Wear Debris Morphology of Silicon-Nitride Generated from a Hip Simulator Model

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Statement of Purpose: Although only alumina has a proven long-term clinical history in total hip replacements (THR) [1], other ceramics such as zirconia, alumina-zirconia composites, silicon-carbide, and silicon-nitride have also been examined as possible materials for THR [2-4]. Recent studies have suggested that alumina-zirconia composites may provide improved performance although the clinical performance of such components is very short [3]. Silicon-Nitride is another ceramic used commercially in many applications [2,4]. It's modulus and hardness are in the range of other ceramics, but the fracture toughness is closest to Zirconia (Table 1). However, few studies have investigated the actual wear and debris from all-ceramic silicon-nitride THR. Therefore, this study evaluated the wear debris morphology of silicon-nitride in a hip simulator model.

Table 1: Comparison of the mechanical properties of structural ceramics [2-4]. AMC is an alumina-zirconia composite material [1-3].

Material	Modulus (GPa)	Hardness (Hv)	Fracture ($MPa*m^{1/2}$)
Alumina	380	1878	4.00
AMC	350	1840	6.00
Silicon-Nitride	300	1450	9.00
Zirconia	210	1300	12.00

Methods: Femoral heads and acetabular cups made of silicon-nitride (Amedica, Inc., Salt Lake City, UT) were studied using a commercial hip simulator (Shore Western, Monrovia, CA). The specimens were run to five million cycles total duration in increments of approximately 100,000 cycles (Paul curve, 2kN max load). Bovine serum was used as the lubricant and samples at 4 million cycles duration were collected for debris analysis. The serum was digested using HCl acid, washed, filtered and prepared for SEM examination. Images were obtained and the particles measured using commercial software (Image J, NIH). Equivalent circular diameter (ECD), aspect ratio (AR), and circular shape factor (CSF) were determined and descriptive statistics were performed.

Results / Discussion: A total of 716 particles were retrieved from approximately 60ml of lubricant. The wear particles were in the size range of 0.1 to 6.3 microns with a median of 0.51 microns (Table 2). Approximately 75% of the particles were <1micron in size (ECD, Figure 1). The median aspect ratio was 1.5 and the median CSF was 0.82. The size range and shape of silicon-nitride was comparable to that of alumina debris from simulator studies [3]. The size range was also comparable to the known range of both UHMWPE and alumina debris from clinical retrievals [5,6]. UHMWPE particles are the most bioreactive in the 0.1 to 1 micron range while alumina is much less bioreactive [7]. In general, studies have shown that for the same size particle and concentration (number of particles/volume) alumina is less bioreactive than UHMWPE [7]. The spectrum of biocompatibility studies (ISO-10993) also showed silicon-nitride to have a benign biological response.

Table 2: Descriptive Statistics for silicon-nitride wear particles.

	ECD (microns)	Aspect Ratio	CSF
Average	0.692	1.615	0.806
Standard Dev	0.617	0.538	0.098
Median	0.505	1.477	0.821
Minimum	0.113	1.000	0.277
Maximum	6.272	6.547	0.998

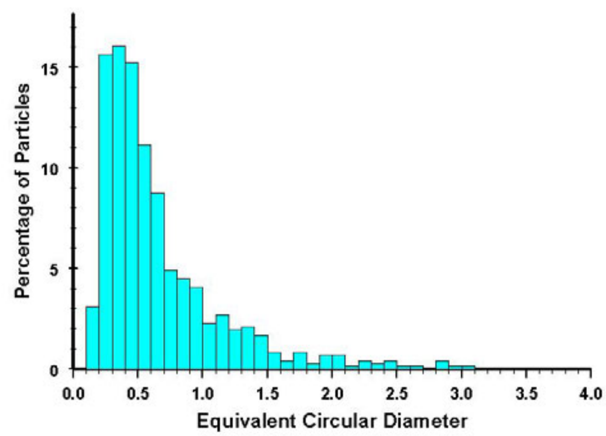

Figure 1: Histogram of the silicon-nitride wear particles from the simulator study.

Conclusions: This appears to be the first wear debris study of conventional silicon-nitride THR components. The overall particulate debris morphology was comparable to that of all-alumina THR under similar conditions. The silicon-nitride debris was similar to alumina in size and shape. Given the 35 year osteolysis-free history of alumina, the silicon-nitride debris may also prove benign.

References: [1] D. Hannouche *et al.*, *Clin Orthop Relat Res*, 62-71, 2005. [2] J. Kusaka et al., *Wear* **225-229**, 734-742, 1999. [3] T. D. Stewart *et al.*, *J Biomed Mater Res Part B-Applied Biomaterials* **66B**, 567-573, 2003. [4] Y. S. Zhou, K. Ikeuchi, M. Ohashi, *Wear* **210**, 171-177, 1997. [5] S. Lerouge et al., *J Biomed Mater Res* **32**, 627-33, 1996. [6] P. F. Doorn, P. A. Campbell, H. C. Amstutz, *Clin Orthop*, S206-16, 1996. [7] E. Ingham, J. Fisher, *Proc Inst Mech Eng [H]* **214**, 21-37, 2000.