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Intelligent robot-assisted minimally invasive reduction system for reduction of unstable pelvic fractures

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ABSTRACT

Objective: Currently, minimally invasive internal fixation is recommended for the surgical treatment of unstable pelvic fractures. The premise and difficulty of minimally invasive internal fixation are minimally invasive reduction of fractures. This review aimed to investigate the indications, surgical strategy and techniques, safety, and efficacy of intelligent robot-assisted fracture reduction (RAFR) system of pelvic ring injuries.

Methods: This retrospective study reviewed a case series from March 2021 to November 2021. A total of 22 patients with unstable pelvic fracture injuries underwent minimally invasive internal fixations. All pelvic ring fractures were reduced with our intelligent RAFR system. The robot system intelligently designs the optimal position and reduction path based on the patient's preoperative 3D CT. During the operation, the three-dimensional visualization of the fracture is realized through image registration, and the Robot completes the automatic reduction of the fracture. The global 3D point cloud error between the preoperative planning results and the actual postoperative reduction results was calculated. The postoperative reduction results of residual displacement were graded by the Matta Criteria.

Results: Minimally invasive closed reduction procedures were completed in all 22 cases with our RAFR system. The average global 3D point cloud reduction error between the preoperative planning results and the actual postoperative reduction results was 3.41mm±1.83mm. The mean residual displacement was 4.61mm±3.29mm. Given the Matta criteria, 16 cases were excellent, five were good, and one was fair, with an excellent and good rate of 95.5%.

Conclusion: Our new pelvic fracture reduction robot system can complete intelligent and minimally invasive fracture reduction for most patients with unstable pelvic fractures. The system has intelligent reduction position and path planning and realizes stable pelvis control through a unique holding arm and a robotic arm. The operation process will not cause additional damage to the patient, which fully meets the clinical requirements. Our study demonstrated the safety and effectiveness of our robotic reduction system and its applicability and usability in clinical practice, thus paving the way towards Robot minimally invasive pelvic fracture surgeries.

Introduction

Pelvic fractures account for 2%-8% of all fractures, they are often caused by high-energy trauma, and these patients often have multiple injuries . The main characteristics of pelvic fractures are pelvic ring fracture and fracture displacement. Accurate reduction for unstable pelvic fractures has been recognized as the cornerstone of treating unstable pelvic fractures [1,2]. Studies have shown that misalignment and poor rotation of fracture fragments often lead to postoperative complications such as fracture malunion or nonunion[3]. Pelvic tilt or limb shortening caused by poor pelvic reduction can cause complications such as gait changes and walking difficulties, which can significantly affect the long-term life quality of patients[4,5]. 63% of patients with poorly reduced pelvic fractures will have persistent pain[6]. Sensory and motor abnormalities were seen in 28% of patients with poorly reduced pelvic fractures[7],32% of such patients were unable to continue their previous work[8].

Abbreviations: DOF, degree-of-freedom; CBCT, Cone-beam CT; 3D, three-dimensional; RAFR, robot-assisted fracture reduction.

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Traditional open reduction and internal plate fixation techniques can achieve more accurate reduction but rely extensively on the surgeon's experience and have the risk of iatrogenic injury to nearby critical blood vessels, nerves, and abdominal organs[9]. In recent years, closed reduction and minimally invasive internal fixation have become a trend in treating unstable pelvic fractures [10–12]. It is emphasized that the closed reduction technique has certain advantages in effectively shortening the operation time, reducing blood loss, reducing complications such as infection, nerve, and blood vessel damage[10,13]. In traditional minimally invasive fracture reduction, the surgeon must manually reduce the fracture fragment under continuous intraoperative fluoroscopy monitoring, leading to high intraoperative radiation exposure of the patient and medical staff [14]. Due to the limited imaging capabilities of the C-arm, the fracture reduction depends primarily on the surgeon's technique and experience. With the development of robotic technology, Robot-assisted orthopedic surgery (RAOS) has been used in various orthopedic surgeries, including total knee arthroplasty, total hip arthroplasty, spine surgery, bone tumor surgery, arthroscopic surgery, and fracture fixation[15–17]. However, the current RAOS technology in fracture mainly focuses on location and screw placement in clinical practice. Few studies focused on robot-assisted fracture reduction. The studies on robot-assisted fracture reduction systems established previously were designed for lower extremity diaphyseal fracture. For pelvic fracture reduction, it is a more difficult task requiring higher accuracy and more complex 3D trajectories[18]. The robot-assisted fracture reduction system for pelvic fracture was still in the preliminary stage, which was limited to a model or cadaveric studies[19,20].

After careful investigation, our team developed an intelligent robot-assisted fracture reduction (RAFR) system for pelvic fracture, utilizing modern techniques such as three-dimensional (3D) imaging data, navigation, and robotics. In previous experiments[21], we have tested the accuracy in image registration and fracture reduction of our RAFR system with good results. Now we have formulated an automated surgical procedure for pelvic reduction with the RAFR system. We identified 22 patients with unstable pelvic fractures who underwent minimally invasive internal fixations. We have performed pelvic fracture reduction for the 22 cases of unstable pelvic fractures with our RAFR system. The purposes of this study were: to analyze the safety and efficacy of our RAFR system; and to discuss surgical strategy, techniques, and existing limitations with our RAFR system for pelvic fracture reduction.

Methods

Inclusion and exclusion criteria

The study protocol was approved by our Institutional Review Board (No: 202006-13). Informed consent was obtained from all participants included in the study. This retrospective study reviewed a consecutive series of patients selected after application of the inclusion criteria from March 2021 to November 2021. A total of 22 patients with unstable pelvic fracture injuries underwent minimally invasive internal fixations at the first author's institution. All operations were performed by one team of surgeons who have adequate clinical experience.

The inclusion criteria was closed, unstable pelvic ring injuries (Tile-type B or C fractures), with fracture displacement. The exclusion criteria was: (1) presence of severe open injuries or rupture of the abdominopelvic cavity and organs with wound contamination; (2) unstable hemodynamics; (3) hardware such as metal Internal fixation plate or screws in the CBCT collecting image area or severe obesity resulting in poor image acquisition; (4) poor condition of local skin, or infection of the soft tissues at or around the screw insertion site; (5) inability to tolerate anesthesia or surgery; (6) Stable pelvic ring injuries (Tile-type A fractures)

Preoperative treatment

Patients with unstable hemodynamics were treated with temporary pelvic external fixation. Patients with vertical instability were treated with lower extremity traction. Routine imaging of the pelvis was performed using X-ray with anteroposterior, inlet, and outlet views and CT scans. The surgical plans were formulated based on the injury type of the pelvic ring, the effectiveness of the reduction, and the availability of bone tunnels.

Intelligent RAFR system

Our RAFR system consists of two main parts: One main part is an intelligent surgical robot system based on 3D vision. It is the core structure of the Robot and consists of three parts (Fig. 1A) [22]: pelvic fracture reduction software (including reduction path planning software, intraoperative navigation, and registration software), optical tracking device (NDI Polaris Vega and trackers), and reduction robot (UR16e). The optical tracking device is connected to the patient's pelvis and the Robot for real-time tracking during the reduction. The other main part is the auxiliary structure of the Robot. It consists of two parts (Fig. 1B) [22]: two holding equipment connecting to the operating table through a designed U-shaped device and an elastic traction device installed at the end of the operating table. The healthy side holding equipment consists of two nine-degree-of-freedom (DOF) electronically controlled passive arms (Pass Arm 1, Rossum Robot Co., Ltd., RPC) to achieve stable holding of the healthy side pelvis. The elastic traction device is driven by an electric screw nut, which provides quantitative traction and resists the binding force of the soft tissue around the pelvis [23,24]. Additional surgical equipment included a C-arm X-ray machine (Siemens, Germany)

Preoperative preparation of RAFR system

The pelvic 3D CT was routinely taken before the operation, and the pelvic fracture images were divided into two parts: the healthy side and the affected side by computer software (Fig. 2A) [22]. Based on the mirror symmetry principle of the human body, the mirror model of the uninjured hemipelvis could be regarded as the anatomical position of the injured hemipelvis [25]. The doctor could adjust the target position slightly and finally generate a clinically satisfactory reduction target position (Fig. 2B) [22]. Based on the target position, the RAFR system developed an automatic reduction algorithm in which the shortest path planning is adopted (Fig. 2C)[22]. If any impingement occurs during the reduction process, the surgeon can manually set one or more path points to avoid impingement. We printed the pelvis 3D model for complex fracture and simulated the fracture reduction process in advance to ensure the smooth reduction process.

Surgical strategy and procedures

Isolated anterior pelvic ring injuries were treated with percutaneous cannulated screw fixation of the pubic ramus. Posterior pelvic ring injuries were treated with percutaneous cannulated screw fixation of the sacroiliac joint. Complex anterior pelvic ring injuries were treated with cannulated pubic ramus screw fixation alone, INFIX fixation or "hybrid surgery" (open reduction and internal plate fixation).

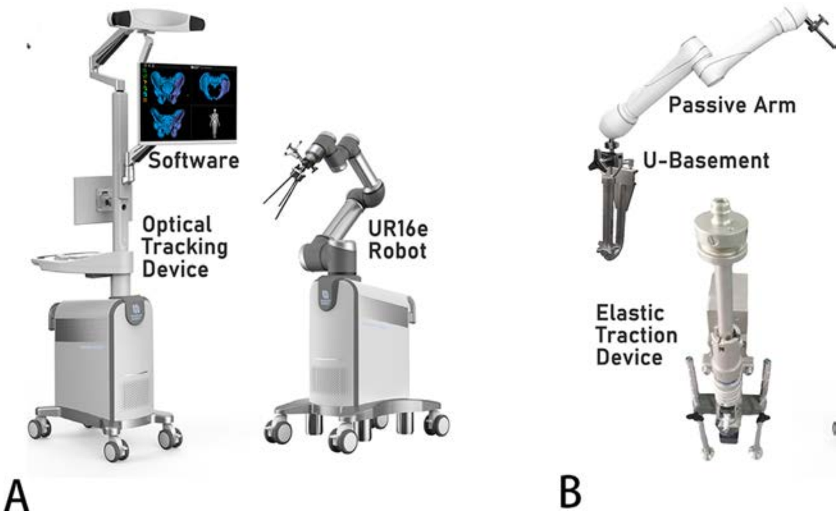

Fig. 1. A. Core structure of robot system which consists of pelvic fracture reduction software, optical tracking device and reduction robot (UR16e); B.Auxiliary structure of the Robot which consists of two holding equipment through a designed U-shaped device and an elastic traction device

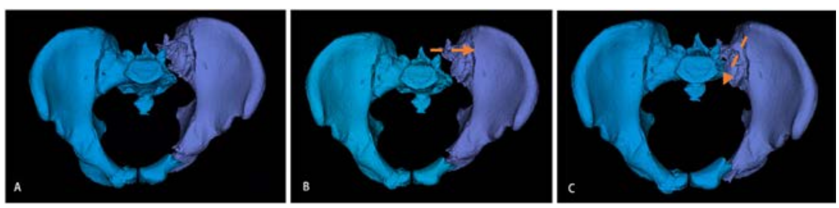

Fig. 2. A. Preoperative CT reconstruction model; B. Preoperative path planning of reduction planning; C. Final target position of path planning

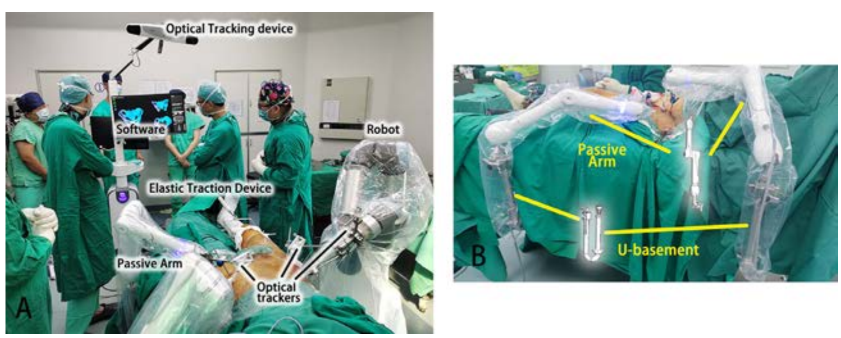

Fig. 3. A.The spatial location of the robot system in the operating room.B. The U-shaped base of the two holding arms was connected to the healthy side of the operating bed

Surgical procedures

1 The patient was placed supine on the translucent orthopedic operating table with the hip slightly elevated. They were administered general anesthesia to reduce muscle tension. The spatial location of the robot system in the operating room was shown in Fig. 3A[22]. The U-shaped base of the two holding arms was connected to the healthy side of the operating bed, and the position of the two holding arm bases was 60 cm away from the pelvis to provide enough space when image acquisition, fluoroscopic verification, and internal fixation during surgery (Fig. 3B)[22]. The skins were sterilized by routine disinfection and draping.
2 A tracker was fixed on both sides' anterior superior iliac spine, and two Kirschner wires were inserted to achieve stable fixation.
3 The pelvic and tracker's Cone-beam CT(CBCT) data were collected by the C-arm X-ray machine (Siemens, Germany). The CBCT data was transmitted to the computer system for image registration with the preoperative CT 3D image. The navigation registration software registered the reconstructed high-resolution CT with the CBCT, and the position of the pelvic can be tracked in real-time and displayed on the screen (Fig. 4)[22].
4 After the image registration, a sterile working environment for the robotic arm was established by assembling and fixing two holding arms and the end of the robotic arm with a sterile protective sleeve.
5 We have designed a hand drill navigation system. The navigation software could calculate the optimal position of Schantz pins placement. The optical navigation device can track the tracker installed on the hand drill; then, the software can display the depth and position of the Schantz pin in real-time. In the healthy half pelvis, two Schantz pins (diameter 5mm) are placed in the widest part of the iliac wing (the gluteal tuberosity position) and the anterior inferior iliac spine above the acetabular dome (the position of the LC2 screw). In the affected half pelvis, except for the two Schantz pins which were the same as those on the healthy side, a third Schantz pin was

Fig. 4. After image registration, the position of the pelvic can be tracked in real-time and displayed on the screen.

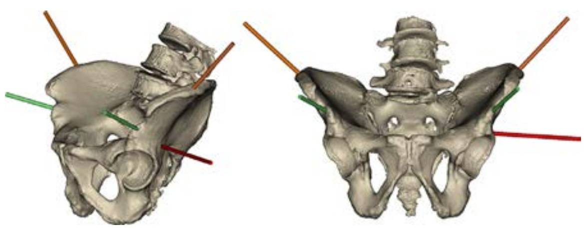

Fig. 5. two Schantz pins are placed in the widest part of the iliac wing (the gluteal tuberosity position) and the anterior inferior iliac spine above the acetabular dome (the position of the LC2 screw). In the affected half pelvis, a third Schantz pin was inserted horizontally above the top of the acetabulum

inserted horizontally above the top of the acetabulum (Fig. 5) [22]. All Schantz pins were stably fixed with the end of the passive mechanical arm.

6 Supracondylar bone traction was performed on patients with vertical displacement of pelvic fractures. The bone traction was connected with elastic traction devices. The traction force was dynamically set according to the image changes of the three-dimensional navigation after registration, and the traction force remained unchanged during the operation.
7 The robotic arm slowly moves the affected side of the pelvis according to the preoperative reduction plan until it reaches the target reduction position. All reduction processes are completed under the supervision of 3D real-time navigation. Finally, the fracture fragments moved to the target position, and the Robot's active reduction was completed. The positioning of the reduction was verified by fluoroscopy.
8 The choices of implants for definite treatment were primarily based on the classification of the fracture. Isolated anterior pelvic ring injuries were treated with percutaneous cannulated screw fixation of the pubic ramus; posterior pelvic ring injuries were treated with percutaneous cannulated screw fixation of the sacroiliac joint; and complex anterior and posterior pelvic ring injuries were treated with cannulated pubic ramus screw fixation alone, INFIX fixation, External fixator or small Ilium wing plate.
9 The positioning of the implants was verified by fluoroscopy. The subcutaneous layer and skin were sutured, and the surgery was completed.

Tabel 1
Radiological grading of the reduction according to Matta and Tornetta.

Radiological grading of the reduction according to Matta and Tornetta	
Excellent	Residual displacement <5 mm
Good	Residual displacement of 5-10 mm
Fair	Residual displacement of 11-20 mm
Poor	Residual displacement >20mm

10 Figs. 6 and 7 have shown a typical case presentation[22]: A 56-year-old man had a crescent-shaped pelvic fracture (Tile C) combined with lumbar 4 and 5 vertebral fractures (second spinal surgery after pelvic surgery) and right proximal humerus fracture (Conservative treatment). On the 7th day after admission, the minimally invasive closed reduction procedures were completed with our robot system and Posterior pelvic ring injuries were treated with percutaneous cannulated screw fixation.

Evaluation method

After initial operation, follow-up radiographs were obtained when the patients became hemodynamically stable. Radiological outcomes were determined through postoperative CT and plain radiographs using three standard pelvic radiographic views: anteroposterior, inlet, and outlet views. Regarding the reduction quality, we adapted the Matta criteria, the most used grading system to evaluate vertical displacement [26–30]. According to the Matta and Tornetta Criteria, reductions were graded by the maximal displacement (Table 1)[22].

The preoperatively planned 3D image model of target position and the postoperative actual CT scan pelvis model was imported into Geomagic Qualify 2013 (Geomagic Inc, USA) software. The global 3D point cloud error between the preoperative planning results and the actual postoperative reduction results was calculated by Geomagic Qualify 2013 (Geomagic Inc, USA). The mean of the absolute values of all deviations is recorded as the reduction error. The mean of total reduction distance on anterior pelvic ring and posterior pelvic ring were also recorded. Evidence for neurovascular injury, iatrogenic fracture, wound infection, screw loosening was observed in all patients.

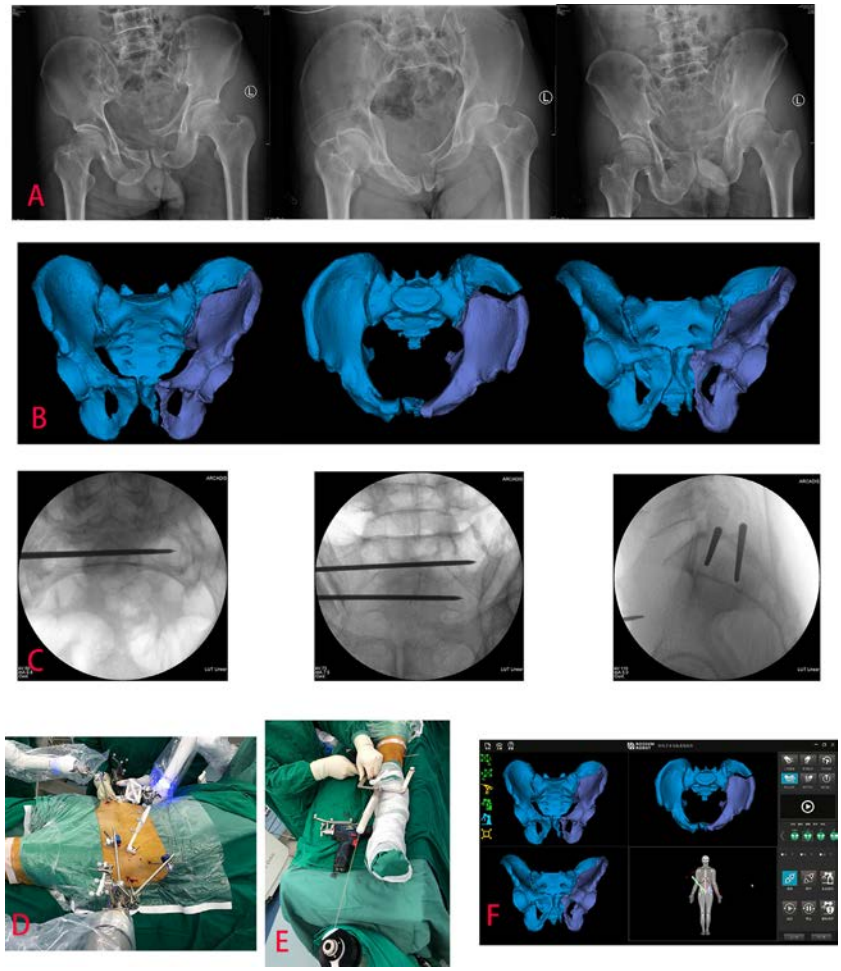

Fig. 6. Typical case presentation. A. Preoperative X-ray of unstable pelvic fracture using three standard pelvic radiographic views: anteroposterior, inlet, and outlet views.B. Preoperative path planning of reduction planning.C. The sacroiliac screw guide pin is inserted from the posterior ring of the pelvis on the unaffected side in advance. When the reduction is completed, guide pin can directly penetrate the sacroiliac joint of the affected side, which can assist the temporary fixation of the posterior ring, and can also penetrate the guide pin through the skin of the affected side pelvis to guide the sacroiliac screw fixation of posterior ring. D. All Schantz pins were stably fixed with the end of the mechanical passive arm. E. The bone traction was connected with elastic traction devices. F. After completing image registration, pelvic holding and elastic traction, the position of the pelvic fracture was directly displayed in the monitor.

Statistical analysis

Statistical analysis by analysis of variance was performed using SPSS 25 (SPSS Inc., Chicago, Ill). Data were presented as means ± SD. The global 3D point cloud error distribution was calculated by Geomagic Qualify 2013 (Geomagic Inc, USA).

Results

The study population included 15 men and seven women, with an average of 50±12.5 years (range, 25–76 years). The mean BMI was 24.2±3.45 (range,18.5–30.5) .All pelvic fractures were closed fractures. Among them, 19 patients had comorbidity with other fractures or organs (Table 2)[22]. According to the Tile classification, there were 4 type B and 18 type C fractures. The mean interval from injury to surgery in this study was 7.8±4.1 days (range, 2–19 days) (Table 2). The average operative time was 220±64 min (range, 120–360 min). The average intraoperative blood loss was 159 ±138.6 mL (range, 50–600 mL). The mean residual displacement was 4.61mm±3.29mm (range,0.18–14.84mm). According to the Matta criteria, Among the 22 cases, 16 cases were excellent, five were good, and one was fair, with an excellent and good rate of 95.5% (Table 3)[22]. The average global 3D point cloud reduction error between the preoperative planning results and the actual postoperative reduction results was 3.41mm±1.83mm(range,0.85–7.66mm). Based on the global 3D point cloud reduction error, we found the most obvious reduction error mainly occurred in the posterior pelvic ring, including the sacral and sacroiliac joint regions. As for the reduction distance(Table 4)[22], the mean of total reduction distance on anterior pelvic ring was 12.19±6.97 (range,3.8-28.43mm) , the mean of total reduction distance on posterior pelvic ring was 8.33±3.97 (range,1.84–15.61mm) . No postoperative complications such as neurovascular injury, iatrogenic fracture, wound infection, screw loosening was observed in all patients.

Discussion

For unstable pelvic fractures with significant displacement, the premise of minimally invasive percutaneous fixation is minimally invasive reduction. At present, there are relatively few minimally invasive reduction methods for pelvic fractures in clinical practice. Therefore, although the minimally invasive treatment of pelvic fractures has huge advantages compared with open surgery, It is not widely used in clinical practice because of the difficulty of reducing pelvic fractures [17]. To solve the reduction problem, some researchers designed a series of reduction frames that connected

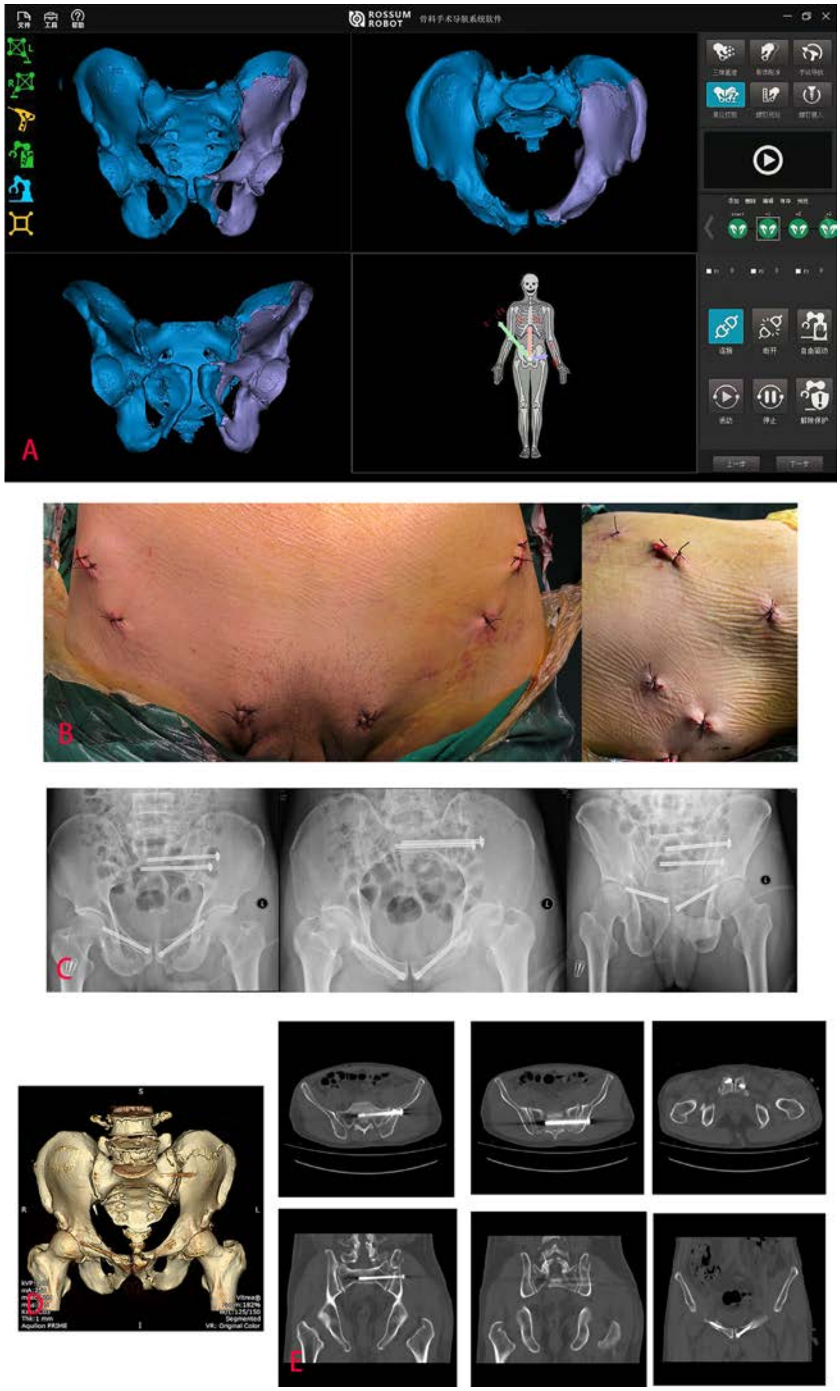

Fig. 7. Typical case presentation. A. The reduction processes are completed under the supervision of 3D real-time navigation. B. The skin incisions. C. Postoperative plain radiograph using three standard pelvic radiographic views: anteroposterior, inlet, and outlet views. D. Postoperative CT 3D reconstruction images. E. Postoperative CT coronal and axial scans.

the operating table to pelvic external fixators to better support pelvic fracture reduction manipulations. However, Limited by the bulky size of the frame, it is challenging to complete the flexible reduction of the multi-dimensional displaced pelvic fracture fragments. Surgeons still required complete reduction manually under intraoperative fluoroscopy. The reduction also mainly depends on the surgeon's experience. To mitigate the above disadvantages, Researchers developed some Robot-assisted reduction systems. However, most Robot-assisted reduction system mainly focuses on lower extremity diaphyseal fracture[31–35]. Moreover, most of the existing robotic fracture reduction and navigation systems belong to the laboratory and cannot solve the clinical problem of pelvic fracture[35–37]. Cristina B et al. have designed a specific device interfaced with existing surgical tables. [38]. This study explored the use of a robotic system for closed reduction of pelvic fractures, but it was only a model study, and repeated intraoperative fluoroscopy was also required to verify the location of fracture reduction. Finally, the author also proposed that if the design and planning can be made according to the preoperative images, the application of the navigation system to track the real-time reduction of fractures will further improve the performance of the robotic system.

Table 2
Demographic and clinical variables of the patients treated for unstable pelvic fractures.

Case number	Gender	Age (years)	BMI	Injury to surgery time (days)	Tile type	Combined injury
1	Male	49	28.9	11	C1	None
2	Male	47	28.1	7	C1	Ankle fracture, acetabular fracture
3	Female	55	25.4	6	C2	Fracture of lumbar vertebra, rib fracture
4	Male	63	26.6	9	C2	Craniocerebral trauma
5	Female	25	25.6	19	C2	Tibiofibular fracture, fracture of the metatarsal, calcaneal fracture, thoracolumbar vertebral fracture, cervical spinal fractures, rib fracture, intracranial hemorrhage, pneumothorax
6	Male	55	24.8	5	C2	Rib fracture
7	Male	42	30.5	5	C2	Acromial fracture, fracture of lumbar vertebra, Fracture of great tubercle
8	Female	63	20.8	5	B2	Fracture of lumbar vertebra
9	Male	58	29.3	16	C1	Fracture of lumbar vertebra, Pillon fracture
10	Male	47	27	2	C1	Femoral Shaft Fracture
11	Male	51	23.6	5	C2	Acetabular fracture
12	Male	61	23.3	6	C1	Retroperitoneal hematoma, ascending colon injury
13	Male	51	19.4	10	B2	Open tibia fracture, fibular fracture
14	Male	76	24.2	8	C1	cervical spinal fractures, Retroperitoneal hematoma, thoracolumbar vertebral fracture, Pleural effusion
15	Female	45	18.8	10	C1	Rib fracture
16	Female	34	21.5	2	B2	Fracture of lumbar vertebra
17	Male	26	22.7	6	C1	Contusion of kidney
18	Female	39	19.2	6	C1	Rib fracture, Craniocerebral trauma
19	Male	40	22	6	B1	None
20	Male	65	19.5	12	C2	Rib fracture, Seroperitoneum, urethral injury
21	Male	56	20.8	7	C1	Fracture of lumbar vertebra, fracture of great tubercle
22	Female	53	30.3	8	C1	None

Table 3
Clinical outcome of the patients treated for unstable pelvic fractures.

Case number	Fracture location	Operation time (min)	Blood loss(ml)	The residual displacement/mm	Post-operative imaging Matta evaluation
1	Sacrum Denis zone II	240	100	2.27	Excellent
2	Sacrum Denis zone II	315	50	9.58	Good
3	Sacrum Denis zone II	360	600	3.92	Excellent
4	Sacrum Denis zone II	240	100	2.77	Excellent
5	Sacrum Denis zone II	160	300	8.53	Good
6	Sacroiliac joint	195	500	8.32	Good
7	Sacrum Denis zone II	300	50	6.38	Good
8	Sacroiliac joint	120	100	4.15	Excellent
9	Sacrum Denis zone II	320	100	1.56	Excellent
10	Sacroiliac joint	160	100	3.7	Excellent
11	Sacrum Denis zone II	170	100	3.01	Excellent
12	Sacroiliac joint	170	100	2.51	Excellent
13	Sacroiliac joint	260	200	4.58	Excellent
14	Sacroiliac joint	210	100	5.22	Good
15	Sacrum Denis zone II	240	100	1.23	Excellent
16	Sacroiliac joint	240	100	4.33	Excellent
17	Sacrum Denis zone II	240	200	4.94	Excellent
18	Sacrum Denis zone II	240	150	3.58	Excellent
19	Sacroiliac joint	120	100	0.18	Excellent
20	Sacroiliac joint	180	150	14.84	Fair
21	Sacroiliac joint	180	100	2.58	Excellent
22	Sacroiliac joint	180	100	3.19	Excellent

To the best of our knowledge, no 3D-based image-guided intelligent serial RAFR system for pelvic fractures has been reported in the relevant literature. There are also no reports of intelligent RAFR systems used in pelvic fracture reduction clinical cases. Our intelligent RAFR system was the first 3D-based image-guided serial Robot for pelvic fracture reduction. Our report was also the first to apply the intelligent RAFR system in clinical pelvic fracture reduction cases and achieve good results. It is important to note that we only work with the reduction of pelvic fractures. An extension to screw placement is the task of further work.

Our RAFR system is different from frame-assisted closed reduction and early robot systems for pelvic fracture. It truly realizes intelligent and minimally invasive surgery for pelvic fractures. The robot system designs an image algorithm concerning the mirror-symmetric theory of bilateral lower extremities and pelvis [39–43]. During reduction path planning, the mirror model of the intact bone was considered the reference of the fractured bone for navigation. The target position of reduction is computed first. By knowing the desired target position, the paths of fracture reduction are analyzed and planned to reduce the fracture fragments accurately. However, pelvic anatomy studies show a broad and small range of spatial asymmetry in the pelvis[44,45]. We also found that there will be a certain degree of poor matching, which may affect the accurate target position [21]. Therefore, we designed a manual adjustment function for the planning software. Based on automatic computer planning, if the doctor finds that the planned image position deviates, he can make a slight adjustment for the 3D image of the displaced hemipelvis, and finally confirm the reduction target position that meets the actual clinical requirements.

For the reduction of pelvic fractures, it is difficult to obtain a complete two-dimensional image of the pelvis in the current clinical imaging equipment. Projecting the 3D pelvic geometry onto a

Table 4
Reduction outcome of the patients treated for unstable pelvic fractures.

Case number	Reduction distance on anterior pelvic ring /mm	Reduction distance on posterior pelvic ring /mm	Global 3D point cloud reduction error/mm
1	4.79	11.46	6.35
2	6.86	11.19	1.38
3	11.68	4.44	4.11
4	15.82	11.88	2.66
5	12.8	9.1	3.34
6	14.86	13.66	4.73
7	11.89	15.25	3.91
8	7.32	15.61	3.07
9	6.85	1.84	0.85
10	17.52	12.65	3.47
11	10.52	4.95	7.66
12	3.8	4.13	6.79
13	6.48	6.83	2.21
14	6.36	3.79	3.77
15	28.43	5.53	1.67
16	8.04	9.93	4.71
17	6.3	7.34	3.83
18	9.1	5.15	2.72
19	23.62	3.79	1.19
20	17.75	8.48	3.05
21	26.55	8.36	1.18
22	10.83	7.89	2.39

2D X-ray may not reflect the accurate position of the pelvis, particularly the complex posterior rings. Therefore, the traditional closed reduction surgery under fluoroscopy guidance has a steep learning curve, and there may be a significant deviation in judging fracture reduction by intraoperative fluoroscopy images[14,46]. The method of 3D-based registration method with preoperative marker placement is an invasive operation, and the skin incision for placing the marker also has a particular influence on the subsequent sterile operation, limiting the application of the method[47]. The intraoperative CT method to realize intraoperative 3D image navigation is difficult to be widely used in clinical practice because of the high price of intraoperative CT equipment and the need for a unique hybrid operating room [48].

The registration is a crucial part of the clinical workflow. Accurate image registration can enable us to accurately judge the displacement of fracture fragments through navigation image, the location of holding pin placement, the actual movement path of displaced fracture fragment during reduction, and the final reduction result. Combined with previous studies, we developed a new registration method based on not only preoperative CT but also intraoperative CBCT. After scanning the CBCT image data of both side pelvis where the tracker is installed, the preoperative CT image is registered and calculated with the CBCT data by the software system, so the CBCT image and the preoperative CT image can be accurately fused. By tracking the position of the optical markers placed on both sides of the pelvis, the optical camera can reproduce the real-time position of the pelvis with preoperative CT images and realize the complete visualization of the whole reduction path. With the new registration method of intraoperative CBCT, the movement of the pelvic fracture fragment before the operation does not affect the registration results. The following reduction procedure could only be carried out when the registration accuracy meets the surgical requirements. Compared with the technique of implanting optical or metal markers on the bone before CT scan[49,50], The registration of our system did not require patients to implant markers before surgery which reduces the patient's pain and the risk of infection.

Our RAFR system designed the shortest path for the reduction. However, sometimes an additional obstacle occurs when there are possible fragment collisions. The movement with the shortest path is obstructed, making the reduction process interrupted. Our system simulates the clinician's intraoperative operation method and provides a reduction waypoint design to ensure a smooth reduction path. The surgeon can design one or more waypoints to avoid bony impact. The fracture fragments are visualized on a screen and reduced until the target position is reached. Unnecessary and prohibited movements can be avoided.

It is essential to hold the unaffected pelvis during the closed reduction of pelvic fractures[11,38]. In our study, we independently developed the handle arm system. The handle arm with multiple DOF can be quickly and rigidly fixed to the orthopedic operating table and the pelvic handle pin. It can provide a solid and stable grip and fixation for the pelvis. At the same time, to facilitate the disinfection process during the operation, we designed a U-shaped connection device suitable for the operating table. The device can keep the handle arm system away from the surgical field to avoid interfering with the reduction and fixation of fractures. All 22 patients in our study achieved stable fixation of the healthy hemipelvis in this way. To increase the holding stability, we added a horizontal holding Schantz pin at the top of the acetabulum based on the original two holding Schantz pins so that the robotic arm can hold the affected side hemipelvis more stably. At the same time, to prevent the damage caused by the poor placement of the holding pin, after the intraoperative image registration, the system can provide a navigation path for the insertion of the holding pin during the operation. This function can provide the best placement position of the holding pin, which is beneficial for the Robot to hold the pelvis stably and exert maximum force during reduction. This navigation path also reduces the risk of holding pin loosening and even intraoperative iatrogenic fractures.

Appropriate axial traction can significantly improve the displacement of pelvic fractures[51,52].In this study, we used a self-developed elastic distraction device for pelvic fractures with vertical instability. The device uses a spring device to connect with the traction pin on the patient's femoral condyle, and the traction force is adjusted through a special control panel. During the reduction process, the device provides a stable traction force. Our previous study[23] evaluated three reduction methods for the closed reduction of pelvic fractures. They are reduction without traction, reduction with ordinary traction, and reduction with an elastic traction device. The study results showed that the elastic traction group required the minimum reduction force, and the no-traction reduction group required the maximum reduction force. Using elastic traction devices can reduce the force required for fracture reduction in pelvic fracture. This reduction in force requirements makes the closed reduction of fractures performed by the Robot more flexible, thereby improving the success rate of reduction.

The strategy of our robotic reduction system for pelvic fracture reduction is to stably hold the patient's unaffected pelvis and the affected pelvis and use the robotic arm to complete the reduction of the affected pelvis with computational planning. The basis of this strategy is to divide the pelvis into two parts: the affected and the healthy part, but in some patients with severe pelvic fractures, there may be two or more unstable pelvic parts. In an epidemiological study of 537 pelvic fracture patients, unstable fractures requiring surgical intervention accounted for 74.5% of the total cases. 18.3% of the unstable fractures were bilateral fractures (types B3 and C3)[53]. In another study, severely comminuted iliac fracture accounted for 2% of the total pelvic fractures[54]. Although our system can reduce most unstable displaced pelvic fractures. Our system has no way to track them accurately for severely comminuted patients. However, we are also trying to make a step-by-step reduction to solve the problem of two or more unstable pelvic parts. For patients with bilateral pelvic fractures, if the displacement of one pelvis is not large, we can fix this part of the pelvis with percutaneous channel screws first, then the pelvis is divided into two parts: the healthy side (pre-screwed side) and the affected side with significant displacement. In this case, we can reduce the fracture fragment by the robotic system.

The maximum residual displacement of pelvic fracture fragments is usually less than 35 mm[55], so the spatial range of reduction robot movement is not extensive. However, the reduction force carried by the manipulator during the reduction process is a problem that needs paid attention. When we performed reduction force analysis using an elastic traction device, we found that the force required for most pelvic fracture reductions with the assistance of an elastic traction device was less than 160N, so the maximum load of the robotic arm of our robotic system was 160N. However, due to different types of fractures and different waiting times before surgery, The maximum reduction load of some pelvic fractures is greater than 200N[23]. In this case, to prevent the robot arm from being overloaded and shut down during the operation, the system provides a manual-assisted mode of reduction. During the reduction path of the robotic arm, the mechanical sensor at the end of the robotic arm will analyze the reduction resistance of the arm in real-time and decompose the force into the X, Y, and Z axes on display. According to the results of the mechanical analysis on the monitor, the surgeon can hold the connecting rod of the robotic arm to increase the force of the robotic arm. When the surgeon's force offsets the excess reduction resistance and the load of the robotic arm return to the normal range, the robotic system will continue to complete the fracture reduction according to the planned path. This manual-assisted mode improves the success rate of the reduction. We believe that with the improvement of the mechanical arm structure and technology, a higher-loaded robotic arm will be developed to solve the problem of limited force in closed reduction.

The cases in our study were all Tile-type B and C pelvic fractures, and most of them were type C, mainly because relatively severe pelvic fractures have more fracture displacement, and these patients are suitable for reduction with our robotic system. Since severe fractures are often accompanied by many combined fractures and other organ injuries, this may lead to a longer preoperative waiting time. Delaying the operation time may lead to the patient's peripelvic hematoma maturation and soft tissue fibrosis, which increases the failure risk of closed reduction risk[56,57]. Therefore, on the premise of ensuring patient safety, we should minimize the preoperative waiting time to improve the reduction process.

In some cases, the estimated total blood loss is high. The reasons mainly include the following, First, with our robot system, the holding needles, tracers, and channel screws require twelve to thirteen percutaneous incisions, which may have blood loss of 100 milliliters. Second, in some cases, the pelvic fractures were combined with other fractures that require simultaneous surgery, the blood loss of other fractures was also included in the estimated total blood loss. Third, one case had local vascular hemorrhage when puncturing the skin tunnel to place the sacroiliac joint screw. However, considering that these fractures are all complex B2 and B3 fractures with large displacement, we believe compared with traditional surgery treating these complex fractures, the blood loss of treatment for pelvic fracture with our system is still small.

The purpose of our robotic reduction is to create conditions for the next minimally invasive percutaneous internal fixation of pelvic fractures. The better the result of pelvic fracture reduction, the more favorable it is to maintain the stability of the fracture. Traditional closed reduction surgery requires manual operation and fluoroscopy to move the displaced hemipelvis. The fluoroscopy image is only a partial two-dimensional image, and it is not easy to judge the result of the reduction. Moreover, it is not easy to maintain the reduction position by manual operation, the surgeons often encounter the situation that the reduction position changes. Our robot system moves the displaced half-pelvis slowly until it reaches the planned reduction, and it can maintain the final position stably, which will create conditions for the next minimally invasive fixation. Our robotic system will not cause additional damage to the human body during the operation. The insertion of the holding Schantz pin is assisted by navigation, which is safer than conventional surgery. The maximum load of the robotic arm during the reduction process is 160N, which is less than the force of the doctor's bare-hand operation in conventional surgery. The bone distraction pin inserted into the femoral condyle for distraction is consistent with the conventional orthopedic treatment, which will not cause additional trauma. The Robot will automatically stop when the software or hardware fails, and the surgeon can also do emergency shutdowns manually, ensuring safety during the operation. In all 22 reduction procedures, there was no adverse safety events occurred.

The initial clinical application of the new robotic system still has certain limitations: First, our robotic system cannot reduce all pelvic fractures. For severely comminuted pelvic fractures, the fracture reduction planning and effective control of displaced pelvis cannot be achieved with the robot system. So, for these patients, we don't use the 3 pinned reduction technique. Second, we speculate that severe obesity may interfere with the system. The highest BMI in our case is 30.5 which didn't cause failed registration. Based on the limited number of cases, we can't give the BMI threshold that will cause failed registration. We believe that with the C-arm equipment technology improves, obesity may not affect image registration. Third, due to the load limitation of the robotic arm, our system does not work well for old pelvic fractures which have malunion or there is no abnormal pelvic movement on the physical examination. In addition, the registration and reduction path planning algorithm of our robot system relies on intraoperative CBCT equipment. It is believed that with the innovation of imaging equipment, the breakthrough of 2D-3D registration technology, and the development of robotic arm structure technology, the clinical application of this robotic system will be more convenient in the future. Lastly, our study is a retrospective study without a control group for comparison, and we required a adequately powered and randomized controlled trial study with long-term follow-up to reach a firmer conclusion.

Conclusion

Our new pelvic fracture reduction robot system can complete intelligent and minimally invasive fracture reduction for most patients with unstable pelvic fractures. The system has intelligent reduction position and path planning and realizes stable pelvis control through a unique holding arm and a robotic arm. We complete the closed reduction of the pelvis safely and accurately under the real-time supervision of three-dimensional images. The operation process will not cause additional damage to the patient, which fully meets the clinical requirements. In summary, our study demonstrated the safety and effectiveness of our robotic reduction system and its applicability and usability in clinical practice, thus paving a way towards Robot minimally invasive pelvic fracture surgeries.

Ethics approval

Our study was approved by the Ethic Committee of Beijing Jishuitan Hospital (No: 202006-13).

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://data.mendeley.com/datasets/k89kbnx8f5/1

Declaration of Competing Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

CRediT authorship contribution statement

Chunpeng Zhao: Conceptualization, Supervision, Validation, Visualization, Writing – original draft. **Qiyong Cao:** Formal analysis. **Xu Sun:** Data curation. **Xinbao Wu:** Conceptualization, Supervision, Validation, Visualization. **Gang Zhu:** Formal analysis. **Yu Wang:** Data curation, Investigation.

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Supplementary materials

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