The Relationship Between Wear and Ion Release for Large Diameter Metal-on-Metal Hip Bearings

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STATEMENT OF PURPOSE: Currently there is a strong clinical trend worldwide towards large-ball (>36 mm) metal-on-metal (L-MOM) hip prostheses. Although these large-balls systems are showing good clinical promise [1], there still remains little in-vitro data on their performance, especially the relationships between wear, ion levels and the effect of ball-size.

There has only been one in-vitro study comparing wear and ions from 28 mm versus 36 mm MOM bearings [2]. However, over half the wear rates were negative in this study, possibly due to variability in cleaning and weight-loss procedures. Thus there was no clear relationship between wear, ions and ball-size. Schroeder [3], investigated the ions from a 28 mm size, and reported a 70 PPM increase in cumulative ion concentration per 1.0 mm^3 wear volume.

Therefore, our goal was to determine the relationship between wear and ion levels for L-MOM bearings. A secondary aim was to investigate running-in wear and inherent variability of L-MOM bearings with identical diametral clearance and sphericity.

METHODS: We investigated five 50 mm diameter L-MOM bearings (cast, high-C Co-Cr-Mo; ISO 5832-4: Stryker, NJ). Diametral clearances were held tightly to 184–189 µm and sphericity ranged 4–7 µm. The cups were inclined physiologically at 45° in an orbital ±23° hip simulator (Shore-Western, US). The component fixtures were plastic coated to minimize any ion contamination. Test duration was 1.5 million cycles (Mc) of standard walking (2.2 kN max, 1 Hz). Wear was assessed at intervals of 0.2, 0.4, 0.6, 1.0 and 1.5 Mc. The lubricant was 50 per cent alpha-calf serum (HyClone, UT, pH 8.0), ~20 mg/ml protein content with additive EDTA (20 ml/litre) and chamber volume was 600 ml. Evaporation was corrected by adding serum and all serum was replaced at every test interval. All components were cleaned and weighed (Sartorius micro-balance, 0.1 mg) using standard protocols (ASTM F 1714) and volumetric wear calculated (density 8300 kg/m^3 for Co-Cr-Mo). Any strongly adherent bio-films were removed with a polishing cloth.

Serum samples were collected at every test interval and frozen (–25 °C, total 35 samples). The serum samples were digested in hydrochloric acid and the amounts of Co and Cr ions assessed using an ICP/MS (ELAN DRCII, EPA 200.8 Method, Weck Laboratory, CA).

RESULTS: The transition point between running-in and steady-state wear was approximately 0.4 Mc for all bearings (Fig 1). The mean combined (ball+cup) wear-rates between 0–0.4 Mc and 0.4–1.5 Mc were 2.5 and 0.72 mm^3/Mc. The total combined wear at 1.5 Mc ranged 1.0 to 2.7 mm^3 (mean 1.8 mm^3, variability 70 %).

There was a good correlation (R^2=0.78) between L-MOM interval wear and Co and Cr ion concentrations. The mean cumulative Co and Cr ion concentration increased by 20 PPM per 1.0 mm^3 of wear (total of 35 PPM at 1.5 Mc). Co concentrations were typically 3–times higher than Cr. The Co ion concentration peaked at 0.2 Mc (13 PPM) then quickly reduced to a mean concentration of 3.0 PPM per 1.0 Mc (Fig 2).

We did not see any difference in color between running-in and early steady-state phases. Neither grey nor black serum was encountered at any interval.

DISCUSSION/CONCLUSIONS: i) To our knowledge this is the first ion analysis for 50 mm MOM bearings run in hip simulator studies. The cumulative ion concentrations for our 50 mm L-MOM were 3.5 times lower compared to that reported for a 28 mm MOM [3] and similar to that reported with 36 mm MOM [2].

ii) Our L-MOM bearings (n=5) with virtually identical diametral clearances (± 2.5 µm) and sphericity (± 1.5 µm) showed 70 % variability in total wear at 1.5 Mc. This indicated that diametral clearance and sphericity were not solely responsible for the large variability in MOM wear seen in hip simulator studies.

iii) Our data also supported a prior study [4] that L-MOM (>36 mm) bearings with diametral clearances less than 200 microns could produce 'low' running-in wear. The clinical significance of these data suggested that L-MOM bearings did not suffer the 'big-ball Charnley concept' as reported for conventional UHMWPE cups.

REFERENCES: [1] Smith TM et al, Clin Orthop Relat Res. 2005 Dec;441:137-42. [2] Liao Y-S et al, 31st Soc, Biomat, 2006. [3] Schroeder D, 24th Soc Biomat, 212, 1998. [4] Dowson D et al, J. Arthrop, 19(8), 124-130, 2004.

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Figure 1. ***Cumulative wear vs. cumulative Co and Cr ion levels.***

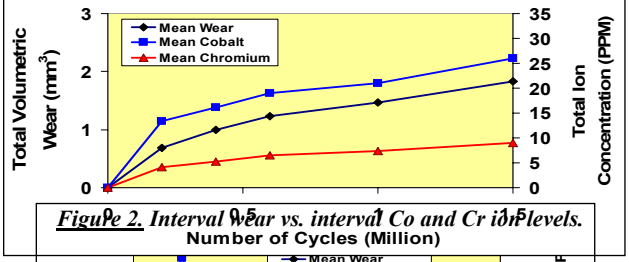

Figure 2. ***Interval wear vs. interval Co and Cr ion levels.***