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Biomechanical strength impact of lateral wall breach on spinal pedicle screw fixation

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Abstract. – OBJECTIVE: The purpose of our study was to make a comparison between the fixation strength of optimum placed pedicle screw (OS) and re-directionally accurate placed pedicle screw (RS) after lateral pedicle breach.

PATIENTS AND METHODS: A total of 30 fresh lumbar vertebrae (L1-5) were gained from 6 male or female pigs weighing about 100 kg, which were divided into 2 groups according to different ways of pedicle screws placement: OS group (n=30) and RS group (n=30). MTS machine was employed to detect the screw loosening and axial pullout. We examined seating torque, screw-loosening force, the maximal torque and post-loosening axial pullout in each pedicle screw.

RESULTS: Maximal insertion torque of OS was (111.6±8.4) N·cm and RS was (79.0±6.3) N·cm, which indicated a significant difference (Z=3.012, *p*=0.003). Seating torque of OS and RS were (85.9±5.6) N·cm and (60.3±4.8) N·cm separately, and the difference was statistically significant (Z=2.799, *p*=0.006). Screw loosening force of OS and RS were (75.9±7.0) N and (52.4±6.3) N respectively, and the difference was statistically significant (Z=2.652, *p*=0.003). Post-loosening axial pullout force of OS and RS were (328.5±11.3) N and (269.1±9.6) N separately, demonstrating that the difference was statistically significant (Z=2.865, *p*=0.004).

CONCLUSIONS: RS placement is an alternative for remediation following a lateral wall breach evidenced by significantly decreased seating torque, screw loosening force, the maximal torque and post-loosening axial pullout compared with OS.

Key Words
Pedicle screw, Biomechanics, Lumbar spine, Spinal fixation, Pig.

Introduction

Pedicle screw fixation has become a standard option for internal fixation of various spinal disorders, such as degenerative diseases, deformities, trauma, congenital diseases and tumors[1]. Free-hand technique is the primary method for placement of pedicle screw. Computed tomography (CT), fluoroscopy-based navigation systems, and ultrasonic technique have been applied with the purpose of advancing the accuracy in the process of pedicle screw placement. However, malposition is not a rare occurrence[2-4]. It has been known that the majority of breaches occur in lateral wall of pedicles and the breach rate is higher especially in free-hand pedicle screw placement[4,5]. After a lateral wall violation occurs in surgery, re-directionally correctly placed pedicle screw (RS) is the most common option for remediation. Until now, limited researches have been reported on biomechanical effects of RS on spinal fixations. The primary purpose of this study was to investigate the effects of RS on fixation strength by comparing the fixation strength of OS with RS following a violation of lateral pedicle in pigs.

Material and Methods

Preparation of Specimen

A total of 30 fresh lumbar vertebra (L1-5) were obtained from 6 male or female pigs weighing about 100 kg. Their lumbar spines were examined with conventional radiographs to exclude tumors,

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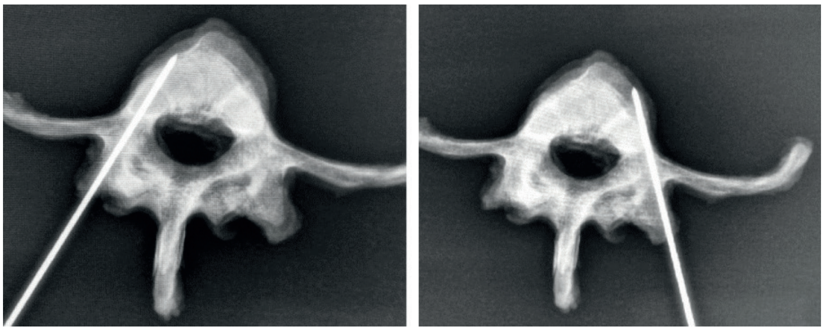

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Figure 1. Pedicle paths were done by guide wires. **A**, Perfect screw path for OS was done. **B**, Lateral pedicle wall violation for RS was done.

fractures, and metabolic bone diseases. All musculatures, fascias and ligaments were removed and only bone tissues were left for testing. These specimens were conserved at -20°C. Twenty-four hours before testing, specimens were unfrozen at room temperature. This study was approved by the Animal Ethics Committee of Nanjing Medical University Animal Center.

Methods

We use two different ways to instrument a monoaxial pedicle screw into each pedicle in each vertebrae. The operations of pedicle screw placement for both sides were completed by the same surgeon. On one side, a perfect screw path was created using direct visualization and fluoroscopy (Figure 1A). A pedicle screw (OS) of 5 mm in diameter and 35 mm in length was placed with a digital torque driver (Toolead, Shenzhen, China). On the other side, a guide wire was used to make a perfect screw path of lateral pedicle wall violation. The entry point was the same as OS and the direction was at the pedicle-vertebral body junction. Then, the guide wire was exited from the junction. After that, a lateral pedicle wall breach was done by a screw tap and a pedicle probe (Figure 1B). This pathway was then redirected into an accurate position, advanced, and instrumented with a 35 mm in length and 5 mm in diameter pedicle screw (RS) using the same technique as OS. All processes were confirmed both by direct visualization and fluoroscopy (Figure 2). OS and RS were screwed into both sides of the pedicles alternatively.

Parameters of Testing

MTS machine (Mini-Bionics, Minneapolis, MN, USA) was employed to detect the screw loosening and axial pullout. We examined seating torque, screw-loosening force, the maximal torque and post-loosening axial pullout in every pedicle screw. Dual-energy X-ray absorptiometry (Hologic Discovery QDR series, Waltham, MA, USA) was used to measure bone mineral density (BMD). The width and height of every pedicle were measured using a digital caliper (Shanghai, China) with accuracy of 0.01 mm in the middle of long axis of the pedicle. During the placement of screws, digital screwdriver was used to monitor the torque. The highest value was the maximal torque. At the last circle of screwing, the highest value was seating torque.

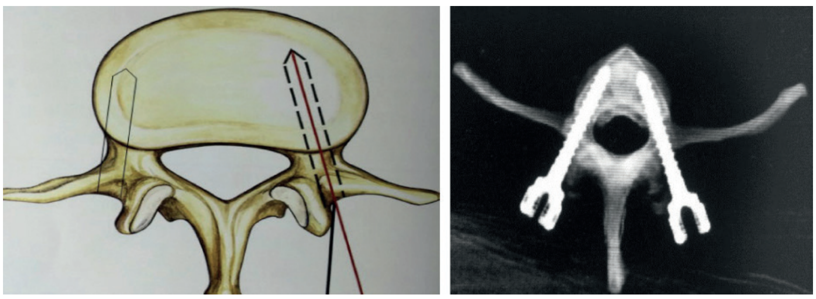

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Figure 2. Schematic diagram of screw channels and image of placed pedicle screws. **A**, RS channel (the solid arrow in the left) and the OS channel (the dotted arrow in the right). **B**, RS was placed in the left pedicle, while OS was placed in the right pedicle.

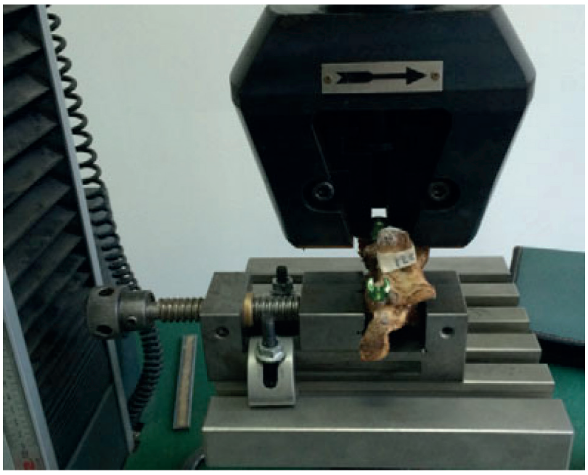

Figure 3. The image of axial pullout force test.

Vertebrae was put with pedicle screws placement on the MTS machine, then 5 mm mental bar were fixed at the end of pedicle screw using tail cap and the other end of mental bar was fixed with MTS machine. The bar was moved up and down to simulate the applied force of pedicle screws in body at the place of spinal flexing and stretching. The initial reaction set was 10 N up with 5 s, then 10 N up with 5 s. Three independent observers determined whether screws loosed by touching screws. 10 N were added each time and 5 N were added each time after 50 N to repeat the test until the screw loose. Before screw loose, the power of last circle was screw loose power[6]. Meantime, the strength of pulling screw out was axial pullout strength[7] (Figure 3).

Statistical Analysis

Statistical analysis was done using Statistical Product and Service Solutions (SPSS) 19.0 software (IBM, Armonk, NY, USA). All quantitative data were expressed as mean ± standard deviation. Comparison between groups was done using One-way ANOVA test followed by Least Significant Difference (LSD) Post Hoc Test. Pearson's correlation analysis was used to evaluate the relationships between biomechanical parameters and BMD. $p<0.05$ was considered statistically significant.

Result

BMD, Height and Width of Pedicles

In all specimens, BMD was 0.48-1.01 g/cm, mean 0.78 g/cm^2. In OS group, the width of pedicles was 10.28-11.99 mm, mean 11.13 mm. Meanwhile, in RS group, the width of pedicles was 10.68-12.82 mm, mean 11.59 mm. There was no significant difference between two groups (t=0.186, p=0.788). In OS group, the height of pedicles was 18.88-21.98 mm, mean 20.32 mm. Meanwhile, in RS group, the width of pedicles was 18.19-23.05 mm, mean 20.51 mm. There was no significant difference between two groups (t=0.289, p=0.771) (Table I). For pedicle, axial lengths of all specimens were more than 40-mm-long, 35-mm-long pedicle screws were used in our testing without anterior edge of vertebral body breakthrough.

Maximal Torque and Seating Torque

Maximal insertion torque of OS was (111.6±8.4) N•cm and RS was (79.0±6.3) N•cm; and the difference was statistically significant (Z=3.012, p=0.003). Meanwhile, seating torque of OS and RS were (85.9±5.6) N•cm and (60.3±4.8) N•cm, respectively. The difference was statistically significant (Z=2.799, p=0.006) (Table II).

Screw Loosening Force And Post-Loosening Axial Pullout Force

Screw loosening forces of OS and RS were (75.9±7.0) N and (52.4±6.3) N respectively; the difference was statistically significant (Z=2.652, p=0.003). Meanwhile, post-loosening axial pullout forces of OS and RS were (328.5±11.3) N and (269.1±9.6) N, respectively. The difference was statistically significant (Z=2.865, p=0.004) (Table III).

Table I. Comparison of Height and width of pedicles between OS and RS (mm).

	OS (n=30)	RS (n=30)	*t*	*p*
Width of pedicles	11.13±1.98	11.59±2.01	0.186	0.788
Height of pedicles	20.32±3.08	20.51±3.16	0.289	0.771

Note: OS: optimum placed pedicle screw, RS: re-directionally correctly placed pedicle screw.

Table II. Comparison of maximal torque and seating torque between OS and RS (N•cm).

	OS (n=30)	RS (n=30)	Z	*p*
Maximal torque	111.6±8.4	79.0±6.3	3.012	0.003
Seating torque	85.9±5.6	60.3±4.8	2.799	0.006

Note: OS: optimum placed pedicle screw, RS: re-directionally correctly placed pedicle screw.

Relationships Between Biomechanical Parameters and BMD

According to Pearson's correlation analysis, there was a strong, positive correlation in OS group between post-loosening axial pullout force and BMD (r=0.736, N=30, *p*=0.003). In OS group, a strong positive correlation was also confirmed between maximal torque and BMD (r=0.732, N=30, *p*=0.004). Medium positive correlations were proved between seating torque and BMD both in OS group (r=0.565, N=30, *p*=0.004) and RS group (r=0.486, N=30, *p*=0.006). In OS group, there was a medium, positive correlation between screw loosening force and BMS (r=0.540, N=30, *p*=0.005). In RS group, small positive correlations were confirmed between BMS and maximal torque (r=0.224, N=30, *p*=0.031), screw loosening force (r=0.185, N=30, *p*=0.040) and post-loosening axial pullout force (r=0.023, N=30, *p*=0.046).

Discussion

Pedicle screw systems have been essential part of spinal fixations and are routinely used in posterior spinal surgeries. Although intraoperative fluoroscopy and stereotactic-guided techniques slightly increase the first-time accuracy of pedicle screw placement, malposition is not a rare occurrence and breaches locate more frequently in a lateral pedicle wall[4,5,8]. In RS model, the direction of screws was determined according the joint of vertebrae and pedicle, which is constant and easy to operate. The line of entry point and the joint of vertebrae and pedicle were across part of lateral wall of pedicles, which ensured reliability and repeatability of RS model. In addition, the direction has angle with sagittal line, which is in accordance with clinical operation. In our study, varieties of biomechanical changes in RS were observed as follows: screw loose force, maximal insertion torque, seating torque and post-loosening axial pullout force fell by 29.2%, 30.8%, 30.5%, and 16.3% separately on average. Thus, compared with OS, RS is easy to insert and liable to loosening and pulling out at the same time. When RS was located in the middle part of the fixed system, with both ends anchored reliably, biomechanical tests revealed no significant decline. However, when RS was located at the head or the end of the fixed system, lack of reliable fixation on one side would lead to unbalance of RS and even cause the failure of internal fixation. On this occasion, RS augmentation is regarded as an effective remedial option. As we know, there are rare researches on biomechanics of RS following a violation of lateral pedicle. Only 2 studies focused on biomechanics of thoracic vertebra following a violation of pedicles in cadavers. In the study of Brasiliense et al[9], axial pullout force was down 21% from good position of pedicle screws to lateral deviation and redirection was not mention. In our study, axial pullout force was down 16.3% from good position of pedicle screws to RS. However, there are no comparable in both studies, because in our study, axial pullout force of RS was measured following the loosening and redirection of the screws. In the other study, Lehman et al[10] focused on maximal insertion torque of RS following a violation of lateral pedicle using free hand technology and proved that maximal insertion torque of RS was only 62% of OS. Meantime, we showed that maximal insertion torque of RS is 70.8% of OS. Various investiga-

Table III. Comparison of screw loosening force and post-loosening axial pullout force between OS and RS (N).

	OS (n=30)	RS (n=30)	Z	*p*
Screw loosening force	75.9±7.0	52.4±6.3	2.652	0.003
Post-loosening axial pullout force	328.5±11.3	269.1±9.6	2.865	0.004

Note: OS: optimum placed pedicle screw, RS: re-directionally correctly placed pedicle screw.

tions[11-14] have been reported on biomechanics of lumbar pedicle screws; however, most of them focused on factors of affecting the strength of internal fixation. In the study of Okuyama et al[15] and Ozawa et al[16], maximal torque or seating torque can scarcely predict pedicle screw loosening or failure in the patients with posterior lumbar intervertebral fusion and pedicle screw fixation. Cadaver experiment has the advantage of repeatable force on pedicle screws, such as axial pullout strength and resultant force of buckling and pullout strength, which is similar *in vivo*[11,17,18]. In our study, loosen screws model was built to simulate failure cases, which are often occurred in clinic. Axial output test was carried out after screws loosening in order to reduce the influences of screwing torque and seating torque, helping to compare axial pullout strength between OS and RS more accurately. The effects of thoracolumbar pedicle screws fixation are positively correlated with BMD[14,15,19]. Paxinos et al[19] showed that there was a positive correlation between post-loosening axial pullout force and BMD. Okuyama et al[15] proved that there was a positive correlation between seating torque and BMD. In our research, post-loosening axial pullout force and maximal torque of OS are proved to have strong positive correlations with BMD. Meanwhile, seating torque and screw loosening force were proved to have medium positive correlations with BMD respectively. In our study, for correlations between four biomechanical parameters and BMD, RS group was smaller significantly than OS group. The destruction of the lateral pedicle wall is likely to have a significantly negative influence on pedicle screw - bone interface that is irrelevant to bone mineral density. The lower correlations are very important, especially on maximal torque and axial pullout strength. Higher bone mineral density cannot compensate for decrease of fixed strength caused by lateral pedicle wall damage. In consequence, initial successful placement of pedicle screws is vital for reliable fixed strength.

Conclusions

RS placement is an alternative for remediation following a lateral wall breach evidenced by significantly decreased seating torque, screw loosening force, the maximal torque and post-loosening axial pullout compared with OS. However, our experiment was only conducted on animal specimens. With no medium- and long-term biomechanical outcomes of RS, more related research is required.

Conflict of Interests:
The authors declare that they have no conflict of interest.

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