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Quantitative Comparison of UHMWPE Wear Particles Generated from ProDisc-L Total Disc Replacements Tested under ISO and ISO Plus Anterior-posterior Shear Inputs

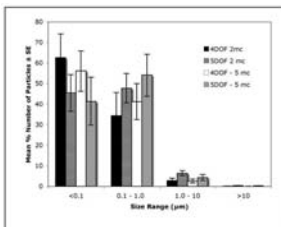
J.L. Tipper¹, R.E. Vicars¹, T.D. Brown², J. Fisher¹, E. Ingham¹, R.M. Hall¹

¹University of Leeds, Institute of Medical & Biological Engineering, Leeds, United Kingdom, ²University of Iowa, Department of Orthopaedics & Rehabilitation, Iowa, IA, USA

Introduction: The biological response to UHMWPE particles generated by joint replacements is one of the key factors in osteolysis, which leads to late failure of implants. Particles ranging from 0.1-1.0µm have been shown to be the most biologically active, in terms of osteolytic cytokine release from macrophages [1]. Current designs of lumbar total disc replacements (TDR) contain UHMWPE as a bearing surface and the first reports of osteolysis around TDR *in vivo* have appeared recently in the literature [2]. The current wear testing standard (ISO18192-1) for TDR specifies only four degrees of freedom (4DOF), axial load, flexion-extension, lateral bend and axial rotation. However, Callaghan *et al.* [3] described a fifth DOF, anterior-posterior (AP) shear. The aim of this study was to investigate the effect of this additional AP shear component on the size and morphology of the wear particles generated by ProDisc-L TDR devices over five million cycles in a spine simulator.

Methods: A six-station lumbar spine simulator (Simulation Solutions, UK) was used to test ProDisc-L TDR components (Synthes Spine, USA) under the ISO 18192-1 standard inputs and with the addition of an AP load of +175 and -140N. Wear particles were isolated at 2 and 5 mc using a modified alkaline digestion protocol [4]. Particles were collected by filtration and imaged by high resolution FEGSEM. Particle number and volume distributions were calculated as described previously [4] and were compared by one way ANOVA (p< 0.05).

Results: Similar particle morphologies were observed under 4DOF and 5DOF inputs, including flakes, fibrils and granules. No significant differences were observed between the size and volume distributions under 4DOF and 5DOF when comparisons were made at the same time point (Figure 1). The mode of the frequency distribution was either in the < 0.1 µm or 0.1-1.0 µm size range (Figure 1) with the volume distributions showing greater variability.



[Figure 1]

Discussion: This study represents the first comprehensive wear particle analysis comparing 4DOF (ISO conditions) to 5DOF inputs on a single TDR device. Vicars *et al.* [5] reported no significant difference in the wear volume of ProDisc-L TDR components under 4 and 5DOF inputs. The present study has shown that the particle size distributions and particle morphologies were not affected by the addition of AP shear. The wear particles isolated were in the biologically active size range and similar in size and morphology to those previously reported for THR and TKR [6], indicating that debris produced by TDR may have the potential to cause osteolysis.

References:

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