Estimation of Pedicle Screw Fixation Strength from Probe Indentation force and Screw Insertion Torque: A Biomechanical Study on Bone Surrogates of Various Densities

H.N. Mehmanparast, JM. Mac-Thiong, and Y. Petit

Abstract— **Posterior pedicle screw fixation is commonly used for patients with spinal disorders. However, failure of fixation is reported in many cases and surgeons have only little information. The objective of this study was to assess the correlation between the probe indentation force, screw insertion torque and the pullout force using bone surrogates of different densities. The indentation force and insertion torque were measured using a custom made test bench during screw insertion into polyurethane foam blocks. The two variables were significantly correlated to pullout force and to density. A high correlation was also found between indentation force and the peak insertion torque. The proposed methods for measuring indentation force and screw insertion torque were reproducible. This study suggests that the peak screw insertion torque and the indentation force can predict the screw fixation strength in synthetic bone models. Additional tests should be performed on animal and human specimens to confirm and to translate these findings to clinical applications.**

I. INTRODUCTION/PROBLEMATIC

Pedicle screw fixation in spinal fracture, degenerative changes and deformities is widely used by orthopedic surgeons. Clinical studies have reported many cases of fixation failure through loosening at screw-bone interface [1-4]. Therefore, screw-bone interface is an important factor affecting pedicle screws fixation strength. Other factors such as screw design, bone quality, pedicle anatomy and insertion technique can also affect the fixation strength [5-7].

Several biomechanical studies have investigated pedicle screw fixation strength using pullout tests, insertion torque measurements or bone indentation tests [6, 8-12]. However, important discrepancies and poor agreements could be observed in the results, possibly because of a lack of standardization and reproducibility.

The present study investigates for the first time, the two mechanical evaluation methods of screw-bone interaction in synthetic model of cancellous bone of different densities. Using custom-made instrumentations, insertion torque and indentation force were assessed in a reproducible manner, and correlated with pullout force. This is considered as a preliminary study before in-vitro evaluation on cadavers.

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II. MATERIAL AND METHOD

A. Specimen preparation

This study used polyurethane foams (Sawbones, Pacific Research Laboratories, Vashon, WA, USA) as cancellous bone surrogate to avoid the inhomogeneity, complex anatomical characteristics and inter-subject variability of human vertebral bone density. Thirty six foam blocks of 5cm x 5cm x 4cm with 3 different densities were used to represent vertebral cancellous bone ranging from weak osteoporotic to normal human bone: 0.16 g/cm^3 (E=86MPa), 0.32 g/cm^3 (E=284MPa) and 0.48 g/cm^3 (E=592MPa). Pedicle screws of 5 mm x 35 mm (DePuy Spine, Inc., Raynham, MA, USA) were used for all tests.

B. Test Fixture

Each foam block was embedded into an aluminum box with polyester resin. A custom-made fixture (see Figure 2) composed of a translation table and a universal joint was used to align the specimen and eliminate residual forces. This fixture was designed to provide coaxial alignment of the pedicle with the testing system actuators during the biomechanical tests.

C. Indentation force measurement

The custom-made indentation probe was designed with a conical tip of 3mm major diameter and 100mm length to resemble the spinal pedicle finder surgeons use to create a pilot hole into the pedicle (Figure 1). The indentation probe was secured into the grips of material testing system (858 Bionix II, MTS Corp, Eden Prairie, MN). The test fixture was placed and aligned along with the indenter longitudinal axis. The indentation was conducted at rate of 1mm/sec to a depth of 25mm. The load and displacement were recorded during indentation. Indentation force was defined as the maximum load during penetration of polyurethane foam specimens.

D. Insertion torque measurement

Following the indentation test, the test fixture was installed in a custom-made test bench for torque measurement (Figure 2). The test frame is composed of a rotating motor seated on a plate free to slide vertically. A set of counterweights allow adjusting the longitudinal force applied during screw insertion. In this study, this force was

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set to 11.1 N. The screw driver was secured under the rotating motor using grips with a wedged shape slot and a 5 mm x 35 mm pedicle screw was secured into the screw driver. Once the foam block center was aligned with the screw tip, screw insertion started at rotation speed of 3 r/min until complete insertion of all threads into the foam block.

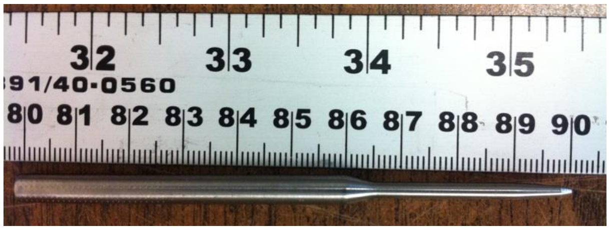


Figure 1. Custom-made indenter used to measure the maximum indentation force.

The torque and longitudinal force were monitored during the test using a calibrated torque/load cell with maximum torque capacity of 5.7 N.m and axial load capacity of 444.8 N (Model 1516 DMW-100, Bose Corporation, Eden Prairie, MN, USA). The insertion torque was defined as the peak torque for fully inserting the pedicle screw into the foam specimens. Insertion depth was measured using Optotrak 3020 cameras (Northern Digital Inc., Ontario, Canada).

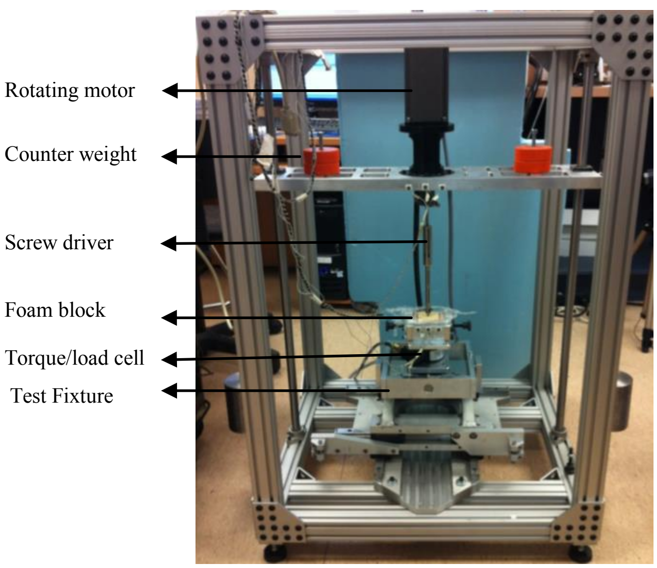


Figure 2. Custom-made torque measurement test bench.

E. Pullout test

After indentation and screw insertion in all specimens, the test fixture was transferred back into material testing machine for an axial pullout test. The test fixture was adjusted to ensure proper alignment of the screw longitudinal axis with pullout direction. The screw head was linked to the actuator using a shackle and bolt (Figure 3). A tensile displacement was applied to the screw head at a rate of 5 mm/min according to ASTM F 543-07 [14] until the screw released from the foam block. Load and displacement were recorded with a 2.5 kN load cell (model no, MTS Corp, Eden Prairie, MN) and analyzed for extracting the pullout force and stiffness. The stiffness was determined by calculating the slope of the most linear part of the load-displacement curve before the yield point in pullout test. Pullout force was defined as the peak load taken from load-displacement curve during the pullout test.

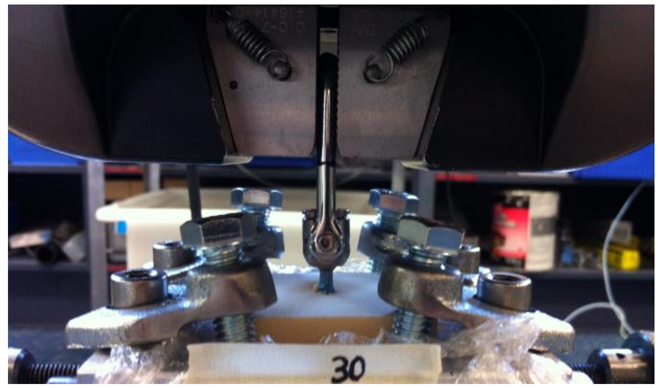


Figure 3. The test fixture placed in the material testing system for pullout test . Custom test fixture was the same as for indentation and torque measurement tests.

E. Statistical analysis

The data from all biomechanical tests were analyzed to investigate on potential relationships between insertion torque, indentation force and the strength of pedicle screw fixation. The peak insertion torque and the peak indentation force were related with pullout force and stiffness using simple linear regression. A *P*-value of less than 0.05 was taken as significant.

III. Results

The results show that indentation forces, insertion torques, pullout force and stiffness significantly increase with density (Table 1). The statistical analysis using a linear regressions showed that there is a strong relationship between the indentation force and the pullout force (R^2=0.98) and stiffness (R^2=0.97) (Figure 4). Similarly, the insertion torque is significantly related to the pullout force (R^2=0.99) and stiffness (R^2=0.96). Significant relationships were also found between indentation force and torque (R^2=0.99) and between pullout force and stiffness (R^2=0.96). The *P*-value in all relationships are much smaller than 0.05.

IV. Discussion

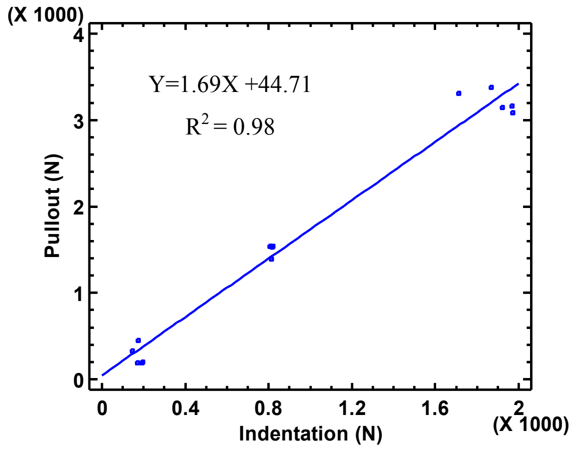
The strength of pedicle screw fixation depends on several factors such as the screw design, the insertion technique, the bone density and their interactions. In this study the screw design and insertion technique were kept constant in order to take into account of only the bone surrogate properties and their effect on screw fixation strength through the measurement of the maximum probe indentation force and the maximum screw insertion torque. The insertion torque significantly increases with the bone surrogate density. A similar trend was observed for the indentation force, pullout force and stiffness. The relations found between the pullout force and the foam density is consistent with previous studies

[15][16] using polyurethane foam of grade 10 and grade 20 to measure axial pullout force for different screw types. Moreover, the present results indicate that the screw pullout force and stiffness can be estimated from measurements performed during screw insertion (i.e. indentation force and insertion torque). This was confirmed through significant relationships between indentation and torque and pullout force and stiffness. The outcomes of the present study should be confirmed by performing additional investigations on animal and/or human specimens.

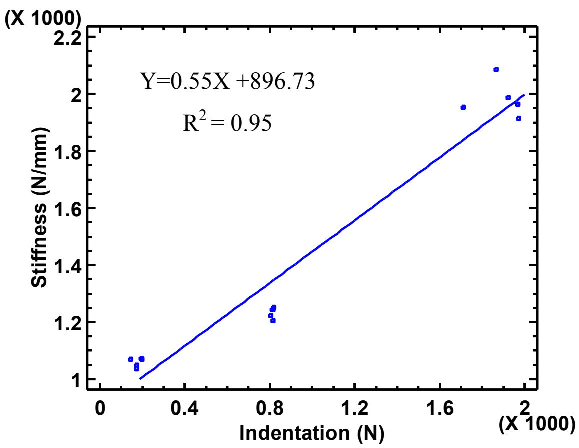
TABLE1. INDENTATION FORCES, INSERTIONAL TORQUES, PULLOUT FORCES AND STIFFNESS WITH CORRESPONDING STANDARD ERRORS

Density grade (g/cm3)	Indentation force (N)	SE*	Insertional torque (N.m)	SE*	Pullout force (N)	SE*	Stiffness (N/mm)	SE*
10 (0.16)	175.79±20.52	9.18	0.78±0.11	0.05	271.16±114.74	51.32	1059.60±16.38	7.32
20 (0.32)	812.94±5.77	2.58	2.75±0.03	0.02	1507.68±64.19	28.71	1233.000±19.27	8.62
30 (0.48)	1888.25±107.52	48.08	5.71±0.22	0.10	3216.045±121.45	54.31	1980.400±64.79	28.97

***SE is the standard error**



(a)



(b)

Figure 4. Relationships between Indentation and: (a) pullout; (b) stiffness

V. CONCLUSION

The measurement of maximum indentation force and peak insertion torque seems to be convenient for the prediction of pullout force in relation with a surrogate bone density. In order to verify this conclusion, the test protocol should be applied on animal and cadaveric models.

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