INITIAL WEAR CHARACTERIZATION OF A SPINAL ARTIFICIAL DISC

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ABSTRACT
Local reactions to wear debris generated by hip and knee replacement devices have been shown to lead to failure of some devices via osteolysis and component loosening. This has not been shown to be a clinical issue with the most widely used spinal artificial disc prostheses, but because of the proximity of these devices to sensitive neural structures in vivo, the issue deserves examination. The purpose of the present study was to investigate the wear characteristics of a lumbar artificial disc under simulated motion and loading conditions. In vitro testing using a modern joint simulator with loads and motions representative of possible lumbar spine motions show a relatively low polyethylene wear rate out to 10 million cycles with a dependence of resulting wear on input load and motion parameters.

INTRODUCTION
Ultra High Molecular Weight Polyethylene (UHMWPE) is a widely-used orthopaedic bearing material in total joint replacement. It is often used in hip, knee, shoulder, and spinal implant components where it articulates against polished surfaces of mating metallic or ceramic components. Although these components generally perform very well, wear of the UHMWPE component especially is a possibility. Some cases of loosening of hip, knee, and shoulder replacement have been shown to be associated with a biological response of osteolysis to UHMWPE particulate debris generated as a result of relatively large amounts of wear [1].

The CHARITÉ™ artificial disc (DePuy Spine, MA, USA) is made up of three components – two F-75 Cobalt-Chromium (CoCr) endplates, each having a highly polished concave articular surface, and a UHMWPE core with opposing convex articular surfaces (Fig. 1). This device has been used for replacement of degenerative discs in the lumbar spine for over 17 years with only a single known case having suspected wear-related osteolysis.

The clinical experience for some total hip and knee replacement designs, however, as well as the fact that spinal disc replacement prosthesis components are implanted near sensitive neural elements, makes it desirable to gain an understanding of the wear performance of disc replacements.

The present study was undertaken to investigate the wear characteristics of a lumbar artificial disc under simulated motion and loading conditions. Guidelines for such testing to assess spinal disc wear have been suggested in draft ASTM specifications which continue to evolve. In vitro testing was carried out incorporating these suggested guidelines using a modern joint simulator with loads and motions representative of those commonly seen in the lumbar spine.

MATERIALS AND METHODS
Size 1, 7.5 mm thick UHMWPE CHARITÉ™ artificial disc cores from stock were used. These had been gamma sterilized in a vacuum and packaged and were obtained after 4 years of shelf storage. The components were soaked in serum for 30 days prior to testing to allow fluid absorption. They were then assembled with correspondingly sized CHARITÉ™ endplates mounted in fixtures with polymethylmethacrylate.

Six of these assemblies were placed in an AMTI (Watertown, MA, USA) Boston hip simulator for wear testing. The wear testing was conducted in 25% (17 g protein/l) bovine serum maintained at 37 °C and collected and replaced every 200,000 to 300,000 cycles. Changes in core mass and height were recorded at every serum change. A precision balance with a repeatability of 0.02 mg was used to measure mass.

Wear debris was filtered from the collected serum and characterized by an outside laboratory. Debris was isolated by NaOH digestion followed by ultra-centrifugation and sputter
coating. Particulate size and morphology were analyzed via image analysis software.

Loads and ranges of motion representative of those possible in the lumbar spine were applied incorporating test parameters from the ASTM draft of 02/17/03 for artificial disc wear testing. Three implants were cycled in flexion-extension ($\pm 7.5^\circ$) in phase with axial rotation ($\pm 2^\circ$). Three other assemblies were cycled in left/right lateral bending ($\pm 7.5^\circ$) in phase with axial rotation ($\pm 2^\circ$). Motions were applied at the rate of 1.35 Hz. The axial load was also cycled from 900 N to 1850 N at the rate of 2.7 Hz so that the maximum axial load was achieved during maximum flexion, maximum extension, and maximum L/R bending. A total of 10 million motion cycles (20 million axial cycles) were performed. (Figure 2)

Figure 2. CHARITÉ disc prosthesis components with tested directions of loading and motion shown schematically.

Preliminary wear testing (to 1 Million cycles) was also done to examine the effect of out of phase coupling of the same applied motions. With all else being the same as the testing described above, three implants were cycled in flexion-extension ($\pm 7.5^\circ$) out of phase with axial rotation ($\pm 2^\circ$).

Six other UHMWPE cores were kept in 37 °C serum (following the same replacement schedule as the 10 million cycle wear test assemblies). Three of these were axially loaded in the same way as the wear test assemblies and served as loaded soak controls. The remaining three were not subjected to wear or load and served as unloaded soak controls.

RESULTS

For the assemblies tested to 10 million cycles, the wear ranged from 0.08 to 0.13 mg/Million cycles and averaged 0.11 and 0.13 mg/Million cycles with unloaded and loaded soak control adjustment, respectively. The total height loss was 0.2 mm $\pm 0.02$ mm, and only faint scratches were apparent on the cores after 10 million cycles of testing. (Table I, Fig. 3)

Approximately 700 particles were analyzed from the serum baths. Particle morphologies tended to be flakelike in earlier cycles and globular/granular in later cycles. The median diameter of the particles was approximately 0.2 microns, with sizes from 0.08 to 16.3 microns.

<table>
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DISCUSSION AND CONCLUSIONS

The results demonstrate good wear performance and the importance of test parameter selection. Compared with metal–on–polyethylene hip and knee joint replacements, (in vivo hip wear has been reported at 15 mm$^3$ per million cycles [2] (14 mg/Million cycles for UHMWPE with r = 0.935 mg/mm$^3$)) both the 10 million cycle and the preliminary results for the artificial spinal disc in the present study are relatively low. This is likely due to the fact that the loads and sliding distances are smaller for the artificial disc than with hip or knee implants and that activities such as gait result in cross-path articulating motions for hip and knee implants. The design of the CHARITÉ may also be a factor in its low wear rate as it allows anterior-posterior translation and rotation by sliding of the core relative to both endplates, thus possibly reducing UHMWPE stresses.

The in phase testing for the spine in the present study results in reciprocal articulation and simulates the repeated application of loads and motions encountered in the lumbar spine during a ‘significant bend’ activity. Hedman et al. [3] have suggested that 125,000 such significant bends are performed annually. The present study (10 million cycles) thus represents approximately 80 years of this loading condition. The preliminary out of phase testing in the present study shows the effects of cross-path motions on wear for this device, but this motion does not correspond to motions in the lumbar spine commonly encountered in daily life.

Few other artificial disc wear studies have been reported in detail. Delamarter disclosed an in vitro wear rate of 4.2 mg of polyethylene per million cycles for the ProDisc® artificial disc (Spine Solutions/Synthes, New York, NY).[4] Comparisons with these results, however, are difficult because wear test parameters were not fully reported.

It is not known how much UHMWPE debris can be present in the spine before eliciting an adverse biological response, but Cunningham et al [5] have shown that PE debris is well tolerated by the spinal cord. The results of the present study, in combination with the long history of the CHARITÉ disc indicates that wear debris is not a clinical concern.

Future investigation of spinal load and motion is planned to determine and appropriately simulate activities of daily living. This will allow more complete characterization of wear.

ACKNOWLEDGMENTS

SEM analysis of particulate debris was performed at the Joint Replacement Institute, UCLA, CA, USA.

REFERENCES

[4] Delamarter, verbal communication, March 12, 2004