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Research Article

Characterizing the Pedicle Screw-Bone Interface During Cycling: A Better Alternative to Pullout Strength?

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Abstract

Introduction: Pedicle screw fixation provides spinal stabilization in degenerative spondylolisthesis and scoliosis. Although prior studies have demonstrated screw loosening as an effect of toggling, they ultimately focus on the pullout force after cycling loading rather than the screw-bone interface stiffness decay.

Objective: To develop a stiffness model that predicts pedicle screw loosening.

Methods: Thoracolumbar vertebrae (T1-L5) were harvested from cadaveric spines, and pedicle screws toggle testing was conducted, followed by pullout tests. Linear regression modeling and Pearson's correlation tests were used to compare the stiffness decay coefficient with the ratio of the screw diameter to the pedicle width and the pullout strength.

Results: Sixty-eight pedicles were harvested. There were 23 in the undersized group and 21 pedicle screws in the normal-sized group. The average screw diameter was 53% of the pedicle width in the undersized group and 77% in the normal-sized group ($p<0.001$). A significant association was found between the SD/PW ratio and the natural log of the stiffness decay coefficient ($p=0.035$). The average pullout force was 170 N in the under-sized pedicle group and 194 N in the normal-sized group ($p=0.40$). Higher pullout force was associated with a lower stiffness decay coefficient ($p=0.005$). Pullout force and stiffness decay coefficients decreased with toggling force.

Conclusion: Pedicle screws with a high stiffness decay coefficient during toggle testing had lower pullout strengths. While higher SD/PW ratios were associated with increased stiffness decay coefficient, there was no relationship between pedicle screw size and pullout strength.

Keywords: Pedicle screw diameter; Pullout force; Toggling; Spine; Biomechanics

Introduction

Pedicle screws have become essential to providing spinal fixation in degenerative spine pathology. Pedicle screw fixation provides spinal stabilization and prevents vertebral motions in degenerative spondylolisthesis and scoliosis. Multiple studies have shown that pedicle screws of varying sizes can provide fusion after transforaminal lumbar interbody fusion [1]. In addition, pedicle screw anchoring has been shown to produce comparable or superior results in multiple measures of bone-screw fixation strength compared to cortical bone trajectory screw fixation, translaminar facet screw fixation, and lateral mass screws [2-4].

However, pedicle screw fixation requires several parameters to be optimized at the screw-bone interface to minimize clinical and biomechanical failure, including screw trajectory, bone density, and screw sizing [5-8]. Screw misplacement can lead to iatrogenic pedicle fractures, neurovascular injuries, screw loosening, and impaired mechanical stability. The trajectory of screw placement is driven by anatomical landmarks and intraoperative imaging, although modeling studies have advocated for patient-specific templates given the distortion of anatomical landmarks [9]. In non-osteoporotic bone models, every 10 degrees increase in insertion angle was associated with an approximately 160 N decrease in screw pullout strength

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[10]. In a clinical study of 52 participants after pedicle screw insertion for posterior lumbar fusion, Bone Mineral Density (BMD) was significantly lower measured by DEXA in patients demonstrating radiographic nonunion or screw loosening [11]. Biomechanically, a study of 21 human cadaveric spines implanted with pedicle screws showed a positive correlation between BMD and cycles to failure, suggesting that patients with BMD less than 80 mg/cm3 may require additional fixation [12].

Appropriate sizing of the inserted pedicle screw also affects the success of the fixation procedure as adequate screw purchase in the pedicle is required for optimal fixation [13]. However, complexities arise in clinical practice. The pedicle's bony structure is not uniform between patients and spinal levels [14]. Traditional methods of screw diameter selection require preoperative and intraoperative imaging, recommending the selected screw diameter to be at least 0.5 mm narrower than the outside pedicle diameter or 80% of the width of the pedicle to minimize rates of breach [15,16]. Other techniques include measuring insertional torque as the screws are placed [17].

Biomechanically, cortical bone provides approximately 60% of the fixation strength, with less than 20% of the fixation strength derived from cancellous bone [18]. The increased density of cortical bone relative to the surrounding bone allows the pedicle screw to better anchor into the cortical bone, thereby increasing fixation strength [19,20]. Multiple factors impact cortical bone fixation. A Computer Tomography (CT) scan study examining trabecular, subcortical, and cortical bone mineral density found that, in osteoporotic pedicles, the cortical layer demonstrated thinning, with the authors suggesting that larger screw sizes may lead to increased fracture risk of the cortical bone [21]. A systematic review showed a weak negative, rather than positive, correlation between screw diameter to pedicle width ratio and the reported pullout force [19].

Methodologically, previous studies have examined the strength of pedicle screw fixation by measuring uniaxial pullout force and cyclic loading force [17, 22–25]. Some studies have also strictly investigated pullout force after cyclic loading, referred to as toggling, to better replicate physiological conditions [26,27]. For example, two studies by Aycan et al. compared the pullout force of various pedicle screws in bovine vertebrae and polyurethane foams before and after toggling to demonstrate that following the early period after pedicle screw placement with cement augmentation, pullout strength decreases [28,29]. A recent study by Viezens et al. measured stiffness at the beginning, middle, and end of cyclic loading by incrementing the force [30].

Although these studies demonstrate screw loosening as an effect of toggling [31], they ultimately focus on the magnitude of the pullout force after limited cyclic loading rather than the screw-bone interface during cycling.

To the authors' knowledge, no prior literature has examined the effect of pedicle screw toggling on the decay in fixation strength across loading cycles. This study aims to develop a stiffness decay model that better predicts screw stability and investigates the effect of screw diameter to pedicle width ratio on overall screw stability following cyclic loading in the thoracolumbar spine. We hypothesize that a high decay coefficient will be associated with lower pullout strength. Additionally, we hypothesize that changing the screw diameter to pedicle width ratio will impact the stiffness decay function, which will better indicate screw efficacy than measuring traditional uniaxial pullout force.

3. Methods

3.1. Specimens Preparation and Implant Selection

Thoracolumbar vertebrae (T1-L5) were harvested from two fresh frozen human cadaveric spines. Both specimens were from female donors aged 68 and 85. Each vertebra was skeletonized. Pedicles that displayed signs of being damaged or prior instrumentation were excluded.

The left and right pedicle widths of each vertebra were measured from the medial border to the lateral edge using digital calipers with an accuracy of 0.01 mm (Mitutoyo 500-196-20, Mitutoyo America Corporation). Each pedicle was then randomly distributed into two groups: one group was instrumented with pedicle screw of a diameter less than 60 percent of the measured pedicle width ("under-sized group"), and the second group was instrumented with a pedicle screw of a diameter greater than 70 percent of the measured pedicle width ("normal-sized group"). Pedicle screws were of poly-axial design and were one of 4 possible diameters: 4.5 mm, 5.0 mm, 5.5 mm, and 6.0 mm) available (SpineCraft, Westmont, IL). The screw length was 35 mm for all pedicle screws.

3.2. Surgical Technique

The starting point for screw placement was determined using anatomic landmarks defined for each vertebral level, as previously described utilizing Arbeitsgemeinschaft für Osteosynthesefragen (AO) free-hand pedicle screw placement technique. All instrumentation was performed under the supervision of a fellowship-trained orthopaedic spine surgeon. After cannulation of the pedicle utilizing a hand-held pedicle finder, a 4.5 mm diameter tap was applied to the pathway. After an intraosseous trajectory was confirmed using a pedicle-sounding instrument, a 35 mm cortically threaded screw of predetermined diameter was inserted and placed using the manufacturer-specific screwdriver until the poly-axial head made contact with the bone. Parts of adjacent facet hypertrophy and/or transverse process were removed if they obstructed the screw head from contacting the bone. Visual inspection was used to confirm the appropriate placement of the pedicle screw and no breach.

Mechanical Testing

The screw head coupled with a connecting rod utilizing a set screw tightened to 80 N torque so that the screw head and the loading axis were in perpendicular alignment. The specimen was fully immobilized by fixing the vertebral body to a custom testing apparatus using cranially two metal plates and a caudally immobilized specimen (Figure 1a).

Toggle testing was conducted with a uniaxial load frame (MTS 30/G machine, Eden Prairie, MN). The connecting rod was attached to the MTS load cell used to drive the toggling of the pedicle screw (Figure 1a). The cyclic load was directed in the sagittal plane of the vertebra to produce a displacement of ± 1 mm, the average pedicle screw head displacement recorded during walking [32]. The bending force (Newtons) required to maintain the prescribed displacement was measured for each cycle. The test development method showed that the bone-screw interface decay function reaches a plateau between 200 and 500 cycles, consistent with studies reporting non-fatigue tests. All pedicle screws were toggled for 500 cycles, simulating a walking pace of 60 steps per minute as describe by Pinto et al [33]. The load cell moved at a rate of 1 mm/s (1 Hz) [31]. A failure was defined to have occurred when we could observe visible fracture lines or a sudden drop in load force on the uniaxial load frame before the completion of 500 cycles (Figure 2).

Following the toggling cycling test, an axial pullout test was performed with a uniaxial load frame utilizing the same MTS machine. The initial rod was exchanged with a shorter version and clamped to the load frame grip using a customized holder (Figure 1b). The vertebral body was immobilized on its cranial and caudal surfaces with a metal clamp. An upward force was applied along the same axis of the pedicle screw at a rate of 0.1 mm/s. Pullout force was measured, and testing was stopped when the screw loosened completely from the vertebra. This procedure allowed us to test each instrumented vertebrae's toggling and axial pullout.

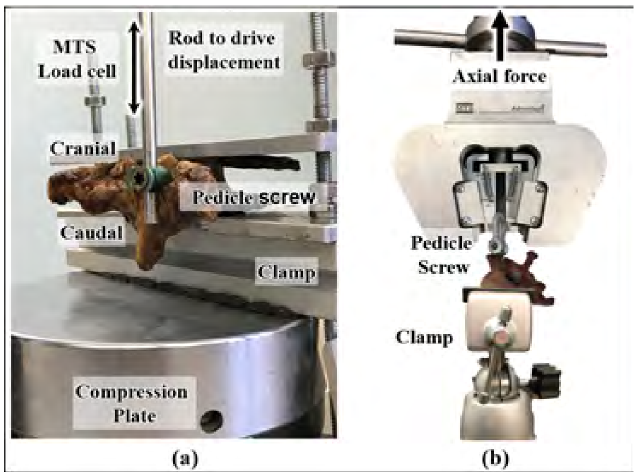

Figure 1: Experimental setup (a) toggle testing: the pedicle screw was fastened to a rod that was moved ±1mm for 500 cycles by the uniaxial load frame. (b) Pullout strength: after completing 500 cycles to toggle testing, the vertebra was rigidly clamped to the base of the axial frame. The pedicle screw was coupled to a hook and then fastened to a clamp attached to a load cell that provided an upward-directed force.

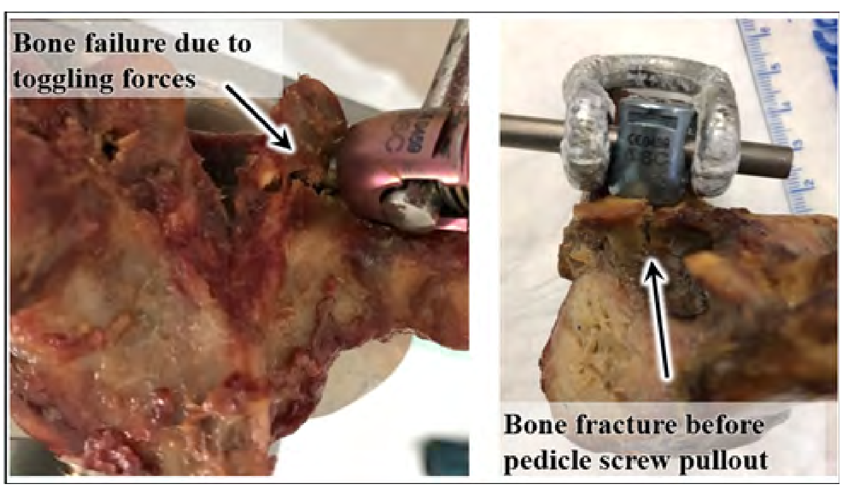

Figure 2: Two examples of pedicle failure during toggle testing as noted on visual examination demonstrating fracture. Arrows highlight a visible fracture line.

Statistical Analysis

Continuous variables as mean and Standard Deviation (SD). Categorical variables are summarized using frequencies and proportions. Loosening was defined as the percentage change in the final bending force from the initial bending force throughout toggle testing. Exponential and logarithmic decay models were calculated for each pedicle to describe the toggling decay response over the cycling period for each screw. The "stiffness decay coefficient" is defined as the coefficient of the exponential model shown below, where the stiffness decay coefficient is b:

$$f(x)=ae^{bx}$$

Linear regression modeling and Pearson's correlation test were used to compare the stiffness decay coefficient with the screw: pedicle diameter ratio (%) predictor of pullout strength and loosening. In addition, subgroup analysis was performed for screws in the undersized and normal-sized groups. The Ordinary Least Squares assumptions (OLS) were checked for every linear model. Variables were log-transformed if they violated OLS assumptions.

The linear regression models for the stiffness decay coefficient and screw: pedicle ratio were compared using the Akaike Information Criterion (AIC). All statistical analyses were performed in R software version 4.1.1 (R Foundation for Statistical Computing, Vienna, Austria), and significance was defined as $p<0.05$.

Results

Sixty-eight pedicles were harvested. Nineteen had evidence of prior instrumentation or were found to have visible fractures and were excluded. Therefore, forty-nine pedicles underwent instrumentation and testing. Five pedicles failed during toggle testing and were excluded from the final analysis. After excluding outliers, 44 pedicles were ultimately included in the analysis. This included 33/44 (75%) pedicles from the thoracic spine, and 11/44 (25%) were from the lumbar spine. There were 23 pedicles in the undersized group and 21 pedicles in the normal-sized group. Screws sizes were 4.5x35 mm (n=7), 5.0x35mm (n=11), 5.5x35mm (n=12), and 6.0x35mm (n=14). The mean screw: pedicle ratio was 64% (SD 13.4%). In the undersized group, it was 53% (SD 5%), and in the normal-sized group, it was 77% (SD 8%) ($p<0.001$).

Overall, loosening was 36% (SD 10.7%) after 500 cycles. There were no differences in loosening or maximum applied force between the undersized and normal-sized groups ($p > 0.05$).

Toggle Testing

Figure 3 illustrates the exponential and logarithmic regression models for the force required for each displacement cycle from 0 to 500 for four representative pedicles. For example, for the T10 pedicle results shown in figure 3a, the initial bending force was 173 N. The final bending force was 123 N. Therefore, the loosening after 500 cycles of toggling was 29%. In the exponential fit equation shown, y=154.88e-5E-04, the stiffness decay coefficient is 5E-04. Although the stiffness decay coefficient could seem small, the exponential model is susceptible to this value. As shown in figures 3(a-d), a higher stiffness decay coefficient denotes a steeper initial portion of the exponential curve.

The components of the regression that includes stiffness decay coefficient and screw: pedicle diameter as variables for predicting loosening are shown in Table 1. The stiffness decay coefficient was log-transformed as described in the Methods. The stiffness decay coefficient (natural log) was found to be a significant predictor of loosening ($p<0.001$), with higher stiffness decay coefficient associated with more considerable loosening. In other words, a steeper initial portion of the curve predicts a more significant percent decrease in the force required to toggle the screw by 1 mm. Screw: pedicle ratio had a negative coefficient in the model, though this was not statistically significant, and the 95% confidence interval is wide.

When including all pedicles, a significant association was found between the screw: pedicle diameter ratio and the natural log of the stiffness decay coefficient ($R2 = 0.1$, $p = 0.035$). In other words, a higher screw: pedicle ratio predicted a higher stiffness decay coefficient. In subgroup analysis, however, the differences in the mean stiffness decay coefficient between the undersized and normal-sized groups, 0.008 and 0.007, respectively, were not statistically significant ($p = 0.9$).

4.2. Pullout Force Testing

Figure 4 demonstrates an example of pullout testing for the pedicles shown in figure 3. Maximum pullout force was recorded for each pedicle. Overall, for all pedicle screws, the average pullout force was 183 N (SD 95N). The average pullout force was 170 N (SD 75N) in the undersized group and 194 N (SD 109N) in the normal-sized group ($p=0.40$). Subgroup analysis demonstrated a negative association between screw: pedicle ratio and pullout force in the normal-sized pedicle screw group ($R2 = 0.26$, $p=0.019$). In other words, a higher screw: pedicle ratio predicted lower pullout force in the normal-sized group. On the other hand, no significant association was found between the screw: pedicle ratio and pullout force in the under-sized screw group ($p = 0.83$).

The components of the regression that include pullout force and screw: pedicle diameter as variables for the loosening prediction of loosening are shown in Table 1. In this model, neither pullout force nor screw: pedicle ratio were statistically significant predictors. The coefficient for pullout force is negative. In other words, a higher pullout force is associated with less loosening after 500 cycles. Higher pullout force was associated with a lower stiffness decay coefficient ($p = 0.005$).

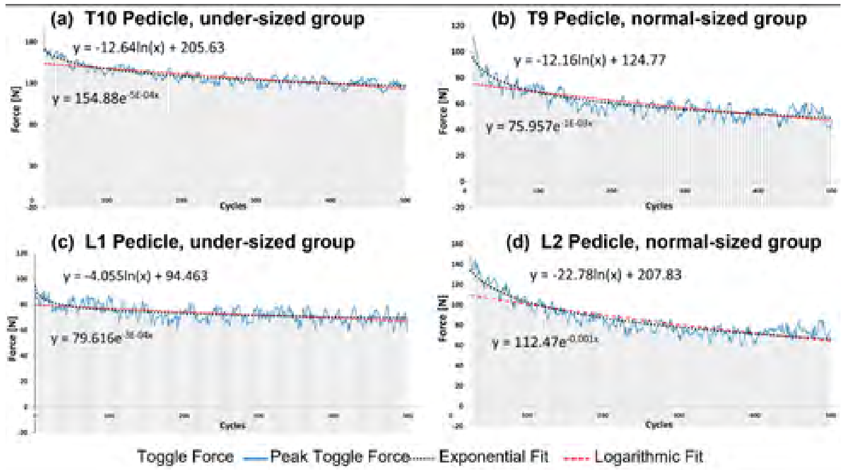

Figure 3: Maximum force measured at each toggle test cycle 9 through 500 for four representative pedicles: a) T10 pedicle in the under-sized group; b) T9 pedicle in the normal-sized group; c) L1 pedicle in the under-sized group; d) L2 pedicle in the normal –sized group. Exponential and logarithmic fit functions were built for each pedicle.

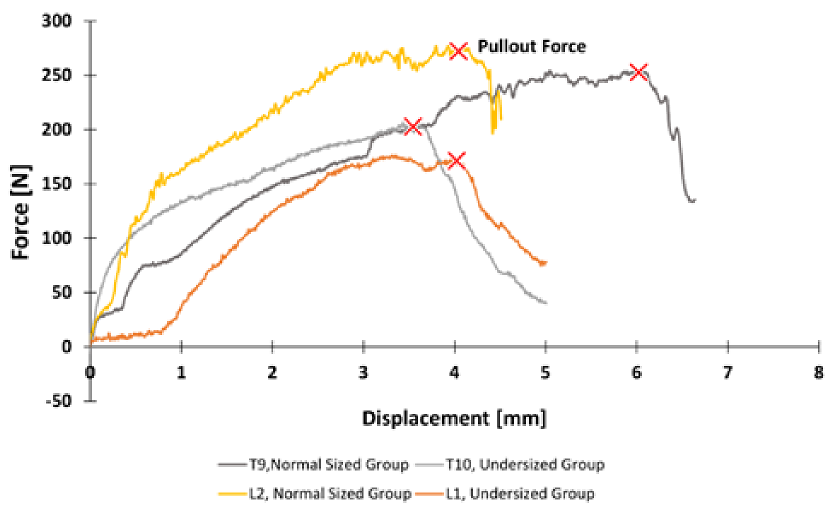

Figure 4: Pullout force versus displacement data for pedicle screws; T10 and L1 in the under-sized group, and T9 and L2 in the normal-sized group.

Table 1: Comparing predictive models for drop in maximum toggling force after 500 cycles utilizing the pullout force versus the stiffness decay coefficient.

Predictor	**Drop in Maximum Toggling Force in 500 cycle (%)** *Estimates*	**Drop in Maximum Toggling Force in 500 cycle (%)** *Estimates*
(intercept)	28.67*** (12.61 - 44.72)	46.62*** (28.49 - 64.75)
Level.factor: T	10.62** (3.75 - 17.50)	11.51*** (5.39 - 17.63)
Screw: Pedicel Diameter	6.81 (-15.92 - 29.53)	-1.41 (-22.25 - 19.44)
Pullout Force [N]	-0.03 (-0.06 - 0.00)	
log Decay]		2.90*** (1.42 - 4.39)
Observations	44	44
R^2/R^2 adjusted	0.34/0.29	0.47/0.43
AIC	324.123	313.816

*p<0.05, **
p<0.01, ***
p<0.001

Comparing Pullout Strength versus Stiffness Decay Modeling

Pullout force and the natural log of the stiffness decay coefficients were associated with the drop in maximum toggling force after 500 cycles ($p = 0.026$ and $p < 0.001$, respectively). The model that included stiffness decay coefficient as a predictor provided a better fit for loosening than the model that had pullout strength, as evidenced by a lower Akaike information criterion (AIC), Table 1.

Discussion

The screw-bone interface plays an integral role in the strength and stability of pedicle screw fixation in vertebral bone. As hypothesized, pedicles with a high stiffness decay coefficient during toggle testing had lower pullout strengths. In addition, higher pedicle screw to bone diameter ratios is associated with increased stiffness decay coefficient, whereas no significant relationship was detected between pedicle screw size and pullout strength. Moreover, in a subgroup analysis of the normal-sized group, increasing pedicle screw to bone diameter ratios was significantly associated with lower pullout strength. Finally, as hypothesized, incorporation of the stiffness decay coefficient better predicted the loosening of pedicle screws after toggle testing compared to utilizing pullout force. These results challenge the commonly held perception among surgeons that large diameter pedicle screws are preferred to increase pullout strength.

A Computer Tomography (CT) study of bony architecture and quality in health subjects' and osteoporotic lumbar pedicles found increasing bone mineral density from trabecular to subcortical to cortical bone [21]. The authors hypothesized that, with normal bone quality, larger diameter screws push trabecular bone outward and obtain better fixation in increasingly dense bone. However, in osteoporotic vertebrae, the thinning of the cortical layer combined with the decreased BMD in all layers may explain the lack of increased fixation with increasing screw diameter [34]. A similar mechanism may explain our findings that, in the undersized pedicle screw group, increasing the proportional size of the screw did not impact its maximum pullout force after cyclic loading. Three-fourths of the pedicles assessed in our study were derived from the thoracic spine. Anatomically, thoracic pedicles have a lower cortical thickness than lumbar pedicles [35]. Given this lower cortical thickness, the increase in screw diameter may not necessarily lead to a greater cortical purchase, analogous to what was reported in osteoporotic bone. This lack of cortical purchase, combined with the increased risk of unobserved breaches when utilizing a larger diameter screw, may explain why increasing the screw size was associated with a decreased pullout strength during testing in the normal-sized pedicle screw group [36]. However, there were no differences in the toggling force between the normal-sized and under-sized groups, suggesting that under-sized screws provide appropriate purchase in the thoracic bone. These results indicate that oversizing screws may not lead to enhanced bony fixation countering a widely held convention.

In contrast to our results, Viezens et al. concluded that screws with a size of roughly 90% of the diameter of the pedicles in L4 had higher fatigue loads compared to their standard screw group [30]. Methodologically, our study examined the screw-bone interface during cycling by keeping the pedicle screw head displacement constant within an acceptable physiological range. In contrast, Viezens et al. applied and increased fatigue load with each toggling cycle [32]. Their endpoints differed from those used in this present study. In addition, our study focused on determining the stiffness decay function to better understand the behavior of the pedicles during the entirety of the toggling cycling rather than at three discrete time points during the testing.

Finally, the results of Viezens et al. showed higher fatigue loads than those observed in our study, which could be due to the fact they exclusively used L4 pedicles. Lumbar vertebrae have been shown to have greater cortical thickness than thoracic and cervical levels [35]. These high fatigue loads may be partly due to the increased stiffness of the L4 pedicles. Our study examined multiple spinal levels, predominantly thoracic spinal levels. After testing various spine levels at different spine regions, our results showed that under-sized screws were no different than those typically sized in terms of toggling force, pullout strength, and stiffness decay.

Clinically, selecting a screw size that maximizes the pedicle diameter-screw ratio may not lead to better fixation in all spine levels or regions. Nevertheless, our results add to the ever-growing body of literature on the good selection and placement of pedicle screws in spine surgery.

In addition to examining the final screw-interface strength after toggle testing, this study introduces the novel concept of utilizing regression modeling to predict the effect that toggle cycling has on the loosening of pedicle screws. Toggle testing with sequential pullout has been used methodologically to compare the effect of multiple parameters, including screw diameter, bone density, and cement fixation [26-28,30]. However, the authors only found one study comparing the pullout force before toggling to that after toggling [28]. Another study reports a beginning, midpoint, and final fatigue load during toggle testing.30 In contrast, this study incorporates the maximum toggling force at each cycle, demonstrating that the impact of toggle cycling on pedicle loosening is not linear. Instead, an exponential and logarithmic model implies a more significant initial decrease in screw purchase. By describing the relationship of the screw-bone interface as a best-fit curve across toggle cycles, a more nuanced understanding can be achieved rather than strictly examining pullout force. Additionally, a decrease in more than two units of the Akaike information criterion demonstrates that examining a decay coefficient is a better fit model than using pullout force for predicting final screw loosening after 500 cycles.

This study focuses on the importance of toggling in the early phase of pedicle screw loosening. The test development method showed that the bone-screw interface decay function reached a plateau after 200 cycles for some specimens. Different from fatigue tests with more than 500 cycles and up to 5,000 cycles, the authors consider that the toggling effect in early cycles provides the most for the interface decay.28,29 Based on testing and observation, the foremost decay takes place within the first 50 cycles; hence a decay function in the early stage of toggling is more indicative of showing changes in strength and stability in the bone-screw interface. The toggling of the pedicle screw decay function indicates slope changes as it relates to fixation due in part to bone quality and screw threads designs.

Nonetheless, our study has some limitations. First, the number of vertebrae units was limited; therefore, comparing thoracic and lumbar vertebrae was unviable. However, including all the vertebrae levels in the same study allowed us to elucidate that the thoracic and lumbar vertebrae exhibit the same decay phenomena, and they seem to respond similarly with different slopes but reaches the plateau at or after 200 cycles. Secondly, pedicle screws were placed using anatomical landmarks rather than radiographic guidance. However, the safety and efficacy of free-hand screw placement in the thoracic and lumbar vertebrae are well-established [37]. The effect of BMD on the pullout strengths and decay coefficients is not a subject of this study. Finally, while pedicles were derived from a limited number of spine specimens, there may be variability in BMD by vertebrae level.

Additionally, 500 cycles of toggling may only represent only early-placement pedicle screw loosening. Increasing the number of toggling cycles may better elucidate the relationship between the number of toggle cycles and screw loosening, further validating the utility of an exponential or logarithmic predictive model. Future studies should examine the effect of BMD, include younger specimens if possible, and increased toggling cycles on the decay in fixation strength of thoracic pedicle screws.

Finally, our study compared undersized screws with standard-sized screws. Further studies should compare the oversizing of pedicle screws against undersized ones at different spinal levels.

6. Conclusion

The screw-bone interface plays an integral role in the strength and stability of pedicle screws in vertebral bone. Higher pedicle screw to bone diameter ratios was significantly associated with increased stiffness decay coefficient, while no relationship was detected between pedicle screw size and pullout strength. In other words, undersizing pedicle screws, particularly in the thoracic vertebrae, provides non-inferior pedicle screw fixation compared to normally-sized screws.

Future studies should look into understanding how decay and decay stiffness coefficients play a role in a better understanding fixation strength in spine surgery instrumentation.

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