Wear and deformation of ceramic-on-polyethylene total hip replacements with joint laxity and swing phase microseparation

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Abstract: Wear of polyethylene and the resulting wear debris-induced osteolysis remains a major cause of long-term failure in artificial hip joints. There is interest in understanding engineering and clinical conditions that influence wear rates. Fluoroscopic studies have shown separation of the head and the cup during the swing phase of walking due to joint laxity. In ceramic-on-ceramic hips, joint laxity and microseparation, which leads to contact of the head on the superior rim of the cup, has led to localized damage and increased wear *in vivo* and *in vitro*. The aim of this study was to investigate the influence of joint laxity and microseparation on the wear of ceramic on polyethylene artificial hip joints in an *in vitro* simulator. Microseparation during the swing phase of the walking cycle produced contact of the ceramic head on the rim of the polyethylene acetabular cup that deformed the softer polyethylene cup. No damage to the alumina ceramic femoral head was found. Under standard simulator conditions the volume change of the moderately crosslinked polyethylene cups was 25.6 ± 5.3 mm^3/million cycles and this reduced to 5.6 ± 4.2 mm^3/million cycles under microseparation conditions. Testing under microseparation conditions caused the rim of the polyethylene cup to deform locally, possibly due to creep, and the volume change of the polyethylene cup when the head relocated was substantially reduced, possibly due to improved lubrication.

Joint laxity may be caused by poor soft tissue tension or migration and subsidence of components. In ceramic-on-polyethylene acetabular cups wear was decreased with a small degree of joint laxity, while in contrast in hard-on-hard alumina bearings, microseparation accelerated wear. These findings may have significant implications for the choice of fixation systems to be used for different types of bearing couples.

Keywords: wear, polyethylene, artificial hips, joint laxity, separation

NOTATION

v/v	volume per volume
GVF	gamma irradiated and vacuum foil packed
R_a	surface roughness

1 INTRODUCTION

Ultra-high molecular weight polyethylene acetabular cups are used extensively as one of the bearing surfaces in artificial hip joints. Currently over fifty thousand hip prostheses are implanted in the United Kingdom every year and more than ten times that number worldwide. Although in the short to medium term hip prostheses generally provide excellent clinical performance with over 90 per cent success rates at ten years, in the longer term, aseptic loosening is a major cause of failure. A major cause of loosening is polyethylene wear debris-induced osteolysis. In particular, micrometre and sub-micrometre sized polyethylene wear debris activates macrophages in the periprosthetic tissue, which release cytokines, and this leads to osteolysis [1]. In the last five years considerable improvements have been made to polyethylenes in order to reduce wear. Sterilization with gamma irradiation in the presence of oxygen, which increases oxidation and wear [2], is no longer used, and there is an increased use of damage-resistant alumina ceramic femoral heads [3]. Additionally, irradiation in an inert atmosphere which crosslinks the polyethylene [4] and intentional crosslinking followed by heat

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treatment to recombine the free radicals has also been shown to reduce wear [**5**, **6**]. Further consideration is now being given to the recent findings that both higher molecular weight polyethylenes [7] and crosslinked polyethylenes [**8**] produce smaller and more biologically active wear particles, which may negate some of the benefits of lower wear volumes.

Alternative hard-on-hard bearings such as metal-on-metal [9] and alumina ceramic-on-ceramic [**10**] bearings are being used more widely in an attempt to address concerns over polyethylene wear debris-induced osteolysis. These produce lower wear rates than polyethylene [**11**] and in the case of alumina ceramic debris it has been shown to be less biologically active than one type of lightly crosslinked polyethylene wear debris [**12**].

Clinically there is considerable variation in the wear rates observed with polyethylene acetabular cups [**13**], and this may be related to many factors, including activity [**14**], patient weight [**14**], the composition of the lubricant [**15**, **16**], the presence of third-body damage [**13**] and the oxidative state of the polyethylene [**17**]. When the wear of hip prostheses is studied in the laboratory it is often tested under a standard simulated walking cycle [**18**]. However, recent fluoroscopic studies have shown interesting differences in kinematic patterns *in vivo* [**19**]. In particular, separation of the head and the cup during the swing phase of walking has been reported [**20**], and this separation has been shown to be greater in polyethylene acetabular components articulating against a metal or ceramic head, compared to hard-on-hard bearings. It has been shown that when lateral and inferior microseparation of the head and cup occurs during the swing phase, upon heel strike, the head contacts with the superior rim of the cup, producing stress concentrations [**21**], as shown in Fig. 1. The level of microseparation required to produce rim contact is closely related to the radial clearance of the head and cup [**22**] (typically 30 μm for hard-on-hard bearings and 125 μm for polyethylene bearings). In alumina ceramic-on-ceramic couples, it has been shown that microseparation increased the wear rate, produced a characteristic stripe of wear on the head and caused corresponding rim damage, and a bimodal size distribution of wear particles was observed, which is replicated *in vivo* and *in vitro* [**21**, **23**]. It has been postulated that microseparation of the head and cup in polyethylene bearings may produce increased multidirectional wear patterns and cross shear of the polyethylene, leading to accelerated wear [**4**, **20**]. The aim of this study was to investigate wear of polyethylene on ceramic bearing couples *in vitro* under microseparation conditions and to compare this to standard walking cycle conditions.

2 MATERIALS AND METHODS

Size 28 mm diameter acetabular cups and heads were used in this study. Biolox Forte alumina ceramic heads (Ceramtec, Germany) were used since they had previously been found to produce head damage under microseparation conditions in an alumina-on-alumina bearing couple [**21**, **23**]. Moderately crosslinked polyethylene was used in the acetabular cup material; GUR1020 GVF polyethylene was sterilized with 4 Mrad of gamma irradiation in a vacuum foil pack (DePuy International, UK). This material has been extensively used clinically over the last five years and has been studied previously when articulating against metallic femoral heads in the same simulator [**8**]. This is an established bearing couple with which to investigate the effect of the microseparation kinematics. Five pairs were studied under microseparation conditions and five pairs were studied under standard conditions in a ten-station Leeds Prosim hip joint simulator [**24**].

A station of the Leeds Prosim hip joint simulator [**24**] is shown in Fig. 2. The cups were positioned superiorly inclined at 35° to the horizontal plane in an anatomical configuration. The simulator applied two independently controlled motions. The head underwent flexion/extension $+30°$ and $-15°$ and the acetabular insert $\pm 10°$ rotation (Fig. 2). These two motions have been previously compared to a three-axis motion simulation [**18**] and been found to produce similar wear rates for polyethylene acetabular cups. A twin-peak time-dependent loading curve was applied with a peak load of 3 kN at heel strike and toe off and a swing phase load of 50 N for the standard kinematic conditions. For the five microseparation stations a small negative force (less

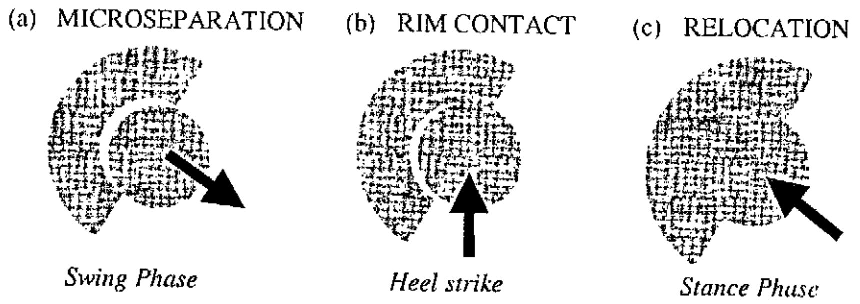

Fig. 1 Swing phase microseparation (a) followed by head rim contact at heel strike (b) and relocation during the stance phase (c)

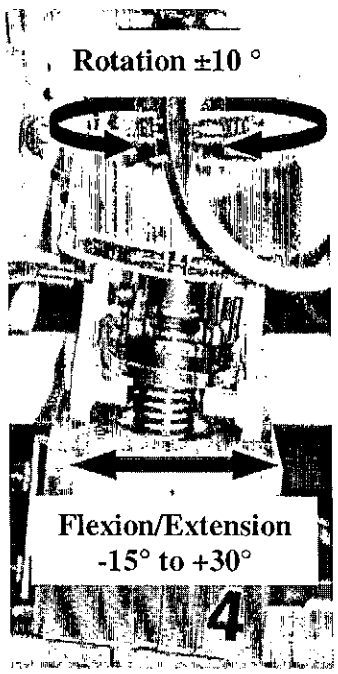

Fig. 2 Movement of a station in the Prosim hip simulator; components are contained in a latex garter of testing lubricant

than 100 N) was applied to separate the components during the swing phase. This produced an inferior and lateral translation of 0.7 mm. The lateral translation of the femoral head was produced by the constraint of the rim of the acetabular cup. Upon the application of the force at heel strike, the head translated superiorly and contacted the superior rim of the acetabular cup before relocating into the normal articulating position.

Tests were carried out in 25% (v/v) new-born calf serum (Seralabs, New Zealand) with 0.1% (v/v) sodium azide to retard bacterial growth. The lubricant was changed every 0.33 million cycles when the components and articulating cell were cleaned *in situ*. Wear was determined volumetrically every million cycles. The three-dimensional geometry of the cups was determined before the test and every million cycles using a coordinate measuring machine (CMM) (Kemco 400 3D, Keeley Measurement Company, UK). The flat, upper posterior surface of the cup was used as a reference plane. The axes and origin were set by measuring the position of the centre of each of the diametrically opposite 'introducer' holes in the upper surface of the cup. After the datum had been set, the CMM was programmed to track data points 3° apart on the x axis across the cup, the cup was rotated 10° and this was repeated until the entire interior cup surface was mapped. The accuracy and repeatability of this method has been previously discussed [25]. The volume change corresponds to wear plus creep. Previous studies under standard conditions have shown that creep predominately occurs in the first million cycles and after that period volume loss and penetration are predominantly due to wear [18]. The geometrical mapping also allowed the three-dimensional reconstruction of the surface of the cup to show the areas of maximum wear and penetration. In addition to the geometrical measurements the wear surfaces and local rim geometries were mapped with a contacting profilometer (Form Talysurf, Taylor Hobson, UK). The surface topography of the ceramic femoral heads was also measured at the beginning and end of the tests using the same contacting profilometer.

3 RESULTS

The average volume change for the two sets of five cups articulating under microseparation and standard conditions plotted against the number of cycles is shown in Fig. 3. The average rate of volume change (mean volume change $\pm$ 95 per cent confidence limits) for standard and microseparation conditions was 25.6 ± 5.3 and 5.6 ± 4.2 mm^3 per million cycles respectively. The fourfold reduction in volume loss with the microseparation conditions was highly statistically significant (Students t-test $p < 0.01$). Analysis of the three-dimensional maps of the volume change in the acetabular cups provided further insight into the different wear/creep processes under standard and microseparation conditions. The volume change map of a standard condition cup, after three million cycles, is shown in Fig. 4. This showed the volume loss in the superior lateral quadrant, as described previously [24]. In contrast, all the cups undergoing microseparation showed deformation of the rim of the cup where the head contacted the rim at heel strike, but characteristically much less penetration and wear over the rest of the articulating surface (Fig. 5). The volume change occurring at the rim of the cup could be attributed to both creep deformation and wear; it was not possible to differentiate this. While previous studies [18] have demonstrated the amount of creep occurring

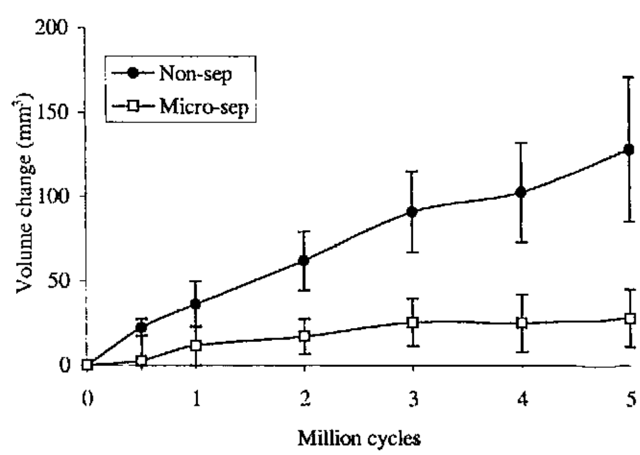

Fig. 3 Volume change of the cups plotted against number of cycles (mean $\pm$ 95% confidence limits)

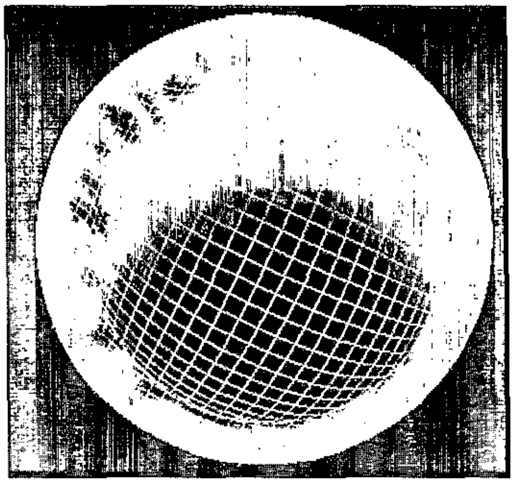

Fig. 4 Polyethylene cup (standard conditions) following 3 million cycles; dark central area shows increased wear

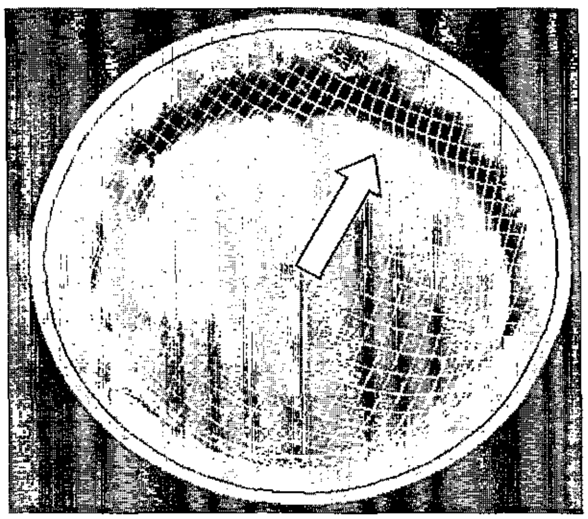

Fig. 5 Polyethylene cup (microseparation conditions) following 4 million cycles; dark area on the rim (as shown by arrow) shows rim damage

between conforming surfaces in a standard condition test, the creep behaviour of the non-conforming cup rim and the effect on volume change throughout the test is not known. The total volume change accounted for contributions from both creep and wear processes.

The rim damage was also readily shown by two-dimensional profilometry. The non-deformed rim of a standard test and the deformed rim of the microseparation test are shown in Fig. 6. This shows a localized deformation of the rim of about 0.5 mm over a localized region of the cup surface.

Surface analysis of the alumina ceramic femoral heads showed no change or damage throughout the test for either the standard or the microseparation conditions. The surface roughness R_a of the alumina ceramic femoral heads remained very smooth ($R_a = 0.005$ μm) throughout the test. This was in contrast to the previously reported damage and wear to alumina ceramic heads in alumina-on-alumina bearing couples when microseparation occurred [**21**, **23**].

4 DISCUSSION

The volume change of the ultra-high molecular weight polyethylene cups tested under standard conditions (25.6 ± 5.3 mm^3 per million cycles) compares to the wear rate reported for similar types of cups articulating against cobalt–chrome femoral heads (35 ± 9 mm^3 per million cycles) in the same simulator [**8**]. Wang *et al.* [**26**] showed polyethylene wear rates of 30 mm^3 per million cycles for polyethylene irradiated with 5 Mrad of gamma irradiation and 50 mm^3 per million cycles for 2.5 Mrad of gamma irradiation when articulating with CoCr heads; in this study components were inverted. The lower volume change found in this study under standard conditions may be attributed to the use of alumina ceramic femoral heads.

The remarkable finding of this study was that the introduction of swing phase microseparation with polyethylene acetabular cups reduced the volumetric change by a factor of four. Although it has been postulated that separation would introduce additional multidirectional wear vectors and cross shear of the polyethylene and hence accelerate wear [**20**], this hypothesis was not supported in this particular study. Microseparation certainly produced deformation and wear to the rim of the acetabular cup (Fig. 5) but, more importantly, the head also produced less volume change when relocated into the normal articulating surface. This is probably due to the microseparation increasing the potential for transient elastohydrodynamic squeeze film lubrication and the reduction of the wear during the stance phase after relocation [**27**]. Moreover, microseparation did not produce damage or wear to the alumina ceramic femoral head articulating against the polyethylene acetabular insert. This is in contrast to the alumina-on-alumina couple in which microseparation and rim contact produced damage and increased wear to the alumina ceramic femoral head [**21**, **23**].

Volumetric loss was determined by three-dimensional geometrical mapping in this study. Previous studies have shown that this includes wear plus creep and that creep predominantly occurs in the first million cycles of bedding-in [**18**, **24**] in the case of conforming surfaces. In previous studies a slightly higher volume change was found in the first million cycles and therefore wear rates were averaged over the period of 1–5 million cycles. In the microseparation stations creep deformation of the rim could not be isolated from the wear; assumptions that have been made previously could not be made in this instance, due to the non-conforming nature of the cup rim, and hence the total volume change was calculated. In order to enable the same methodology to be

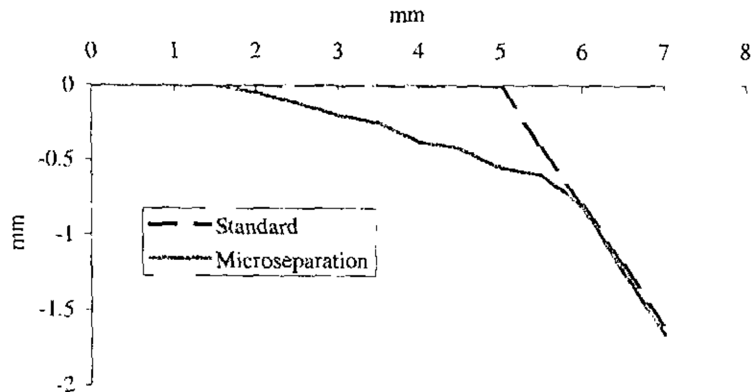

Fig. 6 A comparison of the two-dimensional profile of the rim of the cups for standard and microseparation conditions

presented for both sets of cups in this study, the volume change was averaged over the whole test duration. This included both creep and wear. While under standard conditions previous studies show that the creep contribution is small, it is not possible to estimate the percentage of creep deformation in the total volume change in the microseparation cups. The true wear will be less than the total volume change measured.

It is interesting to compare the relative effect of microseparation on the wear of polyethylene-on-alumina and alumina-on-alumina hip prostheses (Fig. 7). Under standard conditions the wear of moderately crosslinked polyethylene on alumina is 500-fold higher than alumina on alumina. However, under microseparation conditions there is a fourfold reduction in polyethylene wear and a corresponding increase in the wear of the alumina-on-alumina bearing. The polyethylene bearing, therefore, has an approximately thirtyfold higher wear rate under microseparation conditions. A recent study has also

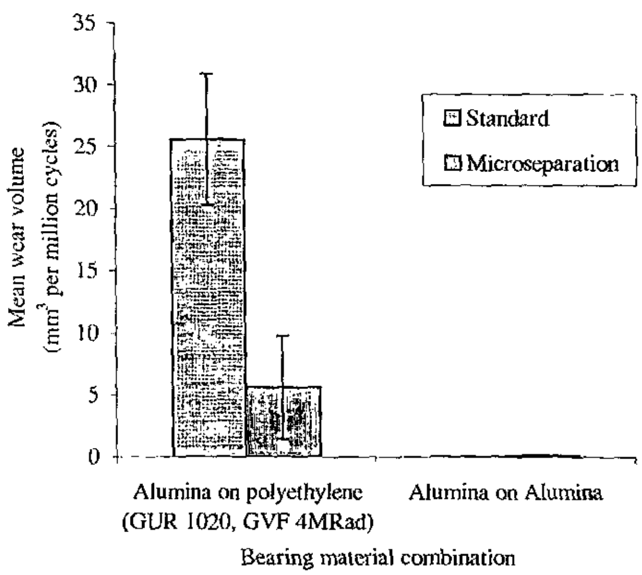

Fig. 7 Comparison of wear of polyethylene on alumina and alumina on alumina under standard and microseparation conditions

shown accelerated wear in metal-on-metal bearings in simulation tests with microseparation [**28**].

A microseparation of 0.7 mm was chosen for this study. Clinically larger separations have been reported for polyethylene cups. In the present *in vitro* simulations larger separations of several millimetres could produce gross dislocation and damage to the joint, which is not supported by a soft tissue capsule. The effect of larger separations may be more damaging for polyethylene acetabular cups. Nevertheless, at mild or moderate separations of less than 1 mm, the wear was substantially reduced, and the results did not support the postulated increase in wear due to elevated multidirectional wear patterns. In contrast, the reduction in volume change may have been assisted by improved lubrication.

Microseparation is believed to be caused by factors such as laxity of soft tissues, translation or subsidence of the components, polyethylene and cement creep. Pederson *et al.* [**29**] have demonstrated increased wear *in vivo* in cementless polyethylene acetabular cups in comparison to cemented cups. Some cemented femoral stems are designed to subside a controlled amount and cement creep can also occur in the acetabulum. These factors may increase microseparation and may contribute to the lower wear of cemented prostheses observed *in vivo*. Surgical procedures that produce a small and controlled amount of separation may lead to a reduction in the wear of polyethylene acetabular cups. This is in contrast to hard-on-hard bearings such as alumina on alumina and metal on metal in which microseparation is damaging and accelerates wear. The selection of more stable fixation systems that do not allow subsidence or migration are clearly important in hard-on-hard bearing couples.

5 CONCLUSION

Swing phase microseparation introduced to the normal gait cycle of a hip simulator reduced the volume change of polyethylene cups when articulated against alumina ceramic heads by a factor of four. This was in contrast to alumina-on-alumina bearings in which microseparation can increase wear.

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