QUANTITATIVE ANALYSIS OF WEAR DEBRIS FROM METAL ON METAL HIP PROSTHESES TESTED IN A PHYSIOLOGICAL HIP JOINT SIMULATOR.

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Introduction. Osteolysis and loosening of artificial joints caused by UHMWPE wear debris has prompted a renewed interest in metal on metal (MOM) hip prostheses. Quantitative analysis of metal wear debris from hip simulator studies has not been previously reported. This study investigated the wear debris morphology of MOM prostheses in a physiological anatomical hip simulator for alloys of different carbon content.

Methods. Four 28 mm femoral heads and acetabular cups were manufactured from medical grade wrought cobalt chrome alloys according to ASTM F1537. The carbon contents for the low and high carbon components were < 0.07% and > 0.2% respectively. The diametral clearances of the heads and cups were 50 μm and surface roughness R_a values < 0.02 μm. The implants were tested in the anatomical position in a physiological hip simulator with three independently controlled motions and with three axis of loading. Articulation and loading patterns were applied similar to Paul type curves. The pairings for each test station are shown in **Table 1**.Bovine serum (25%) was used as the lubricant. The implants were tested between 2 and 5 million cycles. Interruptions were made at various intervals for lubricant collection for wear debris analysis and gravimetric wear analysis. Metal wear particles collected from lubricant from the first million cycles were isolated by digestion with 12 M KOH at 60°C for 48 hrs. Lipids and proteins were removed and wear particles were recovered by filtration onto 0.1 μm polyester filters. A section of each filter was coated with gold for SEM analysis. Particles were sized using digital image analysis. An average of 100 particles were analysed for each sample. Statistical analysis of all the results was carried out using single classification of analysis of variance.

STATION	HEAD & CUP PAIRING	ABREVIATION
1	low carbon head & low carbon cup	LH/LC1
2	low carbon head & low carbon cup	LH/LC2
3	low carbon head & high carbon cup	LH/HC
4	high carbon head & high carbon cup	HH/HC

Table 1. Test station pairings.

Results. The combined wear rates ($mm^3/10^6$ cycles) for both components (ball and cup) are shown in **Table 2**. The lowest wear rate occurred with the mixed carbon content pairing. The wear rates for the low carbon pairings in the first million cycles were nearly 3 fold the size of there mean wear rates. The wear scar in all cups and heads was localized to the superior quadrant, as found clinically on retrieved specimens. The metal wear particles isolated from serum had mean lengths between 25 and 36 nm (**Figure 1**). The high carbon content pairing produced significantly larger (p<0.05) wear particles than the other material combinations. The majority of the particles were oval to round.

Discussion. MOM hip prostheses have been shown clinically to survive for over 20 years with low wear and little or no osteolysis present [1]. Previously, metallic wear debris has been successfully isolated and characterized from serum used in simple configuration pin on plate tests [2]. The mean particle sizes were in the range of 60 to 90 nm, however these wear tests were harsh and the wear results obtained were very different to those of clinical components. This present study has isolated and characterized metallic wear debris from serum used in a physiological hip simulator test. The size of the particles was significantly smaller than the pin on plate tests but still in the nm scale. The size and appearance of the particles isolated were similar in size to metallic particles previously characterized from tissue obtained from clinical MOM total hip replacements [3]. Although the particles generated in the high carbon content pairing were significantly larger than the other particles produced, it is unlikely that this difference would be biologically significant *in vivo*. The change in size of particles generated with the different pairings could have occurred due to subtle tribological differences. The mean wear rates obtained in this study were also found to be similar to previous simulator studies [4, 5], however the wear rates reported for clinically used first generation hip prostheses were up to an order of magnitude higher, 6 mm^3 [6]. This difference in wear rates between *in vivo* and *in vitro* studies requires further investigation.

If a metal particle is assumed to be spherical, the average number of wear particles generated per year by the low carbon content pairing would be between 10^{13} and 10^{14} particles. The average number of wear particles generated per year by a UHMWPE acetabular cup has been estimated as 5 x 10^{11} particles, based on a sub micron particle size and 60 mm^3 of wear per year [7]. It is clearly shown here that the smaller size of the metal wear particle has a dramatic effect on the number of particles produced per year, however the biological reaction to metal particles *in vivo* may be markedly different to that produced by UHMWPE wear debris [8], and metallic particles and elevated ion levels have been found systemically in other parts of the body. The small size of the metallic debris is probably an important factor influencing its transportation away from the periprosthetic tissue. This may also contribute to a reduction in the local osteolysis compared to polyethylene implants.

STATION	HEAD & CUP PAIRING	DURATION) (million cycles)	MEAN WEAR RATE ($mm^3/10^6$ cycles)
1	LH/LC1	5	0.56
2	LH/LC2	5	0.51
3	LH/HC	3	0.18
4	HH/HC	2	0.25

Table 2. Mean combined wear rates for the test.

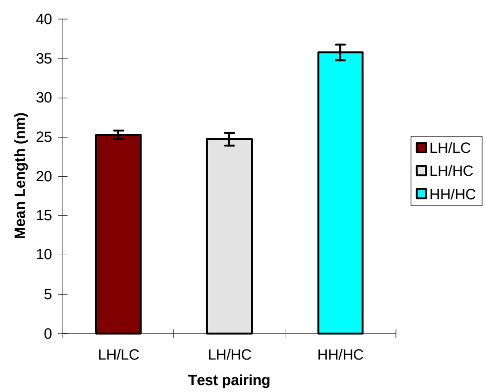

Figure 1. Mean particle length +\- 95% confidence limits for all material combinations.

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