WEAR DEBRIS GENERATION IN ALUMINA-ALUMINA TOTAL HIP JOINTS, AN IN VIVO AND IN VITRO COMPARISON.

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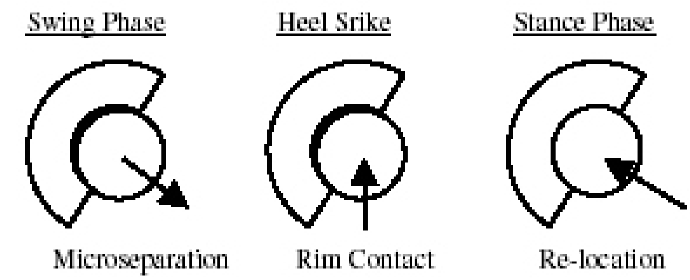
Introduction
There is currently much interest in alumina-alumina bearings and their potential to provide an osteolysis free solution for hip arthroplasty. The wear volumes of these bearings have generally been reported to be low (of the order of 1-5 mm^3 per annum or less) from *in vivo* studies [1], however, little is known about the wear particles generated. Limited clinical studies have shown contradictionary evidence and direct comparisons are difficult due to the different methods used for particle characterisation [2,3]. Recently a new simulation method was developed which, for the first time, produced clinically relevant wear rates, wear patterns and mechanisms using microseparation during the swing phase [4]. This micro-separation motion is shown
in Figure 1.

Figure 1. Micro-separation Motion



This study directly compares the wear debris from retieved tissues, standard simulator testing and micro-separation simulator testing of alumina-alumina hip bearings.

Materials and Methods
Simulator studies were run on the Leeds MkII hip simulator, which holds the head and the cup in the anatomical position, using similar ceramic materilas to those used in the Mittelmeier prosthesis [5]. Both tests were conducted at 1 Hz using a 25% (v/v) bovine serum lubricant with sodium azide as an antibacterial agent. This lubricant was changed approximately every 300,000 cycles. Standard conditions involved flexion/extension and internal/external rotation motions, and a Paul-type twin peak load, with a maximum of 3.5kN. Micro-separation motion was achieved by applying a force in the M/L direction. Serum was collected after 1 million cycles from both conditions of testing and the wear debris was characterised from the serum by transmission electron microscopy (TEM), using methods described by Firkins *et al.* [6]. Periprosthetic tissues were collected from 10 Mittelmeier alumina-alumina THAs. A histological analysis of these tissues has already been described [7]. The retrieved tissues were fixed in 10% neutral buffered formalin (NBF) for 10-14 days, then embedded in paraffin for sectioning. Eight micrometer sections were taken using a standard microtome and stained using haematoxylin and eosin. Using a light microscope, regions of ceramic wear debris were identified and their location noted. Laser capture microdissection (LCM) was then used to extract the regions of ceramic wear debris directly from the stained sections. A thermoplastic polymer film was placed on the tissue under the light microscope in the LCM device. Once the region of ceramic wear debris was selected, a laser was pulsed onto the polymer layer directly above the region of interest. The polymer melts into a very small region of the tissue and this can then be removed from the tissue for analysis. All 10 patient samples were analysed by TEM and 5 by scanning electron microscopy (SEM). The photographs of the wear debris were digitised and the mean maximum diameter was measured for a minimum of 100 particles per sample by image analysis (Image Pro Plus, Media Cybernetics, USA).

Results
Standard simulator studies produced a wear rate of approximately 0.1mm^3 per million cycles. No wear was visible on the components tested under standard conditions. Micro-separation studies produced a wear rate of 1.7mm^3 per million cycles and produced a wear stripe on the femoral head. Wear scars were almost always visible on the retrieved ceramic components from THA.

Table 1. Wear Debris Size Ranges and Mean Values.

Test/Material	Small Particles	Large Particles
Histology (clinical)	5-90nm (24 ± 19nm)	0.1-3μm (0.43 ± 0.33μm)
Standard Simulator	4 -20nm (9.22 ± 0.52nm)	None found
Micro-separation simulator	3–35nm (6.4 ± 10.8nm)	0.2-1μm

The sizes of the wear particles found in the tissue/serum are shown in Table 1. Two size ranges of particles: small (1-100nm) and large (0.1-3μm), were found in the retrieved tissues and under micro-separation testing. Only small particles were found under standard simulator testing conditions. The size range of particles found are listed in the table with means ± 95% confidence limits shown in brackets.

Discussion
The *in vitro* tests demonstrated two different types of wear processes and wear particles. Under standard conditions wear particles were generated by surface polishing and only small particles (4-20nm) were found. Under these conditions the wear surfaces remained very smooth. Introduction of microseparation
produced the rim contact and elevated stress levels which were
more consistent with *in vivo* conditions. This led to a wear stripe on the heads and also generated larger (0.2-1μm) particles as well as the smaller polishing debris (3-35nm). All the clinical specimens except one produced this bimodal size distribution of small (nm sized) and large (μm sized) debris which was associated with roughened areas of the bearing components, and this indicated
that micro-separation and rim contact may be a common occurrence *in vivo*. Even though the larger wear particles were in the same phagocytosable size range as polyethylene particles that cause osteolysis, the average volume of ceramic wear debris of 1-5mm^3 per annum would lead to a much lower particle load in the tissues. Inflammatory response in the tissues was low [5]. Alumina-alumina bearings have much lower osteolytic potential than traditional polyethylene bearings and thus have the potential for very long osteolysis-free lifetimes *in vivo.*

[1 Nevelos *et al.* J. Biomat, 20, 1833-1840, 1999.]
[2 Lerouge *et al.* JBJS, **79-B**, No.1, 1997.]
[3 Yoon *et al*. JBJS **80-A**, No. 10: 1459-1468; 1998.]
[4 Nevelos *et al*. J Arthroplasty, 2000. In press.]
[5 Nevelos *et al*. Trans 45th ORS, 857, 1999]
[6 Firkins *et al*. Trans 45th ORS, 49,1999.]
[7 Hatton *et al*. Trans 6th WCB, Hawaii, USA, 1188, 2000.]

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