Study of Ion Release by Wear Debris Generated from Simulation tests for Metal-on-Metal Orthopaedic Prostheses

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Statement of Purpose: Due to polyethylene debris induced osteolysis, more and more interest has been focused on alternatives to the commonly used Polyethylene-on-Metal (PoM) type of hip implants. Metal-on-Metal (MoM) total hip prostheses were found to have a very good durability. Some of the early ones survived for 30 years [1]. However, potential damages to patients from those small metallic particles and released metallic ions are still a great concern. It has been identified that metallic ions were released through corrosion processes [2,3]. Tribocorrosion is a main process in the release of metal ions from surfaces of implants and particles [4]. Millions of debris can be released to the body from the contacted surfaces of implants.

Those small debris can not only be transferred to other organs or remain in local tissues which can cause concern such as pseudotumors but also it can corrode and release more metallic ions. A new integrated hip simulator with electrochemical setups was developed in lab, which enables us to have *in-situ* measurements of biotribocorrosion system under simulated conditions.

Methods: High Carbon Cobalt-Chromium-Molybdenum alloys (Co 65.5% Cr 27.3% Mo 5.8% C 0.19%) were studied. An integrated Pin-on-plate tribometer and a hip friction simulator were used to generate wear debris. The lubricant used in this study was 25% bovine serum. Particles were then immersed in 25% serum for periods of 1, 2 and 3 weeks. Particles were scanned under Malvern HPPS (High Performance Particle Sizer) to characterize the size distribution of debris. Extracted wear debris were examined by FEGSEM (Field Emission Gun Scanning Electron Microscope) and EDX (Energy Dispersive X-ray). Extracted wear particles were left in 25% serum for periods of 1, 2 and 3 weeks and concentrations of metal ions in solutions were detected by ICP-MS (Inductively Coupled Plasma Mass Spectroscopy).

Results:

After 4 hours test, 3100 ppb Co, 1200ppb Cr and 335ppb Mo were detected from the solution. The total material degradation was 0.06mm^3. The distribution of particle size can be seen in Fig. 1. The peak particle size is 13.5 nm. It is in an agreement with previous literature. Metallic particles were found in the size range of 10- 40 nm [5].

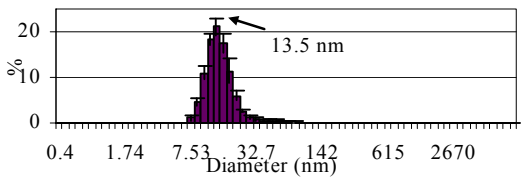

Fig. 1 Size distribution of wear particles

Following immersion of wear particles in serum for up to 3 weeks, Co was preferentially released (Fig. 2). It slowly reached a steady phase after the initial increase.

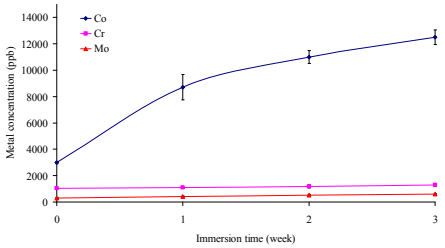

Fig. 2 Metal ion concentration

The release of Cr and Mo remained relatively constant compared with Co. As a result, Cr seemed to remain in solid form as debris, which explained that from some studies, debris embedded in patient tissue was rich in Cr. By using EDX , the ratio of Co/Cr is 1.5 which is less than the original material (Co/Cr 2.44). Due to the small size of that debris, the total number of particles is enormous (estimated as $3*10^{13}$) which gives a surface area of 160 cm^2. The active area under tribological contacts was 22 cm^2. Although the total volume of that debris is not significant in terms of changes to rheology of the fluid, it provides a relatively large surface area to react with the environment. A depassivation process could also be present which resulted in the rapid release of metal ions.

Conclusions: The released metal ions from tribology tests were generated by two sources: (a) activated bearing surfaces and (b) wear debris. The protective passive film (chromium oxide) was removed by the tribological movement, which resulted in the acceleration of release of metallic ions from the material surfaces. After 4 hours tests, 18% of total material loss has already dissolved in to the solution and became ionic form and 82% of the material degradation from bearing surfaces still remained in a solid form – debris. The questions then become how long it would take for those remained material to dissolve and if they would all react with the surrounding biological environments. However, studies on the effect of metallic ions and nano sized particles to hypersensitities and any other biological/immunological issues are still undergoing investigation.

References:

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