THE EFFECTS OF ROD CONTOURING ON SPINAL CONSTRUCT FATIGUE STRENGTH

INTRODUCTION:
Instrumentation with pedicle screws and rods has become the hardware gold standard in posterior spinal fusion procedures. Devices used to deliver significant permanent deformation, such as a French Bender, are used intra-operatively to contour spinal rods in order to match the normal kyphotic (thoracic) or lordotic (cervical or lumbar) curvature. However, this process also induces notches onto the surface of the rod. It is well-known from basic engineering principles that notches, or discontinuities in the structure of a material, can create points of concentrated stress, which can initiate failure. Previous studies have highlighted the reduction in fatigue resistance for stainless steel and titanium orthopaedic wire when there are surface alterations (1) and other studies have conducted fatigue tests on different spinal constructs (2). However, we are not aware of any study that has investigated the cyclic deformation of titanium and stainless steel constructs with contoured/notched spinal rods. Accordingly, the purpose of this study is to detect differences in fatigue resistance of titanium and stainless steel spinal constructs that utilize rods that have been contoured using a French Bender.

METHODS:
Constructs with rods consisting of four different materials were evaluated in this study: titanium alloy (Ti6Al4V), commercially pure titanium (CpTi), Orthinox®, and 316L stainless steel (Stryker Spine, Allendale, NJ, USA). Rods were cut to a length of 100 mm and bent at two points (30mm from each end) to a curvature of 13°-15° each (~25°-30° total). The procedure was strictly adhered to in order to eliminate variability in rod deformation. Spinal constructs were tested using a corpectomy model (ASTM F1717-01). Ultra high molecular weight polyethylene blocks (UHMWPE) represented the vertebral elements to ensure the consistency of pedicle screw fixation and to eliminate variability in bone mineral density due to age, size, history, etc). Two pedicle screws (35 mm long and 7.5 mm diameter) were tapped into each UHMWPE vertebral body. Each pedicle screw/UHMWPE unit was mounted on a custom designed mechanical fixture that conformed to the ASTM guideline.

Each construct (two UHMWPE blocks and four pedicle screws) was mounted in an MTS servohydraulic testing frame. Rods were rigidly coupled to the head of the pedicle screws using blocker screws. Each blocker screw was tightened using a 12 Nm torque wrench. Constructs were cycled such that the load ratio (R) was consistent for each test: 

\[ R = \frac{\text{minimum load}}{\text{maximum load}} = 10 \]

Given the apparatus geometry, the MTS loading delivered a combined flexion-extension moment and compression on the hardware. In order to generate the appropriate endurance curves, each spinal rod material was subjected to minimum (~250N/25N) and maximum (~700N/70N) loading regimes, with the other loading magnitudes falling between these extremes. Cyclic, sinusoidal loads were applied at a frequency of 4 Hz. The resulting construct was cycled to failure or until two million cycles (defined as “run-out”) were reached. Data was collected using standard MTS data collection software (MTS TestStar, Eden Prairie, MN).

RESULTS
Six constructs were tested for the CpTi, Ti6Al4V and 316L rods, and three constructs were tested for the Orthinox® rod (Fig. 1). Loading for 600N and 700N on the Orthinox® specimens was not readily achievable and was reducible due to slippage at the screw-rod interface. All of the CpTi and Ti6Al4V tests fatigued at the bend/notch point in the rods, which were induced by the French Bender (Fig. 2). Of the tests that utilized stainless steel pedicle screws (for 316L rods and Orthinox® rods) and did not reach ‘run-out’ (2 million cycles), fatigue failure occurred at the neck of the pedicle screw at higher loads and at the bend/notch point for loading lower regimes (316L/J350N test and the Orthinox/400N test).

DISCUSSION:
At the high load levels, the stainless steel constructs consistently failed at the neck of the poly-axial pedicle screw. However, at lower cyclic loads, the contoured Orthinox® and 316L rods failed at the point of induced deformation (rod bending). The clinical implication of this finding is that patients who are more active or obese should probably have stainless steel screws with a larger diameter implanted in order to avoid temporal hardware failure. The data also indicates that the titanium constructs (CpTi and Ti6Al4V) are not only less resistive to fatigue failure than the stainless steel constructs, but the point of failure consistently occurred at the bend in the rod for the titanium constructs. This indicates intra-operative contouring likely compromises the integrity of the titanium construct. While this reduction in fatigue resistance is inherent in the mechanical properties of titanium, we found Ti6Al4V to be more resistant than CpTi; however the lower yield strength of CpTi may be confounding our results. The disparity in fatigue resistance between the two titanium materials was magnified at higher load levels. It should be noted that the ASTM standard used in this investigation represents a total corpectomy model, providing a “worst-case” scenario in which the hardware bears the entire load without anterior support. In conclusion, the process of bending spinal rods, especially titanium rods, induces surface defects, which can act as a point of failure initiation in both titanium (at all loading levels) and stainless steel (at lower loading levels) alloys.

REFERENCES: