3.1 Wear and Debris Generation in Artificial Hip Joints

J. Fisher, E. Ingham, M.H. Stone, B.M. Wroblewski, P.S.M. Barbour, A.A. Besong, J.L. Tipper, J.B. Matthews, P.J. Firkins, A.B. Nevelos, J.E. Nevelos

Introduction

Over the last thirty years the majority of artificial hip joints used clinically have utilised ultra high molecular weight polyethylene UHMWPE as the bearing surface of the acetabular cup. Although these bearing surfaces rarely wear out and indeed provide a very effective solution for the elderly patient, it is now recognised that in the longer term, micron and submicron UHMWPE wear particles generated at the articulating surfaces, lead to chronic inflammatory tissue reactions, osteolysis and loosening of the prostheses. This has led to renewed interest in metal on metal and ceramic on ceramic bearing couples. There is now a real need to focus attention, not just on the wear volume generated, but also the actual wear particles produced and their osteolytic potential. In this paper, research studies from our laboratory are reviewed which quantify the wear and wear debris generated in hip joint simulators and are compared to data from retrieved prostheses, for metal and ceramic on UHMWPE, metal on metal and ceramic on ceramic bearing couples.

Methods

The Leeds physiological hip joint simulators have six degrees of freedom and test the prostheses in the anatomical position. The Mark 1 simulator has independently controlled forces, applied to three axes and three independently controlled motions (4). The force and motion wave forms are applied as defined in the Paul walking cycle. It has been shown that for UHMWPE acetabular cups simplification of the loading cycle to a single axis of loading does not substantially alter the wear rate (3). The Mark 2 simulator has one axis of loading and two independently controlled motions (2). This has been shown to produce volumetric wear rates for UHMWPE acetabular cups equivalent to the Mark 1 simulator.

The results of tests carried out on size 28 mm metal and ceramic heads on UHMWPE cups, size 28 mm, metal on metal, and size 28 mm Ceramtec Biolox Forte ceramic on ceramic hips are reviewed. The analysis of debris is presented from metal and ceramic on UHMWPE and from metal on metal hip prostheses and a comparison is made with clinical retrievals.

Results

Metal and Ceramic Heads on UHMWPE Acetabular Cups

Ultrahigh molecular weight polyethylene UHMWPE acetabular cups that were gamma irradiated in the presence of air and tested within three years of sterilisation were studied. Stainless steel, cobalt chrome and zirconia femoral heads were tested in the Mark 1 and Mark 2 simulators for 5 million cycles. The volumetric wear rates are presented in Table (1). There was a statistically significant difference in the wear rates with the different heads.

These volumetric wear rates were compared with a clinical series of retrieved Charnley hip prostheses that had failed by aseptic loosening.

Table 1 Volumetric wear rates for UHMWPE acetabular cups

Material			Volumetric Wear
Head	Cup	Simulator	mm^3 per million cycles ± 95% CL
Stainless Steel	UHMWPE	Mark 2	41 ± 4
Cobalt Chrome	UHMWPE	Mark 2	35 ± 10
Zirconia	UHMWPE	Mark 2	31 ± 4
Zirconia	UHMWPE	Mark 1	32 ± 3.4

The mean age of these prostheses was 13 years range (10 to 19) and the prostheses had 22 mm stainless steel femoral heads with UHMWPE cups that had been γ irradiated in air (10). The mean volumetric wear rate (± 95% CL) was 59.6 ± 17.9 mm^3/year. There was substantial variation in the wear rates. The group was further analysed by dividing into two groups of explants, one with low damage to the femoral head and one with high damage to the femoral head. The low damage group had a significantly lower wear rate, which was comparable to the wear caused by the undamaged heads in the simulator (Table 2).

Table 2 Volumetric wear rates for explanted Charnley prostheses (10)

Material	Volumetric Wear Rate	
	mm^3/year	± 95% CL
Low damaged heads	39.5	± 22.6
High damaged heads	79.6	± 21.2

Difference significant at the 93% level

The polyethylene wear debris was isolated and characterised from the Mark 1 simulator test. The particles were primarily micron or submicron in size. The quantitative analysis of the particles is summarised in Table (3).

Table 3 Quantification of wear debris from hip simulator (mean ± 95% CL)

Mode of the particle size distribution	0.1 to 0.5 µm
% Mass of particles < 10 µm	73 ± 6
Number of particles per mm^3 x 10^9	35 ± 25
Volumetric wear rate per million cycles mm^3	32 ± 3.4
Number of particles per million cycles x 10^9	1100

The UHMWPE debris from the retrieved tissues showed considerable similarity to the debris from the simulator, although there was greater variation and some important differences. The mode of the particle size distribution and the percentage mass of the debris which was less than 10 µm, were similar. However, there were less particles in the very small size range in the retrieved tissues compared to the simulator debris, possibly due to them being transported away *in vivo* and lost from the analysis. This resulted in a calculation of less particles per mm^3 of debris resulting in less particles per year. The explant debris data are summarised in Table 4.

Table 4 Wear debris analysis for explanted tissue mean ± 95% CL (10)

Mode of the particle size distribution	0.1 to 0.5 µm
% Mass of particles < 10 ± µm in size	68 ± 15
Number of particles per mm^3 x 10^9	13.2 ± 9.6
Mean volumetric wear rate mm^3/year	59.6 ± 17.8
Number of particles generated per year x 10^9	496

In addition to an increase in the volumetric wear, damage to the femoral head of the explanted prostheses also significantly increased the number of UHMWPE wear particles generated.

Metal on Metal Hip Prostheses

Six metal on metal hip prostheses were tested in the Leeds Mark 1 physiological simulator for up to 5 million cycles. The cobalt chrome alloys consisted of two pairs of low carbon content alloys, two pairs of high carbon content alloys and two pairs of mixed alloys (low carbon head and high carbon cup).

The volumetric wear rates are shown in Table (5). They were all much lower than found with UHMWPE. All the prostheses showed a higher initial bedding in wear followed by a lower steady state wear. The mixed and high carbon pairings showed lower wear than in the low carbon pairing (5). Clinical studies have reported higher volumetric wear rates with first generation McKee Farrar Prostheses (1).

Table 5 Volumetric wear rates for metal on metal hip prostheses (5)

Material	Volumetric wear mm^3/year per million cycles		
	Average	Initial	Steady State
High Carbon Alloy	0.09	0.32	0.03
Mixed Carbon Alloy	0.09	0.31	0.03
Low Carbon Alloy	0.51	1.36	0.33

The metal debris was isolated from the serum and quantified using SEM. The resolution of the measurement system was 10 nm. The metal debris was much smaller than the polyethylene debris and more uniform in size and shape (see Table 6).

Table 6 Particle sizes of metal on metal debris (5)

Material	Particle Size nm Mean	± 95% CL
High Carbon Alloy	36	± 2
Mixed Carbon Alloy	25	± 1
Low Carbon Alloy	25	± 1

For the high carbon content alloy, taking a mean size of 36 nm and a spherical geometry the mean size of a particle was estimated as $0.24\ 10^5\ (nm)^3$. The estimate of the number of particles generated is presented in Table (7).

Table 7 Estimated number of particles per year for metal-on-metal prostheses

Number of particles per mm^3	$4.2\ 10^{13}$
Volumetric wear rate mm^3/million cycles	0.09
Number of particles per million cycles	$4\ 10^{12}$

Although the volumetric wear rate was 100 times less than UHMWPE, the number of particles generated per million cycles was greater due to the particles being much smaller in size. It should be noted however that the detection level for metal particles was lower than for UHMWPE.

Ceramic on Ceramic Hip Prostheses

Six Biolox Forte alumina alumina hip prostheses were tested in the Mark 2 Leeds Physiological simulator. After two million cycles, the angle of inclination of four of the cups was increased from 45° to 60°. This did not, however, alter the wear rate. The cups showed a higher initial bedding-in wear rate then a lower steady state wear rate (9). The volumetric wear rate is shown in Table (8).

The steady state wear rate was similar to that achieved with metal on metal prostheses and three orders of magnitude lower than achieved with UHMWPE.

Table 8 Volumetric wear rates for Biolox Forte Hips (9)

Material Biolox Forte	Volumetric Wear Rate mm^3/million cycles	± 95% CL
Initial Wear	0.12	± 0.6
Steady State Wear Rate	0.05	± 0.02

Clinical wear rates with Mittelmeier Biolox prostheses have been reported as greater in certain cases of stripe and severe wear (8). Debris has not been characterised from the simulator tests. However, there was very little surface disruption indicating very fine debris, perhaps in the order of 10 nm with this very low wear. In the more severe wear cases found clinically with Biolox ceramic, the wear surfaces were rougher with fragments of grains removed and evidence of larger debris in the size range 0.1 to 5 μm (8).

Discussion

The volumetric wear rates in the simulators showed a clear ranking with UHMWPE being greater than metal on metal or Biolox Forte alumina ceramic. There was good agreement between the simulation volumetric wear rates and clinical retrievals for UHMWPE, but for metal on metal and ceramic on ceramic, the simulators produced lower wear rates than found *in vivo*. This may be due to the clinical retrievals being different older types or inferior materials, or possibly due to the more adverse conditions that can occur *in vivo*.

The UHMWPE debris produced was predominantly in the 0.1 to 10 μm size range. This size range has been shown to be highly biologically reactive in activating macrophages and causing bone resorption (6, 7). There is evidence that very small UHMWPE particles (< 0.5 μm) are transported away form the prosthesis and surrounding tissues. The metal particles were much smaller than the UHMWPE particles. Although there were a greater number of the smaller metal particles generated, compared to UHMWPE, the total number of metal particles produced in the size range that caused high levels of biological reactivity for UHMWPE (0.1 to 10 μm) was much lower than for UHMWPE. As a result of the different sizes, chemical activity and ion release, the metal particles are likely to be distributed more widely around the body and cause different biological reactions. These biological reactions to small metal particles are currently being studied.

There is limited understanding of the types of ceramic debris produced. The evidence presented so far indicates that for very low wear conditions, very small particles may be produced but with more severe wear as found with older Biolox ceramic larger particles in the size range 0.1 to 10 μm, a similar size to that of UHMWPE, can be found. The biological reactions and distribution *in vivo* will be dependent on size, and this needs to be studied further. The clinical evidence with the Biolox ceramic Mittlemeir prosthesis indicates that as the volume of wear was much smaller than with UHMWPE, the resulting number of particles in the biologically active size range (0.1 to 10 μm) was much less and the occurrence of osteolysis was reduced considerably (8).

Conclusions

The reduction in wear volumes with alternate bearing surfaces to UHMWPE, provides considerable potential for extending the osteolysis free life of artificial hip joints beyond 20 years. However, the size of the wear particles varies considerably for the different materials. Future research will focus on the performance of new bearing designs under adverse conditions, on quantifying the size, number and the biological activity of the different wear particles.

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