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DOI:
10.1016/j.wear.2013.03.052

Wear 303 (2013) 473–479

Contents lists available at SciVerse ScienceDirect

Wear

journal homepage: www.elsevier.com/locate/wear

A tribological assessment of a PEEK based self-mating total cervical disc replacement ☆

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ARTICLE INFO

Article history:
Received 29 January 2013
Received in revised form
28 March 2013
Accepted 30 March 2013
Available online 17 April 2013

Keywords:
Cervical total disc replacement
Friction
Lubrication
Poly-ether–ether–ketone (PEEK)
Spine simulator
Wear

ABSTRACT

This paper presents an in-vitro tribological investigation of the PEEK (Poly-ether–ether–ketone) based self-mating articulation of the NuNec® cervical disc replacement. All tests were undertaken using Bose spine simulator. Discs were subjected to wear tests and this involved applying the load and motions given in ISO 18192-1. Wear was determined from the mass loss from the specimens. Testing continued until 5 million cycles had been completed. Disc were subjected to friction tests, before and after the wear testing; each specimen was tested under a constant axial compressive and then subjected to the motions given in ISO 18192-1. Stribeck analysis was used to determine the lubrication regime. The wear rates for the initial phase (0–2 million cycles) and the steady stage (2–5 million cycles) were 4.8 ± 1.5 mg/million cycles and 1.0 ± 0.9 mg/million cycles, respectively. Over the entire test period, the total mass loss was 12.5 ± 0.4 mg. The Stribeck analysis showed that this cervical disc will operate under boundary or mixed lubrication.

1. Introduction

Intervertebral discs separate the bony vertebrae in the human spine. They are susceptible to degenerative diseases, nutritional deficiency and ageing [1]. A dysfunctional intervertebral disc can lead to chronic spinal pain with a limited degree of motion. A traditional surgical treatment for this condition is spinal fusion, however clinical follow up studies show that this intervention may induce a high incidence of adjacent disc degeneration [2]. To overcome this problem, motion preservation devices, such as cervical total disc replacement, have been introduced as an alternative treatment. Cervical total disc replacement is a relatively new technique and it is uncertain whether its performance is superior to that of fusion, based on the available short-term clinical results [3–5].

Cervical total disc replacement can be readily applied in patients presenting with neurological deficit, radiculopathy or myelopathy [6]. A number of cervical total disc implants that have been approved for use in patients [7]. The designs include a variety of bearing materials. The Prodisc-C (Synthes, Paoli, PA, USA) and PCM (Cervitech, Rockaway, NJ, USA) both have an ultra high molecular weight polyethylene (UHMWPE) against cobalt chromium molybdenum alloy (CoCrMo) bearing coupling [8,9]. The Prestige (Medtronic Sofamor Danek, Memphis, TN, USA) has a stainless steel or titanium ceramic composite self-mating bearing [10]. A polyurethane against titanium bearing coupling is used in the Bryan (Medtronic Sofamor Danek, Memphis, TN, USA)[11].

Among these current designs, the ball-on-socket design configuration dominates; a metal-on-metal combination or metal-on-polyethylene combination is normally adopted for the articulation surfaces. Since wear is an inevitable consequence of normal function, wear debris induced complications are a possible failure mode for cervical total disc replacements. Problems associated with wear debris, such as osteolysis and metal ion accumulations, have already been seen in lumbar total disc replacements [12–15]. Metal based discs, such as the Maverick lumbar disc can result in undesirable metal ion (cobalt and chromium) accumulations in the peri-prosthetic tissue, and can lead to potential health problems [12,13]. Polymer detritus (i.e. UHMWPE) can trigger a foreign body granulomatous response, and stimulate bone re-absorption (i.e. osteolysis) which can eventually lead to implant loosening [14,15].

Recently, a new bearing combination of PEEK (polyether–ether–ketone) based self-mating articulation has been introduced, with great potential to overcome current wear debris induced issues. PEEK is a semi-crystal aromatic thermoplastic [16] with proven biocompatibility [17]. PEEK and carbon reinforced PEEK have been used in a variety of medical devices such as fusion cages and fracture plating systems [18]. An animal model biocompatibility study demonstrated that PEEK based implants were well tolerated by the spinal tissues with only mild inflammation [19]. Moreover, an in-vitro monocyte study showed that PEEK based particles (i.e. wear debris) was non-cytotoxic, and less inflammatory than UHMWPE particles of similar size and shape [20]. The aim of this

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http://dx.doi.org/10.1016/j.wear.2013.03.052

study was to undertake and an in-vitro tribological investigation of the PEEK (Polyether–ether–ketone) based self-mating articulation of the NuNec® cervical disc replacement.

carry out a comprehensive wear, friction and lubrication analysis of a PEEK against PEEK cervical disc replacement, via in-vitro spine simulator tests.

2. Materials and methods

2.1. Specimen

In-vitro simulations were performed with the NuNec® cervical disc replacement (Pioneer Surgical Technology Inc., Driebergen, Netherlands) of the smallest available footprint (Anterior–Posterior 12 mm and Lateral 14 mm) with a nominal total disc height of 5 mm. This cervical replacement is a two-piece PEEK-on-PEEK articulating device, and adopts the conventional ball-on-socket design configuration, as shown in Fig. 1. A unique titanium cam fixation mechanism is used for immediate short-term fixation, whereby metal blades extend from the device to grip the bone; long-term fixation is achieved via the hydroxyapatite coated endplates. Tantalum based radiopaque markers are adopted to facilitate the postoperative diagnostic visualization.

To attach the disc replacement to the spine simulator, disc fixtures were made from 316 L stainless steel by 3T Rapid Product Development Ltd. (Newbury, Berkshire, UK). Each pair of fixtures consisted of two parts with the inner contour cut to accommodate the end plates of the artificial discs, as shown in Fig. 2. Fixation was achieved by a press-fit of the disc replacement into the fixture with the addition of locking pins; note that the original fixation cams were removed.

2.2. Wear and surface characterisation

All wear tests were performed according to ISO 18192-1 [21] using Bose SDWS-1 Spine Simulators (Bose Corporation, ElectroForce Systems Group, Minnesota, USA), controlled by Win test software (Fig. 3). The SDWS-1 is a single station spine simulator designed to carry out multi-directional motions ($\pm 15^\circ$ flexion/extension, $\pm 12^\circ$ lateral bending, and $\pm 9^\circ$ axial rotation), under ± 3 kN axial load, at 0 to 2 Hz test frequency. A dynamic load soak control was performed using a Bose 3330 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnesota, USA). It was also controlled by Win test software and is capable of providing a ± 3 kN axial dynamic load, at 0 to 100 Hz test frequency.

A disc replacement was initially mounted on the disc fixture; this assembly was then attached to a custom-designed fixture adaptor to allow the correct alignment and orientation within the simulator. The instantaneous centre of rotation of the artificial disc (i.e. the centre of the sphere from which the ball component is created) was positioned at the centre of the axes of rotation of the spine simulator. The inferior endplate of the disc replacement was aligned parallel to the base of the spine simulator, with a 0° inclined angle; the radiopaque markers of the ball and socket components were aligned in the vertical plane. The axial load and axial rotation were applied through the lower disc fixture. The upper disc fixture applied flexion–extension and lateral-bending.

Four NuNec® discs were used for the simulations; three for wear tests (discs 1 to 3) and one for the load soak control (disc 4). A similar number of specimens have been used in previous wear studies [22–24]. For the wear tests, a sinusoidally varying load (50–150 N at 1 Hz) was applied to the disc replacement, together with the motions of $\pm 7.5^\circ$ flexion/extension, $\pm 6^\circ$ lateral bending and $\pm 4^\circ$ rotation, all at 1 Hz. All motions were out of phase in accordance with ISO 18192-1 [21]: the lateral bending was 90° relative to the flexion/extension axis; the axial rotation and the lateral bending were 180° out of phase. Disc 4 was subjected to a dynamic axial load (50–150 N at 1 Hz) without motion, which was used as a reference point to correct for fluid uptake during the wear simulations. Prior to the commencement of the wear testing, each disc replacement was soaked in deionised water for more than four weeks to stabilize the mass [25]. Simulations were performed using a newborn calf serum based lubricant (Sera Lab Ltd., West Sussex, UK) which was diluted with deionised water to give a protein content of 20 ± 2 g/l at 37 °C [21]. A 0.3 g/l concentration of sodium azide was also added to retard bacterial growth. The lubricant lost by evaporation during testing was replenished twice daily with de-ionised water, and the serum was completely replaced every 0.5 million cycles.

The disc specimens were tested for 5 million cycles. At each measurement interval (0, 0.25, 0.5, 1, 2, 3, 4 and 5 million cycles), the specimens were cleaned [26]. The disc specimens were initially cleaned using a liquid detergent (Fairy washing liquid, Procter & Gamble, Surrey, UK) and then rinsed twice with distilled water.

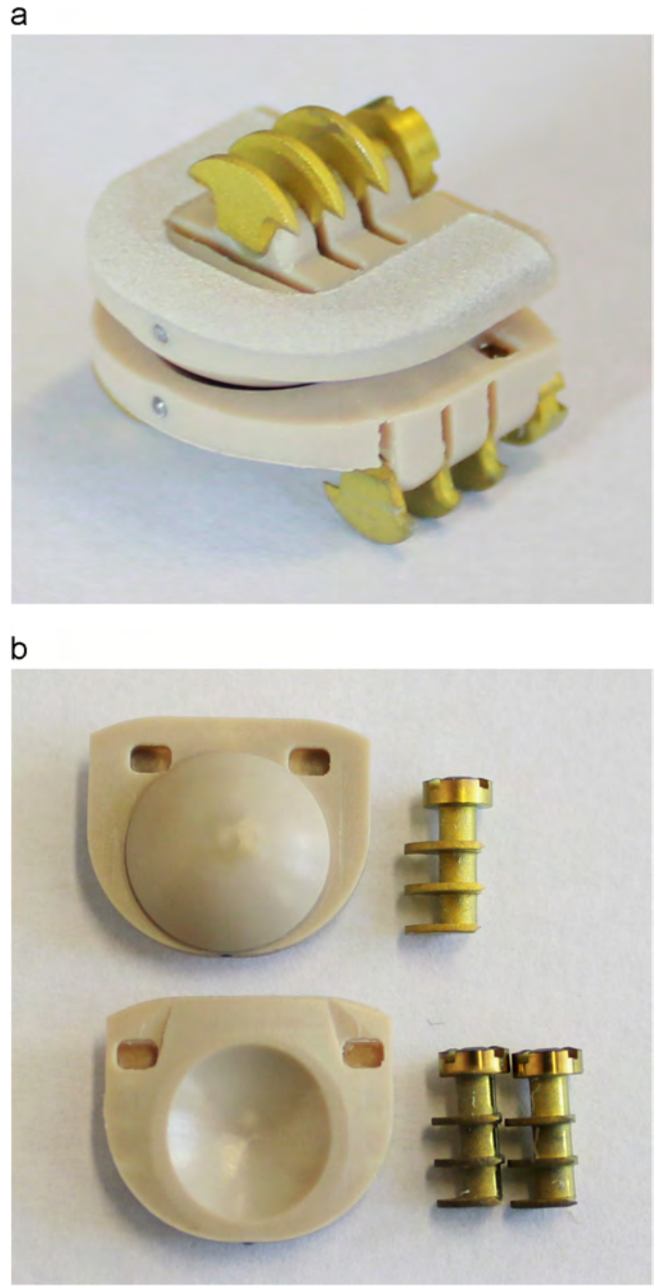

Fig. 1. The NuNec® cervical disc replacement system (a) assembled; (b) unassembled. The dimensions of the device in the anterior–posterior and lateral directions are 12 mm and 14 mm, respectively.

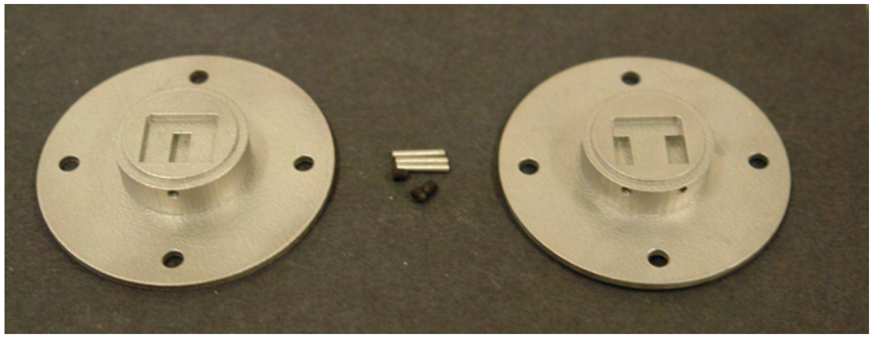

Fig. 2. Disc fixtures: lower disc fixture (left); locking pins (centre); upper disc fixture (right). Note the hollow for placement of the disc replacement with the dimensions in the anterior–posterior and lateral directions being 12 mm and 14 mm, respectively.

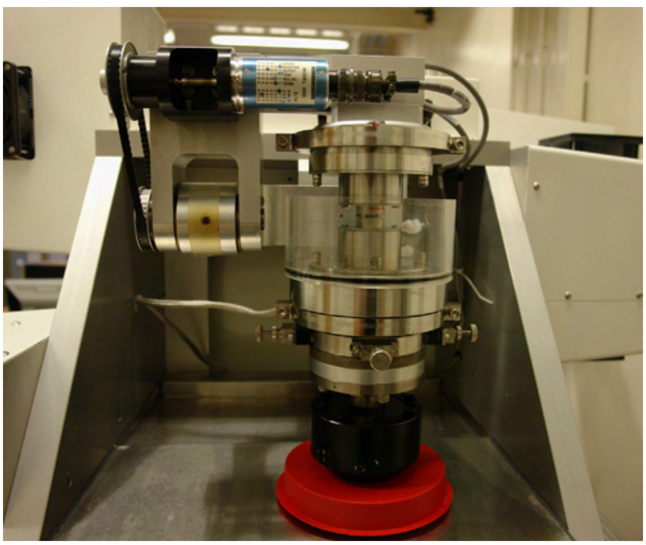

Fig. 3. Bose spine simulator.

Specimens were then soaked in Virkon disinfectant solution (Antec International Ltd., Sudbury, UK) for 20 min, rinsed twice and ultrasonically cleaned in a propan-2-ol bath (Scientific Laboratory Supplies, Hessle C, East Yorkshire, UK) for at least 5 min. Finally, the specimens were wiped with acetone (Sigma-Aldrich, MO, USA) and placed in a dust free container. After being left at room temperature for 48 h, the average mass of each specimen was recorded (from six separated measurements with different orientations) using an OHAUS GA200D digital balance (OHAUS Europe GmbH, Switzerland) with 0.1 mg precision. To adjust for the effect of fluid absorption and other unrelated wear reasons, the change in mass of the control disc was subtracted from that of the wear tested disc.

Surface examination was performed before and after wear tests using a white light non-contacting MicroXAM 2 interferometer (Omniscan Ltd., Penycase, UK). A 10 × objective lens was used to give an area of view of 639 × 859 μm at the centre of the specimen. Scanning Probe Image Processor software (Image Metrology A/S, Copenhagen, Denmark) was employed for the analysis of surface topology. The arithmetic surface roughness S_a, root mean square surface roughness S_q and surface skewness S_{sk} were measured.

2.3. Frictional torque

Frictional tests were performed using the same Spine Simulator (Section 2.2) equipped with an AMTI MC3-6-1000 multi-axial load cell (Berkshire, UK), with a torque precision of 0.01 N m. Frictional tests were performed on discs 1 to 3, before and after the wear simulation. Each specimen was tested under a constant axial compressive load of 150 N, combined with a single degree of sinusoidal motion for 100 cycles. The motions of 0° to +7.5° flexion, 0° to +6°lateral bending, and 0° to +4° axial rotation were each individually applied. Each motion was tested within a range of frequency from 0 Hz to 2 Hz, at 0.25 Hz increments. An average peak frictional torque (T) was calculated based on the values from the last 10 cycles during each simulation [26].

To determine the lubrication regime under which the disc replacement was acting, Stribeck analysis was used where friction factor (f) was plotted against the Sommerfeld number (Z). These two parameters were calculated from [26–28]:

$$f = T/rL \tag{1}$$

where r is the ball radius and L is the applied load. The ball radius of NuNec® disc was found to be 6.3 mm in a previous study [29]:

$$Z = \eta ur/L \tag{2}$$

where η is the lubricant viscosity and u is the entraining velocity which can be obtain from:

$$u = \omega r/2 \tag{3}$$

where ω is the angular velocity (in radians) and can be expressed as follow:

$$\omega = 2\theta h\pi/180 \tag{4}$$

where θ is the angular displacement in each motion (e.g. 7.5° for flexion), and h is the test frequency.

The viscosity of the lubricant was measured using an AR-G2 cone-on-plate rheometer (TA instruments, West Sussex, UK) for shear rates between 0.01 s^{-1} to 100 s^{-1}, at 37 °C. Four repeated measurements were taken and the mean (± standard deviation) viscosity of the lubricant was found to be 1.03 ± 0.12 mPa s.

2.4. Statistical analysis

The post-wear friction data was compared with the pre-wear results by plotting the 95% confidence intervals. Error bars were used to represent the 95% confidence intervals. If the confidence regions overlap with each other, it indicates there is no significant difference; if there is no overlap, it indicates a significant difference. This method has been used previously to determine the variation of frictional torque of a metal-on-polymer based lumbar disc replacement after the bearing material was reversed [30].

3. Results

3.1. Wear results

For the PEEK-on-PEEK bearing combination subjected to in-vitro wear simulation, the accumulated mass loss was plotted against the number of cycle for each individual disc (Fig. 4). There was no mass gain of the control specimen, but rather there was mass loss due to the hydroxyapatite coating break off during each cleaning procedure. After 5 million cycles, the coating was completely removed (see Fig. 5).

After correcting the mass loss using the control disc, the mean PEEK mass loss from the discs (1 to 3) was plotted against the number of cycles, as shown in Fig. 6. An initial run-in phase with a higher wear rate was observed (from 0 to 2 million cycles); this was followed by a steady-state phase with a reduced wear rate. The wear rates, for each wear phase, are summarised in Table 1. The corresponding volumetric wear rates were calculated, by taking into account the density of 1.3 g/mm^3 for PEEK [25,31]. Over the entire wear test period, the total mean mass loss of PEEK was 12.5 ± 0.4 mg and the corresponding mean volumetric loss was 9.6 ± 0.3 mm^3.

Fig. 7 shows the articulation surfaces before and after 5 million cycles for disc 1. Prior to testing, fine machining marks were observed on the bearing surfaces. However, these had been removed with some burnishing after testing. The characteristics of these wear patterns were consistent for all tested discs. Closer examination of the articulation surfaces (Fig. 8) shows the change in surface topography, with wear tracks seen on the bearing surface for the same disc. The change in surface profile is summarised in Table 2. The surface roughness parameters (S_a and S_q) were reduced in both components after 5 million cycles, while the surface profile (S_{sk}) of socket component was reversed from positive to negative skewness.

3.2. Frictional results

The frictional torque results are presented in Fig. 9. The mean maximum frictional torques, prior to and at the end of the wear tests, occurred during flexion and were 3.71 ± 0.22 N m and 3.58 ± 0.13 N m, respectively. Statistical analysis showed that there was no significant difference between pre-wear and post-wear mean friction torques at each test frequency, for every motion, as the 95% confidence intervals overlap each other.

The mean frictional torques taken from discs (1–3) were used to generate Stribeck plots to determine the general lubrication regime for the disc replacement and are shown in Fig. 10. Prior to wear simulation, under flexion or lateral bending motion, a slight downward trend was seen as Sommerfeld number increased which indicates boundary or mixed lubrication. For axial rotation, boundary lubrication dominated with a fairly constant trend observed for the friction factor with increasing Sommerfeld number. After 5 million cycles, there was no obvious change in

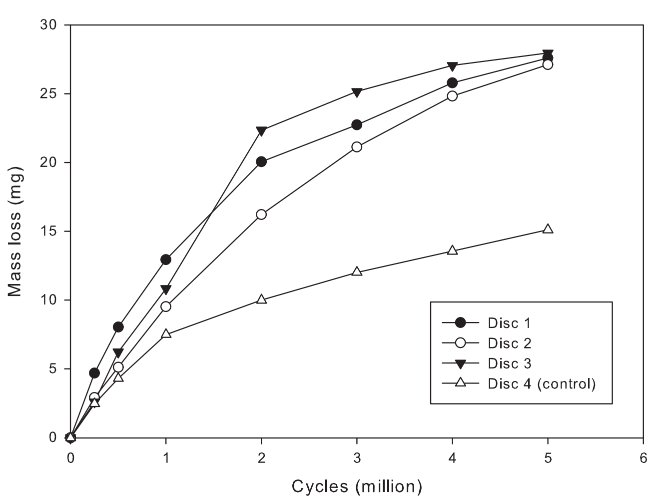

Fig. 4. Cumulative mass loss against number of cycles, for each disc.

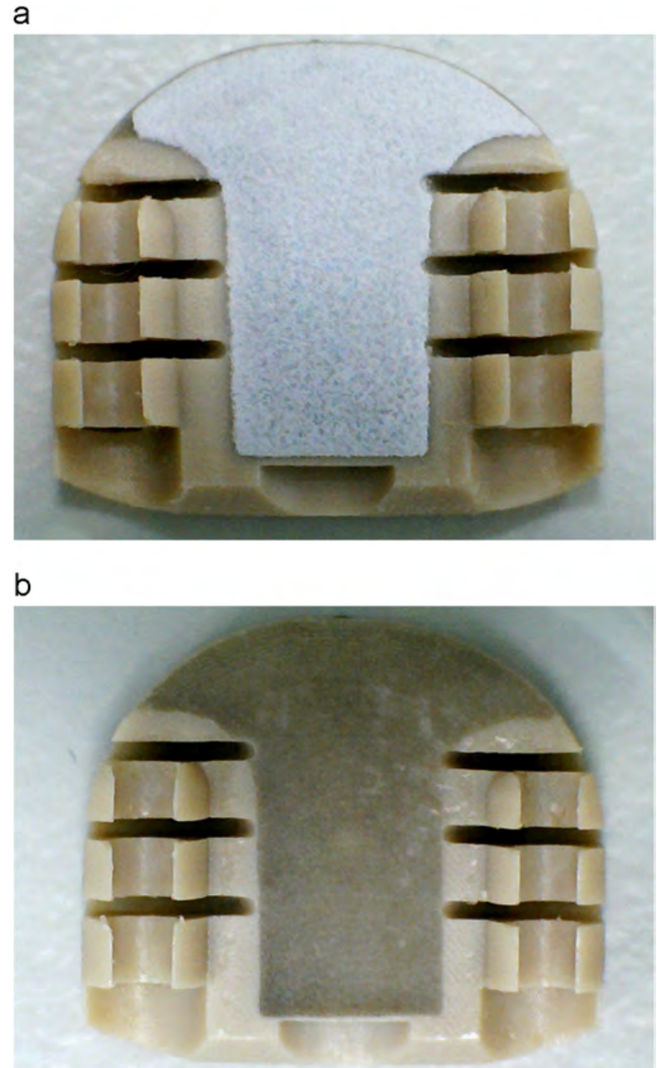

Fig. 5. Disc 1 superior end plate (a) pre-wear and (b) after 5 million cycles.

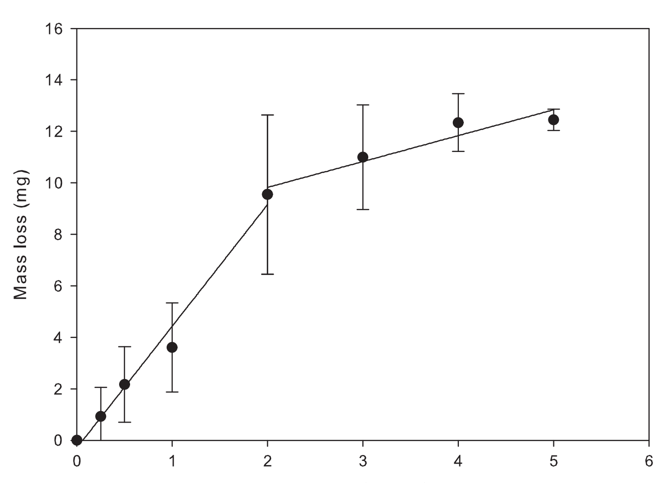

Fig. 6. Mean PEEK mass loss against number of cycles for discs 1 to 3. Error bars represent the standard deviation. Two regression lines have been fitted $y=4.7x-0.3$ ($R^2=0.98$) and $y=x+7.8$ ($R^2=0.91$) to show the initial run-in phase and steady-state phase. Note that the actual wear rates were calculated from the data and not gradient of the graphs were not used.

Table 1
The mass loss rate for each individual disc. The mean mass loss and mean volume loss are also presented.

Number of cycles ($\times 10^6$)	Disc 1 (mg/10^6 cycles)	Disc 2 (mg/10^6 cycles)	Disc 3 (mg/10^6 cycles)	Mean $\pm$ SD. (mg/10^6 cycles)	Mean $\pm$ SD ($mm^3/10^6$ cycles)
0–2 (Run-in)	5.0	3.1	6.2	4.8 ± 1.5	3.7 ± 1.2
2–5 (Steady-state)	0.8	1.9	0.2	1.0 ± 0.9	0.7 ± 0.7
0–5 (Overall)	2.50	2.40	2.6	2.5 ± 0.1	1.9 ± 0.1

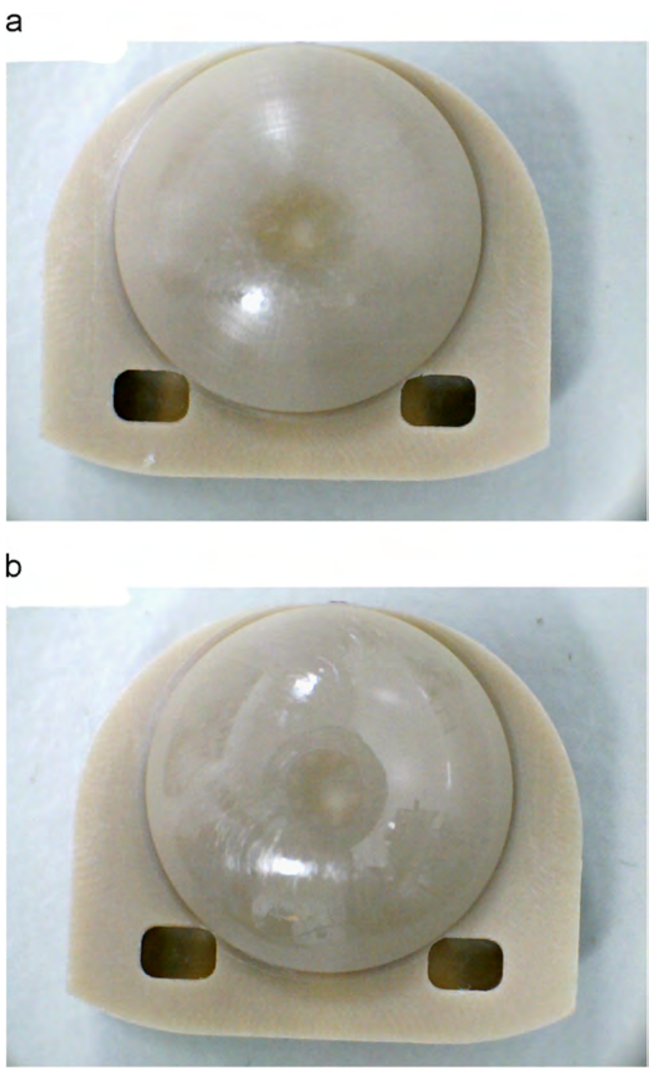

Fig. 7. Disc 1 ball part (a) pre-wear and (b) after 5 million cycles.

the Stribeck curve for each motion; the disc arthroplasties still operated under a boundary to mixed lubrication regime.

4. Discussion

In this study, the tribological performance of a PEEK-on-PEEK NuNec® cervical disc replacement was assessed. Laboratory wear simulation was conducted via single station spine simulators, in accordance with ISO 18192-1 [21]. The measured wear rates of 4.8 ± 1.5 (run-in) and 1.0 ± 0.9 (steady-state) mg/million cycles, correspond well to literature spine simulator studies. These wear rates are for the smallest size of the NuNec® cervical disc replacement and the other sizes of devices would need to be tested to gain a full understanding of relationship between implant size and wear rate. Grupp et al. [25] determined a wear rate of 1.4 ± 0.4 mg/million cycles during steady-state conditions for a generic PEEK self-mating cervical disc using the Activ® C cervical disc as the prototype. They conducted a 10 million cycle laboratory wear simulation using an Endolab multi-station spine simulator, under the 2008 version of the ISO 18192-1 [21] protocol, in a bovine serum based lubricant with 30 g/l protein content. In another wear study, under identical test conditions as Grupp et al. [25], a higher test frequency of 2 Hz was used; a PEEK based generic cervical disc had a steady-state wear rate of 1.44 mg/million cycles and a run-in wear rate of 5.09 mg/million cycles [32]. Brown et al. [33] previously reported a relative low wear rate of 0.4 mg/million cycles (steady-state) for the same NuNec® cervical disc replacement. In their study, a MTS multi-station spine simulator was used and followed the 2008 version of ISO 18192-1 [21] protocol. However, the actual composition of lubricant, the test frequency and the disc size were not disclosed, thus it is difficult to identify the reasons for the difference found.

In this study three cervical disc replacement devices were subjected to the wear tests. Although a similar number of specimens have been used in previous wear studies of joint replacement devices [22–24] it is acknowledged that more samples would be desirable. Further, the standard deviations in this study are higher than some other previous studies Grupp et al. [25].

The gravimetric wear rates of cervical disc replacement with UHMWPE against CoCrMo bearing combination have been reported as 1.0 ± 0.1 mg/million cycles [25] and 2.8 mg/million cycles [32], in spine simulator wear studies. These values correspond to volumetric wear rates of 1.07 mm^3/million and 3.0 mm^3/million cycles, respectively. In comparison, a lower volumetric wear rate of 0.7 ± 0.7 mm^3/million cycles of PEEK self-mating bearing articulation was observed in this study. Therefore, a PEEK based bearing is likely to generate less volume of wear particles than UHMWPE against CoCrMo. It is worth mentioning that a preliminary pin-on-disc screen study [34] showed completely opposite wear results. It was shown that PEEK based self-mating articulation had a wear factor 4 times larger of that of UHMWPE against CoCrMo. This inconsistency is due to the adoption of different testing conditions and different motion profiles. The Pin-on-disc wear study involved applying a 2 MPa static compressive loading, combined with reciprocation and rotating-pin motion, and was conducted in 15 g/l protein content bovine serum [34].

After 5 million cycles, mild burnishing was found on the bearing surfaces (Fig. 7b). This was consistent with the observed surface topology change. The surface roughness of the ball and socket components was reduced (Table 2) which indicated a smoother contact surface. Examination of all the articulating surfaces indicated that the main mechanisms of wear were abrasion and adhesion. Examination of the wear traces (Fig. 8) indicates that third body abrasion also occurred and was likely to have been caused by PEEK wear debris or the hydroxyapatite coating particles that became detached during the testing and cleaning process. No other surface damage was observed on the articulation surfaces after 5 million cycles.

Further examination of the socket surface showed that it was initially positively skewed with many asperities, thus these could have led to the high abrasive wear during the running-in phase. After 5 million cycles many of these asperities have been flattened or removed, so the socket surface showed a negative skewed and a smooth surface profile. Topography such as this, facilitates a higher contact area, which may be more suitable for lubricated sliding. This may explain the observed low wear rate after steady-state

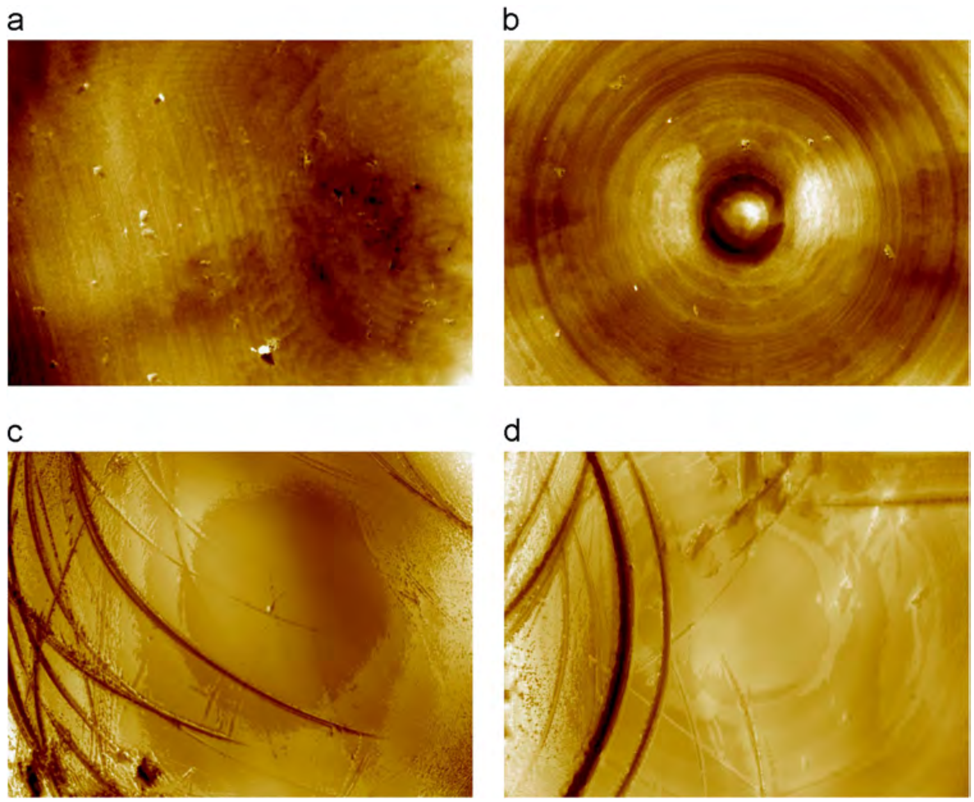

Fig. 8. Surface scan of disc 1 (a) ball pre-wear, (b) socket pre-wear, (c) ball after 5 million cycles and (d) socket after 5 million cycles. Area of view is 639 × 859 μm at the centre of the specimen.

Table 2
Surface roughness values (mean ± SD.) during wear testing for discs 1 to 3.

	Socket component		Ball component	
Parameters	Pre-wear	Post-wear	Pre-wear	Post-wear
S_a (μm)	0.967 ± 0.056	0.412 ± 0.035	0.949 ± 0.058	0.267 ± 0.033
S_{rms} (μm)	1.273 ± 0.058	0.599 ± 0.069	1.190 ± 0.066	0.350 ± 0.037
S_{sk}	0.408 ± 0.228	−1.453 ± 1.498	−0.303 ± 0.121	−0.362 ± 0.465

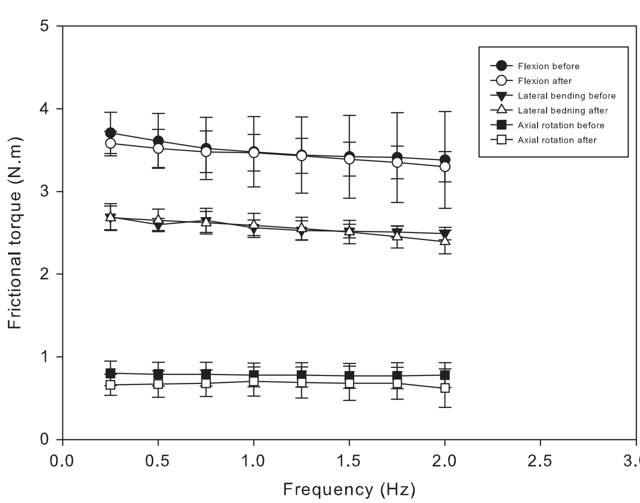

Fig. 9. Mean frictional torques of discs (1–3), before and after wear testing, plotted against frequency. Error bars represent 95% confidence intervals.

wear was reached. Disintegration of the bearing surfaces (pitting and delamination) observed by other studies [25,32] after run-in wear stage, was not seen in our study.

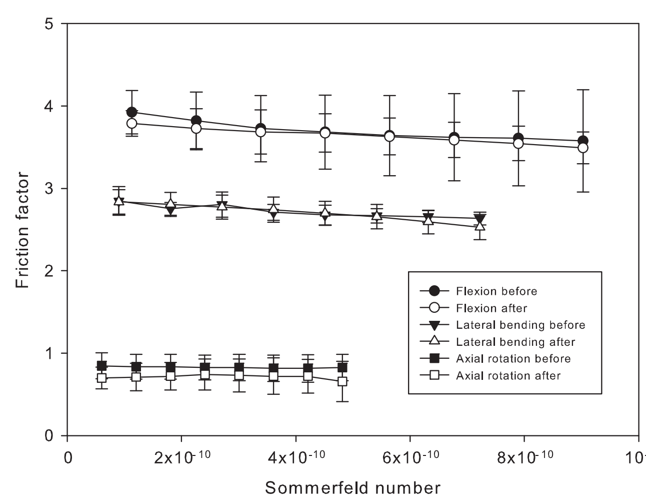

Fig. 10. Stribeck plots of discs in flexion, lateral bending and axial rotation, before and after wear testing. Error bars represent 95% confidence intervals.

The main wear mechanism was abrasion wear rather than fatigue wear. Fatigue wear mainly depends on the contact stress and the bearing material, which in turn depend on the prosthesis design [27]. A previous contact stress analysis showed that the maximum Hertzian contact stress of NuNec® cervical disc replacement of the smallest size is 32.1 MPa [29]. The experienced contact stresses between the bearing surfaces of other comparable studies were unknown [25,32], due to lack of information of the bearing design (ball radius and radial clearance).

Temperature at the bearing surfaces was not measured in the study and previous studies that have investigated devices with PEEK based self-mating bearing surfaces have not made any reference to temperature or heat dissipation [25,34]. Further, the wear tests in this study were carried out in accordance with ISO

18192-1 [21] where the fluid in the bath surrounding the disc replacement was maintained at 37 °C under similar conditions the devices will experience in vivo.

The Stribeck analysis showed that this cervical disc will operate under boundary or mixed lubrication regime, both before and after wear testing to 5 million cycles. A previous theoretical analysis of PEEK based cervical disc shows that NuNec® cervical disc will operate with a boundary lubrication, under natural cervical spine operating conditions [29].

The hydroxyapatite coating from the discs was lost during the experiments as a result of the cleaning process. The loss of the hydroxyapatite coating was not as a result of the wear testing as the coating was also lost from the control disc where there was no motion. Clearly the loss of the hydroxyapatite coating is not something that would occur in vivo, but it does raise a question about alternative methods of cleaning that may need to be developed for wear testing of implants that have hydroxyapatite. It could have potentially introduced third body wear into the tests that could result in different wear rates.

5. Conclusions

In this study, the tribological performance of the NuNec® cervical disc was assessed. The PEEK-on-PEEK self-mating bearing combination showed a steady state wear rate of 1.0 ± 0.9 mg/million cycles. The corresponding volumetric wear rate was 0.7 ± 0.7 mm^3/million cycles. This all-polymer based cervical disc arthroplasty is likely to operate under a boundary or mixed lubrication regime, and the main wear mechanism is abrasive wear. The hydroxyapatite coating from the discs was lost during the experiments and alternative methods of cleaning that may need to be developed for wear testing of implants that have hydroxyapatite or implants are tested without the coating.

Acknowledgements

We thank Dr James Bowen for the help measurements of surface roughness and viscosity. This work was supported by the Engineering and Physical Science Research Council [grant number EP/F014562/1]. The MicroXAM 2 interferometer (Omniscan Ltd., Penycase, UK) and AR-G2 rheometer (TA Instruments, West Sussex, UK) used in this research were obtained, through Birmingham Science City: Innovative Uses for Advanced Materials in the Modern World (West Midlands Centre for Advanced Materials Project 2), with support from Advantage West Midlands (AWM) and part funded by the European Regional Development Fund (ERDF).

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