Presence of Biofilm on Passivated Metal:
An Experimental Approach to Analyze the Sulzer Orthopaedics Inc. Recall

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Statement of Purpose: In December 2000, Sulzer Orthopaedics Inc. initiated a recall of its Inter-Op™ acetabular component after various surgeons reported early patient discomfort and implant loosening.[1-2] It was found that the nitric acid passivation step had been eliminated during the manufacturing process of a select portion of the implants.[1-5] It was believed that eliminating nitric acid passivation may have allowed an oil residue to remain on the implants and this may have led to the reported clinical loosening, inflammation and revision of over 2,000 implants.[5] However, independent studies have suggested that biofilm and/or its residues may have contaminated the implants during the manufacturing process and that biofilm remained on the surface of those implants that were not passivated with nitric acid.[6]

Using a hypothesis-driven approach, our study was designed to determine if biofilms of *Staphylococcus epidermidis* would remain on the surface of commercially pure titanium (cpTi) metal if it was not passivated with nitric acid, but only sonicated in detergent, rinsed in water and sterilized—similar to the Sulzer Orthopaedics Inc. method.

Methods: Using the CDC biofilm reactor, biofilms of *S. epidermidis* were grown on the surface of commercially pure titanium coupons.

1) Coupons (n=30) were sonicated in detergent, passivated with nitric acid, rinsed in water and sterilized.
2) Additional coupons (n=30) were sonicated in detergent, rinsed in water and sterilized.
3) Positive control coupons (n=30) were not treated, but observed for positive biofilm growth on the surface of the coupons.

Coupons were imaged using scanning electron microscopy (SEM) to confirm the presence of biofilm following the treatment procedure.

Results: All (100%) of the positive control coupons had biofilm on the surface (Figure 1A). Eleven of 30 (36.7%) coupons passivated with nitric acid had biofilm on the surface (Figure 1B). Eighteen of 30 (60%) that were not passivated with nitric acid had biofilm on the surface (Figure 1C, 1D). There was no statistically significant difference between the groups ($p>0.05$).

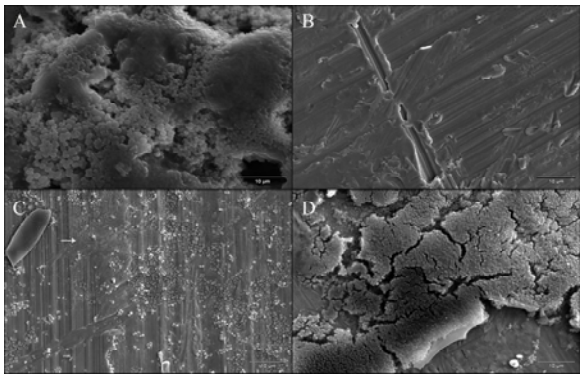

Figure 1: Representative SEM images of biofilm on the surface of cpTi coupons. (A) Biofilm on positive control coupon. (B) No biofilm on the surface of a passivated coupon. (C &D) Residual biofilm and matrix components (arrow) on the surface of coupons that have been sonicated in detergent, rinsed and sterilized.

Conclusions: This study indicated that biofilms, which contaminate the surface of metal, may remain on the surface whether nitric acid passivation is carried out or eliminated from the manufacturing process. Even if non-viable, the presence of bacteria in a biofilm, on the surface of an implant, will lead to a host inflammatory response by providing a source of antigenic endotoxin to the immune system. Taken together, biofilm contamination may have contributed to the reported clinical loosening and inflammation of more than 2,000 Inter-Op™ implants that required revision.[1] In conclusion, the results of this study support that a rigorous scientific approach should be taken to establish if the cleaning, passivation and sterilization process used by manufacturers eliminates biofilm, endotoxin and other contaminants from the surface of devices before implanting them into patients where they may lead to inflammation and implant loosening,.

References:

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