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CLINICAL ARTICLE

Percutaneous Robot-Assisted *versus* Freehand S_2 Iliosacral Screw Fixation in Unstable Posterior Pelvic Ring Fracture

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Objectives: To assess the efficiency, safety, and accuracy of S_2 (IS) screw fixation using a robot-assisted method compared with a freehand method.

Methods: This is a retrospective clinical study. We analyzed the patients treated with S_2 IS screw fixation for unstable pelvic fractures from January 2016 to January 2019 in our institution. Sixty-three patients (17 men and 46 women) aged between 21 and 55 years (with an average age of 39.22 ± 9.28) were included in this study. According to the Tile classification, there were 26 (41.3%) type B fractures and 37 (58.7%) type C fractures. All patients were divided into robot-assisted (RA) group (38 patients) or the traditional freehand (FH) group (25 patients). In RA group, the S_2 IS screws were implanted with a robot-assisted technique. And S_2 IS screws were implanted with a traditional freehand technique in FH group. The screw-related complications were recorded during and after the surgery. The position of all screws and fracture reduction was assessed by postoperative CT scans according to the Gras classification. The number of guide wire attempts and the radiation exposure for S_2 screw implantation during operation were also recorded. Finally, the Matta standard was used to evaluate the fracture reduction of the IS joint.

Results: A total of 89 IS screws were implanted into S2 iliosacral joint. Fifty-four screws were placed by RA (38 patients) and 35 screws were by FH (25 patients). There was no difference between the two groups with respect to demographic data. There was no screw-related complications or revision surgery in any group. In terms of screw placement, the excellent and good rate was 100% in the RA group, better than that in the FH group where it was only 85.7% ($P < 0.001$). The fluoroscopy time was 8.06 ± 3.54 s in RA group, which was much less than that in the FH group (27.37 ± 8.82 s, $P < 0.001$). The guide wire attempts in the RA group (0.685 ± 0.820) were much less than those in the FH group (5.77 ± 3.34) ($P < 0.001$). Both the fluoroscopy time per screw and the number of guide wire attempts in the RA group were much less than those in the FH group ($P < 0.001$). The overall postoperative excellent and good rate of Matta standard in RA and FH groups were 86.8% (34/4) and 90.0% (23/25), respectively ($P = 0.750$), and there was no statistical difference.

Conclusion: The robot-assisted surgery is an accurate and minimally invasive technique. S_2 IS screw implantation assisted by TiRobot to treat the posterior pelvic ring fractures, have a high success rate than the freehand technique. Percutaneous RA S_2 IS screw fixation for unstable posterior pelvic ring injuries is safe and clinically feasible and has great clinical application value.

Key words: Iliosacral screw; Pelvic fracture; Percutaneous; TiRobot; Traditional freehand

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Introduction

Posterior pelvic fractures are usually unstable and are caused by high-energy trauma. Surgeons often perform fixation of both anterior and posterior pelvic rings to stabilize this unstable fracture. Traditional treatment methods include external fixation, open reduction internal fixation with plates from the anterior and posterior pathways. With the minimally invasive technique invading the orthopaedic field, the clinical application of open reduction and plates fixation is less frequent at present. The percutaneous iliosacral (IS) screw fixation, which was described by Routt, is a simple, effective, minimally invasive therapy for posterior pelvic ring fractures[1]. Compared to the traditional open reduction methods, the percutaneous IS screw fixation has many advantages: less bleeding, less surgical trauma, fewer complications, less infection rates, and further acceleration of the postoperative recovery[2]. These advantages of percutaneous IS screw fixation under fluoroscopic guidance for unstable pelvic fractures is becoming increasingly popular worldwide.

The first sacral vertebral body (S_1) implantation of IS screws is the preferred method of fixation. Because the structure of blood vessels and nerves of the sacroiliac joint and sacrum is complex, it still requires detailed knowledge and abundant clinical experience to implant the IS screws through inlet and outlet fluoroscopic X-rays. Several studies showed that the malposition rates of IS screw under tradition fluoroscopic guide were 2%–15% and the neurologic injury rates were 1%–7%[3,4]. Furthermore, sacral dysmorphism may influence and even rule out S_1 fixation. Gardner *et al.*[5] reported that up to 44% of patients have S_1 dysmorphism. These patients may have inadequate S_1 osseous site for the screw insertion. In this situation, the second sacral vertebral body (S_2) can be used as an alternative. Conflitti *et al.*[6] found that in the dysmorphic sacrum patients, the S_2 body has a relatively bigger bone site for screw insertion than the S_1 body. Therefore, some authors recommended fixation of the S_2 body in the unstable posterior pelvic ring fracture[7,8]. But the major concern with S_2 screw fixation is the greater potential risk of damaging nearby nerve roots with screw malposition. Studies showed that the malposition rates of S_I screws were 3%–13%[9–12], which may result in serious implant-related neurovascular complications, such as injury to the nerve roots or the iliac vessels[13]. As such, it is a highly demanding and challenging operative technique. Therefore, we need to find a safe and effective method to solve this problem. The fluoroscopy navigation system is a substantial improvement for the operator. This technology could provide a simultaneous visualization of the guide wire and the screws in relation to the patient's anatomy in four views. However, the navigation cannot plan and calculate the screw trajectory.

From 1988 to 2005, more than 100 types of robot prototypes were developed[14], and RA orthopaedic surgeries were widely used in the USA, Germany, Israel, and Korea. Through several years of development, high-accuracy RA screw placement in cadaver studies were published[15]. The aim of these robots was to enhance and complement the freehand ability of surgeons. With the development of robot technologies, many orthopaedic robots have been developed, such as Rosa and Mazor. These RA systems were considered as refinements of spinal navigation, which could increase the accuracy of spine screw placement, reduce invasiveness, as well as reduce the radiation exposure. Thus, RA surgery has been accepted by an increasing number of orthopaedic doctors and has been promoted in clinical practice. The RA system not only allows the surgeon to know the alignment of the guide wire in real time corresponding to intraoperative fluoroscopy, but also guide or assist the surgeon to perform the operation. However, few RA systems focus on screw implantation in pelvic fractures.

The third orthopaedic robot "TianJi" from China has been certified by the China Food and Drug Administration (CFDA) and applied for clinical use in both trauma and spine surgery. This new robot system has proven to enhance the accuracy of cannulated screw placement in both the femoral neck fracture and the pelvic fracture. Notably, TiRobot is an orthopaedic surgery robot that can be used for implantation of S_1 screws for unstable pelvic injury[13,16]. However, the robot-assisted S_2 IS screw implantation has been rarely reported. This third generation of Chinese manufactured orthopaedic robot (Tianji) was introduced into our hospital and we have performed the S_2 IS screw fixation for pelvic fracture using it since January 2016. Therefore, we collected the medical data of the patients who were treated with S_2 IS screw fixation using robot-assisted technique compared with patients who were treated with traditional freehand technique. The objectives of this study were: (i) to access the safety and accuracy of internal cannulated screw fixation; (ii) to analyze results and complications of this RA system; and (iii) to discuss the surgical strategy and clinical application of RA technique on S_2 IS screw fixation for pelvic ring fracture in comparison with the freehand conventional technique.

Methods

Population

We retrospectively analyzed 63 consecutive patients who underwent S_2 screw fixation for unstable posterior pelvic ring fracture between January 2016 and January 2019 at our institution. Preoperative X-rays and computer tomography (CT) scans of all patients were used to evaluate the management protocol of pelvic fracture. The indication for IS S_2 screw fixation was dysmorphic sacrum or inadequate bone stock of S_1 body, as described previously[8,10].

All operations were performed by the TianJi Robot (TiRobot) system (TINAVI medical Technologies, Beijing, China). This system is composed of a mechanical arm, an

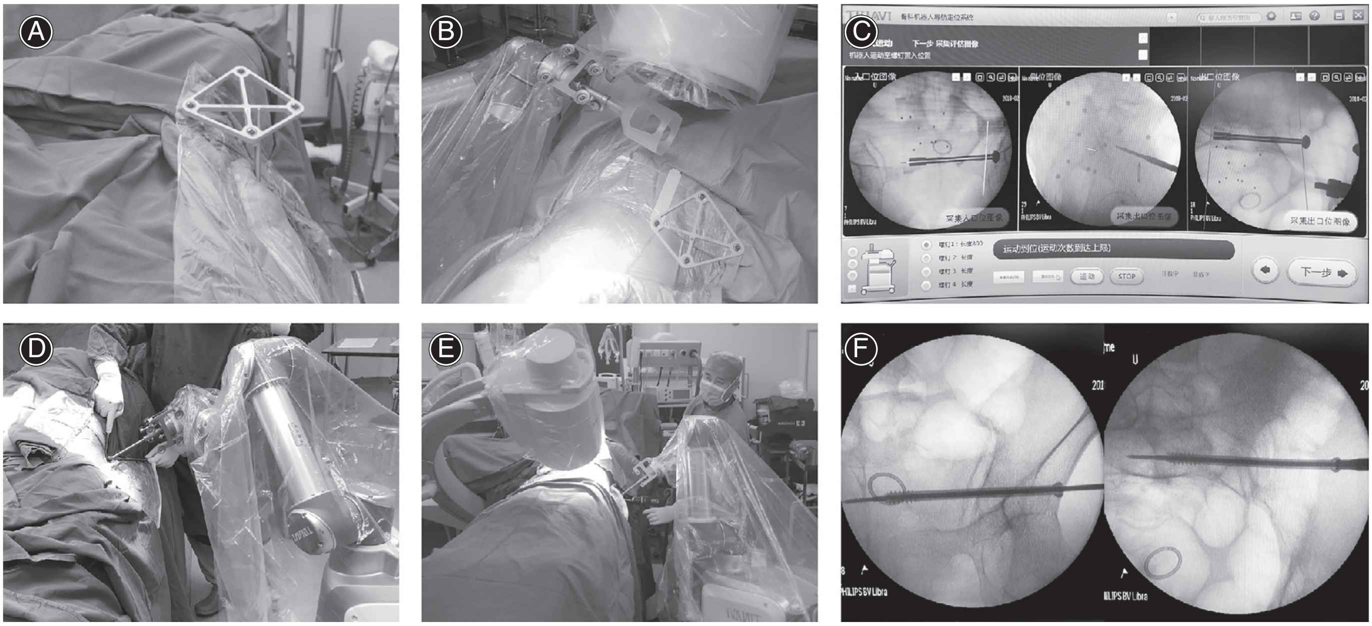

Fig. 1 The six steps of percutaneous S_2 IS screws with TiRobot system. (A) Install patient's tracker; (B) Digital image acquisition and registration; (C) Planning the screw position on the workstation; (D) The mechanical arm moves to the inserted position automatically; (E) Insert the guide wire; (F) Confirm the position of screw.

optical tracking system, and an operative planning and controlling workstation. All the surgeries were performed by the same surgeon team (J.W., X.W., W.H., and T.Z.), which is very familiar with TianJi Robot system. The steps of percutaneous S_2 IS screws with TianJi Robot system was performed as previously reported[17]. In brief, the six steps were shown below and in Fig. 1.

1. The anterior superior iliac spine (ASIS) was exposed and the surgeon placed a patient tracer on the ASIS.
2. A tool tracker was connected to the mechanical arm. All the markers on the tool tracker were confirmed by X-ray.
3. The entry point, angle, and length of S_2 IS screws were designed on the operative planning and controlling workstation.
4. According to the planning path in step 3, The mechanical arm moved the pilot sleeve to locate the screw entry point and direction.
5. The operator inserted the guide wire through the pilot sleeve into the S_2 IS joint.
6. The position and depth of the screw was confirmed by a C-arm

Sixty-three patients were divided into two groups, RA group (38 patients with S_2 IS screws implanted with robot-assisted technique) and FH group (25 patients with S_2 IS screws implanted with traditional freehand technique). RA-B subgroup: RA group with type B injury (15 patients with 21 screws); RA-C group: RA group with type C injury (23 patients with 33 screws); FH-B group: FH group with type B injury (11 patients with 17 screws); FH-C group: FH group with type C injury (14 patients with 18 screws).

The demographic data, body mass index (BMI), injury type of pelvic fracture, and the preoperative time were recorded.

Radiographic Measurements

The main outcome of the study was the postoperative S_2 IS screw position. Postoperative CT scans were used to evaluate the accuracy of S_2 IS screws for all the patients. All the images were assessed according to the Gras classification of the S_2 IS screw[18] by three independent observers who did not participate in the operation:

1. Excellent: secure positioning, completely within the cancellous bone;
2. Good: secure positioning, but contacting cortical bone without perforation;
3. Poor: misplaced positioning, penetrating the cortical bone.

All the screws were measured by each observer, and a data collection sheet was used to record the measurements. The final screw position classification was determined by consensus among three observers. Then, we performed a subgroup analysis for both groups according to the Tile classification on S_2 screw accuracy.

Radiation Exposure Monitor

Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie. Radiation exposure measurements were performed in

TABLE 1 Demographic data of two groups

Groups	Population	Screws	Gender (M/F)	Age (yrs)	BMI (kg/m^2)	Injury Type (B / C)	Pre-OP time (days)
RA	38	54	11/27	38.66 ± 9.81	25.85 ± 5.23	15/23	9.63 ± 5.60
FH	25	35	6/17	40.08 ± 8.55	24.72 ± 5.57	11/14	8.28 ± 5.65
Statistics			0.187	0.592	0.815	0.128	0.934
P			0.665	0.556	0.418	0.721	0.354

our theater. During each X-ray exposure, the fluoroscopy system calculated and displayed the real-time exposure seconds. The total fluoroscopy time of each screw implantation was recorded. This can reflect the radiation exposure of surgeons and patients. To minimize the radiation risk, fluoroscopy should always be performed with the shortest time necessary.

Guide Wire Attempts

During guide wire insertion, we used fluoroscopy to confirm the position. We had to adjust the direction of the guide wire if it is was malpositioned. Thus, the times of guide wire attempts of each IS screw implantation, which can reflect the accuracy and the proficiency of surgeons, were also recorded. Guide wire attempts should be as few as possible, because more attempts measn less accuracy, more bleeding, more surgical trauma, and more complications.

Fracture Reduction

An anatomical fracture reduction should be aimed and checked intraoperatively to restore IS joint. Radiographic criteria suggested by Matta are generally used to evaluate the quality of fracture reduction. Excellent: less than 4 mm displacement; Good: 5–10 mm displacement; Fair: 11–20 mm displacement; Poor: more than 20 mm displacement[19]. The quality of fracture reduction graded using Matta' criteria might imply the IS joint reduction ability of TianJi Robot system.

Statistical Analysis

Statistical analysis was performed using SPSS Version 25.0 (IBM, Corporation, Armonk, NY). Student *t*-test was used for continuous variables, which were expressed as mean ± SD; whereas the chi-square test or Fisher's exact test were used for categorical variables. Statistical significance was defined as P <0.05.

Results

Patients Characteristics

The demographic data was shown in Table 1. There were 38 patients (54 S2 screws) in the RA group and 25 patients (35 S_2 screws) in the FH group. There were no significant

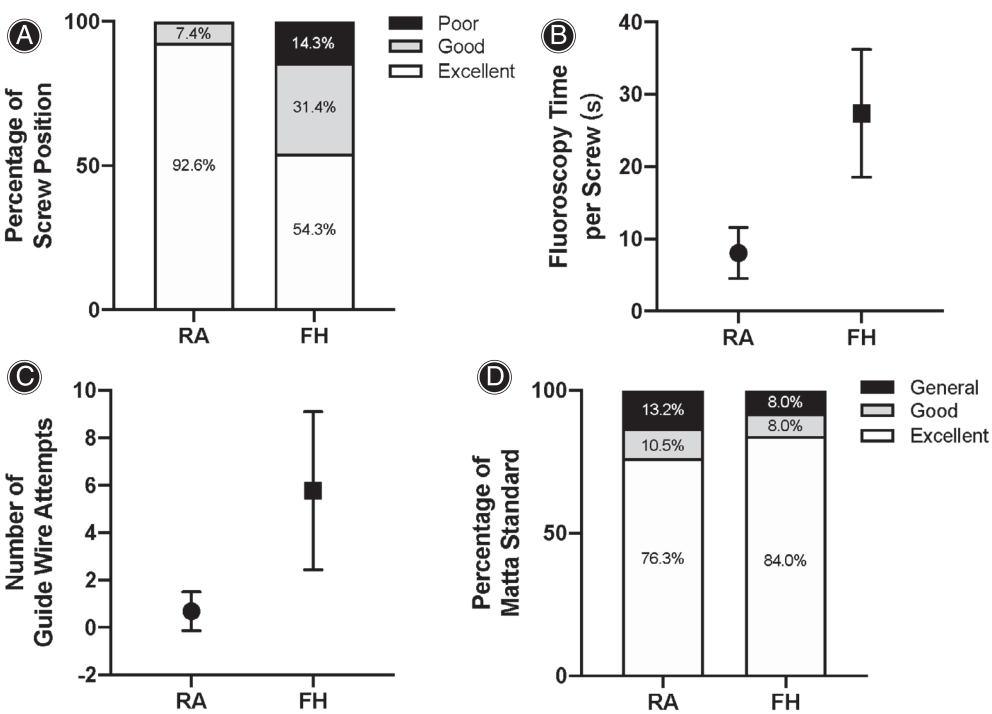

Fig. 2 The outcomes of RA *vs* FH. (A) The percentage of screw position according to Gras classification between two groups; (B) The fluoroscopy time per screw between two groups; (C) The number of guide wire attempts between two groups; (D) According to Matta standard, the pelvic fracture reduction between two groups.

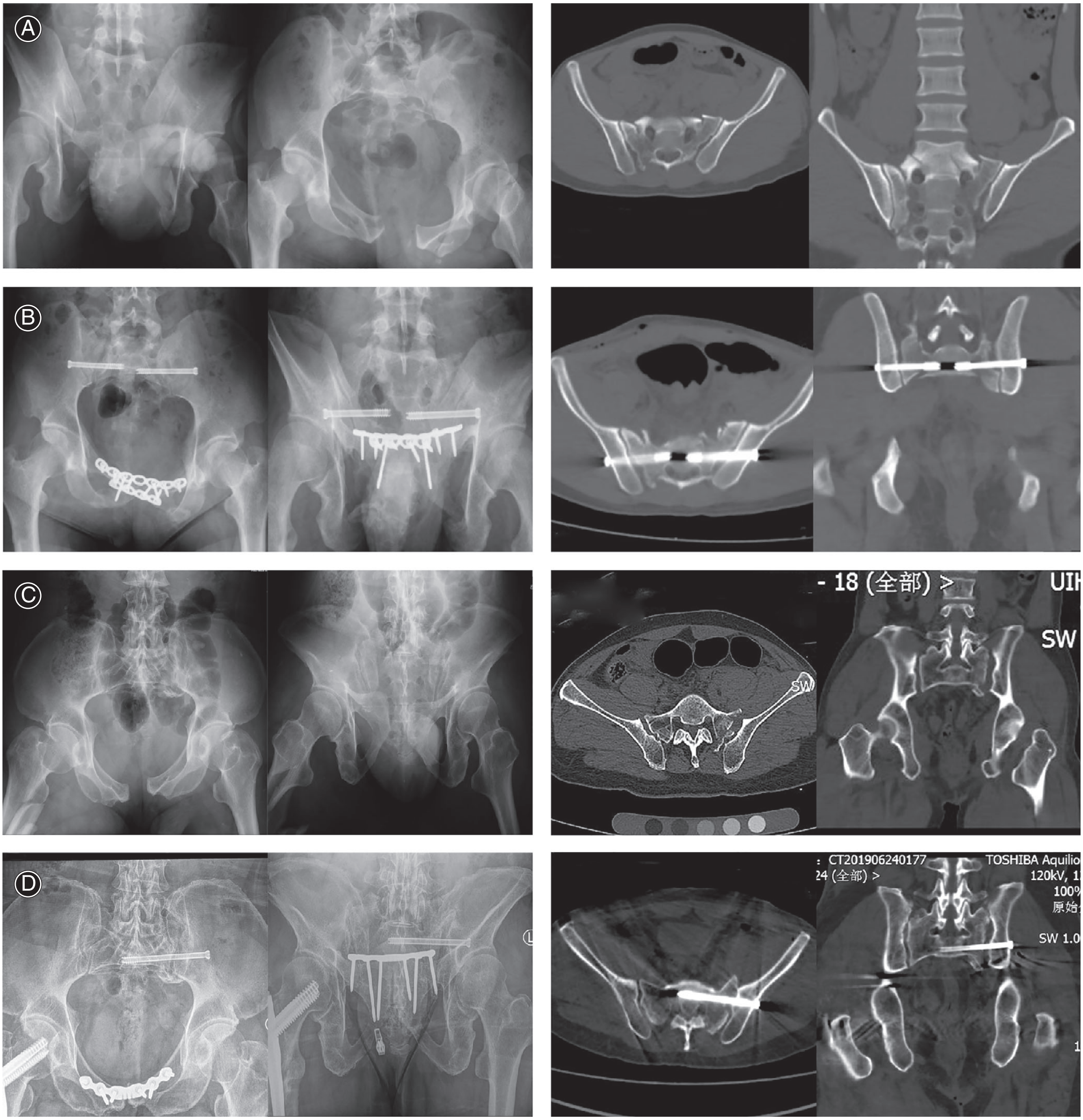

Fig. 3 Typical cases. (A and C) Preoperative X-ray, transverse and coronal views of preoperative CT scan showed posterior pelvic fracture and separation of sacroiliac joint. (B and D) Postoperative X-ray showed fractures were well-reduced. Transverse and coronal views of postoperative CT scan showed S_2 IS screws were completely within the cancellous bone.

differences in gender distribution ($P = 0.665$), age ($P = 0.556$), and BMI ($P = 0.418$). In the RA group, the type B pelvic fracture was 39.2% (15/38) and the preoperative time was 9.63 ± 5.60 days. In the FH group, the type B pelvic fracture was 44% (11/25) and the preoperative time was 8.28 ± 5.65 days. No significant difference was found between the two groups. No screw-related complications or revision surgery occurred in the two groups. Each patients in the RA group needed to register before screw fixation, which required some time.

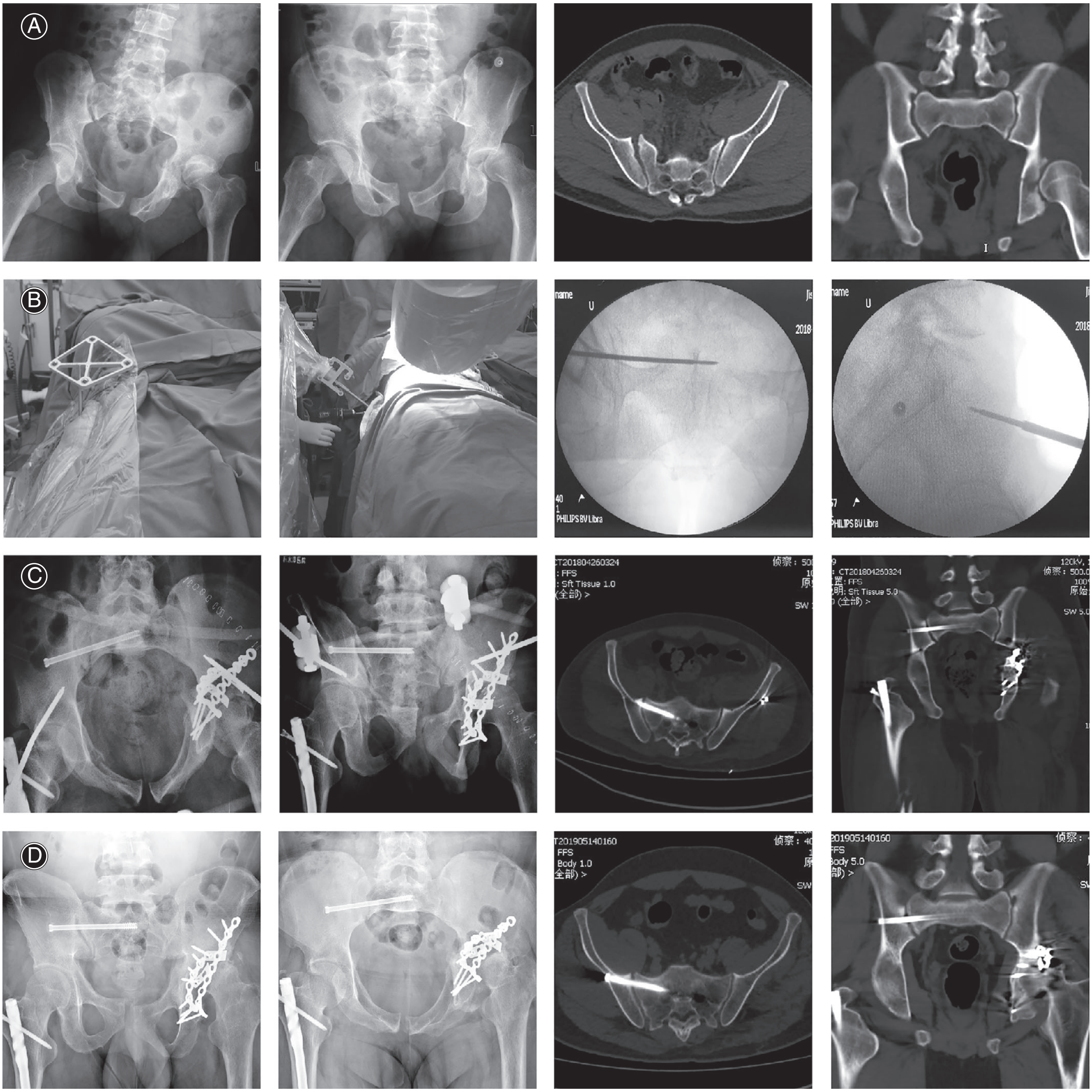

Fig. 4 A series of images of typical case. Preoperative X-ray and CT scan (A); intraoperative images (B); postoperative X-ray and CT scan (C); and 1-year follow-up X-ray and CT scan (D).

S2 Screw Accuracy

According to the Gras classification[18], the difference in the screw distribution between RA and FH group was significant (P < 0.001). The overall excellent and good rate of screw accuracy was 100% in RA group (50 excellent and four good), better than 85.7% in FH group (19 excellent, 11 good, and five poor). This means that robot-assisted S_2 IS screw implantation had more accuracy (Fig. 2A). The subgroup analysis on S_2 screw analysis was also performed. The excellent and good rates in RA-B subgroup and FH-B subgroup was 100% (20 excellent and one good) and 88.2% (nine excellent, six good, and two poor), respectively ($P = 0.009$). Furthermore, the excellent and good rates in RA-C subgroup and FH-C subgroup was 100% (30 excellent and three good) and 83.3% (10 excellent, five good, and three poor), respectively ($P = 0.007$).

Fluoroscopy Time Per Screw

The fluoroscopy time per screw was also analyzed, which showed a significant difference between the two groups ($P < 0.001$). The fluoroscopy time was 8.06 ± 3.54 s in RA group, much less than that in the FH group (27.37 ± 8.82 s). This means the robot-assisted technique can reduce radiation exposure during the screw placement (Fig. 2B).

Guide Wire Attempts

The guide wire attempts in the RA group were much less than those in the FH group ($P < 0.001$). There were 0.685 ± 0.820 in the RA group and 5.77 ± 3.34 in the FH group. Less guide wire attempts suggest less damage to patients and are consistent with less fluoroscopy time and more accuracy of the screw implantation (Fig. 2C).

Fracture Reduction

According to the Matta standard[19], the overall excellent and good pelvic fracture reduction rates were 89.4% in the RA group (29 excellent cases, five good cases, and four general cases) and 92.0% in the FH group (20 excellent cases, three good cases, and two general cases). No significant difference was found between the two groups (Fig. 2D). Two typical cases were shown in Fig. 3.

Discussion

The Accuracy of TiRobot

S_2 body has a relatively small "safe zone" and an increased risk for nerve root injury. Most of the trauma orthopaedic surgeons avoided was in carrying out S_2 IS fixation, because it has been reported that the misplacement rate in S_2 level was 32.8%, which is much higher than that in the S_1 level, where it was only 7.2%[3]. Some surgeons recommended S_2 IS screws should be less than 4.5 mm diameter because of the limited bone stock of S_2 body[20]. With the fast-developing robot-assisted technique, it has been accepted by surgeons and was wildly used in trauma surgeries. It has been reported that RA is more accurate and has less surgical trauma in the percutaneous screw internal fixation[21,22]. In our study, we found that the RA S_2 IS screw was more accurate than the traditional FH. The controlling workstation of this third generation TiRobot can real-time monitor the screw position and correct the screw position deviation during the guide wire insertion in a timely manner. The movement of robot or patients may affect the accuracy of the screw position. The optical tracking system of TiRobot can monitor the relative movement between the robot and patients and adjust the entry point of the guide wire. Finally, the mechanical arm of TiRobot controls the insertion angle and point, which significantly increases the accuracy and stability of screw implantation. A series of images of typical cases (preoperative, intraoperative, postoperative, and follow-up) in radiographic figures are shown in Fig. 4.

Radiation Exposure and Guide Wire Attempts

In addition, the radiation exposure during the percutaneous IS screw implantation is a potential issue. Multiple intraoperative fluoroscopies are needed to confirm the skeletal structure and the screw position, especially for the S_2 body[10]. Variation of the sacrum makes the screw more difficult to implant and may further increase the radiation quantity. It has been reported that robot-assisted minimally invasive pedicle screw placement could significantly reduce the fluoroscopy exposure to both surgeons and patients[23]. In this study, we also found that the fluoroscopy time and the number of guide wire attempts in the RA group are much less than that in the FH group. This reflects that surgeons have great confidence in the accuracy of the robot. In the FH group, the entry point and direction of the screws is entirely dependent on the fluoroscopy. This result is consistent with other studies. In a cadaveric study, the preoperative planning of the angle and the entry point of screws could increase the accuracy of percutaneous screw implantation of the IS joint, reduce the operation time, and minimize the radiation exposure[24]. Long *et al.*[17] also reported that shorter fluoroscopy time was found in TiRobot. After satisfactory planning of screw position, TiRobot system can indicate the direction of screws accurately, which greatly reduces the irradiation time.

Fracture Reduction

Furthermore, there were no significant differences between the RA group and the FH group in the postoperative pelvic reduction. This means the robot-assisted technique does not affect the reduction rate, and it has a good reduction ability, repeatability, and operability.

Limitations

To our knowledge, this is the first study on the comparison between RA and FH on S_2 IS screw implantation. However, this study has several limitations. First, because of this new TiRobot system, only a small sample size was reported in this study. Second, this is a retrospective study and the follow-up period is short. Further, a multicenter prospective study with a large number of cases should be performed and guidelines for robot-assisted minimally invasive pelvic fracture treatment should be developed. The above results are for early work and the follow-up time was relatively short. Long follow-up periods should be performed in the next study. Also, the biomechanics is not investigated, and further investigation of the differences between S_1 and S_2 iliosacral screw is also required in future studies.

Conclusion

In conclusion, the robot-assisted S_2 IS screw fixation is more accurate than the traditional freehand method. In addition, the RA technique has the advantages of less radiation exposure and less guide wire attempts. In terms of pelvic fracture reduction, the two surgical techniques are equivalent. Further well-designed randomized prospective clinical trials are required to confirm and update the findings of this study.

The RA technique has great clinical application value on the treatment of unstable posterior pelvic ring injuries.

Author Contributions

Conceptualization, supervision, validation: W.H. and J.W.; funding acquisition, project administration: W.H.; methodology, investigation: Y.S. and X.W.; formal analyses and data curation: C.Z. and L.Z.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Beijing Jishuitan Hospital Ethical Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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