This is an author-produced version of the following Elsevier-published article:
Joyce, T.J. Examination of failed ex vivo metal-on-metal metatarsophalangeal prosthesis and comparison with theoretically determined lubrication regimes. *Wear* 2007, 263(7-12), 1050-1054
doi:10.1016/j.wear.2006.11.045

Examination of failed ex vivo metal-on-metal metatarsophalangeal prosthesis and comparison with theoretically determined lubrication regimes

T.J. Joyce

School of Mechanical and Systems Engineering

Newcastle University

Stephenson Building

Claremont Road

Newcastle upon Tyne

NE1 7RU

UK

E-mail:t.j.joyce@ncl.ac.uk

Tel: +44 191 222 6214

Fax: +44 191 222 8600

Abstract

Replacement of the first metatarsophalangeal (MTP) joint is a relatively uncommon procedure compared with hip and knee arthroplasty. A cobalt chrome-on-cobalt chrome MTP prosthesis, which had a diamond like carbon (DLC) coating applied to its articulating faces, was obtained for ex vivo analysis. By modelling the ball and socket implant as an equivalent ball-on-plane model and employing elastohydrodynamic theory, the predicted lubrication regimes applicable to this implant design were determined. These calculations were undertaken for a 10 to 1500N range of loading values and a 0 to 30mm/s range of entraining velocities, for both worn and unworn situations. Calculations showed that the implant would almost always operate in the boundary lubrication regime. The presence of scratches on the articulating faces of the ex vivo sample further implied boundary lubrication. The DLC coating had been removed from the entire face of the phalangeal component and from most of the face of the metatarsal component. From the latter it appeared as if the coating had been scratched and then flaked away parallel to the scratches. In turn this suggested a corrosion based failure of the interface between the DLC coating and the cobalt chrome subsurface.

Keywords: metatarsophalangeal, metal-on-metal, lubrication regimes, diamond like carbon

1 Introduction

The key joint of the forefoot during gait is the first metatarsophalangeal (MTP) joint. It is subject to high loads and plays an important role in propelling the human form. Unfortunately the first MTP joint can be subject to a number of diseases, such as hallux valgus, hallux rigidus and rheumatoid arthritis, all of which can eventually lead to replacement of the natural joint with a prosthesis.

Historically, such prostheses have tended to be single-piece designs manufactured from silicone. A single-stem Swanson implant was one of the first designs to be implanted, but a number of problems were encountered, primarily relating to wear of the silicone material [1]. Due to such disappointing clinical results this design was replaced by a double-stem Swanson design, which has given better results [2-4]. More recently, the Swanson prosthesis has been supplied with a pair of titanium grommets which are intended to protect the soft silicone material from damage due to cuts from the surrounding bone [5]. Comparable double-stem silicone designs of first MTP prosthesis exist, such as the Gait from Sgarlato labs [6]; the Helal universal joint spacer [7]; the Primus™ flexible great toe and the Classic flexible great toe, both produced by Futura™ Biomedical [8].

However, concerns exist over such silicone double-stem designs. Granberry et al abandoned use of the Sutter silicone prosthesis after finding a 29% fracture rate, and their opinion was applied to all silicone MTP prostheses [9]. As well as such unease regarding the prosthesis designs there are wide concerns about possible material problems due to silicone synovitis [10-12].

Given such concerns, and in an attempt to apply positive experience from larger total replacement joints, a number of two-piece articulating designs for the first MTP joint have been proposed [8]. These include metal-on-polymer designs such as the Kenetik Great Toe Implant and the ReFlexion™ [13], and a ceramic-on-ceramic design, the Moje [14]. With such articulating joints, wear of the bearing surfaces becomes critical, as it is widely recognized from experience with artificial hip joints that prosthetic wear debris can lead to osteolysis and the eventual failure of the replacement joint [15].

Metal-on-metal articulations have been used successfully for total hip replacements [16] and the same concept has been applied in the application of a first MTP prosthesis. The particular design employed cobalt chrome for both the metatarsal and the phalangeal components. The stems were covered with hydroxyapatite to encourage bony ingrowth. The articulating faces were covered with a diamond-like carbon (DLC) layer, presumably as such layers have been shown to offer a low wear combination [17].

A single explant from a cohort of implants was obtained and is shown in Figure 1. It was removed approximately four years after implantation. At revision there was black staining of the surrounding joint synovium and osteolysis of the bone ends. The explant was analysed and a calculation of the theoretical lubrication regime when new, and at the time of removal of the implant, was undertaken using elastohydrodynamic theory.

2 Methods and Materials

2.1 Explant analysis

The explant was examined macroscopically by eye and then in greater detail using a ZYGO NewView 100 non-contacting profilometer and an environmental scanning electron microscope. In addition, the shape and radii of the articulating faces were determined using a co-ordinate measuring machine.

2.2 Calculation of lubrication regimes

Modelling the ball and socket implant as an equivalent ball-on-plane model and employing elastohydrodynamic theory [18] allowed the minimum effective film thickness (h_{min}) to be calculated from:

$$\frac{h_{\min}}{R_x} = 2.80\left(\frac{\eta u}{E^* R_x}\right)^{0.65}\left(\frac{w}{E^* R_x^2}\right)^{-0.21} \qquad \text{Equation 1}$$

Where R_x is the equivalent radius (m), η is the viscosity of the lubricant (Pa s), u is the entraining velocity (m/s), E* is the equivalent elastic modulus (Pa), and w is the load (N). In turn, given that R_a is the surface roughness and assigning subscript 1 to the ball (metatarsal component) and subscript 2 to the socket (phalangeal component) of the MTP prosthesis under consideration, then the lambda ratios were calculated from:

$$\lambda = \frac{h_{\min}}{\left[(R_{a1})^2 + (R_{a2})^2\right]^{1/2}}$$ Equation 2

This allowed the lubrication regime to be identified, as $\lambda < 1$ indicates boundary lubrication, $\lambda > 3$ designates fluid film lubrication, and between these values mixed lubrication is indicated [19].

Before these calculations could be undertaken, the equivalent radius (R_x) was calculated from:

$$\frac{1}{R_x} = \frac{1}{R_1} - \frac{1}{R_2}$$ Equation 3

Where R refers to the radius of the component and subscript 1 refers to the ball and subscript 2 to the socket of the MTP prosthesis. The equivalent modulus of elasticity was determined from the equation:

$$\frac{1}{E^*} = 0.5\left(\frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2}\right)$$ Equation 4

Again, E refers to the Young's modulus of the component and again subscript 1 refers to the ball and subscript 2 to the socket of the MTP prosthesis, similarly for the two Poisson's ratios.

Clearly, the natural first MTP joint will encounter a range of loads during a lifetime and similarly the joint will move at a range of speeds. In terms of loading, values in the range of 0.8 to 1 x body weight have been suggested by researchers [20-21]. For a person of 70kg this would equate to a load across the first MTP joint of some 590N [20]. Clearly people of greater weight exist, and additionally it has been shown that loading across the first MTP joint can be doubled by the wearing of high heels [22]. Therefore a 10 to 1500N range of loading was chosen for the calculations of lubrication regime.

If an 'average' speed during gait of 1Hz is taken, for a 'typical' first MTP joint of 13mm radius (r) [20] moving through an arc of 32° during gait [23] then an average entraining velocity of 14mm/s can be calculated from:

$$u = r\omega/2 \qquad \text{Equation 5}$$

Where ω is the angular velocity [24]. This value of 14mm/s was taken as a constant when the different load calculations were undertaken. Again allowing for higher frequencies and larger sizes of joints gave an estimated upper limit of 30mm/s for the series of calculations involving entraining velocity. The minimum speed was taken as zero and was incremented in 5mm/s steps. A constant load of 590N was assumed.

Roughness measurements of worn and unworn regions of the articulating faces were taken. These values allowed the lambda ratio to be calculated for the prosthesis when new (unworn) and at the time of retrieval (worn). 'Worn' and 'unworn' sets of calculations were undertaken for the 0 to 30mm/s range of entraining velocities and the 10 to 1500N range of loading values justified above.

A viscosity of the synovial fluid lubricant of 0.005Pa s was assumed [25]. Other relevant values were taken from the literature, and a summary is given in Table 1.

3 Results

Measurements taken from the CMM showed that the articulating faces of the explant were part spherical surfaces. The phalangeal component of the explant was measured to have a spherical diameter of 20.081mm, while that of the metatarsal component was 19.881mm. Therefore the diametral clearance was 0.200mm and the radial clearance was 0.100mm. The DLC coating had been removed from the entire face of the phalangeal component and from most of the face of the metatarsal component. From the latter it appeared as if the coating had been scratched and then flaked away parallel to the scratches (Figure 2). In turn this suggested a corrosion based failure of the interface between the DLC coating and the cobalt chrome subsurface, a result noted recently elsewhere [17]. Even within the apparently undamaged DLC coating, closer investigation revealed relatively deep pits which again were felt to indicate damage due to corrosion.

The DLC coating which remained had a typical roughness value of 0.020μm Ra, while that of the surface without the DLC coating was 0.030μm Ra on the metatarsal component and 0.063μm Ra on the phalangeal component. The presence of multi-directional scratches on the articulating faces of the metatarsal (Figure 2) and the phalangeal component implied boundary or mixed lubrication. On the phalangeal component, an unusual localized area of damage was seen. This is shown in Figure 3 where, in addition, more of the multi-directional scratches can be seen. The DLC coating was found to have a thickness of approximately 0.35μm.

Calculations showed that, for the range of entraining velocities (Figure 4) and loads (Figure 5) considered, the worn implant would operate in the boundary lubrication regime ($\lambda < 1$) thus supporting the results of the visual examination, where the presence of scratches on the articulating faces of the explant implied that surface to surface interaction had occurred. Such surface to surface contact would indicate that the lubrication regime was either boundary or mixed, so supporting the results of the theoretical calculations. Therefore surface to surface contact would most frequently take place, with little separation due to lubrication between the articulating surfaces. However, it was also noted that when new it was possible that the implant could have operated under the somewhat more favourable condition of mixed lubrication ($3 > \lambda > 1$), especially at lower loads and under higher entraining velocities.

4 Discussion

It has been recognised that replacement of the first MTP joint is a relatively uncommon procedure compared with hip and knee arthroplasty. Part of the reason for this is that available first MTP prostheses have not shown clinical results as admirable as those generally achieved by hip and knee replacements. A crucial part of the process of making first MTP implants more successful is to learn from explants and so it is hoped that the information offered in this paper adds to the available data on retrieved first MTP prostheses. It should also be recognized that while DLC coatings have given low wear results in certain applications [17], their biotribological application may offer more challenges, particularly in terms of adhesion between the subsurface and the DLC coating [26]. Indeed, an earlier paper showed that, in the presence of biological fluids, perforations in the DLC coating allowed the fluid to penetrate and slowly corrode the interface between the DLC coating and the substrate [27].

In addition, the influence of three-body wear should be recognised. The black staining of the surrounding joint synovium at revision operation was likely due to the myriad parts of the DLC coating which had been removed from the articulating faces of the implant. This hard wear debris would likely have contributed to three-body wear and roughened the articulating surfaces and cobalt chrome substrate.

Due to the multifaceted nature of calculating the lubrication regimes, there are a number of factors which can have a critical impact. These include load and entraining velocity, both of which have been discussed earlier. It has been seen that an increase in load and a decrease in entraining velocity both have a negative impact on minimum film thickness and thus on lubrication regime.

Values of roughness of the articulating faces have a crucial impact on the lubrication regime that can be achieved. By measuring an unworn surface of the DLC coating remaining on the metatarsal component, a value of 0.020µm Ra was found. This is a viable figure, as values between 0.002 and 0.006µm Ra have been reported for the femoral heads of total hip prostheses, including those of 16mm and 22mm diameter which are similar to the 20mm diameter MTP prosthesis in this study [28]. Evidence has been taken from similar diameter metal-on-metal hip prostheses, as their articulating faces would likely be manufactured by a similar method to that used for the MTP prosthesis. For the phalangeal component, a value of 0.063µm Ra was measured, though this may be on the high side as the DLC coating had been removed. The study by Smith et al just quoted further suggests that a value of 0.010µm Ra can be achieved for the concave surface of a 20mm nominal diameter phalangeal component [28].

Another critical factor is the clearance between the metatarsal and phalangeal components. In this study, the radial clearance between the worn components was measured to be 100µm. Unfortunately there is no manufacturer's data available to compare this value with. As the DLC coating is relatively thin, of the order of 0.35µm, loss of the coating on both articulating surfaces, totalling 0.7µm, is unlikely to have had a great impact on the radial clearance. Therefore loss of the coating would cause an increase in radial clearance from 99.3µm to 100µm. Given that manufacturing tolerances need to be considered, perhaps the prosthesis was manufactured with a radial clearance of 100µm.

On the other hand, for a 16mm diameter metal-on-metal hip prosthesis a radial clearance of 30µm has been reported [28]. In addition, tests of metal-on-metal hip prostheses with 22μm and 40μm radial clearances have been detailed [29]. Therefore a radial clearance of 30μm was taken and, together with roughness values of 0.003 and 0.010μm Ra offered by Smith et al for similar diameter head and cup components [28], the calculations were repeated. With such a clearance and roughness values it was found that the lubrication regime could be moved from mixed to fluid film for an unworn prosthesis. Thus the potential for fluid film lubrication of ball-in-socket two-piece metal-on-metal first MTP prostheses does exist during part of the gait cycle, if appropriate manufacture can be achieved.

Conversely, it should be recognized that when the surfaces of the artificial joint are not articulating, for example when a person is at rest, there is likely to be surface to surface contact of the implant as there will be zero entraining velocity and the joint will be under a compressive load from the muscles acting across the MTP joint. Therefore other factors in addition to lubrication analysis should be considered if designing an MTP implant.

5 Conclusion

Theoretical lubrication analysis indicates that, when new, the design of metal-on-metal MTP prosthesis could operate under mixed lubrication, particularly at lower loads. However, analysis of the explant showed that surface damage to the articulating faces occurred in vivo, resulting in an increase in surface roughness and a diminution in the theoretical lubrication from mixed to boundary. In addition, it was seen that the DLC coating had been removed from the entire articulating surface of the phalangeal component and from the majority of the face of the metatarsal component. While scratching of the coating had been a factor in its removal it was felt that corrosion at the interface of the coating and the cobalt chrome substrate was a more important cause, based on evidence from the topography of the articulating faces and the work of previous researchers investigating the corrosion of DLC coatings in the presence of biologically relevant fluids.

Acknowledgements

Mr. Derek McMinn, consultant orthopaedic surgeon at Birmingham Nuffield Hospital, UK, kindly supplied the MTP explant.

Figure 1 The metal-on-metal MTP prosthesis. The metatarsal component is on the left, the phalangeal component on the right. The remaining DLC coating can be seen on the articulating face of the metatarsal component

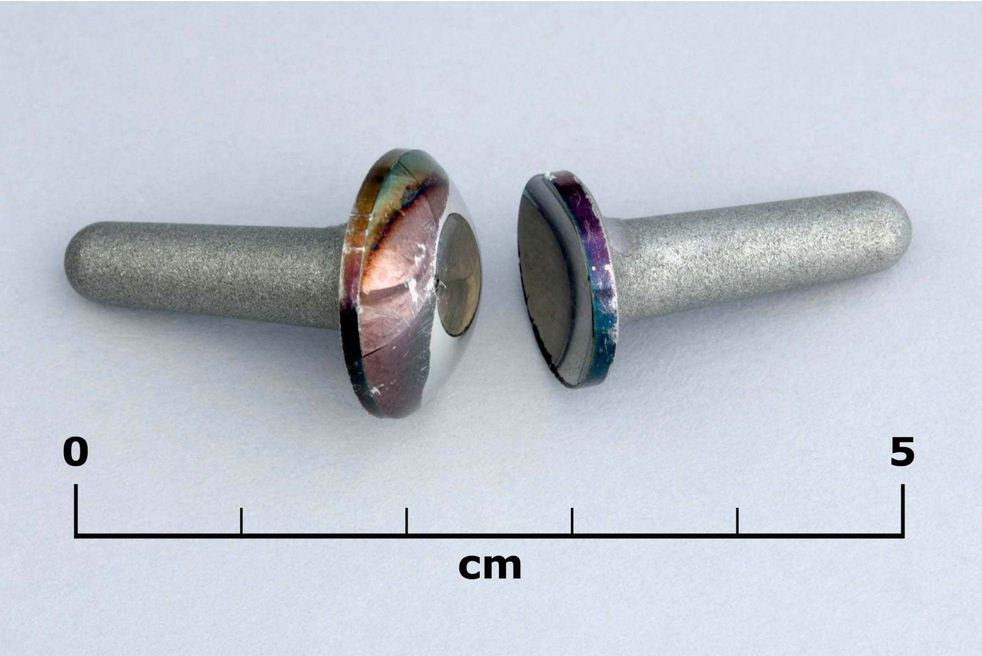


Figure 2 Damage to DLC coating on the metatarsal component, image from non-contacting profilometer

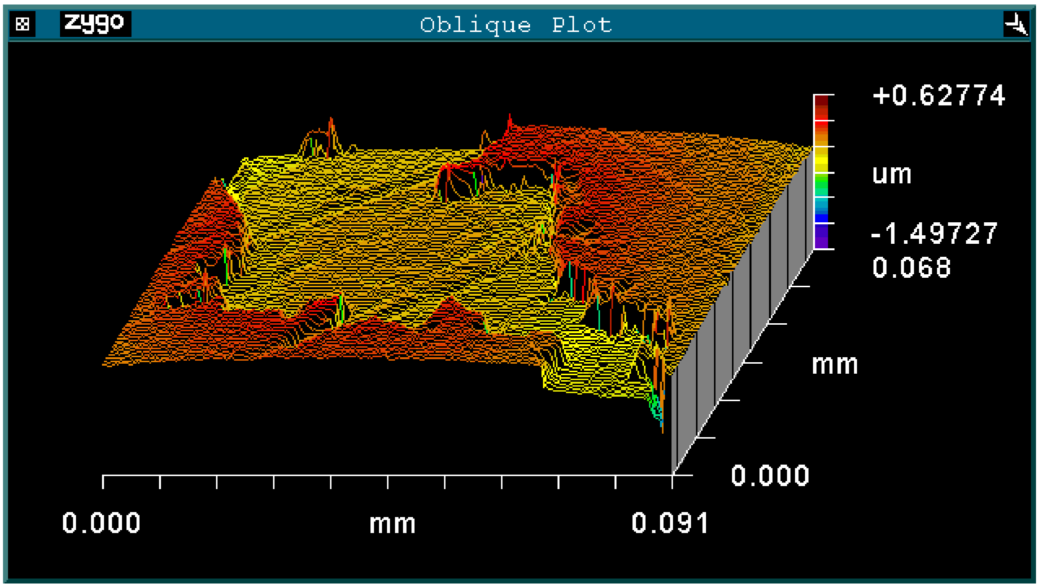


Figure 3 Localized damage to articulating surface of the phalangeal component, image from environmental scanning electron microscope

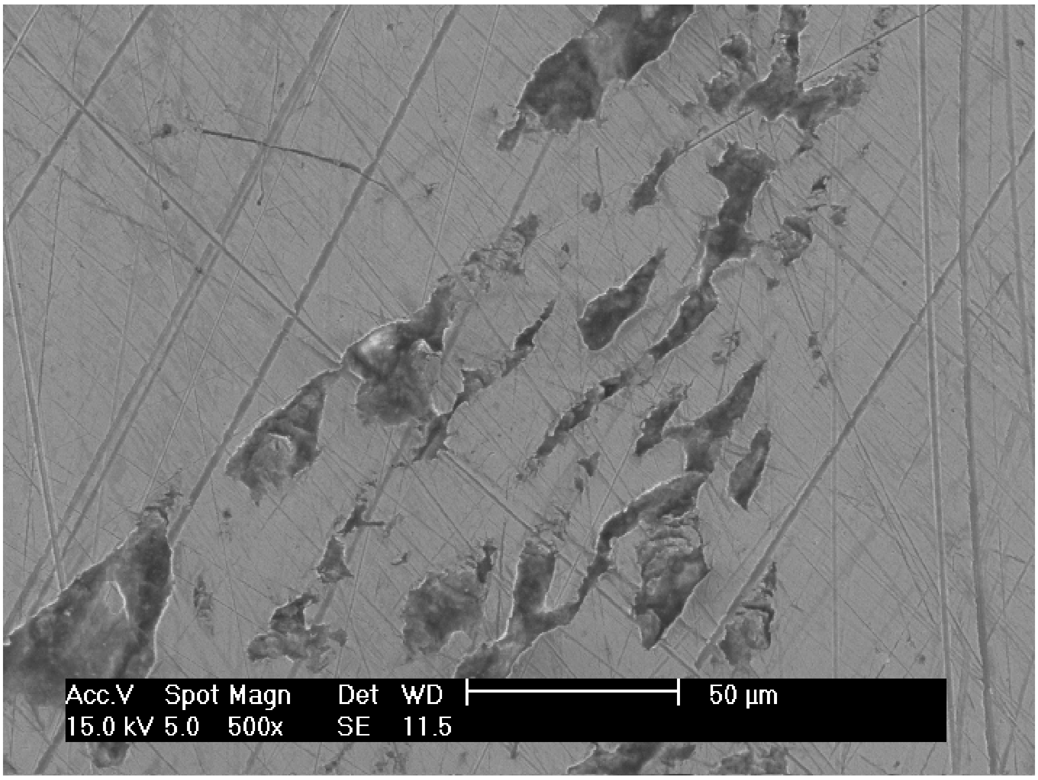


Figure 4 Variation of lambda ratio with entraining velocity

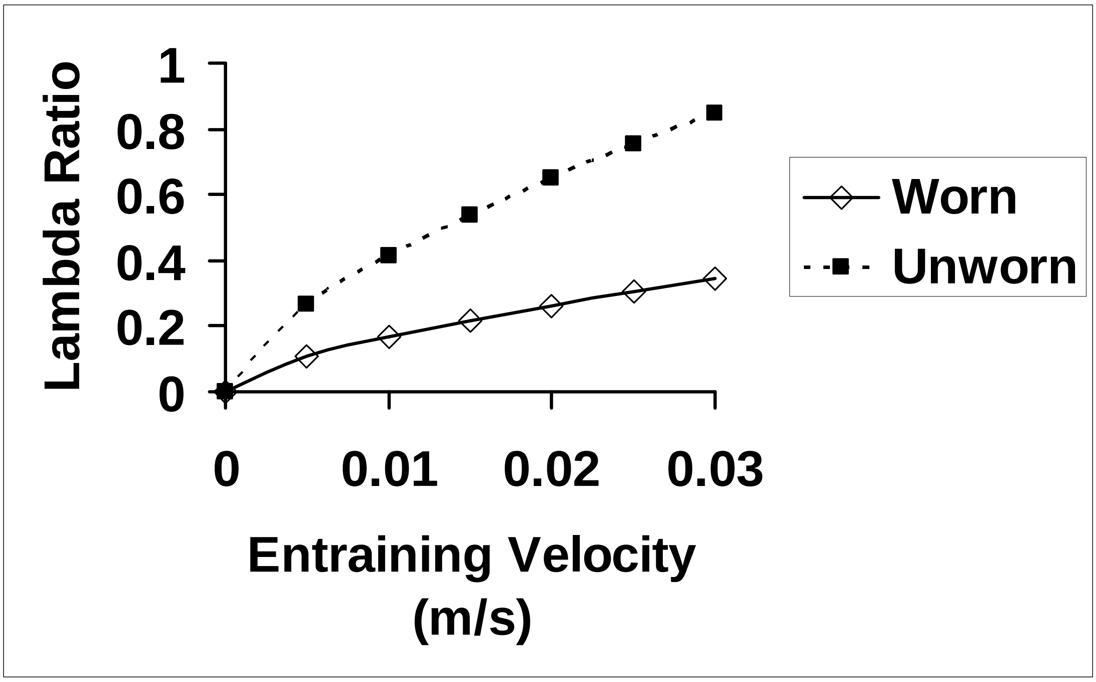
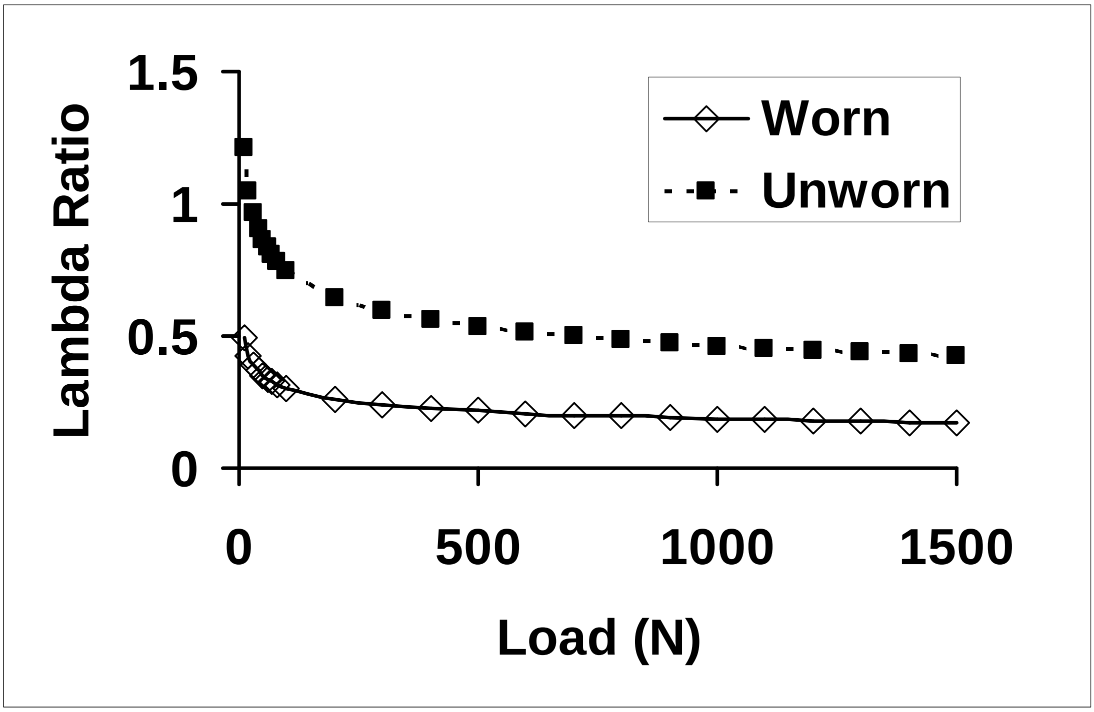


Figure 5 Variation of lambda ratio with load



References

1. H. Rahman, P.S. Fagg, Silicone granulomatous reactions after first metatarsophalangeal hemiarthroplasty, J. Bone Jt. Surg. 75B (1993) 637-639.

2. T. Hanyu, H. Yamazaki, H. Ishikawa, K. Arai, C.T. Tohyama, K. Nakazono, A. Murasawa, Flexible hinge toe implant arthroplasty for rheumatoid arthritis of the first metatarsophalangeal joint: long-term results, J. Orthop. Sci. 6 (2001) 141-147.

3. M.J.K. Bankes, R.R. Shah, D.L. Grace, Swanson double-stem arthroplasty of the hallux: a survivorship analysis, Foot Ankle Surg. 5 (1999) 235-243.

4. R. Bommireddy, S.K. Singh, P. Sharma, M. El Kadafi, D. Rajan, M. Rowntree, Long-term follow-up of silastic joint replacement of the first metatarsophalangeal joint, Foot 13 (2003) 151-155.

5. A.B. Swanson, G. de Groot Swanson, Use of grommets for flexible hinge implant arthroplasty of the great toe, Clin. Orthop. Rel. Res. 340 (1997) 87-94.

6. W. Money, A. McCulloch, R. Graham, Retrospective analysis of the Sgarlato double-stem flexible (gait) implant for arthroplasty of the first metatarsophalangeal joint, Brit. J. Podiat. 6 (2003) 64-68.

7. B. Helal, A long-term review of replacements of the great toe metatarsophalangeal joint using a bistemmed silicone elastomer ball-shaped spacer, Foot 7 (1997) 61-67.

8. T.J. Joyce, Implants for the first metatarsophalangeal joint and prospective considerations, Expert Rev Med Devs 2 (2005) 453-464.

9. W.M. Granberry, P.C. Noble, J.O. Bishop, H.S. Tullos, Use of a hinged silicone prosthesis for replacement arthroplasty of the first metatarsophalangeal joint, J. Bone Jt. Surg. 73A (1991) 1453-1459.

10. C.T.K. Khoo, Silicone synovitis: the current role of silicone elastomer implants in joint reconstruction, J. Hand Surg. 18B (1993) 679-686.

11. Y. Minimikawa, C.A. Peimer, R. Ogawa, K. Fujimoto, F.S. Sherwin, C. Howard, In vivo experimental analysis of silicone implants used with titanium grommets, J. Hand Surg. 19A (1994) 567-574.

12. C. Peimer, J. Taleisnik, F. Sherwin, Pathologic fractures: a complication of microparticulate synovitis, J. Hand Surg. 16A (1991) 835-843.

13. P. Ess, M. Hamalainen, J. Leppilahti, Non-constrained titanium-polyethylene total endoprosthesis in the treatment of hallux rigidus. A prospective clinical 2-year follow-up study, Scand. J. Surg. 91 (2002) 202-207.

14. T. Ibrahim, G.J.S.C. Taylor, The new press-fit ceramic Moje metatarsophalangeal joint replacement: short-term outcomes, Foot 14 (2004) 124-128.

15. W.H. Harris, The problem is osteolysis, Clin. Orthop. Rel. Res. 311 (1995) 46-53.

16. J.H. Dumbleton, M.T. Manley, Metal-on-Metal Total Hip Replacement: What Does the Literature Say?, J Arthroplasty 20 (2005) 174-188.

17. R. Hauert, An overview on the tribological behavior of diamond-like carbon in technical and medical applications, Tribology Intl 37 (2004) 991-1003.

18. B.J. Hamrock, D. Dowson, Elastohydrodynamic lubrication of elliptical contacts for materials of low elastic modulus. I: fully flooded conjunction, Trans ASME. J Lubn Tech 100 (1978) 236-245.

19. K.L. Johnson, J.A. Greenwood, S.Y. Poon, A simple theory of asperity contact in elastohydrodynamic lubrication, Wear 19 (1972) 91-108.

20. H.A.C. Jacob, Forces acting in the forefoot during normal gait - an estimate, Clin. Biomech. 16 (2001) 783-792.

21. I.A.F. Stokes, W.C. Hutton, J.R.R. Stott, Forces acting on the metatarsals during normal walking, J. Anat. 129 (1979) 579-590.

22. I.D. McBride, U.P. Wyss, T.D.V. Cooke, L. Murphy, J. Phillips, S.J. Olney, First metatarsophalangeal joint reaction forces during high-heel gait, Foot Ankle 11 (1991) 282-288.

23. D.A. Nawoczenski, J.F. Baumhauer, B.R. Uberger, Relationship between clinical measurements and motion of the first metatarsophalangeal joint during gait, J. Bone Jt. Surg. 81A (1999) 370-376.

24. I.J. Udofia, Z.M. Jin, Elastohydrodynamic lubrication analysis of metal-on-metal hip-resurfacing prostheses, J Biomech 36 (2003) 537-544.

25. D. Jalali-Vahid, M. Jagatia, Z.M. Jin, D. Dowson, Prediction of lubricating film thickness in UHMWPE hip joint replacements, J Biomech 34 (2001) 261-266.

26. S. Reuter, B. We[ss]kamp, R. Buscher, A. Fischer, B. Barden, F. Loer, V. Buck, Correlation of structural properties of commercial DLC-coatings to their tribological performance in biomedical applications, Wear 261 (2006) 419-425.

27. L. Chandra, M. Allen, R. Butter, N. Rushton, A.H. Lettington, T.W. Clyne, The effect of exposure to biological fluids on the spallation resistance of diamond-like carbon coatings on metallic substrates, Journal of Materials Science: Materials in Medicine, 6 (1995) 581-589.

28. S.L. Smith, D. Dowson, A.A.J. Goldsmith, The lubrication of metal-on-metal total hip joints: a slide down the Stribeck curve, J Engng Tribology 215 (2001) 483-493.

29. S.C. Scholes, S.M. Green, A. Unsworth, The wear of metal-on-metal total hip prostheses measured in a hip simulator, J. Engng. Med. 215 (2001) 523-530.