PEEK (Polyether-ether-ketone) Based Cervical Total Disc Arthroplasty: Contact Stress and Lubrication Analysis

H. Xin, D.E.T. Shepherd* and K.D. Dearn

School of Mechanical Engineering, University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK

Abstract: This paper presents a theoretical analysis of the maximum contact stress and the lubrication regimes for PEEK (Polyether-ether-ketone) based self-mating cervical total disc arthroplasty. The NuNec® cervical disc arthroplasty system was chosen as the study object, which was then analytically modelled as a ball on socket joint. A non-adhesion Hertzian contact model and elastohydrodynamic lubrication theory were used to predict the maximum contact stress and the minimum film thickness, respectively. The peak contact stress and the minimum film thickness between the bearing surfaces were then determined, as the radial clearance or lubricant was varied. The obtained results show that under 150 N loading, the peak contact stress was in the range 5.9 – 32.1 MPa, well below the yield and fatigue strength of PEEK; the calculated minimum film thickness ranged from 0 to 0.042 μm and the corresponding lambda ratio range was from 0 to 0.052. This indicates that the PEEK based cervical disc arthroplasty will operate under a boundary lubrication regime, within the natural angular velocity range of the cervical spine.

Keywords: Cervical disc arthroplasty, contact stress, elastohydrodynamic, hertzain, lubrication, PEEK.

1. INTRODUCTION

This paper investigates important design parameters for PEEK (Polyether-ether-ketone) based self-mating cervical total disc arthroplasty. The human spine consists of a series of bony vertebrae that are separated by intervertebral discs, which consist of the inner nucleus pulposus and the outer annulus fibrosus [1]. The intervertebral disc is susceptible to degenerative diseases, nutritional deficiency, and ageing. A dysfunctional intervertebral disc can lead to spinal pain with a limited degree of motion [2].

There are generally two types of treatments for medium to severe neck pain: fusion surgery (FS) and motion preservation implantation, such as total disc arthroplasty (TDA). FS is considered as the 'gold standard' which can successfully relieve pain, however the spinal motion is also removed at the operation level. The primary aim of utilizing TDA is to restore pain-free motion [3]. Cervical TDA is a relatively new technology and there is much debate as to whether its performance is superior to that of fusion [4-7].

A number of cervical total disc implants that have been approved for use in patients including [3]:

- Bryan (Medtronic Sofamor Danek, Memphis, TN, USA) – Polyurethane against Titanium bearing coupling;
- Prestige (Medtronic Sofamor Danek, Memphis, TN, USA) – Stainless steel or Titanium ceramic composite self-mating bearing;
- Prodisc-C (Synthes, Paoli, PA, USA) – Ultra High Molecular Weight Polyethylene (UHMWPE) against Cobalt Chromium Molybdenum alloy (CoCrMo) bearing coupling;
- PCM (Cervitech, Rockaway, NJ, USA) – UHMWPE against CoCrMo bearing coupling.

Among these current designs, the ball and socket design configuration dominates. Different material combinations have been used under this configuration to achieve the best tribological and fatigue outcomes; however some degree of inherent deficiencies or defects still exists for these combinations. Metal implants such as the Maverick lumbar disc can release metal ions (cobalt and chromium) in the form of wear debris. This detritus can cause localised tissue ion accumulation and eventually lead to cell death at excessive concentrations [8, 9]. This is also expected to happen in metal based cervical discs, since wear is an inevitable consequence of normal function. Polymer joint implants (*e.g.* Ultra High Molecular Weight Polyethylene) generate wear debris which can provoke an adverse biological response (*i.e.* inflammation), and stimulate osteolysis which finally leads to implant loosening [10, 11]. With the intention of overcoming the above shortcomings, new bearing materials have been introduced. PEEK (Polyether-ether-ketone) is one such material with great potential for cervical total disc replacement. However, its full performance needs to be analysed to investigate if it overcomes the problems of other material combinations. PEEK is a semi-crystal (i.e. having both amorphous and crystal phases) thermoplastic of the poly-aryl family. The aromatic backbone (*i.e.* benzene rings) is interconnected by the ether and ketone functional groups. This kind of chemical structure, generally shows high radiation and thermal ageing resistance with good mechanical and

*Address correspondence to this author at the School of Mechanical Engineering, University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK. Tel: +44 121 414 4266; Fax: +44 121 414 3958;
E-mail: d.e.shepherd@bham.ac.uk

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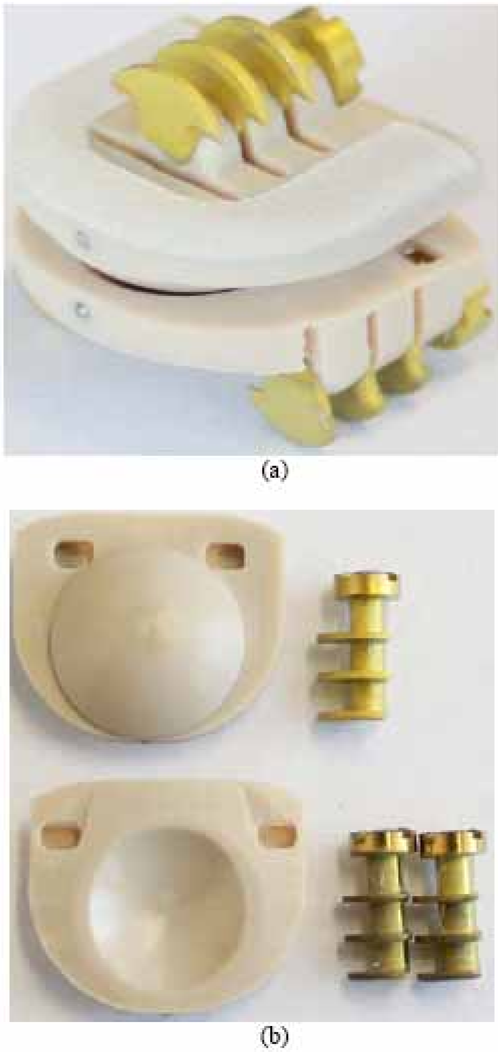


Fig. (1). The NuNec® cervical arthroplasty system **a**) assembled; **b**) unassembled.

tribological performance [12]. The overall aim of this study was to use theoretical analysis to investigate the maximum contact stress and lubrication regime of PEEK based cervical TDA.

2. MATERIALS AND METHODS

2.1. Model

The NuNec® cervical disc arthroplasty (Pioneer Surgical Technology Inc., Driebergen, Netherlands) was selected as the candidate TDA for this study. The smallest available footprint was chosen with the intention of replicating the worst case operational scenario. This cervical prosthesis consisted of two parts made from PEEK only, and adopted the conventional ball-on-socket design configuration as shown in Fig. (**1**). A unique cam fixation design is used for immediate short-term fixation, whereby metal blades extend from the device to grip the bone.

The TDA was modelled as a ball-and-socket joint with the ball having a radius R_1 and socket having a radius of R_2. The Young's modulus and Poisson's ratio for both the ball and socket was E and ν, respectively. The radial clearance c between the ball and socket was defined as:

$$c = R_2 - R_1 \tag{1}$$

2.2. Contact Stress

A Hertzian fully elastic contact model was employed to analyze the maximum superficial contact stress between the bearing surfaces, assumed to be smooth, along with a negligible adhesion force between the contact zone [13, 14]. The maximum contact stress between the bearing surfaces was determined from:

$$P_{\max} = \left[\frac{6FE'^2}{\pi^3 R^2}\right]^{\frac{1}{3}} \tag{2}$$

where F is the applied force, E' is the equivalent elastic modulus for the two bearing materials and R is the equivalent radius for ball and socket. These two parameters were calculated from:

$$E' = \frac{E}{2(1-\nu^2)} \tag{3}$$

and

$$R = \frac{R_1(R_1 + c)}{c} \tag{4}$$

2.3. Lubrication Regime

The Hamrock-Dowson formula was used to predict the minimum film thickness ($h_{\min}$) between the bearing surfaces and given as [15, 16]:

$$h_{\min} = 2.8R\left(\frac{\eta u}{E^* R}\right)^{0.65}\left(\frac{F}{E^* R^2}\right)^{-0.21} \tag{5}$$

where E^* is the equivalent modulus of elasticity and u is the entraining velocity. These two parameters were calculated from:

$$E^* = \frac{E}{(1-\nu^2)} \tag{6}$$

and

$$u = \frac{\omega R_1}{2} \tag{7}$$

From these values, the lubrication regime was predicted by calculating the lambda ratio:

$$\lambda = \frac{h_{\min}}{\sigma} \tag{8}$$

where σ is the compound surface roughness given by:

$$\sigma = \sqrt{R_{a1}^2 + R_{a2}^2} \tag{9}$$

where R_{a1} and R_{a2} are the mean surface roughness of the bearing surfaces for the ball and socket, respectively. If the lambda ratio is greater than 3, then a fluid film lubrication regime occurs and complete separation of the bearing surfaces is achieved. A lambda ratio of less than unity indicates boundary lubrication and substantial contact

Table 1. Summary of Parameters Used in the Analysis

Parameter	Constant Value	Range
Load, F (N)	150	0-150
Radius of ball, R_1 (mm)	6.3	-
Angular velocity, ω (rad/s)	-	0-4.5
Radial clearance, c (mm)	0.7	0.05-0.70
Young's modulus, E' (GPa)	3.7	-
Poisson's ratio, ν	0.36	-
Viscosity, η (mP·S)	0.9, 1.24	-
Mean surface roughness of ball, R_{a1} (µm)	0.585	-
Mean surface roughness of socket, R_{a2} (µm)	0.525	-
Compound surface roughness, σ (µm)	0.786	-

between surface asperities will occur. A lambda ratio of between 1 and 3 indicates a mixed-lubrication regime.

2.4. Parameters

The radii of the ball and socket of the NuNec® cervical disc arthroplasty were measured using a DEA-Swift coordinate measuring machine (CMM) (Hexagon Metrology Ltd., Telford, UK). The principle of the CMM was based on using a 2 mm diameter probe to take 15 randomly selected points across the whole bearing surface of the specimen. The collected data points were then computationally reconstructed to generate the profile of the specimen. Eight repeated measurements were taken for the ball and five repeated measurements were taken for the socket. The socket was found to have a mean radius of 7.010 ± 0.022 mm and the ball had a radius of 6.307 ± 0.004 mm. For analysis the ball radius was chosen as 6.3 mm and the socket radius was chosen as 7 mm, thus giving a radial clearance of 0.7 mm. In this study the aim was to understand the effect of different radial clearances on stress and lubrication regime, so as well as a radial clearance of 0.7 mm, radial clearances of 0.05, 0.1 and 0.15 mm, which have been used by other investigators [17-19], were also used in the analysis. Surface roughness of the bearing surfaces was measured using a Taylorsurf-120L (Taylor Hobson Ltd., Leicester, UK) profilometer with a 2 µm radius diamond stylus and an examining area of 5 × 5 mm. Talymap universal 3.1.8 (Taylor Hobson Ltd., Leicester, UK) equipped with a Gaussian filter (cut-off length 0.08 mm) was used to manipulate the data and hence remove measurement noise. The obtained arithmetic mean surface roughness was found to be 0.585 µm for the ball and 0.525 µm for the socket, respectively. The corresponding compound surface roughness value (Eq. 9) was calculated to be 0.786 µm.

The angular velocity for the human cervical spine has been reported to be in the range of 0 to 4.5 rad/s [20]. This can be easily converted into an entraining velocity using Eq. 7. Interstitial fluid was proposed as the natural lubricant for the intervertebral disc, however bovine serum which is normally used for *in-vitro* wear testing of disc replacements was also considered [21]. An interstitial fluid with a viscosity of 1.24 mPa·s was considered as the primary lubricant [22, 23]; 25% bovine serum (diluted with deionised water) with a viscosity of 0.9 mPa·s was used as a comparison [16, 24]. For this study, the maximum compressive loading for the cervical disc was assumed to be 150 N, selected according to the recommended value from the ISO 18192-1 standard for testing intervertebral disc prostheses [21]. The Young's modulus (E) and Poisson's ratio (v) of PEEK were taken to be 3.7 GPa and 0.36, respectively [12, 25]. Finally, the radial clearance was investigated in the range 0.05, 0.1, 0.7 mm and 0.15 mm, while other design parameters were kept constant. A summary of the parameters used are shown in Table **1**.

3. RESULTS

3.1. Contact Stress

Fig. (**2**) shows the variation of maximum contact stress with force for TDA with different radial clearances. For a PEEK cervical disc under 150 N loading, the maximum contact stress is in the range 5.9 (for a radial clearance of 0.05 mm) to 32.1 MPa (for a radial clearance of 0.7 mm).

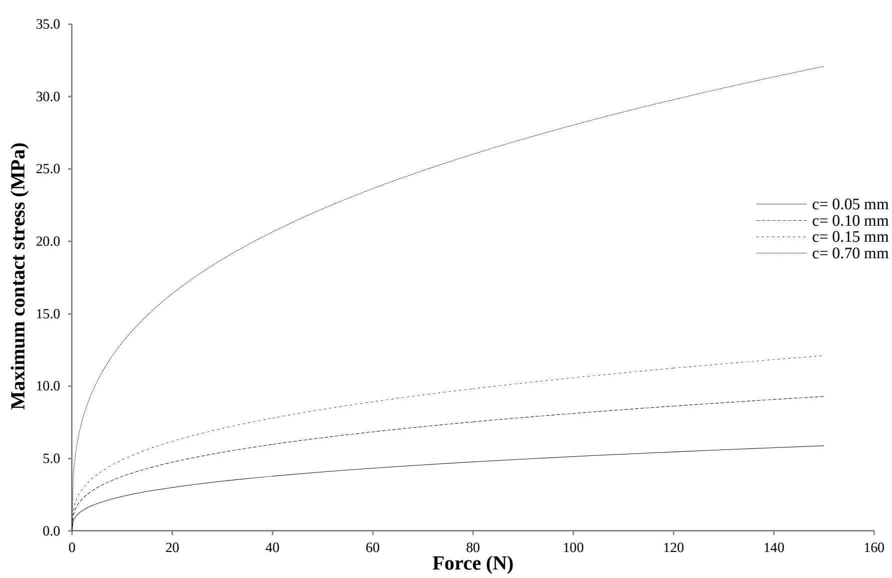
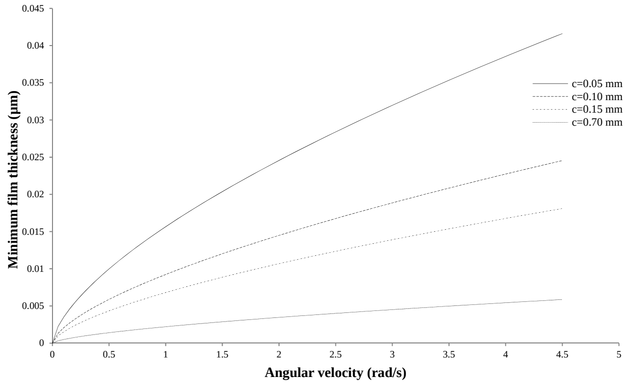


Fig. (2). Variation of maximum contact stress with force for radial clearance values of 0.05, 0.10, 0.15 and 0.7 mm.



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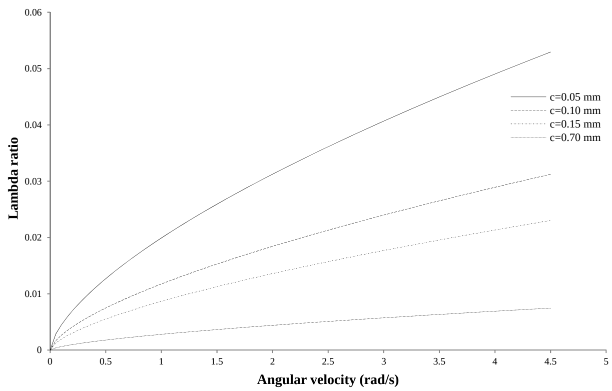

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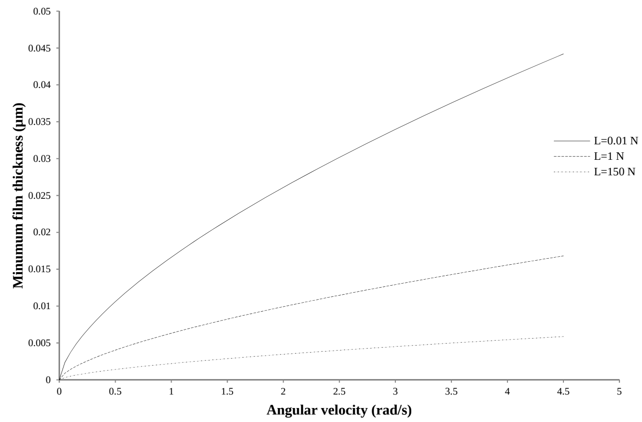
Fig. (3). a) Variation of minimum film thickness with angular velocity; **b**) Variation of Lambda ratio with angular velocity. Each figure is plotted for a cervical disc arthroplasty under 150 N load, using interstitial fluid as the lubricant, at radial clearance values of 0.05, 0.1, 0.15 and 0.7 mm.



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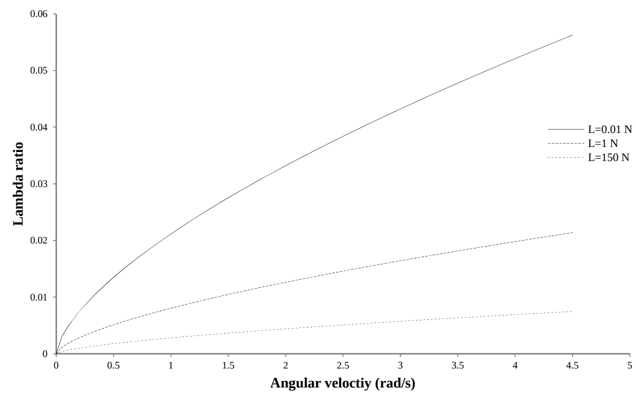


b)

Fig. (4). a) Variation of minimum film thickness with angular velocity; **b**) Variation of Lambda ratio with angular velocity. Each figure is plotted for a cervical disc arthroplasty at a radial clearance value of 0.7 mm, using interstitial fluid as the lubricant, under three different load levels 0.01, 1 and 150 N.

3.2. Lubrication Minimum Film Thickness

Fig. (**3a** & **b**) show the variation of minimum film thickness and lambda ratio, respectively, by incorporating different radial clearances. The predicted minimum film thickness was in the range 0 to 0.042 μm and the corresponding lambda ratio range was from 0 to 0.052. This indicates that the PEEK cervical discs will operate within a boundary lubrication regime across the whole range of angular velocities, under 150 N loading.

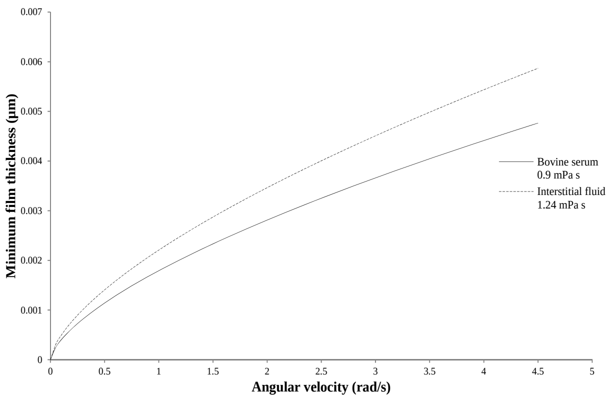
The effects of load level on the minimum film thickness and lambda ratio are displayed in Fig. (**4a** and **4b**), respectively. They show that the loading level has a detrimental effect on both the minimum film thickness and the lambda ratio. Moreover, the obtained lambda ratio is always below unity and indicates boundary lubrication.

Fig. (**5a** & **b**) show the variation of minimum film thickness and lambda ratio, respectively, when different lubricants are employed. The minimum film thickness can be enhanced by incorporating a more viscous lubricant; the lambda ratio can be increased in a similar manner. In spite of this, the lubrication regime is still boundary lubrication, regardless of the lubricant used.

4. DISCUSSION

This paper has predicted the likely contact stress and minimum film thickness between the bearing surfaces of a PEEK self-mating cervical disc. The calculated maximum Hertzian contact stress was in the range 5.9 – 32.1 MPa under 150 N loading. Higher stresses were found for discs with a higher radial clearance. These values of stress are well below the yield strength of PEEK 450G under compression which is documented as 120 MPa [25]. Furthermore, the fatigue strength of PEEK 450G with a crystallinity value of 22.5% was reported as 58.72 MPa, at one million cycles [26, 27]. It is predicted that the stress experienced by the contact surface of this disc is insufficient to result in material fatigue. Nevertheless, high cycle fatigue tests of at least 10 million cycles are still required to ensure the structural safety of cervical disc arthroplasty during long-term application [21]. Hertzain contact theory assumes that the contact surface is ideally smooth and frictionless and consequently the interaction force (*i.e.* adhesion force) between the contact surfaces within the contact zone was not considered. Although other elastic-smooth contact models, such as the Johnson-Kandall-Roberts model take the adhesion force into account [28], there would not be any significant difference between these two models, because the surface energy of PEEK is negligibly small at 0.044 J/m^2 [28, 29].

The lubrication analysis assumes steady-state is achieved, under a given constant angular velocity. This is a simplified ideal situation to represent the motion of the neck, which



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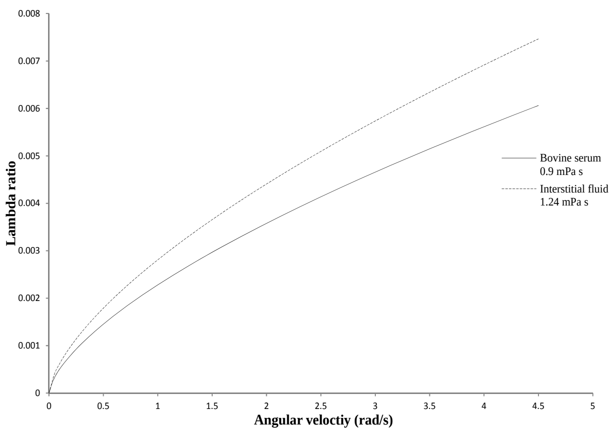

b)

Fig. (5). a) Variation of minimum film thickness with angular velocity; **b**) Variation of Lambda ratio with angular velocity. Each figure is plotted for a cervical disc arthroplasty at a radial clearance value of 0.7 mm, under 150 N load, using two different lubricants bovine serum and interstitial fluid.

may not be achievable in practice. The intention of adopting this model is to ascertain the potential of cervical discs to operate under a fluid lubrication regime by altering its radial clearance or lubricant. The basic assumption of the elastohydrodynamic theory is that the lubricants (bovine serum and interstitial fluid) utilized are Newtonian fluids and there are no shear-thinning effects [16]. According to the obtained lambda ratio results, the PEEK cervical disc, for all parameters, will operate under a boundary lubrication regime, which means that there will be significant surface asperities contact and wear will occur. A previous study has shown that for lumbar disc arthroplasty most devices will also operate with a boundary lubrication regime [17]. According to the recent literature, the wear rate of PEEK self-mating cervical disc arthroplasty is reported as 1.4 ± 0.4 mg per million cycles; the historical cervical disc control (*i.e.* UHMWPE against CoCrMo) has a wear rate of 1.0 ± 0.4 mg per million cycles [30].

There are concerns that debris generated as a result of wear may induce an adverse tissue response, such as chronic inflammation and osteolysis. Goodman proposed that the immune response to polymer particles is non-specific and macrophage mediated via the production of cytokines [31]. It is widely agreed that UHMWPE wear particles in the size range 0.1 to 1.0 µm have been shown to be the most biological reactive [11, 32]. Moreover, quantity, composition, and shape of the wear particles all play important roles in determining the host tissue response [33]. There are plenty of studies [32-34] that report on the biocompatibility of PEEK wear debris, however none focus on wear debris generated in cervical TDA. A recent *in-vitro* wear study pointed out that the wear particle size distribution of a PEEK-on-PEEK cervical disc was from 0.23 to 0.51 µm with a mean roundness of 0.5 [30]. A more targeted host tissue response study is demanded to further ascertain the biocompatibility of PEEK wear debris generated from cervical total disc replacement.

Cervical disc arthroplasty is a relatively new technology and there is still much debate as to whether its performance is actually superior to that of fusion [4-7]. This study has discussed a new bearing material combination of PEEK against PEEK, but other devices have a longer record of use. Currently, there are three cervical disc arthroplasty (Prestige ST, Bryan, and ProDisc-C) undergoing a US FDA investigational device exemption trial [35]. Studies that have investigated the wear of other cervical disc arthroplasty are few. Anderson *et al.* [36] found that the Bryan disc had a wear rate of 1.2 mg per million cycles and that this was satisfactory. Implantation of of a porous coated cervical disc arthroplasty into goats showed no inflammatory response from wear debris after six months implanted in the animals [37]. Lumbar disc arthroplasty have been studied in more detail [38-40], but a direct comparison with cervical discs is unwise due to the different motions and loads.

CONCLUSIONS

From this theoretical study, it can be confirmed that a PEEK based artificial cervical disc will operate under a boundary lubrication regime, with the generation of wear debris likely. The maximum contact stress was found to be 32.1 MPa, but this is less than either the compressive yield strength or fatigue strength of PEEK 450G.

CONFLICT OF INTEREST

None declared.

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GLOSSARY

R_1	=	Radius curvature of ball component.
R_2	=	Radius curvature of socket component.
c	=	Radial clearance equals to the difference between the R_2 and R_1.
P_{max}	=	Maximum contact stress.
F	=	Applied force.
E'	=	Equivalent elastic modulus for the two bearing material.
R	=	Equivalent radius for ball and socket.
E	=	Youth's modulus of the material.
v	=	Poisson's ratio of the material.
h_{min}	=	Minimum film thickness.

μ	=	Viscosity of the lubricant.
u	=	Entrance velocity of the disc.
*E**	=	Equivalent modulus of elasticity.
λ	=	Lambda ratio.
σ	=	Compound surface roughness.

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