New Method for Performance Analysis of Pedicle Screw Designs
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**Introduction:** Traditionally, pedicle screw designs have been compared using static pullout. While pullout techniques are standard, they are not clinically relevant as this loading condition is not manifested in-vivo. Further, pullout tests tend to be insensitive to unique design features as the bone within the vertebral body fails in shear. To better differentiate the characteristics associated with pedicle screw designs, this work focused on toggle testing to evaluate mechanical functionality of pedicle screws.

**Materials and methods:** Bovine vertebrae from T11 to L4 were subjected to bilateral randomized insertions of 45mm long pedicle screws (N=6 for all); (Trio 6.5mm, Expedium 6.0mm, Pangea 6.0mm, Xia 6.5mm and Osteogrip 6.5mm) and subjected to sinusoidal toggle testing from ±340N to 2600 cycles at 0.5 Hz. Load and displacement data were collected at 100-cycle intervals with total deflection at each 100-cycle interval computed. Individual screw deflections were normalized to zero to illustrate increase in toggle versus cycle number. The average deflection per interval was subjected to non-linear regression. The area under the load versus deflection curve at each interval was used to determine the work done for a complete loading cycle with the resulting work summed for subsequent cycles. Statistical comparisons for both the resulting fitted parameters and work done and between screw designs were performed using a one-way ANOVA and a Tukey post-hoc analysis.

**Results:**

**Toggle Fatigue Testing:** The non-linear analyses of each screw type resulted in an exponential fits with R$^2$>0.94. From the resulting rate (k values) of the exponential regressions, half-life (= ln2/k) computations were performed and revealed that only the Pangea screw displayed significantly reduced time to achieve half-life (P<0.05) as compared to the Osteogrip screw design. The remaining designs displayed comparable and increased settling time.

**Work:** The analysis of cumulative work versus cycle number resulted in a linear function for all screws. (R$^2$>0.99 for all screws) At 100 cycles, the Pangea screw displayed reduced work transfer with respect to the Osteogrip screw, while other comparisons were not significant. At 500, 1000, 1500, 2000 and 2500 cycles both the Expedium and Pangea screws displayed significantly reduced work transfer with respect to both the TRIO and Osteogrip screws (P<0.05 for all).

**Discussion:** Half-life may be characterized as a mathematical characterization for settling. As a consequence, screw design performance can be evaluated. It should be realized that the methods displayed in this study could be correlated to patient outcomes with respect to screw design used during surgery. This would permit optimization of thread characteristics. The parameters that can be determined using the toggle test method combined with non-linear analysis may be employed to avoid stress shielding resulting from clinically over rigid configurations. The DL screw displayed work values within the midrange of all screws tested. The combination of a cortical and cancellous thread associated with this may represent an appropriate balance between under- and over- stabilized pedicle fixation. The work data presented in this study can also be correlated to clinical outcomes and may represent a viable indicator of load sharing at a specific vertebral level.