Long Term Simulator Studies of Alumina Ceramic/Ceramic Hip Joints with Swing Phase Micro-separation; Analysis of Wear and Wear Debris Generation

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Introduction

Significant differences have been found between wear of alumina ceramic/ceramic hip joints *in-vivo* (1) and the wear found in standard simulator tests (2). *Ex Vivo* specimens have shown wear rates of the order of 1mm³/year, stripe wear on the head with surface roughening, inter-granular fracture and wear debris from 10nm up to 1µm in size(3). In contrast standard simulator studies have shown wear rates of less than 0.1 mm³/million cycles, with only relief polishing wear of the alumina ceramic (2). It has been recently discovered that introducing micro-separation(4) of the head and insert into the swing phase of the hip joint simulator cycle, produced rim contact on heel-strike and stripe wear of the head similar in size and wear mechanism to that found in *ex-vivo* specimens (4).

The aim of this in vitro study was to compare the long term wear and wear debris generated in alumina/alumina hip joints with micro-separation during the swing phase, to standard simulator conditions and *ex-vivo* specimens.

Materials and Methods

Hip joint simulator studies were carried out on a physiological hip joint simulator. The insert was positioned anatomically 'on top' inclined at 60° to the horizontal axis. The head underwent flexion/extension +30° to -15° and the insert internal/external rotation ±10°. A twin peak time dependant loading curve was applied vertically to approximate the loading conditions found in-vivo. Standard conditions comprised of a small positive swing phase load which ensured the head remained located correctly in the insert. Micro-separation (200-400µm) during the swing phase was achieved by applying a small medial to lateral load which produced lateral and inferior displacement of the head, which repositioned against the superior rim of the insert on heel-strike followed by relocation in the insert (4). Tests were carried out for 5 million cycles with 25% bovine serum as a lubricant. Wear was determined gravametrically every million cycles, surfaces analysed with a 3D form Talysurf and wear debris analysed using digestion centrifugation and TEM. Three HIPed alumina THR's were tested under micro-separation conditions and three under standard conditions.

Results

Table 1 shows the volumetric wear rates in mm³/million cycles . The wear rates were extremely low (~0.1mm³/million cycles) under standard simulation conditions. Wear increased markedly with micro-separation, particularly during the first million cycles (0.55mm³/million cycles) when the stripe wear on the head was initiated and the wear on the rim of the insert occurred (Figure 1). However, after the first million cycles the micro-separation stabilised and the wear rate reduced considerably to produce an overall wear rate of 0.2 mm³/million cycles. This was significantly higher than for standard conditions.

There was little change in the surface roughness of the head and insert during standard simulation testing (R*a* <0.01µm). However, under micro-separation a stripe of wear was formed on the head which increased the surface roughness R*a* to between 0.14 and 0.3 µm. The wear surface showed inter-granular fracture under SEM. Under standard conditions the wear debris was uniformly small with a mode of the size distribution being 10nm. Under micro-separation the distribution of wear debris was small particles 10 to 100nm, but also larger particles in the range of 100 to1000nm.

Table 1 - Wear Rates (mm³/million cycles) mean ±95%CL

	Bedding-in	Overall
Standard	0.11 ± 0.05	0.07 ± 0.04
Micro-Separation	0.55 ± 0.39	0.2 ± 0.1

Figure 1. “Stripe” wear of HIPed alumina components

Discussion

Clinical retrieval studies of non-HIPed alumina THR's have shown a range of wear rates around 1mm³/million cycles with stripe wear and wear debris ranging from less than 10nm to 1000nm in size. Stripe wear on the head (Figure 1) has also been found on some HIPed alumina retrievals(1). This is believed to be associated with micro-separation of the head and insert during the swing phase of gait followed by rim contact at heel strike(4). This is the first long term simulator study of alumina/alumina hips which includes micro-separation. In the initial million cycles the wear rate increased to over 0.5 mm³/million cycles and the stripe wear was generated on the head with wear mechanisms and debris reproducing those found *in-vivo*. Surprisingly, after 1 million cycles the wear rate stabilised at a lower level to produce an overall wear rate of 0.2mm³/million cycles. The simulator produced a regular pattern of micro-separation and the resulting stripe area was narrower than generally found *in ex-vivo* specimens. *In-vivo* a broader range of movement occurs and this may lead to the wider stripe and perhaps greater wear. Furthermore, most explant data relates to the condition where insert fixation was less than optimal, and it is believed that this additional instablity may contribute to the formation of a broader stripe.

Soft tissue laxity and micro-separation caused acceleration of wear in ceramic bearings, but this stabilised to a low level in long-term tests.

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References

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