JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE **12** (2001) 1053–1056

Long-term wear of HIPed alumina on alumina bearings for THR under microseparation conditions

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The long term wear and wear debris generated in HIPed alumina on alumina bearings for hip prostheses with microseparation *in vitro* is compared to standard simulator conditions and *ex vivo* specimens. Microseparation studies were completed to five million cycles at two severity levels in attempts to rigorously evaluate the long-term tribological performance of the bearings. During the first million cycles (bedding-in) of the microseparation tests characteristic stripe wear was observed on all of the femoral heads with a matching area on the rim of the acetabular inserts. Under mild microseparation conditions an average wear rate of 0.55 mm^3/million cycles was observed during the initial million cycles which reduced to a steady state level of 0.1 mm^3/million cycles. Under more severe conditions an average wear rate of 4.0 mm^3/million cycles was observed during bedding-in which reduced to a steady state level of 1.3 mm^3/million cycles. These compare to a bedding-in wear rate of 0.11 mm^3/million cycles and steady-state wear rate of 0.05 mm^3/million cycles for the same material under normal simulation with no microseparation. Furthermore, under microseparation the wear mechanisms and wear debris were similar to those observed in previous alumina retrieval studies with debris ranging from 10 nm to 1 μm in size.

1. Introduction

Substantial differences have been found between the wear of alumina ceramic on ceramic hip prostheses *in vivo* [1] and the wear found in standard simulator tests [2]. *Ex vivo* specimens have shown wear rates of the order of 1 mm^3/year, stripe wear on the head with surface roughening, intergranular fracture and wear debris from 10 nm up to 1 μm in size [3]. Standard simulator studies have shown wear rates of less than 0.1 mm^3/million cycles, with only relief polishing wear of the alumina ceramic [2]. It has been recently discovered that hip joint separation occurs *in vivo* during normal gait and that introducing microseparation of the femoral head and acetabular insert into the swing phase of the hip joint simulator cycle, produces rim contact on heel-strike and stripe wear of the head similar in quantity and wear mechanism to that found in *ex vivo* specimens [4, 5]. As microseparation testing is still in its infancy there remain questions relating to test variability, conditions and long term performance of the bearings.

The purpose of this study was to evaluate the long-term performance of hot isostatic pressed (HIPed) alumina/alumina hip prostheses under mild and severe microseparation conditions. Wear rate, surface analysis and debris morphology was evaluated and the results compared to standard simulator studies and retrieval specimens.

2. Materials and methods

All components were commercially available and manufactured from HIPed third generation alumina ceramic. The Leeds MKII six station hip simulator was used providing a physiological twin peak time dependant loading curve with an elliptical wear path. Inserts were positioned anatomically ''on top'' inclined at 45° to the horizontal axis (Fig. 1). Heads underwent flexion/extension +30° to −15° and the insert internal/external rotation ±10°(2).

Under standard conditions the Leeds MKII simulator applies a small positive swing phase load which ensures the head remains located correctly in the insert. To provide microseparation a small lateral to medial load was applied with a spring. Microseparation conditions were varied by altering the swing phase load from 400 N for mild to 50 N for severe separation. The medio-lateral separation load was regularly adjusted in each of the six stations to provide between 200 and 500 μm of medio-lateral motion.

Tests were carried out for five million cycles with 25%

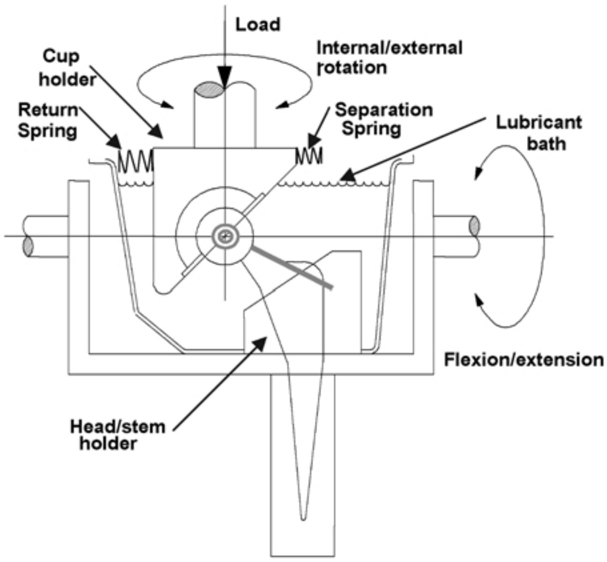

Figure 1 *In vitro* microseparation schematic.

bovine newborn calf serum as a lubricant. Nine pairs of components were tested, three with mild and three with severe separation, and three under standard conditions. Wear was determined gravimetrically every million cycles using a Mettler microbalance with an accuracy of 0.01 mg. Surfaces were analyzed with a Taylor Hobson 3D Form Talysurf and scanning electron microscope (SEM). The wear debris were analyzed using digestion centrifugation and transmission electron microscopy (TEM) [6].

3. Results and discussion

This is the first long term simulator study of alumina on alumina hip joint prostheses which includes micro-separation. With this method a small lateral to medial load was applied to the acetabular insert, which, during the swing phase when the joint load was reduced, produced medial and superior translation of the insert relative to the head. This movement was limited by the radial clearance between the articulating components and ceased when the superior rim of the insert contacted the head. The impact occurred with reapplication of the joint load at heel-strike where, momentarily, the load was supported by the small contact at the rim before the head relocated in the insert. When the swing phase load in the simulator was reduced it became easier for the medial separation force to both overcome friction and to produce superior translation between the head and insert. This increased the velocity of the insert and upon impact with the head produced an increased momentum and impact energy which resulted in a more severe microseparation condition. The low swing phase load may be representative of a model of greater joint laxity.

Average wear volumes are summarized in Fig. 2 for severe, mild and no separation. It can be seen that in the microseparation mode the wear with the mild and the severe conditions increased considerably compared to the standard condition.

Wear rates are further summarized in Fig. 3 during bedding-in (0–1 million cycles), steady-state (1–5 million cycles) and overall (0–5 million cycles). For standard

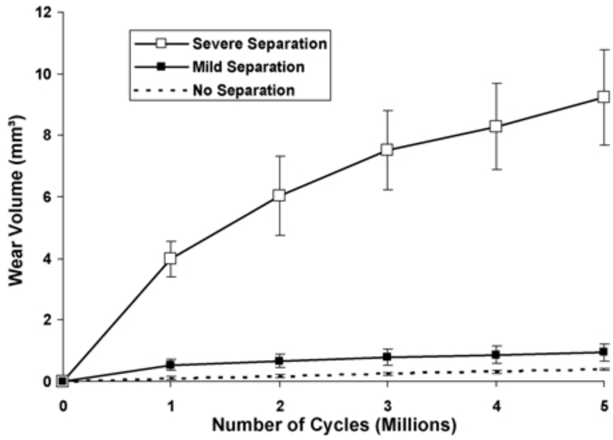

Figure 2 Wear volumes $\pm$ standard error, n = 3 for each group.

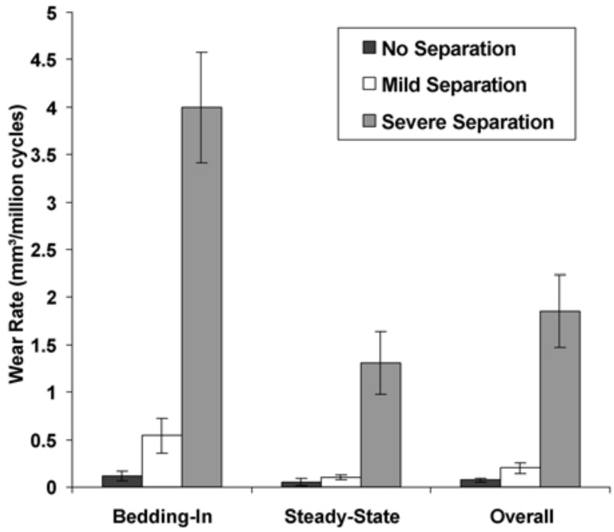

Figure 3 Average wear rates of HIPed alumina $\pm$ standard error, $n = 3$ for each group.

conditions a bedding-in wear rate of $0.11 \pm 0.05\,\text{mm}^3/$million cycles and steady-state wear rate was $0.05 \pm 0.02\,\text{mm}^3/$million cycles was found. With mild separation, a bedding-in wear rate of $0.55\,\text{mm}^3/$million cycles was observed during the first million cycles when the stripe wear on the head was initiated and the wear on the rim of the insert occurred. However, after the first million cycles the wear rate reduced considerably to produce a steady-state wear rate of $0.1\,\text{mm}^3/$million cycles.

Severe separation produced a significantly higher bedding-in wear rate of $4.0\,\text{mm}^3/$million cycles during the first million cycles, once again when the stripe wear on the head was initiated and the wear on the rim of the insert occurred. After the first million cycles the wear rate reduced to produce a steady-state wear rate of $1.3\,\text{mm}^3/$million cycles. This was significantly higher than for both mild and standard conditions and resulted in an overall wear rate of $1.84\,\text{mm}^3/$million cycles. No severe wear, as reported for some historical retrieved Mittelmeier alumina couples [1], was observed with any of the microseparation modes although a part of the articulation occurred by an unintended convex on convex contact on the rim.

Under both mild and severe separation a stripe of wear was formed on the heads (Figs 4a and 4b), which

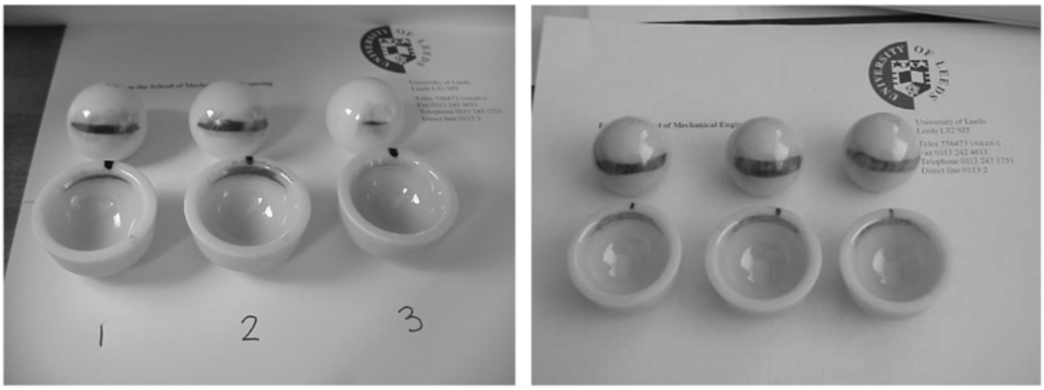

Figure 4a Pencil rubbing across wear stripes from mild (left) and severe (right) separation.

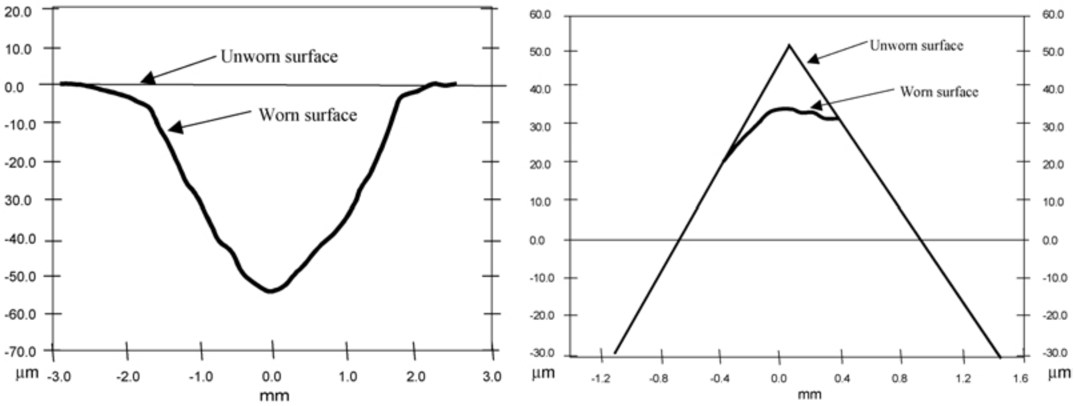

Figure 4b Talysurf across head (left) and rim stripe (right), curve fit to unworn surface.

increased the surface roughness R*a* from < 0.01 μm to between 0.14 and 0.3 μm. Under the SEM the stripe area on the heads showed inter-granular fracture similar to those from clinical retrievals [4]. Corresponding surface change on the rim was also observed for both conditions.

The simulator produced a regular pattern of micro-separation. The resulting stripe area was narrower than generally found in historical non-HIPed Mittelmeier first generation alumina retrievals, but, very similar to the stripes observed in early retrieved HIPed alumina retrievals [4]. *In vivo* a broader range of movement occurs and this may lead to the wider stripe observed on the retrievals. Furthermore, most non-HIPed alumina explant data relates to the condition where acetabular cup fixation was less than optimal, and it is believed that this additional instability may contribute to further micro-separation and the formation of a broader stripe. *Ex vivo* average wear rates of well-positioned non-HIPed alumina prostheses have been reported in the range of 1–5 mm^3/year. In comparison the two well-positioned early HIPed alumina retrievals of Nevelos [4] were found to have stripe wear volumes of approximately 0.5 mm^3 after one year, which is comparable to the wear found during the initial million cycles under mild separation conditions in this study.

Typically under standard simulator conditions the wear debris was uniformly small with a mode of the size distribution being 10 nm. Debris analysis under both mild and severe microseparation showed wear debris typically ranging in size from 10 to 1000 nm (mean $=$ 4220 nm), similar to clinical retrieval studies of non-HIPed alumina hip prostheses. It is postulated that the small nanometer sized debris is formed from normal articulation of the joint while the larger shards are formed from the intergranular fracture as a result of the action of microseparation.

4. Conclusions

Long term *in vitro* microseparation of HIPed alumina ceramic bearings produced overall average wear rates of 0.2 and 1.84 mm^3/million cycles under mild and severe conditions respectively, reproducing a range of clinically relevant levels of wear and wear patterns which was higher than under standard conditions. A characteristic stripe of wear was observed on the femoral heads with a corresponding area on the rim of the acetabular inserts. Although microseparation produced an unintended tribological situation no severe wear, as reported for some historical retrieved Mittelmeier bearings, occurred and a steady state wear was established.

The wear debris from microseparation testing was similar to debris from retrieved tissues with both small nanometer sized particles and larger particles up to one micrometer in size. The mean particle size was 42 nm. Even with severe microseparation the wear rates of HIPed alumina ceramic bearings remained low and are predicted to solve the problem of long-term particle induced osteolysis for total hip joint prostheses.

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*Received 14 May
and accepted 21 May 2001*