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Accuracy of Robot-Assisted Percutaneous Pedicle Screw Placement for Treatment of Lumbar Spondylolisthesis: A Comparative Cohort Study

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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: With the in-depth development of minimally invasive spine surgery in recent years, robot- and computer-assisted technologies have been increasingly used and successfully applied to spinal surgery.

Material/Methods: We performed a retrospective analysis of 60 patients with grade I or II lumbar spondylolisthesis who underwent minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) from January 2017 to December 2017. A robot-assisted surgical system was used in 30 patients for pedicle screw placement. The other 30 patients underwent fluoroscopy-guided percutaneous pedicle screw placement.

Results: There were 130 screws placed under fluoroscopic guidance, with 26.2% penetration of the pedicle wall. There were 130 screws placed in robotic-assisted surgery, with 6.2% penetration of the pedicle wall. Severe screw deviation (Neo grade III) was identified in 4 screws in the fluoroscopy-guided group, while no severe deviation was noted in the robot-assisted group. In the fluoroscopic group, 15.6% of screws penetrated the superior articular process, and 2.1% screws had severe complications (Babu grade III). However, only 5.1% of screws in the robot-assisted group had severe complications. The mean screw insertion angle was significantly greater in the robot-assisted group than in the fluoroscopy-guided group (23.8±6.1° *vs.* 18.4±7.2°, P=0.017).

Conclusions: Compared to fluoroscopy-guided percutaneous pedicle screw placement, robot-assisted percutaneous pedicle screw placement has the following advantages: greater accuracy, lower incidences of screw penetration of the pedicle wall and invasion of the facet joints, and better screw insertion angle. Combined with MIS-TLIF, robot-assisted percutaneous pedicle screw placement is an effective minimally invasive treatment for lumbar spondylolisthesis.

MeSH Keywords: Orthopedic Fixation Devices • Robotics • Spine • Spondylolisthesis

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Background

Lumbar spondylolisthesis is a common disease that requires spine surgery and manifests as lower back pain and leg pain. Surgical intervention should be considered when systematic and conservative treatments fail. Compared to conventional posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF) has the following advantages: less soft tissue damage, shorter operative time, and lower risk of nerve root and thecal sac injury [1]. However, conventional open TLIF requires extensive stripping of the paravertebral muscles to fully expose the articular and transverse processes. Postoperative scarring in the low back muscles may compromise the short-term or long-term clinical effectiveness. With the development of the percutaneous and trocar techniques, minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) has been gradually introduced for the treatment of single-segment lumbar spondylolisthesis. A meta-analysis showed that MIS-TLIF does not increase the operative time or the incidence of intraoperative and early postoperative complications and has no effect on the long-term fusion rate. In addition, MIS-TLIF can reduce intraoperative blood loss, length of hospital stay, and early postoperative pain, and promote functional recovery. These findings indicate that MIS-TLIF is an ideal surgical approach for the treatment of single-segment lumbar spondylolisthesis [2]. The percutaneous fixation technique can reduce the degree of paravertebral muscle mass stripping for screw placement. If combined with MIS-TLIF, the fixation technique can further reduce iatrogenic injury of the lumbar and back muscles. However, studies have shown that invasion of the superior segment facet joint is more common in percutaneous screw placement than in open surgery [3,4]. Biomechanical tests, finite element analysis, and clinical studies have shown that screw invasion of the upper facet joints can change the stress distribution of the facet joints to result in the spontaneous fusion of the facet joints and the occurrence of spondylolisthesis in the adjacent disc(s) and increase the likelihood of revision surgery in the future [5–8]. With the in-depth development of minimally invasive spine surgery in recent years, robot- and computer-assisted technologies have been increasingly used and successfully applied to spinal surgery. We conducted a retrospective analysis of 56 patients with lumbar spondylolisthesis who underwent robot-assisted or fluoroscopy-guided TLIF from January 2017 to December 2017, and compared the accuracy of screw placement and the incidence of superior segment facet joint violation.

Material and Methods

The inclusion criteria consisted of the following: (1) patients with mild to moderate (Meyerding stage I/II) single-segment lumbar spondylolisthesis; (2) patients with low back pain or severe leg pain with a visual analogue scale (VAS) score >5 who had no response to 3-month standardized conservative treatment and who experienced significantly persistent symptoms that severely affected their daily life and work; (3) preoperative computed tomography (CT) and magnetic resonance imaging (MRI) showed disc herniation or lateral recess and foraminal stenosis caused by facet joint inclination, hyperplasia of the soft tissues surrounding the isthmus, and osteophytosis; and (4) no evidence of cauda equina syndrome before surgery. The exclusion criteria were as follows: (1) patients with a history of lumbar surgery; (2) patients with lumbar infections, tumors, or loss of stability in the upper vertebral body of the segment with spondylolisthesis; and (3) patients with degenerative scoliosis or severe kyphosis. A total of 56 patients with lumbar spondylolisthesis met the inclusion criteria and were included in the study. The first 30 cases were assigned to the robot-assisted group and the next 30 cases were included into the fluoroscopy-guided group. The demographics and treated vertebral segments of the patients are shown in Table 1. This study was approved by the Ethics Committee of Xi'an Honghui Hospital (IRB number 20170203), and all patients signed an informed consent form.

Table 1. Summary of the preoperative demographics of patients undergoing minimally invasive PPS placement with intraoperative Robot or Fluoroscopy.

	Intraoperative technique	
	Robot (n=30)	Fluoroscopy (n=30)
Age (years)*	54.1±7.7	55.1±8.1
Gender (Female/Male)	14/16	12/18
BMI (kg/m^2)*	23.5±1.9	23.2±1.7
Surgical level		
L3–L4	5	4
L4–L5	16	15
L5–S1	9	11
Primary diagnosis		
Degenerated spondylolisthesis	23	22
Isthmic spondylolisthesis	7	8
Meyerding Classification		
I°	21	20
II°	9	10

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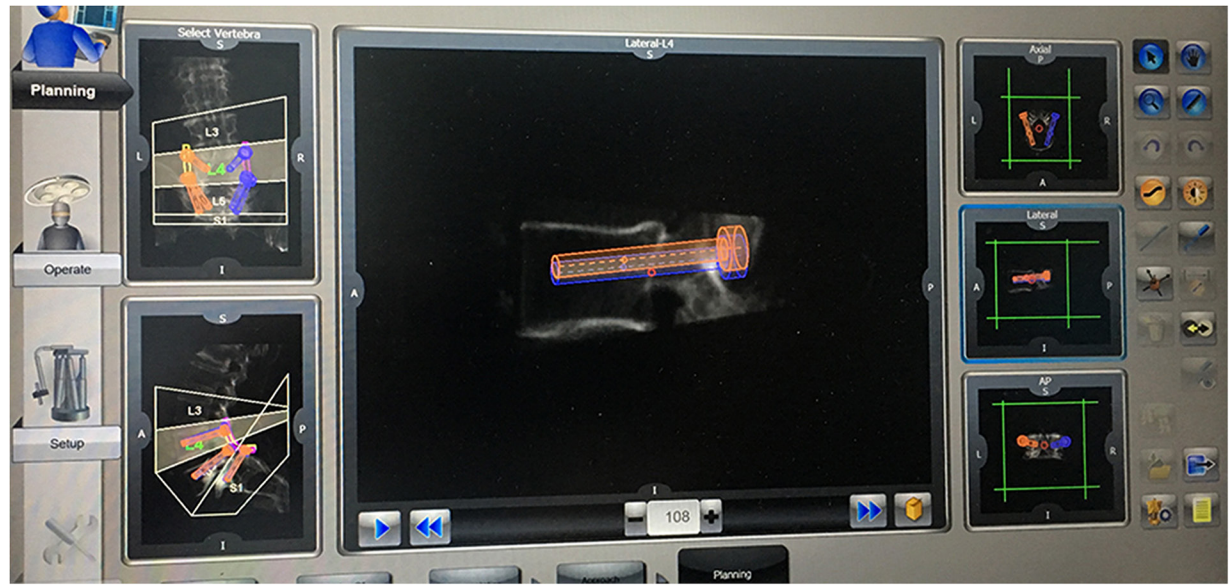

Figure 1. Each vertebral body was isolated in the preoperative plan.

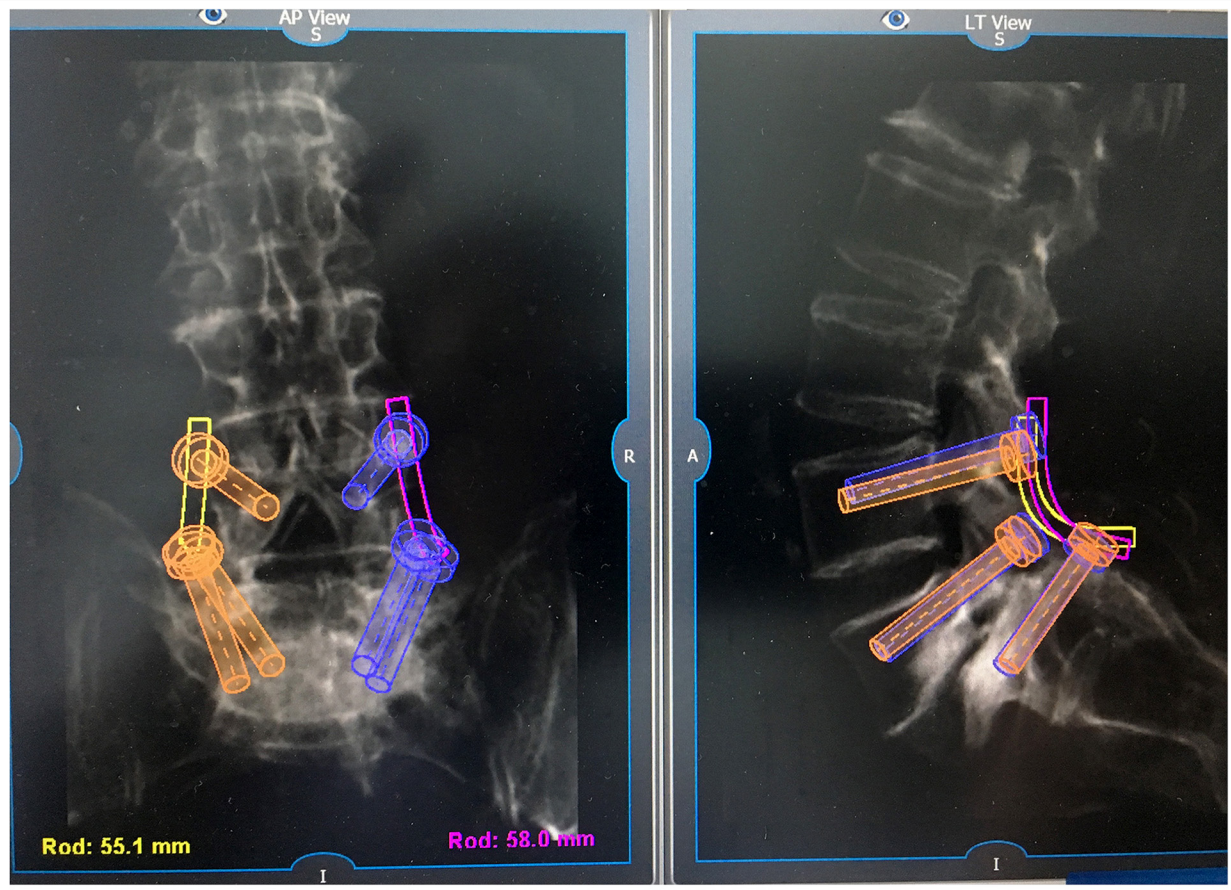

Figure 2. The appropriate screw length and diameter according to the ideal entry point and insertion angle of the screw was planned preoperatively.

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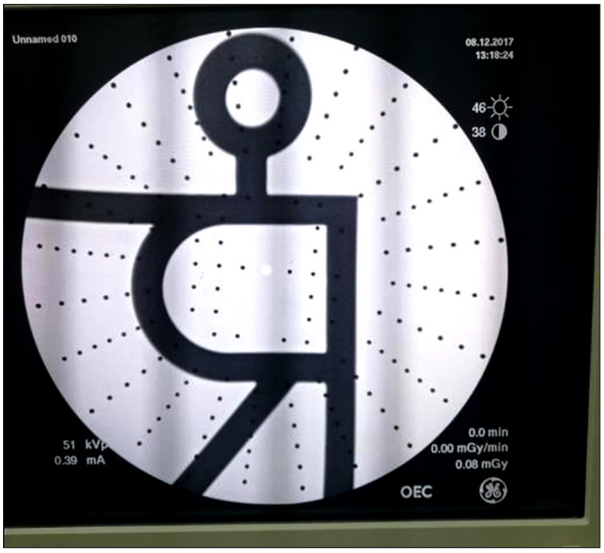

Figure 3. The position mark was placed.

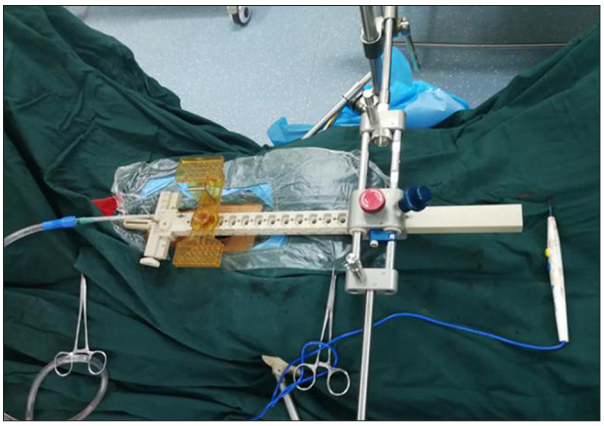

Figure 4. The appropriate working platform was selected and installed.

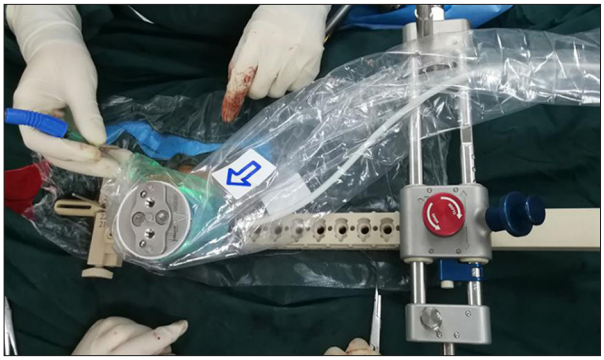

Figure 5. After completing calibration, robots can automatically adjust according to the planned trajectory of the pedicle screw.

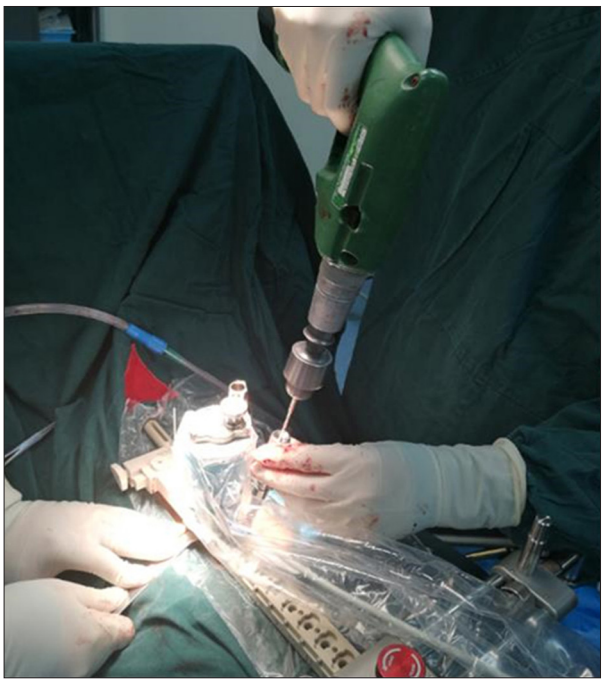

Figure 6. A depth-limited drill was used to tap in the pedicle under the guidance of robotic arm.

Surgical procedure

Robot-assisted group

Preoperative thin-slice CT data were input into a Renaissance workstation for preoperative design. Each vertebral body was isolated and analyzed to determine the appropriate screw length and diameter according to the ideal entry point and insertion angle of the screw (Figures 1, 2). During surgery, the position mark was placed (Figure 3), and the initial baseline images were sent to the Renaissance workstation. The patients underwent general anesthesia with endotracheal intubation. The patients were placed in prone position with the abdomen unsupported and both arms extended and placed on the hand racks. The fluoroscopic area was free of metal objects. Based on the required screw insertion angle, the appropriate working platform was selected, and an individual platform was installed (Figure 4). Anteroposterior and oblique fluoroscopy views were obtained with three-dimensional marks on each patient, and the obtained images were transferred to the console. The system software compares the images with the preoperative CT images using algorithms to register each vertebra, evaluates the error rate, and performs minor adjustments in some screw trajectories. After completing calibration, the robot can automatically adjust according to the planned trajectory of the pedicle screw (Figure 5). Once the robot was fixed in a satisfactory position, the skin incision location was determined with robot assistance. A depth-limited drill was used to tap in the pedicle under the guidance of a robotic arm (Figure 6), and a guidewire was inserted. For patients presenting with unilateral symptoms, decompression was performed on the ipsilateral side. For patients presenting with bilateral symptoms, bilateral decompression was performed via

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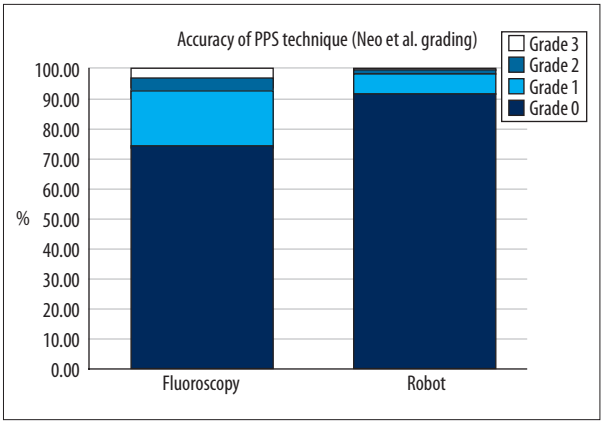

Figure 7. The assessment of positional accuracy was based on the position of the screw and the pedicle wall as described by Neo et al.

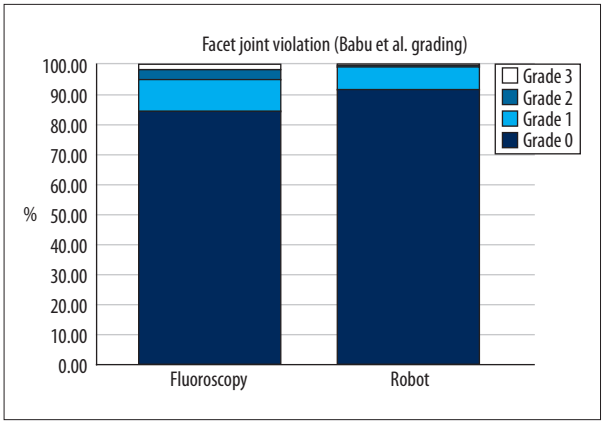

Figure 8. Facet joint violation was evaluated according to the classification system described by Babu et al.

a unilateral port or bilateral ports. The decompression started on the side showing milder symptoms. The vertical incision above the decompression site was extended downward to meet the skin incision under the site. The subcutaneous tissue and muscular fascia were incised in layers. The retractor was inserted after stepwise dilation using a dilator cannula secured to the fixed arm and connected to the cold light source system. The residual muscle tissue in the port was completely removed to visualize the facet joint and the lateral edge of the lamina. Then, the hyperplastic spurs of the facet joint were removed, followed by removal of the unilateral facet joint and part of the lamina. The ligamentum flavum was incised to expose the thecal sac, and then complete decompressions in the central canal, lateral recess, and nerve root canal were performed. The disc was removed, and the cartilage endplate was scraped. On the opposite side of the decompression, the screws were inserted over the guide wire. The connecting rod was installed and secured for reduction of the vertebral body. The bone graft and the fusion cage were placed in the anterior and posterior spaces between the vertebral bodies, respectively, on the decompression side. The screws were placed over the guide wire on the decompression side, and the pre-bent rod was inserted through the skin. The exiting and traversing nerve roots were re-examined to confirm the absence of tension, and then the incision was rinsed and closed. A negative-pressure drainage tube was placed in the incision.

Fluoroscopy-guided group

The patients were placed in a prone position with the abdomen unsupported after successful general anesthesia. A C-arm fluoroscopic machine was used to identify the slipped vertebral body and to determine the segment levels for surgery. The bilateral pedicle projections were marked on the body surface. A 1-cm vertical incision was made in the bilateral pedicle projection area. In the C-arm anteroposterior and lateral views, the bilateral vertebral pedicles of the adjacent upper and lower segments were punctured, and a puncture needle was inserted. After confirming the position of the puncture needle in the anteroposterior and lateral views of the C-arm fluoroscopy, the stylet was removed from the puncture needle, and a guide wire was inserted. Then, the sheath of the puncture needle was withdrawn. The procedures for decompression, reduction, and screw placement were the same as those used in the robot-assisted group.

Postoperative management

The drainage tube was removed at 24 to 48 hours after surgery. The routine use of antibiotics did not exceed 48 hours after surgery. On the 2nd day after surgery, the patient was asked to begin straight leg raise exercises. Follow-up X-ray and CT imaging of the lumbar spine was performed to confirm reduction of the slipped vertebrae and to determine whether the position of the internal fixation was satisfactory. The patients were allowed to start ambulating with a waist support device as appropriate. Vigorous movement of the waist and excessive weight bearing were prohibited. The waist support device was removed 3 months after surgery, and back muscle strengthening training was emphasized.

Imaging assessment

A 64-slice spiral CT study with 1-mm slice thickness was performed in all patients. The angle between each pedicle screw and the perpendicular line (the screw insertion angle) was measured on axial CT images. The assessment of positional accuracy was based primarily on the position of the screw and the pedicle wall, as described by Neo et al. (Figure 7) [9]. Facet joint violation was evaluated according to the classification system described by Babu et al. (Figure 8) [10]. All criteria are shown in Table 2. Two spine surgeons who were not involved in the surgery evaluated the accuracy of the screw

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Table 2. Summary of computed tomography grading criteria.

Grade	Accuracy of PPS technique according to Neo et al. [9]
0	No deviation; the screw was contained in the pedicle
1	Deviation <2 mm (i.e., less than half of the screw diameter)
2	Deviation >2 and <4 mm
3	Deviation >4 mm (i.e., complete deviation)
	Grade Facet joint violation according to Babu et al. [10]
0	Screw not in facet
1	Screw in lateral facet, but not in facet articulation
2	Penetration of facet articulation by screw
3	Screw travels within facet articulation

PPS – percutaneous pedicle screw.

placement and the rate of violation of the superior segment facet joints. In cases of disagreement, the results were discussed with the other authors of this study to determine the final assessment results.

Statistical analysis

The Mann-Whitney test, Fisher's exact test, and the chi-square test were used to determine whether the differences between the 2 groups were statistically significant. SPSS 19.0 software was used for data analysis. A value of $P<0.05$ was considered statistically significant.

Results

The accuracy of screw placement was evaluated according to the classification system (grades I–III) proposed by Neo et al. A total of 130 screws were placed under fluoroscopic guidance, with 26.2%% (34/130) penetration of the pedicle wall. A total of 130 screws were placed in robotic-assisted surgery, with only 6.2% (8/130) penetration of the pedicle wall. Severe screw deviation (Neo grade III) was identified in 4 (3.1%) screws in the fluoroscopy-guided group, while no severe deviation was noted in the robot-assisted group (Figure 9). The difference between these 2 groups was significant (P=0.012). Facet joint violation was evaluated according to the classification system (grades I–III) described by Babu et al. A total of 130 screws

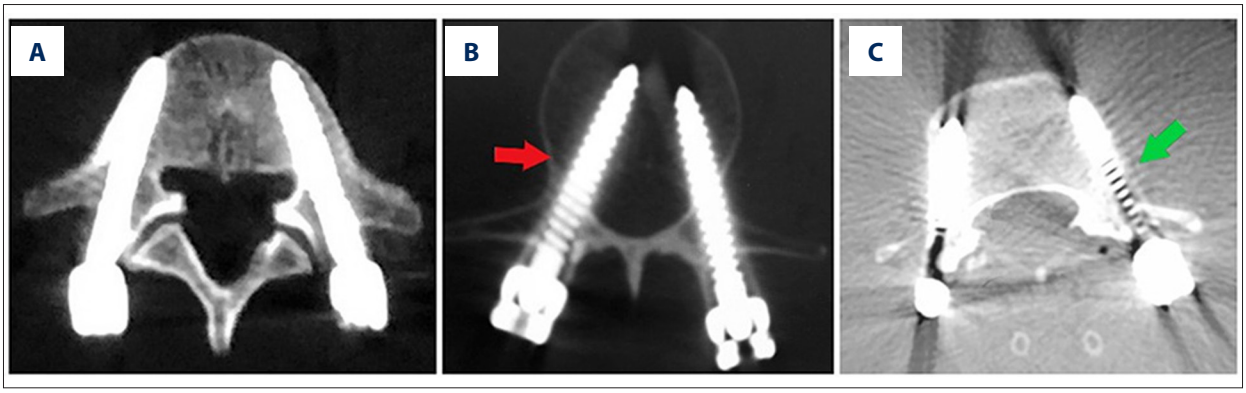

Figure 9. (**A–C**) Graph comparing the accuracy of percutaneous pedicle screw (PPS) placement between robotic assisted and intraoperative fluoroscopy, according to the classification system (Grades I–III) proposed by Neo et al.

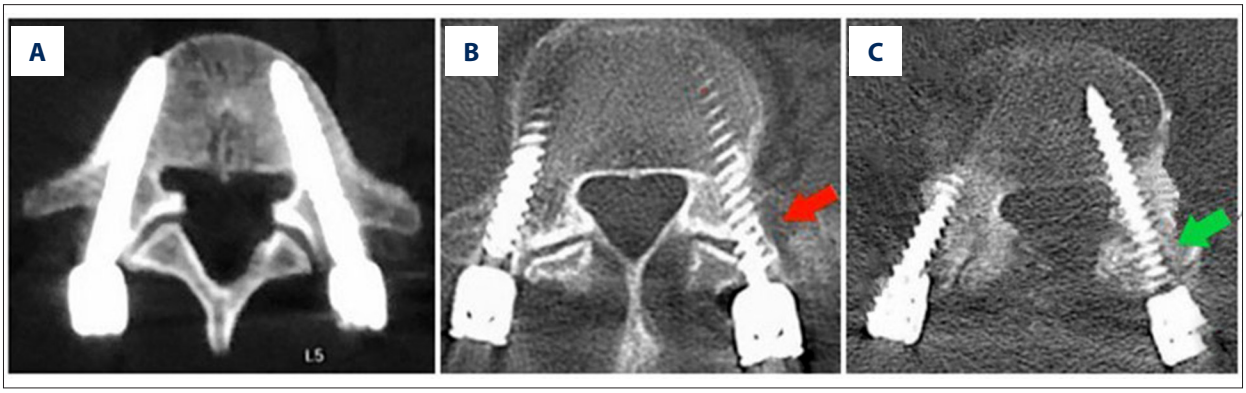

Figure 10. (**A–C**) Graph comparing the facet joint violation of percutaneous pedicle screw (PPS) placement between robotic assistance and intraoperative fluoroscopy, according to the classification system (Grades I–III) described by Babu et al.

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Table 3. Summary of radiographic outcomes by grading criteria.

Grade	Robot	Fluoroscopy
	Accuracy of PPS technique (Neo et al. grading) [9]	
0	122*	96
1	6	24
2	2	6
3	0	4
	Facet joint violation (Babu et al. grading) [10]	
0	93*	81
1	4	10
2	1	3
3	0	2

Values are the number of screws (%). PPS – percutaneous pedicle screw. * p<0.05.

were placed under fluoroscopic guidance. Since partial facetectomy was performed in some facet joints on the decompression side, a total of 96 screws were placed in pedicles with an intact facet joint with 15.6% (15/96) penetration of the superior segment articular process. A total 130 of screws were placed in robotic-assisted surgery. Since partial facetectomy was performed in some facet joints on the decompression side, a total of 98 screws were placed in the pedicle with an intact facet joint, with 5 (5.1%) screws penetrating the superior segment articular process. Notably, 2 patients had severe complications (Babu grade III; i.e., the screw traveled through the facet joint and entered the superior segment inferior articular process) in the fluoroscopy-guided group, but no such complication was reported in the robot-assisted group (Figure 10). The difference between these 2 groups was significant (P=0.021). The results of the accuracy comparison are shown in Table 3. The mean screw insertion angle was significantly greater in the robot-assisted group than in the fluoroscopy-guided group (23.8±6.1° *vs.* 18.4±7.2°, P=0.017).

Discussion

Conventional open TLIF was first reported by Harms et al. [11] in 1982 and was later applied for the treatment of lumbar spondylolisthesis. To minimize the trauma caused by open surgery, reduce perioperative blood loss, and promote rapid recovery of patients, Foley et al. [12] combined the trocar technique with the TLIF technique and introduced MIS-TLIF for the first time in 2002. In MIS-TLIF, a minimally invasive retractor is used to separate and expose the muscle for decompression and transpedicular interbody bone grafting. The advantages of MIS-TLIF in the treatment of lumbar spondylolisthesis include reductions in intraoperative blood loss, postoperative pain, and infection rates [13–15]. In the conventional MIS-TLIF surgery, screw placement is performed under direct vision. In contrast, percutaneous screw placement does not require complete stripping of the muscles attached to the articular process. This can further reduce muscle injury. Therefore, MIS-TLIF combined with percutaneous fixation is an ideal surgical procedure for treatment of mild to moderate (Meyerding I/II) single-segment lumbar spondylolisthesis. For percutaneous screw placement, the trajectory of the screws was determined by the tactile sensation of the puncture needle under multiple fluoroscopic views. In contrast, open surgery provides more three-dimensional and intuitive visualization, which helps to determine the screw entry point. In recent years, percutaneous screw placement has been reported to have a higher risk of superior segment facet joint injury than traditional open screw placement [3,4]. A finite element analysis by Kim et al. suggested that the degree of screw invasion into the intervertebral joints is associated with increased stress of the facet joints and increased pressure of the adjacent discs [7]. Proietti et al. also found that screw invasion of facet joints increased the rate of degeneration of the facet joints at 6–8 months after percutaneous screw placement [8]. A recent study by Wang et al. demonstrated that excessive obesity, preexisting intervertebral disc degeneration, and screw invasion of facet joints confirmed by radiography are risk factors for the occurrence of postoperative adjacent disc degeneration [16]. Because the lumbar spine is physiologically lordotic, and the surrounding muscles and adipose tissue are thicker and the use of percutaneous screw placement requires high-precision incision design; otherwise, it is difficult to obtain an ideal inclination angle of the screw. Most patients with degenerative spondylolisthesis are older and have facet joint hypertrophy and hyperplasia. The needle insertion point may not be accurately identified by tactile sensation alone. Moreover, due to the existence of lumbar lordosis, the ideal anteroposterior view may not be obtained when the intraoperative projection angle in fluoroscopy is poor. Therefore, a poorly designed incision may result in an insufficient insertion angle of the screw and require increasing the insertion angle. However, this may result in inward slippage of the puncture needle, which increases the risk of later screw invasion of the facet joint. Yson et al. [17] reported that screw placement in the lower lumbar spine is more likely to cause screw invasion of the facet joints. Furthermore, Park et al. [18] reported that pedicle screw placement in the L5–S1 segment has a 3.3-fold higher risk of causing screw invasion of facet joints than in other segments. A recent study by Teles et al. [19] showed that the angle between the facet joint and the vertical line is the main factor influencing screw invasion of the facet joint. An increase in this angle is associated with a higher incidence of the screw invasion. The incidence of facet joint violation was only 7.5% when this angle was >45°, but increased to 40% when the angle was >60°. The incidence of facet joint violation

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was 43.8% in the percutaneous screw placement group. From the cephalic to caudal side of the lumbar spine, the size of the pedicle medullary cavity increases, but the facet joint becomes more inclined, and the articular surface of the facet joint gradually changes from the sagittal position to the coronal position. Therefore, a greater risk of screw penetration into the pedicle wall exists during treatment of the upper lumbar segment, but the possibility of screw invasion to the facet joint should also be noted when treating the lower lumbar segment.

Digital orthopedics is a new digital medicine discipline that is closely integrated with computer digital technology and orthopedic clinics. It is based on orthopedics and assisted by computer graphic technology, including robot-assisted technology, surgical navigation with three-dimensional virtual simulation, finite element technology, and three-dimensional printing technology. Robot-assisted techniques and surgical navigation have created favorable conditions for the precise performance of minimally invasive spine surgery. Lau et al. [20] compared the incidence of screw invasion of the facet joints using O-arm navigation with that using fluoroscopy, and found that the rate was only 4.8% in the O-arm navigation group, which was much lower than that in the fluoroscopy-guided group (10%). Ohba et al. [21] also reported similar results; the incidence of screw penetration of the facet joint under CT navigation was only 2.53%, but it was 13.9% in the fluoroscopy-guided group. In a recent study, Fan et al. [22] compared the accuracy of pedicle screw insertion among 4 guided technologies in spine surgery, and found that there was no clear advantage of robotic-assisted technology in terms of accuracy compared to the navigation template or O-arm systems for screw implantation, but it showed the advantages of significantly reducing adverse events, fluoroscopy time per screw, postoperative hospital stay, and blood loss. In this study, we, for the first time, compared the differences in the accuracy of percutaneous pedicle screw placement under robotic guidance *vs.* fluoroscopic guidance. We assessed the outcomes based on the incidence of pedicle screw penetration through the pedicle wall and the incidence of screw invasion of the facet joints. The overall excellent rate of screw placement was significantly better in the robot-assisted group than in the fluoroscopy-guided group. No serious screw deviation (Neo grade III) or invasion of the superior segment inferior articular process (Babu grade III) occurred in the robot-assisted group. Mild screw deviation (Neo grade I/II) and screw invasion of the facet joints (Babu grade I and II) were identified for 5 and 3 screws, respectively, in the robot-assisted group. However, no neurological symptoms were reported, and no revision surgeries were performed. Considering that these patients were treated during the early stage when we started performing robotic surgery, a possible cause of screw deviation in robot-assisted screw placement may be a lack of experience. The actual drilling point was slightly different from the proposal entry point because tapping was not performed on the sloped surface of the pedicle. The screw insertion angle was greater in the robot-assisted group. The thickness of subcutaneous fat and soft tissue are factors that affect the accuracy of percutaneous screw placement. Therefore, a reasonable and accurate design of the incision is a prerequisite for maintaining the screw at the desired angle. Robot-assisted surgery can be used to plan the ideal screw trajectory before surgery, accurately design the skin incision during surgery, and tap the pedicle according to the planned angle. Therefore, a greater insertion angle of the screw can be obtained via high-precision screw placement in robotic surgery. In terms of vertebral reduction in patients with spondylolisthesis, accurate screw placement provides sufficient holding force, which creates favorable conditions for reduction of the slipped vertebral body and reduces the risk of the screw slip-out due to excessive retraction during reduction.

The Renaissance robot is one of the most widely used robots in spinal surgery, whose advantages in increasing accuracy and controlling complications had been proven in several studies [23,24]. The fully automatic robot can adjust according to the planned trajectory of the pedicle screw. In addition to use in the process of pedicle screw implantation, it could provide assistance for biopsy and cement injection. Robot-assisted screw placement in the lower lumbar spine has 3 advantages: (1) Because the operation can be planned on the workstation before surgery, the optimal screw entry point, trajectory, size, and depth can be determined according to the different pedicle directions and sizes. In this group of patients, some were elderly and had poor bone quality. Thicker and longer screws were selected, and a greater insertion angle was used to increase the holding force of the screws for reduction and reduce the risk of screw slip-out. Therefore, it is important to maintain a precise angle of screw placement. (2) During the operation, according to the preoperatively planned screw trajectory, a proper skin incision can be selected with the aid of the robotic surgical system and used to incise the deep fascia. An ideal incision is a prerequisite for maintaining an ideal screw angle. Conventional fluoroscopy can be used to locate osseous landmarks; however, the positioning of the incision is based primarily on the surgeon's experience. When the incision site was not appropriately selected, the insufficient incision of the fascia increased the difficulty of advancing the puncture needle along the ideal puncture angle due to blockage of the soft tissue, especially in the obese patients who were included in this study. Some patients in the fluoroscopy-guided group had a higher BMI, and the poor design of the incision in these patients might be responsible for the deviation of percutaneous screw placement. (3) From the perspective of the learning curve, fluoroscopy-guided percutaneous screw placement requires skilled pedicle puncture techniques. In particular, elderly patients with lumbar spondylolisthesis may present with severe

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hyperplasia of the facet joint. Thus, to ensure the ideal puncture angle, repeated punctures are unavoidable because adjustment may be needed due to poor screw position. This will reduce the holding force of the screws and increase the risk of postoperative loosening of the internal fixation. However, the robot-assisted surgery learning curve is steeper. The screws can be accurately placed under the assistance of the robotic surgical system once surgeons are familiar with its operation. This reduces the complications related to poor screw position, such as secondary neurovascular injury. The robotic surgical system also assists in teaching and training resident physicians.

Conclusions

Compared to conventional percutaneous pedicle screw placement, robot-assisted percutaneous pedicle screw placement has the following advantages: high accuracy, lower incidence of screw penetration of the pedicle wall and screw invasion of the facet joints, and greater screw insertion angle. Combined with MIS-TLIF, robot-assisted percutaneous pedicle screw placement is an effective minimally invasive treatment for lumbar spondylolisthesis.

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