# Intraoperative biomechanics of pedicle screw loosening in the lumbar spine

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## Abstract

Pedicle screw loosening has been implicated in recurrent back pain after lumbar spinal fusion, but the degree of loosening has not been systematically quantified in patients. Instrumentation removal is an option for patients with successful arthrodesis, but remains controversial. This study measured pedicle screw insertion and/or removal torques in one hundred and eight patients (age 47 ± 11 years) who experienced pain recurrence despite successful fusion after posterior lumbar interbody fusion (L2-S1). Between implantation and removal, pedicle screw torque was reduced by 58%, indicating significant loosening over time. Extent of loosening correlated with screw placement as measured by EMG stimulus threshold, and an analytical stress analysis revealed increased local stresses in pedicles with decreased pedicle-screw clearance. Loosening was greatest in vertebrae at the extremities of the fused segment, with reduced biomechanical stability. Instrumentation removal also significantly reduced patient pain. These data indicate that pedicle screws can loosen significantly in patients with recurrent back pain, which may be ameliorated by instrumentation removal following successful arthrodesis.

Key Words: Pedicle Screw, Lumbar Spinal Fusion, Loosening, Torque

## Introduction

Chronic low back pain is the second most-common reason for visits to a physician in the United States, and interbody fusion is common in patients non-responsive to non-surgical options [1]. In 2012, over 413,000 lumbar fusions were reported in the US, and demand for surgical treatment continues to rise [2,3]. Improvements in surgical approaches [4], as well as fixation instrumentation [4,5] and inductive bone formation agents [2,6,7] have improved patient outcomes, reduced the frequency and extent of complications, and have collectively made lumbar spinal fusion a common procedure that has improved quality of life for millions of patients.

However, reoperation secondary to recurrent back pain has been reported in approximately 14-27% of patients [8], with complications including improper instrumentation placement, loss of fixation, fatigue and bending failure, dural tears, nerve root injury, infection, and pedicle screw loosening [9,10]. While successful fusion is correlated with a desirable clinical outcomes [11], recurrent pain can occur even in patients with solid arthrodesis, which may be associated with instrumentation loosening, requiring revision or removal.

Over the past ten years, posterior pedicle screw systems have increased in strength and rigidity [12,13], increasing pre-fusion stability and decreasing the incidence of pseudarthrosis [13,14]. However, this has also increased the loads present at the bone-screw interface, even after successful fusion due to increased load-sharing, which may contribute to pedicle screw loosening [15]. Surgical removal of pedicle screws has been much discussed [10,16], and remains controversial due to the associated risks of secondary surgery. However, when unexplainable recurrent pain is severe, screw removal has been recommended [17–20], and may also reduce risks of metal toxicity and hypersensitivity [21].

Importantly, the loosening of pedicle screws *in vivo* has not been thoroughly evaluated, and the ability of pedicle screw removal to alleviate recurrent pain remains understudied. Therefore, the aims of this study were to quantify pedicle screw loosening in patients with recurrent back pain following successful posterior instrumented lumbar fusion (PILF) surgery and determine whether instrumentation removal can ameliorate secondary pain.

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## Methods

### Patients

A total of 108 patients (75 male, 33 female), 29-78 years of age (mean 47, SD 11), were voluntarily enrolled in this retrospective cohort study. Each had been diagnosed with degenerative spinal stenosis with associated instability, degenerative spondylolisthesis, or annular tears and discogenic pain that had failed conservative treatment for at least one year. All subjects gave informed consent to participate, and the study was approved by Sterling Institutional Review Board, Atlanta, GA (#5187). Patients received 2- to 5-level spinal fusion of lumbar vertebrae between L2 and S1, and only patients with successful arthrodesis were selected for evaluation. Measurements at insertion were taken in seventy-two patients (44 male, 28 female). Subsequently, seventy-three patients (43 male, 30 female), of whom thirty-seven (12 male, 25 female) had been measured at insertion for paired assessment, received instrumentation removal and torque measurement at 266 ± 73 days post-implantation.

### Surgical approach

Patients received anterior lumbar interbody fusion with posterior pedicle instrumentation (Figure 1A). Briefly, patients were placed prone on a Jackson operating table, prepped, and draped in usual sterile fashion. After open exposure of the pedicles, pedicle holes were tapped using the 3D system by Medtronic® and pedicle screws were inserted. Holes were tapped 1mm diameter smaller than the screw size, yielding a pedicle-screw interference ($\delta_B$) of 0.5 mm.

After the fusion was solid as diagnosed by computed tomography (CT) scan, patients with recurrent back pain were returned to the operating room no sooner than 6 months after insertion and up to 3 years after the initial procedure. Instrumentation was exposed in routine fashion, and side connectors and rods were removed. The fusion was evaluated by CT scans at the time of pedicle screw removal and was verified solid either anterior or anterior and posterolateral.

### Pedicle screw insertion and removal torque

Pedicle screw insertion (N = 467) and removal (N = 477) torques were measured using a customized, sterilizeable, manual mechanical torque wrench, with N = 139 paired insertion and removal measurements in the same patients. To ensure changes in torque between insertion and removal surgeries did not occur due to hole tapping by the insertion screw, pedicle screw back-out torque (at the time of insertion) was also measured (N = 204).

### Evoked EMG stimulus threshold

Evoked electromyographic (EMG) stimulus threshold through the screw hole were measured at insertion (N = 394) and removal (N = 430) [22]. Paired stimulus threshold measurements at insertion and removal were taken in N = 98 screws.

### Pedicle and screw measurements

Vertebra level, screw type, diameter, and length were recorded for each sample. Pedicle thickness was measured from pre-operative digital CT scans (Figure 4A), and pedicle-screw clearance, defined as pedicle thickness minus screw diameter, was also computed.

### Stress analysis

A 2D analytical analysis of monotonic cantilever loading induced by lumbar extension and press fit loading caused by screw insertion was performed. Peri-implant pedicle bone was assumed to have an effective modulus of 300 MPa and a Poisson ratio of 0.3 [23–25]. For the press fit analysis, the interface pressure, p, was defined as

$$p = \frac{\delta_B}{\frac{r_S}{E_B}\left(\frac{{r_B}^2+{r_S}^2}{{r_B}^2-{r_S}^2}+\nu_B\right)} \qquad \text{Eqn. 1}$$

where $\delta_B$ = (pedicle screw diameter – screw hole diameter)/2, is the screw-hole interference, $r_S$ is the radius of the screw hole, $r_B$ is the radius of the pedicle screw, $E_B$=300 MPa is the bone elastic modulus, and $\nu_B$ =0.3 is the Poisson's ratio [23–25]. The radial stress was defined as $\sigma_r = -p$ and the circumferential stress as $\sigma_\theta = -p$ . The stress resulting from transverse loading of the pedicle screw was defined as:

$$\sigma_f = \frac{-F_t}{D_S L_S} \qquad \text{Eqn. 2}$$

where $F_t$ is the applied transverse force, $D_S$ is the diameter of the screw, and $L_S$ is the length of the screw. The octahedral (von Mises) stress, $\sigma_H$, was defined using $\sigma_1=\sigma_r+\sigma_f$, $\sigma_2=\sigma_\theta$, and $\sigma_3=0$ and calculated as:

$$\sigma_H = \frac{1}{\sqrt{2}}[(\sigma_1-\sigma_2)^2+(\sigma_2-\sigma_3)^2+(\sigma_3-\sigma_1)^2]^{\frac{1}{2}} \qquad \text{Eqn. 3}$$

The contributions of $\delta_B$ (Figure 4D) and $F_t$ (Figure 4C) to local octahedral shear stress were computed and varied as a function of pedicle-screw clearance (p.s.c. = (pedicle thickness – screw diameter)/2).

### Visual analogue scale assessment of patient pain

Finally, to evaluate the effect of instrumentation removal on patient perception of lumbar pain, patients (N = 31 complete responders) were self-assessed using the visual analog scale (VAS; 0-100 mm) prior to fusion surgery, 1 month after insertion, prior to removal, 0-3 months after removal, and 3-6 months after removal. Self-reporting of the degree of analgesic medicine use and activity were also assessed using the same VAS approach.

Statistical analysis

Differences between groups were evaluated by two-tailed Student's t-test or analysis of variance (ANOVA) followed by Tukey's post-hoc test for single and multiple comparisons, respectively, when assumptions of normality and homoscedasticity were met by D'Agostino-Pearson omnibus normality and F tests, respectively. Otherwise, non-parametric Mann-Whitney and Kruskal-Wallis followed by Dunn's multiple comparison tests were used. P-values less than 0.05 were considered significant. For paired measurements, differences were analyzed by paired Student's t-test or Wilcoxon's matched-pairs signed rank test. Correlations between groups were assessed by linear regression using Pearson's coefficient of determination ($R^2$).

## Results:

Insertion and removal torque

Paired insertion and removal torque measurements revealed a significant 58.1% lower removal torque compared to insertion of those same screws ($p < 0.0001$), with only 9% of screws loosening by less than 15% (Figure 1B). To ensure that this reduction in torque between insertion and removal was not simply due to tapping of the screw hole upon insertion of the screw, the single-rotation back-out torque was also evaluated at the time of insertion. The immediate torque loss between insertion and back-out was 1.4 ± 5.6% (Figure 1C; $p = 0.68$, $\beta > 0.98$). Samples were clustered at a percent change of 0% (Figure 1C, right). Quantification of insertion and removal torque in unpaired pedicle screws, enabling a higher sample size, exhibited a similar 68% difference in torque between insertion and removal ($p < 0.0001$, Figure 1D).

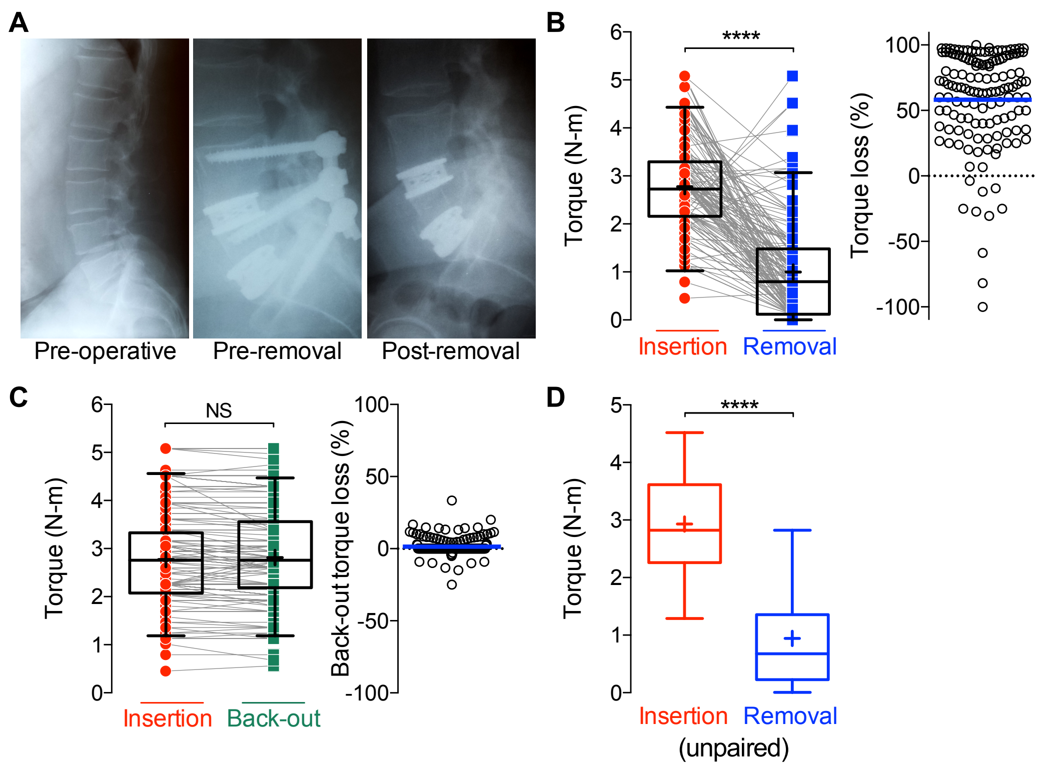



**Figure 1. Measurement of pedicle screw loosening by insertion and removal torque.** (A) X-ray images pre-operative, post-fusion, and post-removal. (B) Insertion and removal torque with paired samples connected by gray lines (N = 139 pairs), and scattergram of percent torque loss for those same pairs. (C) Insertion and immediate back-out torque (N = 204 pairs). (D) Unpaired insertion and removal torque (N = 467 and 477 for insertion and removal, respectively). Box plots show median line and 25th, and 75th percentiles, with whiskers at 5th and 95th percentiles, respectively. Mean values indicated by + symbol. Scattergrams show mean values indicated by blue line. Statistical differences assessed by paired (A, C) and unpaired (E) two-tailed Student's t-test. **** $p < 0.0001$, NS not significant.

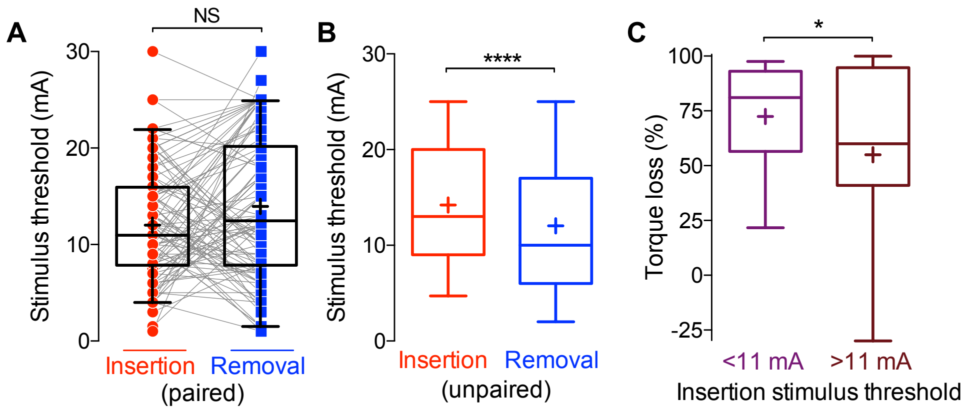



**Figure 2. Evoked EMG stimulus threshold at insertion and removal.** (A) Insertion and removal stimulus threshold with paired samples connected by gray lines (N = 98 pairs). (B) Unpaired insertion and removal stimulus thresholds (N = 394 and 430 for insertion and removal, respectively). (C) Percent torque loss for paired samples with stimulus threshold less than (purple) or greater than (brown) the 11 mA cutoff indicative of pedicle screw placement quality [22]. Box plots show median line and 25$^{th}$, and 75$^{th}$ percentiles, with whiskers at 5$^{th}$ and 95$^{th}$ percentiles, respectively. Mean values indicated by + symbol. Statistical differences assessed by paired (A) and unpaired (B,C) two-tailed Student's t-test. * $p < 0.05$, **** $p < 0.0001$, NS not significant.

Evoked EMG stimulus threshold

For paired samples, the difference in stimulus threshold at the screw hole was not significant between insertion and removal ($p > 0.05$, $\beta = 0.89$; Figure 2A). However, for unpaired measurements the stimulus threshold at screw removal was 15% lower than the stimulus threshold at insertion ($p < 0.0001$, Figure 2B). Torque loss in samples with less than 11 mA threshold at insertion, which has been identified as an indicator of screw placement and pedicle cortex violation [22], was significantly greater than those with insertion threshold above 11 mA ($p < 0.05$, Figure 2C).

Correlation analysis

To determine whether insertion torque, removal torque, or insertion stimulus threshold loss correlated with pedicle screw loosening, the torque loss percentage in paired samples was regressed against these parameters in matched samples. Linear regression demonstrated a significantly positive correlation ($p < 0.01$) between torque loss and insertion torque, with a Pearson's coefficient of determination ($R^2$) of 6% (Figure 3A). Regression of torque loss against removal torque revealed a significantly negative relationship ($p < 0.0001$), with a Pearson's coefficient of determination of 79% (Figure 3B).

Paired torque loss and unpaired removal torque were regressed against pedicle screw diameter and length, pedicle thickness, and pedicle screw clearance (defined as difference between pedicle thickness and screw diameter, Figure 4A). These measures were then combined to define pedicle-screw clearance as a measure of geometric pedicle integrity post-insertion (Figure 4A,B). Torque loss was significantly negatively correlated with pedicle-screw clearance ($p< 0.05$, $R^2$ = 22%, Figure 3D). Correlations of additional measurements were also evaluated, and are reported in the appendix (Appendix Figure 2).

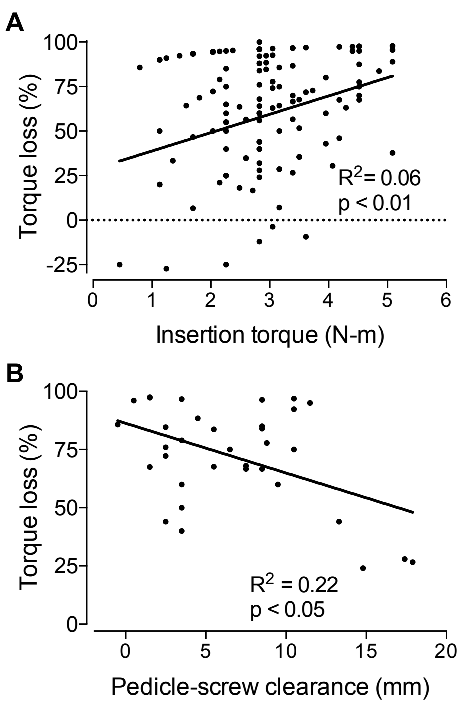



**Figure 3. Linear regression analysis of pedicle screw loosening for intraoperative measurements.** Correlation of percent torque loss with: (A) insertion torque (N = 139 pairs), (B) removal torque (N = 139 pairs)

Stress analysis

Analytical models varying transverse screw load and screw-hole interference (Figure 4) revealed similar trends between local von Mises stress and measured torque loss, with improved agreement with the data compared to simple linear regression (Figure 3D).

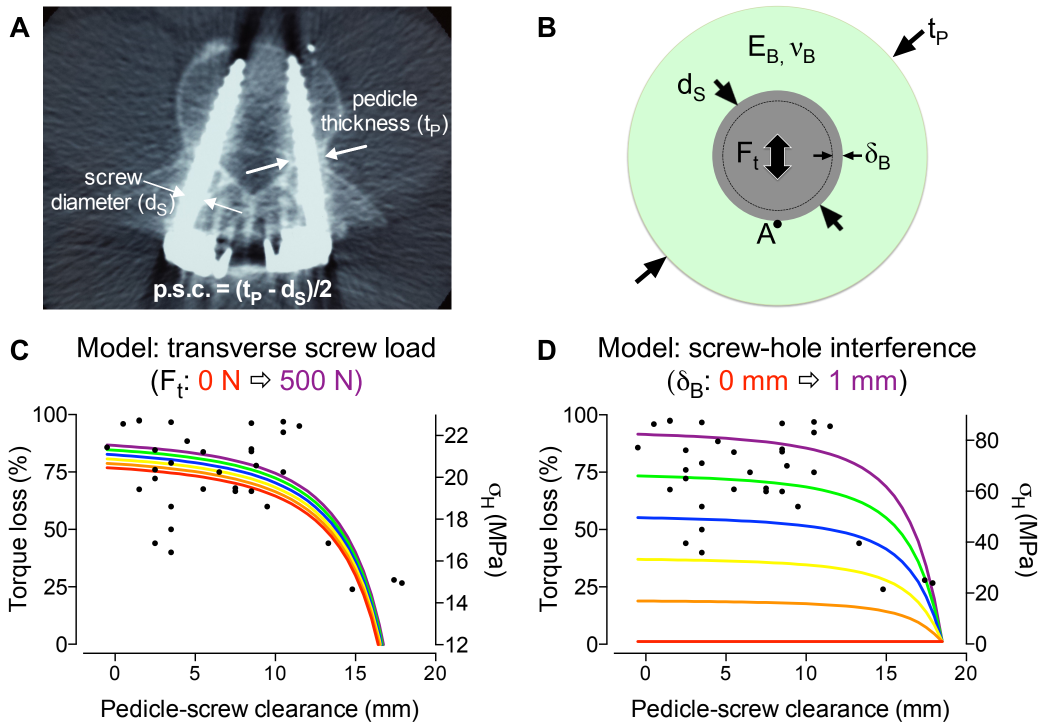



**Figure 4. Analysis of von Mises (octahedral shear) stress ($\sigma_H$) induced by transverse screw load ($F_t$) and screw-tap difference ($\delta_B$) as a function of pedicle-screw clearance.** Analytical stress analyses shown on the right y-axis, overlaid on the torque loss data from Figure 3D on left y-axis. (A) CT scan illustrating pedicle-screw clearance (p.s.c.). (B) Variables used for analysis of $\sigma_H$ at point A. (C) Percent torque loss and $\sigma_H$ vs. p.s.c. with variable $F_t$. $F_t$ increases from 0 N, in red, to 500 N, in purple. (D) Percent torque loss and $\sigma_H$ vs. p.s.c. with variable $\delta_B$. $\delta_B$ increases from 0 mm in red to 1 mm in purple.

Pedicle-screw clearance substantially influenced local stress values, dependent acutely on screw-hole interference (Figure 4D), but less on transverse screw load (Figure 4C). Increases in applied cantilever load (varied from 0-500 N) increased the von Mises stress, but did not dominate behavior, while increased screw hole interference (varied from 0 – 1 mm) dramatically increased the local stress adjacent to the screw.

Loosening by vertebra level

The percent torque loss by vertebra level in paired samples (Figure 5A) and removal torque in unpaired samples (Figure 5B) were evaluated at five levels of vertebrae from L2-S1. Both analyses exhibited similar trends, with the greatest degree of loosening in L2 and S1, and the least in L4.

Patient pain perception

While pain perception was significantly reduced by 19% within 1 month after surgery, pain was recurrent, and returned to 89% of pre-surgery levels, causing patients to return for instrumentation removal surgery (Figure 6A). Following removal, mean VAS pain scores decreased again, to 5.8 mm below the levels reported post-insertion. Three to nine months after removal surgery, mean VAS pain scores continued to decline to 27% lower than the pre-fusion levels. No differences were found in patient-reported use of analgesics or physical activity between any time points (Appendix Figure 3A,B).

## Discussion

Taken together, these data indicate that pedicle screws may loosen dramatically over time, even after successful fusion in patients with recurrent back pain. Though insertion torque has been reported as a better predictor than bone mineral density [26–28], this correlation is weak ($R^2$=0.04-0.4) for predicting linear pullout strength [29,30]. In the present study, insertion torque correlated significantly with torque loss, but the predictive power was poor ($R^2$ = 6% for N = 140 pairs), indicating that intraoperative measurement of pedicle screw insertion torque is not uniquely sufficient to predict the degree of loosening, consistent with a prior pilot report [31].

Evoked EMG stimulus threshold is used to detect screw placement and pedicle cortex violation [22,32]. Intraoperative EMG measurements indicated that poorly-seated screws have a greater likelihood of loosening; however, EMG stimulus threshold could not linearly predict the degree of loosening, so surgeons cannot rely on this measure alone to predict pedicle screw loosening.

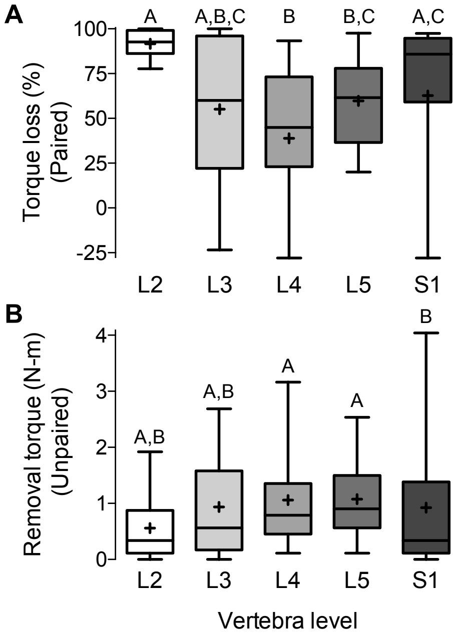



**Figure 5. Pedicle screw loosening by vertebra level.** (A) Percent torque loss for vertebra levels L2-S1 for paired measurements (N = 139). (B) Unpaired removal torques for vertebra levels L2-S1 (N = 430). Box plots show median line and 25th, and 75th percentiles, with whiskers at 5th and 95th percentiles, respectively. Mean values indicated by + symbol. Significance indicator letters shared in common between or among vertebra level groups indicate no significant difference.

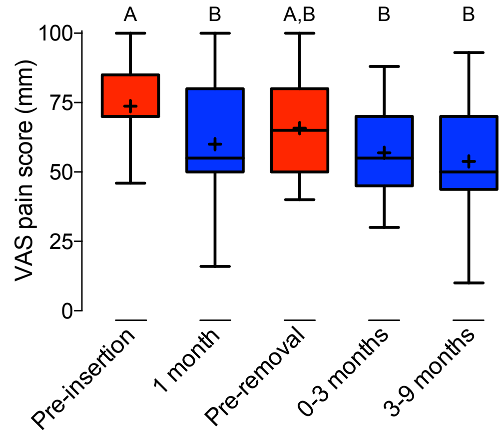



**Figure 6. Patient assessment of pain.** Visual Analog Scale (VAS; 0-100mm) assessment of pain (N = 31). Box plots show median line and 25th, and 75th percentiles, with whiskers at 5th and 95th percentiles, respectively. Mean values indicated by + symbol. Significance indicator letters shared in common between or among vertebra level groups indicate no significant difference.

The degree of loosening was vertebra level-dependent in a biphasic manner, with the least amount of loosening in the middle of the range of operated segments, and increased loosening in vertebrae at the extremities of the fused segments, suggesting that presence of adjacent fused vertebrae enhanced biomechanical stability.

Several potential biomechanical mechanisms can contribute to pedicle screw loosening. One possibility is instrumentation-induced stress shielding and subsequent disuse osteopenia. A decrease in bone mineral density has been seen in both canine [33,34] and human [35] implanted fixation devices. Another likely contributor is local plastic deformation at the bone-screw interface caused by the insertion and cyclic loading of the pedicle screws, resulting in screw loosening. Pedicle screw insertion induces residual stresses and stress concentrations that superimpose with cyclic loads to contribute to local tissue failure. These stress concentrations are highest at the cap-rod-screw interface [36,37]. We therefore used this location for further analytical analysis, using the von Mises stress as a measure of failure propensity. Calculated maximal stresses reached the reported yield stress of 95.6 MPa for trabecular bone [38], suggesting local stresses may contribute to loosening through load-induced toggling. These values are consistent with prior reports of static vertebral von Mises stresses up to 100 MPa at the pedicle body junction [36].

Based on the stress analysis, transverse screw load is not the sole driver of acute loosening, though may increase in importance with cyclic fatigue. However, there was a distinct correlation between pedicle-screw clearance and local stress: as pedicle screw clearance decreased, local stress increased with intraoperative torque loss. This suggests selection of optimal pedicle screw interference may be improved by accounting for pre-operative pedicle thickness measurement.

This model did not account for bone remodeling induced by local damage or biological responses to the implant, which progress over time [39]. High static stresses, combined with cyclic loading, may drive local stress above the yield point and cause loosening over time. These observations together suggest that increasing screw size relative to either pedicle thickness or initial hole diameter may impair long-term stability. It is therefore recommended that pedicle-screw clearance be maximized to decrease the local stresses that may cause screw loosening and pain. For patients with small pedicle thicknesses, increased loosening is likely, and careful observation or augmentation may be recommended.

Finally, observations of patient pain perception are in agreement with several studies, suggesting that pedicle instrumentation removal following successful arthrodesis may relieve recurrent pain [17–20], potentially caused by pedicle screw loosening. Further research will be necessary to fully evaluate clinical and pain outcomes and to establish pedicle screw loosening as a causative factor.

## REFERENCES


1 Phillips, F. M., Slosar, P. J., Youssef, J. A., Andersson, G. and Papatheofanis, F., 2013, Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine (Phila. Pa. 1976). 38(7): E409–22.

2 Rajaee, S. S., Bae, H. W., Kanim, L. E. A. and Delamarter, R. B., 2012, Spinal fusion in the United States: analysis of trends from 1998 to 2008. Spine (Phila. Pa. 1976). 37(1): 67–76.

3 Deyo, R. A., Gray, D. T., Kreuter, W., Mirza, S. and Martin, B. I., 2005, United States trends in lumbar fusion surgery for degenerative conditions. Spine (Phila. Pa. 1976). 30(12): 1441–5; discussion 1446–7.

4 Fischer, C. R., Ducoffe, A. R. and Errico, T. J., 2014, Posterior lumbar fusion: choice of approach and adjunct techniques. J. Am. Acad. Orthop. Surg. 22(8): 503–11.

5 Goldstein, C. L., Macwan, K., Sundararajan, K. and Rampersaud, Y. R., 2014, Comparative outcomes of minimally invasive surgery for posterior lumbar fusion: a systematic review. Clin. Orthop. Relat. Res. 472(6): 1727–37.

6 Griffin, K. S., Davis, K. M., McKinley, T. O., Anglen, J. O., Chu, T.-M. G., Boerckel, J. D. and Kacena, M. A., 2015, Evolution of Bone Grafting: Bone Grafts and Tissue Engineering Strategies for Vascularized Bone Regeneration. Clin. Rev. Bone Miner. Metab. 13(4): 232–244.

7 Benglis, D., Wang, M. Y. and Levi, A. D., 2008, A comprehensive review of the safety profile of bone morphogenetic protein in spine surgery. Neurosurgery 62(5 Suppl 2): ONS423–31; discussion ONS431.

8 Martin, B. I., Mirza, S. K., Comstock, B. A., Gray, D. T., Kreuter, W. and Deyo, R. A., 2007, Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures. Spine (Phila. Pa. 1976). 32(3): 382–7.

9 Fritsch, E. W., Heisel, J. and Rupp, S., 1996, The failed back surgery syndrome: reasons, intraoperative findings, and long-term results: a report of 182 operative treatments. Spine (Phila. Pa. 1976). 21(5): 626–33.

10 Alanay, A., Vyas, R., Shamie, A. N., Sciocia, T., Randolph, G. and Wang, J. C., 2007, Safety and efficacy of implant removal for patients with recurrent back pain after a failed degenerative lumbar spine surgery. J. Spinal Disord. Tech. 20(4): 271–7.

11 Kornblum, M. B., Fischgrund, J. S., Herkowitz, H. N., Abraham, D. A., Berkower, D. L. and Ditkoff, J. S., 2004, Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective long-term study comparing fusion and pseudarthrosis. Spine (Phila. Pa. 1976). 29(7): 726–33; discussion 733–4.

12 Hu, X.-Q., Wu, X.-L., Xu, C., Zheng, X.-H., Jin, Y.-L., Wu, L.-J., Wang, X.-Y., Xu, H.-Z. and Tian, N.-F., 2014, A systematic review and meta-analysis of unilateral versus bilateral pedicle screw fixation in transforaminal lumbar interbody fusion. PLoS One 9(1): e87501.

13 Hart, R., Hermsmeyer, J. T., Sethi, R. K. and Norvell, D. C., 2015, Quality and Quantity of Published Studies Evaluating Lumbar Fusion during the Past 10 Years: A Systematic Review. Glob. spine J. 5(3): 207–18.

14 Feiertag, M. A., Boden, S. D., Schimandle, J. H. and Norman, J. T., 1996, A rabbit model for nonunion of lumbar intertransverse process spine arthrodesis. Spine (Phila. Pa. 1976). 21(1): 27–31.

15 Halvorson, T. L., Kelley, L. A., Thomas, K. A., Whitecloud, T. S. and Cook, S. D., 1994, Effects of bone mineral density on pedicle screw fixation. Spine (Phila. Pa. 1976). 19(21): 2415–20.

16 Brodsky, A. E., Kovalsky, E. S. and Khalil, M. A., 1991, Correlation of radiologic assessment of lumbar spine fusions with surgical exploration. Spine (Phila. Pa. 1976). 16(6 Suppl): S261–5.

17 Jeon, C.-H., Lee, H.-D., Lee, Y.-S., Seo, J.-H. and Chung, N.-S., 2015, Is It Beneficial to Remove the Pedicle Screw Instrument After Successful Posterior Fusion of Thoracolumbar Burst Fractures? Spine (Phila. Pa. 1976). 40(11): E627–33.

18 Wild, A., Pinto, M. R., Butler, L., Bressan, C. and Wroblewski, J. M., 2003, Removal of lumbar instrumentation for the treatment of recurrent low back pain in the absence of pseudarthrosis. Arch. Orthop. Trauma Surg. 123(8): 414–8.

19 Salerni, A. A., 2004, Minimally invasive removal or revision of lumbar spinal fixation. Spine J. 4(6): 701–5.

20 Hume, M., Capen, D. A., Nelson, R. W., Nagelberg, S. and Thomas, J. C., 1996, Outcome after Wiltse pedicle screw removal. J. Spinal Disord. 9(2): 121–4.

21 Pihlajamäki, H., Böstman, O., Ruuskanen, M., Myllynen, P., Kinnunen, J. and Karaharju, E., 1996, Posterolateral lumbosacral fusion with transpedicular fixation: 63 consecutive cases followed for 4 (2-6) years. Acta Orthop. Scand. 67(1): 63–8.

22 Clements, D. H., Morledge, D. E., Martin, W. H. and Betz, R. R., 1996, Evoked and spontaneous electromyography to evaluate lumbosacral pedicle screw placement. Spine (Phila. Pa. 1976). 21(5): 600–4.

23 Mackiewicz, A., Banach, M., Denisiewicz, A. and Bedzinski, R., 2015, Comparative studies of cervical spine anterior stabilization systems - Finite element analysis. Clin. Biomech., Elsevier Ltd 3272–79.

24 Whyne, C. M., Hu, S. S. and Lotz, J. C., 2001, Parametric finite element analysis of vertebral bodies affected by tumors. J. Biomech. 34(10): 1317–1324.

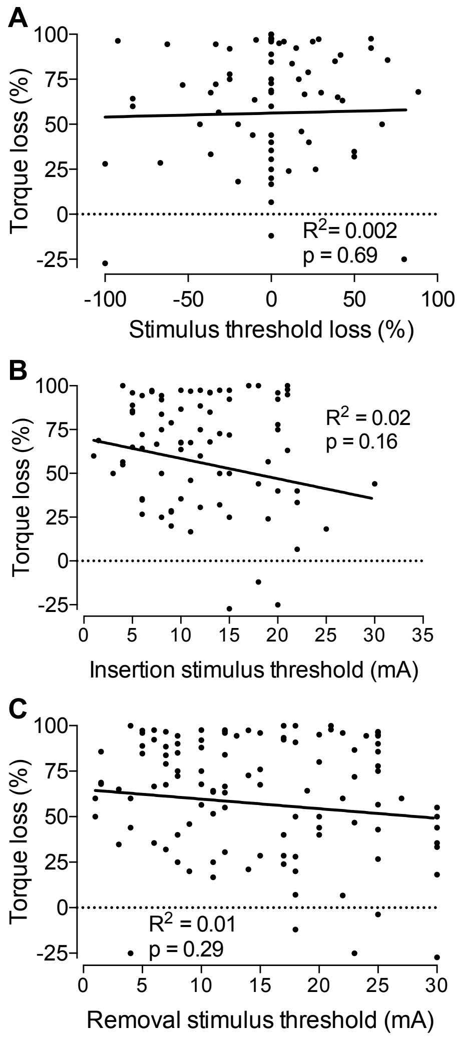
25 Keaveny, T. M., 1997, Mechanistic approaches to analysis of trabecular bone. Forma 12(12): 267–275.

26 Zdeblick, T. a, Kunz, D. N., Cooke, M. E. and McCabe, R., 1993, Pedicle screw pullout strength. Correlation with insertional torque. Spine (Phila. Pa. 1976).

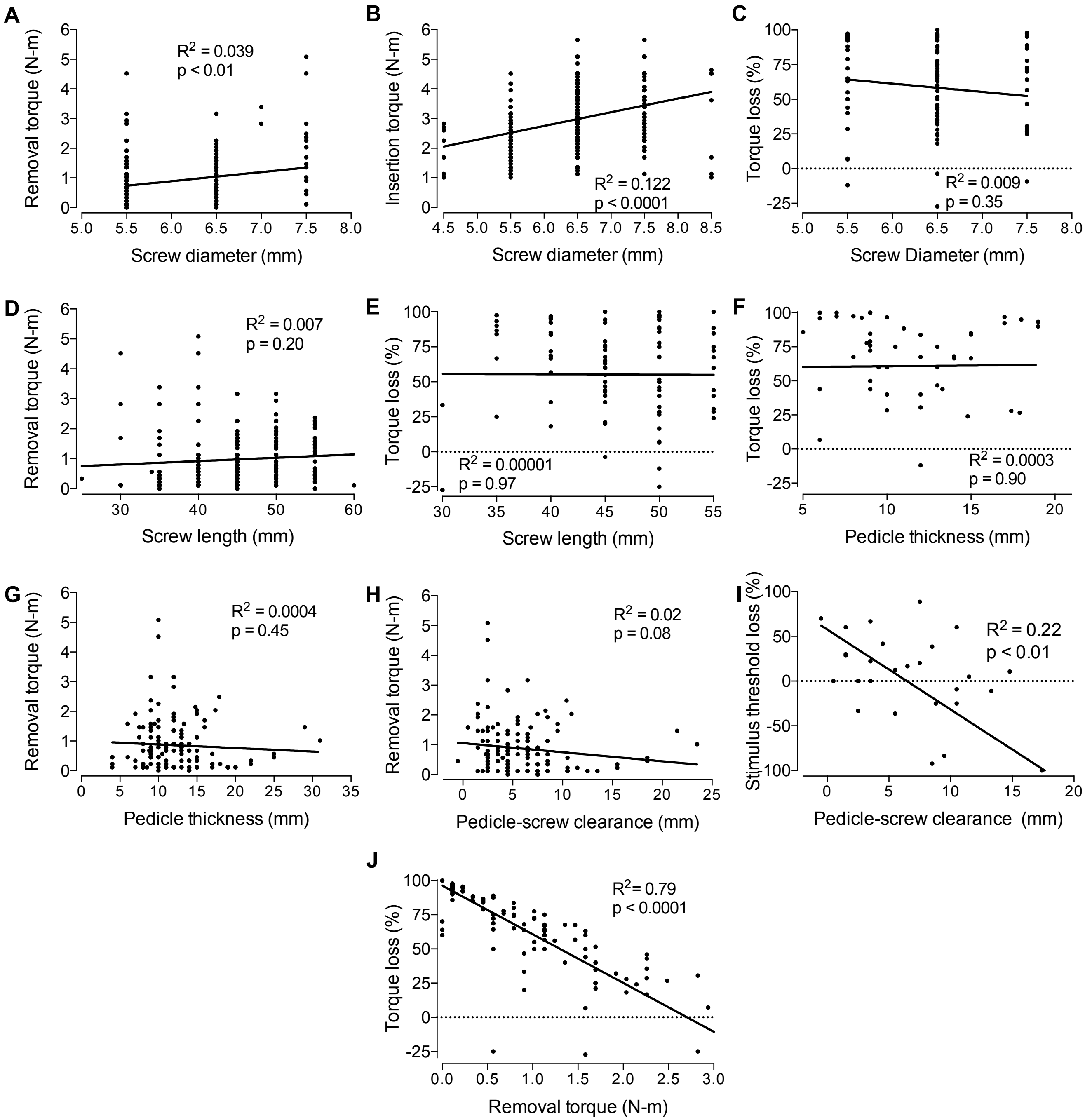
27 Mehmanparast, H., Petit, Y. and Mac-Thiong, J.-M., 2015, Comparison of Pedicle Screw Loosening

Mechanisms and the Effect on Fixation Strength. J. Biomech. Eng. 137(12): .
28 Mehmanparast, H. N., Mac-Thiong, J. M. and Petit, Y., 2014, Biomechanical evaluation of pedicle screw loosening mechanism using synthetic bone surrogate of various densities. 2014 36th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. 4346–4349.
29 Helgeson, M. D., Kang, D. G., Lehman, R. A., Dmitriev, A. E. and Luhmann, S. J., 2013, Tapping insertional torque allows prediction for better pedicle screw fixation and optimal screw size selection. Spine J., Elsevier Inc 13(8): 957–65.
30 Inceoglu, S., Ferrara, L. and McLain, R. F., 2004, Pedicle screw fixation strength: Pullout versus insertional torque. Spine J. 4(5): 513–518.
31 Sandén, B., Olerud, C., Larsson, S. and Robinson, Y., 2010, Insertion torque is not a good predictor of pedicle screw loosening after spinal instrumentation: a prospective study in 8 patients. Patient Saf. Surg. 4(1): 14.
32 Oner, A., Ely, C. G., Hermsmeyer, J. T. and Norvell, D. C., 2012, Effectiveness of EMG use in pedicle screw placement for thoracic spinal deformities. Evid. Based. Spine. Care. J. 3(1): 35–43.
33 McAfee, P. C., Farey, I. D., Sutterlin, C. E., Gurr, K. R., Warden, K. E. and Cunningham, B. W., 1991, The effect of spinal implant rigidity on vertebral bone-density - a canine model. Spine (Phila. Pa. 1976). 16(6): S190–S197.
34 Farey, I., McAfee, P., Gurr, K. and Randolph, M., 1989, Quantitative histologic study of the influence of spinal instrumentation on lumbar fusions: a canine model. J Orthop Res 7(5): 709–722.
35 Myers, M. A., Casciani, T., Whitbeck Jr., M. G. and Puzas, J. E., 1996, Vertebral body osteopenia associated with posterolateral spine fusion in humans. Spine (Phila Pa 1976) 21(20): 2368–2371.
36 Chen, S. I., Lin, R. M. and Chang, C. H., 2003, Biomechanical investigation of pedicle screw-vertebrae complex: A finite element approach using bonded and contact interface conditions. Med. Eng. Phys. 25(4): 275–282.
37 Duan, Y., Wang, H. H., Jin,  a M., Zhang, L., Min, S. X., Liu, C. L., Qiu, S. J. and Shu, X. Q., 2015, Finite element analysis of posterior cervical fixation. Orthop. Traumatol. Surg. Res., Elsevier Masson SAS 101(1): 23–29.
38 Bayraktar, H. H., Morgan, E. F., Niebur, G. L., Morris, G. E., Wong, E. K. and Keaveny, T. M., 2004, Comparison of the elastic and yield properties of human femoral trabecular and cortical bone tissue. J. Biomech. 37(1): 27–35.
39 Slyfield, C. R., Tkachenko, E. V., Fischer, S. E., Ehlert, K. M., Yi, I. H., Jekir, M. G., O'Brien, R. G., Keaveny, T. M. and Hernandez, C. J., 2012, Mechanical failure begins preferentially near resorption cavities in human vertebral cancellous bone under compression. Bone 50(6): 1281–1287.

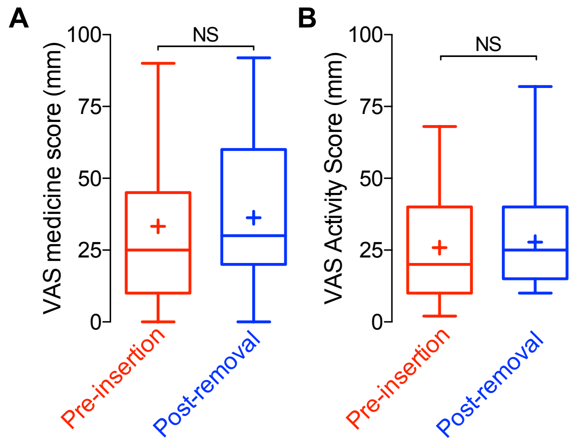
**APPENDIX**




**Appendix Figure 1. Linear regression analysis of pedicle screw loosening for intraoperative stimulus threshold measurements.** Correlation of percent torque loss with (A) percent stimulus threshold loss for paired samples (N = 84 pairs), (B) insertion stimulus threshold (N = 98 pairs), (C) correlation of percent torque loss with removal stimulus threshold (N = 114 pairs). $p > 0.05$ indicates the slope of the regression line is not significantly different from zero.




**Appendix Figure 2. Additional linear regression analysis of pedicle screw loosening for screw and pedicle size.** (A) Correlation of removal torque with screw diameter (N = 236). (B) Correlation of insertion torque with screw diameter (N = 467). (C) Correlation of percent torque loss with screw diameter for paired samples (N = 139 pairs). (D) Correlation of removal torque with screw length (N = 236). (E) Correlation of removal torque with screw length (N = 236). (F) Correlation of percent torque loss with pedicle thickness for paired samples (N = 52 pairs). (G) Correlation of removal torque with pedicle thickness (N = 146). (H) Correlation of removal torque with pedicle-screw clearance (N = 142). (I) Correlation of stimulus threshold loss with pedicle-screw clearance (N = 52 pairs). (J) Correlation of torque loss with removal torque (N = 139 pairs). $p < 0.05$ indicates the slope of the regression line is significantly non-zero.




**Appendix Figure 3. Analgesic use and activity VAS scores.** (A) VAS analgesic medicine use assessment. (B) VAS physical activity assessment.