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Stability and Spine Pedicle Screws Fixation Strength—A Comparative Study of Bone Density and Insertion Angle

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Abstract

Study Design: Analysis of insertion angle and bone density on the pedicle screw fixation strength with a novel testing protocol that accounts for the articular processes.
Objective: To analyze the relationship between pedicle screw fixation strength and bone mineral density for different transverse screw insertion angles.
Summary of Background Data: The stability of the screw can become compromised by demineralization of the vertebral bone due to diseases such as osteoporosis. A weakening of the bone-screw interface, and therefore, a decrease in the fixation strength of the screw, leads to an increased probability of instrument failure, most commonly by screw loosening or screw pullout.
Methods: Using the ASTM F543 as reference, we performed pullout tests with an Instron mechanical testing machine of a posterior fixation construct mimicking two pedicle screws connected at a distance of 40 mm as suggested by the ASTM F1717 on four densities of polyurethane foam in accordance with the ASTM F1839-08 standard to simulate bone densities ranging from osteoporotic (5 pcf) to higher than normal (20 pcf) in four transverse insertion angles.
Results: A linear regression with two independent variables was found to be $Y = -354.8812 + 91.8102 \times X_1 - 6.8747 \times X_2$ (X_1 = density [pcf], X_2 = angle [degrees]), with a correlation coefficient of 0.95 for all the experimental data.
Conclusions: Pedicle screw insertion angle and bone density are critical to pullout strength. However, in osteoporotic bone, the insertion angle has only a marginal influence on pullout strength.
Level of Evidence: V.
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Keywords: Pedicle screw; Pullout strength; Insertion angle; Bone density; Testing protocol

Introduction

In the treatment of acute and chronic instabilities or deformities of the spine, instrumentation is required for stabilization and immobilization of the spine during recovery. One of the standard methods of instrumentation used in the thoracolumbar spine is pedicle screw fixation. The advantages of pedicle screws versus other methods of fixation are well documented [1].

However, instrument failure related to pedicle screws has also been clinically reported [2-5] and proves that screw fixation has its flaws. In a study performed by Katonis et al. [2], complications were observed in 57.1% patients. Complications included general problems such as junctional problems, problems in the instrumented segments, and problems of balance. Instrumentation problems, related to screws, occurred in 10.7% of the patients. DeWald et al. [4] performed a retrospective follow-up study of patients over a 5-year period, and complications involving loosening of the pedicle screws occurred in two patients (7%). Pihlajamaki et al. [6] analyzed the complications encountered in 102 patients who had a posterolateral lumbosacral fixation for

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nontraumatic disorders after a minimum of 2 years. There was a total of 76 complications encountered in 48 patients. Screw loosening was observed radiologically in 18 patients, with five undergoing reoperations for non-union. The stability of pedicle screws depends mainly on the interface between the screw and bone, and when this interface is negatively altered, the stability of the screw can become compromised [5]. One way this interface can be altered is by demineralization of the vertebral bone due to diseases such as osteoporosis [7,8]. Loosening of pedicle screws can be determined clinically by examination of radiograph images [9]. Observation of a distinct radiolucent halo surrounding the pedicle screw is indicative of screw loosening. Sanden et al. [9] performed a clinical study on 21 patients in which instruments were removed after implantation for 11 to 16 months and found that insertion torque was significantly lower in screws with radiolucent zones than in screws without radiolucent zones.

The influence of BMD on the fixation strength of pedicle screws in the thoracolumbar spine has been studied extensively over the years. Okuyama et al. [5] performed a clinical study on 52 patients who had undergone pedicle screw fixation over a period of 2 to 6 years, and 11 of the patients experienced some degree of loosening. The average bone mineral density of patients who experienced screw loosening was 0.72 g cm^{-2}. The average bone mineral density of patients who did not experience loosening was 0.922 g cm^{-2}.

Correlation between BMD and pullout load is documented in literature for thoracic and lumbar spine [1,5,10-12]. In Coe et al. [1] a correlation between BMD and pullout strength of $Y = 43.6 + 499X$ ($r = 0.30$) was found in thoracolumbar spines (T3–L5). Similarly, Liljenqvist et al. found for thoracic vertebrae (T4–T12) a correlation coefficient of 0.92 between BMD and pullout strength [13]. Hackenberg et al. reported a different correlation for the upper ($r = 0.59$) and lower thoracic spine ($r = 0.79$) [14]. Positive correlations were also found between density and pullout strength when polyurethane foam, used to minimize experimental variability, was utilized instead of cadaveric vertebrae for testing [15-17]. In addition to bone density, the pedicle screw insertion angle has been indicated as a critical factor to fixation strength [18-20].

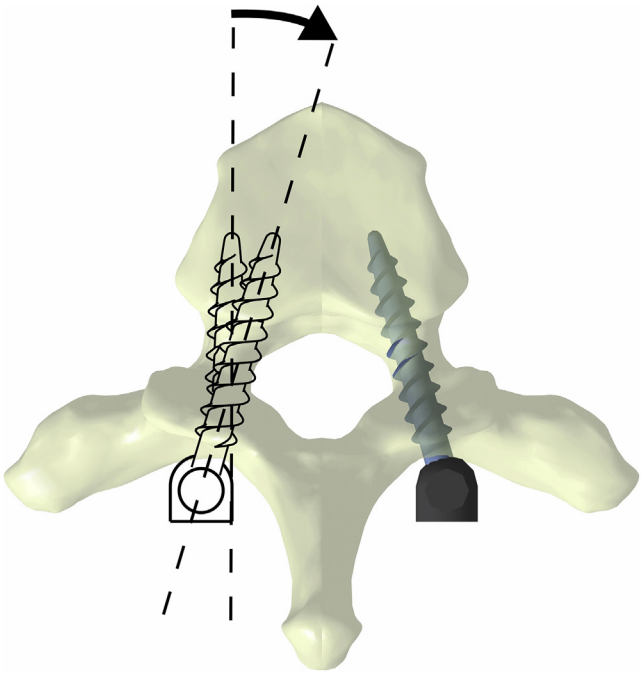

Fig. 1. Placement of a screw into the vertebral pedicle and the direction of the imposed insertion angles in the transverse plane.

The sagittal inclination depends on the desired trajectory technique [21]. When anatomical technique is performed, sagittal angles can have value of 12.6 ± 5.8 degrees in T1 [22] and can be high as 18.9 degrees on T2 [23]. Although when a straightforward technique is chosen, a uniform entry point can be used with transverse angles of 30 degrees at T1 and T2 and 20 degrees from T3 to T12 [24]. Generally, the transverse inclination has not been specified for particular trajectory techniques. Zindrick et al. [22] found pedicle transverse angles for T1 ranging from 16 to 33.5 degrees, with average values of 26 ± 5.6 degrees and, similarly, Shiu-Bii Lien et al. [23] measured the largest mean transverse pedicle angle of 28.2 degrees on T1.

In this study, we focused on the thoracic spine and used the recommendation of Fennel et al. [24], investigating insertion angles pullout using 30 degrees as an upper threshold limit to basically cover most of the previous reported work. The goal of this research project is to analyze the relationship between pedicle screw fixation strength and bone mineral density for different transverse screw insertion angles (Fig. 1).

Materials and Methods

In this study, we merged the ASTM standards relevant to thoracic spine instrumentation with a constraint resembling physiological loads. Following the ASTM F1717, the object of the evaluation is a posterior fixation construct composed of two pedicle screws connected at a distance of 40 mm. Using rigid polyurethane foam models to simulate the vertebras, we have simulated the null transversal displacement of the surfaces characterizing the endplates and the null anteroposterior displacement of the extreme portion of the superior edges characterizing the articular facets (Fig. 2, in blue) in their orientation as documented for thoracic spines [25,26]. In order to simplify the testing procedure and reduce variability due to erroneous unsymmetrical screw placement for each vertebral segment, we have tested one screw characterizing half of the construct and established a structural symmetry by imposing null transversal displacement to the brick surface representing the middle sagittal plane (Fig. 2, in green) and to the rod composing the construct. Using the ASTM F543 (Test Methods for Metallic Medical Bone Screws) as a reference

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