A hip joint simulator study using new and physiologically scratched femoral heads with ultra-high molecular weight polyethylene acetabular cups

P S M Barbour[1], **M H Stone**[2] and **J Fisher**[1]*
[1]School of Mechanical Engineering, University of Leeds, UK
[2]Leeds General Infirmary, Leeds, UK

Abstract: This study validates a hip joint simulator configuration as compared with other machines and clinical wear rates using smooth metal and ceramic femoral heads and ultra-high molecular weight polyethylene (UHMWPE) acetabular cups. Secondly the wear rate of UHMWPE cups is measured in the simulator with deliberately scratched cobalt-chrome heads to represent the type of mild and severe scratch damage found on retrieved heads. Finally, the scratching processes are described and the resulting scratches compared with those found in retrieved cobalt-chrome heads.

For smooth cobalt-chrome and zirconia heads the wear rates were found to be statistically similar to other simulator machines and within the normal range found from clinical studies. An increased wear rate was found with cobalt-chrome heads scratched using either the diamond stylus or the bead cobalt-chrome but the greatest increase was with the diamond scratched heads which generated scratches of similar dimensions to those on retrieved heads. A greater than twofold increase in wear rate is reported for these heads when compared with smooth heads. This increased wear rate is, however, still within the limits of data from clinical wear studies.

Keywords: hip joint simulator, wear, UHMWPE, load conditions, scratch-damaged heads

1 INTRODUCTION

Hip joint simulators are being used regularly for the *in vitro* testing of new prosthetic materials and designs as they provide the best representation of the conditions likely to be found once a component is in clinical service [**1, 2**]. The use of a quasi-elliptical wear path [3–5], cyclic loading [6] and a biological lubricant [7, 8] ensures that the data coming from these studies are relevant to the final application. The conditions of the components can be monitored throughout the test and as the time scale is relatively short compared with *in vivo* lifetimes the degradation of the components over the duration of the test is not usually considered significant. However, components retrieved at revision have shown changes to both the polymer cup [**9**] and metal femoral heads [**10–12**], the ultra-high molecular weight polyethylene (UHMWPE) cups becoming oxidized and brittle [**13–15**] and the heads scratched and roughened [**11, 16**]. There has been a large amount of interest in reliable accelerated aging methods allowing new materials to be tested under new and 'aged' conditions [**17, 18**] but there has been no similar work for the damage or 'ageing' of the metallic components.

Studies of retrieved components show large differences in wear rates for the UHMWPE acetabular cups and some of this variation could be due to differing degrees of head damage. Studies of metallic heads retrieved at revision surgery have shown that the initially smooth metallic surfaces of the femoral head can become damaged *in vivo* and that this can lead to accelerated wear of the UHMWPE leading to premature failure [**19, 20**]. These scratches are thought to be generated by hard foreign bodies of bone, bone cement or metal becoming trapped in the articulating surfaces which leads to the permanent damage of the metallic counterface [**21**]. This damage causes a change in the dominant wear mechanism from adhesive/fatigue to abrasive which accelerates the UHMWPE wear causing rapid loosening due to osteolysis [**22**].

In the past a number of hip joint simulator configurations have been used [**4, 5, 23**] and it has been found that the best method of simulating physiological wear

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* *Corresponding author: School of Mechanical Engineering, University of Leeds, Leeds LS2 9JT, UK.*

rates was to use a biaxial wear path. This is when the head and the cup move in an elliptical or quasi-elliptical track changing the direction of the friction force vector throughout the cycle. However, all of these tests have used smooth, new femoral heads and cups which results in wear data for undamaged head surfaces [**4, 5, 23, 24**].

This study aims to compare the wear of irradiated UHMWPE acetabular cups articulating against new and *in vitro* scratch-damaged femoral heads using a validated hip joint simulator configuration and to develop a simple and reliable method for reproducing *in vivo* scratch geometry. The first phase of this study compares the wear of new components with data from other hip joint simulators and the second phase examines the effect of two *in vitro* scratching methods on the wear rate of UHMWPE acetabular cups and compares the scratch geometry with that found on retrieved femoral heads.

2 MATERIALS AND METHODS

Ten UHMWPE (GUR 1120, Howmedica International Inc., Shannon, Ireland) acetabular cups of 28 mm inside diameter were used throughout this study. The cups had been gamma irradiated in air and were identical in design, material and age since irradiation. Once the sterile packaging was opened the cups were soaked in 0.1 per cent sodium azide solution for 14 days to allow moisture uptake to stabilize prior to being fixed, using acrylic cement, into metallic cup holders ensuring that the centre of the cup was at the centre of rotation of the simulator. The inside surface of the cup was measured using a coordinate measuring machine (CMM) (Keely Measuring Company, Derby, UK) to provide the datum surface for calculating wear. The cups were remeasured after 500 000 cycles to allow the creep deformation to stabilize and subsequently at intervals of 1 million cycles.

In phase one, five cobalt-chrome (Francobal Forged 'C', Howmedica International Inc.) and five zirconia (Zircone Prozyr 'ZR', Howmedica International Inc.) modular femoral heads of identical design and batch numbers were used. In phase two, ten cobalt-chrome heads were used, four remaining undamaged, three scratched using a diamond stylus and three with a spherical cobalt-chrome bead embedded into a UHMWPE pin. A diamond stylus, with a tip diameter of 25 μm and included angle of 90°, was used with a load of 2.5 N to generate three equally spaced scratches extending 180° from the equator, through the pole and back down to the equator to form a regular asterisk on three heads. A cobalt-chrome bead of 250 μm diameter embedded into a UHMWPE pin was used with a load of 80 N to generate a similar scratch pattern on three heads, a new bead being used for each head.

The baseline surface roughness of the femoral heads was measured using a contact profilometer (Form Talysurf, Rank Taylor Hobson, Leicester, UK) at three places on each head, twice across the pole at right angles and once along the equator. Table 1 shows the surface roughness parameters from phase 1 where it can be seen that the zirconia heads are considerably smoother than the cobalt-chrome heads. Table 2 shows the surface roughness of the heads used in phase 2 where it can be seen that the diamond stylus generates the most severe damage to the surfaces with the highest peak R_p and deepest valley R_v values increasing significantly.

A ten-station hip joint simulator (Prosim Limited, Manchester, UK) with two independently controlled axes of rotation and a single axis of loading was used throughout this study. The prostheses were mounted in holders in an approximate anatomical position with the cup at an angle of 35° to the horizontal plane (see Fig. 1). The flexion/extension (F/E) motion was applied to the head in a modified sine wave with an amplitude of $+30°$ and $-15°$ and a frequency of 1 Hz. The internal/external (I/E) rotation was applied to the cup as a sine wave with an amplitude of $\pm 10°$ at an identical frequency but 270° out of phase with the flexion/extension motion. The load cycle consisted of two peaks of 3 kN separated by a trough to 1 kN applied smoothly over 65 per cent of the cycle time with a residual force of 100 N over the remainder of the cycle. This configuration has been shown to give a biaxial wear path between the articulating surfaces resulting in wear rates similar to those found in surviving hip prostheses [**4, 5, 23, 24**].

The components were enclosed by a flexible bag sealed to the cup and head holders containing the bovine serum lubricant. As is consistent with this type of wear testing the bovine serum (newborn calf serum, sterile, filtered (Harlan Sera-Lab Limited, Loughborough, UK)) was diluted to 25 per cent with a 0.1 per cent w/v solution of sodium azide to reduce the protein levels to those

Table 1 Surface roughness parameters (μm) for new femoral heads used in phase 1 (mean ± 95% confidence limits, 20 × 0.25 mm cut-off)

Parameter	CoCr	Zirconia
Roughness average R_a	0.017 ± 0.003	0.001 ± 0.000
R.m.s. roughness average R_q	0.027 ± 0.005	0.006 ± 0.001
Highest peak R_p	0.152 ± 0.057	0.037 ± 0.018
Average peak height R_{pm}	0.053 ± 0.011	0.017 ± 0.003
Deepest valley R_v	0.317 ± 0.074	0.025 ± 0.008

Table 2 Surface roughness parameters (μm) for scratched femoral heads used in phase 2 (mean ± 95% confidence limits, 20 × 0.25 mm cut-off)

Parameter	Unscratched	Embedded bead	Diamond stylus
Roughness average R_a	0.007 ± 0.001	0.017 ± 0.004	0.035 ± 0.019
R.m.s. roughness average R_q	0.010 ± 0.002	0.038 ± 0.012	0.189 ± 0.143
Highest peak R_p	0.085 ± 0.080	0.278 ± 0.114	2.909 ± 2.310
Deepest valley R_v	0.072 ± 0.029	0.541 ± 0.029	2.686 ± 1.339

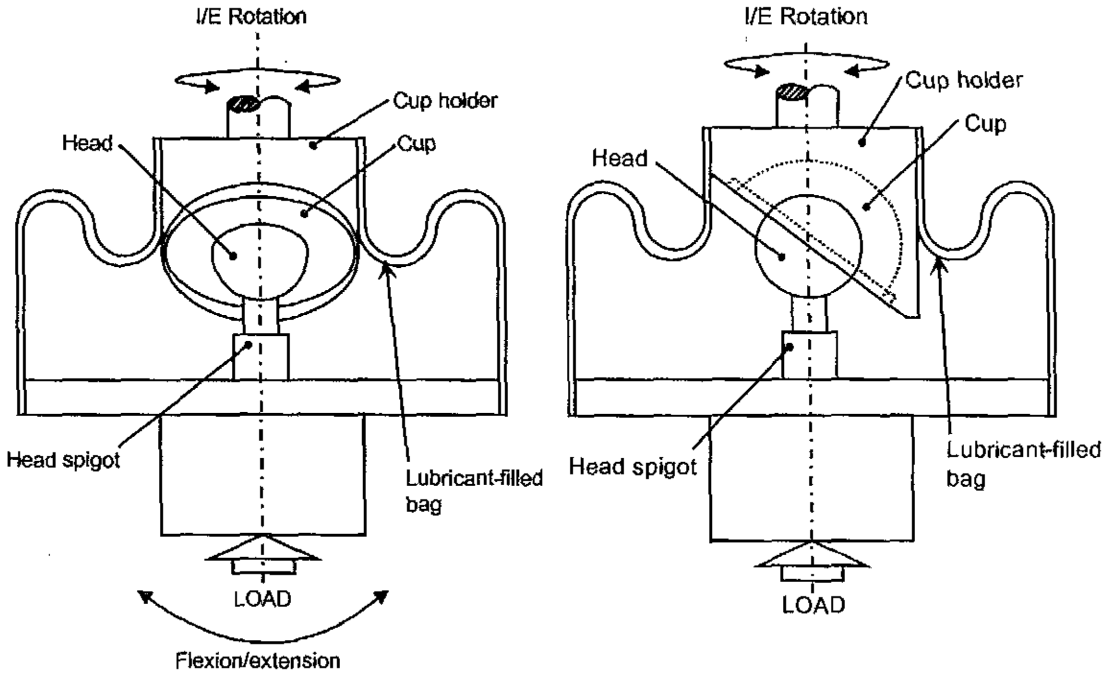

Fig. 1 Schematic diagram of Prosim hip joint simulator

of synovial fluid and inhibit bacterial growth. During testing the bovine serum was replaced every 100 h. The cups were measured using the CMM every 1 million cycles allowing the wear volumes and penetrations to be calculated and the heads inspected for damage.

3 RESULTS

3.1 Phase 1: wear rates with unscratched heads

Figure 2 shows the mean wear rates for the UHMWPE acetabular cups when articulating against the unscratched cobalt-chrome and zirconia femoral heads. From this it can be seen that although the metal heads were rougher, this difference was insufficient to cause a statistically significant increase in wear rate ($P > 0.05$, Student's t test). The wear was observable as a smoothing of the original machining marks in the superior quadrant of the cup giving it a shiny appearance. All the heads remained smooth throughout this test phase and no transfer film was observed.

3.2 Phase 2: wear rates with scratched femoral heads

After 4 million operating cycles the zirconia heads were replaced with new cobalt-chrome heads and six heads were scratched to represent mild and severe damage as described above. The test was restarted and run for another 2 million operating cycles with wear being measured at intervals of 1 million cycles. A control group of

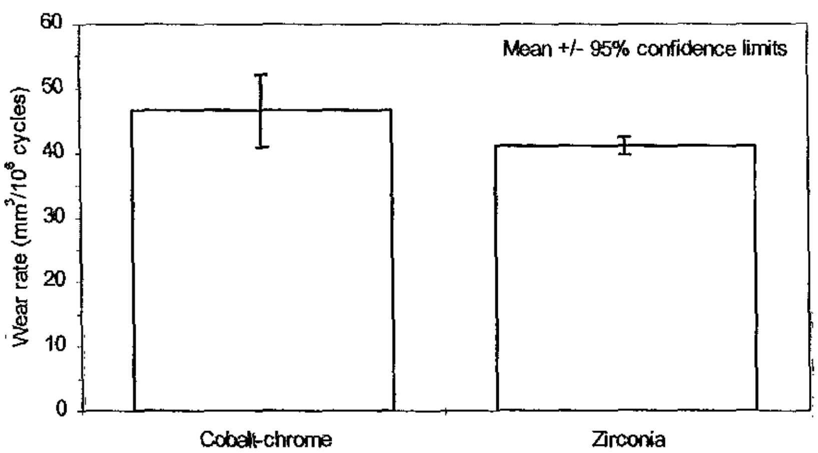

Fig. 2 UHMWPE wear rates with unscratched femoral heads

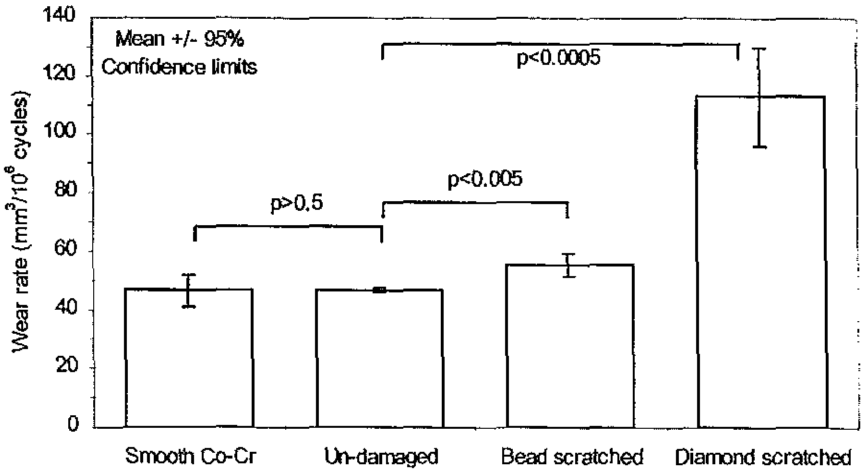

Fig. 3 UHMWPE wear rates with scratched femoral heads

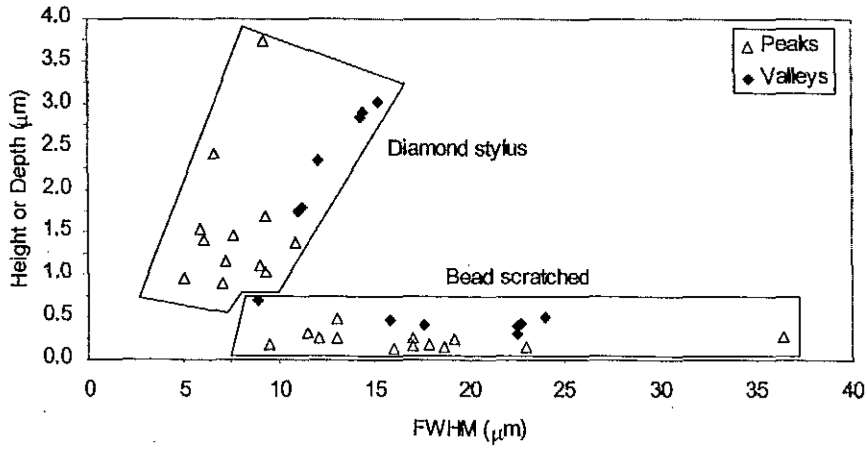

Fig. 4 Geometry for diamond stylus and embedded bead scratches from phase 2

four undamaged heads was retained. The mean acetabular cup wear rates are shown in Fig. 3 and were compared, using Student's t test, with the undamaged control group. It can be seen that there was no statistical difference between the smooth cobalt-chrome heads in phase 1 and the undamaged control group in phase 2 ($P > 0.5$). A small increase in wear rate was found with the bead-scratched heads (mild damage) which was statistically significant to $P < 0.005$, mainly due to the small error bars on the control group. The most dramatic increase in wear was seen when the control group were compared with the severely damaged diamond-scratched heads. In this case the wear rate more than doubled and was statistically different to $P < 0.0005$. The scratch geometry was measured at the beginning and end of phase 2 testing and no change in the geometry was found.

3.3 Scratch geometry

The peak height and valley depths are plotted against full-width half-maximum (FWHM) in Fig. 4 which indicates that scratches made by the diamond were significantly higher and deeper and narrower than the scratches made by the bead. The FWHM was defined as the width of the peak or valley measured at half its height or width as shown in Fig. 5 as this method avoided problems defining the exact end of the surface feature which can be difficult in some circumstances.

This difference in geometry was due to the difference

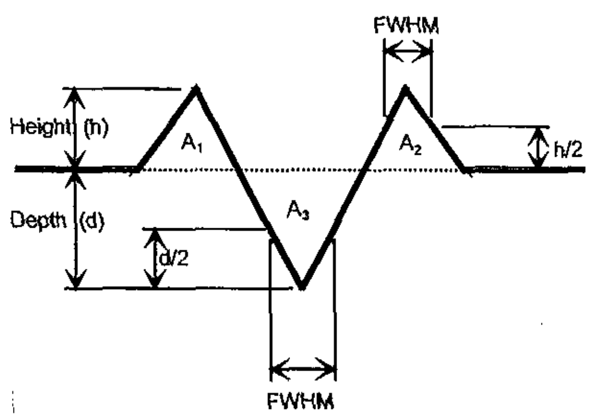

Fig. 5 Scratch geometry details

in point radius and the relative stiffness between the point and the femoral head. At the scratch depths in this study the diamond stylus can be considered to be spherically ended as the cone angle did not affect the scratch shape until scratches approximately 8 μm deep were generated. It was also likely that the bead had flattened during scratching leading to wide shallow scratches as the materials were of similar hardness. From these scratch geometries it was no surprise that the diamond-scratched heads led to greater wear of the UHMWPE cups.

4 DISCUSSION

4.1 Phase 1: wear rates with unscratched heads

The wear rate results for the smooth femoral heads in phase 1 indicated that this hip joint simulator reproduced physiological wear rates in the laboratory. Studies of explanted cups retrieved due to aseptic loosening after sliding against metallic heads have shown wear rates of 55–74 mm^3/year [**19, 25**] and radiographic studies of functioning cups have shown wear rates of 13–148 mm^3/year [**26, 28**]. Another study of functioning cups retrieved at post-mortem puts the wear rate at 39.8 ± 32.0 mm^3/year [**29**]. Therefore the wear rates generated in this simulator were of the correct order considering the age of the UHMWPE and the lack of scratch damage to the femoral heads.

If these results are compared with other hip joint simulators [**5, 23, 30**] this configuration gave similar results when used with similar materials. For example, Wang *et al.* [**23**] in the MTS (materials testing system) simulator found a wear rate of 43 ± 3 $mm^3/10^6$ cycles for gamma-irradiated UHMWPE and McKellop and Röstlund [**30**] using the MMED simulator obtained slightly lower wear rates of 32–38 $mm^3/10^6$ cycles. The movement of the load vector with the flexion/extension has not produced any measurable difference in the wear rates when compared with an almost identical simulator where the load vector is fixed. In an earlier test using similar cups and heads, Barbour *et al.* [**24**] found a wear rate of 38 ± 4 $mm^3/10^6$ cycles when the load vector was fixed in the superior/inferior direction. Also, Barbour *et al.* [**24**] reported no statistical difference in wear rates between zirconia and cobalt-chrome femoral heads.

4.2 Phase 2: wear rates with scratched femoral heads

The deliberate scratching of the cobalt-chrome heads led to a significant increase in cup wear rates. The bead-scratched heads representing mild damage showed a small increase in wear but the severely damaged diamond stylus-scratched heads showed a more than twofold increase in wear rate. This increase was due to the introduction of an abrasive wear mechanism caused by the raised edges of the scratch accelerating the wear of the softer UHMWPE. If the results for the severely damaged group are compared with clinical results from radiographic studies of functioning cups [**26–28**] the wear rates were still less than the maximum values found from *in vivo* wear studies. This indicates that the model of severely scratching femoral heads with a diamond stylus has a role in testing bearing materials against a head with damage representative of that found *in vivo*.

4.3 Scratch geometry

One of the aims of this study was to reproduce the scratch geometry found on retrieved femoral heads by a simple and reliable method in the laboratory. The diamond stylus generated deep, narrow scratches with sharp, high peaks whereas the embedded bead produced shallower, wide scratches with correspondingly shorter peaks.

A previous study [**21**] analysed the scratch geometry from ten cobalt-chrome heads retrieved during revision surgery and this data was analysed again using the same parameters described above. If the scratch valley geometry from this study is compared with that from the retrieved heads in Fig. 6 it can be seen that diamond stylus scratches are deep and narrow compared to *in vivo* scratches which are more like the embedded bead scratches. However, in Fig. 7 the peak geometry is compared and it can be seen that there is a wide variation from the retrieved heads which are of the same order in height as the diamond stylus scratches but significantly wider. The peaks on the embedded bead scratches are lower and narrower than the *in vivo* scratches.

As it is the peaks at the edge of the scratch which will generate abrasive wear the diamond stylus scratches will be more like the *in vivo* scratches and hence it is likely that these will generate the most physiological accelerated wear due to an abrasive wear mechanism. With the scratches on the retrieved heads being significantly wider than either of the *in vitro* methods and shallower than the diamond stylus scratches it is apparent that the material ploughed out of the valley is not present on the scratch edges. Figure 8 shows the area ratio as calculated using equation (1), an area ratio of unity indicates that none of the material has been transferred from the valley to the peak. It can be seen that with the *in vitro* methods most of the material removed from the scratch valley has been transferred to the scratch edges whereas with the retrieval scratches 80 per cent of the material has been lost from the scratch valley with only 20 per cent being transferred to the edges. These mean that either the material is being progressively worn away from the raised edges after the scratch occurred and before measurement, or it is not originally being transferred. This is important as it may indicate that the actual

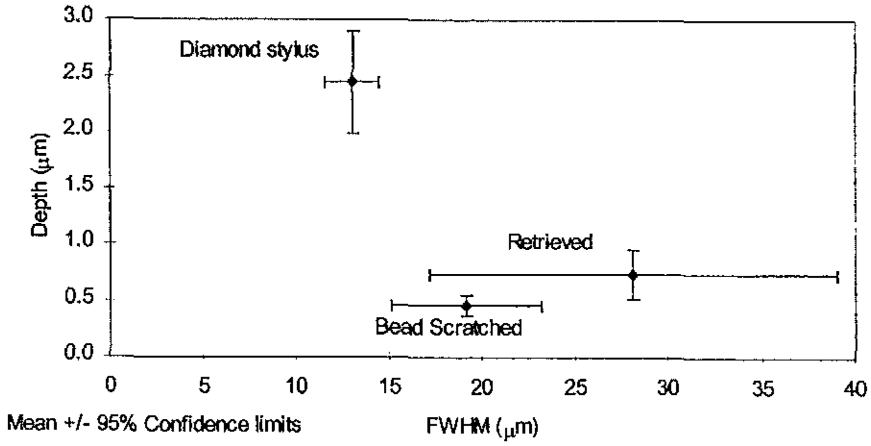

Fig. 6 Comparison of valley geometry between retrieved, diamond and bead scratches

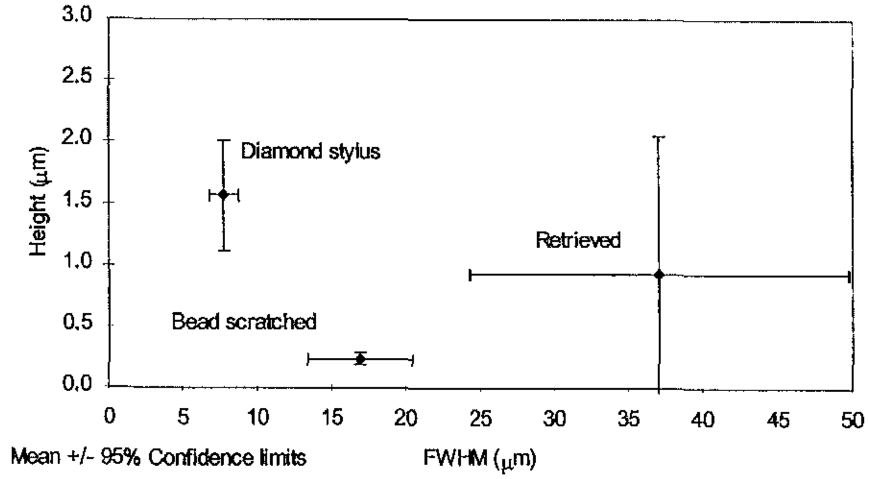

Fig. 7 Comparison of peak geometry between retrieved, diamond and bead scratches

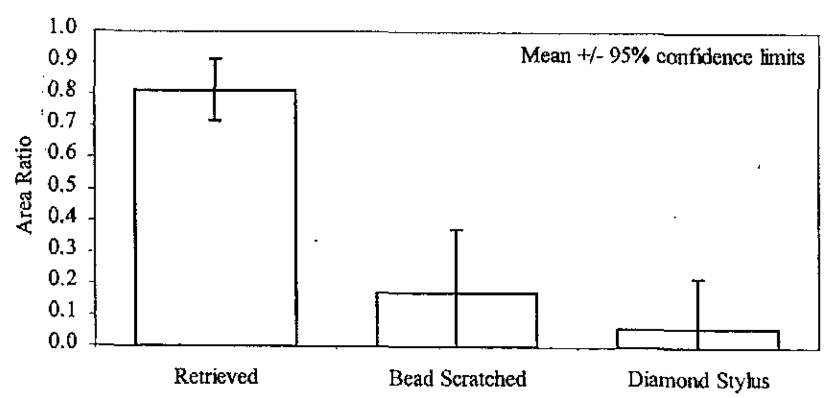

Fig. 8 Area ratios for the different scratching methods

functional scratch geometries *in vivo* may be more severe than those found on retrieval (Fig. 5).

$$\text{Area ratio} = \frac{\text{valley area} - \text{peak area}}{\text{valley area}} = \frac{A_3 - (A_1 + A_2)}{A_3} \quad (1)$$

In order for the peaks or raised edges to occur during scratching, metal must flow plastically requiring significant amounts of plastic strain to occur over a finite time period as the indentor passes any particular point along the scratch. If the scratching were to occur at speeds which prevented plastic flow the resulting strain hardening would cause chips to form and material would be lost rather than form sharp edges [31]. However, if the edges did form and were subsequently removed (this was not the case during this study) this process would occur over time. Hence, the time since the scratch was formed would relate to the area ratio with the area ratio increasing as the edges are removed. Thus older scratches would have greater area ratios implying the effect of an old scratch on the UHMWPE wear rate would decrease over time. However, the cumulative effect of an increased wear rate over a long period of time may be significant as a large number of wear debris particles could have formed. Therefore if a single scratch formed on a smooth femoral head, its effect on the UHMWPE wear rate may decrease over time but subsequent scratching events could maintain high UHMWPE wear rates.

Overall, the diamond stylus was found to generate more reproducible scratches as it can be assumed to remain perfectly stiff relative to the head material. Therefore the only variables to consider are the point radius and applied load, the cone angle may become important for deep scratches or very small point radii where the depth is greater than the transition point between the cone and the radius. With the embedded bead not only are the bead size, material, substrate material properties and applied load important but also there is the possibility that the bead deforms or breaks down during scratching which leads to less reproducible scratches.

5 CONCLUSIONS

The first phase of this study shows that changing the configuration of a hip joint simulator from a fixed load vector [24] to one which moves with the flexion/extension motion has no significant effect on the resulting wear rates with smooth femoral heads. When the data were compared with previous studies which used components of similar materials the wear rates can be seen to be statistically similar. Also, no statistical difference was found between cobalt-chrome and zirconia ceramic heads.

The second phase of this study measured the wear rate of UHMWPE cups when articulated against cobalt-chrome heads scratched *in vitro* by the two methods described above. From this it was found that the diamond-scratched heads produced wear rates more than twice as high as those of undamaged femoral heads. This wear rate was also of the same order as the maximum clinical wear rates found from radiographic studies. The geometry of the diamond stylus scratches was found to be narrower and deeper than those on the retrieved heads with the raised edges of the scratch being similar in height but narrower. The scratches made with a cobalt-chrome bead embedded into a UHMWPE pin generated the smallest scratches and hence only caused a small increase in the cup wear rate. If the ratio between the areas of the valley and the edges is studied it can be seen that the scratches on the retrieved heads show that 80 per cent of the material gouged out from the valley was lost whereas on the *in vitro* scratches less than 20 per cent is lost. The remainder forms the raised edges which lead to the increased abrasive wear and higher wear rates.

Therefore it is possible to conclude that using a diamond stylus to generate physiological-type scratches *in vitro* can simulate *in vivo* wear when the femoral head has become severely damaged.

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