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# Effect of various factors on pull out strength of pedicle screw in normal and osteoporotic cancellous bone models

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ABSTRACT

Pedicle screws are widely used for the treatment of spinal instability by spine fusion. Screw loosening is a major problem of spine fusion, contributing to delayed patient recovery. The present study aimed to understand the factor and interaction effects of density, insertion depth and insertion angle on pedicle screw pull out strength and insertion torque. A pull out study was carried out on rigid polyurethane foam blocks representing osteoporotic to normal bone densities according to the ASTM-1839 standard. It was found that density contributes most to pullout strength and insertion torque. The interaction effect is significant ($p < 0.05$) and contributes 8% to pull out strength. Axial pullout strength was 34% lower than angled pull out strength in the osteoporotic bone model. Insertion angle had no significant effect ($p > 0.05$) on insertion torque. Pullout strength and insertion torque had no significant correlation ($p > 0.05$) in the case of the extremely osteoporotic bone model.



## 1. Introduction

Lower back pain is a leading cause of chronic disability and psychological distress affecting at least 80% of individuals at some point in their lifetime [1]. One of the causes for lower back pain is spinal instability [2]. According to the American Academy of Orthopedic Surgeons [3], instability is defined as an abnormal response to applied loads, characterized by motion in the motion segments beyond the normal constraints. In order to treat these forms of lower back pain, surgical spinal fusion is carried out with or without instrumentation. Lumbar spinal fusions have become the gold standard for treatment of spinal disorders. The principle behind fusion is to minimize or cease all flexibility at the motion segment augmented which stiffens the resulting construct. According to the Cochrane review by Gibson and Waddell [4], lumbar fusion surgery with instrumentation has a higher success rate than an uninstrumented fusion.

The pedicle screw as spinal implant was first described by Boucher [5] in 1950s and was reintroduced by Roy-Camille et al. in the 1980′s [6] and are practical, safe, and superior to uninstrumented fusion in treating various spinal conditions [7]. However, these implants are not immune to failures such as screw loosening or screw breakage. The incidence of screw loosening occurs between 0.6% and 11% [7–9] and screw breakage due to stress concentration has ranged between 2.6% and 60% [10,11], causing fusions to become unstable, causing serious postoperation complications which may require subsequent surgery. Pedicle screw loosening is widely seen, especially in patients with osteoporosis [12]. Hence, surgeons need a thorough understanding of the holding and stability mechanisms of pedicle screws. Currently, osteoporosis is not a contraindication for fusion surgery, but it is challenging for surgeons due to potential complications such as screw back-out, migration or loosening which may compromise the surgical outcome [13,14]. These complications may lead to nonunion, making surgical revision necessary. According to a recent study, there were 9% revision cases in 643 adult spinal deformity surgeries of this 40% were related to nonunion of the spine fusion segment [15]. Some methods to reduce the risk of screw failure are to use bone cement augmentation [16–18] or expandable screw [19–21]. Although these methods are useful, their use can lead to a complication during revision surgery. Therefore, achieving stable pedicle screw fixation to osteoporotic bone is a challenge to both spinal surgeons and engineers alike.

Clinically, there are several studies in the literature on the effect of some important factors such as density, insertion angle and screw length on the holding power of pedicle screw [22–25]. Several researchers have studied the effect of BMD on the pullout

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**Table 1**
Material property of foam used in the study (density and compression test were carried out on a foam block according to ASTM D1622 [38] and ASTM D 1621 [39] respectively).

| S. no | Density (kg/m$^3$) | Experimental measurement | | ASTM standards [36] | |
|---|---|---|---|---|---|
| | | Density (kg/m$^3$) | Compression Modulus (MPa) | Density (kg/m$^3$) | Compression Modulus (MPa) |
| 1 | 80 | 84 ± 5 | 19 ± 8 | 72–88 | 12–20 |
| 2 | 160 | 162 ± 15 | 63 ± 14 | 144–176 | 45–71 |
| 3 | 240 | 232 ± 10 | 125 ± 10 | 216–264 | 98–151 |

strength of pedicle screw and have found a positive correlation. These studies have been carried out using cadaver [26–28] or foam based models [29,30]. Halvorson et al. [13] found a positive correlation between pullout strength and bone mineral density while experimenting on human cadaveric spine. Effect of insertion angle has been studied by Lehman et al. [31] on cadaveric thoracic vertebrae and found that straight forward technique resulted in a 27% increase in pullout strength compared to an anatomical technique. Patel et al. [23] studied the effect of bone screw insertion angle using a rigid polyurethane foam model representing a normal cancellous bone model (0.32 g/cm$^3$) and found that screws inserted at 0° and 10° exhibited higher pullout force compared to screws inserted at 20°, 30° and 40°. Once the screw type is selected, the major factors affecting holding power of pedicle screws are density, insertion angle, and insertion depth. Currently, the studies on factor effects of density, insertion depth and insertion angle have been carried out individually. In this context, the present study aims at knowing the effect of bone density, insertion angle and insertion depth on the insertion torque, pullout strength, stiffness, and strain energy of pedicle screws in normal and osteoporotic cancellous bone models. The assumptions made for the current study are: the complex geometry of pedicle and vertebra are not taken into account and a uniform block was assumed to represent the spinal structure. It was assumed that complex geometry was not going to play a role in pull out study but might influence the loading pattern physiologically. Pedicle region, which contributes 60% to the holding power [32,33] was not considered since osteoporosis mostly affects the vertebral body and hence the contribution of pedicle was assumed to be uniform in all bone types. Cyclic loading was not considered, since the scope of paper is to understand, the initial holding power of pedicle screw mimicking the postoperative stage of instrumentation. Clinically, during in vivo loosening, there is an increase in hole size due to toggling and also there is a change due to bone remodeling effect. In foam models even if we apply cyclical loading, we cannot mimic this effect, thus cyclic loading was not considered in the study.

## 2. Materials and methods

### 2.1. Pedicle screw instrumentation in synthetic cancellous bone

Studies with rigid polyurethane foam help in developing a biomechanical model of the vertebra and have been widely used in literature to study the pullout strength phenomenon [26–30]. The polyurethane foam model (synthetic cancellous bone) reduces the inter-individual variability of bone mineral density, size and other complications associated with cadaveric bones [24]. Literature studies have shown that certain densities of rigid polyurethane foams can mimic the microstructure of human trabecular bone. The compressive strength of vertebral trabecular structure of 0.7–4.33 MPa is comparable to polyurethane foam of grade 5–15 [34,35]. The foam types and their representative bone densities are regulated and standardized as per the American Society for Testing and Materials (ASTM-1839-08) protocol [36]. Three different PU foams obtained from POLYNATE FOAM®, (Bangalore, India) were used in this study; Grade 5 foam of density 80 kg/m$^3$ representing extremely osteoporotic bone, Grade 10 foam of density 160 kg/m$^3$ representing osteoporotic bone and Grade 15 foam of density 240 kg/m$^3$ representing normal bone [24,29,37]. The polyurethane foam materials used for the study were evaluated for their properties (Table 1) so as to conform to the ASTM standard requirement. A block 120 mm × 60 mm × 40 mm was used for instrumenting with pedicle screws for pullout strength test.

**Table 2**
Dimensions of the pedicle screw used in the study (All dimensions are in mm).

| S. no | Major diameter | Minor diameter | Thread length | Pitch |
|---|---|---|---|---|
| 1 | 6.5 | 4.2 | 45 | 2.7 |

**Table 3**
Selected variables for pull out strength studies.

| Factor | | Levels | | | |
|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 |
| $A$ | Density, $\rho$ (kg/m$^3$) | 80 | 160 | 240 | |
| $B$ | Insertion depth, $l$ (%) | 70 | 85 | 100 | |
| $C$ | Insertion angle, $\theta$ (°) | 0 | 10 | 20 | 30 |

A CE approved cylindrical, self-tapping polyaxial pedicle screw of 6.5 mm diameter and 45 mm length made out of medical grade titanium alloy, Ti −6Al −4 V (Globus Medical® USA) shown in Fig. 1(a) was used in the study. The dimensions of pedicle screw are shown in Table 2. Along the 60 mm depth direction of the foam, 3.2 mm diameter pilot holes were drilled at different angles to the foam using a swivel angle vise. Holes were drilled at 25 mm away from each other to avoid the interaction effect. A study was carried out to see if there is any significant difference in pullout strength between screw in individual block versus multiple screws in a single block with 25 mm spacing. It is found that there is no significant difference. The details of study are presented in Appendix A. Pretapping was not done on the pilot hole and pedicle screw was inserted manually into the foam block at varying depth and angle as shown in Fig. 1(b) and insertion torque was measured using Tohnichi® dial type torque wrench (DB6N4S). The rotation speed was kept to approximately three full rotations to a minute for every screw insertion to neglect any inter-specimen variation as well as to minimize any damage to foam due to frictional heat. The maximum torque obtained while inserting the pedicle screw was noted as the insertion torque of pedicle screw. The maximum torque was obtained while inserting the terminal threads. A study was carried out to check for inter-person variation in the measurement of insertion torque. There is no significant variation between different surgeon hands and thus this factor can be neglected. The detail of the experiments and analysis regarding the same is available in Appendix B. The factors, namely the polyurethane foam density ($A$), screw insertion depth ($B$) and insertion angle ($C$) were varied in three levels to create a full factorial design of experiment as shown in Table 3. The density range was chosen to represent the range of osteoporotic to normal bone density as per ASTM-1839-08 [36]. A 45 mm long screw was chosen because of

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