

## 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

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### 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  $0.72 \text{ g cm}^{-2}$ . The average bone mineral density of patients who did not experience loosening was  $0.922 \text{ g cm}^{-2}$ .

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].

The sagittal inclination depends on the desired trajectory technique [21]. When anatomical technique is performed, sagittal angles can have value of  $12.6 \pm 5.8$  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  $26 \pm 5.6$  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 vertebrae, 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

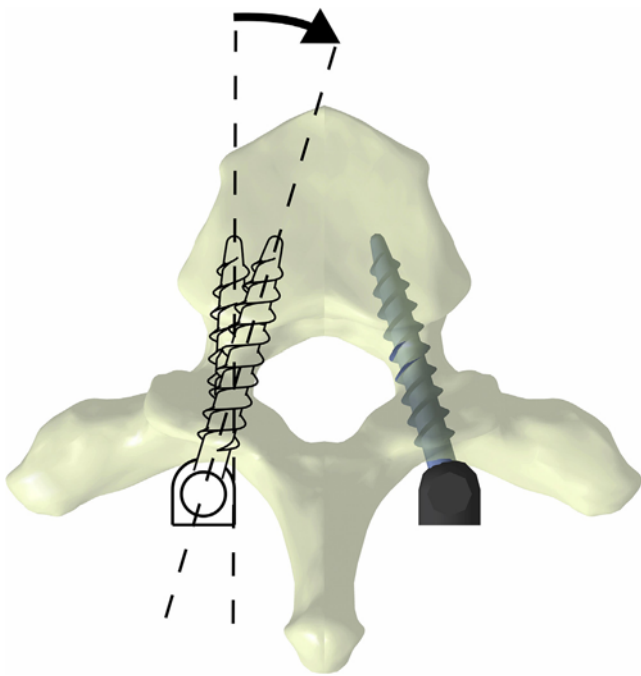


Fig. 1. Placement of a screw into the vertebral pedicle and the direction of the imposed insertion angles in the transverse plane.

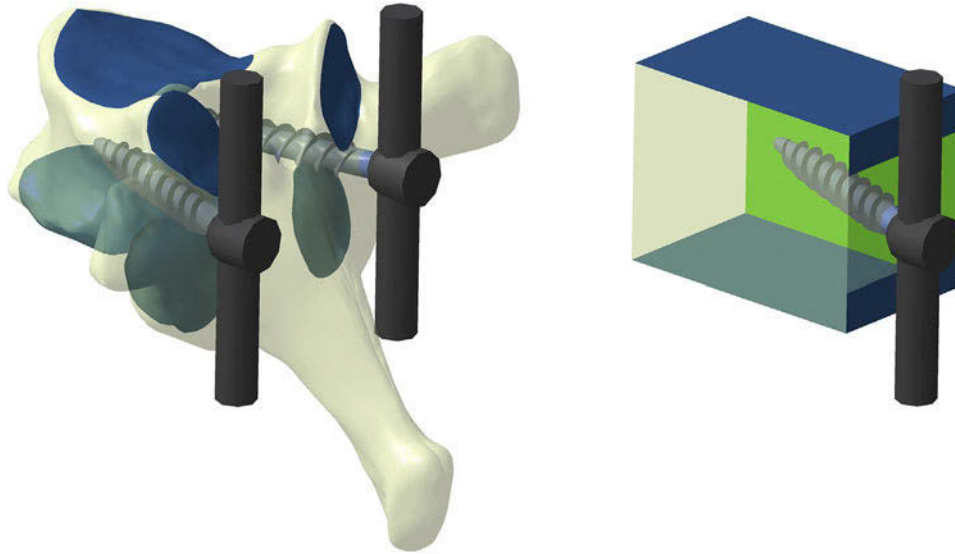


Fig. 2. Comparison of the physical restraints of a real vertebra to the corresponding constraints imposed on the foam block during our experiments.

for the performed tests, we used a grip span equivalent to five times the diameter of the screw tested with supports extended, to resemble the height of the articular facets [26], for a total dimension equivalent to seven times the screw diameters with a total measure of 35 mm to approximate reported heights of thoracic vertebrae [27,28].

The 70-mm rod has been attached to the mechanical testing machine with displacement imposed along the anterior-posterior direction to measure the needed pullout force. Any displacement of the rod in the caudal-cephalic direction was allowed but negligible during the experiments. The following picture (Fig. 3) is a schematic cross section according to the two planes of the designed fixture.

As shown in the plane equivalent to the sagittal one, the fixture mimics the ASTM standard (screw pullout standard). With our testing configuration, the screw is considered parallel to the endplate with angulation in the transverse plane (Fig. 2).

The screws used in this study are 35-mm-long Expedium Single Innie Polyaxial Screws (DePuy Spine, Inc., Raynham, MA), with a diameter of 5 mm and characterized by a maximal angular inclination of 30 degrees. We performed tests on four densities of polyurethane foam in accordance with the ASTM F1839-08 standard to simulate various bone densities [16]. We used grade 5 ( $0.08 \text{ g cm}^{-3}$ ) foam to represent very osteoporotic bone, grade 10 ( $0.16 \text{ g cm}^{-3}$ ) for

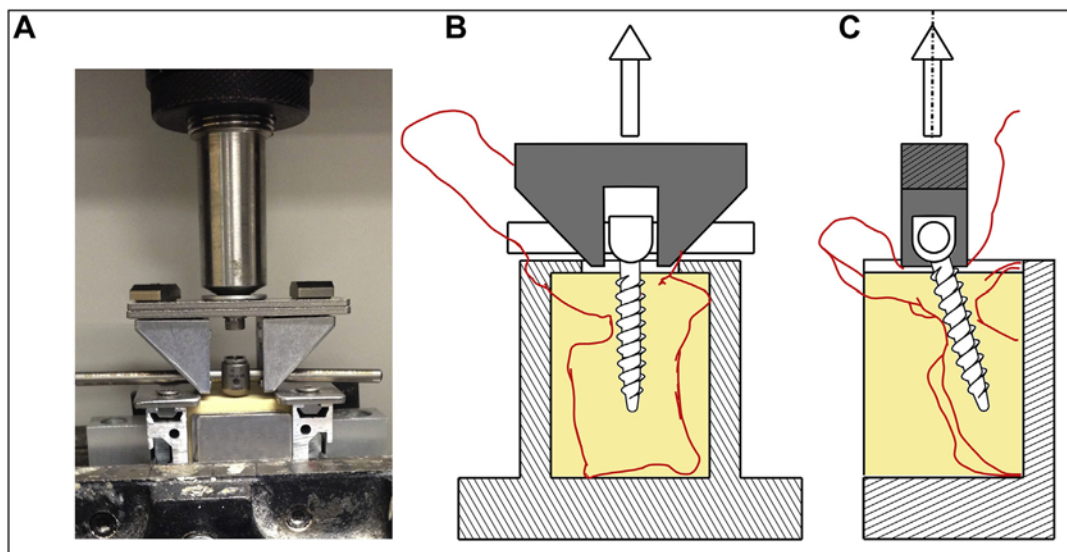


Fig. 3. (A) The custom-designed jig used for the axial pullout tests. (B) Schematic showing direction of applied force to screw with superimposed vertebra in both sagittal and (C) transverse planes.

osteoporotic bone, grade 15 ( $0.24 \text{ g cm}^{-3}$ ) for normal bone, and grade 20 ( $0.32 \text{ g cm}^{-3}$ ) for higher than normal bone densities. For each density, we have imposed four different inclination angles ranging from 0 to 30 degrees, with a sampling of 10 degrees in the transverse plane identified as parallel to the idealized endplates.

Holes were predrilled into the foam with a drill bit of  $\frac{1}{8}$  in. thickness, which was 67% of the outer diameter of the screw. This hole diameter was chosen after analyzing average hole diameters from previous studies [15,16,19]. Each angle was imposed using a drill guide, and each hole was drilled to a depth 1 mm deeper than the measured thread length to ensure full coverage of the thread. A Mitutoyo Digimatic Caliper Series 500 with an accuracy of 0.05 mm was used to measure the depth of the hole. Each screw was implanted at a rate of 5 revolutions per minute, measuring the maximal torque for the first three revolutions, and each screw was inserted until the head was flush with the surface of polyurethane foam brick. The insertion torque was measured for each screw using a Mark-10 MTT03-100 digital torque gauge with a resolution of 1 N·cm. Insertion torque required to make each screw flush with the brick varied by density and was limited at 20 N·cm for grade 5 foam, 60 N·cm for grade 10, 120 N·cm for grade 15, and 300 N·cm for grade 20. After screw insertion, an electromechanical tensile-testing Instron Machine 5569 (Instron, Norwood, MA) was used to pull the custom-designed jig at a rate of 5 mm/minute as indicated by the ASTM F543, and the reaction force and displacement were recorded at a frequency of 50-Hz or 1-N increments.

**Results**

The mechanism of screw failure was dependent on both foam density and insertion angle of the screw. In the grade 20 foam with angles greater than 0 degrees, the observed mechanism of failure involved fracture of the foam block into one or more fragments. In all other densities of foam and angles of 0 degrees in the grade 20 foam, the observed mechanism of failure was stripping of the internal screw threads. Maximum pullout strength occurred during screw failure and was recorded. The average pullout force in the grade 5 foam was 126.41 N ( $\pm 16.54 \text{ N}$ ). For grades 10 and 15 foam, the pullout forces were 360.97 N ( $\pm 41.81 \text{ N}$ ) and 753.10 N ( $\pm 86.24 \text{ N}$ ), respectively. The highest average

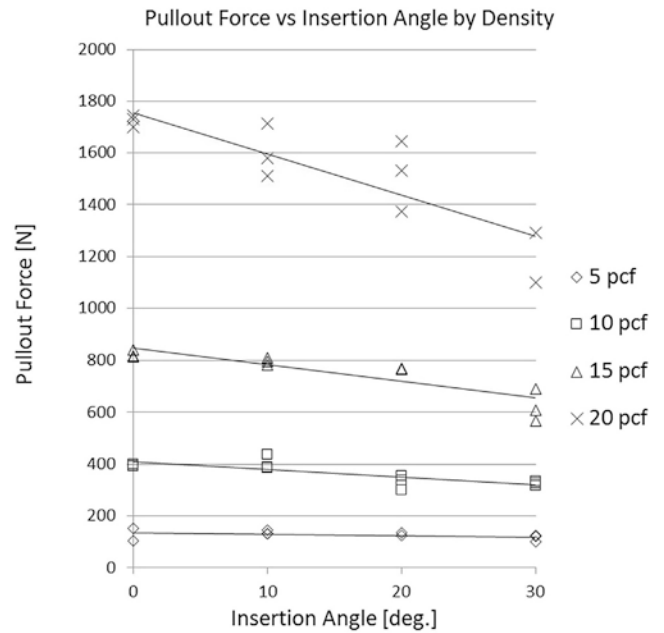


Fig. 4. Scatter plot of pullout force versus insertion angle with overlaid best-fit lines for each foam density.

pullout force was found in the grade 20 foam and was 1538.26 N ( $\pm 207.77 \text{ N}$ ). A linear regression with two independent variables was found to be  $Y = -354.8812 + 91.8102 \times X_1 - 6.8747 \times X_2$  ( $X_1 = \text{density [pcf]}$ ,  $X_2 = \text{angle [degrees]}$ ), with a correlation coefficient of 0.95 for the correlation of all the experimental data. The average pullout force at each combination of angle and density can be found in Table. Analyses of variance were performed to compare the average pullout forces with different densities and angles. At each insertion angle, there was a significant increase in pullout strength with increasing polyurethane foam density (Fig. 4). In the grade 5 foam, there was no significant difference in pullout strength with increasing angle of insertion. In foams of grades 10, 15, and 20, there was a significant difference in pullout strength with increasing angle of insertion. A multivariable linear regression was performed on the data to determine the influence of both foam density and insertion angle on pullout strength (Fig. 5). A linear regression equation of  $Y = -354.8812 + 91.8102 \times X_1 - 6.8747 \times X_2$  ( $X_1 = \text{density [pcf]}$ ,  $X_2 = \text{angle [degrees]}$ ) was found with a correlation coefficient of 0.95. Excluding the data from the grade 20

Table  
Average axial pullout force [N] ( $\pm$ standard deviation) for each density of bone surrogate at each angle of insertion.

Bone surrogate density ( $\text{g cm}^{-3}$ )	Insertion angle (degrees)			
	0	10	20	30
0.08	126.89 $\pm$ 34.65	138.24 $\pm$ 8.02	128.89 $\pm$ 7.83	110.46 $\pm$ 13.97
0.16	395.02 $\pm$ 5.58	399.43 $\pm$ 28.76	326.66 $\pm$ 28.76	330.8 $\pm$ 7.93
0.24	821.06 $\pm$ 14.72	797.69 $\pm$ 15.03	768.17 $\pm$ 15.03	649.01 $\pm$ 62.50
0.32	1729.87 $\pm$ 22.19	1596.2 $\pm$ 103.49	1588.68 $\pm$ 103.49	1117.67 $\pm$ 135.95



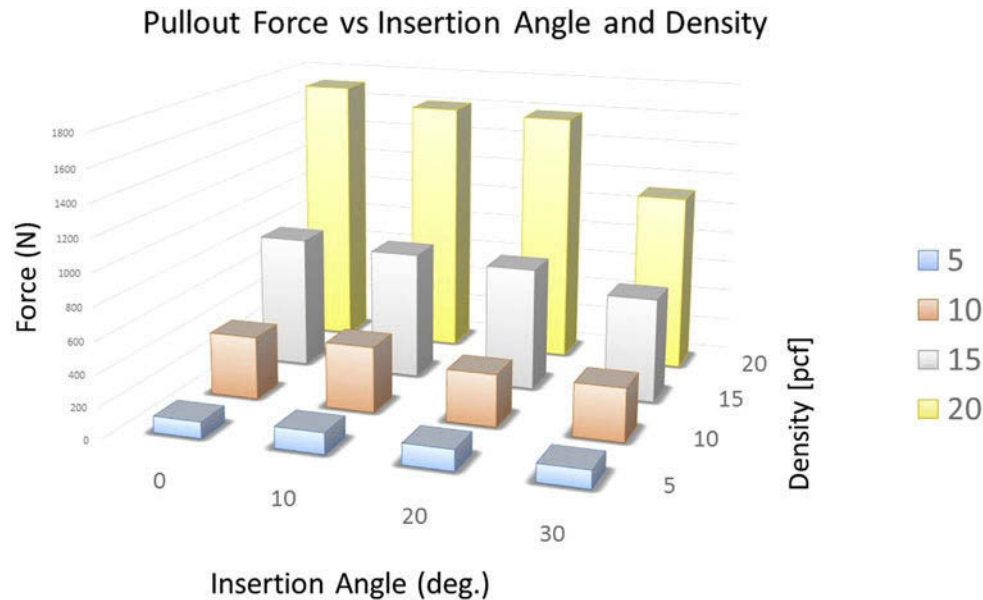


Fig. 5. Three-dimensional column chart plotting pullout force against both foam density and insertion angle.

foam, the regression equation was  $Y = -157.79215 + 62.77132 \times X_1 - 3.58287 \times X_2$  with a correlation coefficient of 0.98.

## Discussion

The different densities of polyurethane foam used in this study were chosen to represent various conditions of human bone. The linear regression equation of force versus density and angle shows that screw pullout force is positively correlated with material density and negatively correlated with insertion angle. Pullout force is greatest when an insertion angle of 0 degrees is used and decreases at each successively higher angle until its lowest value at an insertion angle of 30 degrees. The multivariable regression equation showed that the coefficient for density is much greater than that for the angle of insertion. Increasing the density increases the pullout strength by a factor greater than 10. Increasing the angle of insertion from 0 to 30 degrees only decreases the pullout force by approximately one fifth.

The influence of density on pullout strength is strongest in lower densities of the host material. The biggest reduction in strength occurs when the density is decreased from grade 10 to grade 5, with a decrease of 64% being observed. Comparatively, reductions of only 50% are observed when decreasing from grade 15 to grade 10 and from grade 20 to grade 15.

For every increase in insertion angle of 10 degrees, pullout strength was decreased by an average of approximately 160 N. In the lowest density considered, the same increase in insertion angle only decreased the pullout force by an average of 5 N.

Our experimental setup was done to better simulate the physical restraints imposed on a vertebra in vivo. Our results on the effect of host material density were consistent with results found from similar experimental studies done with polyurethane foam. Hsu et al. found significantly higher pullout strength in  $0.32\text{-g cm}^{-3}$ -density foam compared with  $0.16\text{-g cm}^{-3}$ -density foam [15]. Kim et al. performed tests using foams of densities 0.08, 0.16, and  $0.32\text{ g cm}^{-3}$ . Pullout strength was found to be greater in each increasingly higher density of foam [16]. Pullout strength has also been found to increase with increasing bone mineral density when cadaveric vertebrae are used for testing [1,10-16]. The effects of insertion angle on pullout strength in our experiments were also similar to results from previous experimental studies.

Robert et al., using polyurethane foam with a density of  $0.32\text{ g cm}^{-3}$  and the simple pullout method, found that pullout strength was greatest at an insertion angle of 0 degrees compared with angles of 10, 20, 30, and 40 degrees [17]. Kilincer et al., using lumbar spinal vertebrae, found that average pullout strength was greater when the angle between two pedicle screws in the same vertebra was 60 degrees than when it was 90 degrees [18].

Our experimental study was not without its limitations. One limitation is that polyurethane foam was used instead of vertebral bone. It was used because it closely mimics the densities of different types of bone; moreover, it is cost effective and allows reduction of uncontrolled experimental factors seen in experiments involving real bone because of high variability [29-31]. However, although polyurethane foam is consistent in density and structure throughout, real bone is not. Real vertebrae can vary greatly in density throughout, especially in osteoporotic specimens, and requires extensive number of specimens for comparative

studies. We tested 48 samples, using three samples for each combination of density and angle. However, the resultant low standard deviations suggest that simply increasing our sample size would not significantly alter our results. The experiments were designed to account only for variation in transverse angle without accounting for simultaneous variations of the sagittal angle, but given the marginal influence of inclination angle compared with bone density and the isotropy of the material used, the simultaneous inclination in both angles would have not significantly influenced the main conclusion. Another limitation to this study is that only one type of screw was tested. This screw's length, diameter, thread shape, and pitch all contributed in various effects to its pullout strength and the results we found may not be translated to other screw designs. The test protocol presented in the current study was designed to apply constraints with spacing and orientation characteristic of the thoracic vertebrae, so the results are limited in applicability to the thoracic spine. This specificity introduced in the setup design, on the other hand, allowed more realistic results compared with the largely used [16,32,33] ASTM standards and can be easily extended to other segments.

In conclusion, insertion angle has a marginal influence on pedicle screw pullout strength when compared with bone density. This minimal influence is most evident in osteoporotic bone, where changes in insertion angle have little to no effect on pullout strength.

Spinal navigation has been proven to be feasible in terms of time and cost [34] and in its latest evolution represented by robotic surgery, the control of the screw trajectory accuracy is significantly greater than with freehand technique [35,36]. The placement accuracy of these systems allows the practical execution of screw trajectories optimized for maximal pullout strength. According to our findings, in assisted surgical techniques, the cortical purchase should be pursued regardless the needed insertion angle, especially in osteoporotic bone.

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