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Original Article

Percutaneous short-segment pedicle instrumentation assisted with O-arm navigation in the treatment of thoracolumbar burst fractures

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ABSTRACT

Object: To compare the clinical and radiological outcomes of O-arm navigation assisted percutaneous pedicle fixation and open freehand pedicle fixation in treatment of AO type A3 thoracolumbar burst fractures (TBFs) without neurological deficit.
Methods: This retrospective study involved 72 patients with type A3 TBFs who underwent O-arm navigation assisted percutaneous pedicle fixation (MIS group) or open freehand posterior pedicle fixation (OPPF group) from September 2015 to December 2017. Demographic data and clinical characteristics were comparable between these two groups before surgery. Operating time, intraoperative blood loss, and the time of hospitalisation stay were analysed. Visual analog scale (VAS) scoring and Oswestry disability index (ODI) was assessed for each patient pre- and post-operatively. Radiographic follow-up was assessed by the Local kyphosis angle (LKA), Vertebral wedge angle (VWA), and Anterior body height (ABH). The accuracy of screw placement was examined by computed tomography.
Results: The two groups were matched in terms of demographic and clinical features. Intraoperative blood loss was significantly less in the MIS group compared to the OPPF group ($p < 0.05$). The average time for hospitalisation stay in the MIS group was significantly shorter than OPPF group ($p < 0.05$). However, the operative time revealed no significant difference between two groups ($p > 0.05$). Meanwhile, the VAS score and ODI score in the MIS group were significantly lower than that in the OPPF group after surgery ($p < 0.05$). Radiographic assessments revealed no obvious difference between the 2 groups immediately after surgery or at the final follow-up ($p > 0.05$); The accuracy rate of pedicle screw position in the MIS group was higher than OPPF group (97.8% vs 78.5%, respectively; $p < 0.001$). No deep wound infection, additional surgery, implant failure, or neurological complications were recorded in either group.
Conclusions: Percutaneous short-segment pedicle instrumentation assisted with O-arm navigation represents an effective and safe alternative for type A3 TBFs. It has several advantages compared with open approach, including less blood loss, shorter hospitalisation, less postoperative pain, higher accuracy of pedicle screw placement, and faster recovery period in treating TBFs. However, it requires a longer learning curve and long-term results have to be studied in other well-designed studies.
The translational potential of this article: Percutaneous short-segment pedicle instrumentation assisted with O-arm navigation represents an effective and safe alternative for type A3 TBFs. The utilization of O-arm navigation and percutaneous pedicle screw fixation guaranteed the high accuracy of screw placement, protected staff from radiation exposure and offered benefits of minimal invasive technique.

Introduction

Thoracolumbar fracture is one of the most common areas of spine fractures [1], and fractures of burst type account for approximately 20% of thoracolumbar fractures [2]. Short-segment pedicle instrumentation is one of the most standard methods for treating thoracolumbar burst fractures (TBFs). Traditional open posterior pedicle fixation (OPPF) is performed using a long incision, which has shown to cause intraoperative trauma to paraspinal muscles, dissection of ligamentous structures, extensive blood loss, significant post-operative pain, long recovery times, and a high risk of wound infection [3–5].

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Percutaneous pedicle screw fixation system has been growing in popularity, for it produces less surgical trauma leading to a good clinical result. However, the conventional method of this minimally invasive technique was heavily based on 2D fluoroscopic guidance, which could result in higher radiation exposure [6]. Besides, the accuracy of pedicle screw placements could not be guaranteed through the small incision. A systematic review showed that the accuracy of pedicle screw placement using the conventional 2D fluoroscopy was 68.1% [7]. Misplacement of screws can lead to vascular injury, neurological injury, dural tear, and pedicle fractures that can compromise stable fixation [8].

With progressive technology, various navigation systems have been introduced to improve the accuracy of screw placement. O-arm navigation is a three-dimensional (3D) fluoroscopy system that provides images of almost computed tomography (CT) scan quality, which helps to detect screw misplacements and guarantee the accuracy of pedicle screw placement [9,10]. Besides, The O-arm and Stealth navigation technology can reduce radiation exposure significantly [11,12]. Thus, percutaneous pedicle screw fixation assisted with O-arm navigation may be a novel and safe method for minimally invasive surgery (MIS). To our knowledge, there were few literature studies to focus on the use of O-arm navigation–assisted percutaneous pedicle fixation in the treatment of TBFs so far.

From September 2015 to December 2017, patients with thoracolumbar burst fractures were selected at our centre, and O-arm and StealthStation navigation was used to ensure the accuracy of pedicle screw placement and decrease radiation exposure. The purpose of this study was to evaluate the safety and efficacy of percutaneous short-segment pedicle fixation assisted with O-arm navigation in the treatment of Type A3 TBFs.

Materials and methods

Subjects

The inclusion criteria for this study were as follows: diagnosis of thoracolumbar fractures (T11-L3) with Type A3 in accordance with the Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification [13]; short-segment pedicle instrumentation; absence of neurological deficits; no posterior direct decompression; minimum follow-up of 1 year. The exclusion criteria were as follows: long segment instrumentation; combined anterior–posterior surgeries; posterior decompressed patients; follow-up of less than 1 year; and pathological fractures. In accordance with the criteria, 72 patients with Type A3 TBFs who had been treated with either minimally invasive surgery (MIS) or OPPF between September 2015 and December 2017 were included in this retrospective comparative study. Of these, 36 patients had undergone a MIS, and 36 patients had undergone an OPPF. All the patients were informed of both surgical techniques in detail preoperatively, and the advantages and disadvantages of the two techniques were discussed with them. Meanwhile, we told the patients that there was no sufficient evidence-based medicine showing which technique was better. The final surgical approach was determined by patients after being fully informed. Institutional review board approval for this retrospective study was obtained from the Ethics Committee and Institutional Review Board of the first-affiliated hospital of Soochow University.

Surgical technique

For the MIS, each patient was positioned prone on a radiolucent Jackson spinal table (Mizuho OSI, Union City, CA) with the StealthStation (Medtronic Sofamor Danek, Memphis, TN, USA) camera placed at the head. The O-arm (Medtronic Sofamor Danek) was positioned and the first intraoperative 3D scanning was acquired. A paramedian 2-cm incision overlying the target spinal segment was made (Fig. 1A). The Universal Drill Guide (Medtronic) was used to ascertain the entry point and guide the trajectory of the drill (Fig. 1B). After checking the medial and caudal inclination, the surgeon drilled holes along the central axis of the pedicles through the Universal Drill Guide under the navigation. A guidewire was then inserted and the hole was then tapped in the same trajectory. After measuring the length and diameter of pedicle screws on the screen of the navigation system, the appropriate pedicle screws were

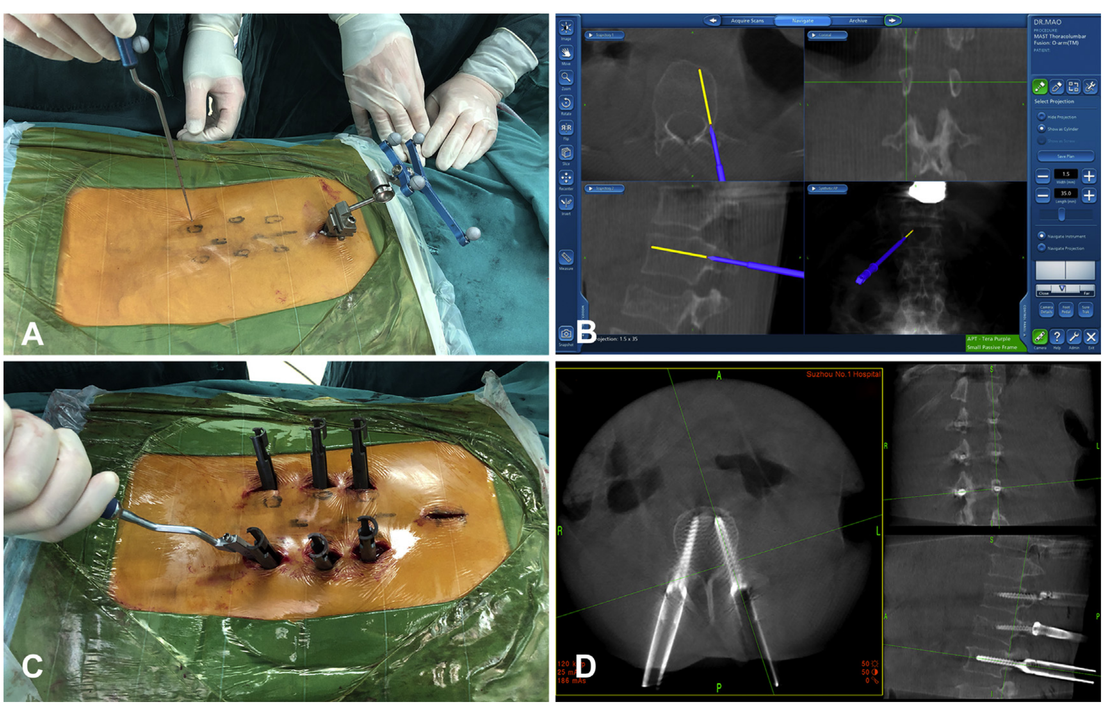

Figure 1. (A) By moving Passive Planar Probe, the entry point was chosen and a paramedian 2-cm incision overlying the target spinal segment was then made. (B) Intraoperative snapshot was used to ascertain the entry point and guide the trajectory of pedicle screw under O-arm navigation guidance. (C) The precontoured rod was placed in a cephalocaudal manner with the assistance of screw extenders. (D) The intraoperative 3D scan with the O-arm was performed to confirm screw placement when all screws were placed.

Figure 2. Grading used for pedicle perforation on axial CT scan and the representative images: (A) both pedicle screws completely within the pedicle (Grade 0); (B) Grade 1 (<2 mm) perforation of the medial wall of the right pedicle and Grade 2 (2–4 mm) perforation of the lateral wall of the left pedicle; (C) Grade 2 (2–4 mm) perforation of the medial wall of the left pedicle and Grade 0 perforation of the right pedicle; (D) Grade 3 (>4 mm) perforation of the lateral wall of the left pedicle and Grade 1 (<2 mm) perforation of the medial wall of the right pedicle. CT, computed tomography.

inserted. The second intraoperative 3D scan with the O-arm was performed to confirm screw placement when all screws were placed (Fig. 1D). The precontoured rod was placed percutaneously from either the cephalad or caudal side with the assistance of screw extenders (Fig. 1C). The reduction of the fracture and indirect decompression of the spinal canal were accomplished by extension manoeuvres with a special adjustable fulcrum before tightening the screws. Then, the screw extenders and rod inserter are removed. The reduction effect is verified by O-arm.

Open freehand posterior procedure was performed using a midline open approach as described in our previous literatures [14–17]. The pedicle screws were placed under C-arm fluoroscopy. All surgeries in the two groups were performed by fully qualified surgeons with more than 10 years of experience in spinal surgery.

Radiographic assessment

The patients' demographic, clinical, and injury details (age, sex, trauma aetiology, fracture level, and fracture type) were studied. All patients had preoperative radiographs, CT, and magnetic resonance imaging to evaluate the fracture. Thoracolumbar injury classification and severity scores (TLICS) [18] of all cases were calculated. Preoperative, postoperative, and most recent follow-up radiographs of the patients have been evaluated. The following radiographic parameters were measured including: Local kyphosis angle (LKA, defined as the angle between the superior endplate of the upper vertebra and the inferior endplate of the lower vertebra in accordance with the Cobb's method), Vertebral wedge angle (VWA, defined as the angle of the superior endplate and inferior endplate of the fractured vertebra) and anterior body height (ABH, expressed as percentage of the mean values for the adjacent vertebrae) of the fractured vertebra.

Clinical assessment

The duration of operation, amount of blood loss, length of hospital stay, and complications were compared between two groups. The visual analogue scale (VAS) score was used to evaluate the pain before and after operation. The Oswestry Disability Index (ODI) scores were used to evaluate patients' daily life functions.

The assessment of the radiographic and clinical data were performed by a surgeon who was independent of the study.

Accuracy assessment of the pedicle screws

Accuracy of the pedicle screw placement was evaluated by postoperative CT images in the OPPF group and intraoperative O-arm films in MIS group. Pedicle perforation was graded as per the 2-mm increment classification [19–21]: Grade 0, completely within the pedicle; Grade 1, perforation < 2 mm; Grade 2, perforation 2–4 mm; and Grade 3, perforation > 4 mm. In addition, Grade 0 and 1 were considered acceptable, whereas Grade 2 and 3 were regarded as perforated. Both medial and lateral perforations were considered in deciding misplacements (Fig. 2). The pedicle screw grading was performed by an independent observer who was blinded to an instrumentation technique.

Statistical analysis

Data were analysed using SPSS for Mac (version, 23.0; SPSS Inc., Chicago, IL, USA). Values were presented as the mean ± standard deviation. A Student t-test was used for comparing continuous variables between the two groups preoperatively, postoperatively, and at the last follow-up time. Chi-squared and Fisher exact tests were applied to analyse malposition rates and basic descriptive statistics. $p < 0.05$ was considered statistically significant.

Results

Patient baseline demographic and clinical characteristics of the two groups were compared between the MIS and OPPF groups (Tables 1, 2). These two groups were matched in terms of age, sex, mechanism of injury, fracture level and type, TLICS score, and follow-up ($p > 0.05$). No cases in MIS group were converted to open surgery. None of the patients

Table 1
Baseline characteristics of the two groups.

Variable	MIS	OPPF	*p*
No. of patients	36	36	–
Mean age (years)	48.7 ± 9.7	49.3 ± 11.2	0.809
Gender			0.617
Male	25	23	
Female	11	13	
Follow-up (months)	28.2 ± 4.3	27.8 ± 4.2	0.741

MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.

Table 2
Perioperative parameters of both groups.

Variable	MIS	OPPF	P
Mechanism of injury			0.465
Traffic accident	12	15	
Fall	24	21	
Fracture level			0.866
T11	4	6	
T12	10	8	
L1	16	15	
L2	6	7	
Fracture type			0.440
A3.1	15	10	
A3.2	4	6	
A3.3	17	20	
TLICS score	4.9 ± 1.3	5.1 ± 1.7	0.577

TLICS = thoracolumbar injury classification and severity scores; MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.

had neurological deficits. In accordance with the AO classification, 25 were Type A3.1, 10 were Type A3.2, and 37 were Type A3.3. The majority of fractures resulted because of falls (45 cases; 62.5%), and rest of the cases resulted from traffic accidents (27 cases; 37.5%).

Clinical evaluation

Blood loss and hospital stay in the MIS group were significantly better than the OPPF group ($p < 0.05$). However, no statistical difference was observed between two groups in the aspect of mean surgical duration ($p > 0.05$) (Table 3). Average VAS and ODI scores for back pain were improved significantly after operation and maintained till the last follow-up. The patients in MIS group had lower VAS score and ODI score than the patients in OPPF group immediately, 1 month and 6 months after surgery ($p < 0.05$), whereas VAS score and ODI score were nonsignificantly lower in the MIS group at the last follow-up (Table 4). No complications related to surgery such as infection, blood vessel, or neurological injury were observed in these two groups. No patient needed revision for correction loss or instrumentation failure during follow-up.

Radiographic evaluation

As was described in Table 5, the average preoperative LKA of MIS group and OPPF group were 15.7 ± 7.4° and 16.5 ± 6.5°, respectively. The average preoperative VWA of the MIS group and OPPF group were 16.9 ± 6.6° and 17.2 ± 5.9°, respectively. The average preoperative ABH of the MIS group and OPPF group were 63.6 ± 14.3% and 62.5 ± 12.9%, respectively. The preoperative radiographic data were similar in both groups (all $p > 0.05$). After surgery, LKA and VWA angles were significantly corrected, and ABH was well restored in two groups ($p < 0.05$). No significant differences were noted in postoperative LKA, VWA, ABH or correction loss between two groups ($p > 0.05$). As correction loss were summarised in Table 5, we could conclude that MIS and OPPF group were similar both in terms of postoperative sagittal alignment restoration and maintenance of the restoration until the last follow-up (Figs. 3 and 4).

Table 3
Summary of operation values.

Variable	MIS	OPPF	p
Mean operation time (min)	134.3 ± 35.0	120.6 ± 30.3	0.08
Mean hospitalisation (day)	10.8 ± 2.5	12.8 ± 2.8	0.002*
Mean blood loss (mL)	90.7 ± 77.0	350 ± 20.4	<0.001*

*Statistically significant ($p < 0.05$).
MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.

Table 4
Comparison of clinical parameters between two groups.

Variable	MIS	OPPF	p
VAS score			
Preoperative	8.0 ± 1.5	7.8 ± 1.7	0.598
Immediately postoperative	2.2 ± 1.3	3.8 ± 0.9	<0.001*
1 mo postoperative	1.9 ± 0.8	2.7 ± 0.8	<0.001*
6 mo postoperative	1.8 ± 0.6	2.2 ± 0.8	0.009*
Last follow-up	2.2 ± 0.6	2.5 ± 0.9	0.101
ODI			
Preoperative	45.7 ± 7.8	46.8 ± 9.0	0.581
Immediately postoperative	31.1 ± 3.5	37.8 ± 2.7	<0.001*
1 mo postoperative	22.4 ± 2.5	26.8 ± 3.1	<0.001*
6 mo postoperative	14.2 ± 2.7	18.5 ± 2.5	<0.001*
Last follow-up	4.5 ± 2.6	4.7 ± 3.3	0.776

VAS = visual analogue scale; ODI = Oswestry Disability Index; MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.
*Statistically significant ($p < 0.05$).

Accuracy rate of pedicle screw position

As shown in Table 6, we made the assessment of pedicle screw position postoperatively. The accuracy of pedicle screw position (Grades 0, 1) was significantly higher in the MIS group than in the OPPF group (176/180, 97.8% vs. 135/172, 78.5%, respectively; $p < 0.001$).

Discussion

Most traumatic TBFs occur at the thoracolumbar junction (T11-L3) which is confirmed to be weak for stress biomechanically [1,22]. In general, surgery is suggested when there is a severe deformity and/or neurologic deficit. Posterior short-segment pedicle fixation is a traditional treatment option for TBFs [23]. However, open-exposure approach leads to large incisions, paraspinal muscle atrophy, massive blood loss, significant postoperative pain, and long recovery times [24].

To avoid these disadvantages, minimally invasive spinal surgical techniques have been widely used. Percutaneous pedicle screws are a critical minimally invasive technique and currently used in the treatment of TBFs [5,25,26]. Various studies have compared surgical results between open and percutaneous pedicle screw fixation for TBFs [26–29]. Vanek et al [26] compared clinical and radiological outcomes after percutaneous transpedicular system and standard open approach for TBFs. Notably, no significant differences were observed between the groups in radiological results after a 2-year follow-up. A systematic review [30] was conducted in 2015 to compare surgical results of

Table 5
Summary of radiographic measurements.

Variable	MIS	OPPF	P
Local kyphosis angle (LKA) (°)			
Preoperative LKA	15.7 ± 7.4	16.5 ± 6.5	0.628
Postoperative LKA	6.0 ± 2.5	5.4 ± 2.6	0.321
LKA at the final follow-up	10.7 ± 3.2	9.2 ± 3.6	0.066
Correction loss	3.3 ± 1.4	3.0 ± 1.2	0.332
Vertebral wedge angle (VWA) (°)			
Preoperative VWA	16.9 ± 6.6	17.2 ± 5.9	0.840
Postoperative VWA	6.5 ± 2.3	5.7 ± 3.1	0.218
VWA at the final follow-up	11.7 ± 3.5	11.3 ± 3.2	0.614
Correction loss	4.7 ± 1.5	5.3 ± 2.2	0.181
Anterior body height (ABH)			
Preoperative ABH	63.6 ± 14.3	62.5 ± 12.9	0.733
Postoperative ABH	86.5 ± 16.8	88.6 ± 10.7	0.529
ABH at the final follow-up	82.8 ± 15.7	83.6 ± 13.9	0.820
Correction loss	4.5 ± 1.1	4.9 ± 2.1	0.315

LKA = local kyphosis angle, VWA = vertebral wedge angle, ABH = anterior body height; MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.

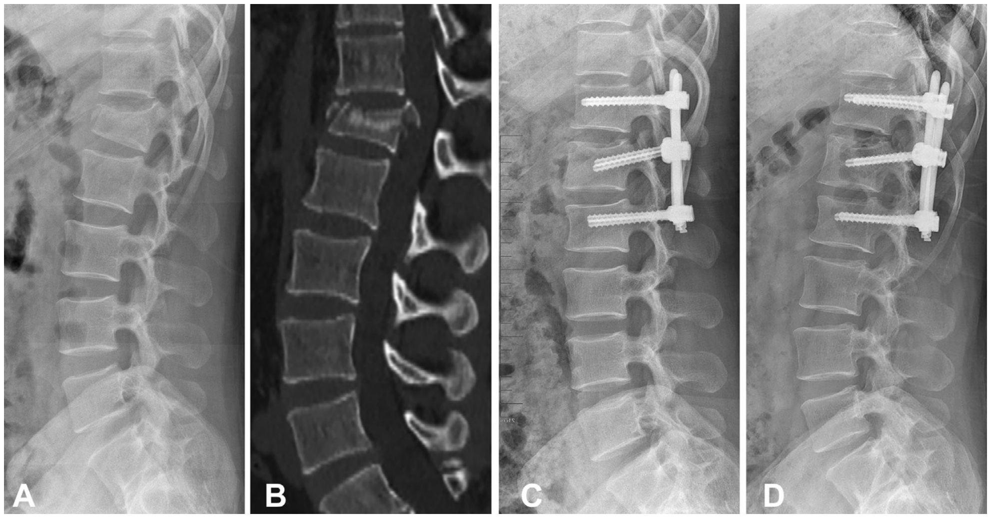

Figure 3. A 30-year-old man with a L1 burst fracture (AO classification: A3, TLICS: 5). (A and B) The lateral radiograph and sagittal computed tomography images obtained before surgery. (C) The patient was treated by MIS. (D) Plain radiograph obtained at the 1-year follow-up. TLICS, Thoracolumbar injury classification and severity scores; MIS, minimally invasive surgery.

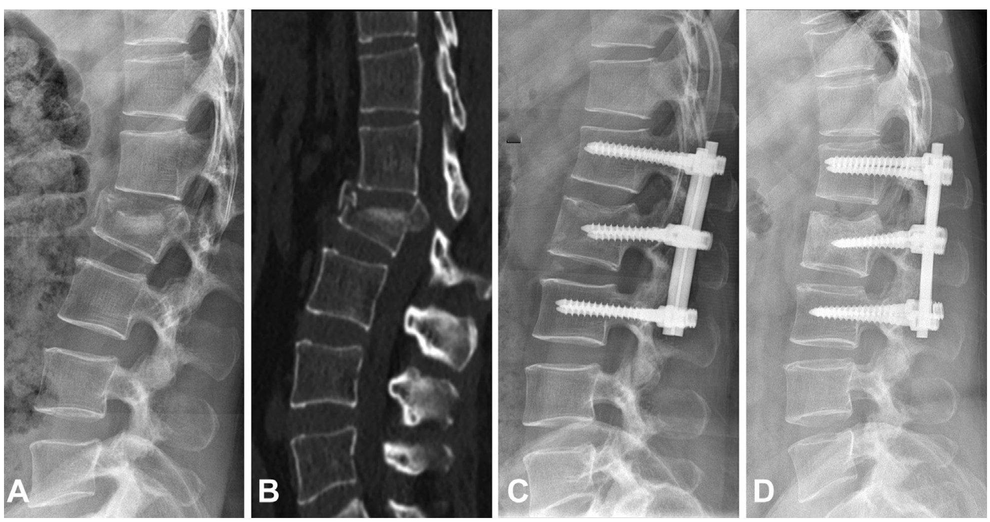

Figure 4. A 49-year-old woman with a L2 burst fracture (AO classification: A3, TLICS: 5). (A and B) The lateral radiograph and sagittal, axial computed tomography images obtained before surgery. (C) The patient was treated by OPPF. (D) Plain radiograph obtained at the 1-year follow-up. TLICS, Thoracolumbar injury classification and severity scores; OPPF, open posterior pedicle fixation.

open versus percutaneous pedicle screw fixation for TBFs. However, the percutaneous pedicle screws in the aforemetioned studies were inserted under 2D fluoroscopic navigation, which could result in significant occupational radiation exposure, conflicting accuracy of PPS insertion, rib cage interference, bulky apparatus, and increased operating time [6,31].

O-arm navigation is an intraoperative 3D CT image–guided navigation which has been proven to offer several advantages including significantly higher accuracy of pedicle screw position, minimal to no radiation exposure, and potentially a short registration time [32]. In general, percutaneous pedicle screw fixation assisted with O-arm navigation is a safe alternative for TBFs. Therefore, the purpose of this article is to compare the surgical outcomes between open and percutaneous short-segment pedicle screw fixation assisted with O-arm navigation in the treatment of TBFs.

In accordance with our results, the patients in MIS group had significantly less intraoperative blood loss and hospitalisation stay. As for clinical outcomes, the VAS and ODI score in both groups significantly improved after surgery, and what is more, the MIS group performed better 1 week after surgery in our study. Besides, radiological parameters

Table 6
Accuracy of pedicle screw placement between two groups.

Group	No. of pedicle screws	Grade 0	Grade 1	Grade 2	Grade 3	Accuracy rate (Grade 0&1)	Malplacement rate (Grade 2&3)
MIS	180	158	18	3	1	176 (97.8%)	4 (2.2%)
OPPF	172	121	14	27	10	135 (78.5%)	37 (21.5%)
p						<0.001*	<0.001*

*Statistically significant ($p < 0.05$); MIS = minimally invasive surgery; OPPF = open posterior pedicle fixation.

in our study were analysed and did not deviate from that of previous studies. In terms of all monitored radiological parameters, significant corrections were obtained after immediate surgery, and no significant differences were observed between the two groups. During follow-up, no significant degradation was noted in any monitored radiological parameters, besides, the mean corrections were well maintained in both groups. This suggested that there was no significant difference in the recovery of thoracolumbar fracture and no greater change in the thoracolumbar anatomical structure, which was beneficial to its function restoration.

Percutaneous pedicle screw fixation can avoid muscle traction and detachment, reduce muscle damage, and meet minimally invasive standard. With the O-arm navigation, real-time intraoperative images and placing trajectory of screws are visible, so MIS group becomes more accurate and safe. In our study, the MIS group showed higher accuracy rate of pedicle screw position than OPPF group (97.8% vs. 78.5%). The high accuracy in the MIS group was in conformity with that we reported previously in the open pedicle fixation using O-arm navigation technique [33]. Furthermore, radiation exposure under navigation in spinal surgery should be undoubtedly of great concern. A prospective clinical research assessed intraoperative radiation exposure during lumbar fusion surgeries with O-arm imaging system, and the radiation exposure is proved to be minimal to the surgical staff [11]. Grelat et al [12] compared the radiation exposure to the surgeon between O-arm and fluoroscopy during a minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF), suggesting that O-arm navigation system is safe and can significantly reduce the radiation exposure to surgeon. In our study, the surgeon and operating room staff could leave the operating room temporarily while O-arm scanning, so the radiation exposure to them was significantly reduced during MIS operation. However, the radiation exposure to the patient may increase [34,35], but it was no harmful, as the average radiation exposure is less than a single lumbar CT scan, and it could be compensated by avoiding immediate postoperative CT scans. Percutaneous pedicle screw fixation is a more technically demanding and time-consuming technique which needs certain experience. This technique has an obvious learning curve, and the longer operative time for MIS proved it. However, once such the initial learning curve is overcome, this technique could be an effective and reliable option for the surgical treatment of TBFs.

MIS for TBFs should only be performed in carefully selected patients. TBFs which do not require significant reduction and decompression are suitable for MIS. Such fractures include those Type A1, A2, particular A3 fractures, and those with TLICS score$<$5 [30]. When posterior ligament structures were injured but without subluxation or dislocation, these patients may also be amenable for MIS. We recommend routine use of polyaxial pedicle screws at the level of the fractured vertebra for A3 fracture in MIS surgery. Owing to limited extension of percutaneous pedicle screws, the polyaxial screws of the injured vertebra can push the fracture vertebra forward which is beneficial for fracture reduction. In addition, the use of intermediate screws has been proven to offer improved biomechanical stability, decrease correction loss, provide a better pull-out strength, and thus theoretically reduce the rate of instrumentation failure [36]. Besides, based on our experience for MIS surgery, it is recommended to use monoaxial pedicle screws at the adjacent vertebra, preflexed rods on the basis of the normal spinal sagittal curvature, good hyperextension prone position, vigorous pressing at the fractured level in combination with distraction tool to obtain good reduction and kyphosis correction.

Our study focused on the use of O-arm navigation–assisted percutaneous pedicle instrumentation for treating TBFs. The advantage of MIS group in our study lies in the use of O-arm navigation and percutaneous pedicle screw technique, which guaranteeing the high accuracy of screw placement, protecting staff from radiation exposure, and offering benefits of minimal invasive technique. Meanwhile, there are some limitations in our study. First, our study was a retrospective study which might have selection bias. Second, the number of included patients was small and the follow-up period was limited. Third, we did not have the data on radiation dose for both study groups, but the way we used C-arm and O-arm was similar to that used in previously published studies measuring radiation exposure [11,37]. Future prospective randomised studies with larger study sample size, longer follow-up period and more research details are warranted.

Conclusion

In summary, O-arm navigation–assisted percutaneous pedicle instrumentation represents an alternative in the treatment of preselected TBFs. We can confirm that this technique is a viable alternative for AO Type A3 TBFs. Compared with the open approach, the outcomes of MIS technique are promising with significant reduction in blood loss, hospitalisation duration, VAS score, and ODI score 1 week after surgery. With the help of O-arm navigation, higher accuracy of pedicle screw placement could be achieved during MIS technique. Clinical and radiological results of MIS technique are quite the same as those obtained in the open group after a 1-year follow-up. But long-term results should be studied in other well-designed studies before routine use of the novel technique.

Conflict of Interest Statement

The authors have no conflicts of interest to disclose in relation to this article.

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Ethical approval

This study received approval from the Ethics Committee and Institutional Review Board of the first-affiliated hospital of the Soochow University. Informed consent was obtained from all patients.

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