Biomechanical Evaluation of Pedicle Screw Loosening Mechanism using Synthetic Bone Surrogate of Various Densities

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

Abstract—**Pedicle screw fixation is a well-established procedure for various spinal disorders. However, pedicle screws failures are still reported. Therefore, there is a need for a greater understanding of the pedicle screw failure mechanism. This experimental study investigates the biomechanical stability of pedicle screws using a synthetic bone surrogate with a special focus on the screw loosening mechanism. Pedicle screws have been inserted in thirty six polyurethane foam blocks of three different densities. In half of the specimens from each density group, pedicle screws were submitted to cyclic bending (toggling) before pullout. The rest of specimens were solely loaded in axial pullout. The peak pullout force and stiffness were determined from load-displacement curve of each specimen. Statistical analyses were performed to investigate on the effect of toggling and bone surrogate density on the pedicle screw's pullout force. The results suggest that the pullout force and stiffness were significantly affected by toggling and density. Higher pullout forces resulted from higher grades of density. The proposed method allowed investigating the pedicle screw loosening mechanism. However, conducing further experimental tests on animal or cadaveric vertebrae are needed to confirm these findings.**

I. INTRODUCTION/PROBLEMATIC

Pedicle screw fixation is widely used for different spinal disorders since it allows to reduce the length of fused segments and provides high fixation stability[1, 2]. Fixation failure, however, can lead to loss of fixation and severe complications. The rate of pedicle screw failure is reported to be 0.8% to 17% [3-5].

There are numerous factors affecting the fixation strength including the vertebral body bone density, anatomy of pedicles, screw design and the screw insertion technique [6-10]. Modification of the screw design can improve the incidence of implant failure, yet the reasons for such failure have not been elucidated yet [5, 11, 12]. Biomechanical studies commonly use the axial pullout test to assess fixation strength of pedicle screws by measuring the peak pullout force from synthetic or cadaveric bone materials [13]. However, there is no agreement in results of such studies in the literature [7, 14, 15]. This could be due to the fact that the screw failure occurs in other condition than axial pullout in vivo. Therefore, there is a need to modify the biomechanical test method to examine the pedicle screw fixation strength.

To the author's knowledge, no previous study has compared the pedicle screw pullout forces with and without cyclic bending (toggling) prior to pullout in different bone surrogate densities. Therefore, this study was designed to investigate the screw loosening mechanism and its possible effect on the pullout force.

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II. MATERIAL AND METHODS

A. Specimen preparation

This study was conducted on thirty six solid rigid polyurethane foam blocks (5cm x 5cm x 4cm; Sawbones, Pacific Research Laboratories, Vashon, WA, USA). Foam blocks of three different density grades (twelve blocks of each grade) [16] were used to avoid inherent variability of cadaveric bone including the bone quality and geometry: grade 10 (0.16 g/cm3), grade 20 (0.32 g/cm3) and grade 30 (0.48 g/cm3) . Pedicle screws of 5 mm x 35 mm (DePuy Spine, Inc., Raynham, MA, USA) were entirely inserted in the pre-drilled foam blocks at a speed of 3r/min (Figure 1).

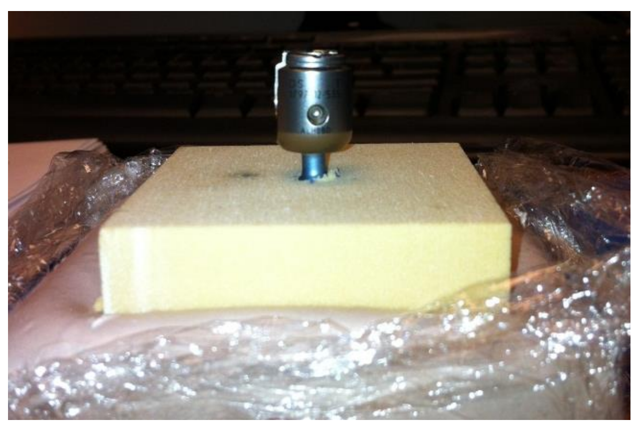


Figure 1. Pedicle screw has been fully inserted into polyurethane foam specimens

B. Biomechanical testing

The foam blocks were embedded into an aluminum frame using polyester resin. Biomechanical testing was conducted on two specimen groups for each density grade. Six specimens were taken for toggling prior to pullout as group I and the other six specimens were used for standard pullout test as the control group II. For the toggling test, the specimens were secured into material testing system (MTS

858, Bionix, Eden Prairie, MN, USA) using custom jigs (Figure 2).

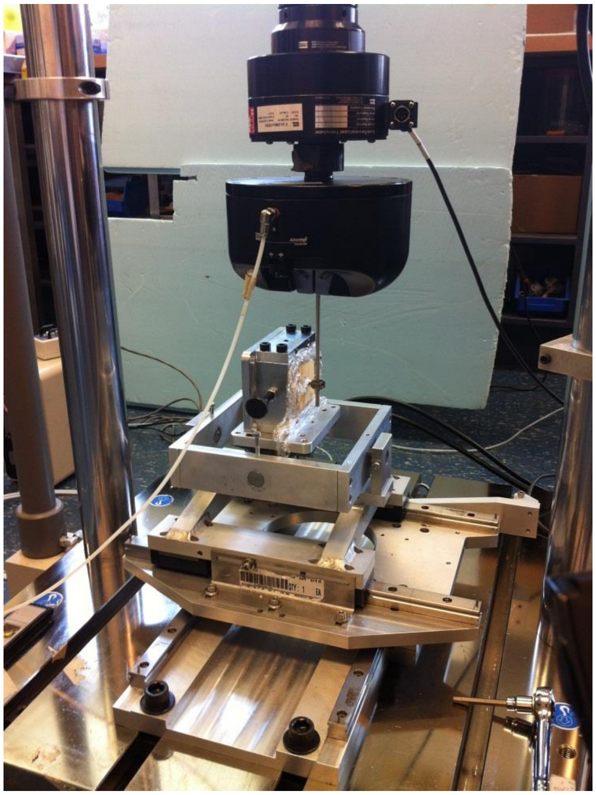


Figure 2. Test fixture and load frame for toggling test.

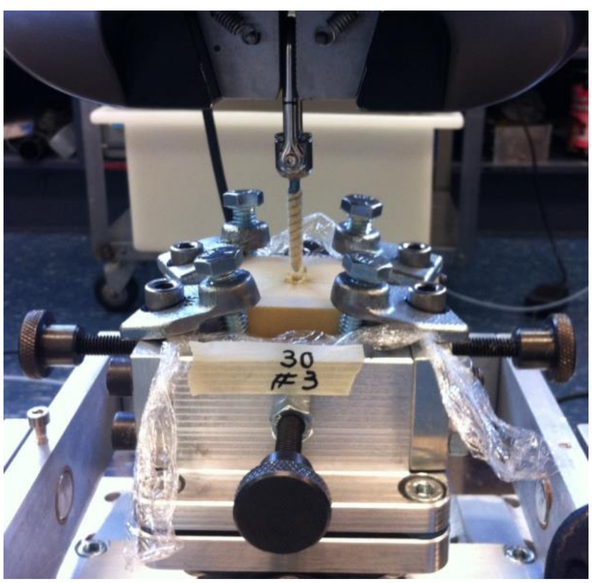


Figure 3. Pedicle screw pullout test.

The screw heads were coupled with a rod and bolt provided by the screw manufacturer. The cyclic bending load was applied through the rod perpendicular to the longitudinal axis of the screw with maximum displacement of ± 1mm at a frequency of 3 Hz for 5000 cycles while the force and displacement were monitored. This displacement magnitude was chosen to provide a nondestructive physiologic load comparable to those generated during normal walking [17]. According to preliminary tests, no damage such as crack or breakage was observed on the foam materials of various densities.

Subsequently, toggled and non-toggled specimens were placed and oriented in a custom fixture for the axial pullout test. A tensile displacement was applied at constant rate of 5 mm/min until the screw released from the test block (Figure 3) according to standard test method for medical bone screws [13]. Axial force, displacement and time data were monitored.

C. *Statistical analysis*

To characterize the pedicle screw fixation strength, two dependent variables were evaluated: pullout force and stiffness. The pullout force was defined as the maximum force during axial pullout of the screw and the stiffness was calculated as the slope of load-displacement curve before complete pull-out. These parameters were used to assess the effect of independent variables (density and loading condition) and their interactions using multiple factorial analyses of variance (ANOVA). Pareto charts were used to compare the relative importance of the main effects and interaction of these parameters on the studied responses (pullout force and stiffness). Those effects exceeding the reference line in the Pareto chart are related to statistically significant parameters at 95% confidence level. Wilcoxon test was performed to determine the significant difference between toggled and non-toggled data for pullout force and stiffness.

III. RESULTS

Figure 4 shows the pareto charts of standardized effect for pullout force and stiffness. It is observed that pedicle screw's pullout force and stiffness are significantly affected by loading condition (toggling) and bone surrogate density. Increasing the density significantly increases the pullout force whereas screw toggling significantly decreases the pullout force.

Detailed evaluation of direct effects of foam density grades on pullout force and stiffness with respect to toggling method used is illustrated in Figure 5. Significant differences were observed for the stiffness between toggled and non-toggled screws for density grade 10 ($p=0.03$), grade 20 ($p=0.03$) and grade 30 ($p=0.03$). Similarly, the difference from toggled and non-toggled pullout force was found as significant for grade 20 ($p=0.01$).

IV. DISCUSSION

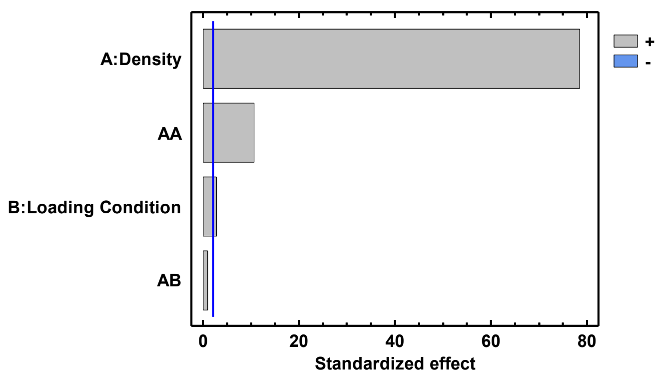
The in vitro test method to evaluate the pedicle screw fixation strength is currently the standard axial pullout test. However, it does not mimic the realistic situation of screw failure secondary to loosening from individual’s daily activities. This study proposed a new method for testing the screw fixation strength by toggling before pullout test and compared with the conventional pullout test. The measured parameters in this study i.e. the pullout force and stiffness allowed evaluating the strength of screw by measuring the maximum load at failure point and the rigidity of screw that shows the resistance to deformation. The statistical analysis shows a significant effect of toggling on the pullout force, supporting the use of this new method to better assess screw fixation strength.

Lotz *et al.* [17] evaluated the screw pullout forces with and without toggling on osteoporotic cadavers. They did not find statistical difference between the two groups. It is, however, notable that their study used pedicle screws with cement augmentation and did not investigate for the stiffness [17]. To the author's knowledge, no other study has compared the pullout forces of toggled and non-toggled pedicle screws.

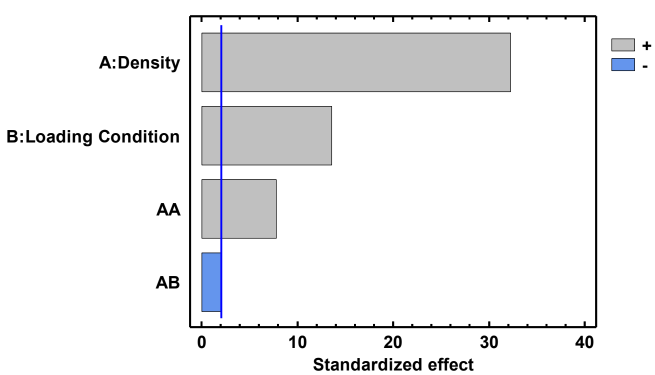
The direct interpretation of our results for clinical application is limited since the bone inhomogeneity and the effect of pedicle geometry are not considered in the bone surrogates used this study. Therefore, further investigations are needed to be performed on animal or cadaveric vertebrae to confirm the results.

V. Conclusion

A novel method was implemented to study pedicle screw loosening mechanism. It allows improving our understanding of the failure mechanism that happens clinically. Toggling is more likely to affect pedicle screw stiffness than pullout force. However, further experimental tests are needed to confirm these findings.

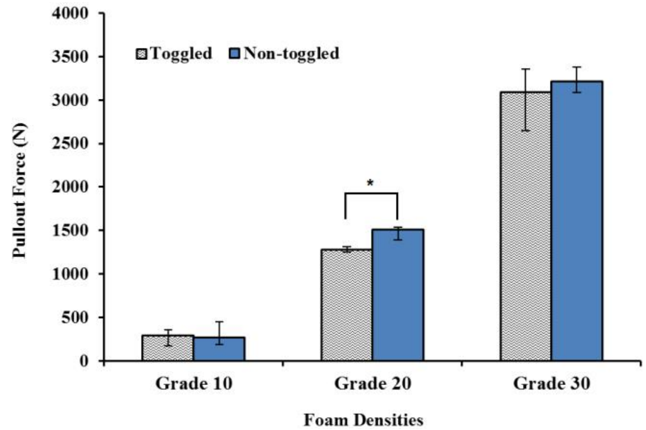


(a)

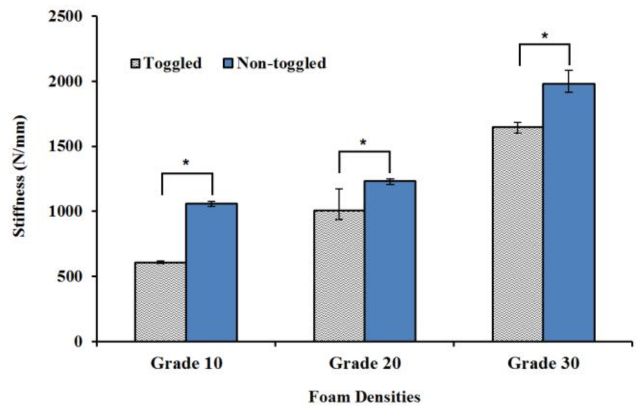


(b)

Figure 4. Pareto chart of the standardized effect on: (a) Pullout force; (b) stiffness. Blue lines define the thresholds for significant effects. ($p<0.05$).



(a)



(b)

Figure 5. Comparison between cycled and non-cycled tests at various densities: (a) pullout strength and (b) stiffness. * Significant differences.

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