Fretting Corrosion Performance Test For Spinal Screw and Rod Implants: Method Assessment

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Statement of Purpose: Fretting corrosion of metallic biomaterials continues to be a concern for high-load medical device applications. Mechanical factors like cyclic loading, interfacial contact and micro-motion can lead to disruption of passive oxide films on metallic surfaces. Degradation of oxide films accelerates corrosion processes, decreases structural integrity of implants and can elicit severe biological reactions in patients. In spinal devices, there has been a progressive increase in use of multi-segmental spine-rod-screw fixation systems for various spinal conditions like scoliosis, spinal stenosis syndrome and post-traumatic spine instability. These constructs typically consist of multiple screws and rods with connectors, all of which lead to multiple points of metal-metal contact and high cyclic-load transmission. These constructs can have crevice-like geometries that result in restricted local environment. When these factors are combined (local fluids, fretting and restricted geometries) they may lead to significant increase in corrosion rates. In this preliminary study, the objective is to develop a highly controlled fretting corrosion performance test method for spinal devices that can control, monitor and assess the electrochemical processes present at fretting interfaces in terms of current and voltage response. We investigate *in vitro* corrosion and fretting behavior of spinal rod-screw constructs under physiological loading conditions. This helps us determine the onset motion/load required to induce fretting corrosion and the magnitude of the electrochemical response at specific cyclic displacements.

Methods: A single rod-connector-screw construct (i.e. 2 screws, 1 rod with connectors) made of stainless steel (SS 316L) and of Titanium alloy (Ti-6Al-4V) are used for testing (Medtronic -CD Horizon Legacy Spinal System). The construct is mounted to two polyethylene blocks to represent two vertebral bodies with no support between them other than the construct (Fig.1). The test set-up consisted of a spinal construct, a second electrode made from an identical construct and a reference electrode (Ag/AgCl) immersed in phosphate buffered saline (PBS) solution of pH 7.4 at room temperature. The PBS only rises above the bottom screw-rod junction to isolate a single junction. Cyclic displacement of varying magnitude is applied at about 2 cm from the rod axis using a dynamic Instron test frame. The spinal construct is allowed to reach its resting Open Circuit Potential (OCP) for 2 hours prior to testing. The voltage between the sample and reference, and the current between sample and second construct are then measured and used to assess the extent of fretting corrosion taking place. Measurements by data acquisition (National Instrument DAQ card and Lab view) of current, voltage, load and displacement are made simultaneously and used to determine displacement onsets and fretting current magnitudes. The single-segment construct has three principle bending axes (anterior-posterior, lateral, and axial twisting) each of which can give rise to fretting corrosion processes. These constructs are loaded to give anterior-posterior bending response with increasing cyclic displacement (R= 0.5 to 2.5) at a fixed frequency (2 Hz). All tests are conducted in triplicate for each principal bending axis.

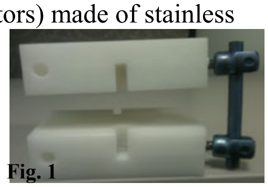

Fig. 1

Results: Fig. 2 shows the plot obtained from fretting corrosion testing of a single rod-screw construct when subjected to give anterior-posterior bending response. The onset of fretting currents for SS 316L is around 1 mm whereas for Ti-6Al-4V is around 1.5 mm of displacement. This onset is also seen in voltage. The fretting currents rose to about 2.7 µA for SS 316L and 0.37 µA for Ti-6Al-4V at displacement of 2.5 mm due to disruption of the oxide film. The voltage drop is around -235 mV and -63 mV vs Ag/AgCl for SS 316L and Ti-6Al-4V, respectively. The onset load required to induce fretting currents in SS 316L is around 37 N and for Ti-6Al-4V is around 26 N. Fretting currents also increased with increasing load.

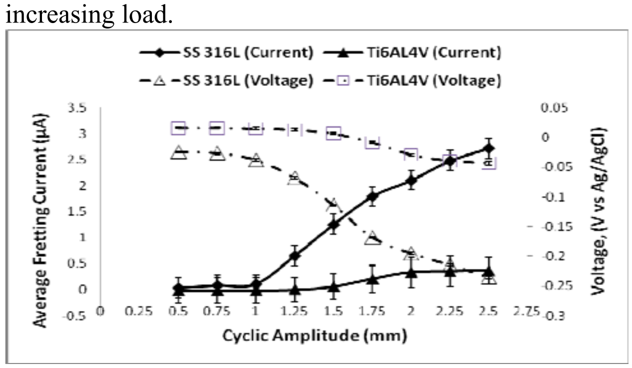

Fig 2. Plot determines onset of fretting currents and voltages at specific displacements in a single rod-screw spinal constructs.

Conclusions: The proposed fretting-corrosion performance test method determines the onset load required to induce fretting currents at specific displacements. SS 316L construct starts fretting at lower displacement with high fretting currents than Ti-6Al-4V construct. However, stiffness differences show SS 316L requires higher cyclic loads than Ti-6Al-4V. Cyclic loading about the three principal axes of the construct can also assess in which orientation fretting corrosion is most significant. This test method can also be used to determine fretting behavior of constructs made of different alloy combinations (316L SS, Ti, CoCr) and also can determine if mixing alloys leads to any increased risk of corrosion degradation.

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References: J.R. Goldberg, J.L. Gilbert, J Biomed Mater Res Part B: Applied Biomater. 2003; 64B:78-93.