Influence of Driver-to-Screw Misalignment on Insertion Torque and Pullout Strength in Medical Screw Testing

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INTRODUCTION: Test standard ASTM F543-17 sections Annex 2 and Annex 3 (A2 and A3) prescribe testing procedures for insertion/removal and axial pullout of medical bone screws. The test method described therein is intended to provide a standardized means of testing medical bone screws to allow for the determination and comparison of basic performance parameters.[1] The standard specifies that the screw must be inserted perpendicular to the underlying polyurethane test block. However, during testing, deviations from perpendicularity were discovered to cause oscillations in resulting torque-rotation graphs, which may lead to skewed data. This study elucidates the extent to which perpendicularity deviations caused by unintended misalignment between driver and screw can impact testing and may thereby help guide test engineers when assessing test setup adequacy.

METHODS: Insertion testing was performed following the procedure outlined in ASTM F543-17 using 3.5 mm non-locking hexalobe screws, which are commonly used in extremity fracture fixation. The test used an Admet® 81T testing machine equipped with a Futek® 100 lb/in-lb capacity load cell. Attached to the load cell was a custom sliding jig which was used to create a measurable offset between the driver tip and the head of the screw. Each screw location had a 2.8 mm pilot hole drilled according to manufacturer recommendation. At the start of each test, the sliding jig was unlocked, and the driver was inserted into the pilot hole to establish the initial, zero-offset, perpendicular location of the screw. The sliding jig was then adjusted until the desired offset was achieved and locked to prevent accidental movement. Offsets increased from 0 mm (perpendicular) to 2.5 mm in half-millimeter increments. The offset distance was measured with digital calipers and confirmed again after the jig was locked. The screw being used for testing was then aligned such that the head of the screw engaged with the driver and the tip of the screw was in the pilot hole (Figure 1). Torque was recorded continuously throughout the insertion of the screw. Two different screw lengths, 15 mm and 30 mm, two different densities of Sawbones® solid rigid polyurethane foam blocks, 30 lb./ft^3 (PCF) and 20 lb./ft^3, and two different insertion depths, 20 mm and 9 mm, were used in the test. In addition, each configuration was repeated five times, which constitutes the minimum sample size recommended in ASTM F543-17. Following the screw's insertion, the screw, imbedded in the foam block, was taken to an Instron 3344 test machine with a 2 kN load cell, where an axial pullout test was performed following ASTM F543-17 A3. The foam block was aligned with the screw directly beneath a slotted pullout fixture, which pulled vertically on the head of the screw. Force was continuously recorded until the screw became dislodged from the foam. Once the data was collected, insertion torque at four revolutions of the screw and pullout strength were averaged and normalized, with both maximum insertion torque and pullout strength at 0-mm offset establishing the 100% baseline. To determine statistical significance, ANOVA tests with Games-Howell post-hoc analysis for unequal variances were conducted in Minitab® at a significance level of .05.

RESULTS: As expected, in general, insertion torque increased, and pullout force decreased as the screw offset angle increased. However, beyond general trends, the data fluctuated and did not consistently increase or decrease between adjacent individual offsets. These findings were consistent both in 20 PCF and 30 PCF foam. The overall results from this test can be seen in Figure 2. The largest increase in insertion torque compared to perpendicular was the 1.5-mm offset of the short screw in 20 PCF foam (+39%). The largest decrease in pullout force (-34%) was observed in the 2-mm offset of the long screw in 20 PCF foam. While only test 2 (20 PCF, long screw, shallow insertion) did not result in statistically significant differences in pullout force, tests 1 (20 PCF, long screw, deep insertion) and 3 (20 PCF, short screw, shallow insertion) are the only tests which yielded statistically significant increases in insertion torque. Tests 3 and 6 (short screws, shallow insertion) were not tested at 2.5- mm offset because the short screws were not able to be driven into the foam block at such an extreme angle.

DISCUSSION: The presented test method establishes the importance of perpendicularity when inserting medical screws into foam blocks following test standards such as ASTM F543-17. Off-angle insertions can lead to oscillations in the resulting data due to the increasingly mismatched interdigitation at the hexalobe drive interface when driver and screw are forced out of angular alignment (Figure 3). These oscillations may have contributed to variability in some of the data, which in turn may have prevented identification of more statistically significant findings, given the relatively small sample size. Furthermore, the presented data show that insertion torque and pullout force can be affected by more >30% as a result of non-perpendicular screw insertion.

SIGNIFICANCE/ CLINICAL RELEVANCE: In a clinical setting, it may be difficult to insert a screw in a perfectly perpendicular manner, though that is how screws are tested per the ASTM F543-17 standard. As we have shown, inserting the screw at an offset may make the screws more difficult to insert and easier to pull out than expected, and if surgeons and regulators rely on test data to estimate the mechanical properties of medical screws, it is important to recognize that offsetting the screw may affect performance. In addition, the provided information can help guide test engineers in assessing test setup adequacy, which may lead to increased reliability and reproducibility of screw testing, ultimately benefiting healthcare providers and patients alike through an increase in reliability and quality of medical screws.

REFERENCES: [1] ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws. 2017, ASTM International: West Conshohocken, PA.

FIGURES:

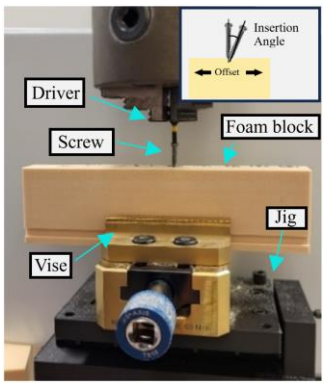

Figure 1- Test set up with screw in perpendicular position.

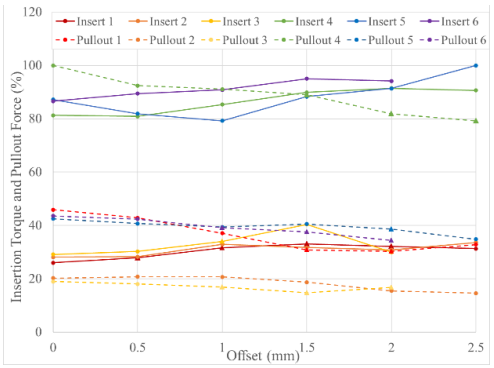

Figure 2-Average insertion torque and pullout force at different offsets. Triangle markers signify significant differences ($p<.05$) vs. zero-offset.

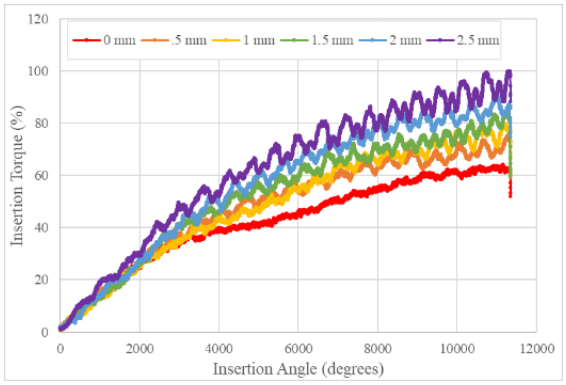

Figure 3- Insertion torque vs insertion angle for different screw offsets (30 PCF, long screw, deep insertions)