



Identification of Pedicle Screw Pullout Load Paths for Osteoporotic Vertebrae

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Study Design: A biomechanical study.

Purpose: To determine the actual load path and compare pullout strengths as a function of screw size used in revision surgeries using postmortem human subject specimens.

Overview of Literature: Pedicle screw fixation has become the standard of care in the surgical management of spinal instability. However, pullout failures are widely observed in osteoporotic spines and treated by revision surgeries using a higher diameter screw, performing cement augmentation, or increasing the levels of fixation. While the peak forces to final pullout are reported, the actual load path to achieve the final force level is not available.

Methods: Six osteoporotic lumbar spines (L2–L5) were instrumented with 5.5×40 mm polyaxial screws and loaded along the axis of the screw using a material testing machine according to American Society for Testing of Materials 543-07 test protocol. Tests were again conducted by replacing them with 6.5×40 mm (group A) or 7.5×40 mm (group B) screws. Force-displacement data were grouped and load paths (mean±1 standard deviation) were compared.

Results: Pullout strength decreased by 36% when the size of the revision screw was increased by 1 mm, while it increased by 35% when the size of the revision screw was increased by 2 mm compared to the index screw value. While the morphologies of the load paths were similar in all cases, they differ between the two groups: the larger screw responded with generally elevated stiffer path than the smaller screw, suggesting that revision surgery using a larger screw has more purchase along the inserted body-pedicle axis.

Conclusions: A larger screw enhances strength and increases biomechanical stability in revision surgeries, although the final surgical decision is made by the clinician, which includes the patient's anatomy and associated characteristics.

Keywords: Lumbar vertebrae; Osteoporosis; Pedicle screws; Pullout strength; Spine fusion; Normalization

Introduction

The spine is a complex load-bearing structure that undergoes various degrees of motion under normal daily activities. It also undergoes degeneration with advancing age. Osteoporosis is one of the leading causes of degeneration

that is characterized by a decrease in the mineral content of the trabecular bone [1,2]. The decrease results in altered load sharing within the intervertebral components and may also result in spine instability. Fusion surgery is an option, wherein the unstable segments are stabilized by pedicle screw fixation. This technique was first described

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in 1959 [3], in which stainless screws were placed through the pedicle, and improvised in 1970 [4] with the additional use of posterior plates/rods connecting the screws. Even though there have been considerable improvements in the screw design and fixation techniques, failures, such as screw pullout and breakages, are continuously reported in the clinical literature. One study reported that pedicle screw failure is the cause of 17% of revision surgeries [5]. Failures due to screw loosening are mostly caused by low bone mineral density (BMD). Several studies have shown a correlation between BMD and pullout [6-8]. Instrumenting an osteoporotic vertebra is a challenge to surgeons and bioengineers. Further, revision surgeries, which are performed through screw removal followed by insertion of a revision screw of higher dimension, are even more complex and demanding [9]. The selection of the revision screw size is subjective, depending on the index screw used, pedicle morphometry, and surgeon's experience. Hence, there is a need to understand the effect of revision screw size on strength and stability of pedicle screw instrumentation.

Studies on pullout strength are routinely used to evaluate the holding power of pedicle screws. They are conducted using Post Mortem Human Subject (PMHS) specimens [10,11], rigid polyurethane foam [12,13], or bovine or porcine specimens [14]. The pullout strength value is used to evaluate the effect of different pedicle screw thread profiles and designs. This single value does not fully characterize the performance of the pedicle screw, as only one number corresponding to its failure point is used. Understanding the load path to reach the peak force/pullout strength is important as it might assist in the decision-making process for revision surgeries. Therefore, the present study aimed to develop a pullout strength response load path for osteoporotic spines and compare the effects of revision screw diameter.

Materials and Methods

Six lumbar spine vertebral specimens from L2–L5 region were obtained from the Department of Anatomy of the Christian Medical College Vellore, India (age, 65 ± 14 years; BMD, 0.743 ± 0.201 g/cm²; T-score, -2.4 ± 1.39). Radiographic examination was performed to rule out pathological deformities, osteophytes, or fractures. The BMD of each vertebral body was measured using a dual-energy X-ray absorptiometry scanner (Discovery A; Hologic,

Mississauga, ON, Canada). The bone was characterized based on T-scores by the World Health Organization classification [15]. The muscles and surrounding soft tissues were removed for pedicle screw instrumentation by an experienced surgeon, the clinical author of this study (V.K.). Pilot holes were drilled using a 3.2-mm drill bit, and screws were inserted after tapping with 4.5-mm drill.

Three cylindrical, polyaxial pedicle screws of 40-mm length made from medical grade titanium (M8 Medtronic; Sofamor Danek, Memphis, TN, USA) with outer diameters of 5.5, 6.5, and 7.5 mm were used. The specimens were divided into two groups. Pedicle screws were instrumented using an index screw with a diameter of 5.5 mm, and postoperative computed tomography was performed on the instrumented vertebra to confirm the position before conducting the pullout strength experiment. After the index screw pullout, the screw was removed, and the pedicle walls were sounded with a pedicle probe/feeler for any breach. None of the pedicles had any breach; thus, the same trajectory was achieved when revision screws were inserted. After the confirmation, the revision screw was inserted at the same site, and the pullout strength test was repeated. The size of the revision screw was as follows: group A, 6.5 mm in diameter; group B, 7.5 mm in diameter; length of the screws in each group, 40 mm.

The pullout strength test was performed using a material testing device (BiSS Nano 25; BISS, Bangalore, India) at the Indian Institute of Technology Madras, Chennai, India. The samples were mounted using a specially designed jig that allowed each screw to be pulled along the loading

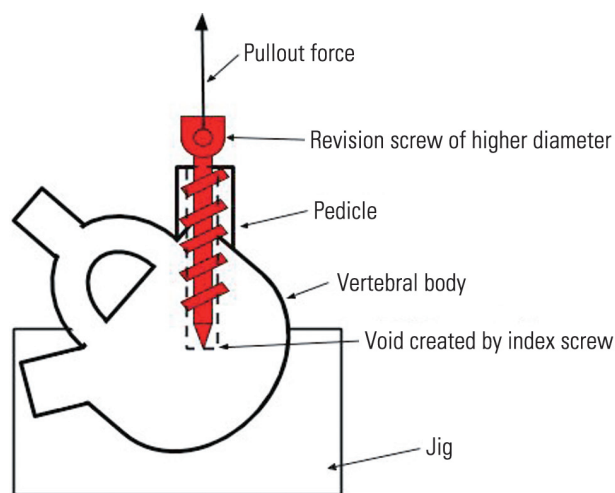


Fig. 1. Schematic showing that the larger screw is placed in the void that was created due to the pullout of the index screw. This applies to group A and group B, i.e., 6.5- and 7.5-mm screws, respectively.

axis (Fig. 1). The screws were distracted at a rate of 5 mm/min, according to the American Standards for Testing of Materials-543-07 [16]. Force and pullout or deflection signals were recorded using a data acquisition system at 50 Hz sampling rate. Force-time and pullout deflection-time signals were filtered, and the time variable was eliminated to obtain force-deflection curves.

Failure was defined as the point on the force-deflection curve at which the force decreases with increasing displacement (Fig. 2). The internal architecture of the cancellous and cortical bony counterparts was disrupted during this process, and the damage along the screw path reflects this process.

The actual load paths were determined as follows. The peak force and displacement corresponding to the peak force were normalized to a 1:1 scale for each specimen. Thus, at every force data point (F_i), the actual force value was normalized by the peak force (F_{max}) for that specimen, i.e., F_i/F_{max} . The deflection was treated similarly; i.e., at every deflection datapoint corresponding to the force datapoint, the actual deflection value (D_i) was normalized by the deflection value (D_{f-max}) corresponding to the maximum force (F_{max}), i.e., D_i/D_{f-max} . This resulted in a 1:1 mapping for the force-deflection curve for each specimen. This curve was dimensionless. The average normalized curve was obtained by averaging the force and displacement values from this process, and this was also on a 1:1 scale. The actual force-displacement curve, expressed in kN-mm, was then obtained by back normalizing the mean dimensionless curve by multiplying the force and displacement values by their means at each paired datapoint. Plus/minus one standard deviation (SD) curves were also obtained in a

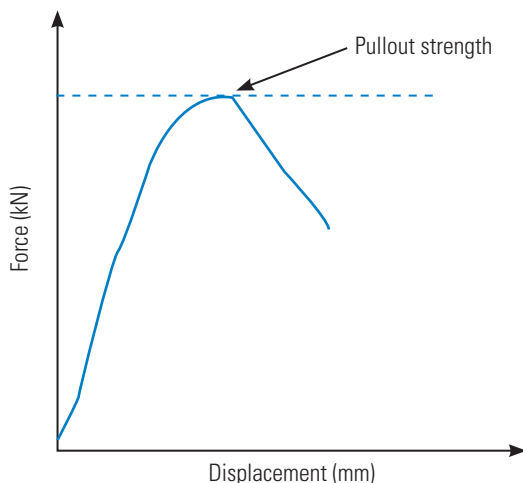


Fig. 2. Schematic of force versus displacement graph.

similar manner, i.e., obtaining the dimensionless SD curves and then using the back-normalizing process [17]. These profiles defined the load path obtained by the respective screws and groups to attain the pullout strength.

Results

The pullout strength profiles developed for revision surgery using two different screw diameters are shown (Fig. 3). The morphologies of the load paths in all cases were similar. The larger screw responded with a generally elevated stiffer path (not the stiffness as expressed by the force-deflection ratio) than the smaller screw. In group A specimens, the pullout strength for the revision screw was lower than that for the index screw. The mean pullout strength was 0.379 ± 0.272 kN for the index pedicle screw but 0.242 ± 0.063 kN for the revision screw. In group B specimens, the pullout strength of the revision screw decreased by 36% of the index screw value. The mean displacement of failure was 5.03 mm for the index screw but 3.18 mm for the revision screw. In group B specimens, the pullout strength of the revision screw was greater than that of the index screw. The mean pullout strength was 0.379 ± 0.272 kN for the index screw but 0.513 ± 0.49 kN for the revision screw. There was a 35% increase in pullout strength for the revision screw in group B specimens compared to the index screw pullout strength value. The mean displacement for failure was 5.03 mm for the index screw but 5.45 mm for the revision screw.

Mean curves for group B lie above those for group A and index curves (Fig. 3). This is likely due to the larger diameter screw that engages with the cortical bony interfaces more than the smaller diameter screws.

The morphology of the curves describing the load paths was obtained by univariate polynomial regression on the mean and SD values corresponding to displacements using the normalized data and then was back normalized. The equation and R^2 of the fit are as follows:

Index screw

$$y = (0.003 x^3 - 0.0362 x^2 + 0.1813x) \pm (-0.0008 x^4 + 0.0098 x^3 - 0.0452 x^2 + 0.0807x); x \in [0, 5.03]$$

$$R^2 = 0.99$$

Group A

$$y = (-0.0027 x^3 - 0.0071 x^2 + 0.1257 x) \pm (-0.0008 x^4 - 0.0069 x^3 - 0.0264 x^2 + 0.0402 x); x \in [0, 3.18]$$

$$R^2 = 0.98$$

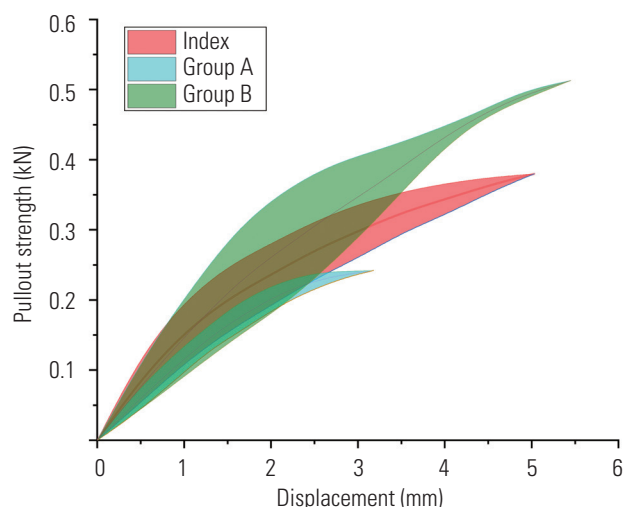


Fig. 3. Overlay of force-displacement paths for the index, group A, and group B tests.

Group B

$$y = (0.009x^3 - 0.0169x^2 + 0.1608x) \pm (-0.0006x^4 - 0.0033x^3 - 0.0152x^2 + 0.0777x); x \in [0, 5.45]$$

$$R^2 = 0.98$$

where y is the load on the pedicle screw in kN and x is the instantaneous screw displacement in mm.

Discussion

The mean pullout strengths of 0.379 ± 0.272 kN from this study are similar to those in the literature. In a study using 21 specimens with a mean BMD of 0.567 ± 0.101 g/cm², the pullout strength was 0.241 ± 0.174 kN [18]. Another study using 37 specimens with a BMD of 0.684 ± 0.197 g/cm² reported a pullout strength of 0.524 ± 0.311 kN [19]. In a study of Li et al. [18], the screw sizes were 6.5×45 mm and 4.5×30 mm. In a study of Jacob et al. [19], the screw size was 6×40 mm. These dimensions are 1 mm and 0.5 mm greater than the index screw diameter of the current study. The pullout strength values of the current study match with those in the literature.

Pedicle screw biomechanics is often reported in terms of pullout strength, i.e., the maximum force that the construct sustains before pullout from the vertebra. Strength values assist the surgeon in the treatment regimen, for example, levels to incorporate the screw for fixation, and advise the patient regarding the activities of daily living following surgery. In this study, in addition to this peak force, the morphology of the path of the force-displacement curve was developed. The load path is a

more comprehensive display as importance is not focused on one number, peak/pullout force. Knowledge about the load path to reach the peak force, i.e., its morphology of the path, may assist revision surgical options. Any extrusion of the screw can be potentially linked to the reserve strength that can be determined from the load path. For example, if longitudinal images show a certain length of extrusion, determining the load-path/force-displacement curve will provide an objective assessment of the reserve/remaining force-deflection response before the full pullout. This data cannot be obtained from the single pullout value, commonly reported in other studies.

The novelty of the present study is the development of the pullout strength profiles to describe the screw load path. They provide more comprehensive information regarding the progression toward the failure of the pedicle screw in contrast to the routinely reported single value of its strength. Thus, they help describe how the pullout strength value was reached from the initial loading. The present study showed that a revision screw with 2 mm greater diameter had better pullout strength than a revision screw with a 1 mm greater diameter. It should be noted that studies in literature, using rigid polyurethane foam models, have shown that there is a decrease in pullout strength with a revision screw of 1 mm greater diameter than the index screw [20,21]. While studies that provide a similar comparison from other PMHS/foam models are unavailable, revision surgeries using a screw with 2 mm greater diameter seem to offer better biomechanical stability. However, this PMHS-based observation needs additional confirmation due to the small sample size and acute mode of force application. Variables such as patient-related factors may also play a role.

One of the applications of the current study is the development of artificial surrogate materials for biomechanical evaluation of pedicle screws. Currently, surrogates, such as rigid polyurethane foams, are widely used as an alternative in conducting pullout strength studies [22]. These materials are inexpensive and easy to handle unlike PMHS specimens [22,23]. The results of the current study can be used to test the surrogate materials and evaluate their performances, i.e., whether they fall within the pullout strength load paths. This will help in developing more biofidelic materials and validation criteria for novel materials in biomechanical testing.

Computational finite element models are used by design engineers to develop newer pedicle screws. The advantage

of these models is that it is effective to quantify local and component variables such as stress-strain distributions and strains. Several studies have been conducted to determine the effect of parameters such as inner and outer diameters, pitch, and thread profile on pullout strength [24-26]. Currently, these models are validated against a single value of pullout strength. The more comprehensive pullout strength load path development profiles presented in this study will assist in better validations. They can also be used with an optimization algorithm to determine the desired configuration of thread parameters for improved pullout strength and newer designs.

Another application of the current study is to develop the region of operation for pedicle screw instrumentation. Currently, machine learning [27] and other statistical approaches, such as surrogate modeling [21], are used in decision support systems for pedicle screw instrumentation. In this technique, the pullout strength is predicted based on the combination of density, insertion depth, and insertion angle. The predicted value of pullout strength is used to evaluate the success or failure of the surgery. The pullout strength load paths can be used to evaluate the region of safety and operating region for different bone densities for pedicle screw instrumentation. While the added complexity of the entire load paths (instead of a single value) poses challenges and is novel, as the clinical treatment is progressing toward personalized medicine, results from the present study can be used for such applications.

The reason for selecting the 1 mm and 2 mm increasing diameters over the initial size, i.e., 6.5 and 7.5 over 5.5 mm, is to demonstrate the biomechanical characteristics associated with these two specific sizes. The characteristics were defined based on the changes in the pullout forces and profiles of force-deflections. Hence, the findings are specific to these two sizes. From a clinical perspective, as the decision-making process is patient (and surgeon) specific, it may be difficult to resort to a 2 mm screw size change due to anatomical or other issues. In such patients, it would be necessary to resort to a lower incremental change (perhaps 0.1 mm), necessitating more frequent follow-ups, which could probably be combined with patient education to improve the outcomes of less optimal biomechanically effective screw revision. Along this vein, it would be prudent to conduct retrospective and, if possible, longitudinal studies to determine precise protocols for longitudinal assessments. The present study has opened these clinical and biomechanical avenues in the area.

Twenty-four vertebrae were excised from PMHS. While this allowed placement and testing of 48 screws to both pedicles, only one side was selected for testing each vertebra, while the other side was used for another exploratory study. Due to experimental difficulties (e.g., specimen alignment), data were available for 12 tests: group A tests consisted of seven index-revision test pairs of 5.5 and 6.5 mm, and group B tests consisted of five index-revision test pairs of 5.5 and 7.5 mm. It is known that the BMD influences pullout strength [6-8]. Because the mean BMDs were not statistically significantly different between the two groups ($0.70 \pm 0.15 \text{ g/cm}^2$ and $0.78 \pm 0.23 \text{ g/cm}^2$), it is difficult to determine its effect on the morphology of the load path. Additional tests are needed to resolve this issue. Likewise, it would also be important to investigate the dependence of parameters such as vertebral level on the load path, and these are future research topics. The present study is only a first step in the analysis of morphological paths and strength.

This study used embalmed vertebrae from osteoporotic lumbar spinal columns to develop the pullout strength load paths. It should be noted that disc degeneration and postural changes may also develop in patients with osteopenia and osteoporosis. Therefore, additional experiments are required to account for factors such as vertebrae with varying BMD, sex, disc degeneration in association with BMD loss/decrease, and other anatomical/structural variables. Although the mean plus-minus one SD method was used to develop the pullout strength load paths in this study, other techniques, such as scaling and normalization, should be evaluated. Telemetrized sensors are used to understand *in vivo* spine loads, but their loading patterns are difficult to mimic *in vivo* [28]. Hence, only axial loading condition was used in this study. However, this allowed the comparison of published results on pullout strengths, i.e., unitary values. As the *in vivo* human sustains cyclic loading, this mode should also be considered. Another limitation of this study is its reliance on a few parameters in characterizing the load paths. The effective pedicular diameter (EPD) variable should be included in the experimental design so that it can be included in the analysis. Tests on the same vertebra with the right side accepting the smaller (6.5 mm) and left side accepting the larger (7.5 mm) screw should be conducted as it can be assumed that the EPDs are not statistically significantly different between the right and left pedicles from the same vertebra. Likewise, spinal levels should also be included

in the design to discern any level-specific changes in the load paths. Adding or controlling for BMD may also be a factor. With a large sample size, these types of accommodations should result in improved estimations of the load paths that may be generalizable in adult populations. These are potential research topics.

Conclusions

While morphologies of the load paths were similar in all cases, they differed between the two groups: the larger screw responded with generally elevated stiffer path than the smaller screw, suggesting that revision surgery using the larger screw has more purchase power along the inserted body-pedicle axis. A larger screw enhances strength and increases stability in revision surgeries. The load path development determined in this study may assist in the decision-making process during revision surgeries for osteoporotic spines.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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