pubic branch is indicated by the blue arrow. The pubic symphysis was separated and displaced, which is indicated by the white arrow. (B) CT obtained before surgery. A displaced fracture was visible on the left metatarsal bone, which is indicated by the red arrow. (C) AP X-ray of the patient's pelvis obtained 3 days after surgery. The buttons of the TightRope® system are shown by red arrows. (D) AP X-ray of the patient's pelvis obtained 45 months after surgery. The buttons of the TightRope® system are shown by red arrows. Heterotopic ossification at the pubic symphysis is indicated by the blue arrow

C1 pelvic fractures underwent surgery with this technique performed by a specialized surgeon at our hospital (Table 1). A total of 11 patients received an external fixator, and seven patients underwent anterior screw plate fixation. The posterior surgery was performed a mean of 4.56 ± 1.29 days after the injury and took a mean of 31.94 ± 4.58 min. No intraoperative vascular or nerve complications were recorded, and the volume of blood loss was trivial (average: $30.28 \pm 6.06 < 40$ ml) (Table 2). Transcondylar traction was required in four patients. All patients could bear weight on a single leg on the injured side in a stable and pain-free manner. A total of 14 patients resumed their pre-injury occupation. According to examination of the AP pelvic radiographs, all patients had healed within 3 months. Full weight bearing was started after 8 weeks (range: 8 to 12 weeks) (Table 2). The load was increased gradually based on the fracture type and follow-up radiography findings. All patients underwent clinical and radiological assessments (Figures 6–8).

Functional Evaluation. The Majeed functional score[35] (average: 65.44 ± 5.18) was excellent in five patients and good in 13 patients at 1 month after surgery (Table 3). The Majeed functional score[35] (average, 72.83 ± 5.47) was excellent in 14 patients and good in four patients at the last follow-up (Table 3). Photos of patients during follow-up are provided in Figures 9 and 10.

Radiographic Improvement. The mean value of vertical displacement was 3.22 ± 1.40 mm at 1 month after surgery and 3.61 ± 1.75 mm at the last follow-up (Table 4). The AP pelvic radiographs of 16 patients revealed excellent outcomes, and those of two patients showed good outcomes based on the Matta[36] and Lindahl[37] evaluation standards at 1 month after surgery (Table 4). At the last follow-up, the AP pelvic radiographs of 14 patients revealed excellent outcomes, and those of four patients showed good outcomes (Table 4).

Complications. Weight bearing was delayed in four patients. In four patients with delayed weight bearing, the Majeed score was good at the last follow-up (Table 3), and the vertical displacement was more than 5 mm at 1 month after
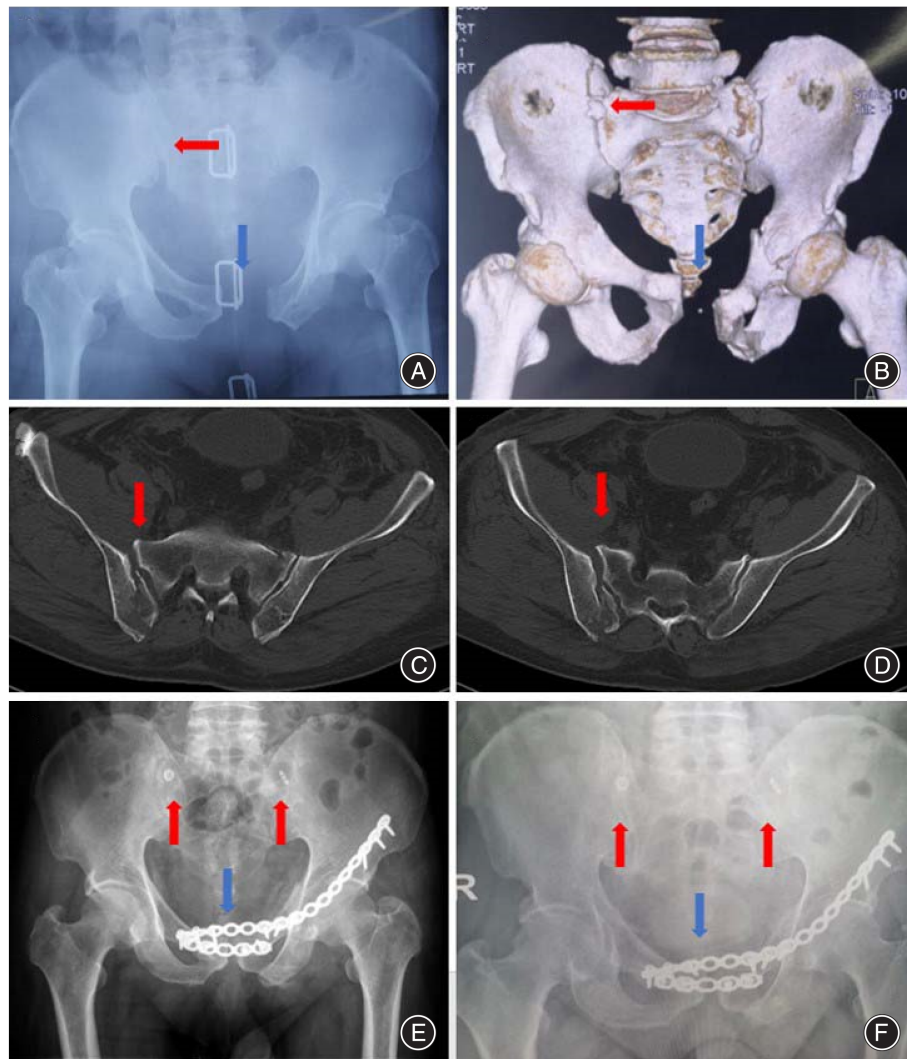
Fig. 8 A 58-year-old man who was injured in a car accident was diagnosed with a pelvic fracture (AO classification, C1.2). Four days after the injury, the unstable posterior pelvic ring fracture was first reduced and fixed with two TightRope® systems, and the unstable anterior pelvic ring fracture was fixed with plates. Thirty-five months later, the functional and radiological evaluations were excellent. (A) AP X-ray obtained before surgery. A displaced fracture was visible on the right iliac bone (indicated by the red arrow). The pubic symphysis was separated and displaced, which is indicated by the blue arrow. (B) AP view of 3D CT reconstruction of the patient's pelvis before surgery. A displaced fracture was visible on the right iliac bone (indicated by the red arrow). The pubic symphysis was separated and displaced, which is indicated by the blue arrow. (C) CT obtained before surgery. A displaced fracture was visible on the right iliac bone, which is indicated by the red arrow. (D) CT obtained before surgery. A displaced fracture was visible on the right iliac bone, which is indicated by the red arrow. (E) AP X-ray of the patient's pelvis obtained 1 month after surgery. The buttons of the TightRope® system are denoted by red arrows, and the anterior pelvic ring fracture was fixed with plates (indicated by the blue arrow). (F) AP X-ray of the patient's pelvis obtained 35 months after surgery. The buttons of the TightRope® system are denoted by red arrows, and the anterior pelvic ring fracture was fixed with plates (indicated by the blue arrow)

surgery (Table 4). The other patients achieved excellent Majeed scores at the last follow-up. The recovery of vertical displacement was preliminarily judged to be closely related to the postoperative function of the patient during surgical reduction. Poor reduction and large vertical displacement may lead to poor function. These patients were female (Table 1), so the results may have been related to the anatomy of the female pelvis. The operation was performed more than 5 days after injury (Table 2). The delay of the operation after injury may be related to dysfunction. One patient had heterotopic ossification at the pubic symphysis (Figure 7). Through active functional exercise, the daily life of these

TABLE 3 Functional (Majeed score) outcomes

Patient	Majeed score (1 month)		Majeed score (6 month)		Majeed score (1 year)		Majeed score (2 years)		Majeed score (Last follow-up time)	
	Score	Grade	Score	Grade	Score	Grade	Score	Grade	Score	Grade
1	55	Good	60	Good	66	Good	66	Good	66	Good
2	71	Excellent	76	Excellent	78	Excellent	80	Excellent	80	Excellent
3	67	Good	71	Excellent	76	Excellent	78	Excellent	78	Excellent
4	70	Excellent	72	Excellent	72	Excellent	76	Excellent	76	Excellent
5	65	Good	70	Excellent	74	Excellent	78	Excellent	78	Excellent
6	64	Good	69	Good	73	Excellent	73	excellent	73	excellent
7	56	Good	56	Good	61	Good	61	Good	61	Good
8	66	Good	71	Excellent	73	Excellent	73	Excellent	73	Excellent
9	62	Good	67	Good	71	Excellent	71	Excellent	71	Excellent
10	67	Good	69	Good	71	Excellent	71	Excellent	71	Excellent
11	71	Excellent	76	Excellent	78	Excellent	78	Excellent	78	Excellent
12	69	Good	74	Excellent	78	Excellent	80	Excellent	80	Excellent
13	66	Good	71	Excellent	73	Excellent	73	Excellent	73	Excellent
14	56	Good	61	Good	63	Good	63	Good	63	Good
15	65	Good	72	Excellent	76	Excellent	76	Excellent	76	Excellent
16	70	Excellent	72	Excellent	72	Excellent	72	Excellent	72	Excellent
17	67	Good	69	Good	69	Good	69	Good	69	Good
18	71	Excellent	73	Excellent	73	Excellent	73	Excellent	73	Excellent

Fig. 9 A 35-year-old male patient treated with the TightRope® system was followed up for 3 years. The lower limb function recovered well, and the Majeed score was excellent. (A) The patient in a standing position, with good functional recovery. (B) The patient in a sitting position, with good functional recovery and no pain. (C) The patient in the squat position, with good functional recovery and no pain

Fig. 10 A 41-year-old female patient treated with the TightRope® system was followed up for 2 years. Lower limb function recovered well, and the Majeed score was excellent. (A) The patient in a standing position, with good functional recovery. (B) The patient in a sitting position, with good functional recovery and no pain. (C) The patient in the squat position, with good functional recovery and no pain

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TABLE 4 Vertical displacement of anteroposterior radiograph outcomes

Patient	Vertical displacement (1 month)		Vertical displacement (6 month)		Vertical displacement (1 year)		Vertical displacement (2 years)		Vertical displacement (Last follow-up time)	
	Displacement(mm)	grade	Displacement(mm)	grade	Displacement(mm)	grade	Displacement(mm)	grade	Displacement(mm)	grade
1	5	Excellent	6	Good	6	Good	6	Good	6	Good
2	3	Excellent	4	Excellent	4	Excellent	4	Excellent	4	Excellent
3	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
4	3	Excellent	3	Excellent	3	Excellent	3	Excellent	3	Excellent
5	3	Excellent	3	Excellent	3	Excellent	3	Excellent	3	Excellent
6	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
7	6	Good	7	Good	7	Good	7	Good	7	Good
8	2	Excellent	3	Excellent	3	Excellent	3	Excellent	3	Excellent
9	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
10	4	Excellent	4	Excellent	4	Excellent	4	Excellent	4	Excellent
11	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
12	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
13	3	Excellent	3	Excellent	3	Excellent	3	Excellent	3	Excellent
14	6	Good	7	Good	7	Good	7	Good	7	Good
15	3	Excellent	4	Excellent	4	Excellent	4	Excellent	4	Excellent
16	2	Excellent	2	Excellent	2	Excellent	2	Excellent	2	Excellent
17	5	Excellent	6	Good	6	Good	6	Good	6	Good
18	3	Excellent	3	Excellent	3	Excellent	3	Excellent	3	Excellent

patients was not significantly affected, and the patients were basically satisfied with their limb function. No neurological or vascular complications occurred.

Biomechanics Research

Displacement of the Specimens under Loading
Under a vertical load from 0 to 500 N, the displacement of specimens fixed with two IS screws was significantly lower than that of specimens fixed with either a TBP or the TightRope® system ($p < 0.05$, specific p and t values are shown in Table 5). Under vertical loads of 100 N and 200 N, the displacement of specimens fixed with a TBP was similar to that of specimens fixed with the TightRope® system ($p > 0.05$, specific p and t values are shown in Table 5). When the load ranged from 300 to 500 N, the displacement of specimens fixed with the TightRope® system was significantly lower than that of specimens fixed with a TBP ($p < 0.05$, specific p and t values are shown in Table 5).

Ultimate Load of Specimens
The ultimate load of specimens fixed with two IS screws (1798 ± 83.53 N) was significantly larger than that of specimens fixed with a TBP (1352 ± 74.41 N) ($t = 9.78$, $P < 0.0001$) and the TightRope® system (1347 ± 54.28 N) ($t = 11.11$, $P < 0.0001$). However, no significant difference was observed between the TightRope® system (1347 ± 54.28 N) group and TBP (1352 ± 74.41 N) groups ($t = 0.13$, $P = 0.90$).

Discussion

Clinical Effects of the TightRope® System
In this study, using the percutaneous TightRope® system fixation technique, the blood loss was less than 40 ml (average: 30.28 ± 6.06 ml), the operative duration averaged 31.94 ± 4.58 min, and there were no vascular or neurological complications in 18 patients. The Majeed score (average: 72.83 ± 5.47) was excellent in 14 patients and good in four patients at the last follow-up (Table 3). At the last follow-up, the AP pelvic radiographs of 14 patients revealed excellent outcomes, and those of four patients showed good outcomes (Table 4).

Our technique utilized TightRope® system fixation, which is a new way to stabilize the posterior pelvic ring. The TightRope® system is a kind of suture tape that is commonly used in treating acromioclavicular joint dislocation[39,40] and in other kinds of fixation.[41–46] It is a minimally invasive fixation method with sufficient stability. The technique of fixation with the TightRope® system is simpler than that with IS screws and has no risk of nerve root injury. Conversely, this semirigid fixation method can also ensure that the sacroiliac joint retains physiological activity and a certain degree of micromovement, so there is no need to remove the implant after surgery, and the possibility of joint stiffness will be reduced.[47,48] Although there were still no reports of the same experiments, suture button fixation (SBF) has better clinical

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TABLE 5 Displacement outcomes

Load (N)	TBP (mm)	TRS (mm)	ISS (mm)	TBP vs TRS		TBP vs ISS		TRS vs ISS	
				t	P	t	P	t	P
100	0.26 ± 0.07	0.27 ± 0.05	0.16 ± 0.02	0.19	0.85	3.35	0.0073*	5.23	0.0004*
200	0.47 ± 0.14	0.51 ± 0.14	0.27 ± 0.05	0.45	0.66	3.26	0.0085*	3.89	0.0030*
300	0.86 ± 0.14	0.60 ± 0.14	0.38 ± 0.04	3.22	0.0092*	8.00	<0.0001*	3.45	0.0062*
400	1.26 ± 0.11	0.80 ± 0.17	0.48 ± 0.05	5.45	0.0003*	15.81	<0.0001*	4.36	0.0014*
500	1.55 ± 0.12	1.09 ± 0.09	0.72 ± 0.14	7.38	<0.0001*	11.29	<0.0001*	5.54	0.0002*

Note: The values are expressed as the mean ± standard deviation (range). $p < 0.05$ was considered statistically significant and is marked with "*."

effect and lower complication rate than metal screw fixation (MSF) in the fixation of syndesmotic injuries.[49,50]

Mechanical Stability of TightRope® System Fixation

Furthermore, to analyze the differences in biomechanical stability among the TightRope® system, IS screw, and TBP fixation, the displacement under loading and the ultimate load of six embalmed specimens of adult pelvises were compared and it was found that the stability of IS screw fixation was the strongest among the three fixation methods. There was no significant difference in displacement between the TBP and TightRope® methods under vertical loads of 100 N and 200 N ($P > 0.05$, specific p and t values are shown in Table 5). When the load ranged from 300 to 500 N, the displacement of specimens fixed with the TightRope® system was significantly lower than that of specimens fixed with a TBP ($P < 0.05$, specific p and t values are shown in Table 5). No significant difference was observed between the TightRope® system group (average: 1352 ± 74.41 N) and the TBP group (average: 1352 ± 74.41 N) ($t = 0.13$, $P = 0.90$) in ultimate load. The stability of TightRope® system fixation was slightly better than that of TBP fixation. Some biomechanical comparisons applied to the acromioclavicular joint also showed that the stiffness of TightRope® system was higher than that of plate,[51,52] which was similar to our study.

Technical Advantages of Minimally Invasive Surgery with the TightRope® System

The TightRope® system can be applied in a minimally invasive manner. Through anatomical landmarks on the body surface, it can be easily positioned during the operation. The damage caused by the use of this system is very small, and the length of the incision is only approximately 2 cm. This method for fixation can often achieve closed reduction without exposing the fracture position, thereby reducing damage to the soft tissue and blood supply around the fracture end. Using gun-shape reduction forceps, accurate positioning and drilling can be performed, and the operative duration is greatly shortened. Due to its minimally invasive characteristics, this process accelerates the recovery of patients and

reduces the possibility of events such as intraoperative blood loss.

TightRope® system is only suitable for treating posterior pelvic ring instability caused by sacral fracture and sacroiliac joint separation. For posterior pelvic ring instability caused by iliac fracture, it is better to fix iliac fracture with plate and screw.[53] For patients with comminuted sacral fracture, it is difficult to fix with the IS screw on the comminuted sacrum,[54] and it is very suitable to choose TightRope® system to stabilize the posterior pelvic ring.

From the above clinical observations and biomechanical results, it can be deduced that TightRope® system fixation for posterior pelvic fractures has a good clinical effect and good biomechanical stability. Although IS screw osteosynthesis is still the most stable fixation method among the three kinds of fixation, its risk of vascular and nerve injury as well as its technical difficulty limit its application. The biomechanical stability of TightRope® system fixation is slightly better than that of TBP fixation and is easier to perform. TightRope® system fixation causes less soft tissue injury during surgery and is less likely to cause complications. Therefore, the TightRope® system is recommended for posterior ring pelvic fracture fixation.

Limitations

Posterior pelvic ring instability is due to disruption of the posterior ligamentous complex, the causes of which include posterior iliac fractures, sacroiliac joint separation, and sacral fractures. In this study, TightRope® system osteosynthesis could only be used to treat sacroiliac joint separation and sacral fractures. Posterior iliac fractures can be fixed using screws and plates. TightRope® system osteosynthesis is not a strong method for rigid fixation but a method for biological elastic fixation. Its biomechanical stability is not as strong as that of IS screw fixation. For cases with fracture or incomplete bone at the posterior superior iliac crest and severely comminuted C3 pelvic fracture, TightRope® system cannot achieve good fixation effect, which is a limitation of this method. Consequently, patients must avoid bearing weight for at least 2 months after TightRope® system fixation in the treatment of some serious

injuries. Only when the clinical X-ray examination of the pelvis shows fracture healing can the patient bear weight. Additional studies including more clinical cases are needed to determine the long-term effects of this treatment.

Conclusions

The newly presented TightRope® system for osteo-synthesis of the posterior superior iliac spine shows promising clinical and biomechanical results for stabilization of the posterior pelvic ring. The system has good biomechanical stability and leads to fracture union and excellent functional outcomes after 38.89 ± 8.72 months of follow-up. Furthermore, its advantage is that implant removal is not necessary, and the procedure has lower surgical demands as well as a lower risk of injury to relevant neural and vascular structures. Percutaneous posterior bi-iliac TightRope® system fixation for the treatment of unstable pelvic fractures is reliable and reproducible.

IRB INFORMATION

This study was carried out in accordance with the guidelines for the care for human subjects adopted by the First Hospital of Jilin University; the study protocol was approved by the Research Ethics Committee of the First Hospital of Jilin University (ref. no. 2020–635); and written informed consent was obtained from all participants. The study was performed following the principles of the Declaration of Helsinki (as revised in Brazil in 2013).

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