Development of a Biomechanical Model to Evaluate Mechanically-Induced Corrosion of Stainless Steel Posterior Lumbar Spinal Implants

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Statement of Purpose: To date, there is limited information regarding the corrosion of spinal devices. The focus of this study was to develop an in vitro biomechanical model to determine if increased rates of corrosion are a result of daily activity loading on stainless steel (SS) posterior lumbar spinal implants.

Methods: Three single-level lumbar discectomy constructs were assembled using stainless steel rods, bone screws, and set screws. The geometry of the construct was selected to mimic the clinical dimensions of lumbar posterior instrumentation. The corrosion test spine simulator used in this study could only operate in angular control, so a custom pneumatic 4-axis mechanical system was utilized to determine the stiffness of the constructs. The construct stiffness values could be then used to derive angles to input into the spine simulator for corrosion testing. The constructs were tested to 7.5 Nm in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) while an axial compressive load was maintained at 140 N. SEM images were taken prior to and after testing at the implant component junctions to assess the damage (if any) caused by biomechanical testing.

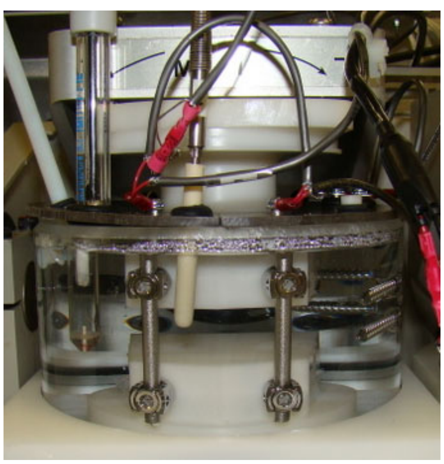

Figure 1. Test construct in the corrosion chamber.

In order to evaluate the susceptibility of spinal instrumentation to fretting corrosion processes, the fretting corrosion test methods utilized by other orthopedic devices, e.g. hip and knee, were adapted to spinal device evaluation. The implants were mounted on an MTS spine wear simulator and submerged in 0.9% NaCl solution. All mounting screws were isolated to prevent exposure and contamination to the test fluid. To measure the mechanically-induced fretting current (I_{frett}), a second SS implant was submerged in the test chamber, and the current was measured between the devices under load and unloaded (counter electrode) states using a picoammeter (Keithley 6485). The open circuit potential (V_{OCP}) was monitored between the loaded construct by a calomel reference electrode submerged in the test chamber (Accumet, Fisher Scientific 13-620-258). Both metrics were recorded throughout the duration of the test using a LabVIEW program. Figure 1 is a picture of the test setup.

In vitro and in vivo studies have previously quantified the loads and moments imposed on spinal devices during walking and moderate activities of daily living, so the following testing conditions were chosen: a constant compressive axial load of 140 N and sinusoidal moments of ±2.0 Nm in FE, ±1.5 Nm in LB, and ±1.0 Nm in AR at a frequency of 2 Hz. The test was conducted to five million cycles.

In order to characterize the corrosion properties, the experimentation was divided in five parts: (1) unloaded condition (base line behavior), (2) short term test (onset loading condition), (3) long term test (fretting corrosion behavior), (4) recovery test (corrosion after loading), and (5) short term test (extent of corrosion after run-in).

Results: *Stiffness testing:* Figure 2 shows the average stiffness of the SS constructs in the biomechanical motions. The stiffest motion was in LB, which was more than 3 times greater than the next stiffest motion of extension.

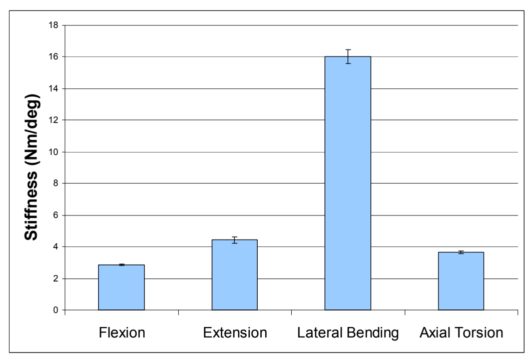

Figure 2. Average construct stiffness.

Corrosion testing: Both I_{frett} and V_{OCP} values were obtained from the corrosion test setup. The results are currently being validated versus known SS corrosion ranges.

Conclusions: The stiffness results were very repeatable with low standard deviations and high R^2 values. LB was much higher than all other motions, with flexion being the least stiff. Corrosion metric data were obtained, showing the model presented here has potential for spinal implant analysis. However, the corrosion data need to be further analyzed to confirm the feasibility of such a model.