High Cup Angle and Microseparation Increase the Wear of Hip Surface Replacements

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Abstract High wear rates and high patient ion levels have been associated with high ($> 55^\circ$) cup inclination angles for metal-on-metal surface replacements. Wear rates and patterns have been simulated for ceramic-on-ceramic bearings by applying microseparation to replicate head offset deficiency. We tested 39-mm metal-on-metal surface replacements ($n = 5$) in a hip simulator with (A) an increased cup inclination angle of 60° and (B) an increased cup inclination angle and microseparation over 2 million cycles. (A) resulted in a ninefold increase in wear rate and (B) resulted in a 17-fold increase in wear rate compared to a standard gait condition study. Wear particles produced under microseparation conditions were larger than those produced under standard conditions but of similar shape (round to oval). The data suggest both head and cup position influence the wear of surface replacements; we believe it likely bearings with high wear either have a high cup inclination angle, an offset deficient head, or a combination of both.

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Introduction

Retrieval studies on current designs of metal-on-metal (MoM) surface replacements have shown a large (40-fold) variation in the wear [5, 15]. The majority of high-wearing retrievals of various designs reportedly have high cup inclination angles ($< 55^\circ$) and deep wear scars suggesting an edge-loading mechanism. These high wear rates have been associated with pain, local necrosis, lymphocytic infiltration, and the development of large metal-stained bursa [7] or “pseudo tumors” [19], which make subsequent revision operations challenging. High systematic ion levels alone in patients are now being recommended as an indicator for revision [7].

Previous studies with metal-on-metal have demonstrated increased wear with increased cup angle both in vitro [23] and in vivo [8, 15]. However, the clinical studies suggest more variation in wear rates and also generally a greater increase in wear than found in vitro. This implies other variables may be playing a large role in determining wear rates in vivo. These variables could include cup version angle (position in lateral plane), impingement between the edge of the cup and the preserved femur, and head position or joint laxity resulting in microseparation during gait. Without the use of CT it is very difficult to measure version clinically so the exact effects of this variable are currently unknown, although it is likely that it will affect the bearing “coverage” in a similar way to the cup inclination angle [8]. Clinically, it is not possible to control femoral offset with surface replacements in the same way it is possible with total hip replacements through the use of different length tapers [20]. This could lead to greater variability in head position and therefore joint laxity.

Ceramic-on-ceramic total hip replacements also reportedly have increased wear with increased cup inclination

angle in vivo [17]. However, increased inclination angle in hip simulator studies alone failed to replicate the same wear rates and mechanisms seen in vivo [18]. One study using a method to include a lateral shift in the contact during swing phase (microseparation) to simulate an offset deficient head or joint laxity resulted in clinically relevant wear rates and patterns [16]. Previous studies have indicated that microseparation can have an effect on wear in metal-on-metal [23]. However, because previous studies have not controlled head diameter or cup angle independently it is not possible to determine relative or synergistic effects of cup angle and microseparation.

The clinical evidence of microseparation is based on fluoroscopy studies that show a lateral sliding of the femoral components to the edge of the acetabular components during gait. Initial fluoroscopic studies suggested that separation was more prominent with metal-on-polyethylene bearings than metal-on-metal bearings, however, at that stage the methodology only had a resolution of 0.8 mm, so any separation below that level was reported as no separation [11]. A recent study claimed higher accuracy (0.5 mm) and showed that separation occurred in all bearings also suggesting that the timing of the separation could vary between patients and bearings [9].

The size of wear debris produced by total hip replacements is thought to play a key role in the biological response to the implants and play a role in their survival. The relevance of particle size with metal is still unclear, however, it could play a role in terms of surface area per unit volume and particle transportation. When ceramic-on-ceramic bearings were investigated under microseparation there was a change in the size and shape of wear particles produced. A bimodal size distribution was reported due to the production of large wear particles from the granular failure of the ceramic under the microseparation conditions [22]. The effect of microseparation on metal wear particles is currently unknown.

By completing three in vitro hip simulator tests under three different sets of conditions (standard, increased cup inclination angle and increased cup angle combined with microseparation) the following questions were addressed: What is the effect of increased cup inclination angle on the wear of surface replacements? What is the combined effect of increased cup angle and microseparation on the wear of surface replacements? How does the size and shape of wear debris produced under microseparation conditions compare to that produced under standard conditions?

Materials and Methods

We used hip simulator studies to investigate the influence of cup inclination angle and microseparation on the wear of

metal-on-metal surface replacements. One study was conducted with the cup positioned in a standard position, one with the cup positioned with a high inclination angle and one with the cup positioned with a high cup inclination angle combined with microseparation. We compared the wear of the bearings in each condition. Wear debris isolated from the lubricant of the standard condition study was compared to that isolated from the lubricant of the high cup combined with microseparation study.

All of the hip simulator studies were conducted on hot isostatic pressed (HIPed) and homogenized cast high carbon cobalt-chromium-molybdenum (CoCrMo) surface replacements with a low profile cup with an internal fixation feature and bearing diameter of 38.5 mm (Table 1). A bearing diameter of 38.5 mm was chosen to replicate a worst case scenario as there have been increased failure rates associated with these smaller bearings [3]. Clinically, the hip reaction force is at an angle of approximately 10°, while the hip simulators used in this study have vertical loading, therefore the effective clinical inclination angle of the cups tested is 10° steeper than the mounting in the simulator. The cup inclination angles quoted in this study are the effective clinical angles. Testing was conducted under standard conditions (cup inclination angle of 45°) on a Prosim hip simulator (Sim Solutions Ltd., Stockport, UK) [13], standard conditions with cup inclination angle of 60° on a Prosim hip simulator and with microseparation combined with a cup inclination angle of 55° on a Leeds Mk II hip simulator (University of Leeds, Leeds, UK). Different simulators were used as only the Leeds Mk II hip simulator has the facility to produce a lateral microseparation, while the Prosim was employed for the standard and high cup studies due to its greater capacity (10 stations Vs 6 on the Mk II) allowing a higher sample number (n) and therefore greater power in the study.

To simulate the loading and kinematics of a patient (70–80 kg) in normal gait we applied a twin peak loading cycle with a peak of 3 kN. Flexion/extension (15°–30°) and internal/external rotation ($\pm 10^\circ$) were applied to the components, the combination of which resulted in the production of both open elliptical and figure of eight wear paths on the surface as described previously [1, 10]. The lubricant (25% [v/v] newborn calf serum with 0.03% [w/v] sodium azide) was changed approximately every 0.33

Table 1. Summary of test conditions

Test	Bearing Size (mm)	Cup inclination angle	Simulator	N
Standard	38.5	45°	ProSim	5
High cup	38.5	60°	ProSim	5
Microseparation and high cup	38.5	55°	Leeds Mk II	5

million cycles. Testing was conducted at a frequency of 1 Hz.

Microseparation was produced on the Leeds Mk II hip simulator by applying a small lateral load to the cup causing approximately 0.5 mm medial and superior translation of the cup relative to the head during swing phase, as described previously [16] with the cup positioned at an inclination angle of 55°. Wear was determined gravimetrically after 1 million and 2 million cycles for the high cup and microseparation studies and at 1 million, 2 million, and 5 million cycles for the standard conditions study using methods reported previously [13]. In addition to gravimetric wear analysis, the wear areas were analyzed by contact profilometer (Form Talysurf 120L, Taylor Hobson, UK), four 19 mm contact profilometer traces were taken across the wear areas. A primary analysis was performed and a least squares arc fitted to the profile with the wear area excluded from the fit. For each bearing, the linear penetration was determined by the maximum measured deviation from the least squares arc. Previous studies report a large amount of variability in the wear rates of metal-on-metal bearings during the first 1 million cycles owing to different bearings having different bedding in volumes [13, 23]. This study was primarily concerned with the effect of the test conditions on the wear therefore to minimize the potential effect of any specimen variability, the wear rates between 1 million and 2 million cycles were compared.

Using methods described previously [2], wear debris was isolated from the biological material in the lubricant by enzymatic digestion and imaged by field emitting gun scanning electron microscopy (FEGSEM) at high magnification ($< 150,000\times$). One hundred and fifty particles from three independent repeats of each test condition were sized using Image-Pro Plus® imaging software (Media Cybernetics, Inc., Bethesda, MD).

We determined differences in the wear rate of surface replacements tested under standard conditions and under both high cup inclination angle and high cup inclination angle combined with microseparation by comparing the three mean values by one-way ANOVA. Where the F-value of the ANOVA was significant, individual group means were then compared using the T-method to determine the minimum difference (MSD) at levels of confidence of $p = 0.05$ and $p = 0.01$. We determined differences in the size and shape parameters of wear debris produced under standard and high cup angle combined with microseparation conditions by Student's t-test.

Results

The bearings tested with the cup inclination angle of 60° had ninefold higher ($0.05 > p > 0.01$) wear rates than the

Fig. 1 Volumetric wear rates of 39-mm surface replacements tested under standard, high cup angle and high cup angle combined with microseparation conditions are shown, demonstrating increased wear rates under high cup angle and microseparation conditions compared to standard. Mean $\pm$ 95% confidence limits.

bearings tested with a cup inclination angle of 45° between 1 million and 2 million cycles (Fig. 1). There was a greater variability in the wear rates of the bearings tested with the cups positioned at 60° compared to at 45° (standard deviation of 4.29 versus 0.64, respectively).

The combined high cup inclination angle and microseparation resulted in a 17-fold increase ($p < 0.01$) in wear rate between 1 million and 2 million cycles compared to standard hip simulator conditions (Fig. 1). Under standard conditions, the mean wear rate decreased from 0–1 to 1–2 and 2–5 million cycles while under the microseparation conditions the mean wear rate increased from 0–1 to 1–2 million cycles (Fig. 1). There was a 17-fold difference in the microseparation and standard conditions wear rates between 1 million and 2 million cycles. There was a 38-fold difference in the wear rates under microseparation conditions at 1 million to 2 million cycles and the eventual steady state standard conditions (2–5 million cycles). The components showed stripe wear on the lateral edge of the cup and in a lateral/superior position on the head. The mean penetration depth on the femoral components was 41 μm (range: 33.2–44.75, st dev: 4.8) compared to 105 μm (range: 85–140, st dev: 24) on the cup (Fig. 2A–B).

Wear debris produced under the harsh conditions was similar in shape to that produced under standard conditions but larger ($p = 0.022$) in size and with a greater size distribution (Fig. 3). The mode for the wear particles produced under standard conditions was 20 to 29 nm while the mode for the wear particles produced under microseparation conditions was 30 to 39 nm. There was no difference in the aspect ratio ($p = 0.057$), roundness ($p = 0.326$), or form factor ($p = 0.873$) of the particles produced by the two different conditions (Table 2).

Fig. 2A–B Contact profilometer traces across wear area of (A) head and (B) cup after two million cycles of testing under high cup angle combined with microseparation conditions are shown. Stripe wear appears on the femoral component and maximum penetration at the edge of the acetabular component.

Fig. 3 The figure shows size distribution of wear particles produced under standard and microseparation conditions, showing increased size of wear particles produced under microseparation conditions. Mean $\pm$ 95% confidence limits.

Discussion

Retrieval studies on metal-on-metal hip surface replacements and patient systemic ion levels suggest substantial variability. The high wear rates experienced by some patients can result in fluid or mass formation with subsequent destruction of soft tissues [7, 19]. It is therefore important to understand the causes and mechanisms of these high wearing bearings. High wear has been

associated with high cup inclination angles, however, the large amount of variability suggests other factors may influence wear. Experience from the in vitro testing of ceramic-on-ceramic bearings suggested that head position also played a role. By performing in vitro hip simulator tests this study aimed to address the following questions. What is the effect of increased cup inclination angle on the wear of surface replacements? What is the effect of increased cup angle combined with a microseparation on

Table 2. Shape parameters of wear particles produced by metal-on-metal bearings tested under standard and microseparation with high cup conditions

Test conditions	ECD	Aspect ratio	Roundness	Form factor
Standard	0.0247 ($\pm$ 0.001)	1.215 ($\pm$ 0.04)	0.987 ($\pm$ 0.045)	0.744 ($\pm$ 0.06)
Microseparation with high cup angle	0.0503 ($\pm$ 0.022)	1.169 ($\pm$ 0.07)	1.024 ($\pm$ 0.14)	0.747 ($\pm$ 0.03)

ECD = equivalent circle diameter. Mean ($\pm$ 95% confidence limits).

the wear of surface replacements? How does the wear debris produced under microseparation conditions compare to that produced under standard conditions?

All experimental hip simulator studies are confounded by the fact that they generally only replicate one single kinematics and loading cycle whereas in vivo, a host of different sets of demands are placed upon an implant during everyday use. Therefore, long-term clinical assessment remains the ultimate means of determining the performance of bearings in hip prosthesis and all simulation methods must only be considered an approximation of the clinical situation. Experimental hip simulator studies remain a valuable tool, however, as they allow the investigation of individual parameters, which is extremely difficult in clinical studies. Efforts must therefore be continued to better model the wide range in results observed in vivo so as to better predict clinical outcomes in the future. The length of test (2–5 million cycles) is a limitation with this study as in vivo patients could take anywhere from one to five million steps per year and the implants are required to perform for many years. However, in this study the differences between the different conditions are well established even after two million cycles, negating the need for the study to be extended. As this study only investigates one design of hip surface replacement the effects may not be directly transferable to all of the other designs currently available. The magnitude of the effect of cup inclination angle and microseparation on wear may be influenced by parameters such as the inclusion angle, clearance, bearing diameter and material processing, the effects of which will be investigated in future studies. However, the studies on retrievals suggest that all current designs show variable wear rates and are affected by edge loading.

The increased wear rates of the 39-mm bearings tested with cup inclination angles of 60° compared to 45° was in agreement with a previous study which reported increased wear rates of 28-mm metal-on-metal bearings with increased cup inclination angle [23]. However the increase in mean wear rates was larger than previously reported [23]. This could be due to the differences in the defined “high” cup angle (60° versus 55°) or the increased inclusion angle of the hemispherical 28-mm total hip replacement bearings. As the increased cup inclination

angle could cause a breakdown or reduction in fluid film lubrication, the increased sliding distance of the larger bearing may also play a role in the increased wear rate of the larger bearing. Conversely, a recent clinical investigation of patient ion levels suggested that larger bearing diameters may be less sensitive to cup position than smaller bearings [12]; however, in this case, a large bearing was defined as larger than 53-mm. Further work is needed to determine the effect of cup angle for different bearing sizes. The increased wear rates observed on the bearings tested with a cup inclination angle of 60° are in agreement with the reported increase in ion levels in patients with cup inclination angles of greater than 55° [8]. De Hann et al. reported a large amount in variability in patient ion levels ranging from below 2 ppb to 111 ppb [8]. If the high cup angle study is compared with the standard study between 1 and 2 million cycles there is a 9-fold increase in wear; if the high cup angle data are compared to the eventual steady state data of the standard condition study the difference becomes 20-fold, but this is still lower than the reported variability in ion levels. The increase in wear rate with increased cup inclination angle suggests MoM bearings are more sensitive to cup position than ceramic-on-ceramic bearings that show no increase in wear with increased cup angle in hip simulator studies [18]. However, it is important to note that clinically, increased cup angle in ceramic-on-ceramic bearings may increase the chances of stripe wear and potential fracture. Under standard testing conditions the MoM bearings had decreased wear rates as the test progressed due to the combined effect of the establishment of an increased contact area between the bearings [14], promoting lubrication and the development of tribochemical reaction layers [4]. The importance of tribocorrosion on the wear of MoM bearings has been demonstrated previously [24]. Increasing cup inclination angle is likely to reduce the contact area that is established and hence reduce lubrication and increase wear. We also suggest edge loading as a result of increased cup angle, microseparation, or a combination may disrupt the formation of tribochemical reaction layers due to high contact stresses that in turn results in an increase in tribocorrosion and wear. This could also be an explanation for the increased variability in the wear rates of the bearings tested

at 60°. Additionally, in the high cup angle study the contact patch approaches the edge, and hence accelerates wear. This is a positive feedback loop, i.e. higher wear equals greater effect of edge, therefore this could differentiate/exaggerate differences between bearings.

The combination of high cup inclination angle with microseparation resulted in greater increases in wear rate than when tested with increased cup angle alone, thus bringing the experimental model closer to replicating the higher wear rates reported clinically when edge loading occurs. The relative amount of wear in vivo could be associated with the amount of lateral head movement (microseparation) occurring during gait which is controlled by head positioning, ligament tension and cup inclination and anteversion angle. Additionally, if the cup is left proud, impingement of the rim on the preserved femoral bone could occur, resulting in microseparation. This multiplicity of factors could explain the reported variable association between cup inclination angle and patient ion levels and the large amount of variability in wear rates. Morlock et al. [15] measured the wear on retrievals and split cases by those seeming to have experienced edge loading and those that had not. If it is assumed two million cycles is equivalent to one year in vivo, the wear rates of the metal-on-metal hip surface replacements tested with increased cup inclination angle combined with microseparation is not dissimilar to the mean values reported by Morlock et al. (21.23 mm³/2 million cycles ($\pm$ 5.83) Vs 26.15 mm³/year (min 2.08 max 70.89) [15]. There is also a good correlation in the mean ratios of wear on the acetabular and femoral components (1.82 on clinical retrievals compared to 1.78 on samples that had been tested under microseparation conditions). This suggests the combination of increased cup angle and microseparation in vitro produces wear rates and wear mechanisms similar to those experienced by metal-on-metal surface replacements undergoing edge loading in vivo. However, it should be noted that any comparison to retrieval data is compromised by a number of different factors: (1) assumptions have to be made regarding the number of cycles that equate to 1 year in vivo; for this comparison we have assumed 2 million [21], however for younger, more active patients this could increase to 3–5 million cycles; (2) different wear measurement methodologies are employed (gravimetric versus geometric); (3) retrieval data encompass several different designs and different head sizes; and (4) there is a large amount of variability in the measured wear on retrievals and therefore the reported mean wear rates vary between studies [5, 15]. For a full understanding of the wear mechanisms, a direct physical comparison should be made between experimental and retrieval samples using consistent methodologies. This will be the focus of future studies.

The sizes of the wear debris produced by standard and microseparation conditions for ceramic-on-ceramic bearings demonstrate a bimodal distribution with both nanometer and micrometer wear particles produced owing to granular failure of the ceramic [22]. Large diameter MoM bearings as investigated in this study have not previously been investigated under microseparation conditions, however 28-mm MoM bearings have been investigated and reportedly produced similar sized particles to those under standard conditions [2]. The clinical importance of the larger particles produced by the surface replacements under microseparation conditions in this study is unclear. It is not possible to directly compare the size of particles reported in this study with studies of in vivo generated particles reported in the literature since different methods of isolation and analysis have been used. However, it is interesting to note that the microseparation wear particles reported here more closely resemble the larger particles reportedly produced by surface replacements in vivo [6].

Our data suggest increasing the cup inclination angle from 45° to 60° results in an increase in wear rate. These data are consistent with clinical ion level studies reporting increasing ion levels in patients who have cups implanted at an angle greater than 55°, however, the ion level studies generally report greater increases than we found. The combination of increased cup angle and microseparation resulted in even higher wear rates. These were not dissimilar to the wear rates reported on clinical retrievals, suggesting these conditions were closer to replicating the clinical situation. The wear debris produced under microseparation was larger in size than that produced under standard conditions. The clinical importance of this change in wear debris size is currently unknown.

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