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The Superiority of Intraoperative O-arm Navigation-assisted Surgery in Instrumenting Extremely Small Thoracic Pedicles of Adolescent Idiopathic Scoliosis

A Case-Control Study

Zhen Liu, PhD, Mengran Jin, PhD, Yong Qiu, MD, Huang Yan, PhD, Xiao Han, PhD, and Zezhang Zhu, MD

Abstract: To investigate the accuracy of O-arm navigation-assisted screw insertion in extremely small thoracic pedicles and to compare it with free-hand pedicle screw insertion in adolescent idiopathic scoliosis (AIS).

A total of 344 pedicle screws were inserted in apical region (defined as 2 vertebrae above and below the apex each) of 46 AIS patients (age range 13–18 years) with O-arm navigation and 712 screws were inserted in 92 AIS patients (age range 11–17 years) with free-hand technique. According to the narrowest diameter orthogonal to the long axis of the pedicle on a trajectory entering the vertebral body on preoperative computed tomography, the pedicles were classified into large (>3 mm) and small (\leq 3 mm) subgroups. Furthermore, a subset of extremely small pedicles (\leq 2 mm in the narrowest diameter) was specifically discussed. Screw accuracy was categorized as grade 0: no perforation, grade 1: perforation by less than 2 mm, grade 2: perforation by 2 to 4 mm, grade 3: perforation over 4 mm.

In the O-arm group, the mean thoracic pedicle diameters were 2.23 mm (range 0.7-2.9 mm) and 3.48 mm (3.1-7.1 mm) for small and large pedicles, respectively. In the free-hand group, the small and large thoracic pedicle diameters were 2.42 mm (range 0.6-2.9 mm) and 3.75 mm (3.1-6.9 mm), respectively. The overall accuracies of screw insertion in large and small thoracic pedicles (grade 0, 1) were significantly higher in O-arm group (large: 93.8%, 210/224, small: 91.7%, 110/120) than those of free-hand group (large: 84.9%, 353/416, small: 78.4%, 232/296) (P < 0.05). Importantly, the overall accuracy of screw placement in extremely small pedicles was significantly higher in the O-arm group (84.3%, 48/57) compared with 62.7% (79/126) in free-hand group (P < 0.05), and the incidence of medial perforation was

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From the Department of Spine Surgery, Drum Tower Hospital of Nanjing University Medical School, Nanjing, China.

MJ and ZL contributed equally to this work.

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significantly lower in O-arm group (11.1%, 1/9) compared with 17.0% (8/47) in free-hand group (P < 0.05).

The O-arm intraoperative navigation system should be acknowledged for its superiority in scoliosis surgery, since it permits more accurate and safer instrumentation for AIS patients with small and extremely small thoracic pedicles.

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Abbreviations: AIS = aadolescent idiopathic scoliosis, CT = computed tomography.

INTRODUCTION

Thoracic pedicle screw fixation has been used for correction of adolescent idiopathic scoliosis (AIS).¹ However, instrumentation on relatively small thoracic pedicles in AIS patients is quite challenging, with high risk of pedicle screw violation, which is more pronounced around middle-thoracic spine.² Moreover, the extremely narrow concave pedicles, combined with the nearby neurovascular structures, increase the risk of concomitant complications significantly.³ It has been documented in the literature that the malpositioning rate of pedicle screw insertion in thoracic spine can be doubled than that in the lumbosacral spine.⁴

The O-arm navigation system is the latest intraoperative imaging platform providing real-time multidimensional images optimized for surgeries. Several studies have documented its high accuracy of pedicle screw placement in lumbar spine.⁵⁻⁸ However, there were scattered studies concerning the utilization of Oarm navigation in screw insertion in thoracic pedicles, particularly in AIS patients, in which the concave pedicles were significantly narrower and more dysplastic than the contralateral convex pedicles at thoracic spine due to serious apical rotation.9 Recently, Jeswani et al³ reported a 100% accuracy of O-arm navigation-based pedicle screw placement in thoracic spine, which comprised only 97 pedicle screws. Also, Jin et al¹⁰ reported a 79% (73/92) accuracy of with-navigation thoracic pedicle screw placement in neurofibromatosis type I-associated scoliosis. However, the pedicle diameters were not specified in this study. Conclusions from these studies with such small subject sample may fail to accurately represent the actual accuracy of O-armbased pedicle screw placement in AIS patients.

Thus, the O-arm navigation-based thoracic pedicle screw placement in AIS patients was retrospectively investigated with a larger volume of patients to document the efficacy of O-arm navigation-assisted screw insertion in small and extremely small pedicles and to compare it with traditional free-hand technique.

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Correspondence: Zezhang Zhu, Department of Spine Surgery, Drum Tower Hospital of Nanjing University Medical School, Zhongshan Road No. 321, Nanjing 210008, China (e-mail: zhuzezhang@126.com).

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METHODS

Patients

After approved from the Institutional Review Board, a retrospective study was conducted to evaluate the accuracy of thoracic pedicle screw insertion in AIS patients in a single scoliosis center between January 2014 and February 2015.

Patients were selected on the basis of the following inclusion criteria: diagnosed as AIS with Lenke type 1, 2, and 3 curve by 2 different senior surgeons¹¹; curve severity over 70 degrees, and pedicle screws inserted by using O-arm navigation system; complete preoperative and postoperative computed tomography (CT) images; pedicle screws inserted at apical region (2 vertebrate above and below the apex [within] each). Revision surgeries were excluded from this study. Therefore, a subset of 46 AIS patients (12 males and 34 females) with 344 thoracic pedicle screws was finally enrolled in the present study. The mean age of patients was 15.6 years (range 13–18 years), and the average preoperative major thoracic curve magnitudes was 87.1 \pm 18.4°. The patients' curves were classified as Lenke type 1 in 34 patients, Lenke type 2 in 8 patients, and Lenke type 3 in 4 patients.

We also reviewed from our scoliosis database and thoracic AIS patients who received pedicle screw placement in thoracic spine by free-hand technique during the same period. These patients with free-hand technique and with O-arm navigation were matched for age, curve pattern, and magnitude, and then matched at a 2:1 ratio. In total, 92 AIS patients (28 males and 64 females) with 712 screws inserted by free-hand technique were selected as the control group. The mean age of patients was 14.0 years (range 11–17 years), and the average preoperative major thoracic curve magnitude was $79.8 \pm 15.3^{\circ}$. The patients'

curves were classified as Lenke type 1 in 68 patients, Lenke type 2 in 16 patients, and Lenke type 3 in 8 patients (Table 1).

The pedicle screws were categorized into 2 groups according to the diameter of pedicle in both groups: the diameter of the pedicle was graded by the criteria described by Jeswani et al.³ Those with >3 mm in the narrowest diameter perpendicular to the long axis of the pedicle on a trajectory entering the vertebral body on preoperative CT were identified as large pedicles. Small pedicles were those with \leq 3 mm in the narrowest diameter perpendicular to the long axis of the pedicle on a trajectory entering the vertebral body on preoperative CT. Furthermore, a subset of "extremely small" pedicles with \leq 2 mm in the narrowest diameter was also analyzed (Figure 1).

O-arm Navigation-assisted Pedicle Screw Insertion

All patients were positioned prone on a Jackson radiolucent spinal table (Mizuho OSI, Union City, CA). Intraoperative neurological monitoring was used for all patients. A longitudinal midline incision exposed the thoracic levels to be instrumented; then a stealth navigation tracker was placed on a spinous process after the detachment of the surrounding musculature. The tracker was placed as close as possible to the instrumented segment. The O-arm was then brought into the surgical filed. Three-dimentional intraoperative images of the instrumented region were automatically reformed and visualized on O-arm viewing station and then transferred to the Stealth Station Treon plus system (Medtronic). Since the images are obtained after all soft-tissue dissection with exposure of bony anatomy, only a 1-time instrumentation verification is needed before instrumentation placement. Obtaining the CT scan

	O-arm	Free-hand	Р
No. of patients	46	92	
Sex (M/F)	12M/34F	28M/64F	NS
Age, years	15.6 ± 3.4	14.0 ± 2.2	NS
Curve type			NS
Lenke 1	34	68	
Lenke 2	8	16	
Lenke 3	4	8	
Initial curve, °	87.1 ± 18.4	79.8 ± 15.3	0.97
Total no. of screws	344	712	0.14
Small group	120	296	
Extremely small	57	126	
Large group	224	416	
Pedicle diameter, mm [†]	3.05 ± 0.85	3.19 ± 0.98	0.86
Small group	2.23 ± 0.57	2.42 ± 0.39	0.57
Extremely small	1.79 ± 0.61	1.83 ± 0.72	0.79
Large group	3.48 ± 0.60	3.75 ± 0.84	0.62
Upper-thoracic pedicle (T1-4) diameter, mm [†]	2.86 ± 0.52	2.78 ± 0.67	0.73
Mid-thoracic pedicle $(T5-8)$ diameter, mm [†]	2.54 ± 0.71	2.61 ± 0.34	0.81
Low-thoracic pedicle (T9–12) diameter, mm [†]	3.21 ± 0.94	3.38 ± 1.07	0.84
• • • • • •	$P_1 = 0.034^*$	$P_2 = 0.029^*$	

TABLE 1. Clinical and Radiographic Data of All Patients in Both Groups

P1: the pedicle diameters of different regions were compared in O-arm group.

P₂: the pedicle diameters of different regions were compared in free-hand group.

NS = statistical nonsignificance.

*Statistically significant if P < 0.05.

[†]The diameters of the two groups were compared.

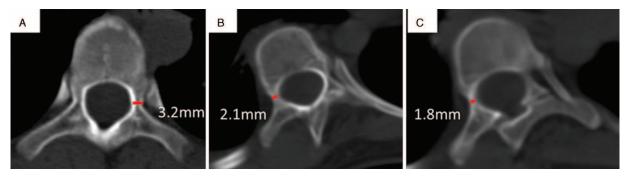


FIGURE 1. Typical "large" pedicle (>3 mm in diameter) (A), and "small" pedicle (≤3 mm in diameter) (B), and "extremely small" pedicle (≤2 mm in diameter) (C).

intraoperatively with the StealthStation reference tracker affixed avoids any further landmark registration. Intraoperative planning of screw placement was based on StealthStation neuronavigation software, including selection of the screw diameter, length, and trajectory based on specific pedicle diameter and relevant anatomy. In the present series, all screws were scheduled for a purely intrapedicular approach if possible. The screws were inserted under the real-time guidance of O-arm system. Once all screws were inserted, a second intraoperative CT scan was not performed out of consideration of radiation exposure.¹⁰

Free-Hand Pedicle Screw Insertion Technique

The screws were inserted based on the conventional technique of Roy-Camille et al,¹² including identifying the entry point, opening with the awl, drilling of the pedicle, and probing of the drill canal. The pedicle screw would not be inserted when the pedicle cortex was violated. Only in the absence of any violation, pedicle screw with suitable length and diameter would be inserted.¹⁰ After all screws were inserted, the pedicle screw position was checked by the C-arm (anteroposterior and lateral).

Postoperative Accuracy Assessment of Pedicle Screw

The accuracy of pedicle screw placement was evaluated based on postoperative axial CT scans in all cases. According to Neo et al's¹³ classification, the accuracy of pedicle screw placement was graded. Screws that were completely within the pedicle were classified as grade 0; screws that were penetrating less than 2 mm were classified as grade 1; screws that

were penetrating between 2 and 4 mm were classified as grade 2; and screws that were penetrating over 4 mm were classified as grade 3 (Figure 2).

Statistical Analysis

Statistical analysis was done using SPSS software (version 17.0.1). The following summary statistics were calculated: means and standard deviation for continuous variables, and frequencies and percentages for categorical variables, and the categorical variables were evaluated using chi-square and Fisher exact tests. A *P* value <0.05 was statistically significant.

RESULTS

Accuracy Assessment of Screw Insertion in Small/Large Pedicles

The overall accuracy of screw insertion in small thoracic pedicles (grade 0, 1) was significantly higher in O-arm group (91.7%, 110/120) compared with that in free-hand group (78.4%, 232/296) (P = 0.02) (Table 2). Similarly, the accuracy of screw insertion in large pedicles was also higher in the O-arm group (93.8%, 210/224) than that in the free-hand group (84.9%, 353/416) (P = 0.03). There was no statistically significant difference between the accuracies of O-arm navigation-assisted instrumentation in small and large pedicles (91.7% vs 93.8%; P = 0.28). In contrast, the accuracy of screw insertion was significantly higher in large pedicles than that of small pedicles in the free-hand group (84.9% vs 78.4%; P = 0.04). Furthermore, the incidence of lateral perforation was higher than that of medial and anterior perforation in both the O-arm group (lateral: 52.4% vs medial: 19.0%, anterior: 28.6%;

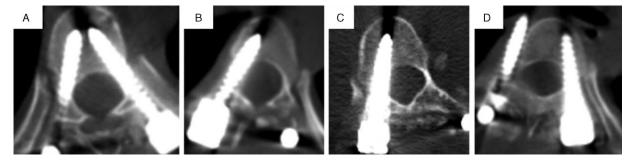


FIGURE 2. Postoperative CT assessment of the pedicle screw position. A, Grade 0: no perforation and the screw was completely contained in the pedicle. B, Grade 1: perforations < 2 mm. C, Grade 2: perforations ≥ 2 but < 4 mm. C, Grade 3: perforations ≥ 4 mm, grades 2 and 3 representing perforation. CT = computed tomography.

		Grade 1		Grade 2			Grade 3				
	Grade 0	Anterior	Lateral	Medial	Anterior	Lateral	Medial	Anterior	Lateral	Medial	Tota
O-arm											
Small											
T1-T4	9		2	1			2	1			14
T5-T8	66	1	9	5	1	1	1		1		88
T9-T12	10	1	4	2	1	1			1		18
Total	85	2	15	8	2	2	3	1	2		120
Per cent	70.8%	20.9%	5.8%	2.5%							
Large											
T1-T4	19	1	3	2	1	1			1	1	29
T5-T8	127	3	21	6	1	2	1	1	1	1	164
T9-T12	22	2	3	1		1	1		1		31
Total	168	6	27	9	2	4	2	1	3	2	224
Per cent	75.0%	18.8%	3.6%	2.6%							
Free-hand											
Small											
T1-T4	31	1	2	4	1	3	3	1	5	1	52
T5-T8	112	5	20	11	3	9	6	1	8	4	179
T9-T12	39	1	4	2	3	5	3		5	3	65
Total	182	7	26	17	7	17	12	2	18	8	296
Per cent	61.5%	16.9%	12.2%	9.4%							
Large											
T1-T4	33	2	8	5	1	4	3	1	3	2	62
T5-T8	196	3	31	17	2	10	5	1	8	4	277
T9-T12	41	3	8	6	3	4	3		5	4	77
Total	270	8	47	28	6	18	11	2	16	10	416
Per cent	64.9%	20.0%	8.4%	6.7%							

TABLE 2. Accuracy of	Pedicle Screw F	Placement in S	Small and Large	Pedicles in Both Groups
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P < 0.001) and the free-hand group (lateral: 54.3% vs medial: 32.2%, anterior: 13.5%; P < 0.001). Particularly, the frequency of medial perforation decreased markedly by using O-arm navigation than that of free-hand technique (19.0% vs 32.2%; P = 0.02).

Accuracy Assessment of Screw Insertion in Extremely Small Pedicles

The distribution of "extremely small" pedicles was shown in Table 3. The overall accuracy of pedicle screw insertion (grade 0, 1) was significantly higher in the O-arm group (84.3 %, 48/57) compared with 62.7% (79/126) of the free-hand group (P < 0.001) (Figure 3), and the incidence of medial perforation was significantly lower in the O-arm group (11.1%, 1/9) compared with 17.0% (8/47) of the free-hand group (P = 0.03), whereas lateral perforation occurred most frequently in both groups.

Screw-Related Complications

No screw was revised, and no screw-related vascular or neurological complication was observed intraoperatively and postoperatively.

DISCUSSION

As a general consensus, inserting pedicle screws in thoracic spine can be particularly challenging in AIS patients, since the pedicle width in the thoracic spine is relatively small.^{2,14} Moreover, pedicles on the concavity of a typical AIS curve were found to be significantly narrow, which can be aggravated in cases with severe axial rotation of the apical vertebrae.^{15–18} In a recent study conducted by Sarlak et al,¹⁹ they reported 29.9% (54/185) of thoracic pedicle screw misplacement by free-hand technique in AIS patients, 45% of which showed significant risk to nearby neurovascular structures. Thus, the importance of accurate screw placement in thoracic pedicles has been highlighted on the base of increased complication rate in cases where the screws were significantly misplaced.

Over the past 2 decades, the accuracy of pedicle screw placement in thoracic spine has been improved with different guidance methods.^{20–22} The O-arm-based navigation system is the latest intraoperative image platform, which generates high-resolution CT images in the coronal, sagittal, and axial planes. Recently, several studies have exhibited the advantages of O-arm-based pedicle screw insertion in lumbar spine surgery, but there were scattered studies illustrating the potential benefits of this new technique in thoracic spine surgery.^{5,6} Jin et al¹⁰ reported 79% accuracy of pedicle screw placement in 13 patients with neurofibromatosis type I. However, the patient cohort was quite small and the pedicle width was not specified in this landmark study.

Several historical studies have reported a relatively low accuracy rate in thoracic pedicle placement between 70% and 75%, and 8% to 23% of the misplaced screws breached the medial cortex.^{23,24} According to Lekovic et al,²⁵ the rate of unintended perforations was found to be dependent on pedicle diameter. Particularly, 50% of pedicle perforation was noted in middle thoracic pedicles with diameters less than 4 mm. In

		Grade 1			Grade 2			Grade 3			
	Grade 0	Anterior	Lateral	Medial	Anterior	Lateral	Medial	Anterior	Lateral	Medial	Tota
O-arm											
T1-T4	4		1	1		2			1		9
T5-T8	29	1	5	2	1	2	1		1		42
T9-T12	3	1	1			1					6
Total	36	2	7	3	1	5	1	0	2	0	57
Percentage	63.2%	21.1%	12.3%	3.4%							
Free-hand											
T1-T4	9	1	2	1	2	2	1	1	2		21
T5-T8	28	4	16	7	3	15	5	3	4	1	86
T9-T12	6	1	3	1	2	3	1	1	1		19
Total	43	6	21	9	7	20	7	5	7	1	126
Percentage	34.1%	28.6%	27.0%	10.3%							

TABLE 3. Accuracy of Screw Placement in Ext	treme Pedicles in Both Groups
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the present study, we reported 91.7% (110/120) and 93.8% (210/224) satisfactory screw placement within small and large thoracic pedicles, using O-arm intraoperative navigation. We also showed 84.9% and 78.4% satisfactory screw placement in large and small thoracic pedicles, respectively, using conventional fluoroscopy-based free-hand technique. In line with expectation, the accuracies of O-arm navigation-based thoracic pedicle screw placement were significantly higher than those of free-hand technique in both large and small groups. Several retrospective studies have also revealed higher pedicle screw accuracy using intraoperative CT-based navi-gation versus traditional techniques.²⁶ On the contrary, it is notable that the accuracy of O-arm navigation-based screw placement was not influenced by the pedicle diameter in the present study, but the accuracy of screw placement was positively correlated with the pedicle diameter in the free-hand group.

Furthermore, for AIS patients, the superiority of intraoperative navigation was pronounced for "extremely small" thoracic pedicle, since the accuracy rate of pedicle screw placement in the O-arm group was significantly better than that of the free-hand group (84.3% vs 62.7%). Meanwhile, the incidence of medial violation was significantly decreased in the O-arm group (11.1% vs 17.0%). A recent meta-analysis by Gelalis et al²⁷ evaluated the position of pedicle screw perforation. They reported that a range from 32% to 87% was found for medial perforation using free-hand technique. In patients where CT navigation was used, the proportion of screws medially perforated was significantly decreased, ranging from 8% to 29%. According to the results stated above, we can speculate that O-arm navigation system ensures the pedicle screw insertion more accurate and safer than traditional freehand technique in AIS surgery, especially in cases with extremely small thoracic pedicles. Therefore, this navigation technique deserted to be recommended for routine use in scoliosis surgery.

The prior study by our team had confirmed that the radiation exposure in surgeons and patients could be significantly decreased by using O-arm navigation compared with fluoroscopic guidance.¹⁰ The radiation dose of 1 intraoperative

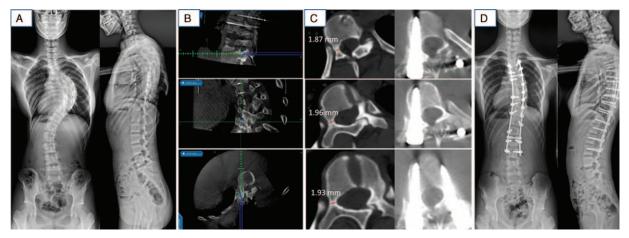


FIGURE 3. A 15-year-old female adolescent idiopathic scoliosis (AIS) patient surgically treated with O-arm navigation system. A, The preoperative main thoracic (MT) Cobb angle was 98°. B, The intraoperative snapshot exhibited that the trajectory and screw diameter were determined using 3D intraoperative images. C, The T7-9 pedicles were extremely small on preoperative CT and the pedicle screws were inserted with O-arm navigation system. D, The postoperative x-rays showed satisfactory correction.

3D scan was approximately 4.2 mSv (range 2.8-7.1 mSv), whereas the radiation dose could be 6 mSv per case for fluoroscopy exposure. Moreover, the navigation procedure was not quite time-consuming, since all the setting procedures were performed by a radiologic technologist while the surgery was in progress simultaneously.

However, the high expense of O-arm navigation is one of the disadvantages, which is more expensive than any other navigation system, not to mention C-arm fluoroscopy. Considering this drawback, it is reasonable that using this navigation system in inserting pedicle screws in cases with mild curves is cost-ineffective. However, inserting pedicle screws in cases with severe rotated and rigid curves is surgically demanding and risky. It would make surgeons and patients be exposed to radiation more frequently owing to anatomical difficulties such as narrow pedicle diameter and the vicinity of vital structures. Thus, it is worthwhile to use O-arm navigation in severe cases, or in the situation of anatomical variation.

This study has some unavoidable limitations such as single-center and its retrospective nature with small cohort. Since this was the first study which stressed the superiorities of O-arm navigation system in instrumenting small thoracic pedicles than conventional free-hand technique, especially in "extremely small" cases, a large prospective study comparing the accuracy of navigated versus non-navigated techniques would better demonstrate the advantages of O-arm navigation in small thoracic pedicles and identify the potential risk factors for navigation-based pedicle screw placement.

CONCLUSIONS

We reported 91.7% and 93.8% satisfactory screw insertion within small and large thoracic pedicles by using O-arm navigation system. O-arm intraoperative navigation allowed for safe and accurate insertion of pedicle screws in AIS patients with small and extremely small thoracic pedicles. Therefore, this new intraoperative navigation system deserved to be widespread used in scoliosis surgery in terms of instrumentation for small thoracic pedicles.

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