Adjustment of Suboptimally Placed Lumbar Pedicle Screws Decreases Pullout Strength and Alters Biomechanics of the Construct: A Pilot Cadaveric Study

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Key words
- Biomechanics
- Lumbar pedicle screw
- Pullout strength

Abbreviations and Acronyms
BMD: Bone mineral density
Cl: Confidence interval
PMMA: Polymethyl methacrylate

BACKGROUND: Lumbar pedicle screws are placed for internal fixation and help to enhance bony fusion. Optimal screws are medially directed, should be parallel or pointing to the superior endplate, and penetrate 50%–80% of the vertebral body. “Nonparallel” pedicle screws can be inadvertently placed within the confines of the pedicle and vertebral body but are sometimes replaced to obtain a more acceptable postoperative image. A nonparallel (suboptimal) screw is one that is located within the pedicle and body and does not violate bone; however, it is not parallel to the superior endplate. These “cored-out” grooves left in the bone from the initial tap and screw placement may compromise the integrity of the bone and the construct.

METHODS: Dual-energy x-ray absorptiometry scans and L4-5 laminectomies were performed on 6 fresh-frozen cadaveric lumbar spines. We placed 2 optimal pedicle screws in L4, 1 optimal screw in L5, and 1 suboptimal screw in L5 (construct A). Axial rotation, flexion/extension, and lateral bending were tested. The suboptimal screw was repositioned in an optimal trajectory and retested (construct B). Pullout strength was performed on optimal and revised L5 pedicle screws.

RESULTS: The mean axial rotation stiffness was 1.31 N-m/degrees ± 0.22 in construct A and 1.19 N-m/degrees ± 0.17 in construct B (P = 0.023; 95% CI [Cl], 0.20–0.02). The mean lateral bending stiffness was 0.015 N/mm ± 0.002 in construct A and 0.16 N/mm ± 0.002 in construct B (P = 0.3; 95% CI, 0.0008–0.001). The mean flexion/extension stiffness was 0.0139 N/mm ± 0.002 in construct A and 0.0126 N/mm ± 0.002 in construct B (P = 0.001). Axial rotation and flexion/extension stiffness were significantly different between the 2 groups. The mean pullout strength was significantly higher in the nonrevised parallel screw group compared with the reimplemented parallel screw group (906.93 N ± 271.17 vs. 608.32 N ± 207.23, P = 0.031). Dual-energy x-ray absorptiometry imaging demonstrated 4 osteopenic and 2 osteoporotic specimens, although differences in bone mineral density did not play a significant role in assessing either the biomechanical parameters or the pullout strength.

CONCLUSIONS: Great care is warranted in the initial placement of lumbar pedicle screws. Revising a nonparallel screw placement decreases pullout strength and alters biomechanical movements (axial rotation and flexion/extension) in patients with decreased bone mineral density. If a screw is inadvertently placed nonparallel to the endplate but is within the confines of the pedicle and vertebral body with adequate bone purchase, it should not be revised and rather be left in its place.

INTRODUCTION
The role of internal fixation in the spine and lumbar pedicle screws is to increase the rate and rapidity of spinal fusion, correct deformities, and provide early stabilization (14). In recent years, the use of pedicle screws has increased tremendously. The indications for pedicle screw placement include trauma, tumors, complex deformities, degeneration, and instability. In addition to the increasing role of pedicle screw fixation in the lumbar spine, there has been a vast amount of biomechanical research dedicated to this topic. Optimal screws are medially directed, are parallel or pointing to the superior endplate, and penetrate 50%–80% of the vertebral body (7, 11, 12, 15). Approximately 60% of the strength of the pedicle screw comes from the pedicle itself, whereas 15%–20% comes from the cancellous bone of the vertebral body, and 20%–25% comes from the anterior cortex (3, 7, 15). Penetration of the anterior lumbar cortex improves pullout strength by 20%–25%, but this benefit is outweighed by the risk of vascular injury (14).

Many studies have addressed the issue of screw pullout. These studies have examined the characteristics of the screw itself; augmentation with polymethyl methacrylate (PMMA), hydroxyapatite cement, and different calcium-based compounds; and autologous bone to enhance risk of pullout, especially in osteoporotic bone where...
pullout risk is increased. To our knowledge, no biomechanical research has addressed the differences between the pullout strength of a screw that was placed within the confines of the pedicle and then redirected.

In the present study, we placed a nonparallel screw that did not breach the pedicle, then removed the nonparallel screw and placed it in the optimal position. Our hypothesis was that the “cored-out” grooves left in the bone from the initial tap and screw placement compromise the integrity of the bone and the construct. The objective of this study is to compare the difference in the biomechanical properties and pullout strength after revising the nonparallel screw in a parallel fashion. A cadaveric study was set up to test both screw pullout strength and biomechanics of the construct.

METHODS
L4-5 laminectomies and facetectomies were performed on 6 harvested fresh-frozen cadavers that were harvested from L1 to sacrum. Dual-energy x-ray absorptiometry scans were performed on the entire lot of specimens at L4-5 levels before the procedures were done. Laminectomies were performed to feel the medial walls of the pedicles to ensure they were not violated. Under live fluoroscopy, pilot holes were drilled with a high-speed burr at the junction of the transverse process and facet joint. Pedicle finders were used to enter the cancellous bone of the vertebral body, followed by a 5.5-mm diameter tap and 6.5-mm diameter screw. A pedicle feeler was used between each step to ensure the superior, inferior, lateral, and medial walls all were intact. Tapping and screw length were determined using lateral fluoroscopy. The direction was parallel to the superior endplate and medial to produce converging screws; this was done for the L4 pedicles bilaterally (Figure 1A) and alternated between the right and left pedicle on L5 on 3 specimens (Figure 1B). The nonparallel screw was initiated in the same fashion but directed toward the anteroinferior aspect of the vertebral body to avoid violating any bony anatomy (Figure 1C).

Rods were placed, the construct was secured, and set screws were locked at 80 N of force. The sacral ends were dipped in Bondo (3M, St. Paul, Minnesota, USA), and the ventral end was fixed with the corresponding cap for the Instron biomechanical testing machine (Instron Corp., Canton, Massachusetts, USA) (Figure 2). After being set overnight, the specimen was biomechanically tested in axial rotation, flexion/extension, and lateral bending. When this testing was done, the set screws and rod were removed on the nonparallel side, and the screw at L5 was replaced. The new trajectory was made with the pedicle-finder and retapped, and the screw was placed at a parallel trajectory (Figure 3). The entry point used at the facet-transverse process junction was the same. After rod placement and final tightening, the system was sent for another round of testing. When testing was completed, the set screws and rods were removed, and the screwdriver used for insertion was placed in the newly placed parallel reimplanted screw and fixed to the Instron. Pullout strength was conducted, keeping the screwdriver in the same parallel as the screw was placed (Figure 4); this was then performed on the contralateral parallel screw. Specimens were discarded in the proposed fashion. Computed tomography scans were performed before and after revision to ensure optimal direction, to ensure no medial or lateral breakout, and to identify “cored-out” in bone (Figure 5).

The nonparallel screws were pulled out after construct A underwent biomechanical testing. This was done using the compatible screwdriver. Construct B consisted of reimplantation of the nonparallel screw in a parallel orientation under fluoroscopic guidance. When this construct was obtained, this group underwent a full cyclic round of biomechanical testing, and subsequently the pullout strength was tested using the Instron machine.

Using similar testing as described by Karim et al. [5], all biomechanical testing was performed on an Instron 8874 biaxial testing frame and was analyzed in Microsoft Excel (Microsoft Corp., Redmond, Washington, USA). Biomechanical testing was performed as follows. For axial rotation, a 25-N axial preload was applied to the segment, and this was rotated ±1.5 degrees for 5 cycles at 0.25 Hz. Flexion/extension was tested by orienting the specimen 90 degrees from axial position and translating the specimen ±1.5 mm for 5 cycles at 0.25 Hz in an anteroposterior plane. Lateral bending testing was performed by rotating the segments 90 degrees about the vertical axis and translating the segments ±1.5 mm for 5 cycles at 0.25 Hz laterally. The torque and degree rotation data were graphed in Excel, and a linear regression was plotted through the data to generate a stiffness value. Calculations for rotational stiffness (N-m/radian) and linear stiffness in flexion/extension (N/mm) and lateral bending (N-mm) were performed. The stiffness value is the slope of best linear fit.

Pullout strength was performed as follows. The vertebrae were aligned in an orientation in which the screw’s axis was aligned with the test machine’s piston. The piston was attached to the screw, and the pullout loading was measured at 1–2 mm/min until visible failure (Figure 4C) or a consistent decline in the slope of the pullout (Figure 6). The pullout strength was gauged by evaluating the rise of the slope, followed by the “catch” and then the maximum the slope achieved before a steady decline. We defined the “catch” (Figure 6) as all systems tightening; this included the Instron to the screwdriver, the screwdriver to the screw, the screw to the bone, and the bone to the metal ring construct. When the construct “caught,” we saw a rapid increase in the slope of the pullout (Figure 6). The constant decrease in the slope corresponded to the visible threads pulling out of the bone (Figures 4C and 5). The order of screw pullout was alternated to prevent bias that might occur.

Statistical Methods
The statistical analysis was done by using JMP statistical software (JMP Software, Cary, NC), version 9. Probability distribution of the data was assessed and compared by using Q-Q plot graphs. Based on the graphic analysis of Q-Q plot, our hypotheses were tested by using parametric statistical methods (paired t test) and nonparametric statistical methods (Wilcoxon signed-rank test, Mann-Whitney U test) appropriately (Figure 1). P value < 0.05 was considered to be significant.

RESULTS
Do Biomechanics Get Altered After Revising the Nonparallel Screw?
Construct A comprised parallel screws a L4 levels bilaterally, whereas at L5 level, one screw was placed parallel and the other was
This construct was subjected to the first round of biomechanical testing. The first construct among 6 specimens was tested for axial rotation, lateral bending, and flexion/extension (Table 1). Subsequently, the lumbar pedicle screw placed nonparallel was revised in all specimens (construct B) and again subjected to the second round of biomechanical testing for the same outcome parameters (Table 1). Our hypothesis was tested by using the paired t test.

The mean axial rotation stiffness in construct A was 1.31 ± 0.22 and in construct B was 1.19 ± 0.17. Axial rotation was significantly greater in construct A compared with construct B (P = 0.023; 95% confidence interval [CI], 0.20, 0.02). The mean lateral bending stiffness in construct A was 0.015 ± 0.002 and in construct B was 0.016 ± 0.002. Lateral bending stiffness was not significantly different between the 2 groups (P = 0.3, 95% CI, 0.0008, −0.001). The mean flexion/extension stiffness in construct A was 0.0126 ± 0.002 and in construct B was 0.0126 ± 0.002. The flexion/extension stiffness was significantly greater in construct A compared with construct B (P = 0.01, 95% CI, 0.002, 0.0004). These results of significantly increased stiffness in construct A in axial rotation and flexion/extension are summarized in Figure 7.

Does Revising the Nonparallel Lumbar Pedicle Screw Change Maximum Pullout Strength?

After the second round of biomechanical testing, the L5 vertebral complex was isolated from the construct with the nonrevised parallel screw on one side and the revised optimal screw on the other side. Maximum pullout force between the 2 groups was measured in all 6 specimens, and the stated hypothesis was tested by using the Wilcoxon signed rank test. The mean difference in the pullout force was significantly different in the nonrevised parallel screw group compared with the reimplanted parallel screw group (906.93 ± 271.17 N vs. 608.32 ± 207.23 N, P = 0.031), in favor of the former (Figure 8).

Does Bone Mineral Density Play a Role in Assessing Maximum Pullout Strength?

We hypothesized that bone mineral density (BMD) may play a role in determining the pullout strength. All 6 specimens underwent dual-energy x-ray absorptiometry scanning before dissections to obtain a baseline for BMD (Table 2). Of the specimens, 2 were significant for osteoporosis, and 4 were osteopenic. After calculating the pullout strength, 4 groups were created: osteopenic revised, osteopenic nonrevised, osteoporotic revised, and osteoporotic nonrevised. Comparisons of the mean pullout strength among the different groups were studied using Mann-Whitney U test. Mean pullout strength among all of the groups was not significantly different (P = 0.23) (Figure 9). The difference in the
pullout strength of the revised versus nonrevised cohort was calculated for each specimen in the osteopenic and osteoporotic groups. The mean of the difference in pullout strength (nonrevised and revised) between the osteopenic group (323.48 N) and osteoporotic group (248.87 N) was calculated and compared. There was no significant difference between the 2 groups ($P = 0.83$).

**Does BMD Play a Role in Assessing the Change in Biomechanics After Revising the Lumbar Pedicle Screw?**

Similarly, the difference in the biomechanical values (axial rotation, lateral bending, and flexion/extension) of revised versus nonrevised cohorts was calculated for each specimen in the osteopenic and osteoporotic groups. There was no significant difference between the 2 groups across any biomechanical parameter (Table 2). In our biomechanical study, BMD did not play a role in assessing the change in either maximum pullout strength or biomechanical properties of lumbar spine after revising the pedicle screw; however, the sample size of the cadavers in our study is low to make that conclusion.

**DISCUSSION**

The commonly accepted indications for pedicle screw fixation of the lumbar spine include 1) stabilization of degenerative spondylolisthesis after a decompressive laminectomy; 2) reduction and stabilization of isthmic or degenerative spondylolisthesis with or without decompression; 3) surgical stabilization of selected unstable lumbar-burst fractures, particularly low lumbar-burst fractures; 4) extensive decompression or resection of primary or metastatic neoplastic lesions of the lumbar spine; 5) surgical revision of symptomatic lumbar pseudarthrosis, particularly in a compression mode; 6) radiographically confirmed segmental instability after decompressive procedures; 7) certain instances of retrolisthetic instability with disk height collapse and facet subluxation, particularly after surgical decompression; 8) surgical stabilization.
and possible correction of adult degenerative lumbar scoliosis; and 9) certain cases of axial rotational instability with symptomatic nerve root irritation in which derotation and segmental stabilization are indicated (14). The broad range of uses of pedicle screws has created a focus to provide the strongest possible constructs to increase the rate and rapidity of spinal fusion, correct deformities, and provide early stabilization. This focus has led to research identifying the proper screw placement, the characteristics of the screw itself, augmentation to enhance pullout strength, and different techniques of placing pedicle screws.

The proper placement of pedicle screws has been well documented. Optimal screws are medially directed, should be parallel or pointing to the superior endplate, and penetrate 50%–80% of the vertebral body (7, 11, 12, 15). Approximately 60% of the pedicle screw strength comes from the pedicle itself, whereas 15%–20% comes from the cancellous bone of the vertebral body, and 20%–25% comes from the anterior cortex (3, 7, 15).

Why would a pedicle screw be replaced after adequate insertion in bone? The reasons appear to be multifactorial: 1) screws have been shown to have better pullout strength when placed parallel to the superior endplate or pointing to the superoanterior vertebral body and the construct in a trigonal fashion, and 2) the picture looks more acceptable once the construct is completed. Screws can be aberrantly placed by residents learning to place screws, because of limited fluoroscopy between pedicle marker placement and tap/screw insertion, and in the thoracic spine where anteroposterior fluoroscopy is used primarily to place the instrumentation. Intuitively, using the same entry point leads to 2 paths that dorsally have more bone “cored-out” than ventrally. This situation results in a portion of the screw, the more posterior part, not having an ideal purchase.

The characteristics of the screw can affect the pullout strength. In this study, we used Medtronic LEGACY cylindrical screws (Medtronic, Inc., Minneapolis, Minnesota, USA). Abshire et al. (1) studied the pullout strength between conical and cylindrical pedicle screws in porcine lumbar specimens. Each pedicle had PMMA injected before placement of the pedicle

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Construct A (control)—3 optimally placed lumbar pedicle screws (both sides at L4 and one side at L5) and 1 suboptimally placed lumbar pedicle screw (the other side at L5).

Construct B—suboptimally placed lumbar pedicle screws (on one side at L5) were revised to make them optimal.

DEXA, dual-energy x-ray absorptiometry; SD, standard deviation.
screw. When the screw was hubbed to the laminar cortex, the conical screw had 17% stronger pullout strength than the cylindrical screw.

Augmentation of pedicle screw placement with bone materials has been evaluated, including the use of PMMA, hydroxyapatite cement, and different calcium-based compounds. Rohmiller et al. (10) studied the one-time axial pullout strength of lumbar pedicle screws in native bone versus augmentation with PMMA and calcium sulfate. In the pedicle group that was augmented with calcium sulfate or PMMA, the one-time axial pullout strength improved by 167% or 199%, respectively; however, the material was allowed to set for a minimum of 24 hours before screw placement. One concern that is not addressed is that strength is improved with calcium sulfate after the initial pullout, but the long-term pullout strength is unknown after reabsorption occurs. The study does note that cyclic load evaluations of the pullout strength would help in understanding the long-term effects of augmentation materials.

Cook et al. (2) evaluated pullout strength in osteoporotic bone with the use of PMMA and expandable pedicle screws. Similar to other studies, the study showed that the pullout strength was significantly higher in expandable pedicle screws with PMMA versus expandable pedicle screws in native osteoporotic bone. A similar study on bone material augmentation of pedicle screws in osteoporotic bone was conducted by Paré et al. This study also showed an increase in pullout strength with the use of bone cement (9). Kiner et al. (6) designed a biomechanical study to look at pedicle screw augmentation with PMMA versus larger diameter pedicle screws that are useful in revision surgeries. The results showed that larger diameter pedicle screws were more rigid.

Advancements in imaging technology have helped improve the accuracy of pedicle screw placement. Although a thorough understanding of the anatomy can help a surgeon with the accuracy of a freehand pedicle screw placement, repositioning screws for optimal placement still occurs. Gelalis et al. (4) conducted a meta-analysis on the accuracy of pedicle screw placement comparing a freehand technique, fluoroscopy, and navigation. They found that with the freehand technique, adequate placement of pedicle screws ranged from 69%–94%, 28%–85% with the aid of fluoroscopy, 86%–100% with computed tomography navigation, and 81%–92% with fluoroscopic navigation. Other studies have shown the utility of navigation in improving the accuracy of pedicle screw placement (8, 13).

To our knowledge, the present study was the first to look at a common intraoperative practice of repositioning of pedicle screws for a more parallel position, despite achieving adequate placement of pedicle screws for optimal strength. Each pedicle screw placed in this study was hubbed to the laminar cortex. This practice allows the use of the entire functional portion of the screw and maximizes the amount of bone in which the screw is placed. The repositioning of the “suboptimal screw” led to a statistically significant difference between the 2 groups with regard to axial rotation \(P = 0.023\) and flexion/extension \(P = 0.01\) in favor of the nonrevised screws. There was no statistically significant difference with regard to lateral bending in the 2 groups \(P = 0.3\). The repositioning of the

Figure 7. Representation of result of the paired t test for testing the difference in the means of construct A and construct B for axial rotation, lateral bending, and flexion/extension. A greater degree of stiffness in axial rotation and flexion/extension was noted in the nonrevised lumbar pedicle screw group compared with the revised lumbar pedicle screw group. F/E, flexion/extension.

Figure 8. Pullout strength is significantly higher in the nonrevised optimal lumbar pedicle screw group than in the revised optimal lumbar pedicle screw group. LPS, lumbar pedicle screw.
nonparallel screw led to a statistically significant difference in pullout strength in the 2 groups in favor of the nonrevised screws (P = 0.031). Of our 6 cadaveric spines, 4 were osteopenic, and 2 were osteoporotic. There was not a difference between these 2 subsets with regard to pullout strength.

There are some limitations to the present study. One limitation is that there were only 6 cadavers used. Although we did find a significant difference in pullout strengths, our power is inherently low. Another way to evaluate our screws would be to compare the pullout strengths of 2 nonparallel placed screws. We would have a more accurate comparison. We set the testing up as we did to perform a more “real-life” experience, where most screws would be placed parallel. The second construct after revising the screws may inherently have reduction or alteration in the various biomechanical forces after the exposure of the first construct to biomechanical testing. Biomechanical testing in a control group to that effect would have been ideal to eradicate that bias.

Multiple studies show using bone augmentation with pedicle screws improves strength of the construct (1, 2, 10, 11). The present study provides insight to the fact that one-time, well-placed pedicle screws can provide for a sturdy construct. Repositioning pedicle screws decreases the amount of bone purchase and requires the use of bone materials. Navigation systems have been shown consistently to improve the accuracy of pedicle screw placement and could theoretically reduce the need for intraoperative repositioning, leading to stronger constructs.

CONCLUSIONS

Great care is warranted to place the lumbar pedicle screw initially in an optimal position. Revising the suboptimal screw results in decreased pullout strength and altered biomechanical movements (axial rotation and flexion/extension) in patients with decreased BMD. We propose that a screw placed within the confines of the pedicle and vertebral body with adequate bone purchase but inadvertently placed nonparallel to the endplate should be left in its place. More specimens would likely increase the power of this pilot study.

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REFERENCES


Table 2. Bone Mineral Densities (g/cm²) in Cadaveric Specimens*

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BMD, bone mineral density; BMI, body mass index; Ht, height; Wt, weight.

* All donors were white men.

Figure 9. Box plot showing the differences in distribution for pullout strength when plotted against various groups: osteopenic revised, osteopenic nonrevised, osteoporotic revised, and osteoporotic nonrevised. No statistically significant differences in mean pullout strength were observed (Mann-Whitney U test, P = 0.23).


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