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Technical note

Comparison of pullout strength of pedicle screws following revision using larger diameter screws

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ABSTRACT

Pedicle screw fixation and fusion are the gold standard for the treatment of spinal instability. Screw failures such as pullout and breakages have been reported during the past several years of research and development in this field. Further, the rate of revision surgeries due to failed pedicle screws is around 2–12%. This creates unavoidable hardship to the patients. Improper screw size for revision surgery can lead to complications such as pedicle fractures, screw pullout, or reduced stability of the fusion construct. We performed pullout strength studies on five osteoporotic lumbar vertebra and a rigid polyurethane foam block to find the effect of the outer diameter of revision screws as per American Standards for Testing of Materials (ASTM) 543–07 protocol. The present study revealed that whereas the use of revision screws that were one millimeter greater in diameter than the original screws decreased the pullout strength by 79% in the foam model, the pullout strength increased by 121% when the original index screws were replaced with screws that were two millimeters greater in diameter. The effect of revision screw diameter on pullout strength was significant ($p < 0.05$). Cadaveric testing reveals a trend that agrees with the foam model tests.

1. Introduction

Lower back pain is a debilitating condition, faced worldwide, and 80% of people suffer from this condition at some point in their life [1]. This can result in a diminished quality of life and impair physical activities. Spinal instability, defined as an abnormal movement in the motion segment of the spine, is one of the principal causes of lower back pain [2]. Spine fusion surgeries correct the instability by using spinal implants such as pedicle screws. It stabilizes the unstable segment by acting as a load-bearing element for the motion segment until bony fusion is achieved [3,4]. The advantages of pedicle screw fixation include improved fusion rate, avoidance of external immobilization and provision of adequate force for correction of the spinal deformity. After years of pedicle screw design development, failures such as pedicle screw loosening, pullout, and breakage continue to be reported [5–7]. In osteoporotic bone, loose pedicle screws are a common phenomenon due to insufficient stability at the bone-screw interface [8]. A survey carried out in 1993 of 617 cases involving pedicle screws found the incidence of screw breakage to be 2.9% [9]. A 2012 study found a 12.9% rate of screw loosening in lumbosacral stabilization cases [10]. These screw failures can lead to additional complications and revision surgeries that cause hardship to the patients.

Revision surgeries are carried out to correct loosening, pseudarthrosis, or misplacement of the screws in the fusion construct [11]. Currently, there are several revision techniques such as the use of larger/longer size screws, cement augmentation, expandable screws, etc. [12–17]. Complications of cement augmentation are cement leakages or necrosis due to exothermic reaction while curing the cement. Moreover, the removal of cemented screws results in more extensive damage to the vertebra and surrounding tissues. Revision using expandable screws is also difficult as it can lead to pedicle or implant fracture. Longer bicortical screws increase the pullout strength but are not advisable as it may puncture the major vessels in front of the vertebra leading to catastrophic complications. The usage of larger diameter screw size can lead to pedicle breakage and smaller screws can compromise the construct stability. Hence, there is an urgent need to understand and identify safer techniques in pedicle screw revision to mitigate pain in the patients.

Pullout strength of the pedicle screw is an important metric used by surgeons, engineers, and designers to understand the fixation stability. These values are obtained by determining

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Table 1
Pedicle screw dimensions (All dimensions in mm).

Screw type	Major diameter, D_{major}	Minor diameter, D_{minor}	Pitch, p	Thread length, L
Ø 5.5 × 40	5.5	3.9	2.7	40
Ø 6.5 × 40	6.5	4.2		
Ø 7.5 × 40	7.5	4.9		

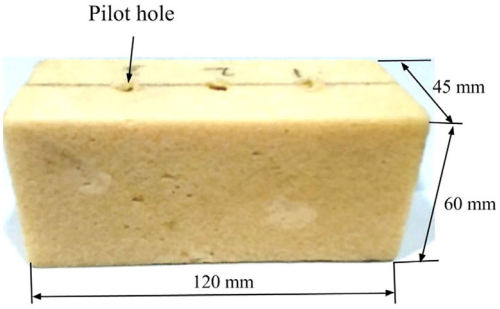

Fig. 1. Rigid polyurethane foam model used for representing osteoporotic vertebra for pullout strength studies.

the amount of force required to remove a pedicle screw from a specimen. The specimens used in these studies are embalmed cadaver specimens, synthetic bone models, rigid polyurethane foams, and bovine or porcine samples. Rigid polyurethane foams are widely used for pullout strength experiments for their homogenous properties, availability, and ease in handling relative to cadaveric specimens [18,19].

Clinically, the decisions regarding pedicle screw size selection for revision surgery are subjective. Further, revision surgeries carried out by screw removal followed by insertion of a revision screw of higher length/diameter, are even more complex [4]. Hence, the objective of the current study is to understand the effect of revision screw diamter on pullout strength and to test the hypothesis that there is no significant difference in the magnitude of the force required to remove screws that are 1 and 2 mm greater in diameter, respectively, than the original screws.

2. Materials and methods

2.1. Pedicle screws

This study used commercially available polyaxial, cylindrical, and self-tapping pedicle screws (M8, Medtronic, Sofamor Danek, Memphis, TN) of length 40 mm and outer diameter 5.5, 6.5 and 7.5 mm made of medical grade titanium alloy with dimensions shown in Table 1.

2.2. Rigid polyurethane foam

Polyurethane foam of density 0.160 g/cm^3 representing osteoporotic bone and complying with American Standards for Testing of Materials ASTM 1839 [20] was obtained from POLYONE FOAM®(Bangalore, India). Pilot holes were created with a 3.2 mm diameter drill (shown in Fig. 1) and tapping was done with one size lower tap than the outer diameter of the screw.

2.3. Cadaver specimen

A total of twenty vertebrae from five embalmed osteoporotic lumbar spine segments (L1- S1) was obtained from the anatomy department of the authors' institution. These specimens were 64 ± 16 years of age and mixed gender (Female = 4, Male = 1), and

Table 2
Pullout studies on cadaveric specimens. The dimensions represent the outer diameter of the pedicle screw (all dimensions are in mm).

Levels	Number of samples tested	Pedicle screw used for index and revision pullout studies	
Group A	12	5.5	6.5
Group B	8	5.5	7.5

measured for bone mineral density (BMD) (0.672 ± 0.129 g/cm^2) and T score (−2.97 ± 0.83). After dissection, an x-ray was done to rule out bridging osteophytes, auto fusion, pathological fractures, and neoplastic conditions. Soft tissues such as muscles and ligaments were intact to capture the in-vivo conditions. All specimens were then scanned for BMD using a DEXA scanner (Discovery A (HOLOGIC, Mississauga, Ontario, Canada)) in the anterior-posterior (AP spine) direction. The samples were classified as osteoporotic based on the World Health Organization definition of bone mineral density (BMD) levels and T-scores. After BMD measurements, the posterior spinal muscles were removed to expose the entry point of the pedicles while preserving the capsular and other major ligaments. Pilot holes were drilled using a 3.2 mm drill and screws were inserted after tapping with one size lower tap than the outer diameter of the screw (4.5 mm tap for 5.5 mm screw). CT scans were done post surgery to check for any wall breach by the screw.

2.4. Experimental design

Pilot hole creation and screw insertion into foam blocks were done as per the same protocol which was used for cadaver specimens. Experiments were carried out on cadaver and foam models as shown in Table 2. In Group A, pullout strength studies were carried out initially (index screw) using 5.5 mm outer diameter screw, followed by revision studies using 6.5 mm outer diameter screws. In Group B, the pullout strength study was carried out using a 5.5 mm outer diameter screws (index screw) followed by revision studies using 7.5 mm outer diameter screws.

A tensile steel rod 5.5 mm in diameter was fixed to the pedicle screw using a set screw mimicking the actual configuration of the pedicle screw. A specially designed jig was used to clamp the cadaveric specimens and foam blocks as shown in Fig. 2. The adjustable jaws provided necessary hold and arrested the specimen from rotation and translation. This assembly tested on a BiSS Nano-25® (Bangalore, India) capable of 15 kN of force actuator operating at 50 Hz data acquisition and resolution of 5 N (accuracy 0.3% of full scale) as shown in Fig. 2. The tensile displacement was applied to the test specimen at a rate of 5 mm/min until the screw released from the specimen. The procedures were controlled under the provision of ASTM: F543-07 protocol [21]. Load and displacement values were recorded, and the maximum load generated during screw pullout was the pullout strength.

Statistical analysis was carried out using two-tailed T-test analysis with equal variance at 0.05 level of significance ($p < 0.05$).

3. Results

3.1. Effect of revision surgery in the foam model

The effect of revision surgery on the pullout strength of pedicle screw in foam model is as shown in Fig. 3. Whereas the pullout strength in the case of Group A decreased, the corresponding values for Group B increased. In Group A, the mean and standard deviation pullout strength of the index screw was 0.54 ± 0.02 kN and for the revision screw it was 0.43 ± 0.02 kN. A 79% of the original pullout strength is achieved when revision is carried out using

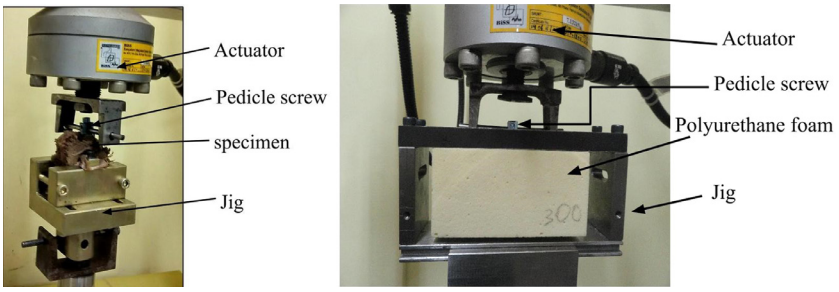

Fig. 2. Experimental set-up for pullout strength testing on a cadaver (left) and rigid polyurethane foam (right).

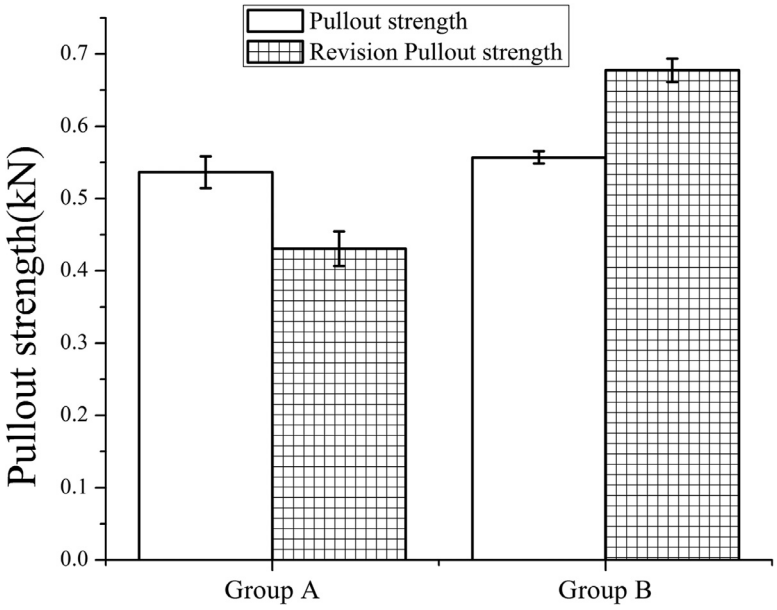

Fig. 3. Effect of revision on pullout strength for foam model.

a pedicle screw that is 1 mm greater in diameter. This difference was found to be significant ($p < 0.05$).

In the case of Group B, on the other hand, there is a 121% increase in pullout strength when a screw that is 2 mm greater in diameter than the original screw is used. The mean and standard deviation of pullout strength for the index screw was 0.56 ± 0.01 kN and for revision screw, it was 0.68 ± 0.10 kN. Based on statistical analysis this difference was significant ($p < 0.05$).

There was a significant difference ($p < 0.05$) between the pullout strength of revision screws (6.5 mm and 7.5 mm) 0.43 ± 0.02 kN and 0.68 ± 0.10 kN respectively.

3.2. Effect of revision in cadaver

The effect of revision on the pullout strength of the pedicle screws in a cadaveric vertebrae is as shown in Fig. 4. The results for the cadaveric study correspond to those in the foam model study insofar as the pullout strength decreased in Group A and increased in Group B. In Group A, the mean and standard deviation pullout strength value of index screw was 0.27 ± 0.11 kN and for revision screw, it was 0.19 ± 0.07 kN. The pullout strength decreased by 72% following revision with a screw that is 1 mm greater in diameter than the index screw.

The results in Group B showed a 125% increase in pullout strength during revision using a two mm higher diameter pedicle screw than the index screw. The mean and standard deviation of pullout strength for the index screw was 0.15 ± 0.05 kN and 0.19 ± 0.1 kN for revision screw.

4. Discussion

A study by Li et al. [22] on thirty-one osteoporotic lumbar spine specimens of BMD 0.567 ± 0.101 g/cm^2 found the pullout strength value to be 0.241 ± 0.174 kN. In a study by Chao et al. [23] on thirty-two osteoporotic thoracic and lumbar spines of BMD 0.41 ± 0.12 g/cm^2 found the pullout strength to be 0.144 ± 0.092 kN. The pullout strength obtained in the current study (0.27 ± 0.11 kN and 0.15 ± 0.05 kN) matched with the data available in the literature. This study explores the screw diameter for revision surgery. The results can be used to build a computational model such as a finite element or mathematical model to understand the micromechanics at the interface. Finite element studies help in understanding the stress pattern around the screw and bone interface as explained in literature [24–30]. These studies have been used to examine the regions of bone remodeling and the stresses around the screws. Researchers have used expandable screws and larger diameter screws to increase the screw purchase and enhance the stability [31,32]. Damage induced to bone is the result of removal and replacement of screws duering revision surgeries. A revision screw that is at least 2 mm greater in diameter than the original screw is recommended for revision surgeries as theseresult in greater thread engagement to the outer bone and allow for greater pedicle fill [33,34].

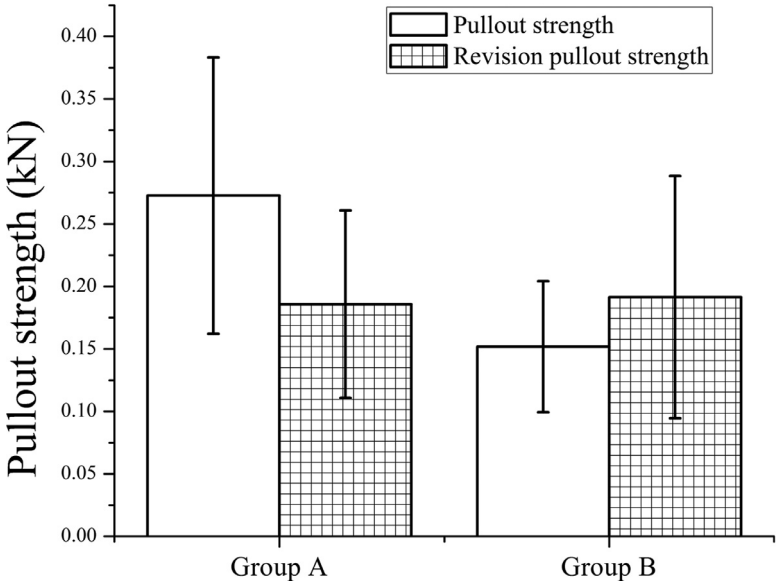

Fig. 4. Effect of revision on pullout strength for cadaveric vertebrae.

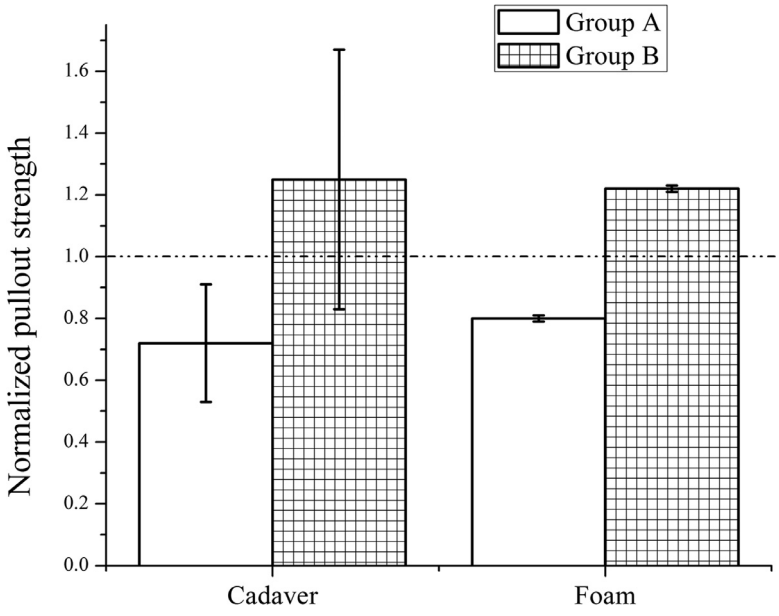

Fig. 5. Normalized pullout strength in cadaver and foam model for Group A and Group B studies.

Normalization of pullout strength was carried out as per Eq. (1) to minimize the variation in pullout strengthvdue to differences in density and anthropometry between the cadaveric specimens. The normalized pullout strength values obtained for the revision studies are presented in Fig. 5. Based on the normalized data, the trends in pullout strengths for revision screws were the same for the cadaver and foam specimens for both groups of studies. Whereas the pullout strength decreases by 72% following revision with a screw that is 1 mm greater in diameter than the index screw, it increases by 125% when the diameter of the revision screw is 2 mm greater than the original screw. There was a significant difference ($p < 0.05$) in pullout strength between both the revision screws (6.5 and 7.5 mm). Cadaver samples provide the closest alternative to in vivo vertebra. They are widely used in biomechanical studies since these experiments cannot be performed *in-vivo*. The major disadvantage with cadaver studies is that it is non-homogenous and has large intersample and intra sample variations which require a larger sample size to obtain statistically significant results. Hence, there are large variations in the pullout values for cadaver samples. There was less variation in the pullout strength for foam samples.

$$\text{Normalized pullout strength} = \frac{Pullout\ Force_{\ Revision\ screw}}{Pullout\ Force_{\ Index\ screw}} \quad (1)$$

The current study can aid surgeons performing revision surgeries for failed pedicle screws. A surgeon performing the revision surgery can choose from: cement augmentation, larger and/or longer screws, or other alternative thread design screws for better purchase. The surgeon decides the technique based on the potential complications associated with each method. Literature studies on the revision of pedicle screws using cement augmentation techniques show that an increase in pullout strength is achieved using

these methods. A study by Polly et al. [34] found no positive effect from the usage of longer screws for revision surgery. There is risk associated with bicortical fixation in the thoracolumbar region due to the presence of vascular structures

Clinically, when there is a failure of a pedicle screw needing revision, the surgeons tend to use a lesser diameter, and longer screw as the pedicle walls are usually breached. Larger screws may be used if the pedicle walls are intact. However if they use a higher diameter, they are likely to use screw of 0.5 mm or 1 mm more in size than the replaced screw. This can affect the strength of the construct which can again lead to implant failure. So, using a smaller diameter screw in revisions can be suboptimal. If they have to be used for any reasons, then we should consider the restriction of activities or using braces postoperatively or if needed extending the level of instrumentation. If a screw of 1 mm larger diameter is used, then we should consider using post-operative bracing or restriction of activities. Based on the present study we recommend that wherever possible, a screw size more than 1 mm larger than the index screw should be considered in revision surgeries for biomechanical advantage and to prevent implant failure. Further studies using finite element methods [24,35] can help in better understanding of the damage region around the bone/foam - screw interface which may influence the pullout strength of revision screws. The results of the current study can be used in building a decision support system which will predict the pullout strength and aid in patient-specific surgery planning [36]. Bioactive coating such as hydroxyapatite improves the fixation potential and enhances the osteointegration of the pedicle screws in patients for revision surgery. This enhanced interface bonding between the bone and screw results in enhanced fixation. These non-exothermic in-situ cement cure rapidly and improve the structural rigidity allowing for long term remodeling and biocompatibility.

Axial pullout is one among the many phenomena associated with pedicle screw loosening. Pullout strength represents the magnitude of screw purchase before loosening due to micromotion and cyclic loading. Fatigue loading is used to describe forces acting on the vertebra during daily activities [37]. Clinically, this loading causes bone remodeling and changes the interface between bone and screws. Bone remodeling occurs only in living tissues and cannot be mimicked in cadaveric or foam specimens. Pullout strength measurement is a standard technique used to understand the fixation stability and facilitates better comparison with literature results. Complex loadings such as fatigue or cyclic loading, cantilever bending and push out [38] were not investigated as the scope of the current study is to examine the immediate post-operative failure causes which are widely seen within one- or two-weeks post-surgery. Embalmed cadaver specimens were used in the present study, and this could affect the results. The embalming of bone can lead to slight changes in material properties of the bone [39], but studies have shown that there is no significant effect on pullout strength [40].

A limitation of the present study was the small sample size, which was due to the preliminary nature of the study. The foam-based studies were carried out to compensate for this limitation by reducing the inter-sample variation and are widely used for representing the vertebra for pullout strength experiments [17,41–43]. The current study investigated revision surgeries which are carried out within a week or two after the initial surgery in response to spinal cord injuries or screw misplacements resulting in neurological deficits. Bone remodeling is a continuous process that changes the microstructure around the bone and implant interface. This phenomenon of osteointegration is a challenging task to simulate in a cadaver or foam model due to lack of techniques and methods to simulate bone remodeling outside in vivo condition and hence was not incorporated in the current study. Computational models such as finite element methods can be used to simulate the bone remodeling and changes in bone microstructure. The present results apply to the screw sizes described in Table 1; caution should be exercised when extrapolating the results to other screw types.

5. Conclusion

Selection of the proper revision screw size for revision surgery in the osteoporotic spine is a challenging task. Improper size can lead to failures such as screw loosening and breakages. In the current study, pullout strength tests are carried out on foam blocks and cadaveric vertebra, using screws of different diameter. Based on the findings of the present study, the use of screws that are 2 mm in diameter greater than the original screws gave rise to significantly higher pullout strengths. Hence, we recommend proper planning of revision surgeries in osteoporotic patients and the use of screws with a diameter more than 1 mm greater than the index screw to avoid pullout related implant failures. Cadaveric testing reveals a trend that agrees with the foam model tests.

Declaration of Competing Interest

None declared.

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Ethical approval

Not required.

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