Increased Mechanical Performance of Spinal Rods with Advanced Alloy Development

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INTRODUCTION: Lumbar spine fusion using traditional metals such as titanium and cobalt chromium alloys have reported >90% fusion rates and >80% improvement in leg pain [1]. However, a recent systematic review found rod fracture rates of 18.7% (titanium: 12.2% and cobalt chromium: 6.5%) indicating the need for more fatigue resistance alloys [1]. This is particularly important for scoliosis devices since growing rod constructs that are subjected to higher mechanical demands from repeated notches due to rod lengthening and greater bending moments from longer constructs. As a result, rod fracture rates as high as 72% have been observed in scoliosis patients [2-3]. This high fracture rate may be due to notch sensitivity in commonly used titanium Ti6Al4V alloy as "V" notches significantly reduced bending fatigue strength [4]. Furthermore, clinically relevant notches created from spinal components (*i.e.*, French bender and connector) in titanium rods displayed reduced bending fatigue strength compared to stainless steel rods [5]. Therefore, further alloy development is necessary to increase spinal rod fatigue strength, particularly greater resistance of these rods to notches created during surgical procedures. In particular, Ti-15Mo was investigated for high-strength orthopedic applications where it was demonstrated that non-traditional processing resulted in a wide range of mechanical properties as well as smooth and notched fatigue behavior [6]. Thus, the objective of this study is to characterize the mechanical performance of alternative metals processed to increase fatigue behavior for spinal applications. In particular, Nitinol ELI (NiTi), titanium-molybdenum (Ti-15Mo), MP35N, and ultra-low inclusion Ti6Al4V alloys are compared to traditional spinal implant metals (*e.g.*, Ti6Al4V ELI).

METHODS: Four-point bend testing was conducted per ASTM F2193-20 (Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System) on 5.5mm diameter lumbar spinal rods (N=5 per group) using an Instron ElectroPuls E10000 mechanical testing system. Initial static testing of Ti-15Mo and Ti6Al4V ELI rods was performed at 5 mm/min to 11mm displacement (beyond the yield point). Mechanical properties such as bending stiffness and yield were compared between materials and used for selecting fatigue conditions for dynamic testing. A student t-test with significance level of $p \leq 0.05$ was utilized for statistical analysis of mechanical properties. Fatigue testing was performed with applied maximum bending stress conditions that were varied between 25%-117% of the bending yield strength (298 to 1393 MPa) at a stress ratio (R) of 0.1. Runout was considered 2.5 million cycles as recommended in the ASTM F2193 standard. In order to determine the reductions in fatigue strength with notch damage, additional bending testing will be performed with spinal rods subjected to notches created from spinal set screws on the tensile side of the rod. The four-point bending results will inform subsequent static and dynamic compression-bend testing per ASTM F1717-21 (Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model) to provide a more clinically relevant loading scenario.

RESULTS: Static bend testing indicated that the bending stiffness of Ti-15Mo rods was slightly lower ($p<0.01$) compared to Ti6Al4V ELI (Table 1). Ti-15Mo possessed slightly higher yield load and displacement Ti6Al4V ELI ($p<0.04$). As shown in Figure 1, Ti-15Mo rods possessed slightly higher fatigue strength (1074 MPa or 90% of yield) than Ti6Al4V rods (1015 MPa or 85% of yield).

DISCUSSION: The results demonstrated that alternative alloys such as Ti-15Mo can have comparable static mechanical properties (*e.g.*, stiffness, yield load) to promote spinal fusion, but also improved fatigue performance of compared to the traditional titanium alloy. This is important as advances in alloy development can decrease spinal rod fracture rates observed in current alloys. Future work will develop processing methods for additional alloys such as NiTi ELI, MP35N, ultra-low inclusion Ti6Al4V to determine whether even greater fatigue resistance can be obtained compared to traditional Ti6Al4V rods including notched configurations of these alloys.

SIGNIFICANCE/CLINICAL RELEVANCE: Spinal rod fractures occur at an ~18% rate clinically and can cause adverse events (*e.g.*, substantial pain) and necessitate reintervention. As such, there is a clinical need to develop alloys with superior fatigue resistance compared those currently used for spinal rods. This is particularly important in adolescent scoliosis where the mechanical environment is more challenging due to patient growth, longer constructs, and notches created during the spinal procedure.

REFERENCES: [1] Mao, JZ., et al. *World Neurosurgery* 146 (2021): e6-e13 [2] Hill, G., et al. *The Spine Journal* 17:10 (2017): 1506-1518 [3] Sankar WN, et al. Spine 35:23 (2010): 2091–6 [4] Roach MD, et al. *Journal of ASTM International*. 2:7 (2005): JAI12786 [5] Dick, JC., *Spine* 26:15 (2001): 1668-1672 [6] Marquardt, B., et al. *Journal of ASTM International*. 2:9 (2005): JAI12779.

Table 1. Static Mechanical Properties of Spinal Rods

	Ti6Al4V	Ti-15Mo
Stiffness (N/mm)	302 ± 2.1	282.1 ± 1.2
Yield Load (N)	1504.4 ± 0.8	1558.3 ± 40.1
Yield Displacement (mm)	5.1 ± 0.1	5.7 ± 0.1

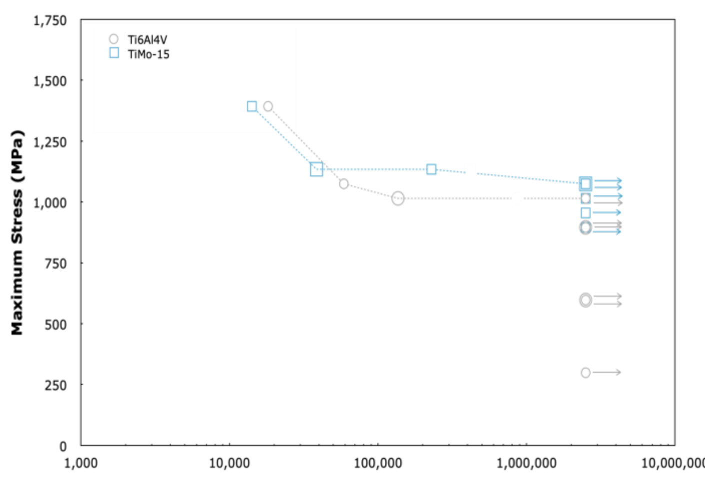

Figure 1. S-N curves of Ti6Al4V and Ti-15Mo (arrows indicate runout achieved)