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Hyde, PJ, Fisher, J and Hall, RM (2016) Wear simulation of a polyethylene-on-metal cervical total disc replacement under different concentrations of bovine serum lubricant. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 230 (5). pp. 481-488. ISSN 0954-4119

https://doi.org/10.1177/0954411915602914

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DOI: 10.1177/0954411915602914

Wear Simulation of a Polyethylene on Metal Cervical Total Disc Replacement Under Different Concentrations of Bovine Serum Lubricant

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Keywords: tribology, TDR, disc, wear, serum, cervical, simulation, spine

Abstract

Metal-on-polyethylene (MoP) total disc replacements (TDR) have been an alternative to spinal fusion in the lumbar spine under certain indications for more than a decade. Recently, cervical total disc replacement (C-TDR) has also become an alternative to cervical fusion. Knowledge acquired from years of in vitro simulator studies on other joint replacements has high-lighted the risks associated with premature wear due to unforeseen adverse clinical conditions and the effect of particulate debris on surrounding natural tissues. Having no evidence of the type and composition of the lubricating fluid that will result after spinal arthroplasty, a study on the effects of lubricant serum concentration was undertaken. The wear rate was shown to be inversely proportional to protein content of the serum over a range of 50 % to 3 % bovine serum to water concentration.

Introduction

Cervical total disc replacement (C-TDR) involves the excision of the natural intervertebral disc (IVD) and replacement with an artificial construct, most commonly a type of articulating bearing. This is an alternative to fusion surgery which has been hypothesised to decrease the risk of adjacent segment disease (ASD). A recent review of the literature on in vivo performance of C-TDRs found that C-TDR is at least as effective in increasing quality of life scores (QOL) as fusion, but found evidence lacking for reducing ASD [1]. In recent years the C-TDR procedure has increased in popularity [2], though the long-term effect of particulate wear on the cervical spinal cord is largely unknown.

The knowledge base for hip and knee replacement success is more mature and in general early failure of these total joint replacements is usually a surgical problem linked to infection or mechanical fault. However, late failure of articulating devices is commonly linked to aseptic loosening instigated by adverse tissue reaction attributed to wear debris produced at the articulating bearing surfaces [3] which leads to osteolysis and bone resorption [4, 5]. A review by Lehman et al. [2] of C-TDR performance in vivo noted that all polymeric-based bearings studied had released wear particles into the surrounding tissue and resulted in inflammatory cells, but no reports of peri-prosthetic osteolysis were reported. However, the oldest time period in vivo was four years, which, considering the time taken for past osteolysis within hip or knee replacement to occur, is too early to assess medium to long-term incidence of osteolysis. Lumbar total disc replacement (L-TDR) has a longer history than C-TDR and reports in the literature of tissue reactions have begun [6-9]. Despite these relatively short service periods, adverse reactions are beginning to be observed in articulating C-TDRs [10-12], although only one of these reports was a metal-on-polyethylene design of disc [11].

Current expectations of an acceptable level of wear in other total joint replacements is less than 10 mm^3/million cycles [13], however, the TDR operates in a domain that is both smaller and in close proximity to the spinal cord. In vitro studies on metallic wear particles have shown that nanoparticles can cause adverse cellular responses in the cells of the meninges [14]. Given that biological reactions are dependent on the local concentration of particles in the tissue, which itself is dependent on the transport as well as generation of the particles, further work on the effect and osteolytic potential of polyethylene particles in the spine is required.

The artificial disc replaces a visco-elastic natural tissue (not a synovial joint) and therefore the replacement device does not operate in a synovial space. The replacement TDR is lubricated by a fluid of unknown protein composition, perhaps derived from synovial, pseudo-synovial or interstitial fluid with variable protein concentration. It is indicated that a fibrous membrane may grow and result in a protein-rich lubricant [15]. Considering the uncertainty of the C-TDR lubricant conditions in vivo, it is important to investigate the wear rates that may be expected for C-TDR through pre-clinical testing under a range of conditions.

This study is an investigation of wear of a typical semi-constrained UHMWPE-on-metal C-TDR operating under ISO18192-1 standard conditions but using various protein concentrations as the lubricating medium.

Methods

Components used in this study were the largest size in the Braun "activ C" range: XXL 7 mm. This device is of ball-in-socket design with a UHMWPE convex dome attached to the inferior baseplate articulating against concave cobalt chromium (CoCr) highly polished bearing on the superior endplate [Figure 1]. According to the manufacturer the devices are sterile, being supplied in sealed foil/plastic packaging and the polyethylene component irradiated at a minimum dose of 2.5 MRad (non-cross-linked). The average radius of the spherical dome was 4.96 mm and height 3.3 mm above the surrounding metallic base. At intervals during simulation wear was assessed gravimetrically every one million cycles using a high precision (0.001 mg resolution) balance (Mettler AT21 balance Leicester, United Kingdom) and adsorption of fluid was compensated for by using the mass of a loaded soak control disc of identical design. Before testing began the UHMWPE components were allowed to stabilise in water for 14 days. Height loss was recorded using digital callipers and CMM (Legex 322, Mitutoyo, UK). The surface topography was monitored by 2D surface profilometry (Form Talysurf PGI800 series, Taylor Hobson, UK) and reported as average roughness (Ra). Over the first five million cycles the CMM was used to record any change in bulk material morphology.

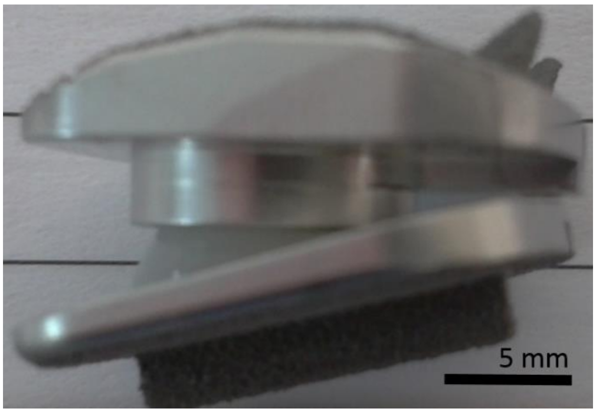

Figure 1 Braun activ C TDR shown in full flexion position

The Leeds spine simulator (Simulation Solutions, Stockport, UK) was utilised throughout testing, undergoing regular calibration procedures for loading and rotational inputs. This machine has seven stations: six used for dynamic simulation with a seventh operated solely to monitor a soak control component in cyclical axial loading. Previously published work from this machine includes semi-constrained and unconstrained lumber disc experiments [16, 17]. For this study the simulator's axial load springs were replaced with lower spring-constant ones and calibrated to the low loads stipulated in the ISO ISO18192-1 standard for C- TDR wear testing (Table 1). The ISO standard stipulates 10 million cycles to be run, however, as this was a comparative parametric experiment utilising the same samples for each test, shorter runs were used for all but the ISO25 study [Table 2].

Discs were submerged in bovine calf serum (Harlan Sera-Lab, Loughborough, UK) with additional 0.03 % sodium azide in the solution to retard bacterial growth. This serum mix was diluted according to the relevant test condition shown in Table 2. Serum was replaced every 333,333 cycles after cleaning the test chambers. A full strip-down of the test chamber was completed every one million cycles. The first study was five million cycles in length; this was followed by three perturbations of the ISO standard test using different serum concentrations.

Table 1 ISO18192-1 standard testing inputs indicating phasing of kinematics with respect to flexion-extension

	Axial Force (N)	Flexion-ext. (˚)	Lateral bend (˚)	Axial rotation (˚)
Magnitude	50 – 150	±7.5	±6	±4
Phase	0	-	-90	+90

Table 2 Table of simulator study conditions under ISO standard input dynamics

	ISO50	ISO25	ISO12	ISO3
Experiment test order	2	1	3	4
Sample size (n)	6	6	3	3
Study length (millions of cycles)	2	5	2	2
Serum concentration (%)	50	25	12.5	3.125
Corresponding protein content (g/L)	30	15	7.5	1.875

Surface topography was recorded pre-test and at the end of each study. A contacting diamond tipped stylus was used and analysis included form removal, cut-off filter of 0.8 mm (UHMWPE) or 0.25 mm (CoCr) and a bandwidth of 100:1. Traces were taken across the full bearing face in x and y directions, plus a shorter trace on the periphery of the wear scar where burnishing was observed.

A coordinate measuring machine (CMM) was used to show the change in shape of the UHMWPE components over the first five million cycles of testing under ISO25 conditions. The CMM was used in contacting trace mode using a 2 mm ball with form error of 3 um. Traces were taken across the full dome of the UHMWPE component in a radial pattern 72 repeats over 360°. Analysis of results was done using SR3D analysis software (Tribology Solutions Ltd, UK).

Results

Wear reduced as protein content diminished (Figure 2). There was no significant difference between the 50 % serum condition (ISO50) and the 25 % concentration test (ISO25). At this time-point (7 million cycles), three discs became damaged due to machine malfunction during a routine load calibration procedure, hence ISO12 and ISO3 experiments used three articulating samples only. The following 12 % (ISO12) and 3 % (ISO3) serum experiments both displayed significantly less wear volume compared to the standard test. The ISO3 test was not significantly different to the ISO12 study. The reason for the damage to three of the UHMWPE discs was as follows: during calibration a load of approximately 200 N was applied to the superior cup, however, the edge of the cup was at the pole of the UHMWPE dome when load was applied. The relatively sharp cup edge sunk into the softer polymer bearing. The 95% confidence limits recorded for the remaining three samples were high due to the reduced number of samples, however, the standard deviations were no larger than the initial (n=6) tests.

Over the ISO25 period of study (5 million cycles) the mean height loss of the articulating discs per million cycles was 0.044 ± 0.005 mm (corrected for a 0.013 mm creep over the same period for the soak control disc).

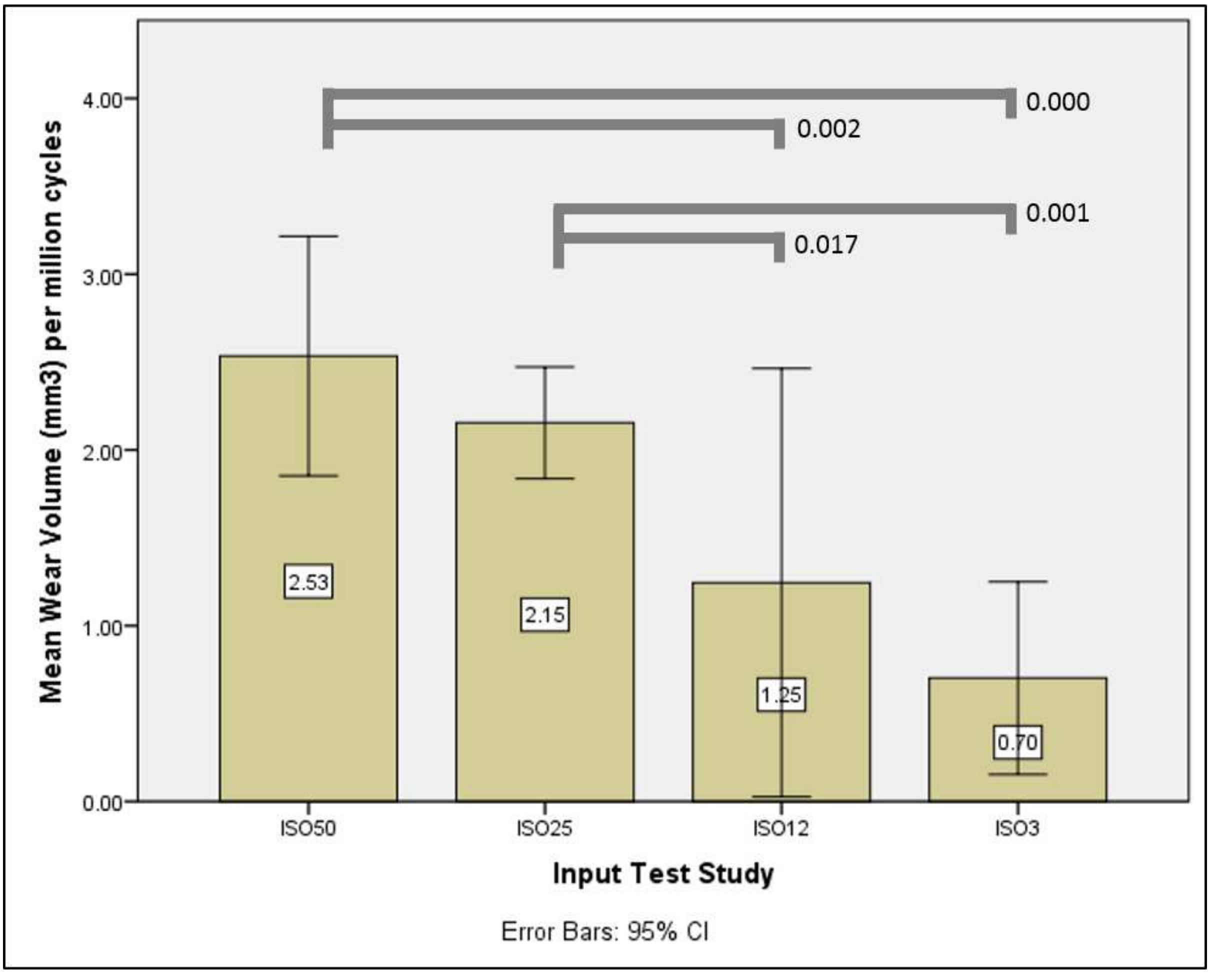

Figure 2 Rates of wear of a cervical disc replacement subject to ISO18192-1 test cycle using various serum concentrations (ISO50 denotes standard ISO inputs with 50 % diluted bovine serum etc.)

Surface roughness of the UHMWPE domes was recorded over 5 million cycles of the ISO25 study. The average Ra value was 0.55 ± 0.08 µm before testing, reducing to 0.27 ± 0.35 mµ at 5 million cycles. Over the study period the trend appeared to be one of smoothing, however the variance in these results was high. The soak control disc roughness was 0.52 µm pre-test and finished at 0.51 µm at end of test. Average roughness was also recorded at the extremity of the contact region on the UHMWPE dome (rim) as there appeared to be a burnishing effect there. However, no difference in Ra between this region and the rest of the disc was detected.

A change in macro morphology over the 5 million cycle ISO25 study was demonstrated in CMM images. Pre-test disc images indicated a slight expansion of the polyethylene domes in the 0˚/180˚ (x) directions (example, disc 5 in Figure 3) and a corresponding compression in the

90˚/270˚ (y) direction. However, by 1 million cycles all discs displayed a consistent topography across the bearing surface, indicative of even UHMWPE bearing wear at the perimeter portion of the bearing contact area. Isolated raised areas of roughening toward the anterior portion of disc number 5 and 6 were also visualised in CMM images (example, disc 5 Figure 4). The roughening appeared at 1 million cycles and remained until 3 million cycles, where the height above the mean surface was between ~50 µm (disc 5) and ~100 µm (disc 6). It was almost impossible to see with the naked eye. Over the next 2 million cycles these slight protrusions regressed until at 5 million cycles the raised areas had largely disappeared (Figure 5). The change in the soak control disc height and typical change in height due to wear was monitored using the CMM method in addition to callipers, the results are shown in Figure 6. The largest amount of creep occurred over the first 1 million cycles, which is similar to that found in UHMWPE hip cups [18] with the 2 to 5 million cycle points not varying greatly.

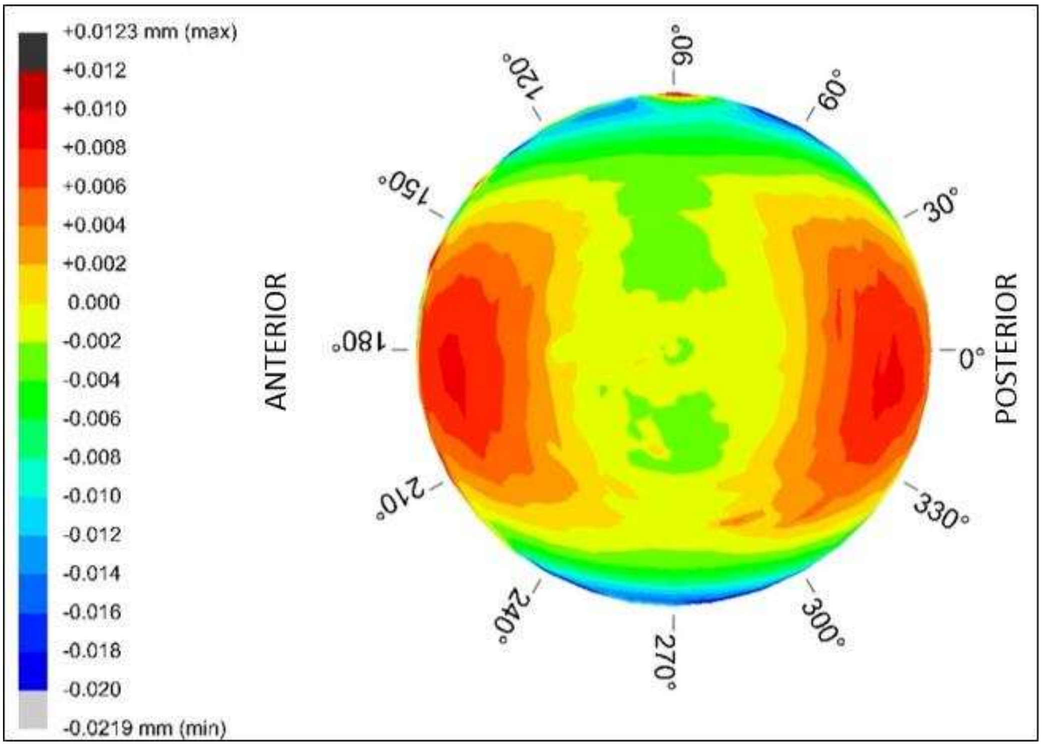

Figure 3 Pre-test CMM contour plot for disc 5 displaying expansion and compression of the UHMWPE bearing in the y (180/0) and x (90/270) directions respectively

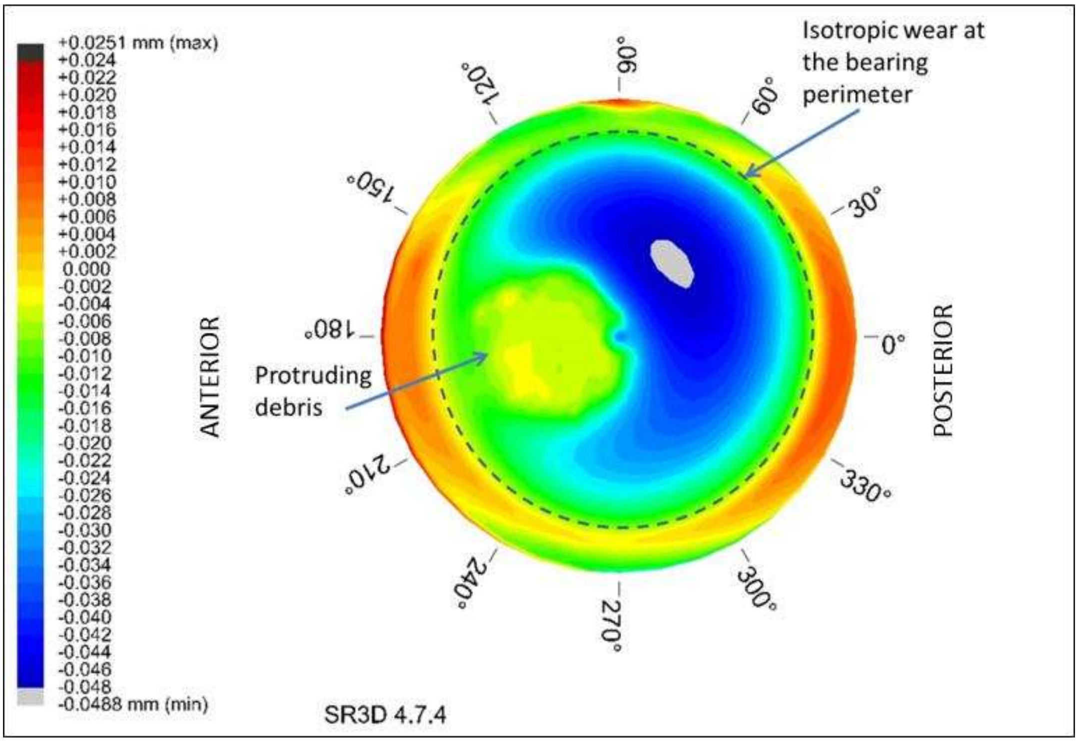

Figure 4 CMM contour plot at one million cycles (disc 5) displaying isotropic wear of the UHMWPE bearing at the perimeter of the wear area and an isolated raised area of roughening (protruding debris)

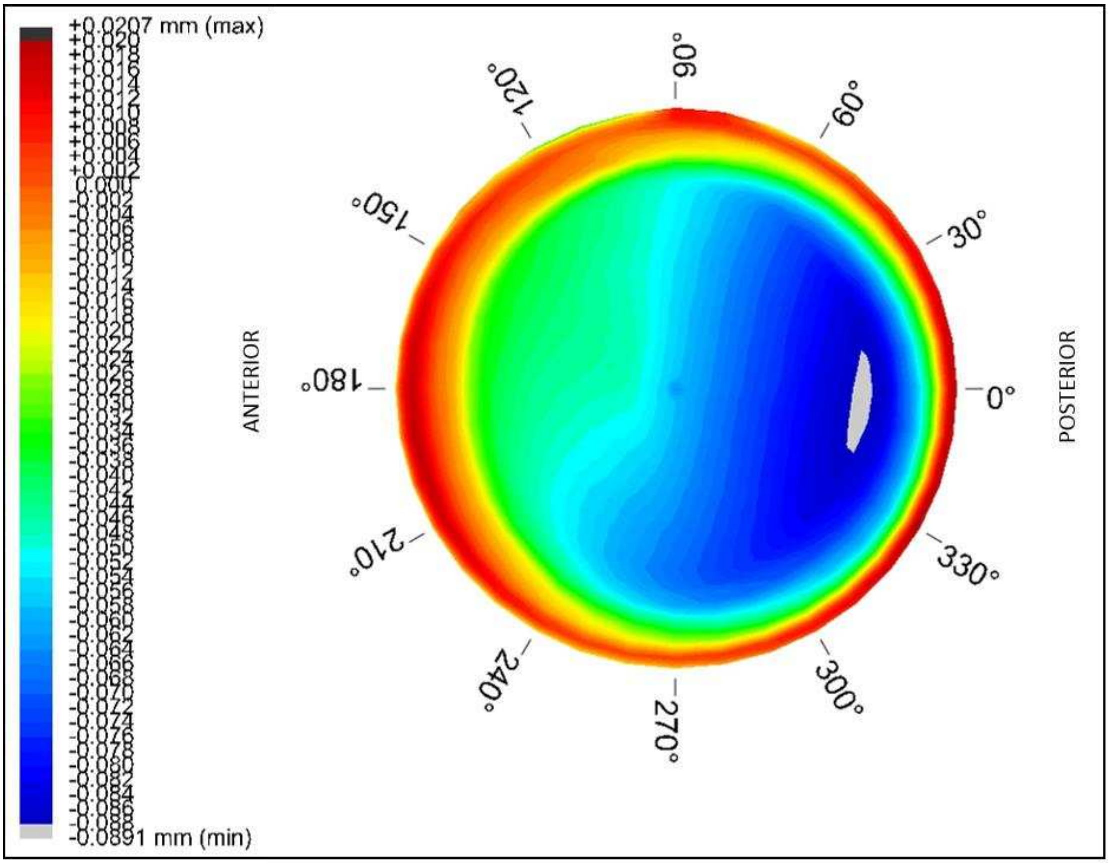

Figure 5 Disc 5 at 5 million cycles showing symmetrical wear and a lack of raised areas

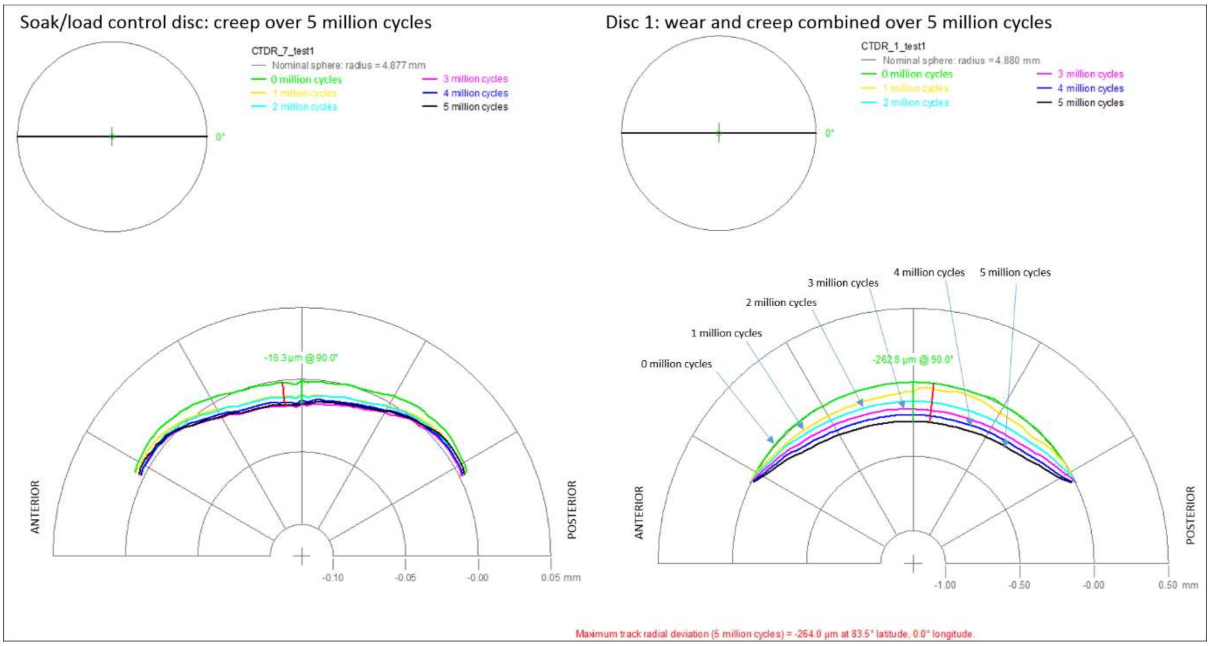

Figure 6 Disc 7 loaded soak control showing the process of creep deformation over 5 million cycles compared to a wearing disc (example disc 1, right)

Discussion

An investigation into the wear rates of a C-TDR subject to varying bovine serum lubricant concentrations was undertaken using a spine simulator. The rate of wear of the C-TDR UHMWPE components increased with increasing serum concentration and decreased as serum protein was reduced. There was no significant difference in wear between the 50 % serum and 25 % serum tests (ISO50 and ISO25 respectively), however further lubricant dilution did show significant difference. The wear study corresponding to the standard ISO18192-1 test was ISO50 (30 g/L protein) which produced a wear rate of 2.5 mm^3/MC. Under these same conditions Grupp et al. [19], Nechtow et al. [20], Anderson et al. [21] and Bushelow et al. [22] reported wear equating to: 1.07, 2.13, 1.28 and 1.95 mm^3/MC respectively. The wear rates quoted have been converted to mm^3/million cycles rather than the original mg/million cycles, since biological reactions are influenced by volumes of particles rather than weight.

Two of these published results align well with the rates of wear reported here. The two-fold difference in wear between this study and that of Grupp et al. may be explicable in terms of the different simulator designs and laboratory environments used. The average wear from this experiment and those described above is approximately six times lower than the average of L-TDR wear results reported for multi-path motions similar to the ISO inputs [19, 22-26] [17]. The increase in wear under higher protein lubricant concentration has been observed in MoP hip replacement tests by Wang et al [27], but conversely, Laio et al. [28] have reported the opposite trend. The accidental damage (and subsequent exclusion) of three of the test discs for the final two simulator studies demonstrated that the UHMWPE discs are susceptible to damage when off-centre positioning of the metallic cup is combined with loading. Thus, surgical mal-alignment coupled with moderate loading of the discs could cause damage.

Height loss of the UHMWPE soak component measured by CMM over the 5 million cycle (ISO25) study was shown to occur over the first million cycles, after which it reached steady state. Average roughness measurements (Ra) of articulating discs pre- and post-test showed a smoothing to approximately 49 % of pre-test values. In contrast, the soak control polymer component did not change roughness. This is in contrast to work examining L-TDR wear, where even the soak control disc was observed to become smoother, due to compression of the machined surfaces [17]. It should be noted that the loads applied to lumbar discs were considerably higher, resulting in increased contact pressure. The periphery of the wear zone showed signs of burnishing, also observed more overtly in L-TDRs [17]. Surface stylus measurement at these areas did not demonstrate any relationship between roughness and the amount of visual polishing. However, previous investigations using L-TDRs has shown a lowering of Ra values at the periphery wear area polishing [17]. The much smaller areas of interest on the C-TDR polymer component made it difficult to isolate areas of interest, which may have hindered isolating a trace on the burnished area.

The CMM measurements at the start of the study showed a noticeable compression and related expansion of the UHMWPE dome material. This was probably a result of the manufacturing process of the Braun activ C C-TDR. The UHMWPE domes are press-fitted into the metallic base and are held in place by tabs of protruding polyethylene (in the x axis) that slot into a recess in the baseplate at the lateral-medial points [Figure 7]. The force required to press fit these components is not insignificant. By 1 million cycles this slight eccentricity in the sphericity had become worn to an isotropic appearance.

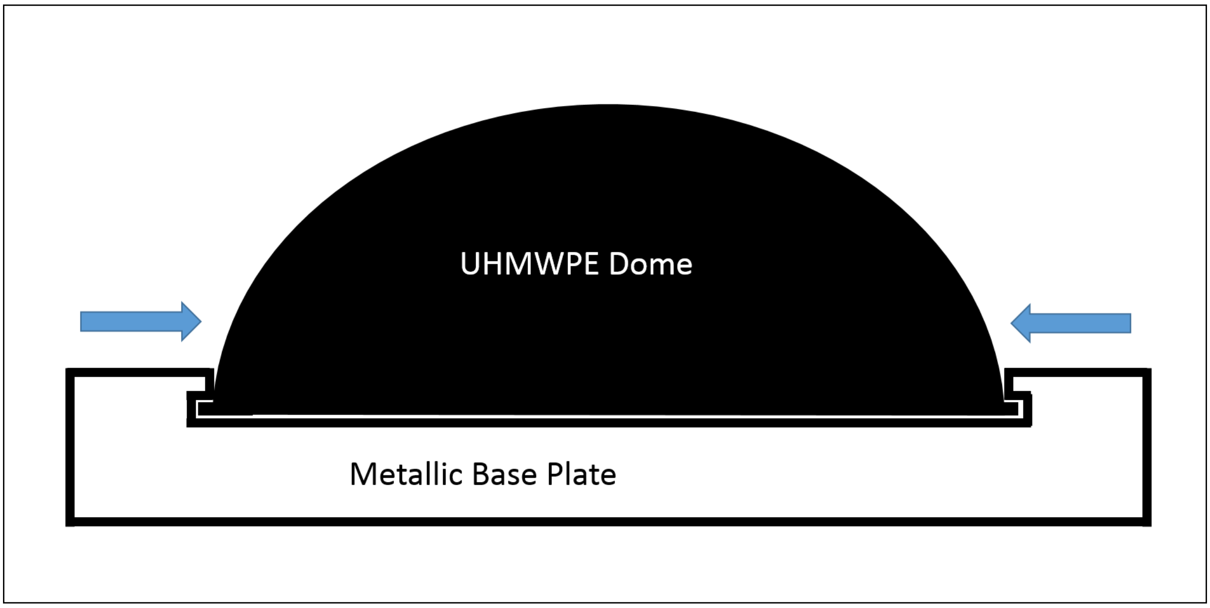

Figure 7 Schematic indicating location of compression (arrowed) of the UHMWPE dome components when fitted into the metallic base plate

The slight roughening recorded on disc 5 and 6 for a short period of time were probably due to particles of polyethylene debris which had re-attached to the convex bearing surface and become worn and part of the bulk material. This phenomenon has been previously observed in L-TDR in vitro studies on the same simulator [17, 23], where the process was more severe. Other in vitro wear tests in the literature have also exhibited similar roughening of UHMWPE orthopaedic bearings under certain conditions, notably high serum concentration [28]. Some ex planted L-TDRs have also exhibited roughening of the polymer components [29]. It is unclear whether C-TDRs in vivo will display that characteristic.

Historical studies of polyethylene have shown formation of polymer transfer film onto the metal counterface when water was used as a lubricant, this increased the counterface roughness and wear (pin on plate, unidirectional). Use of a ceramic counterface inhibits transfer film formation in water and maintains lower wear rate [30]. In hip simulator studies with water lubricant, a transfer film occurred on metal heads increasing the counterface roughness and thus increasing the polyethylene wear rate. However, for ceramic heads that remained free from transfer and surface roughness increase the wear rate was much lower [31]. In a hip simulator experiment when using 25% bovine serum there was no transfer film and the wear rate was higher and similar with both metal and ceramic femoral heads [18]. Comparing Bigsby et al. [18] and Debyshire et al. [31], and in the absence of transfer film and roughening in water lubricated tests with metal heads, this historical data shows lower wear with water (zero serum concentration) than with 25% serum. This comparison of historical data supports the reduction in wear with decreasing protein concentration found in this spine simulator study.

It is interesting to note that even if the in vivo spinal C-TDR is surrounded by a minimal protein-containing lubricant, this may not have an adverse effect of wear of a CoCr-on-UHMWPE device. However, the result of low protein lubrication on metal-on-metal (MoM) TDR implants could be detrimental. It should therefore be a priority to ascertain the type of pseudo-synovial fluid that the C-TDR eventually operates in. Other considerations to note may include anterior-posterior loading of the disc under physiological conditions and susceptibility to oxidation degradation.

Conclusions

The wear rate of C-TDRs was inversely proportional to the serum concentration, with 50 % concentration giving the highest wear and 3 % the lowest. Some adherence of polyethylene debris was observed on the UHMWPE domes. The surface of the UHMWPE components became smoother after testing, but the load-only soak control specimen did not change.

Acknowledgements

The Braun active C discs were provided by Aesculap Spine AG, Tuttlingen, Germany. John Fisher is an NIHR senior investigator and supported through NIHR LMBRU Leeds Biomedical Musculoskeletal Research Unit. Philip Hyde, Professor Fisher and Professor Hall are supported through the Leeds Centre of Excellence in Medical Engineering, WELMEC, funded by the Wellcome Trust and EPSRC, WT 088908/Z/09/Z. Mazen Al-Hajjar is thanked for his CMM advice.

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