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Quantitative analysis of the wear and wear debris from low and high carbon content cobalt chrome alloys used in metal on metal total hip replacements

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The biological reactions to polyethylene wear debris have been shown to result in osteolysis and loosening of total hip arthroplasties. This has led to renewed interest in the use of metal on metal bearings in hip prostheses. This study employed uniaxial and biaxial multistation pin on plate reciprocators to assess how the carbon content of the cobalt chrome alloy and the types of motion affected the wear performance of the bearing surfaces and the morphology of the wear debris generated.

The low carbon specimens demonstrated higher wear factors than both the mixed carbon pairings and the high carbon pairings. The biaxial motion decreased the wear rates of all specimens. Plate wear was significantly reduced by the biaxial motion, compared to pin wear. The metal wear particles isolated were an order of magnitude smaller than polyethylene particles, at 60–90 nm, and consequently, 100-fold more particles were produced per unit volume of wear compared to polyethylene. The low carbon specimens produced significantly larger particles than the other material combinations, although it is thought unlikely that the difference would be biologically significant *in vivo*.

The volumetric wear rates were affected by the carbon content of the cobalt chrome alloy, the material combination used and type of motion applied. However, particle morphology was not affected by the carbon content of the alloy or the type of motion applied.

1. Introduction

Total hip joint replacements have been used for over 30 years with considerable success. Approximately 50 000 and 700 000 hip joints are replaced each year in the UK and the world, respectively. Today the most common type of hip joint implanted comprises a highly polished metallic or ceramic femoral head articulating against an ultra-high-molecular weight polyethylene (UHMWPE) acetabular cup. It has been shown through clinical studies [1] that fewer than 10% of implants require revision in the first 10 years of use. However, as patients requiring total hip replacements become younger and more active, the implants are required to have a life expectancy of over 20 years.

Metal on metal articulations have been used in total hip joint replacements for over 30 years, but the clinical results have not always been positive [2, 3]. This, together with the highly published success in the 1960s and early 1970s of the polyethylene/metal prosthesis, led to a decline in the use of metal on metal hip prostheses during the 1970s and 1980s [4]. However, there has been renewed interest in the metal on metal concept as the long-term problems caused by UHMWPE wear debris have become more apparent. In addition, there has been evidence that some of the early metal on metal articulations have survived for over 20 years, with little wear or incidence of wear debris induced osteolysis [5]. A low wear rate is believed to be critical for extending the implant life of a prosthetic joint, and wear volumes produced by metal on metal articulations have been estimated to be 40–100 times lower than metal on polyethylene bearings [6].

The release of UHMWPE wear particles from the articulating surfaces of metal on UHMWPE hip

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prostheses, and the subsequent biological reactions to these wear particles has been identified as one of the major causes of osteolysis and failure of total hip replacements [7–11]. Polyethylene wear particles in the size range 0.2–10 μm are phagocytosed by macrophages leading to the release of inflammatory mediators, or cytokines, which act upon other cells, such as osteoclasts, leading to bone resorption or osteolysis [12–14]. The presence of metallic wear particles in periprosthetic tissues is well documented from retrieval studies of metal on UHMWPE prostheses [15–18]. However, the effects of the metal particles are difficult to determine as polyethylene wear debris is also present in these tissues. The tissue reaction around metal on metal hip prostheses has been described for early failures [19–22]; however, the pathology of long-term or well-fixed metal on metal implants has not been widely reported.

The majority of studies characterizing metal wear debris have used light microscopy to visualize the particles. The light microscope can only reliably resolve particles of greater than approximately 1 μm, and therefore, reported sizes of the majority of metal wear particles are in the range 0.5–4 μm, with small numbers of particles up to 400 μm in size [23–25]. Using scanning electron microscopy (SEM) irregular, round, sharp-edged and globular metal particles in the range of 0.1–1 μm have been described [24]. However, characterization has been hampered by the tendency of the metal particles to agglomerate during the isolation procedures, which often utilize strong acids or bases and enzymes. Transmission electron microscopy (TEM) has been used to study metal wear particles in thin sections of periprosthetic tissue from around metal on UHMWPE hip prostheses. Angular and shard-shaped particles of < 0.1 μm have been reported, but measurements may have been limited by the thickness of the tissue sections [26]. More recently, TEM has been used to study metal particles isolated from and within periprosthetic tissues from around metal on metal hip joints. The particles were described as needle-shaped or oval to round and ranged in size from 10–400 nm [27, 28] and from 6 nm to 1.2 μm [29].

There have been many studies on the biological response to metallic wear debris *in vitro* [30–33]; however, the cells are generally challenged with non-clinical particles in the 1–10 μm size range. The renewed interest in metal on metal articulations has led to further research and development into new designs and new materials for use in metal on metal total hip replacements. In addition, there has also been a small number of hip simulator studies looking at the *in vitro* wear performance of these new generation metal on metal articulations [34–36]. These simulator studies indicated that there are some advantages to using high carbon content cobalt chrome alloys in their wrought form; however, there remains discussion as to whether these should be used as like on like pairings (high on high) or as pairings of high on low carbon content alloys.

Equally important to the reduction in wear volume is the reduction in biological reactions, both locally and systemically, to the wear particles. It is now essential that the number and morphology of wear particles as well as the total wear volume is investigated in bearings of total artificial joints. To date the isolation and characterization of the wear debris generated in *in vitro* wear tests of metal on metal articulations has not been reported. This study has investigated how the differing carbon contents of cobalt chrome alloys and the types of motion applied affected the wear performance and wear debris morphology of metal on metal articulations in simple configuration pin on plate tests.

2. Materials and methods

2.1. Pin on plate tests

All test specimens were made from medical grade wrought cobalt chrome alloys according to ASTM F1537. The carbon contents for the low and high carbon specimens were approximately 0.07% and 0.2%, respectively. All plates were lapped to produce an approximate surface roughness R_a of 0.01 μm, measured with a cut-off length of 0.8 mm. The R_a for each plate was measured using a two-dimensional contacting profilometer (Form Talysurf Series). All test pins had diameters of 12 mm. In order to produce an intial contact stress of approximately 10 MPa, a flat of 3 mm diameter was machined onto a spherical surface with a radius of curvature of 100 mm on the pin heads. The surfaces were then polished to a surface roughness R_a of 0.01 μm.

Two simple configuration wear tests were performed. Test 1 used a multistation pin on plate reciprocator which applied a uniaxial frictional force, whereas Test 2 used a biaxial multistation pin on plate reciprocator which applied multidirectional frictional forces. The test pins were fixed in a pin holder while the plate was moved beneath them with a uniaxial reciprocating motion. The difference between the uniaxial and the biaxial test rigs was that the test pins remained in a stationary position in the uniaxial rig, whereas the test pins were rotated by a rack and pinion in the biaxial rig. The test pins were loaded axially in compression via the pin holder and a cantilever mechanism. In order to submerge the plates in the test lubricant, the pins and plates were contained in removable stainless steel baths.

The pairings for both tests are shown in Table I. The same conditions were applied to each test. The pins were loaded at 80 N giving a nominal contact stress of 11.3 MPa. The test lubricant was 25% (v/v) newborn bovine calf serum (Sera Labs) supplemented by 0.1% sodium azide to retard bacterial growth. The reciprocating speed was 1 Hz with a stroke length of 30 mm. The tests were run for four 24 h periods ($4 \times 90\,000$ cycles). The pins and plates were cleaned with isopropanol and then allowed to acclimatize in a temperature controlled (20 °C) metrology room before and after each period of testing. The wear volumes of the pins and plates were

TABLE I Pin and plate combinations for both wear tests

Material combination	Pin (carbon content)	Plate (carbon content)
1	low	low
2	high	low
3	low	high
4	high	high

determined gravimetrically after each test period. The pins were weighed using a microbalance (Mettler) accurate to 1 μg and the plates weighed using an analytic balance (Mettler AT201) accurate to 10 μg. The wear volumes were plotted as a function of sliding distance and linear regression analysis provided the gradient of the slope of the line, which represented the wear rate. The incremental wear factors were determined for each measurement interval from Equation 1 [37]. The mean wear factor was also calculated for each pairing

$$\text{Wear factor } (\text{mm}^3\text{N}^{-1}\text{m}^{-1}) = \frac{\text{Volume loss}}{\text{Load} \times \text{sliding distance}} \tag{1}$$

The surface profiles of the pins and plates were measured after testing using a two-dimensional contacting profilometer and also a three-dimensional non-contacting laser profilometer (UBM). The pins and plates were photographed using microscopy techniques. The lubricant from each test station was collected after each test period for wear debris analysis. One high and one low carbon pin were electrolytically etched to study the microstructure.

2.2. Isolation and characterization of metal wear debris

The metal wear debris was isolated from the serum lubricant by digestion with 12 M KOH at 60 °C for 48 h. Lipids and proteins were removed by extraction with chloroform/methanol (2 : 1) and repeated washes with 50% (v/v) acetone. Metal wear particles were separated by sonic disintegration and recovered by filtration on to 0.1 μm polyester membranes (Whatman International Ltd). A section of each filter was coated with gold for analysis by SEM. Particles were quantified using digital image analysis (Image Pro Plus, Media Cybernetic, USA). Parameters measured included mean maximum diameter, aspect ratio (length/width), area and perimeter. An average of 100 particles per material combination were analyzed in duplicate. Statistical analysis of all results was carried out using single-classification analysis of variance. The wear particle factor was also calculated by combining the wear rate and the number of particles generated per unit of wear volume. This allowed the total number of particles produced per unit load, per unit sliding distance to be calculated. This was defined as the wear particle factor with units of particles/Nm. In addition, the number of particles generated per unit volume of wear (mm^3) was also calculated for all material combinations as described previously [38].

3. Results

3.1. Pin on plate tests

The linear regression analysis of the volumetric wear rates as a function of sliding distance are shown in Fig. 1a and b for the uniaxial and biaxial wear tests, respectively. The regression coefficients of the volumetric wear rates $\pm$ 95% confidence limits for all material pairings are shown in Fig. 2. Statistical analysis of the regression lines showed that all the material combinations had significantly different ($P < 0.05$) wear rates in the uniaxial wear tests. The high/high carbon pairing showed the lowest wear rate. In the biaxial wear tests, the high/high carbon pairing had a significantly lower ($P < 0.05$) wear rate than the low/low carbon pairing. There were no significant differences ($P < 0.05$) in the wear rates between the low/low carbon pairings and the differential hardness pairings. The wear rates of the low/low pairing and the high carbon pin/low carbon plate pairing were significantly lower ($P < 0.05$) in the biaxial wear test compared to the uniaxial test. However, there was no significant difference in the wear rates for the high/high carbon pairing and the low carbon pin/high carbon plate pairing in the uniaxial and biaxial tests.

Fig. 3 shows the combined mean wear factors for all the test pairings. It was found that the wear factors decreased when biaxial motion was applied. In addition, when biaxial motion was applied the wear factors for the plates decreased dramatically, whereas the pin wear factors remained steady. The wear factor for the low/low carbon pairing reduced by a factor of three when biaxial motion was applied, but the wear factor for the high/high carbon pairing only reduced slightly.

Fig. 4a and b show typical three-dimensional surface profiles of the wear scars on the plates, recorded using the non-contacting laser profilometer. It can be seen that the low carbon plate tested on the uniaxial rig had far greater penetration/damage than the low carbon plate tested on the biaxial rig. Fig. 5a and b show typical wear surfaces of the test pins used on the uniaxial and biaxial rigs, respectively. The surface of the pin used on the uniaxial rig (Fig. 5a) showed wear tracks which followed the direction of the reciprocator. However, the surface of the pin used in the biaxial rig (Fig. 5b) showed a polished effect, and the wear tracks can be seen to be multi-directional. The surface roughness was measured across the wear tracks on a typical low carbon pin used in Test 1, and measured in three directions, at approximately 60° on a low carbon pin used in Test 2. The mean R_a for the pin used in Test 1 was 1.25 μm, whereas the mean R_a for the pin used in Test 2 was 0.032 μm, (cut-off = 0.25 μm), indicating that the pins subjected to biaxial motion had much smoother surfaces.

It was observed that the serum removed from the baths after each period of testing had darkened in color. The degree of darkness was noted to correspond to the volumetric wear rate, i.e. low wear rate approximated to a slight darkening, high wear rate approximated to increased darkening in color.

3.2. Characterization of metal wear particles

Fig. 6 a–f shows scanning electron micrographs of the metal wear particles isolated from the serum lubricants. It was found that the majority of particles were oval to round in shape. The isolated metal particles were identified as cobalt chrome alloy by atomic absorption spectroscopy (Fig. 7). The metal wear particles had mean maximum diameters of 50–90 nm (Fig. 8). The low/low carbon pairings produced significantly larger ($P < 0.05$) wear particles than the other material combinations. However, there was no significant difference between the low/low particles generated in the uniaxial and biaxial

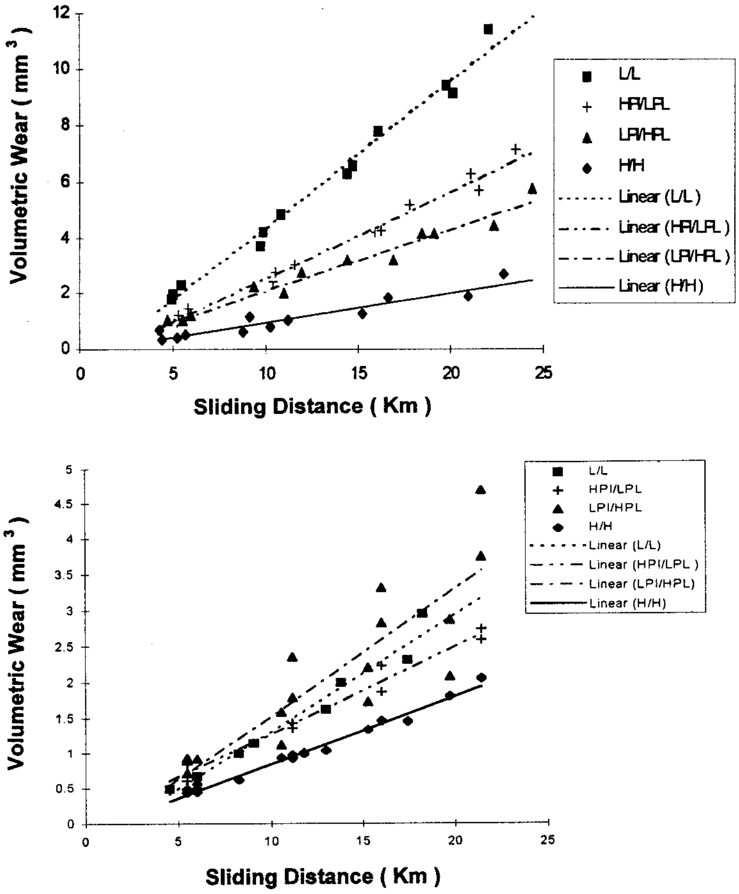


Figure 1 Linear regression analysis of volumetric wear for the uniaxial (a) and biaxial (b) wear tests.

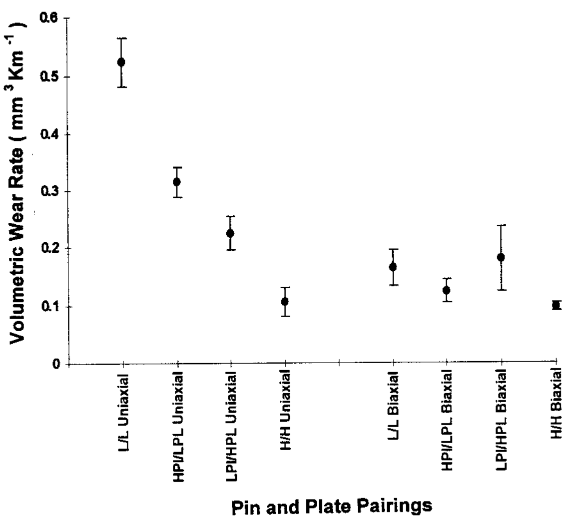


Figure 2 Regression coefficients $\pm$ 95% confidence limits of volumetric wear rate for all material pairings.

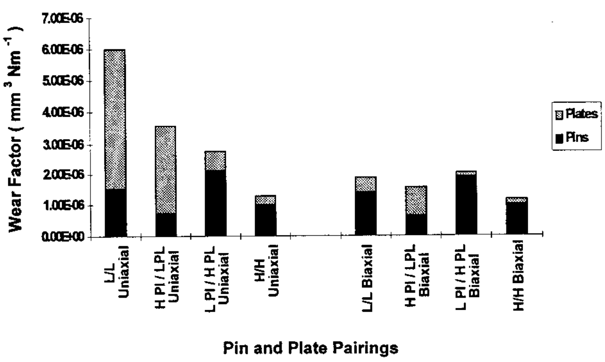


Figure 3 Mean wear factors for pin on plate tests.

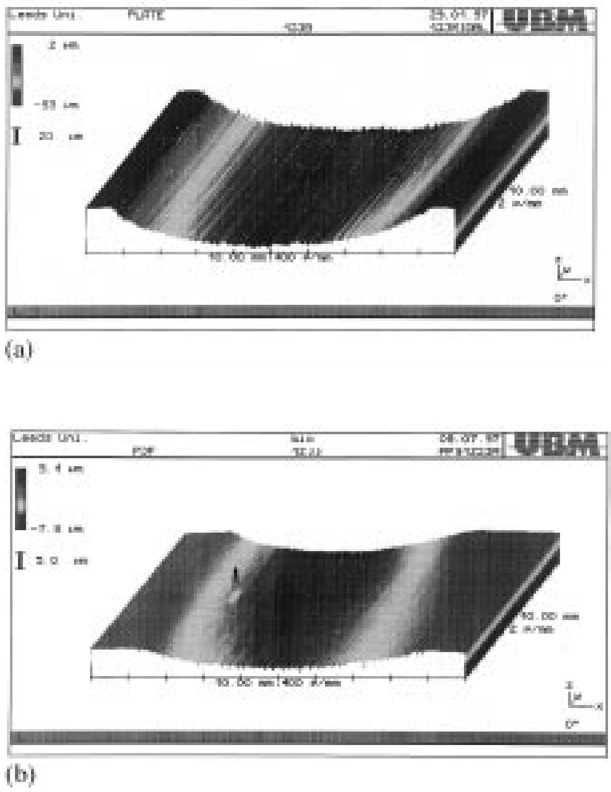
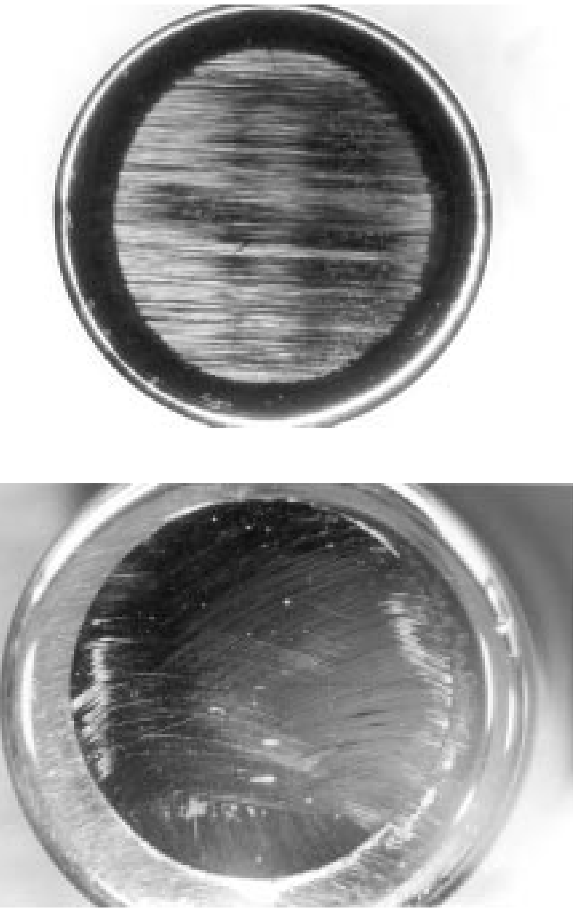


Figure 4 Surface profile of a low carbon plate after (a) uniaxial testing, Test 1; (b) biaxial testing, Test 2.



(a)

(b)

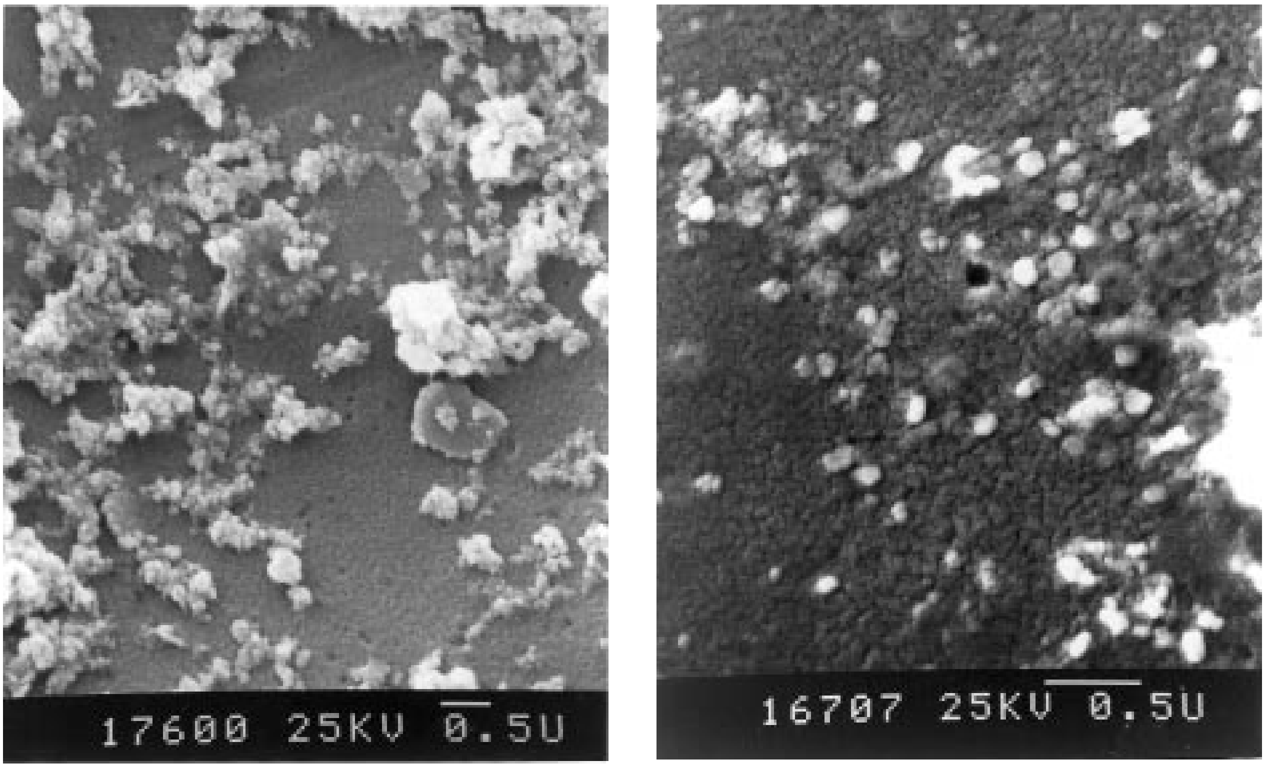
Figure 5 Wear surface of a pin used with (a) the uniaxial rig, Test 1; (b) the biaxial test rig, Test 2.

test. The aspect ratio (length/width) was similar for all material combinations, between 1.18 and 1.42 (Fig. 9). This indicated that all the wear particles were morphologically similar, regardless of material pairings and the motion applied. The mean area of the metal particles varied widely ($1.9 - 8.5 \times 10^{-3}\mu m^2$; Fig. 10). The low/low material combination produced particles with the greatest area, and there was no significant difference between the particles produced by uniaxial motion or those produced by biaxial motion. However, the low/low particles had a significantly larger area ($P < 0.05$) than the particles produced by the other material combinations. The mean particle perimeter also varied (0.14–0.33 μm) with material combination (Fig. 11). The low/low material combination produced particles with significantly larger ($P < 0.05$) perimeters than the other combinations, except the low carbon pin/high carbon plate mixed pairing (uniaxial). However, there was no significant difference between the particles produced by uniaxial and biaxial motions for the low/low pairing.

The wear factor (number of particles/Nm) ranged from 5.87×10^6 to 3.40×10^7. The number of particles generated per unit volume of wear ranged from 2.71×10^{12} to 1.53×10^{13} particles/mm^3.

4. Discussion

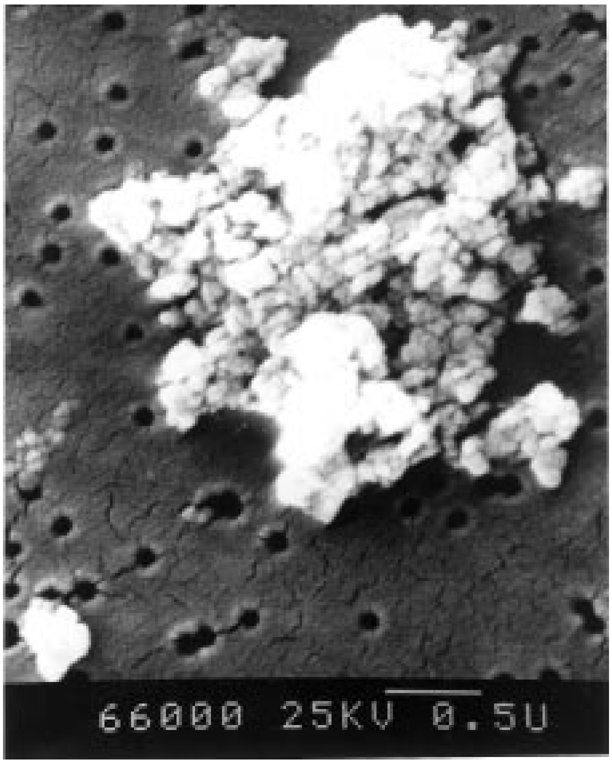
Metal on metal total hip joint prostheses have been shown clinically to survive for over 20 years with low wear and little or no osteolysis present [5]. Laboratory tests using simple configuration uniaxial test rigs have shown that when sliding metal pins on metal counter-



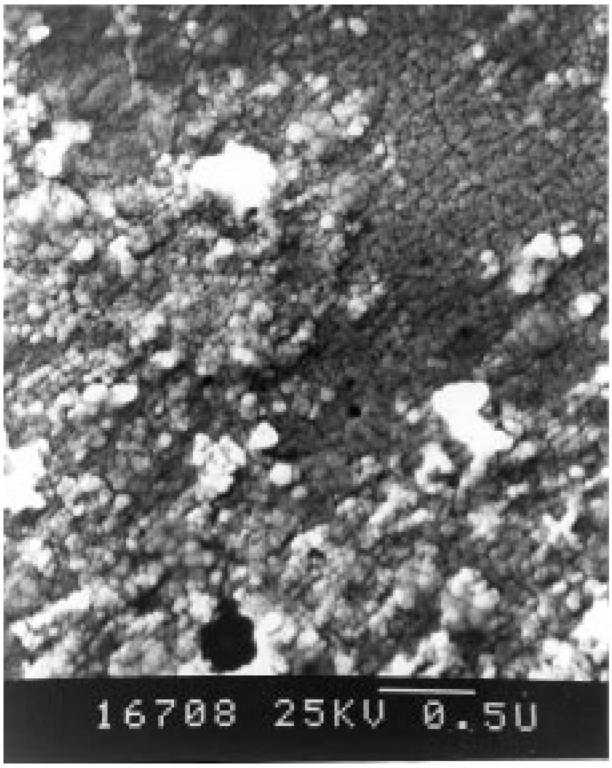
(a)

(b)

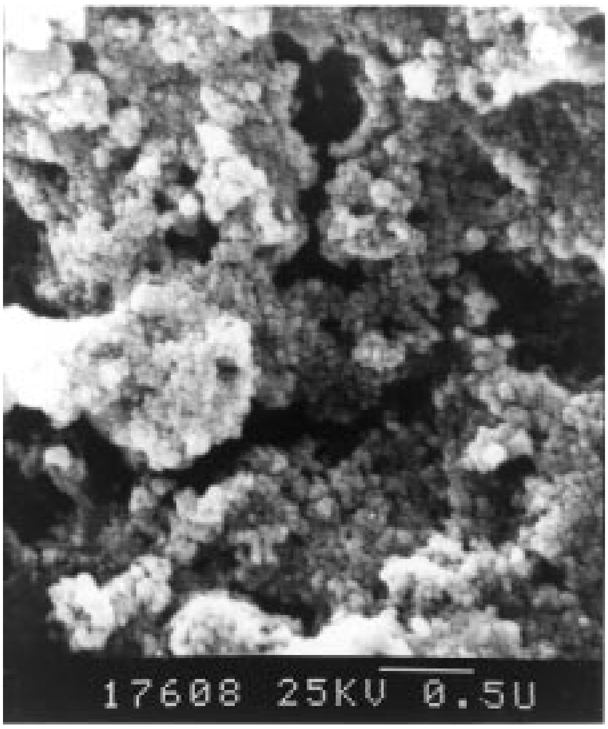
Figure 6 Scanning electron micrographs of metallic wear debris isolated from serum lubricants. (a) Low/low uniaxial (× 15 000); (b) low/low biaxial (× 30 000); (c) high/high uniaxial (× 30 000); (d) high/high biaxial (× 30 000); (e) high PI/low PL uniaxial (× 30 000); (f) high PI/low PL biaxial (× 30 000).



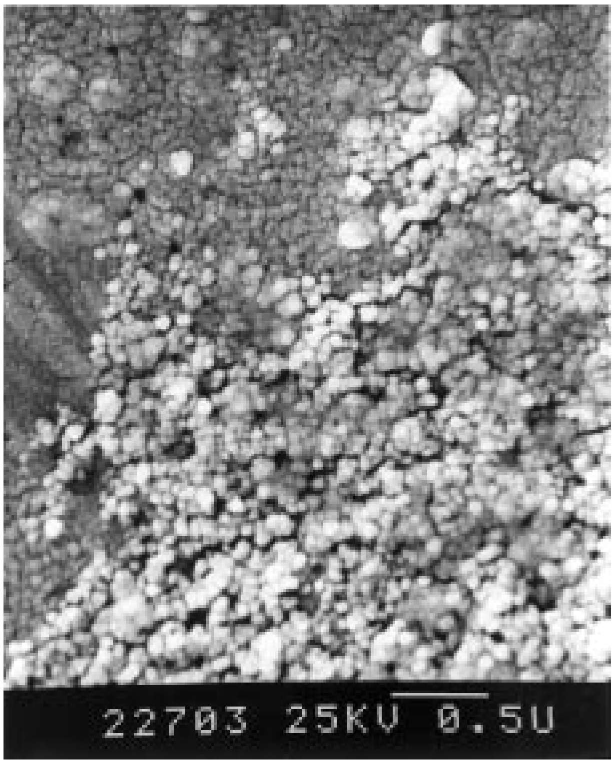
(c)



(d)



(e)



(f)

Figure 6 (Continued)

faces, the wear rates were affected by carbon content, i.e. lower wear with higher carbon content [34]. These simple wear tests were harsh and the results obtained were very different to those of clinical components.

The present study has demonstrated increased wear of low carbon content specimens compared to high carbon content specimens. This was very clearly shown in Test 1. This suggests that the carbon content plays an important role when considering the wear mechanisms operating in these wear tests. Fig. 12 shows the microstructures of high carbon and low carbon content cobalt chrome alloys revealed by etching. The high carbon cobalt chrome alloy demonstrated a biphasic structure, which comprised small grains of Co–Cr–Mo surrounded by embedded hard, scratch-resistant carbides, which restricted the size of the grains. The low

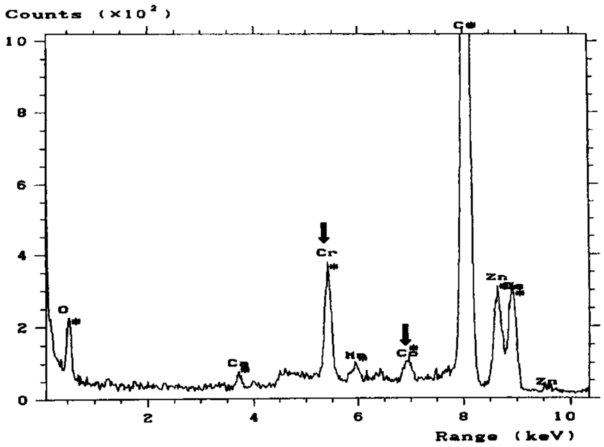


Figure 7 Atomic absorption spectroscopy analysis of low/low carbon cobalt chrome wear particles. The presence of copper, zinc and osmium was attributed to the copper grid that the cobalt chrome particles were mounted on. Arrows show cobalt and chromium peaks.

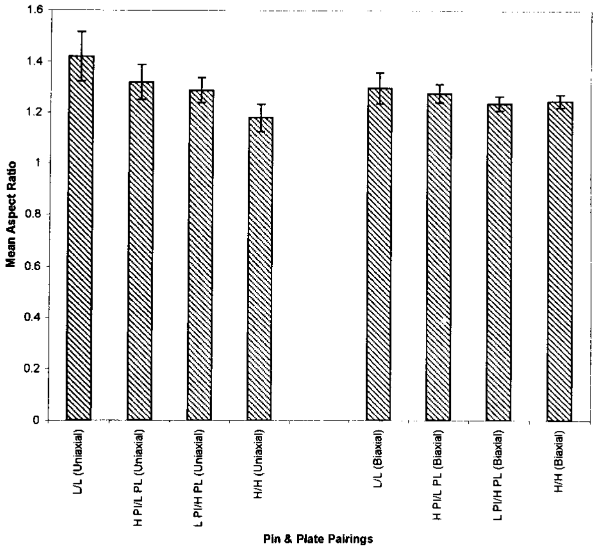


Figure 9 Mean aspect ratio ± 95% confidence limits for all material combinations.

carbon alloy comprised a single phase structure, and the grains were much larger than those in the high carbon specimen, probably due to the absence of carbides. The low carbon content specimens have decreased hardness because of the absence of these hard carbides, consequently this may lead to an increase in wear and damage compared to the high carbon content specimens [34]. A better surface finish was produced with the lower carbon content material because of the decreased hardness, and as a result the high carbon plates had rougher initial surface finishes when compared to the low carbon content plates. A rougher surface finish would normally lead to an increase in wear, but in these tests the opposite was demonstrated. This would suggest that the carbon content, and hence, the differing microstructure, had a significant effect on the amount of wear produced.

When low carbon specimens were paired with high carbon specimens, the total wear decreased compared to the low/low pairings. The use of differential hardness had a beneficial effect, probably as a result of the damage resistance of the high carbon specimens. However, it was concluded that the high/high carbon pairing produced the lowest wear rate. The tests run on the biaxial rig showed reduced total wear, in particular the wear rate of the plates was drastically reduced. This may be explained by the biaxial motion, which caused the multidirectional polishing seen on the wear surfaces, resulting in reduced wear rates. It was also found that the motion affected the relative wear on the differential hardness materials. In the biaxial tests there was no significant difference in the wear rate between the high/high carbon combination and the high pin/low plate combination.

The tests performed in this study have shown that the volumetric wear rates for metal on metal bearing surfaces in simple configuration tests were affected by the carbon content and microstructure of the cobalt chrome alloy, the material combination used, and the type of motion applied by the wear tester. These simple configuration wear tests have indicated that tribological results obtained from hip simulators may be dependent on the types of loads and motions applied, as well as the carbon content of the material. In addition, simulator studies are

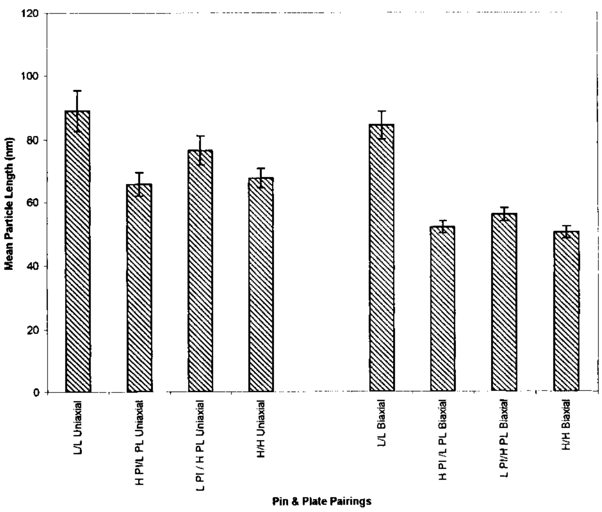


Figure 8 Mean particle length ± 95% confidence limits for all material combinations.

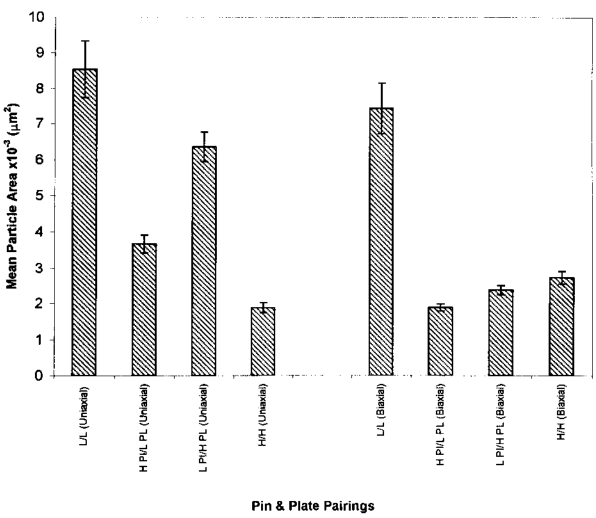


Figure 10 Mean particle area ± 95% confidence limits for all material combinations.

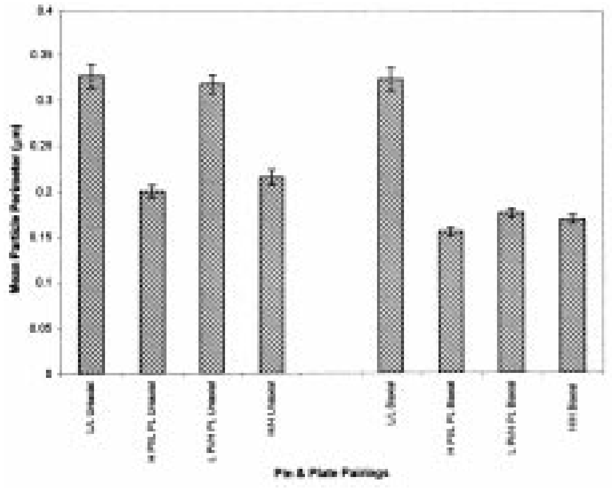


Figure 11 Mean particle perimeter $\pm$ 95% confidence limits for all material combinations.

likely to give a clearer indication of *in vivo* wear performance.

It is interesting to compare the wear factors obtained in this study with the wear of polyethylene under similar conditions. In uniaxial tests the wear factors for metal on metal articulations were higher than the wear factors for metal on polyethylene. However in biaxial tests, the wear factors for polyethylene have been shown to increase by a factor of 10 [39], whereas in this study, the wear factors for metallic materials reduced when multidirectional frictional forces were applied. The increase in polyethylene wear was thought to be caused by the multidirectional friction forces shearing the orientated linear polymer, whereas the reduction of metallic wear may be due to multidirectional polishing. Compared to simulator studies, the wear factors obtained for these simple configuration metal on metal wear tests were higher, approximately $10^{-6}\,\mathrm{mm^3\,Nm^{-1}}$ compared to approximately $10^{-9}\,\mathrm{mm^3\,Nm^{-1}}$ obtained in simulator tests [36]. This is again in contrast to metal on polyethylene where simple configuration tests produce lower wear factors than hip joint simulators.

This is the first time that metallic wear debris has been isolated and characterized from laboratory wear simulations. The results are extremely interesting. It is clear that the particles are smaller than widely characterized UHMWPE wear particles, and smaller than the metal particles previously reported for metal on polyethylene joint replacements. Particle morphology (aspect ratio) was not affected by the type of motion applied by the wear tester or by the carbon content of the cobalt chrome alloy. Particles generated in the uniaxial and biaxial wear tests with the low/low pairings were significantly larger in length, area and perimeter than particles produced by the other material combinations. For the low/low pairing, the type of motion applied by the wear tester did not affect the size of the particles. In general, particle length, area and perimeter measurements of the particles

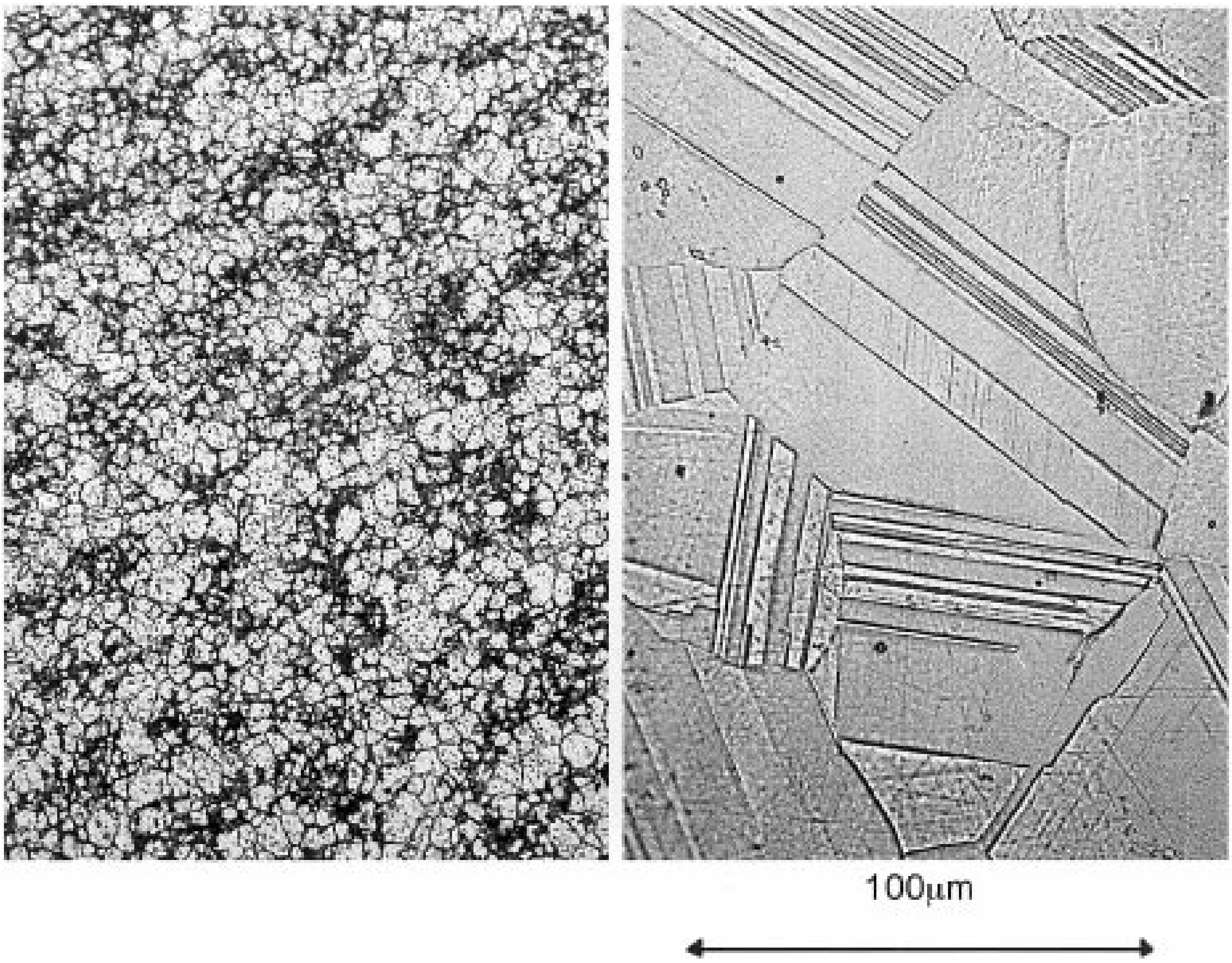


Figure 12 Left: microstructure of wrought high carbon cobalt chrome; right: microstructure of wrought low carbon cobalt chrome.

generated by the other material pairings were significantly reduced by the biaxial motion. However, as the differences between the measurements were relatively small, it is thought unlikely that this difference would be biologically significant *in vivo*.

The biological reaction to metal particles *in vivo* has been shown to be markedly different to that produced by UHMWPE wear debris. The extent of any granulomatous inflammatory reaction and the presence of foreign body giant cells were reported to be much less intense in metal on metal prostheses [23]. This may be due to the smaller size of the metal particles, which possibly facilitates their transport from the periprosthetic tissues via the lymphatic system. Transport of the metal particles from the tissue may also explain the lower reported incidence of osteolysis around metal on metal implants. However, recent reports suggest that osteolysis may also occur in metal on metal articulations at a reduced rate compared to metal on polyethylene prostheses [40].

It is clear that the smaller size of the metal wear particles has a dramatic effect on the number of particles produced per unit volume of wear. In this study, a minimum of 2.71×10^{12}; metal particles were produced per mm^3 of wear, whereas previous studies [38] have shown that an average of 2.4×10^{10} UHMWPE particles were produced per mm^3 of wear from aged irradiated UHMWPE in uniaxial wear tests. In addition, the *in vitro* wear particle factors (particles/Nm) for metal on metal articulations were shown to be more than 100 times higher than the wear particle factors for metal on UHMWPE articulations [38], because of the smaller size of the particles produced in the metal on metal articulations.

The biological reactions to *in vivo* and *in vitro* generated metal wear particles in the nanometer size range remain to be determined. Whether inflammatory cytokines are produced in response to particles in this size range, or whether toxicity and tissue necrosis are the dominant reactions is still to be established. However, it is clear from other studies that biological reactions are dependent upon particle size and morphology [12], and hence, in order to study the biological response, realistically generated wear debris needs to be utilized. Previous *in vitro* studies of artificially generated metal particles in the 1–10 μm size range [32, 33] are unlikely to be predictive of *in vivo* biological reactions.

Clinically, metal on metal bearings have been shown to produce low wear in many cases [6]. This is quite surprising as like on like materials do not produce low wearing surfaces in traditional engineering terms. A number of mechanisms have been suggested as contributing to low wear. These include:

- fluid film lubrication [41], although this is unlikely to be achieved if the surfaces have become roughened;
- boundary lubrication by proteins, lipids and even calcium phosphate deposits;
- high carbon content carbides acting as ceramic/metal composites.

However, the results of this study provide evidence for two alternative low wear mechanisms.

- Multidirectional motion and its polishing action which may act as a mechanism for reducing wear.
- Most importantly, the nanometer sized spherical wear particles may act as self-lubricating ball bearings. The calculations indicate that at least 10^6 particles are generated in each walking cycle *in vivo*. These particles may act as classic third bodies *les troisième corps* between the bearing surfaces [42], rolling, deforming and acting as sites for motion and velocity accommodation and, hence, minimizing the wear to the bearing surfaces themselves.

This study has demonstrated the influence of carbon content and motion on the wear of metal on metal articulations. This is the first report on the quantification of nanometer sized debris from *in vitro* wear tests. The potential effect of these wear particles on both *in vivo* cellular reactions, wear mechanisms and self lubrication indicate that further work should be carried out on the influence of motion in hip joint simulators, and studies of biological reactivity through *in vitro* cell culture.

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