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Quantitative Comparison of UHMWPE Wear Particles Generated from ProDisc-L and Charité Total Disc Replacements Under ISO and ISO Plus AP Shear

UNIVERSITY OF LEEDS

J L Tipper[1], R Vicars[1], P Hyde[1], TD Brown[2], E Ingham[1], J Fisher[1], RM Hall[1]

[1]Institute of Medical & Biological Engineering, University of Leeds, Leeds, LS2 9JT, UK; [2]Dept of Orthopaedics and Rehabilitation, University of Iowa, IA, USA

J.L.Tipper@leeds.ac.uk

Introduction

- Wear-mediated osteolysis in metal-on-UHMWPE total disc replacements (TDR) has largely been overlooked, despite the large body of evidence from hip and knee arthroplasty.
- Recent reports suggest that osteolysis also occurs within this total joint system [1].
- There is considerable debate about the effects of simulator inputs on wear and wear particle generation
- The current wear testing standard (ISO18192-1) for TDRs specifies only four degrees of freedom (4DOF), axial load, flexion-extension, lateral bend and axial rotation.
- However, the disc is a 6 DOF system in which anterior-posterior (AP) shear, may have important implications for wear in total disc replacements [2].

AIMS

The aims of this study were to investigate the effect of AP shear load on the size and morphology of the wear particles generated by ProDisc-L and Charité TDR devices over five million cycles in a spine simulator.

Materials & Methods

- Six station 5DOF simulator (Simulation Solutions, UK) run for five million cycles (MC).
- Six ProDisc-L (Synthes Spine, Warsaw, IA) & six lumbar SB Charité III implants (DePuy Spine, Raynham, MA)
- 4DOF defined by ISO18192-1; 5DOF used ISO18192-1 plus AP load of +175/-140N (ProDisc) or an AP displacement of +2/-1.5mm (Charité)
- Wear assessed by gravimetric measurement every MC. Lubricant: 25% (v/v) bovine serum
- Particles isolated after 2MC by digestion with 12M KOH [3] for each TDR (n=4)
- Sequential filtration through 10 µm, 1 µm and 0.015 µm filters
- Particles analysed using high resolution FEGSEM and characterised into the size ranges: <0.1 µm; 0.1–1.0 µm; 1.0–10 µm and >10 µm
- Particle frequency and area distributions were calculated

Results

- Similar particle morphologies were observed for the ProDisc-L and the Charité devices under 4DOF and 5DOF inputs
- Flakes, fibrils and granules (Fig. 1).
- No significant differences observed between the size and volume distributions under 4DOF and 5DOF (Fig. 2A & B).
- The mode of the frequency distribution was in the submicrometre size ranges (Fig. 2A)
- The mode of the volume distributions were in the >10 µm size range (Fig. 2B)

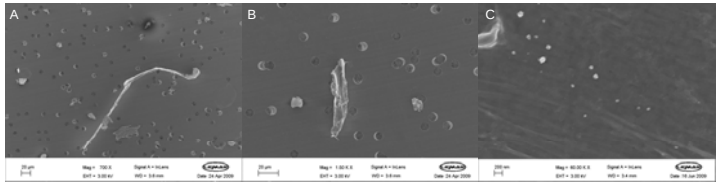

Figure 1 Scanning electron micrographs of UHMWPE particles isolated from ProDisc-L TDR simulated under 5DOF. A large fibril (x700); B large flake (x1500); C nanoscale granule particles (x60,000).

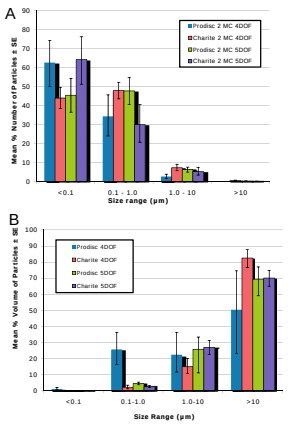

Figure 2 Frequency (A top) and area (B bottom) distributions of UHMWPE particles isolated from ProDisc-L and SB Charité III TDR devices simulated under ISO 18192-1 (4DOF) and ISO plus AP Shear (5DOF) inputs.

Discussion

- This study is the first to comprehensively analyse wear particles from 4DOF (ISO conditions) and 5DOF simulator inputs in two different TDR devices.
- Vicars *et al*. [4] reported no significant differences in the wear volume of ProDisc-L TDR components simulated under 4DOF and 5DOF inputs (12.7±2.1 mg/mc and 11.6±1.2 mg/mc, respectively).
- However, the Charité TDR exhibited significantly higher ($p<0.05$) wear rates under 5DOF inputs (22.3±1.3 mg/mc) compared to 4DOF inputs (12.2±1.0 mg/mc) [5].
- Particle size distributions and morphologies were not affected by implant design or the addition of AP shear.
- Wear particles were similar in size and morphology to those reported recently for retrieved lumbar SB Charité III TDR devices [6].
- Particle size distributions were similar to those obtained for metal-on-UHMWPE THR and TKR devices [7].

Conclusions

- Implant design and kinematics had a significant effect on wear volume but not on particle size.
- Wear debris produced by TDR was similar to particles from THR and TKR and may have a similar potential for osteolysis over the longer term.

References

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