

# LONG TERM SIMULATOR STUDIES OF ALUMINA / ALUMINA CERAMIC HIP JOINTS WITH SWING PHASE MICROSEPARATION. 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*<sup>(1)</sup> and the wear found in standard simulator tests<sup>(2)</sup>. *Ex vivo* specimens have shown wear rates of the order of 1 mm<sup>3</sup> per year, stripe wear on the head with surface roughening, intergranular fracture<sup>(1)</sup> and wear debris from 10 nm up to 1 µm in size<sup>(3)</sup>. In contrast standard simulator studies have shown wear rates of less than 0.1 mm<sup>3</sup>/million cycles, with only relief polishing wear of the alumina ceramic<sup>(2)</sup>. It has been recently discovered that introducing microseparation<sup>(4)</sup> of the head and cup 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 that found in *ex vivo* specimens<sup>(4)</sup>.

The aim of this *in vitro* study was to compare the long term wear and wear debris generated in alumina / alumina hip joints with microseparation 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 cup was positioned anatomically 'on top' inclined at 60° to the horizontal axis. The head underwent flexion extension + 30° to - 15° and the cup internal external rotation ± 10°. A twin peak time dependent 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 cup. Microseparation (200 - 400 µm) during swing phase was achieved by applying a small medial lateral load which produced lateral and inferior displacement of the head, which relocated against the superior rim of the cup on heel strike followed by relocation in the cup<sup>(4)</sup>. Tests were carried out for 5 million cycles with 25% bovine serum as a lubricant. Wear was determined gravimetrically every million cycles, surfaces analysed with a 3D form Talysurf and wear debris analysed using digestion centrifugation and TEM. Three HIPED alumina heads and cups were tested under microseparation conditions and three under standard test conditions.

## Results

Table 1 shows the volumetric wear rates in mm<sup>3</sup>/million cycles. The wear rate was extremely low (0.1 mm<sup>3</sup>/million cycles) under standard conditions. Wear increased markedly with microseparation simulation, particularly during the first million cycles (0.55 mm<sup>3</sup>/10<sup>6</sup> cycles) when the stripe wear on the head was initiated and wear on the rim of the cup occurred. However, after the first million cycles the microseparation stabilised and the wear rate reduced

considerably to produce an overall wear rate of 0.2 mm<sup>3</sup>/million cycles. This was significantly higher than for standard conditions.

	Bedding in	Overall Wear
Standard	0.11 ± 0.05	0.07 ± 0.04
Microseparation	0.55 ± 0.39	0.2 ± 0.1

**Table 1 - Wear Rates mm<sup>3</sup>/million cycles mean ± 95% CL**

There was little change in the surface roughness of the head and cup under standard conditions, but the microseparation produced stripe wear in the head and increased the surface roughness  $R_a$  to between 0.14 to 0.3 µm. The wear surface showed intergranular fracture under SEM. Under standard conditions the wear debris was uniformly small with a mode of the size distribution being 10 nm. Under microseparation the distribution of wear particles was small particles 10 to 100 nm, but also larger particles in the range 100 to 1000 nm.

## Discussion

Clinical retrieval studies of alumina/alumina have shown a range of wear rates around 1 mm<sup>3</sup> / million cycles and additionally wear debris ranging from less than 10 nm in size to 1000 nm in size. Most importantly, stripe wear on the head has been found on the majority of explanted components<sup>(1)</sup>. This is believed to be associated with microseparation of the head and cup during the swing phase of gait followed by rim contact at heel strike<sup>(4)</sup>. This is the first long term simulator study of alumina / alumina hips which includes microseparation. In the initial million cycles the wear rate increased to over 0.5 mm<sup>3</sup> and the stripe wear was generated on the head and wear mechanisms and debris replicated those found *in vivo*. Surprisingly, after one million cycles the wear rate stabilised at a lower level to produce an overall wear rate of 0.2 mm<sup>3</sup>/million cycles. The simulator produced a regular pattern of microseparation and the resulting stripe area was narrower than found in *ex vivo* specimens. *In vivo* a wider range of movement occurs and this may lead to the broader stripe and perhaps greater wear. However, most explant data relates to prostheses where cup fixation was less than optimal and this may lead to additional acceleration of wear. Soft tissue laxity and microseparation leads to acceleration of wear in ceramic ceramic bearings, but this stabilised to a low level in long term tests.

1. Nevelos et al. Biomaterials 20, 1833-1840, 1999.
2. Nevelos et al. Trans 45<sup>th</sup> ORS 852, 1999.
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4. Nevelos et al. J. Arthroplasty, 15, 793-795, 2000.

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