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The pullout strength of pedicle screws following re-direction after lateral wall breach or end-plate breach

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Study Design: Using fresh cadavers, the biomechanical testing were used to examine the pullout strength of each pedicle screw.

Objective: To evaluate pullout strength of: 1) a re-directed pedicle screw following lateral wall breach; 2) a re-directed pedicle screw following end-plate breach; and 3) a pedicle without re-direction after end-plate breach without re-direction.

Summary of Background Data: Screw malposition, such as lateral wall breach or end-plate breach, is one of the main pitfalls of inserting pedicle screws.

Methods: From 17 fresh spines 54 vertebrae were harvested. In each vertebra on one pedicle the screw was inserted correctly down the axis of the pedicle, while on the other pedicle the screw was inserted to breach the lateral wall or the end-plate. The 18 pedicle screws that breached the lateral wall were then removed and re-directed along the correct axis of the pedicle. The 18 pedicle screws that breached the end-plate were removed and re-directed along the correct axis of the pedicle. The **18** other pedicle screws that had breached the end-plate were not removed. The pullout force of pedicle screws was measured.

Results: 1) The mean pullout strength for the re-directed screws following lateral wall breach was 24.0% less as compared to the correctly aligned screws; 2) The mean pullout strength for the re-directed screws following end-plate breach was 23.3% less as compared to the correctly aligned screws; 3) The mean pullout strength for the pedicle screws end-plate breach was 7.6% less as compared to the correctly aligned screws.

Conclusion: The pullout strength of re-directed pedicle screws after either a lateral pedicle breach or end-plate breach is significantly less than the pullout strength of correctly aligned screw. A pedicle screw that is not re-directed after end-plate breach is weaker than a pedicle screw correctly aligned, however the difference is not significant.

Key Words: pedicle screw, thoracolumbar spine, pullout strength, re-directed screw, malpositioned screw

Level of Evidence: N/A

INTRODUCTION

Pedicle screw instrumentation is used in the treatment of many spinal diseases, such as spondylolisthesis, scoliosis, kyphotic deformities, fractures and tumors[1-3]. Although pedicle screw fixation is considered to be stronger than many other types of instrumentation, loosening can still be a problem[4]. Screw malposition, such as lateral wall breach or end-plate breach, is one of the main pitfalls when inserting pedicle screws. When a malpositioned screw is identified intraoperatively the screw is often removed and then re-directed and inserted along the correct axis. The biomechanical strength of a redirected pedicle screw following lateral wall breach or end-plate breach is still not completely understood[5].

We therefore decided to carry out an experiment to test the pullout strength of: 1) a re-directed pedicle screw following lateral wall breach; 2) a re-directed pedicle screw following end-plate breach; and 3) a pedicle without re-direction after end-plate breach.

MATERIAL AND METHODS

Seventeen fresh frozen cadaveric spines were obtained (**15** male, **2** female, mean age **84.6** years, age range 68 to 92 years, **54** thoracic and lumbar vertebrae (T9-L5) were harvested). The cadavers were stored at -20 C. None of the cadavers had any medical history of metastatic disease, metabolic bone disease, fracture, or spine surgery. We were very careful in our selection process. We only selected vertebrae with the same width pedicle diameter between right and left, without sclerosis, without any indication of a compression fracture, and no clear indication of osteoporosis, All muscle, ligament, and tendon tissues were removed, preserving the normal osseous structure. The spines were radiographed in the anteroposterior and lateral planes to eliminate any vertebrae with bone abnormalities that could compromise the subsequent mechanical testing The specimens were removed from the freezer one day before testing and allowed to thaw slowly to room. In each vertebra on one pedicle the screw was inserted correctly down the axis of the pedicle, while on the other pedicle the screw was inserted to breach the lateral wall (**18** vertebrae) or the superior end-plate (**36** vertebrae). Left and right pedicles were alternated on each successive vertebra. The pedicle screws that breached the lateral wall were then removed and re-directed along the correct axis of the pedicle. **Eighteen (18)** of the **36** pedicle screws that had breached the superior end-plate were removed and re-directed along the correct axis of the pedicle. The remaining **18** pedicle screws that had breached the end-plate were not removed.

Each pedicle that received a 6.5 mm diameter screw had more than 80% of the occupation ratio taken up by the screw (as seen by radiographs).

<u>Pedicle screw insertion</u>

The Cotrel-Dubousset (CD) system (Medtronic Sofamor Danek, Warsaw, IN) with pedicle screws of 6.5 mm diameter and 50 mm in length was used.

Each vertebra was individually prepared for insertion of the pedicle screws. A pilot hole was made by decorticating the posterior cortex at each of the left and right entry sites. A screw was inserted into each pedicle using a free-hand technique. After the screw was inserted the position and trajectory were checked using radiographs.

The same depth for each screw was prepared by using a tap. The tap for each screw was 1 mm smaller than the screw diameter. The screws were inserted to a depth consisting of 60% to 70% of the anteroposterior length (as determined by AP and lateral radiographs). Each pedicle screw projected about 1.5 cm from the vertebral body. Care was taken to ensure that this projection distance was the same on the left pedicle as it was on the right pedicle.

On successive vertebra if the right pedicle received a correctly aligned screw and the left pedicle received a lateral wall breach screw or an end-plate breach screw then the right-left order was reversed on the next vertebra.

Correctly aligned pedicle screws

The correctly aligned pedicle screws were inserted using a center-center (CC) technique. For the CC technique, the pedicle probe was used to develop the pedicle and the pedicle screw was inserted under direct visualization; accuracy was confirmed using AP, lateral, and pedicle axis fluoroscopy.

Lateral breach pedicle screw orientation

The entry point and screw-hole preparation were the same as used for the correctly aligned screw. However in this case the inserted screw was laterally angulated to breach laterally at the pedicle-vertebral body junction (Figure 1). **Eighteen (18)** screws were thus inserted. These **18** screws were then removed and re-directed to be correctly aligned. **The levels of vertebrae were as follows; T10 two vertebrae, T11 two vertebrae, T12 three vertebrae, L1 two vertebrae, L2 three vertebrae, L3 four vertebrae and L4 two vertebra.**

<u>End-plate breach pedicle screw orientation.</u>

The entry point and screw-hole preparation were the same as used for the correctly aligned screw. However in this case the inserted screw was medially angulated and inclined cephalad so that the tip of the screw penetrated the superior end-plate (Figure 2). Thirty six (36) redirected screws were thus inserted. In 18 of the vertebrae the screws were removed and re-directed to be correctly aligned. **The levels of vertebrae were as follows; T9 one vertebra, T10 three vertebrae, T11 three vertebrae, T12 two vertebrae, L1 two vertebrae, L2 two vertebrae, L3 three vertebrae, L4 one vertebra and L5 one vertebra.**

The remaining **18** pedicle screws that had breached the end-plate were not removed and re-directed. **The levels of vertebrae were as follows; T9 one vertebra, T10 two vertebrae, T11 three vertebrae, T12 three vertebrae, L1 three vertebrae, L2 two vertebrae, L3 two vertebrae and L4 two vertebrae.**

Pullout Testing.

A special adaptor that had been made to fit around the head of the pedicle screw was applied (see Figure 3). The special adaptor was attached to the ram of the testing machine through a steel cable. Using this method each pedicle screw was pulled out along its long axis (at a displacement rate of 12.5 cm/minute), and the pullout force was recorded. **The differences of the pullout strength within 50 N is recognized "equal".**

Statistical analysisThe other statistical difference of pull-out strength between the straight screw and the end-plate screw was analyzed using the Mann-Whitney U test. All analyses were performed using StatView, version 5.0 (Abacus Concepts, Berkeley, CA), with $p < 0.05$ considered statistically significant.

This study was approved by the ethics committee of university hospitals.

RESULTS

Pullout strength

1)

The mean pullout strength for the re-directed screws following lateral wall breach was 24.0% less as compared to the correctly aligned screws ($P < 0.05$) (Figure 4). The mean pullout force was **581.6 N± 97.8** (SE) for the re-directed and **736.0 N± 90.3** (SE) for the correctly aligned screws. For **15 of the 18** pedicle screws the correctly aligned screw was superior in pullout strength. For 2 of the **18** vertebrae the re-directed screw was superior in pullout strength (Table 1) 2) The mean pullout strength for the re-directed screws following end-plate breach was **23.3%** less as compared to the correctly aligned screws ($P < 0.05$) (Figure 5). The mean pullout force was **517.9 N± 79.6** (SE) for the re-directed and **757.2 N ± 121.9** (SE) for the correctly aligned screws. For **14 of the 18** pedicle screws the correctly aligned screw was superior in pullout strength. For 2 of the **18** pedicle screws the re-directed screw was superior in pullout strength (Table 1). 3) The mean pullout strength for the pedicle screws that were not re-directed following end-plate breach was **7.6%** less as compared to the correctly aligned screws (Figure 6). The average pullout force was **575.6 N± 56.2** (SE) for the end-plate breach and **694.7 N± 76.5** (SE) for the correctly aligned screws. For **12 of the 18** pedicle screws the correctly aligned screw was superior in pullout strength. For 3 of the **18** pedicle screws the end-plate breach screw was superior in pullout strength (Table 2)There was no significant difference in mean pullout strength between correctly aligned screws and end-plate breach screws.

DISCUSSION

The main results to emerge from this experiment are: 1) the pullout strengths for the re-directed lumbar pedicle screw following both lateral wall breach and end-plate breach were significantly lower than the pullout strengths for the correctly aligned pedicle screws; 2) The end-plate breach screws that were not re-directed had lower pullout strengths as compared to the correctly aligned pedicle screw, however the difference was not significant.

A previous biomechanical study showed a significant decrease in axial pullout strength in the re-directed lumbar pedicle screw following lateral wall breach as compared to the correctly aligned lumbar pedicle screw[5]. One other study suggested that the end-plate screw, in which the inserted screw was medially angulated but also inclined as cephalad as possible without the tip penetrating the superior end-plate, showed no difference in pullout strength as compared to correctly aligned pedicle screws[6].

To our knowledge, there is no study extant on testing the pullout strength of pedicle screws after end-plate breach when the screws are 1) re-directed, and 2) not re-directed. A pedicle screw that is not re-directed after end-plate breach is weaker than a pedicle screw correctly aligned, however the difference is not significant. The question then arises: Would it be better to leave the misaligned screw penetrating the end-plate, or remove it and re-direct it? Compared with the correctly aligned screw that penetrates the end-plate, the re-directed screw is **24.0**% weaker, whereas the misaligned screw left in place is only

7.6% weaker On these numbers and considering pullout strength alone, one could be advised to leave the misaligned screw in place.

The exact rate of pedicle breaches that occur intra-operatively cannot be gleaned from the current literature because the reported pedicle screw accuracy rates are based on post-operative assessment, including radiographs and CT. Post-operative assessment does not account for the intra-operative pedicle breaches that are detected by the surgeon and managed with a re-directed screw. It can safely be assumed, however, that the rate of pedicle breaches is most likely higher than the 1-10% pedicle screw accuracy rate found in the literature[7-13]. Although the navigation system can provide an increase of pedicle screw accuracy rate[14], the new technique trajectory such as cortical bone trajectory screw or percutaneous pedicle screw system still has the malpositioned screw[15-18]. Because most studies indicate a lateral pedicle breach to be less prevalent, we designed our cadaver study to focus on end-plate breach.

There are two biomechanical studies that investigated pedicle wall violations in cadaveric thoracic spine specimens. BrasiLiense et al investigated the axial pullout strength of misplaced thoracic pedicle screws, in which the malpositioned screw was left, not re-directed as was the case in our study presented here[19]. In thoracic pedicle screws that missed laterally, there was a 21% decrease in pure axial pullout strength compared with a well-placed screw. This is nearly the same as our 24.0% decrease in axial pullout strength for a redirected lumbar pedicle screw with a lateral pedicle breach.

The lateral wall breach pedicle screw in lumbosacral spine may cause radicular pain and neurological deficits[20]. Adjacent segment degeneration is considered a long-term complication of spinal fusion procedure. Some reports suggest that degeneration in superior adjacent intervertebral disc might be caused by malpositioned pedicle probes or screws into the superior vertebral end-plate or disc during posterior intervertebral fusion[21].

To conclude, the pullout strength of re-directed pedicle screws after either a lateral pedicle breach or endplate breach is significantly less as compared to the pullout strength of a correctly aligned screw. A pedicle screw that is not re-directed after end-plate breach is weaker than a pedicle screw correctly aligned, however the difference is not significant. The biomechanical strength of a pedicle screw at the end of a construct is important and, on the basis of this study, surgeons should consider augmenting re-directed screws (e.g. sub-laminar wiring). However, the case for supplementation is less clear if the pedicle screw has penetrated the end-plate and left in place. Clearly, ensuring that the pedicle screw is correctly aligned in the first place is the best option.

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Figures

Figure 1

The left view shows a screw breaching the lateral wall and a screw that has been correctly aligned. The right view shows the screw that breached the lateral wall has been re directed and inserted along the correct axis. The screw diameter was 6.5 mm.

Figure 2

The left view shows a screw breaching the superior end-plate and a screw that has been correctly aligned. The right view shows the screw that breached the superior end-plate has been re directed and inserted along the correct axis. The screw diameter was 6.5 mm.

Figure 3

Screw pullout testing. A special adaptor was made to fit around the head of the pedicle screw.

Figure 4

As compared to correctly aligned screws the mean pullout strength of a re-directed screws following lateral wall breach was 24.0% less.

Figure 5

As compared to correctly aligned screws the mean pullout strength of re-directed screws following end-plate breach was 23.3% less.

Figure 6

As compared to correctly aligned screws the mean pullout strength of end-plate breach screws left in place was 7.6% less.

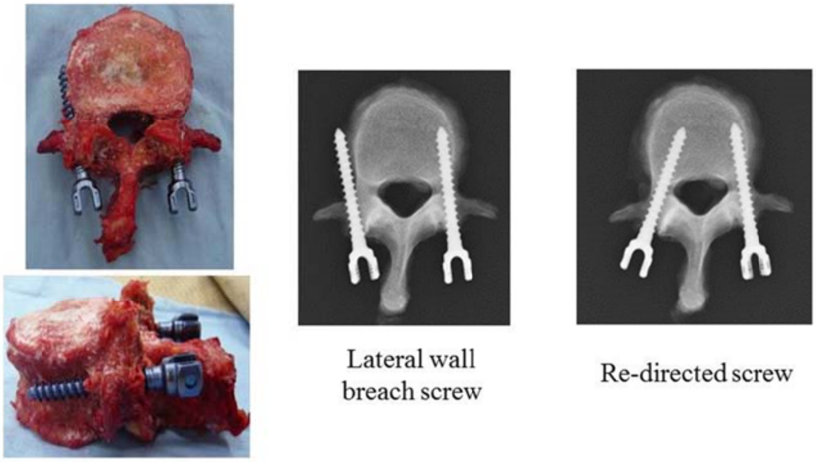

Figure 1 The left view shows a screw breaching the lateral wall and a screw that has been correctly aligned. The right view shows the screw that breached the lateral wall has been re directed and inserted along the correct axis. The screw diameter was 6.5 mm.

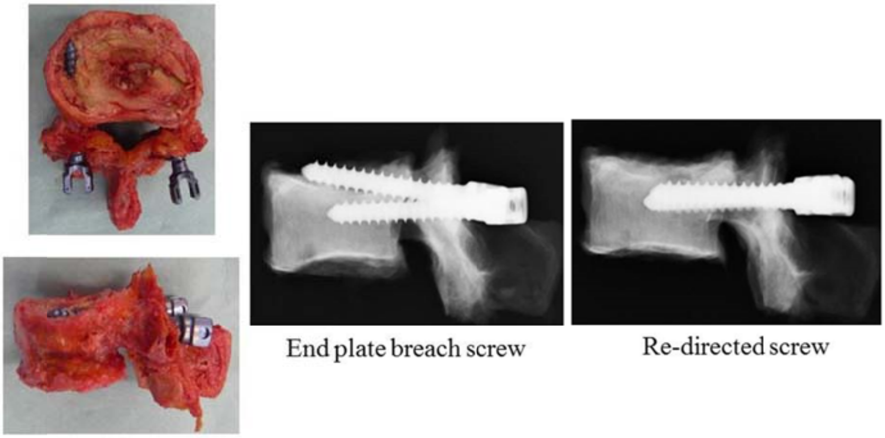

Figure 2 The left view shows a screw breaching the superior end-plate and a screw that has been correctly aligned. The right view shows the screw that breached the superior end-plate has been re directed and inserted along the correct axis. The screw diameter was 6.5 mm.

Figure 3 Screw pullout testing. A special adaptor was made to fit around the head of the pedicle screw.

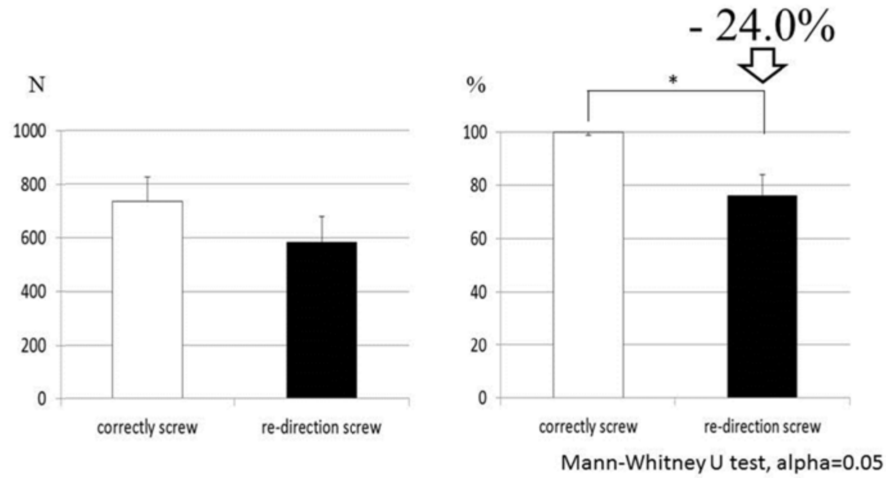

Figure 4 As compared to correctly aligned screws the mean pullout strength of a re-directed screws following lateral wall breach was **24.0%** less.

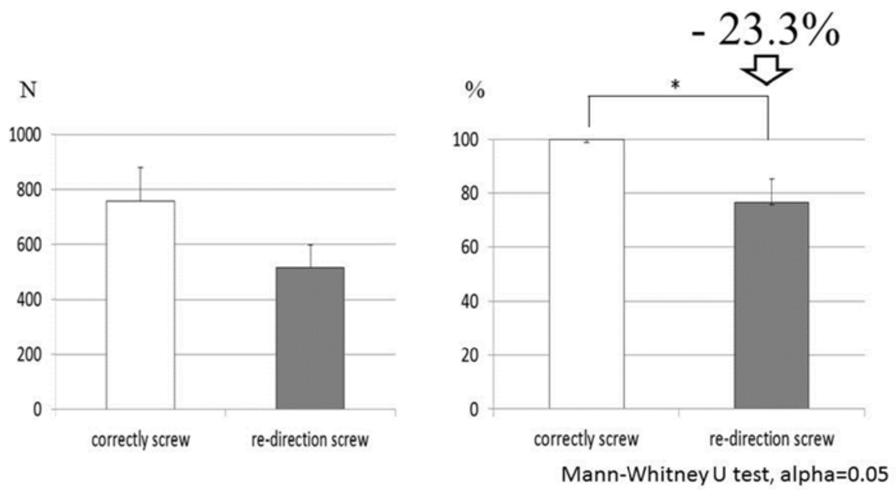

Figure 5 As compared to correctly aligned screws the mean pullout strength of re-directed screws following end-plate breach was **23.3%** less.

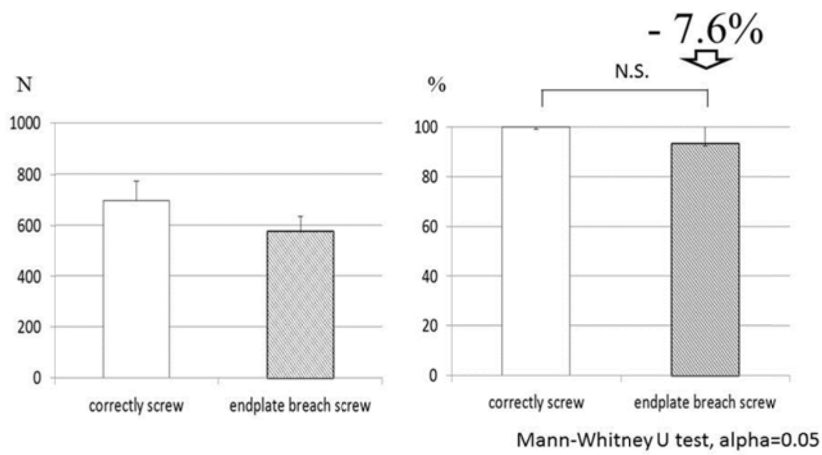

Figure 6 As compared to correctly aligned screws the mean pullout strength of end-plate breach screws left in place was **7.6%** less.

TABLE 1 The number of vertebrae compared the correctly aligned screw fixation with re-direction screws

	correctly aligned screw > re-directed screw	correctly aligned screw < re-directed screw	correctly aligned screw =re-directed screw
re-directed screw following lateral breach **18** vertebrae	**15** vertebrae	2 **vertebrae**	1 **vertebra**
re-directed screw following end-plate breach **18** vertebrae	**14 vertebrae**	2 **vertebrae**	2 **vertebrae**

TABLE 2 The number of vertebrae compared the correctly aligned screw fixation with end-plate breach screws without re-direction.

	correctly aligned screw >end-plate breach screw	correctly aligned screw <end-plate breach screw	correctly aligned screw =end-plate breach screw
end-plate breach screw			
18 vertebrae	**12** vertebra	**3 vertebrae**	**3 vertebrae**