Quantitative Comparison of UHMWPE Wear Particles Generated from SB Charité III Total Disc Replacements Tested Under Different Input Kinematics

+[1]Tipper, J L; [1]Vicars, R; [1]Prokopovich, P; [2]Brown, T D; [1]Ingham, E; [1]Fisher, J; [1]Hall, RM
+[1]Institute of Medical & Biological Engineering, University of Leeds, Leeds, LS29JT, UK; [2] Department of Orthopaedics & Rehabilitation, University of Iowa, IA, USA.
J.L.Tipper@leeds.ac.uk

Significance
Current spine wear simulations test with a 4 degree of freedom (DOF) configuration defined within ISO18192-1. However, two other DOF exist within a functional spinal unit [1]: anterior-posterior (AP) and lateral shear, neither of which has been investigated in wear simulation of total disc replacements to date. In particular, there is some debate as to the effect of AP shear, on the wear of these devices and the wear particles produced.

Introduction
The response to UHMWPE particles generated by joint replacement implants plays a key role in osteolysis, which leads to late failure of implants. The first reports of osteolysis around TDRs *in vivo* have recently been published in the literature [2]. The current wear testing standard (ISO18192-1) for TDRs specifies only 4DOF: axial load, flexion-extension, lateral bend and axial rotation. However, a fifth DOF, anterior-posterior (AP) shear has also been described [3]. The aim of this study was to investigate the effect of this additional AP shear component applied at different magnitudes on the wear of the SB Charité III TDR coupled with investigation of the size and morphology of the wear particles over five million cycles in a spine simulator.

Methods
Six SB Charité III TDRs (DePuy Spine, Raynham, MA) were mounted in a 5 active DOF spine wear simulator and initially tested under ISO18192-1 prescribed (4DOF) conditions. A further six SB Charité III TDRs were then assessed under 4DOF conditions with an anterior-posterior (AP) shear displacement of +2/-1.5mm. This displacement was decreased and then increased by a factor of 2 for 2 million cycles, respectively, to investigate the sensitivity of wear to this parameter. Wear was measured gravimetrically at each 1MC interval and included a soak control assessment to take account of the fluid absorption.
Wear particles were isolated from four simulation stations at 2 million cycles for the four different simulation inputs. A modified alkaline digestion protocol [4] was used to isolate particles and particles were collected by filtration onto 10 µm, 1 µm and 0.015 µm filters. Each filter was imaged by high resolution FEGSEM at a range of magnifications. The following measurements were collected for a minimum of 150 particles per sample; maximum diameter, area, roundness, perimeter. Particle number and volume distributions were calculated as described previously [4] and were compared by one-way ANOVA ($p<0.05$).

Results
The wear rates in the 4DOF tests were observed to be 12.2 ± 1.0 mg/mc. Wear rates were significantly increased ($p<0.01$) for 'standard' 5DOF conditions (22.3 ± 1.3 mg/mc), decreased AP shear (24.3 ± 4.9 mg/mc) and increased AP shear (29.1 ± 7.6mg/mc).
Similar particle morphologies were observed for the SB Charité III devices simulated 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 (Figure 1A & B). The mode of the frequency distribution was either in the <0.1 µm or 0.1-1.0 µm size range (Figure 1A) with the mode of the volume distributions falling in the 1-10 µm size range for the increased AP shear kinematics and in the >10 µm size range for all the other inputs (Figure 1B). Although there were no significant differences, there was a trend towards the production of increased volumes of larger particles with decreasing AP shear and increasing cross-shear (Figure 1B).

Discussion
This study represents the first comprehensive wear particle analysis comparing 4DOF (ISO conditions) to simulator inputs with different magnitudes of AP shear (5DOF inputs) on a single TDR device. The present study has revealed that the particle size distributions and particle morphologies were not significantly affected by the addition of AP shear. However, the wear patterns generated under simulation conditions that incorporated AP shear produced rim damage on the UHMWPE components and may represent more clinically relevant simulation inputs, as rim damage has been identified in retrieved SB Charité III devices [5]. The trend for increased particle size with decreasing AP shear and increasing cross-shear occurred as the motion became more rectilinear, a pattern described previously with knee kinematics [6]. The particle size distributions obtained from simulation of the Charité TDR device were similar to those obtained for metal-on-UHMWPE THR and TKR devices [6], indicating that wear debris produced by TDR may have a similar potential for osteolysis over time

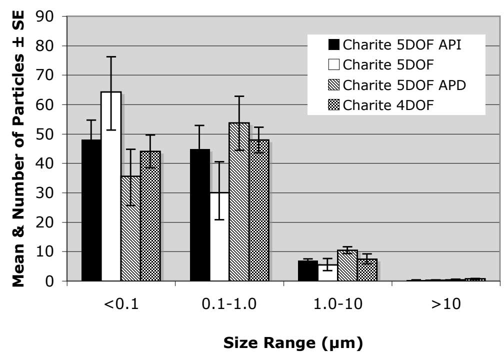

Figure 1A. Frequency distribution of UHMWPE Particles isolated from SB Charité III TDRs simulated under ISO 18192-1 (4DOF) and ISO plus AP Shear (5DOF), increased AP shear (API) and decreased AP shear (APD) inputs.

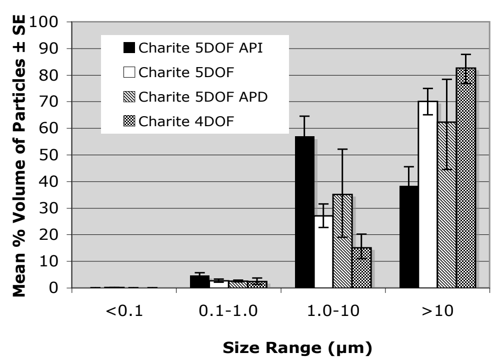

Figure 1B. Volume distribution of UHMWPE Particles isolated from SB Charité III TDRs simulated under ISO 18192-1 (4DOF) and ISO plus AP Shear (5DOF), increased AP shear (API) and decreased AP shear (APD) inputs.

References
[1] White & Punjabi Clinical Biomechanics of the Spine 1990; [2] Punt *et al*., Biomaterials 30, 2079-84, 2009; [3] Callaghan *et al*., Clinical Biomechanics 14, 203-16; [4] Richards *et al*., J Bone joint Surg 90B, 1106-13, 2008; [5] Punt *et al*., Acta Biomaterialia 7, 3404-11, 2011; [6] Tipper *et al*., J Biomed Mater Res 78A, 473-80, 2006.

Acknowledgments
This study was supported by an NIH grant R01-AR052653-01. It was partially funded through WELMEC, a Centre of Excellence in Medical Engineering funded by the Wellcome Trust and EPSRC, under grant number WT 088908/Z/09/Z and additionally supported by the NIHR (National Institute for Health Research) as part of a collaboration with the LMBRU (Leeds Musculoskeletal Biomedical Research Unit).