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Wear and Biological Effects of a Semi-Constrained Total Disc Replacement Subject to Modified ISO Standard Test Conditions

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Abstract

Development of pre-clinical testing methodologies is an important goal for improving prediction of artificial replacement joint performance and for guiding future device design. Total disc replacement wear and the potential for osteolysis is a growing concern, therefore a parametric study on the effects on wear of altered kinematics and loading was undertaken. A standard ISO testing protocol was modified in order to study the wear behaviour of lumbar total disc replacements when subject to low cross shear input kinematics, reduced axial loading and smaller flexion-extension magnitude. Volumetric wear, bearing surface topography, and wear debris biological reactivity were assessed. The ISO standard results were expected, however, the very low cross shear test produced a level of wear approximately two orders of magnitude higher than that reported for zero cross shear motions on UHMWPE bearings. When the osteolytic potential of the wear particles was calculated, all total disc replacement simulations had lower predicted osteolytic potential compared to total hip replacements, as a consequence of the generally lower wear rates found.

1. Introduction[1]

Late failure of total joint replacements has been linked with adverse tissue reactions to particulate debris resulting from the wearing process [1]. The use of articulating bearings in

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[1] TDR; total disc replacement, MoP; metal-on-polyethylene, UHMWPE; ultra-high molecular weight polyethylene, ISO; Standard ISO 18192-1, LXS; Low Cross Shear; LL; Low Load, ISO2; Standard ISO 18192-1 (repeat), HF; Halved FE, MC; million cycles, FBA ; functional biological activity, specific biological activity; FBA

spine arthroplasty has prompted a requirement for an improved understanding of the influence of kinematics and biomechanical conditions on generation of volumetric wear and particulate debris in spinal disc replacements of [2]. The most common total disc replacements (TDR) utilise technology originally developed for existing total joint replacements, most notably the metal-on-polyethylene (MoP) bearings used in hip and knee arthroplasty. Because of the reliance on ultra-high molecular weight polyethylene (UHMWPE), there are concerns over 'particle diseases' such as osteolysis [2, 3]. As in the early cases of MoP hips, the tissue reactions associated with TDR have been recorded following approximately a decade of use. Adverse reactions in TDRs are now being reported in the literature [4-7], indicating MoP TDRs are failing due to osteolyis, the same failure mode that can affect MoP hips [8]. The biological response to UHMWPE particles generated by joint replacements, and their size and volume concentration, is known to play a key role in osteolysis. Particles ranging in size from 0.1-1.0 μm have been shown to be the most biologically active, in terms of osteolytic cytokine release from macrophages [1]. To date there have been few studies which have fully characterised the wear particles generated from TDR devices in vitro or in vivo down to 10 nm in size.

1.1. **Background**

The use of joint simulators to study wear behaviour pre-clinically, using prescribed methodologies such as those created by the standard; ISO (18192-1) and guidance document; ASTM (F2423-05), do not always capture the full range of biomechanical and kinematic conditions which determine the wear observed in vivo [9, 10]. As a result, potentially severe or unexpected wear phenomena may be missed by using only one set of standard input conditions in a preclinical environment, with the consequence that failures in patients may be the first signs of sub-optimal device performance.

It has been shown that the amount of 'crossing path' (cross shear) motion at the bearing interface of polyethylene-based bearings can make a large impact on wear rates [11], in that purely rectilinear or curvilinear wear tracks produce very low wear. Existing knowledge of semi-constrained TDR in vitro wear has been derived using ISO [12-16] and ASTM [14, 16] (purely curvilinear, zero cross shear motion) methodologies. The tribological behaviour under moderate crossing path motion (as opposed to purely curvilinear motion), changes in loading, total articulation angle and their effect on wear are not fully understood or quantified. Body weight varies greatly within the patient population and therefore suggests that the effect of changes in axial loading on TDR wear should also be investigated in vitro.

There is evidence to suggest that in vivo rotations at a single FSU level are lesser in magnitude than those prescribed in either the ISO or ASTM documents, but higher in frequency [17]. Callaghan et al. [18] and Bible et al. [19] measured the motion of the entire lumbar section in healthy volunteers and found flexion-extension (FE) rotation to be approximately ± 3° during normal cadence resulting in a 6° range. It has been estimated by Cobian et al. [17] that for 'daily living' the range of motion of the entire lumbar spine is approximately 11°, with individual segment motion much less than this. Therefore when testing a single level TDR it may be more appropriate to test using reduced inputs rather than those defined in the ISO standard of -3° extension to 6° flexion. The effect of reduced range of motion on the tribology of the replacement joint is unknown.

1.2. **Aim**

In this study a stratified approach to the investigation of wear in TDR was adopted [20], independently investigating the effect of cross shear, load and FE angle on wear rate and particle generation. In addition, the effect that changes to the parameters of the simulation had on wear particle size, morphology and osteolytic potential was investigated in order to provide enhanced pre-clinical testing of these devices, which incorporated both biomechanical and biological factors. This approach utilised semi-constrained TDRs (Prodisc-L, Synthes Spine) and the ISO 18192-1 input cycle as a baseline experiment followed by parametric changes to the kinematics and loading. Four distinct input cycles were applied to the test samples. The following specific questions were addressed in terms of the characteristic wear rate:

1. What is the effect of reduced (rather than zero) cross shear motion?
2. What influence does reduced load have?
3. What effect does reduced flexion-extension angle have?
4. What is the predicted biological reactivity of the generated wear particles?

2. **Materials**

Prodisc-L TDRs (Synthes Spine, Warsaw, Indiana, USA) were chosen as test components due to their semi-constrained design, which is representative of a large proportion of TDR implants.

The design comprises of concave cobalt-chrome (CoCr) and convex UHMWPE bearing surfaces (GUR1020, gamma sterilised at 2.5–4 MRads) mated together in articulation.

2.1. **Methods**

A six-station spine simulator (Simulation Solutions Ltd, Stockport, UK) was used for the wear studies. Its verification and the general methodology used in TDR testing is described in detail in Ref. [12]. The TDR assemblies (n=6) were tested while totally submerged in a lubricant of bovine serum and were reused for each study. Serum was diluted to 15 g/L protein concentration (wt/v), using sterile water containing 0.03 % (w/v) sodium azide to retard bacterial growth. The replacement disc in vivo operates under unknown lubricant conditions, which could be argued will be of lower protein concentration since the natural intervertebral disc is not a synovial joint. The protein concentration used was lower than the ISO 18192-1 standard, however, previous tests have also been done at this level [9, 10, 12]. The 10 million cycles stipulated in the ISO standard was not adhered to due to the excessive amount of time this would have taken. Every 1/3 million cycles the each test cell was cleaned using a standard protocol described in Ref. [12]. Serum from each station was collected every million cycles and stored at -20°C until required for wear particle isolation. The polyethylene inlays (convex bearing components) were separated from their CoCr base and weighed every 1 million cycles after having stabilised in a temperature controlled lab for 48 hours. A loaded soak control disc was used to compensate for fluid uptake in the polyethylene. A conversion factor of 0.935 g/mm^3 [21] was employed to state wear in terms of volume.

The experimental test matrix is listed in Table 1. The wear test conforming to ISO 18192-1 was used as a baseline study [Figure 1] and subsequent wear tests were based on parametric changes to this. Each research question corresponded to a change in one parameter of the prescribed ISO input. Question 1 (effect of reduced cross shear motion) was accomplished by changing the FE and LB motions from being 90° out of phase to 0° in phase. Question 2 (effect of reduced load) was investigated using the ISO cycle but the load at each time point reduced to 50 % of the value prescribed in the standard. The ISO standard experiment (baseline) was then repeated to verify that the simulator was still producing the required baseline performance. Question 3 (effect of reduced FE angle) was studied by halving the FE motion of the ISO input. In each of these experiments the use of classical wear theory (wear proportional to sliding distance and load) would be challenged. Technical details of all changes made to the ISO standard for each parametric study are listed in Table 1. Statistical analysis utilised repeated measures ANOVA with α= 0.05.

Table 1 Experimental studies: Four distinct test cycles applied to Prodisc-L prostheses [a]

Input	ISO	LXS	LL	ISO2	HF
Study Question	Baseline test	Question 1	Question 2	Baseline test 2	Question 3
Description	Standard ISO 18192-1	FE and LB motions placed in-phase	Axial loading halved	Repeat ISO 18192-1 test to verify simulator	FE motion halved
Length of test (MC)	4	2	4	2	3

[a] *ISO; Standard ISO 18192-1 inputs, LXS; Low Cross Shear cycle; LL; Low Load input, ISO2; Repeated ISO 18192-1 cycle, HF; Halved FE input,* MC; million cycles

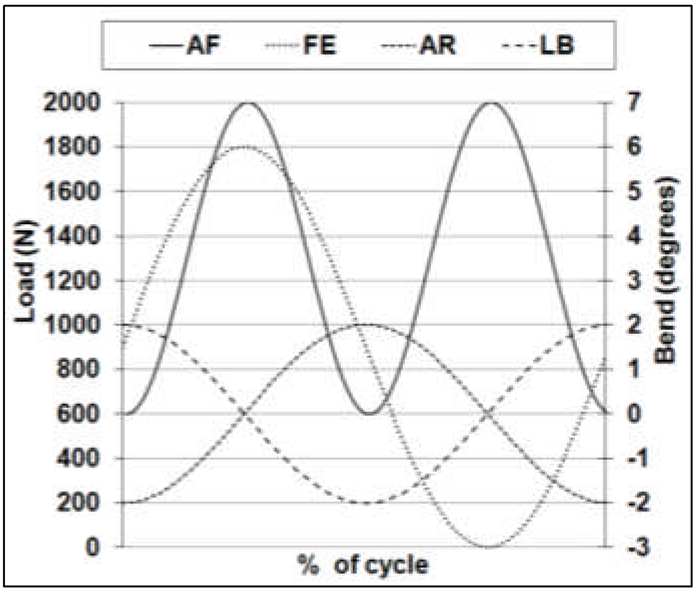

Figure 1 Baseline lumbar TDR wear testing inputs for ISO 18192-1 (AF: axial force; FE: flexion-extension; AR: axial rotation; LB: lateral bend)

The topography of the bearing surfaces was recorded using a contacting profilometer (Talysurf 120L, Taylor-Hobson Ltd, UK) with a diamond tipped stylus. Traces were taken over the entire

UHMWPE convex surface, then perpendicularly across the rim of the wear scar [Figure 2] where the edge of the CoCr bearing articulated. This gave information concerning the overall surface roughness (ALL), the roughness at the pole (POLE) and the effect on topography at the rim (RIM).

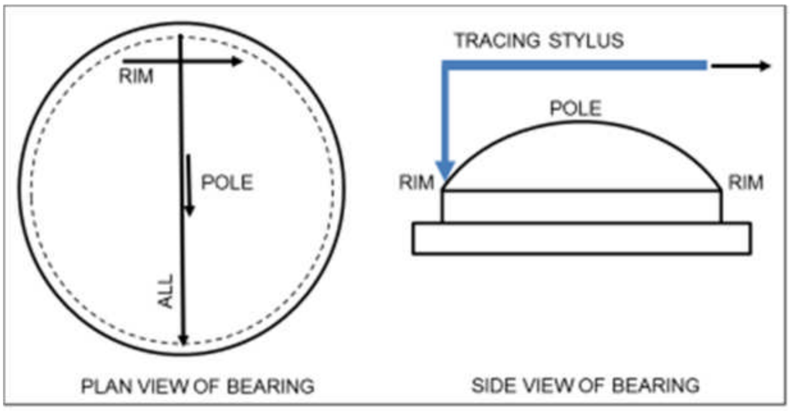

Figure 2 Schematic detailing profile trace positions on a polyethylene Prodisc-L component

Optical micrographs were obtained using a Nikon stereo microscope. Scanning electron microscopy images were obtained using a Phillips XL30. The samples were gold coated and glued with carbon paint to prevent excessive charging at the polyethylene surface.

Changes to the size and morphology of the wear particles were assessed after isolation and characterisation according to methodology developed by Richards *et al.* [22]. Briefly, serum samples were defrosted at 37°C, mixed to ensure even distribution of wear particles and digested using 12M potassium hydroxide at 60°C for between two and five days. Lipids were extracted for 48h using 2:1 chloroform:methanol followed by centrifugation at 2000g for 20 min at room temperature. The process was repeated until all lipids had been removed. Proteins were precipitated using ice-cold ethanol followed by centrifugation at 20,000g for 2h at 4°C. Particles were recovered by sequential filtration through 10, 1 and 0.015 µm filters (Whatman International Ltd.). Particles were visualised using high resolution FEGSEM at magnifications between 400x and 90,000x, after coating with 5 nm platinum/palladium. followed by prediction of specific and functional biological activity potential according to Fisher et al. [23]. These values were also compared with total hip replacements and total knee replacements that used the same UHMWPE bearing. Statistical analysis was completed by one-way ANOVA followed by Tukey HSD post hoc tests (α=0.05) using SPSS for Windows (v18.0, SPSS Inc., Chicago, IL, USA).

3. **Results**

3.1. **Wear Volume**

Output wear rates for all the input conditions are shown in Figure 3. The baseline experiment using the standard ISO 18192-1 inputs produced a rate of wear of 17.2 ± 1.5 mm^3/MC (± standard deviation). Placing the FE and LB in phase (LXS test) produced a significant ($p<0.01$) reduction in wear rate to 6.4 ± 1.3 mm^3/MC compared to the ISO cycle. The reduction in wear rate for the low load study (LL input) was also significant ($p<0.05$) compared to the baseline result, but of lower magnitude (12.6 ± 1.0 mm^3/MC). The repeated ISO study was not significantly different (17.8 ± 3.0 mm^3/MC) compared to the original baseline experiment. The halved FE input (HF) produced a non-significant reduced wear rate of 12.5 ± 2.5 mm^3/MC. For comparison, wear rate, percentage of baseline result, average sliding distance, cross shear (CS) ratio, average loading and wear factor are presented in Table 2. The experiment was terminated at a total of 15 million cycles, due to a delamination failure of one UHMWPE disc. A spur of UHMWPE material became angled vertically away from the surface [Figure 7]. Because this failure was unknown until the test station was stripped down for routine measurement, the area of fatigue failure became a new bearing surface. It was therefore difficult to distinguish surface features that may indicate fatigue (e.g. beach marks, polishing, pull-out) from wear features such as scratching.

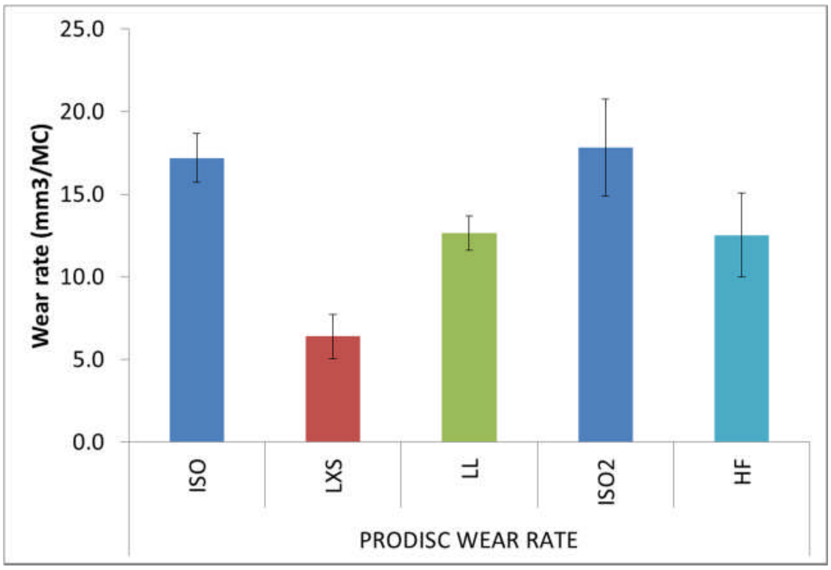

Figure 3: Wear rates of Prodisc-L TDRs under a range of test conditions (± StD) – baseline (ISO 18192-1), lowered cross shear (LXS), lower load (LL), repeated baseline (ISO2) and halved FE (HF)

Table 2 Summary of testing parameters and results for a range of simulator studies

Measurement (Average)	**ISO**	**LXS**	**LL**	**ISO2**	**HF**
Wear rate (mm^3/MC) [b]	17.2	6.4	12.6	17.8	12.5
% of baseline wear	100	37	74	104	73
Wear factor (mm^3/Nm)	2.4E-06	0.92 E-06	3.5E-06	2.5E-06	2.6E-06
% of ISO wear factor	100	39	147	104	112
Motion path distance (mm) [c]	4.9	4.7	4.9	4.9	3.2
CS ratio [c]	0.23	0.05	0.21	0.23	0.25
Mean Load (N)	1300	1300	650	1300	1300

[b] MC; million cycles, CS; cross shear, [c] Computed by F Liu, University of Leeds

The average amplitude of roughness (Ra) of the differentiated wear scar areas is shown in Figure 4. The first four million cycles of standard ISO inputs resulted in a similar overall average Ra value (labelled ALL) to the samples at the beginning of the test. However, the rim area (RIM) became much smoother than at the start of the test. The full wear scar area covered almost the entire area of the UHMWPE dome, indicative of full area sliding contact with the CoCr bearing face. The worn surface had a polished appearance at the periphery (rim) sector but was less burnished in appearance toward the mid areas of the UHMWPE dome. The pole areas tended to be rougher with raised surface irregularities approximately 20-50 µm in height and also displayed some signs of burnishing. SEM images of the UHMWPE dome showed microscopic linear scratching [Figure 5]. The LXS surface topography indicated similar surface characteristics to the ISO-tested discs including polishing and deformation at the rim, but with reduced roughening at the pole area. The LL test also produced burnishing at the rim edge, but the pole area was not roughened. The characteristic topography of the original ISO study was also similar for the second ISO test, showing a return of the roughening effect at the pole, but was not as severe. The HF experiment exhibited similar burnishing at the rim, but not as much roughening at the pole area. However, the Ra values had a large variance due to some discs showing much more roughening than others. The roughening at the pole part of the UHMWPE discs was re-adhered particulate debris and formed part of the bearing surface, showing signs of abrasion similar to the rest of the UHMWPE surface [Figure 6].

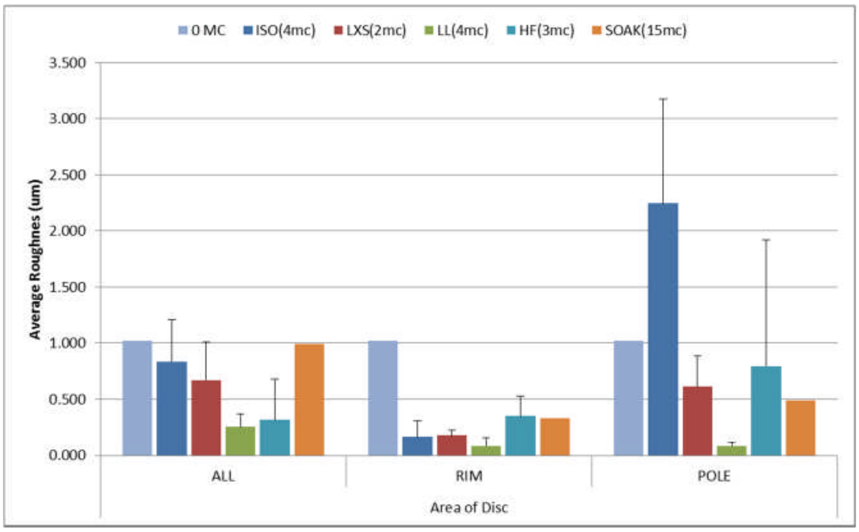

Figure 4 Average roughness values across three areas of the UHMWPE disc subject to four distinct test conditions

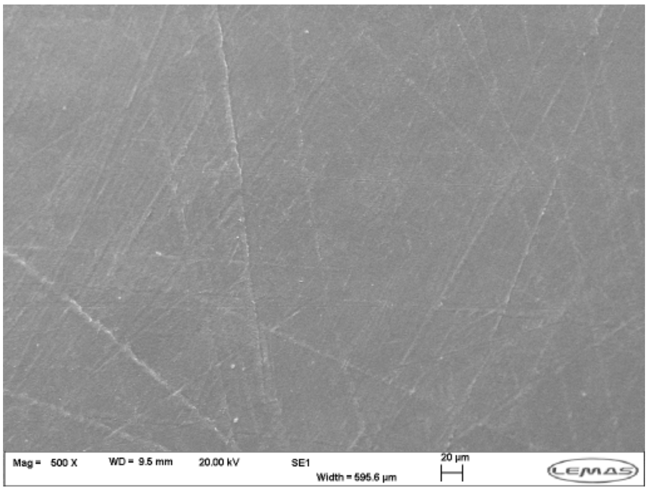

Figure 5 High magnification SEM image showing microscopic linear scratching on the UHMWPE bearing surface

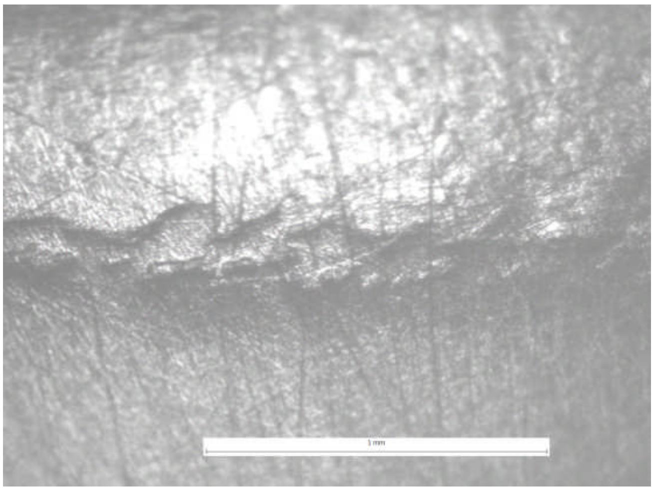

Figure 6 Reflected light microscope image of edge of roughened area at the pole of the UHMWPE discs showing continuation of abrasive scratching onto the raised area (top) from the bearing surface (bottom)

At the 15 million cycle time point one UHMWPE disc produced a delamination resulting in a spur of UHMWPE peeled away from the perimeter of the wear scar [Figure 7]. This area was directly under the edge of the CoCr opposing bearing. After gold-coating, this disc was analysed with SEM. Figure 8 shows the edge of the wear area and position of delamination. Fibrils of stretched polyethylene along the border suggest that this was a sudden failure after a period of sub-surface crack propagation.

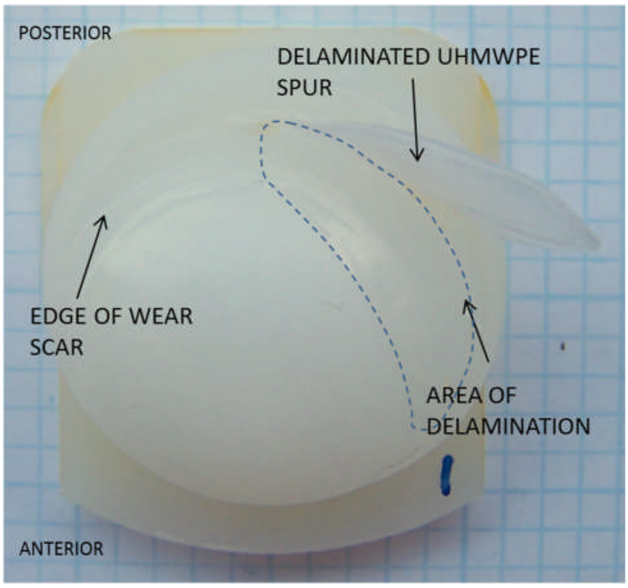

Figure 7 Failed UHMWPE bearing showing delaminated spur of PE material (scale = 2 mm)

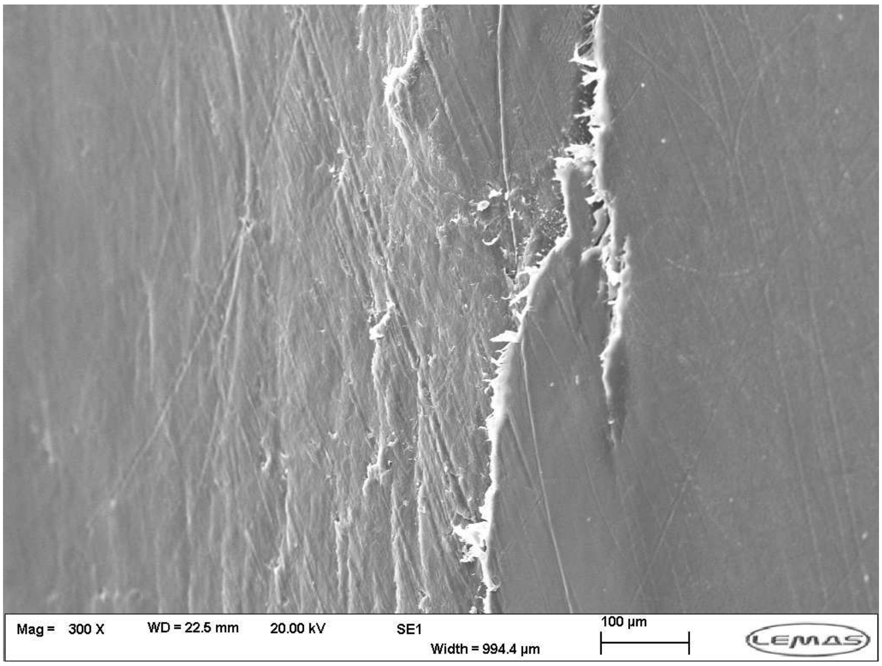

Figure 8 Edge of delamination area showing pull-out fibrils of polyethylene

3.2. Wear Debris

Similar particle morphologies were observed for the ProDisc-L devices simulated under ISO, low cross shear and low load inputs, including flakes, fibrils and granules [Figure 9]. No significant differences were observed between the particle size and volume distributions generated under the different simulator inputs [Figure 10 and Figure 11]. The mode of the frequency distribution was in the <0.1 µm size range [Figure 10] for all inputs, with the mode of the volume distributions falling in the >10 µm size range for all input conditions [Figure 11]. The mean specific biological activity (SBA) index for the particles generated in both the low cross shear and the low load input simulations were significantly lower than the ISO standard input conditions [$p<0.05$, ANOVA; Table 5]. In addition, the particles generated under reduced input kinetics (low cross shear and low load) had significantly lower functional biological activity (FBA) indices compared to the particles generated under standard ISO input conditions [$p<0.05$, ANOVA; Table 3], indicating that the particles generated under reduced input kinetics were larger and less biologically active. When compared to wear particles from total hip and knee replacements utilising the same UHMWPE the particles produced under ISO input conditions had specific biological activity indices most similar to those produced by THRs and the particles produced under reduced kinetic inputs (low cross shear and low load) were most similar to those produced by TKR.

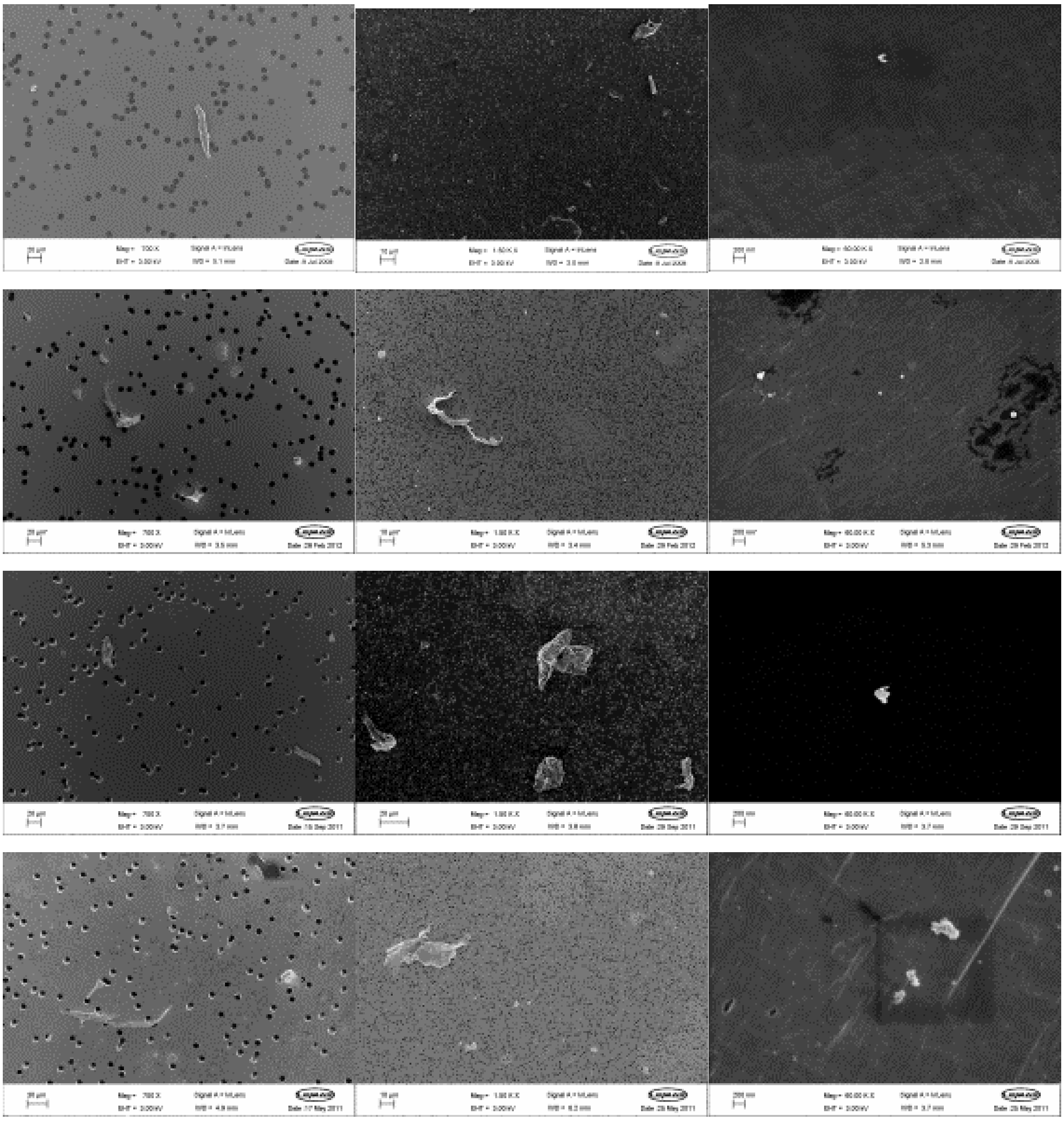

Figure 9 High-resolution field emission gun scanning electron micrographs of wear particles isolated from spine simulator testing of polyethylene-on-metal TDRs under different input kinematics. A-C, 10µm, 1µm and 0.015µm filters containing particles from ISO1; D-F, 10µm, 1µm and 0.015µm filters containing particles from ISO2; G-I, 10µm, 1µm and 0.015µm filters containing particles from low cross shear (LXS) inputs; J-L, 10µm, 1µm and 0.015µm filters containing particles from low load (LL) inputs.

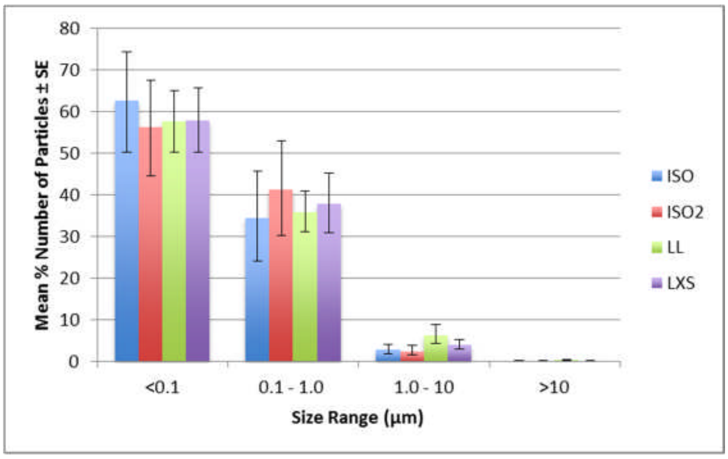

Figure 10 Wear particle size distributions (± SE, n=4) for spine simulator tests with different kinematic inputs.

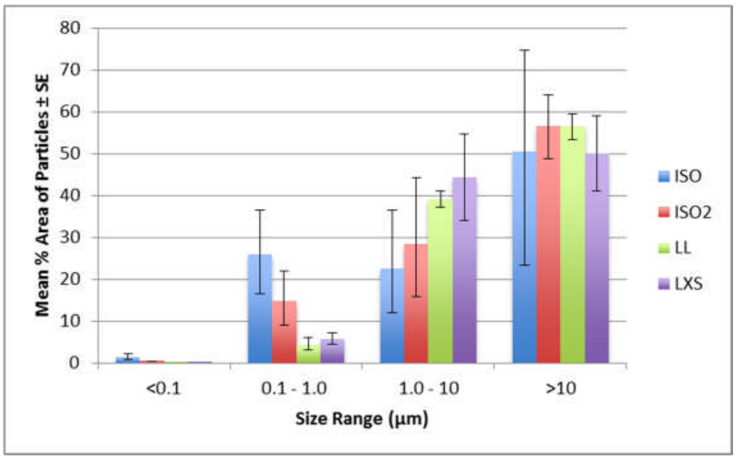

Figure 11 Wear particle area distributions (± SE, n=4) for spine simulator tests with different kinematic inputs.

Table 3 Specific Biological Activity (SBA) and Functional Biological Activity (FBA) Indices for wear particles generated from Total Disc Replacements (TDR) tested under different input kinematics compared to wear debris from total hip replacements (THR) and total knee replacements (TKR) with the same UHMWPE.

Simulator Test/Device	**Mean Specific Biological Activity (SBA) ± 95% CL**	**Mean Functional Biological Activity (FBA) ± 95% CL**
TDR (ISO1)	0.64 ± 0.34	10.37 ± 5.52
TDR (ISO2)	0.52 ± 0.49	8.62 ± 8.16

TDR (LXS)	0.19 ± 0.11	2.20 ± 1.26
TDR (LL)	0.20 ± 0.09	1.17 ± 0.51
TKR*	0.28 ± 0.15	6.33 ± 3.41
THR≠	0.72 ± 0.36	18.27 ± 9.13

TDR, Total Disc Replacement; THR, Total Hip replacement; TKR, Total Knee Replacement; ISO, ISO18192-1 inputs; LXS, low cross shear; LL low load (half ISO)

* 28 mm diameter femoral head on stabilised (2.5-4 MRad irradiated) GUR1020

≠ Fixed bearing PFC Sigma TKR with stabilised (2.5-4 MRad irradiated) GUR1020

4. Discussion

4.1. Wear Volume

The differences in wear rates observed in the present study have highlighted the effect of: shifting the phasing of the principle rotations of flexion-extension and lateral bending from 90° to 0°, reducing the loading by half, shorter flexural rotations of half that of ISO 18192-1 and repeatability of the standard ISO test. The ISO standard baseline data recorded in this study (17.2 mm^3/MC) is toward the high end of previously published results for Prodisc TDRs tested under ISO conditions: 4.96 [24] mm3/MC and 9.83 mm3/MC [15]. A disc from a different manufacturer but of similar design (i.e. ball-in-socket and MoP) reported in the literature exhibited very low wear of 2.7 mm3/MC [16]. A listing of all wear rates for semi-constrained MoP TDRs tested under ISO or similar to ISO conditions is shown in Table 4. It is difficult to confidently compare rates of wear between different sources because of the numerous variables involved: lab equipment, operators, subtlety altered methodologies and different manufacturers of simulator. However, the order of magnitude of the baseline results presented here (ISO and ISO2) are consistent with the literature.

Table 4 Wear rates for semi-constrained metal-on-UHMWPE lumbar disc bearings reported in the literature

Author(s) and year	Wear rate (mm3/MC)	Type of disc and brief methodology
Grupp et al., 2009 [16]	2.89	Activ-L, ISO conditions (Endolab simulator)
Nechtow et al., 2008 [24]	4.96	Prodisc-L, ISO conditions (MTS simulator)

Nechtow et al., 2008 [24]	5.67	Prodisc-L, ISO conditions (Endolab simulator)
Bushelow et al., 2008 [15]	9.83	Prodisc-L, ISO conditions (Endolab simulator)
Vicars et al., 2009 [12]	13.58	Prodisc-L, ISO conditions using 25% serum (Prosim simulator)
Nechtow et al., 2006 [14]	17.74	Prodisc-L, ISO based using "frequency shifted" phasing (Endolab simulator)

The rate of wear was significantly and substantially reduced in the polyethylene components when subject to the lowered crossing path input motion (LXS), probably due to preferential alignment of UHMWPE polymer chains under reduced crossing path motions [25]. The cross shear ratio resulting from the zero-phased FE and LB motions was 4.6 times lower than the ISO standard motions with wear rate 2.7 times lower [Table 2]. However, the volume of wear debris was still nearly two orders of magnitude higher than that reported for zero crossing path motions under similar conditions [14]. If it is assumed that in vivo functional spinal unit movements do not result in purely curvilinear TDR kinematics then volumetric wear and particle production in TDRs will be an issue even if the cross shear levels are very low.

Reduction in wear rate under the lowered load input (LL) was much less than the 50 % reduction expected if predicting wear using classical wear theory (wear proportional to load applied [26]). In fact the wear factor increased by ~50 %, indicating non-linear load dependence. This non-linear load dependence has been observed in simple pin-on-plate wear tests using UHMWPE on cobalt-chrome plates [27]. This tends to suggest that in vivo wear will not be greatly influenced by patient weight, although other factors resulting from higher axial loading, such as sub-surface fatigue, may be accelerated especially if a component of the axial load had significant anterior shear, for example at level L5-S1.

The proportion of fall in wear rate for the half FE experiment (HF) was similar to the proportional reduction in average sliding distance at the bearing surface [Table 2]. However, the wear factor increased, indicating that the smaller rotations may have increased susceptibility to wear. Cobian et al. [17] showed that the amplitude and frequency of lumbar motions may be smaller and higher respectively. From an in vitro testing point of view these results and those of Cobian et al.'s may indicate that using smaller angles of rotation but with much higher frequencies may be worthy of further investigation in the search for a more physiologically relevant test. However, it should be noted that a testing regime should ideally include a range of parameters in order to find weaknesses in orthopaedic bearing designs. The CS ratios of the ISO (0.23) and HF inputs (0.23) were similar and well above the threshold of approximately 0.1 that has been found to induce high wear factors in MoP wear couples in pin-on-plate experiments [28]. Under these circumstances sliding distance rather than CS ratio was the main factor in rate of wear [Table 2]. Computational modellers may consider utilising prediction of wear rate using traditional wear theory for UHMWPE bearings when moderate to high CS value inputs are investigated.

The repeated ISO study (ISO2) produced a rate of wear that was not significantly different to the first ISO test. This confirmed that the simulator methodology and the repeated use of the same samples was valid. However, it was noticed that the standard deviation of the mean wear results had increased over time, indicating a widening of wear rates between different test cells. It is a limitation of this paper that samples were reused, but in simulator testing of artificial bearings this is not uncommon and given the high cost of test samples it is not unreasonable as long as precautions to verify repeatability have been completed, as in this case.

In general, TDR rates of wear were slightly higher than in vitro studies of modern cross linked metal-on-UHMWPE hips (5-10 mm^3/MC [29]) but lower than metal-on-historic UHMWPE hips (25-40 mm^3/MC [20]). The latter have similar UHMWPE acetabular cup material to those of the Prodisc-L TDR UHMWPE component. Wear of MoP total knee replacements under standard ISO conditions is closer to TDR values: 6 - 12 mm^3/MC [20]. Considering the large flexions in hip and knee ISO standard testing it is surprising that the TDR standard ISO wear rate is not lower. Poor tribological conditions caused by short stroke motions and edge loading on the UHMWPE dome may be contributing factors in this, increasing the wear factor value.

Linear scratches on the polyethylene surfaces stretched from the plane area of the UHMWPE dome onto the roughened section at the pole. These scratches may have been caused by larger (perhaps work hardened) particulate debris exiting the bearing surface and leaving tracks as they moved. The roughened areas appeared to be made of polyethylene debris smeared back onto the original surface and was probably a result of a tribologically challenging environment unique to TDRs. Short rotation angles coupled with the absence of a low load swing phase (as in hip simulation) may lead to entrapment of particulate debris.

The reduced loading input (LL) demonstrated virtually no roughening at the pole. It may be that a smaller contact zone allowed the lubricant to access the central bearing area and allow debris to be released into the fluid more readily. Or, that the reduced contact pressure was not high enough to facilitate re-adherence of particles back onto the UHMWPE surface at the pole. The in vitro consequences of debris re-attachment are unknown. This phenomenon may influence other output factors such as friction, fatigue and the release of potentially lager flakes (grouped particles) of debris. An image found in the literature of an explant reported by Choma et al. [30] (retrieved Prodiac-L component after 16 months of service life; the image was described as “at the pole”) shows similarity to the SEM image of pole area roughening [30] reported here. In the present test, optical microscopy revealed linear multi-directional scratches on the UHMWPE surfaces, which were similar to those observed by Anderson et al. [31] using SEM analysis of an explant. This is in opposition to Grupp et al. who reported elliptical wear scars for ISO inputs on both metallic and polyethylene components [16]. A burnished area at the periphery of the wear scar of glossy appearance at the rim of the UHMWPE dome was confirmed as a smooth surface by profilometry results for all input conditions.

The failure mode of one of the UHMWPE discs which experienced a delamination was probably subsurface fracture due to fatigue, however, due to the ongoing wear process this was difficult to quantify in terms of characteristic surface topography. Failure occurred near the rim and could be linked to the relatively high edge-loading of the UHMWPE coupled with effects of repeated sliding contact [9]. No other discs showed signs of imminent fatigue failure.

4.2. Wear Debris

The morphological appearance of the wear particles generated from TDRs under different kinematic and loading conditions were similar to each other and also similar to particles produced in vivo [6,7], with fibrils, flakes and granule type particles typically observed by FEGSEM, which are characteristic of all UHMWPE bearings. The particle size distributions for the different simulator inputs conditions did not show statistically significant differences due to the large amount of variation in some samples, this was particularly relevant to the particles produced under ISO input conditions. These variations may have masked differences between particles produced under ISO inputs conditions and those produced under reduced cross-shear and reduced loading regimes. Larger volumetric proportions of smaller (0.1-1.0

μm) particles were generated under ISO conditions compared to reduced input conditions, although these differences were not significant. When the biological activity indices were calculated these differences translated into a significant difference in specific biological activity per unit volume of wear. Furthermore the lower wear rates of the TDRs simulated under reduced kinematic and loading inputs led to a further significant reduction in functional biological activity index for the reduced input conditions.

The wear particles produced under reduced input conditions were more similar to those produced in total knee replacements, where larger less biologically active particles have been observed due to reduced cross-shear motions in the knee compared to the hip [30]. Whereas the particles produced under the standard ISO inputs were more similar in biological activity to particles produced in the hip in that they were smaller and had high specific biological activity. When the osteolytic potential of the wear particles was calculated, all TDR simulations had lower predicted osteolytic potential compared to THRs, as a consequence of the lower wear rate in the TDRs. This may indicate that osteolysis will occur at a slower rate in TDR compared to the hip where it manifests between 10 and 15 years in approximately 10-20% of patients.

5. Conclusion

In conclusion this study has demonstrated that the changes to the kinematics and loading inputs of the standard testing regime can highlight wear phenomena not found in standard ISO cycle results. TDR wear rates were lower than in vitro metal-on-historic UHMWPE THR results, but still high enough to be of concern over the long term. Without a large pool of explants to compare to, it is unclear whether the changes made to the ISO standard in this paper replicate behaviour in vivo. In vitro testing will, for the time being, be a benchmark between disc designs, rather than an accurate indication of probable in vivo performance. However, simulation over a range of input parameters may highlight a lack of robustness in TDR bearing performance. Wear debris was morphologically similar and of a similar size to that produced in THRs and TKRs, thus lending support to the in vivo reports that osteolysis occurs in the spine and represents a major cause of failure of TDR devices.

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