Fusion and Non-Fusion Spinal Implants: Computational and Experimental Study

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Introduction: Non-fusion, or growing-rods, are commonly used to accommodate a growing spine for curvature correction due to early onset scoliosis. High failure rates are associated with non-fusion instrumentation; most prevalent (15-20%) in rod failure at rod-connector interactions1. The instrumentation uses fewer anchors and spacers to span greater distances while there is increased load shared with construct relative to fusion instrumentation used in mature spines. Hence, a need exists to quantify mechanical performance of non-fusion constructs and compare to fusion constructs. ASTM F1717 is the current standard for testing mechanical performance of fusion constructs – this standard was used for testing fusion constructs and modified for non-fusion constructs. Computational models allow for enhancement, manipulation, optimization, and analysis of pre-submission communication with the regulatory office. The purpose of this study was to experimentally determine structural properties of fusion and non-fusion constructs; use the data to develop and validate finite element analysis (FEA) models.

Materials and Methods: Fusion and non-fusion (growing-rods with side-by-side connectors) constructs were mechanically tested per ASTM F1717 (n = 5/group) using pedicle screws (Ti-6Al-4V & Co-28Cr-6Mo), set screws (Ti-6Al-4V), spinal rods (Ti-6Al-4V), test blocks (UHMWPE), and connectors (Ti-6Al-4V, non-fusion only). Blocks for non-fusion were offset to incorporate connectors, placed at the mid-point between the superior and inferior blocks. Experimental test methods were simulated with FEA by ABAQUS; material properties were obtained from ASTM standards (Ti-6Al-4V & Co-28Cr-6Mo) or through MakeItFrom material properties database (UHMWPE) (Figure 1A). FEA assumed isotropic and linear-elastic for blocks, while the instrumentation was assumed to be isotropic and linear elastic-plastic. Perfect surface-to-surface contact was assumed for all surface interactions. Stiffness, yield strength, and ultimate strength were measured experimentally and through FEA. Fusion and non-fusion constructs were compared by the Student’s t-test; FEA was validated when within 10% difference from the experimental.

Results and Discussion: FEA predicted stiffness and ultimate strength of both fusion and non-fusion constructs within 10% of experimental (Figure 1B, Table 1). However, the yield region deviated from experimental. Non-fusion constructs had a significantly greater ultimate strength and stiffness than fusion (Table 1). Stress distribution analysis illustrates concentrations at apex of curvature for fusion construct and at superior rod-connector interaction for non-fusion.

Translational Impact: Structural properties agreed for stiffness and ultimate strength between experimental and FEA for both constructs. Though these constructs distribute stress differently, their yield strengths were not significantly different. Stress concentrations observed on the non-fusion computational model were consistent with clinical observed failures in the literature, where rod breakage occurs within 1cm of the rod-connector interaction1. Similarities observed between clinical failures and FEA stress concentrations provides a basis for utilizing computation modeling in regulatory submission. Future work is to enhanced understanding of material properties, particularly the yield properties.

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