Introduction: Total joint replacement has long been the most effective treatment for severe arthritis in the hip. The most common clinical problem associated with the surgery is long-term aseptic loosening of the implant. The limited durability of the artificial joint, and the difficulty of revision surgery, have limited the potential applications of this treatment, particularly in younger and more active patients. Several studies using histological and radiographic methods have indicated that debonding at the metal-cement interface of the prosthesis is the first step in the failure process.

One hypothesis for debonding is that body fluid diffuses along the metal-cement interface and weakens the adhesion of the cement to the metal by polar interaction. Additionally, because the cement is porous, fluid may cause swelling or crack growth as the cement cures and shrinks, and fluid moves into the pores. Dental researchers, facing similar concerns of binding a metal to acrylic cement in a fluid environment, have developed a silane coating which has been shown to improve adhesion under both dry and physiologic conditions. Our study attempted to characterize the behavior of silane treated and untreated metal-cement complexes with progressive exposure to a fluid interface.

Methods: Forty cobalt chrome alloy and 40 titanium alloy cylindrical specimens measuring 38.1 mm long and 6.35 mm in diameter were grit blasted using 250 micron aluminum oxide grit sprayed at a pressure of 0.4 MPa from a regulated grit blaster (Basic Mobit, Renfert GmbH, Hilzingen, Germany). The resulting average surface roughness (R_a) following the grit blasting was 0.55 microns as measured by a surface profilimeter (Tencor Inst., Mountain View, CA). This surface roughness corresponds to a satin finish as found on a number of commercial femoral hip prostheses.

Half of the CoCr and half of the Ti alloy rods were treated with a silane coating according to the manufacturer’s instructions. Prior to cement introduction, each specimen in the silane group was treated by applying a preliminary coating of Siloc Pre (Kulzer GmbH, Wehrheim, Germany) followed by heating to 340°C. The specimens were allowed to cool to room temperature and then treated by applying Siloc Bond (Kulzer GmbH, Wehrheim, Germany) which was allowed to cure for 5 minutes in air.

All specimens, both untreated and silane treated, were embedded in PMMA (Simplex-P, Howmedica, Rutherford, NJ) of uniform thickness using the following method. The specimens were placed in a Teflon mold which positioned the specimen concentric and axial to a phenolic tube measuring 12.7 mm tall, 25.4 mm outer diameter, and 19.1 mm inner diameter. After placement, the space between the phenolic and the specimen was filled with curing PMMA. The cement was mixed in a vacuum mixer at 50 kPa below atmospheric pressure and according to manufacturer specifications. The monomer was chilled to 0°C in order to increase the working time. After the PMMA was placed, a conforming aluminum plate was placed atop each polymerizing specimen and pressed downward to induce pressurization on the curing cement and reduce the number of voids incurred during PMMA application.

Once the PMMA was cured, the specimens were exposed to a physiologically relevant saline solution at 37°C, containing a dye marker to trace fluid diffusion. The exposure times were 0, 7, 14 and 30 days. For each soaking time there were five silane coated and five untreated specimens for both the Ti and CoCr alloys. On conclusion of soaking time, the specimens were dried and tested in axial compression to failure on a materials testing machine (MTS 858, Eden Prairie, MN).

Testing was performed by applying an axial load to the alloy and constraining the PMMA and phenolic. All specimens were displaced at a rate of 0.01651 mm/sec, which is equivalent to an imposed interfacial shear strain rate of 0.0013/sec. Failure of the alloy-cement interface was denoted by a dramatic decrease in load followed by a relatively constant low load. The interfacial shear strength values were calculated by dividing the measured failure load by the alloy-cement contact surface area. Once failed, the PMMA-alloy interface was examined under a dissecting microscope for evidence of fluid diffusion.

A three factor analysis of variance with a level of significance of 0.05 was applied to compare mean strength values. Alloy type, coating, and immersion time were the factors. A Scheffe’s post-hoc test was used to determine significant differences.

Results: For all time periods, the mean shear strength of the silane coated CoCr specimens was significantly greater than that of the untreated specimens (Figure 1). Immersion time had no effect on the mean shear strength of either the silane coated or the uncoated CoCr alloy specimens (Figure 1). Also, the mean shear strength of the silane coated Ti specimens was significantly greater than that of the untreated specimens for all time periods, and the immersion time had no effect on the mean shear strength of either the silane coated or the uncoated Ti alloy specimens (Figure 2). There was no significant difference between the mean shear strength of the silane coated CoCr and silane coated Ti alloy specimens, or the uncoated CoCr and uncoated Ti alloy specimens.

In addition, there was no evidence of water diffusion from ink marker along the interface in any specimen. The exposed surface of the PMMA was stained, but this did not extend along the metal-cement interface for any specimen.

Discussion: This study demonstrated an immediate improvement of the interfacial bond strength following application of a silane bonding agent. The expected degradation of shear strength in any of samples following saline immersion was not found, yet this is consistent with the finding of no fluid diffusion in any specimen.

Previous experimental evidence of passive fluid diffusion is inconclusive. The results of the current study seem to indicate that cyclic loading must indeed play an important role in the in vivo diffusion of fluid along the interface. Long-term fixation failure of cemented femoral implants is primarily mechanical and begins with debonding at the cement-implant interface. The increase in strength following silane coating for both CoCr and Ti alloys is believed to increase the functional life of the implant and quality of life of the patient by decreasing the amount of debonding seen at the interface and subsequent failure due to loosening.

References:

**Orthopaedics Division, Stanford University, Stanford, CA.