Validating the Limits for a PEEK Composite as an Acetabular Wear Surface

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INTRODUCTION

Previous studies by Wang et al (1) determined that a carbon fiber composite component in the form of an acetabular cup, when articulated against Alumina or Zirconia, has the potential to form an efficient couple with very low wear. Good bonding between the fiber and matrix material were essential for success. It is known that high contact stresses as in a knee bearing or poor bonding may lead to component failure. This study addresses the wider issues of 5 sizes of cups, and focuses on the wear behavior as a function of surface finish and clearance together with the associated biological properties for a carbon fiber – PEEK composite. The potential advantages over metal – metal and ceramic – ceramic couples are also assessed.

MATERIALS AND METHODS

A series of composite acetabular inserts with an internal diameter of 28-mm and outer diameters ranging from 50 – 58 mm were manufactured by injection molding of a PEEK – carbon fiber composite which contained 30% by weight of milled fibers. Molded samples with a resin rich surface and machined samples with a fiber-exposed surface were both evaluated. As a means for comparison, same size UHMWPE bearing inserts were tested concurrently. Prior to mechanical, wear and biological testing, samples were washed, packaged and sterilized by gamma irradiation at a level of at least 25 kGy.
An eight station MTS hip joint simulator was used for testing the components, with each specimen chamber fitted on to a block inclined at 23º. Heads (Alumina and Zirconia) and test inserts (fitted into Titanium shells) were immersed in serum during the test. Testing was carried out in the anatomical position with the inserts superior and stationary, and the heads articulating. The inclined block rotated at a speed of 1 Hz and compressive loading applied axially to a maximum of 2’450 N. Standard test protocols were used for cleaning and weighing the inserts and a standard loading cycle was applied. The wear testing was carried out for 3 million cycles for screening, and 5 million cycles for the test proper at ambient temperature. A coordinate measuring machine was used to assess liner and replica form of the internal surface, with the overall wear being estimated by either discoloration of the serum or volumetrically from the wear scar diameter as measured on the replica.
Biological tests (cytotoxicity, ISO 10993 part 5; Ames test, an adaptation of OECD No. 471; and the evaluation of chromosomic aberrations in human lymphocytes, OECD No. 473) were carried out on both the machined and molded surfaces to determine if there was any toxicological or mutagenic potential. Analysis was carried out on extractables using both polar and non-polar solvents to determine if any leachables were present. Fully accredited test houses carried out all the biological tests.

RESULTS AND DISCUSSION

A first series of eight bearing inserts were tested to 3 million cycles to determine the effect of wear rate on both diametric clearance and surface finish, any wear being assessed by darkening of the test serum. Wear was not seen when the clearance was less than 600 microns, and the surface finish was better than 2.5 microns, with the requirement for carefully controlled manufacturing being a prerequisite.
Figure 1 shows the wear rate at 3 and 5 million cycles as measured by wear scar analysis of the range of cups, and indicate that the average wear is 0.43 ± 0.17 mm^3 per million cycles. This compares very well with the previous result of 0.39 ± 0.09 mm^3 per million cycles (1), and shows that the machining of the internal form has no significant effect on wear rate. Furthermore, the wear results obtained, as a function of clearance are consistent with calculations for the contact stress analysis for this particular composite. The wear rate for the combination of Zirconia or Alumina and composite inserts were, by at least a factor of 10, lower than for the couple against Polyethylene liner (31 ± 4), and similar to those published for metal – metal and ceramic-ceramic (2).
All of the biological analysis as determined by testing bulk components, leached extracts and debris analysis elicited no unfavorable responses. The results obtained as a whole for these components produced from the composite are very favorable when compared to other bearing couples used for hip arthroplasty.

Figure 1 Wear to 5 million cycles for composite cups and either Zirconia or Alumina femoral heads.
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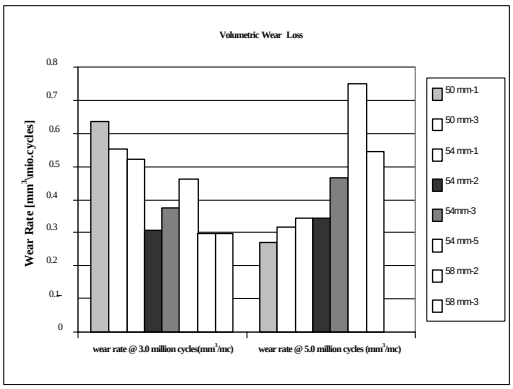

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