

# **Original Article**

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# Risk Factors of Unsatisfactory Robot-Assisted Pedicle Screw Placement: A Case-Control Study

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**Objective:** To identify potential risk factors of unsatisfactory screw position during robot-assisted pedicle screw fixation.

Methods: A retrospective analysis of robot-assisted pedicle screw fixation performed in Beijing Jishuitan Hospital from March 2018 to March 2019 was conducted. Research data was collected from the medical record and imaging systems. Univariate tests were performed on the potential risk factors (patient's characteristics and surgical factors) of unsatisfactory screw position during robot-assisted pedicle screw fixation. For statistically significant variables in univariate tests, a logistic regression test was used to identify independent risk factors for unsatisfactory screw position.

**Results:** A total of 780 pedicle screws placed in 163 robot-assisted surgeries were analyzed. The rate of perfect screw positions was 93.08%, and the unsatisfactory rate was 6.92%. In patients with severe obesity (body mass index  $\geq$  30 kg/m²) (odds ratio [OR], 2.459; 95% confidence interval [CI], 1.199–5.044; p = 0.014), osteoporosis (T  $\leq$  -2.5) (OR, 1.857; 95% CI, 1.046–3.295; p = 0.034), and the segments 3 levels away from the tracker (OR, 2.216; 95% CI, 1.119–4.387; p = 0.022), robot-assisted pedicle screw placement has a higher risk of screw malposition.

**Conclusion:** During robot-assisted pedicle screw placement for patients with severe obesity, osteoporosis, and segments 3 levels away from the tracker, vigilance should be maintained during surgery to avoid postoperative complications due to unsatisfactory screw position.

Keywords: Robot-assisted surgery, Pedicle screw, Accuracy, Risk factor

# INTRODUCTION

Pedicle screw fixation has been widely used in the surgical treatment of spinal diseases. It provides strong support for the stability of the spine immediately after surgery. The accurate placement of pedicle screws is critical to the success rate of lumbar fusion. The unsatisfactory rate of traditional free-hand pedicle screw placement is up to 40%. The surgery of the success rate of lumbar fusion.

In the past 2 decades, intraoperative navigation systems have been used in spine surgery to provide higher screw accuracy. With the development and application of robotics in spine surgery, some studies have reported the advantages of robot-assisted pedicle screw placement, including higher accuracy and safety. The research focus of robot-assisted pedicle screw fixation is to evaluate the accuracy of the screw. According to reports in the literature, the accuracy of robot-assisted pedicle screw placement is 91% to 100%. However, in most of the previous studies, robot-assisted pedicle screw fixation still could not achieve a 100% rate of perfect position. Few studies have paid attention to the factors affecting the accuracy of robot-assisted pedicle screw fixation. We need to identify some risk factors that may affect the clinical accuracy of robot-assisted pedicle screw placement.

The purpose of the study was to explore the potential risk

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factors of unsatisfactory screw position during robot-assisted pedicle screw fixation, including the patient's characteristics and surgical factors.

### MATERIALS AND METHODS

# 1. Study Design

This study is a retrospective study of clinical data. The data was collected from the medical record and imaging system of our hospital. A total of 163 robot-assisted thoracolumbar pedicle screw fixation procedures were performed from March 2018 to March 2019. The study was approved by the Institutional Review Board of Beijing Jishuitan Hospital (20190913).

The inclusion criteria were as follows: (1) diagnosis of lumbar disc herniation, lumbar spinal stenosis, lumbar spondylolisthesis, or thoracolumbar fracture; (2) completion of preoperative and postoperative computed tomography (CT) examinations; (3) surgery was performed using the TiRobot orthopaedic robot (TINAVI Medical Technologies, Beijing, China).

The exclusion criteria were as follows: (1) revision surgery; (2) diagnosis of scoliosis, spinal tumor, or spinal tuberculosis; (3) severe sagittal or coronal spinal deformity.

# 2. Surgical Methods

Robot-assisted procedures were performed according to the guideline for thoracolumbar pedicle screw placement assisted by orthopaedic surgical robot.<sup>11</sup> The patient tracker was placed in the spinal process one segment cranial to the surgical site. Intraoperative CT images were acquired for screw trajectory planning. K-wire was inserted through the cannula on the robotic arm under real-time adjustment. The deviation of TiRobot between the planned and real trajectories was less than 1 mm.<sup>12</sup> It was up to the surgeon to choose percutaneous or open screw placement.

# 3. Group Allocation

Screw positions were evaluated in the postoperative CT multiplanar reconstruction images. One spine surgeon and 1 radiologist who were blind to this study independently assessed the accuracy of the pedicle screws. A third senior doctor was involved for adjudication in case of disagreement (7.3%).

Pedicle screw accuracy was evaluated according to the Gertzbein and Robbins scale. <sup>13</sup> Grade A, completely within the pedicle; grade B, pedicle cortical breach < 2 mm; grade C, pedicle cortical breach  $\ge 2$  mm and < 4 mm; grade D, pedicle cortical breach  $\ge 4$  mm and < 6 mm; grade E, pedicle cortical breach

 $\geq$  6 mm.

According to the accuracy of the screw position, the screws were divided into groups. Group A was a group with perfect screw positions (grade A). Group B was a group with unsatisfactory screw positions (grades B, C, D, and E).

#### 4. Risk Factors

Potential risk factors of unsatisfactory screw position were assessed, including (1) Age:  $\geq 60$  years old, < 60 years old. (2) Sex: male; female. (3) Body mass index (BMI): BMI < 25 kg/m<sup>2</sup> is defined as nonobese;  $25 \text{ kg/m}^2 \le BMI < 30 \text{ kg/m}^2$  is defined as obesity; BMI≥30 kg/m² is defined as severe obesity. (4) Bone density (quantitative CT of lumbar vertebral cancellous bone): T value > -2.5 is defined as nonosteoporosis; T value  $\leq$  -2.5 is defined as osteoporosis. (5) Preoperative diagnosis: lumbar spondylolisthesis; lumbar disc herniation; lumbar spinal stenosis; thoracolumbar fracture. (6) Instrumented segment: thoracolumbar region (T10-L2); lumbo-sacral region (L3-S1). (7) Screw side: left; right. (8) Distance between the instrumented level and the tracker (gap distance): 1 level; 2 levels; 3 levels or more. (9) Surgical approach: percutaneous; open. (10) Surgeons: 1st group; 2nd group; 3rd group; 4th group (every group included 1 senior doctor, 2 associate senior doctors, and 2 attending doctors).

# 5. Data Collection and Quality Control

Patient information and surgical information were collected from the medical record management system. Patient's imaging data were collected from the PACS (picture archiving and communication system) imaging system. Two doctors independently recorded and proofread the data using the EpiData software (EpiData Association, Odense, Denmark). Blinding was applied to the measurer to ensure the objectivity of the screw accuracy evaluation.

# 6. Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics ver. 24.0 (IBM Co., Armonk, NY, USA). Normally distributed continuous variables are represented by mean ± standard deviation. Nonnormally distributed continuous variables are represented by median (quartile). Categorical variables are represented by quantity (percentage). The chi-square test and Fisher exact test were used to evaluate the difference between categorical variables. Univariate tests were carried out on the potential risk factors of unsatisfactory screw position. A logistic regression test was used to identify the independent risk factors. Cal-

culate the odds ratio (OR) and its 95% confidence interval (CI). A p-value of < 0.05 was considered statistically significant.

# RESULTS

# 1. Demographic Data

A total of 163 robot-assisted thoracolumbar pedicle screw placement procedures were included in this study, and a total of 780 pedicle screws were placed. Four groups of spine surgeons performed all procedures. Among the patients, 70 were male, and 85 were female. The average age was  $56.74\pm13.40$  years (range, 14–86 years), and the average BMI was  $25.77\pm3.74$  kg/m². The preoperative diagnosis included 44 cases of lumbar disc herniation (26.99%), 38 cases of lumbar spinal stenosis (23.31%), 53 cases of lumbar spondylolisthesis (32.52%), and 28 cases of thoracolumbar fractures (17.18%). 135 cases underwent decompression and interbody fusion.

#### 2. Pedicle Screw Accuracy

Of the 780 pedicle screws placed, 726 screws were grade A, 43 screws were grade B, and 11 screws were grade C. The perfect rate of robot-assisted pedicle screw placement was 93.08%, and the unsatisfactory rate (grads B-D) of robot-assisted pedicle screw placement was 6.92%.

# 3. Univariate Analysis

Univariate analysis of potential risk factors showed that gender (p=0.672), age (p=0.316), preoperative diagnosis (p=0.899), and instrumented segment (p=0.929), screw side (p=0.573), and surgeons (p=0.634) between group A and group B were not statistically significant. Differences in BMI (p=0.020), bone density (p=0.041), gap distance (p=0.006), and surgical approach (p=0.030) between group A and group B were statistically significant (Table 1).

In patients with severe obesity (BMI  $\geq$  30 kg/m²), the unsatisfactory rate (13.21%, 14 of 106) was higher than other patients (5.93%, 40 of 674) (p=0.020). The unsatisfactory rate in patients with osteoporosis (8.94%, 32 of 358) was higher than that in other patients (5.21%, 22 of 422) (p=0.041). When the gap distance is more than 3 levels (including 3 levels), the unsatisfactory rate was 13.28% (17 of 128), which is significantly higher than 6.44% (21 of 326) at a gap distance of 1 level and 4.91% (16 of 326) at a gap distance of 2 levels (p=0.006). The unsatisfactory rate of percutaneously inserted screws (5.26%, 24 of 456) was lower than that of open inserted screws (9.26%, 30 of 324) (p=0.030).

**Table 1.** Univariate analysis for potential risk factors of unsatisfactory screw position

islactory screw position	C A	C D	
Potential risk factor	Group A (n = 726)	Group B (n = 54)	p-value
Sex			0.672
Male	328 (42.05)	26 (3.33)	
Female	398 (51.03)	28 (3.59)	
Age (yr)			0.316
≥60	352 (45.13)	30 (3.85)	
< 60	374 (47.95)	24 (3.08)	
Body mass index (kg/m²)			0.020
≥30	92 (11.79)	14 (1.79)	
25-30	299 (38.33)	17 (2.18)	
< 25	335 (42.95)	23 (2.95)	
Bone density			0.041
T value ≤ -2.5	326 (41.79)	32 (4.10)	
T value > -2.5	400 (51.28)	22 (2.82)	
Preoperative diagnosis			0.899
Thoracolumbar fracture	142 (18.21)	10 (1.28)	
Lumbar disc herniation	179 (22.95)	13 (1.67)	
Lumbar spinal stenosis	197 (25.26)	13 (1.67)	
Lumbar spondylolisthesis	208 (26.67)	18 (2.31)	
Instrumented segment			0.929
T10-L2	138 (17.69)	10 (1.28)	
L3-S1	588 (75.38)	44 (5.64)	
Screw side			0.573
Left	361 (46.28)	29 (3.72)	
Right	365 (46.79)	25 (3.21)	
Distance between the instrumented level and tracker			0.006
1 Level	305 (39.10)	21 (2.69)	
2 Levels	310 (39.74)	16 (2.05)	
≥3 Levels	111 (14.23)	17 (2.18)	
Surgical approach			0.030
Percutaneous	432 (55.38)	24 (3.08)	
Open	294 (37.69)	30 (3.85)	
Surgeons			0.634
1st group	153 (19.62)	9 (1.15)	
2nd group	125 (16.03)	7 (0.90)	
3rd group	320 (41.03)	28 (3.59)	
4th group	128 (16.41)	10 (1.28)	

Values are presented as number (%).

Group A, perfect screw positions; group B, unsatisfactory screw positions.

Table 2. Multivariate analysis for potential risk factors of unsatisfactory screw position

Risk factor	OR (95% CI)	p-value		
Body mass index (kg/m²)				
< 25	1.000			
25–30	0.893 (0.464–1.716)	0.734		
≥30	2.459 (1.199-5.044)	0.014		
Bone density				
T value > -2.5	1.000			
T value ≤ -2.5	1.857 (1.046-3.295)	0.034		
Distance between the instrumented level and the tracker				
1 Level	1.000			
2 Levels	0.746 (0.380-1.465)	0.395		
≥3 Levels	2.216 (1.119-4.387)	0.022		

OR, odds ratio; CI, confidence interval.

# 4. Multivariate Analysis

Multivariate logistic regression analysis included the following variables: BMI, bone density, gap distance, and surgical approach.

Multivariate logistic regression analysis (Hosmer-Lemeshow test: chi-square = 3.216, p = 0.920) found that the independent risk factors of unsatisfactory screw position were severe obesity  $(BMI \ge 30 \text{ kg/m}^2)$  (OR, 2.459; 95% CI, 1.199-5.044; p=0.014), osteoporosis (OR, 1.857; 95% CI, 1.046-3.295; p=0.034), and gap distance  $\geq$  3 levels (OR, 2.216; 95% CI, 1.119-4.387; p=0.022) (Table 2).

#### DISCUSSION

#### 1. Risk Factors of Unsatisfactory Screw Placement

In this study, robot-assisted pedicle screw fixation achieved a perfect position in 93.08% of pedicle screws. We found 3 primary factors that may affect the accuracy of TiRobot robot-assisted pedicle screw placement, including severe obesity (BMI  $\geq$  30 kg/m<sup>2</sup>) and osteoporosis (T value  $\leq$  -2.5), and gap distance  $\geq$  3 levels.

As our previous report, 16.2% of free-hand pedicle screws did not achieve a perfect trajectory (grade A).<sup>14</sup> Some studies have demonstrated that the robot-assisted technique is superior to the free-hand method in terms of pedicle screw accuracy. 10,15-17 Traditionally, pedicle screws with grades A and B are clinically acceptable. However, we should work towards the most accurate position (grade A) with the application of surgical robots. Similar to our study, Zhang et al.<sup>18</sup> analyzed the risk factors of Renaissance robot-assisted pedicle screw malposition. They found that obesity, osteoporosis, vertebral rotation, and congenital scoliosis were the risk factors of robot-assisted screw malposition.18

#### 2. Obesity

Severe obesity is one of the risk factors of unsatisfactory screw position, which may be due to the excessive thickness and pressure of soft tissue. Overweight and obesity are prevalent in patients who underwent spine surgery. Studies have found a linear correlation between the incidence of postoperative complications and BMI in spinal fusion surgery.<sup>19</sup> Excessive soft tissue pressure may compress the guidewire in obese patients, thereby changing the screw trajectory.<sup>20</sup> Because the guidewire has a certain elasticity, in patients with excessive soft tissue pressure in the lower back, the guidewire may be challenging to enter the pedicle according to the direction guided by the robotic arm.18

# 3. Osteoporosis

Patients with osteoporosis are also more likely to have unsatisfactory screw position. The guidewire could not be firmly fixed to the osteoporotic bone. A slight displacement of the guidewire will cause the screw to deviate from the planned position. Besides, when using the Renaissance robot, osteoporosis may affect the accuracy of image registration, thus compromising the screw accuracy.<sup>18</sup> The biomechanical stability of the pedicle screw fixation mainly depends on the bonding strength of the bone and the screw. The guidewire and the screw could not be firmly fitted with the surrounding bone due to the bone loss caused by osteoporosis, so that displacement may occur.

# 4. Distance Between the Instrumented Level and the Tracker

The distance between the instrumented level and the patient tracker is also a significant risk factor of unsatisfactory screw position. The results of this study indicate that when the gap distance exceeds 3 levels, the unsatisfactory rate of screw position increases significantly. The patient's spine moves up and down with the respiratory movement.<sup>21</sup> This physiological movement of each vertebra is different and may not be adequately detected by the real-time navigation system, especially the levels far away from the tracker and unstable levels.<sup>22</sup> When the guidewire is inserted, the navigation system is unable to reflect the dynamic changes of each vertebral body in real-time, which may cause the guidewire to deviate from the planned trajectory.

Boon Tow et al.<sup>22</sup> found that the accuracy of navigation-assisted pedicle screw placement depends on the distance between the tracker and the screw. Jin et al.<sup>23</sup> also found that the distance between the screw and the tracker over 3 levels is a risk factor for misplacement of navigation-assisted pedicle screws. We suggest that in long-segment surgery, the surgeon can move the patient tracker closer to the instrumented level and reacquire intraoperative CT images for registration.

# 5. Intraoperative Factors of the Surgeon

In addition to the factors included in this study, many other factors may affect the accuracy of robot-assisted pedicle screw placement. Among them, the doctor's intraoperative manipulation plays an important role.

Any new surgical technique has a specific learning curve.<sup>24</sup> When surgeons performed robot-assisted spine surgery initially, there was a cognitive process of the robot's operating principle. In the early stage of robot-assisted surgery, the problem of insufficient screw accuracy may be encountered. Doctors need to complete a certain amount of surgery to acquire robot-assisted surgical techniques.

In robot-assisted surgery, the screw position is planned by the surgeon based on intraoperative 3-dimensional images. Different surgeons may plan various pedicle screw trajectories with discrepant quality, which may also affect the accuracy of the screw. If the planned screw entry point is on a surface with a large slope or an irregular shape, the guidewire and the screw are more likely to slip when inserted. Ghasem et al.<sup>20</sup> found that most of the robot-assisted surgical technical problems with screw malposition were related to the bony surface skidding. Ringel et al.<sup>25</sup> concluded that slipping of the implantation cannula at the screw entrance point seems a vulnerable aspect potentially leading to screw malposition.

The surgeon's intraoperative error will also affect the accuracy of the screws. If the surgeon accidentally touches the patient tracker, the positioning accuracy of the robotic navigation system may be significantly declined if the registration is not performed again. Besides, the relative position of each vertebra is identified as fixed in the robotic navigation system. Nevertheless, there is a slight motion between each vertebra. During the insertion of the guidewire under the robotic guidance, overexertion may cause the instrumented vertebrae to be displaced relative to the proximal segments. Surgeons should avoid using excessive force when inserting the guidewire and the screw. The guide sleeve placed at the distal end of the robotic arm is vulnerable to pressure from surrounding soft tissue, which may

also change the screw position.<sup>20</sup> To avoid the effect of soft tissue pressure, sufficient exposure in open surgery or inserting the sleeve through muscles in percutaneous surgery is recommended.

#### 6. Limitations

This study has some limitations. Firstly, this is a single-center retrospective study. A multicenter prospective study with a larger sample size will be required to verify the results of this study in the future. Secondly, due to the limited sample size, anatomical factors and anesthesia factors (such as spinal rotation, instability, deformity, and intraoperative tidal volume) that may affect the screw accuracy were not evaluated in this study. In the next study, we will further observe whether the patient's anatomical features are related to the accuracy of robot-assisted pedicle screw placement.

# **CONCLUSION**

During robot-assisted pedicle screw placement for patients with severe obesity, osteoporosis, and segments 3 levels away from the tracker, vigilance should be maintained during surgery to avoid postoperative complications due to unsatisfactory screw position.

# **CONFLICT OF INTEREST**

The authors have nothing to disclose.

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