Friction, Lubrication and Wear of Total Joint Replacements

By

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A thesis submitted for the degree of Doctor of Philosophy

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Submitted in June 2010
I hereby declare that this thesis is entirely my own work, with due acknowledgement being made in the text where work has been conducted in collaboration with another. This thesis has not been submitted to any other University or higher education institution, or for any other academic award in this University.

_____________________

Sarah Flanagan
Dedication

This thesis is dedicated to my inspirational parents, Pat & Bernie.

Thank you for your unwavering support and love.
Abstract

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The work described in this report is a contribution to ongoing research to develop more effective orthopaedic joint systems though fundamental studies of the behaviour of various novel material combinations and component configurations. Compliant layer technology, incorporating a low elastic modulus polyurethane layer for the bearing surface, has been proposed to offer prolonged longevity of artificial joints by maintaining a fluid film between the articulating surfaces thus reducing friction and wear.

To ensure a compliant layer joint retains fit, form and function over its lifetime, material characterisation techniques were employed. Dynamic mechanical thermal analysis (DMTA) highlighted the sensitivity of the modulus of Bionate® polyurethanes 80A and 75D to temperature; in particular for 75D it revealed the close proximity of its glass transition temperature to in vivo operating temperatures and this shows a strong need for accurate temperature control during in vitro testing. The ability of aqueous lubricants to plasticise Bionate® materials was also demonstrated through DMTA, with reductions in the moduli and damping behaviour for hydrated samples being seen.

Through a series of creep experiments, the non-linear viscoelastic behaviour of Bionate® polyurethane materials was demonstrated. Creep rupture was not observed over the test periods, and sample deformation increased considerably with increasing stress as well as temperature and lubrication. Bionate® 75D displayed significantly lower creep strain and greater permanent deformation that 80A. The creep data set should essentially allow development of improved designs in compliant layer technology.

The tribological performance of the compliant layer articulation as a function of material combinations, implant conformity and implant size was assessed. In order to do this it was necessary to measure the frictional torque and develop tribological functional plots to determine the mode of lubrication. In this study a variety of material combinations for both hip and knee prostheses were investigated using a friction simulator. Firstly, through correlation with other published studies a friction simulator was validated using conventional ultra-high molecular weight polyethylene. Subsequently, metal-on-compliant layer hip and knee prostheses were assessed both experimentally using Strubeck analysis and theoretically using the theory of Hamrock and Dowson. Overall, the performance of compliant layer bearings was promising of improved in vivo behaviour in that fluid film lubrication and relatively low friction factors were achieved with synthetic lubricants. A strong correlation between experimental results and theoretical predictions were observed.

The wear performance of a newly developed compliant layer glenoid, designed specifically to utilise compliant layer technology, in total shoulder arthroplasty was investigated. Results suggest that this type of glenoid may be more robust compared to the conventional UHMWPE glenoid. Impingement wear on the compliant layer surface was a frequent finding and was caused from repeated contact
between the rim of the hemispherical humeral component and the articular surface of the glenoid, under a constant load.

The addition of Vitamin E to compliant layer acetabular components was shown experimentally to have no effect on the friction characteristics of the material. MPC (2-methacryloyloxethyl phosphorylcholine) grafting on the surface of highly crosslinked polyethylene acetabular components increased the friction and it was postulated that the phospholipids acted as boundary lubricants within a mixed lubrication regime.

Larger joints are being developed to improve joint stability, proprioception and functional longevity. The friction and lubrication properties of large diameter hip bearings of metal-on-metal and ceramic-on-reinforced polymer couplings were assessed. The frictional studies showed that the metal-on-metal joints worked under the mixed lubrication regime, producing similar friction factor values to each other. The ceramic-on-reinforced polymer samples were shown to operate with high friction factors and mixed lubrication. The study demonstrated that the component’s diameter had little or no influence on the lubrication and friction of the large bearing combinations tested.
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First and foremost, I would like to thank my supervisor, Prof. Colin Birkinshaw, for his knowledge, guidance and patience. It has been an excellent experience working with you. I would also like to thank my industrial supervisor, Prof. Eric Jones, for all his assistance and expertise.

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I would have never have been able to get through this project without the untiring support from my amazing family, friends and neighbours. So, to my parents, whom I love dearly, and my two older brothers, Richard and Dermot, thank you for your support and love. To Emma and Maggie, thank you for your friendship and laughter. And last of all, to Mikey, thank you for your encouragement and patience, and above all, thanks for all the fun times we’ve spent together.

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Chapter 1

Introduction

Every year, globally, more and more people take advantage of total joint replacement (TJR) surgery and more arthroplasties are being performed on younger patients. The longevity and proprioception of these joints is therefore becoming increasingly important. Proprioception – one’s ability to sense joint position and joint motion – is important for movement dynamics, balance and joint stability. Results of the assessment of patients who have had joint replacement show the proprioception is better after total joint replacement than before [1-4].

This project concerns itself with the articulation of different artificial bearing systems under applied loads and motions and comprises three related areas: friction, wear and lubrication. Lubrication is the process whereby the wear of one or both surfaces in close proximity, and moving relative to each another, is reduced by interposing a fluid between the surfaces to separate them. In that condition the fluid carries the load applied to the components being separated and thus becomes locally pressurized. This local pressure is, in part, a function of the viscosity of the fluid. Friction is the resistance to relative movement of the two surfaces, whether lubricated or not. As friction is not a fundamental force, but rather is a complex function of surface topography, material mechanical properties and electrostatic interactions, it is difficult to predict from first principles. Experience may give an indication of the likely friction in any given engineering condition, but it must be measured experimentally if accurate data is required. Much of this thesis is concerned with the experimental measurement and analysis of friction in artificial joints, and the information is used to deduce the lubrication conditions.

The equations defining friction and wear will be developed later in the thesis, and the various lubrication conditions formally described, however, the essential feature that determines the characteristics of anatomical bearings is whether or not the prevailing conditions can maintain full fluid film lubrication and, therefore, prevent contact between the two articulating surfaces. If this is the case then all of the load is supported by the fluid between the bearing surfaces resulting in a reduction in both the frictional resistance and wear. However, if contact between the articulating
surfaces occurs then there is generally an increase in friction and a greater amount of wear. Both of these are detrimental to the bearing performance and have implications for proprioception.

Conventional joint replacements consist of a polished metallic or ceramic component articulating against an ultra-high molecular weight polyethylene (UHMWPE) component and these joint systems are generally classified as ‘hard-on-soft’. The perceived problems of UHMWPE are associated with wear and friction. The frictional characteristics of UHMWPE-metal/ceramic couples are inferior to those of the natural healthy joint and so problems of proprioception arise. Polyethylene wear occurs as a result of boundary/mixed lubrication regime by direct asperity contact, abrasion, adhesion and fatigue. Polyethylene wear has been shown to cause adverse tissue reactions which can lead to joint failure.

As the problems associated with polyethylene wear particles have become more apparent, interest in modifying the properties of the material and in alternative bearing material combinations has increased. Compliant bearings comprising layers of low elastic modulus materials are investigated in this study, in TRJ, as a technology that attempts to simulate some of the qualities of the natural synovial joint. The low modulus lining on the bearing surface of the prosthesis is used to promote a continuous film of lubricant between the articulating surfaces and hence reduce both friction and wear. The low elastic modulus layer may be considered to fulfil a similar function to that performed by cartilage in the natural joint. The promotion of a continuous film of lubricant may be attributed to conventional elastohydrodynamic lubrication and squeeze film effects, microelastohydrodynamic lubrication and local deformation of the elastic modulus layers. Great interest has been shown in polyurethanes as these materials exhibited many of the desired properties of the natural cartilage mentioned above.

The performance of large bearings in total hip replacements is of particular interest, in this study, as there is a belief that these will yield better proprioception and functional longevity, especially for the younger more active patient. New ‘hard-on-hard’ material combinations (metal-on-metal and ceramic-on-ceramic) and novel designs of artificial hip implants are being introduced. The precision of modern machining makes it possible to replace a femoral head with a metal or ceramic prosthesis, with a head diameter that matches the patient’s natural femoral head and
this means a better range of movement due to an improved head neck ratio, improved joint stability, and a lower risk of dislocation.

Complete conversion of joint arthroplasties from conventional bearings incorporating UHMWPE is unlikely to occur within the next few years. As a result, reduction of UHMWPE wear debris through modification of polymer morphology is also one of the major aims of orthopaedic device development. New wear-resistance polyethylene liners, called highly crosslinked polyethylene have been introduced. During the manufacturing process, the polyethylene is treated with a short burst of radiation which results in crosslinking and an extremely wear-resistant material. These bearing surfaces may have the additional benefit of allowing a much larger diameter bearing surface to be used. The mechanical properties of polyethylene are altered, however, during the cross-linking process and a reduction of material strength and toughness may result in fracture. Newer second-generation techniques involve annealing rather than melting, improving the strength. The frictional characteristics of these second-generation highly crosslinked polyethylene liners are examined in this work.

1.1 Aims and Objectives
The overall aim of this project is to assess the consequences for friction and lubrication of both material choice and design, in TJR, while considering factors such as conformity, clearance, surface finish and size. The tribological properties of TJRs will be determined using a friction simulator capable of testing both hips and knees. One of the principle criteria of performance will be the ability to achieve fluid film lubrication, as indicated by a Strubeck plot and this will be an output from the analysis. The development of a comprehensive data set relating component designs, material selection and bearing tribological performance will allow the development of improved devices. The main aims and objectives are outlined below under the different subject matters.

1.1.1 Compliant Layer Bearings
One of the principle purposes of this project is to assess the in vitro performance of compliant bearings in TJRs. The frictional properties of both hip and knee joints incorporating compliant bearings will be measured and the modes of lubrication determined. In addition, their friction and lubrication regimes will be compared to the
friction and lubrication regimes of conventional prostheses of a large variety of materials, including ceramic-on-ceramic and metal-on-plastic.

There is also a strong need to quantify the effects of creep and determine the modulus of compliant polyurethanes polymers at temperatures and loads experienced in vivo. This will be done through a series of creep tests and dynamic mechanical thermal analysis. This approach seeks to describe polymer mechanical properties and how they change with time and temperature, without reference to structure. Both experimental techniques are useful in product design and failure analysis. Creep has the potential to alter joint conformity, changing the contact area with consequences for frictional resistance to movement.

A complimentary part of the study into compliant layer technology is the wear evaluation of a novel glenoid component incorporating a compliant bearing in total shoulder arthroplasty (TSA). This particular joint system was designed ab initio to use compliant bearing technology and was not a modification of an existing design. Some limited wear testing had been carried out on these types of joints [5] but a full assessment of their performance was not available. Wear in this work is defined as the erosional loss of material from one or more of the surfaces in relative motion. It is usually associated with high friction and is strongly influenced by the lubrication condition. Wear results from this work provide a practical test of the ideas being evaluated in the previous tasks.

The final element is concerned with modification of compliant layer bearings with the addition of an antioxidant Vitamin E, in order to improve its bio-stability by decreasing the susceptibility of the polymer to degradation in vivo. The in vitro tribological properties of these modified implants will be assessed. The objective here is not to study oxidation and biocompatibility; rather it is to examine the effect of this modification on the friction characteristics of the material. It is possible that surface blooming of included antioxidant may, through modification of electrostatic interaction, alter the friction between the articulating surfaces.

1.1.2 Large Diameter Hip Bearings

The in vitro friction and lubrication properties of large diameter hip bearings will be assessed. One set of metal-on-metal hips, which are currently in clinical use, of varying diameter will be assessed. An exact lubrication regime of this all-metal bearing and the effect of diameter size will be determined.
Similarly one set of ceramic-on-reinforced polymer, of varying diameter will also be investigated. This bearing system comprises a novel thin-walled horseshoe-shaped carbon-reinforced poly(ether-ether-ketone) (CRF_PEEK) acetabular component, designed and manufactured as a flexible component in an attempt to prevent stress shielding within the adjacent bone when implanted in the body. In the same way, the friction and lubrication and the effect of diameter will be determined.

### 1.1.3 Highly Crosslinked Polyethylene

The *in vitro* tribological properties of second generation highly crosslinked polyethylenes that uses a sequential irradiation and annealing process will be assessed in this work. Surface grafting of these components with poly(2-methacryloyloxyethyl phosphorylcholine) (MPC), with the goal of enhancing wear resistance and biocompatibility, will also be investigated. Again the objective is not to study wear and biocompatibility *per se*; rather it is to examine the effect of MPC surface grafting on the friction and lubrication of polyethylene.

### 1.2 Project Sponsor: Stryker Orthopaedics

The work in this project was carried out on behalf of Stryker Orthopaedics, Limerick, who provided all of the artificial implants used. These materials/components are part of the company’s ongoing proprietary research efforts. Although in some cases company confidentiality limits detail that can be given regarding some material preparation methodology in the main the intention is to put the results in the public domain using the usual methods. Also in a small number of cases the high cost of component fabrication limited the number of samples that could be tested. Where this is the case it is noted.

### 1.3 Outline of Thesis

Chapter one has given an introduction to this thesis; it outlines the aims and objectives. In Chapter two, a review on the tribology of natural synovial joints with particular reference to their mechanism of lubrication and their failure through disease or injury, is presented. The current state of materials systems used in TJRs and compliant layer technology, are also discussed. Chapter three gives a description of the mechanical, characterisation, and tribological testing methods used in this thesis.
Chapter’s four to ten discuss and analyse the results from the research completed; these chapters are categorised separately below:

- Chapter four - creep measurement and dynamic mechanical thermal analysis of polyurethane materials, for use in compliant layer prostheses,
- Chapter five - \textit{in vitro} friction and lubrication of compliant layer hip prostheses,
- Chapter six - \textit{in vitro} friction and lubrication of compliant layer knee prostheses,
- Chapter seven - \textit{in vitro} friction and lubrication of large bearing hip prostheses,
- Chapter eight - \textit{in vitro} wear performance of a compliant layer glenoid component for use in shoulder replacements,
- Chapter nine - \textit{in vitro} friction and lubrication of Vitamin E-blended polyurethanes for use in compliant layer prostheses, and
- Chapter ten - \textit{in vitro} friction and lubrication of highly crosslinked polyethylene, grafted with poly(2-methacryloyloxyethyl phosphorylcholine) (MPC).

Chapter eleven concludes with the findings and results obtained from this research. Recommendations for future work are also outlined here.

\textbf{REFERENCES}

Chapter 2

Literature Review

This review aims to give the reader an introduction to the tribological behaviour of natural synovial joints with particular reference to the mechanism of lubrication and their failure through disease or injury. Tribology, derived from the Greek *tribos* (rubbing), is defined as ‘the science and technology of interacting surfaces in relative motion’ [1] and is the study of friction, wear and lubrication.

In addition the current state of materials systems used in total joint replacements is presented. Compliant layer technology, a relatively new concept in artificial joints will also be described

2.1 Model of a Synovial Joint

The hip, knee and shoulder are all examples of natural synovial or movable joints. A simplified representation of a synovial joint is shown in Figure 2.1. A synovial joint is an encapsulated system which encloses its articulating surfaces and lubricant. The end of each bone is covered with a protective layer of articular cartilage, which serves to reduce contact stresses in the joint, protects surfaces from impact stresses, and minimizes friction and wear of the joint [2]. The natural lubricant called synovial fluid is a clear viscous fluid which serves three purposes: it lubricates the articulating surfaces, carries nutrients to the cartilage cells, or chondrocytes, and transports waste products away from the cartilage [3]. The synovial membrane, which surrounds the joint, serves several purposes: it regulates the amount and content of the synovial fluid, it removes waste material from the synovial fluid and allows nutrients to enter the synovial capsule, and it secretes synovial fluid and other macromolecules for lubrication of the joint [4].

2.1.1 Articular Cartilage

Cartilage is a complex material consisting of both solid (22% by weight) and fluid (78% by weight) components [5]. This bearing material is thus sponge-like. The solid portion consists primarily of a network of collagen fibres and brush-like proteoglycan molecules. This network traps water in the material and stores it as a
gel; this gel becomes pressurized upon application of a load to the joint, and enables the cartilage to support relatively high loads [6, 7].

The surfaces of the articular cartilage are slick and smooth. This feature alone can reduce friction during movement at the joint even without the synovial fluid film present [3]. It has been shown that cartilage on cartilage, lubricated with synovial fluid, gives coefficients of friction in the range of 0.002 to 0.02 at rubbing speeds ranging from 0 to 0.1 m/s when loaded within the physiological range [8].

Proper joint function can continue over a human lifespan if the articular cartilage retains its composition and architecture. However, if it is damaged the surfaces can change from a slick, smooth, gliding surface to a rough felt-work of bristly collagen fibres which results in an increase in joint friction and a possible loss of joint function.

![Image of synovial joint](image)

**Figure 2.1:** Representation of a synovial joint.

### 2.1.2 Synovial Fluid

Synovial fluid is a highly non-Newtonian, pseudoplastic fluid (Figure 2.2) i.e. its viscosity rapidly decreases with increasing shear rate [9] and can be described by a power law of the form:

\[ \tau = kS^n \]

Where \( n \) is the flow behaviour index and have a value less than unity and \( k \) is the consistency index. At low shear rates it is tacky and very viscous (gel like) \((\approx 10 \text{ Pas at a shear rate of } 0.1 \text{s}^{-1})\) and watery and very fluid at high shear rates (watery) \((\approx 10^{-2})\).
– $10^{-1}$ Pas at a shear rate of $10^3 \text{s}^{-1}$) [5]. The shear rates encountered in the major load bearing synovial are of order $10^5 – 10^6 \text{s}^{-1}$, and it appears that the viscosity of the fluid is unlikely to be more than 2 or 3 times that of water under these conditions.

**Figure 2.2:** Flow curve for a pseudoplastic fluid.

The variation of viscosity of synovial fluid with shear rate for normal and pathological fluid is shown in Figure 2.3 [9]. The thixotropic behaviour of synovial fluid has been shown to breakdown in patients with rheumatoid arthritis [10].

Synovial fluid is a dialysate of blood plasma. The primary thickening agent of this lubricant is the polysaccharide chain molecule called hyaluronic acid (HA) [11]. HA acts as a partial filter, “excluding bacteria and invading inflammatory cells from the synovial space but allowing small nutrient molecules to move freely through the synovial fluid to cartilage from the capillary bed of the synovium” [12]. HA treatments, in which HA was added to diseased or temporary immobilized joints in experiments by Keller [13], have been shown to reduce surface damage to some degree.

The *in vivo* protein content of synovial fluid in normal joints ranges between 20 and 40g/l [14] while the protein content of synovial fluid taken from patients with prosthetic joint arthroplasty is within a range of 221 to 43 g/l [15]. The actual volume of synovial fluid varies from joint to joint. In fact, there is wide disagreement in the literature regarding the total quantity of synovial fluid within the knee joint capsule, with values of 0.2ml [16], 1.1ml [17] and 25ml [18] reported. Even though the volume of synovial fluid present in a normal human joint is small, it is sufficient to lubricate the joint and to supply nutrient to the articular cartilage.
2.2 Friction

The experimental determination of friction has been used in providing indirect evidence of the lubricating regime within bearing systems. Friction is loosely defined as the resistance to motion. For a dry contact, that is one without lubricant, the frictional forces that are observed are a manifestation of the interaction between the asperities on the bearing surfaces. Asperities come into contact and form adhesive junctions that are disrupted as the bearing continues to slide (Figure 2.4a) [19]. It is the force that is required to disrupt these junctions that reveals itself as the frictional resistance, which acts in a direction opposite to that of the motion (Figure 2.4b) [19]. The laws of friction, as defined by Amonton are:

1. The friction force (F) produced is directly proportional to the load (N) applied across the bearing surfaces. This is represented mathematically as $F = \mu N$, where $\mu$ is the coefficient of friction.
2. The frictional force is independent of the contact area.

Figure 2.3: The variation of viscosity of normal and pathological synovial fluid with shear rate [9].
Figure 2.4: (a) Asperity contact in unlubricated bearings, (b) The relative directions of the frictional resistance and motion in a bearing system [19].

The French physicist Coulomb verified these practical observations and added a third law stating the independence of friction force from velocity once motions starts (i.e. the kinetic force of friction is independent of the sliding speed). These laws require modification under certain loading conditions but remain a useful approximation for most of the bearing systems discussed in this review. It is important to note that the frictional force is independent of the apparent area of contact which is the surface over which the load is applied (i.e. doubling the contact area whilst keeping the load the same would not alter the measured frictional force). Joints found in the human body are essentially rotational systems and therefore it is more meaningful to describe the characteristics of the frictional performance in terms of a torque rather than a force. The approximate frictional torque can be calculated from the following equation:

\[
T \approx F \times r \\
T \approx \mu \times L \times r
\]

Friction testing is a useful method to compare implants of various designs, material and conditions; and is employed in this study (measurement of friction is an indirect method to imply the lubrication of a bearing combination). The friction within an artificial joint can be measured using a pendulum or friction simulator (that can provide a gait cycle consisting of a dynamic vertical load and flexion and extension movement). The measured frictional torque is used to calculate a dimensionless parameter, called the friction factor. This will be demonstrated in detail later. This
friction factor can be used to compare the effect of different variables, such as the material combination, implant size and design, lubricant, and load and motion profiles. Some of these parameters can be conveniently combined to form a dimensionless Sommerfeld number. Furthermore, the variation in the friction factor against the Sommerfeld number can further indicate the mode of lubrication and this technique is discussed in Section 2.3.1.4 of this review. Typical friction factors in various hip joints are summarised in Table 1 [20].

Table 2.1: Typical friction factors for various bearings for artificial joint in the presence of bovine serum [20].

<table>
<thead>
<tr>
<th>Bearings</th>
<th>Friction Factor</th>
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<tbody>
<tr>
<td>UWMWPE-on-metal</td>
<td>0.06-0.08</td>
</tr>
<tr>
<td>UHMWPE-on-ceramic</td>
<td>0.06-0.08</td>
</tr>
<tr>
<td>Metal-on-metal</td>
<td>0.22-0.27</td>
</tr>
<tr>
<td>Ceramic-on-ceramic</td>
<td>0.002-0.07</td>
</tr>
<tr>
<td>Ceramic-on-metal</td>
<td>0.002-0.07</td>
</tr>
</tbody>
</table>

2.3 Lubrication

Lubrication is defined as the process of adding a substance (solid, liquid or gas) to reduce friction and/or wear at the interface between two surfaces in relative motion [21]. Before looking at the lubrication of the natural synovial joint, it is important to review the basic lubrication theory.

2.3.1 Basic Lubrication Theory

There are three main types of lubrication that can operate between two surfaces moving relative to each other carrying a load normal to this motion. These are fluid film, mixed and boundary lubrication. A schematic of each lubrication regime is shown in Figure 2.5.

2.3.1.1 Fluid Film Lubrication

Fluid film lubrication occurs when a layer of fluid that is thicker than the surface irregularities, or asperities, separates the bearing surfaces at all times. This film has to be thick enough to prevent contact of the surfaces, even at the highest asperity peaks.
Normally this requires the film thickness to be at least twice the sum of the average surface roughness (Ra) values of the surface [22]. For most engineering surfaces this requires a minimum film thickness of between 0.2 and 1.0 μm. If the opposing bearing surfaces can be prevented from touching each other by the fluid, wear is almost totally prevented. Because of this situation, fluid film lubrication is often described as the ideal mode of lubrication. Inevitable, solid particles within the fluid will cause some wear or surface erosion to take place with a fluid passing over a surface [23].

Fluid film lubrication is dependent more on the physical properties of the lubricant. The most important property of a lubricant in fluid film bearings is its viscosity. This is because it governs the resistance to motion and the ability of the bearing to develop load-bearing pressures in the film. Values for coefficient of friction when a full fluid film is present are usually between 0.001-0.01 [20].

### 2.3.1.2 Boundary Lubrication

This form of lubrication is better than direct surface-to-surface contact but the wear rate is higher than either fluid film or mixed lubrication. Boundary lubrication is dependent on the ability of the fluid, or an additive within it, to bond to the surfaces by molecular action. The repulsive forces of these absorbed films carry much of the load and intimate contact between unprotected asperities, with associated adhesion, junction growth and scuffing of the solids, is prevented or limited [24].

For boundary lubrication, the friction is no longer governed by the viscosity of the bulk fluid but the physical and chemical properties of the thin surface layers of the lubricant. The coefficient of friction normally obtained with boundary lubrication is highly variable, but often in the range 0.1-0.7 [20].

### 2.3.1.3 Mixed Lubrication

Mixed lubrication occurs when the separation of the bearing surface is such that they make contact over a small fraction of the effective bearing area. The character of such lubrication is a mixture of fluid film lubrication and boundary lubrication [23, 25]. Although many engineering bearings are designed to run with fluid film lubrication, there are times in most bearings during start up and very high loading when some degree of mixed lubrication is taking place.
A mixed lubrication regime has a wide range of possible friction coefficients (usually 0.01-0.1) [20] and wear rates. The physical properties of the bulk lubricant, particularly viscosity, and the properties of the boundary lubricant are important during this form of lubrication.

![Lubrication Regimes Diagram]

**Figure 2.5:** Schematic lubrication regimes and associated characteristics [20].

### 2.3.1.4 Strubeck Curve

A technique for studying the type of lubrication existing in sliding contacts is the Strubeck curve [26] and this has been extensively used in the study of artificial joints most notably by the Durham Centre for Biomedical Engineering. The classical Strubeck graph plots coefficient of friction ($\mu$) against the angular velocity x viscosity /load ($U\eta/W$), also known as the Sommerfeld number, and was established for journal bearings which are basically two dimensional [27]. In the case of hip joints which are spherical, Unsworth [28] modified this technique to plot a dimensionless parameter called friction factor ($f$) against a modified dimensionless Sommerfeld number ($z$). These terms are defined as:

\[
f = \frac{T}{rL} \quad z = \frac{\eta u r}{L}
\]

Where $T$ is the frictional torque, $r$ is the radius of the femoral component, $L$ is the applied load, $\eta$ is the viscosity of the lubricant and $u$ is entraining velocity of the bearing surfaces.
Friction factor is similar to coefficient of friction, but strictly, to obtain the coefficient of friction in a ball and socket, detailed knowledge of the pressure distribution is needed [29]. Friction factor and coefficient of friction become equal for a ball and socket when point contact occurs at the pole of the joint. In all other conditions, the friction factor is greater than the coefficient of friction [28, 29].

Figure 2.6 shows a typical Stribeck curve for a range of Sommerfeld parameters. The curve can be split into three sections. At the low values of the Sommerfeld parameter, the fluid film thickness is very small so most of the friction is generated by solid-to-solid contact and sliding. This results in constant and high frictional values and corresponds to boundary lubrication, which is dependent only on the chemical properties of the lubricant. The centre section of the curves shows the friction factor falling sharply as the Sommerfeld number increases and this behaviour is exhibited by a mixed lubrication layer. As the viscosity or speed increases or the load decreases, the fluid film carries more of the load with less reliance on the boundary lubricant. Hence the frictional torque of the joint is reduced. The right hand section of the curve shows a slight rising tendency, which corresponds to full fluid film lubrication. Here the friction is low, but rises with Sommerfeld number. The only force resisting motion is due to the shearing of the lubrication film.

It is possible for a joint or bearing to exhibit fluid film lubrication at high values of the z term, but mixed or even boundary at low values of z. In this case, the plot may follow part or all of the shape of the theoretical curve in Figure 2.6 below.

![Idealized Stribeck curve](image)

**Figure 2.6:** Idealized Stribeck curve.
2.3.2 Lubrication of the Natural Synovial Joint

The mechanism by which synovial joints are lubricated has evoked considerable interest over the years. All researchers agree that friction is low, but there are differences of opinion as to why this is so. Many mechanisms have been proposed such as boundary, squeeze-film, weeping, elastohydrodynamic, self-pressurised hydrostatic, boosted and fluid-film lubrication. The history of several of these proposed theories is discussed by Furey [21], Unsworth [30] and Dowson [31].

McCutchen [32, 33] proposed a theory in which pockets of fluid in the recesses of the cartilage surfaces pressurize and support the load, and are replenished by fluid from within the cartilage itself. This concept, called “weeping lubrication” became one of the leading joint lubrication theories after its proposal in 1959. McCutchen argued that since cartilage was a porous matrix filled with fluid, if it was compressed, then this would in turn pressurise the pockets of fluid which would carry some of the applied load. At the same time, elastohydrodynamic lubrication (EHL) was being evaluated for heavily loaded contacts and for soft elastomers. In 1963, the case for full fluid film was revived when researchers suggested that EHL occurred in synovial joints [34].

Another theory, known as “boosted lubrication”, introduced the idea that highly viscous accumulations of synovial fluid could accumulate in the surface pores of the cartilage, and separate the surfaces [35, 36]. Other major theories, such as Hlavacek’s [37] squeeze film lubrication theory and combination of elastohydrodynamic and boundary lubrication contributed to the many possible theories of joint lubrication. Squeeze film lubrication has also been suggested by Unsworth et al. [38] and O’Kelly et al. [39] following frictional analysis of human hip joints. Unsworth et al. [38] found that the friction of lubricated joints increased with the number of swing/cycles when a load was applied, an observation not seen in joints that were starved of lubricant, and concluded that squeeze film lubrication was present. O’Kelly et al. [39] suggested that statically loaded joints operated with mixed lubrication. However, they believed that when the joints were dynamically loaded, with squeeze film action of the fluid and elastic surfaces, they appeared to operate with fluid film lubrication.

Mow et al. [40] developed a theory that considered several complex factors, including the dynamics of synovial fluid flow and its interaction with the cartilage surface. The experimental results demonstrated beyond all reasonable doubt that
synovial joints experienced boundary, fluid film and mixed lubrication depending on the magnitude and nature of the loading and the instant in the cycle of motion. The term “adaptive multi-mode lubrication” has been coined by Murakami et al. [41] to describe the nature of mode of lubrication of synovial joints and is accepted by the author as the best description of in vivo lubrication.

The important concepts of joint lubrication which may allow the fluid film to develop and be maintained are considered individually in the following sections.

2.3.2.1 Squeeze Film Lubrication
Squeeze film effects are particularly apparent with soft material where there is a large area over which the load is carried due to local deformation of the material. It relies on the movement of the surfaces toward one another, the high viscosity of the synovial fluid and the elasticity of the articular cartilage to build up pressure by resisting the outflow, or squeezing out, of fluid film from between the surfaces [42] (Figure 2.7). It is the pressure which carries the load. Squeeze film, by its nature requires a loading regime which varies in magnitude or is removed completely to allow the fluid reservoir between the surfaces to be replenished prior to the next period of loading [24].

![Figure 2.7:](Image)

**Figure 2.7:** The squeeze film lubrication mechanism.

2.3.2.2 Hydrodynamic Lubrication
Hydrodynamic lubrication relies on the movement of the surfaces parallel to the plane of their general surfaces to generate the pressure. Fluid is entrained between the two surfaces and a pressure is generated if the surfaces form a converging wedge [42, 43] (Figure 2.8). During movement of the hip such as walking the surface velocity is
present as well as the required surface properties. However, during long periods under load, motion is too slow to provide a complete fluid film and so this mode could only operate in conjunction with another major method of generating the fluid film.

![Figure 2.8: The hydrodynamic lubrication mechanism.](image)

### 2.3.2.3 Elastohydrodynamic Lubrication

Elastohydrodynamic lubrication (EHL) is similar to the hydrodynamic mechanism but relies on the elastic nature of the surfaces to allow deformation under the applied load [44]. The deformation of the surfaces reduces the pressure which must be generated to separate the surfaces and hence reduced the necessary relative speed of the surfaces to support the load. In very heavily loaded contacts, metals may exhibit significant elastic deformation. Under these conditions the dependence of the lubricant viscosity on pressure plays an important role. This type of lubrication is known as hard EHL which occurs when both surfaces have high elastic moduli. For the hip joint a much softer material like cartilage is required under the loading developed, which typically has a maximum load of 1500-2000N. In the lubricated contact of soft elastic bodies such as cartilage, the pressures are much lower and have no effect on the viscosity of the lubricant, only the elastic deformation of the contacting surfaces needs to be considered. This type of lubrication is known as soft EHL.

### 2.3.2.4 Micro Elastohydrodynamic Lubrication

Micro-elastohydrodynamic lubrication (μEHL) may also be present. This relates to the lubrication of a single asperity or roughness of the surface. Each asperity will show a converging wedge, which is one of the requirements of hydrodynamic lubrication, and a pressure is generated as in the above case [23]. The pressure generated partially elastically flattens the very asperities causing it. This relies on the
material having a roughness composed of regularly sized and spaced peaks. Deformation of the surface, as shown in Figure 2.9, will also help to generate the film. This sort of deformation will be most pronounced in soft materials with high Poisson’s ratios, such as cartilage.

![Figure 2.9: The effect of asperities on lubrication- μEHL.](image)

**2.4 Wear**

Wear is defined as the progressive loss of substance from the operating surface of a body occurring as a result of relative motion at the surface. The importance of wear is related not only to the decreased function and replacement cost of a component, but also the adverse effects of wear particles. The focus of wear studies should therefore be on both volume and particles. Five types of wear are described [20]:

(a) Abrasive: The displacement of material by hard particles.

(b) Adhesive: The transference of material from one surface to another during relative motion by the process of solid-phase welding.

(c) Fatigue: The removal of materials as a result of cyclic stress variations.

(d) Erosive: The loss of material from a solid surface due to relative motion in contact with a fluid which contains solid particles. This is often subdivided into impingement erosion and abrasive erosion. If no solid particles are present, erosion can still take place, such as rain erosion and cavitation.

(e) Corrosive: A process in which chemical or electrochemical reactions with the environment dominates, such as oxidative wear.

It should be pointed out that mechanical actions are involved in the above wear types (a-d) while wear type (e) is due to chemical action. Furthermore, it should be noted that the above wear types may occur simultaneously or sequentially. For example,
wear particles, which may be produced as a result of adhesive wear, can then act as third bodies causing abrasive wear. In polymeric bearing surfaces, adhesive, abrasive and fatigue wear can all contribute to the overall wear. Some terms often described for artificial joints can all be related to the above mechanisms. For example, pitting, scratching, burnishing and delamination have all been described for retrieved total knee joint replacements [45, 46]. Pitting and delamination are specific forms of fatigue wear, while burnishing and scratching are different degrees of abrasive wear. Understanding the wear mechanism is also important to design appropriate strategies to reduce wear. Effective cleaning during surgery and possible sealing of the whole joint can also prevent hard particles from entering the articulating surfaces. Fatigue wear mainly depends on the prosthesis design and materials used. It is important to minimise the contact stresses in order to avoid short-term fatigue failure. Effective lubrication, in terms of both boundary and fluid film lubrication is the key to minimise adhesive wear. There are three laws of wear as listed below [20]:

1. Wear volume (V) increase as the normal load (L) increases.
2. Wear (V) increased as the sliding distance (s) increases.
3. Wear (V) decreases as the hardness (H) of the softer sliding component increases

Which can be expressed mathematically as follows:

\[ V \propto \frac{Ls}{H} \]

To a first approximation the amount of volumetric wear generated in either mixed or boundary lubrication regimes can be determined from the following equation [19]:

\[ \text{Wear volume (V)} = \text{wear factor (k)} \times \text{load (L)} \times \text{sliding distance (s)} \]

The wear factor is a constant of proportionality whose values is dependent on the exact condition of the bearing contact including the materials used and the surface roughness. Like frictional forces, the volumetric wear is independent of the contact area. In addition, the volumetric wear is directly proportional to the sliding distance.
so that, for a given articulation, a larger headed prosthesis will generate more wear debris than a smaller headed prosthesis given all other parameters are equal.

A wide range of laboratory equipment, test methods and measuring systems have been employed to study wear mechanisms in total replacement joints. The pin-on-disc/pin-on-plate machines have been widely used in tribology and are particularly useful in the evaluation of the nature of wear and friction of material pairs under well controlled, steady-state conditions of load, sliding speed and environment [47, 48]. However, these are relatively simple wear machines and are only useful as screening devices. A comparative performance evaluation of joints of different designs and material combinations requires joint simulators for in vitro laboratory studies. These simulators generate to a greater or lesser extent the three-dimensional loading and motion patterns experienced by joints, while providing a lubricating environment deemed to be physically and chemically similar to synovial fluid.

An in vivo measurement of wear is usually undertaken by measuring the linear wear from either single radiographs (uniradiographic technique) or by comparing the post-surgery radiograph and the latest one available (duoradiographic technique) [49-51]. The measurements are corrected for magnification by calibration with the known dimensions. Computer techniques are available for the semi-automatic assessment of digitised radiographs. Both volumetric and linear wear can be measured by direct examination of explanted cups gained either from revision or post-mortem [52-55].

2.5 Joint Disease, Wear and Damage

The two most common forms of joint disease are rheumatoid arthritis and osteoarthritis. In joints afflicted by rheumatoid arthritis, the cartilage initially is damaged by enzymes released within the synovial capsule. This condition is chronic and can result in capsular inflammation, pain and even loss of mobility. Osteoarthritis (OA), which can be brought on by age or joint trauma, has traditionally been describes as the “wear and tear” form of arthritis; the degeneration of the cartilage progresses slowly to rapidly throughout the joint and can cause large quantities of cartilage to be worn away at an unusually high rate. OA can result in severe cartilage lesions, joint immobility, and bony growths of the joint. Although the specific causes of OA are still unknown, several researchers have put forth theories regarding the cause and mechanisms of this type of joint generation.
Cartilage is capable of repairing itself only in an extremely limited fashion. Damaged cartilage may be slowly repaired, but the resulting material is typically inferior in load-bearing capability to the original cartilage. “Cartilage response to injury is severely limited, in contrast to tendons and muscles, which usually heal with scar tissue” [56].

Although OA tends to be much more common among the elderly, joint trauma or various other factors can cause an onset of degenerative joint disease. An instability in the joint which could be caused by injury to the ligaments, meniscus, or cartilage, or by a structural deformity in the bone of joint can result in “biochemical, metabolic and mechanical property changes” that can begin the destructive cycle of osteoarthritis [2]. Early signs of OA include cartilage fibrillation and increased hydration, thickening of the walls of the synovial capsule, and biochemical changes in the proteoglycans produced in the joint [2]. Sokoloff [57] suggests that OA may be an exaggerated state of the natural remodelling process within the joint. Applied stresses to the cartilage result in changes in the geometry; repetitive loading may result in removal of material in some areas and growth of new material in others by natural remodelling processes. In many instances, total cartilage mass and proteoglycan production have been shown to increase during the early stages of OA [58].

OA degeneration progresses through four distinct phases as the cartilage damage become more severe; these grades are explained by Marcinko [6]. In grade I, surface and subsurface damage are minor, and limited to small fissures and pits. The damage can be observed only at points of highest stress and the rest of the joint functions normally. In Grade II, more severe cartilage damage can be seen, though the damage is still confined to the areas of greatest loading. Some cartilage loss can occur in this stage. Grade III of the degradation marks the complete loss of cartilage in heavily loaded areas and possibly the formation of bony growths. Pain in the joint would typically begin during this stage. Grade IV is the most severe level of degradation; in this stage, large areas of bone may be completely exposed. The surfaces of the bone can become misshapen and the articular surfaces become irregular [6].

Few treatments exist for OA patients. Part of the difficulty in treating OA results from the difficulty in diagnosing the disease early; the pain and stiffness associated with later stages (Grades III and IV) of the disease are not generally
evident until much cartilage damage has occurred. In less severe cases, a doctor may choose to remove a portion of the affected cartilage to prevent a removed cartilage flap from being released into the joint. In more serious cases of OA, partial or total joint replacement may be required. Joint replacement is undertaken when no other measures can be used to save or prolong the life of the joint.

2.6 Total Joint Replacement
Total joint replacement (TJR) also known as total joint arthroplasty (TJA) is regarded among the most valued developments in the history of orthopaedics. Over 200,000 total hip replacements (THR) and 350,000 total knee replacements (TKR) are carried out annually in the United States [59]. Total shoulder replacement (TSA), although done much less frequently than hip and knee replacements, is the third most prevalent joint replacement procedure done worldwide. Fundamental to replacing damaged joint surfaces with implants fabricated from materials, is the requirement of producing a low friction bearing to minimize surface wear, inflammation in surrounding tissues and possible eventual loosening of the implant, resulting in the need for revision surgery.

2.6.1 Joint Replacement Implant Materials
A number of materials were tried as bearing surfaces in joint arthroplasty, including polytetrafluoroethylene (PTFE), stainless steel and cobalt-chromium alloy. However the preferred bearing, since the 1980s, comprises a cast or forged alloy of cobalt chrome articulating against ultra-high molecular weight polyethylene (UHMWPE). It has been estimated than more than 90% of THR implanted worldwide since the 1990s have incorporated either a conventional or highly crosslinked UHMWPE insert [60]. Introduced clinically in 1962 by Sir John Charnley, the metal-on-UHMWPE remains the “gold standard” bearing surface combination for artificial hips and now for other artificial joints including the knee and shoulder.

It is the ongoing problem of wear that has led to the reintroduction of a number of alternative bearing combinations. Clinically speaking, friction and wear result in very small wear particles that are released to the surrounding joint cavity, initiating an aggressive inflammatory response [61, 62]. The body mounts a cellular reaction to try and deal with wear debris, a reaction unfortunately often leads to unwanted destruction of bone (called osteolysis) around the implant. When osteolysis
becomes severe, it can cause pain and loosening of the implant and need for revision surgery to replace the components. One way to relieve the osteolysis problem and thus increase the longevity of joint replacements is to improve the wear resistance of the bearing materials. Also facilitating this introduction of materials is the shift toward younger and more active patients seeking and receiving joint replacement. Today, metal-on-metal and ceramic-on-ceramic are being considered as alternative bearing materials [63].

All the materials currently in use in joint replacements are considered safe from a medical standpoint. They are highly compatible, meaning that they cause little if any detrimental local or systemic problems due to immune response or an allergic reaction. Nonetheless, as TJRs remain in service for long periods of time, concern remains that adverse tissue responses could arise as a result of the continual release of worn fragments of the prosthetic materials. This concern is most often mentioned in conjunction with the reintroduction of metal-on-metal bearings.

### 2.6.2 Metal on Metal Bearings

Metal-on-metal bearings were among the first to be used in total hip arthroplasty and found clinical success in the 1960s and 1970s. However, failures during this time were due in part to poor metallurgy and implant design. The casting process used to make metallic implants suffered from poor quality control, sometimes leading to products that had inferior wear resistance and were prone to fracture in the body. Early metal-on-metal designs often had small head to neck ratios, so that impingement between the neck of the femoral component and the rim of the acetabular components was a common occurrence. This impingement provides another source of wear and can knock the acetabular component loose from the surrounding bone. However, some of the first generation McKee-Farrar metal-on-metal hip prostheses performed well for 20 years or more [64] with wear rates reported to be 1-6mm³ per year compared with 30-100mm³ of traditional metal-on-UHMWPE hips [65-67]. These favourable clinical results led to resurgence in the use of metal-on-metal (second generation) bearings for hip replacements, which are superior in terms or both design and materials. Cobalt-chromium alloys with well controlled grain sizes and finely distributed carbides provide superior hardness and wear resistance compared to earlier versions of the alloy and to stainless steel and titanium alloy. Clearance and conformity between the bearing surfaces and a smooth
finish on the metallic bearings are now recognised as important factors that must be controlled as a part of the design and manufacturing processes. Laboratory evidence from *in vitro* hip joint simulator studies has confirmed that these bearing surfaces can provide low wear joint implants [68]. Short term clinical performance has been encouraging, with reports of mean wear rates as low as 0.3mm³ per year [69-73]. The strength of cobalt-chromium alloys in comparison to polyethylene and their increased toughness over ceramics provide additional benefits from the standpoint of hip implant design. For example, the surface thickness of a one-piece metallic acetabular component can be smaller than modular components made from polyethylene, so larger femoral head sizes can be incorporated, providing an advantage in cases where joint stability is an issue. Similarly, the ability to manufacture large metallic shells allows for surface replacement of the hip joint, a bone-conserving operation geared toward young, active patients with good bone stock in the femoral head and neck. In this study, the friction and lubrication of large diameter metal-on-metal hip implants manufactured by Finsbury Orthopaedics exclusively for Stryker will be investigated. A friction simulator that accurately matches both the loading and motion profiles encountered by the body during the walking cycles will be employed. The effect of diameter on the lubrication regime acting within this all metal system will be determined.

The suitability of new material and designs has traditionally been assessed on wear volume alone; however, a low wear volume is not the only important factor governing the long-term clinical outcome of a total hip replacement. The size, morphology and biological activity of any wear particles released are all equally important. Recent studies have shown that the wear particles generated in metal-on-metal hip prostheses are in the nanometre size range [74-76]. Consequently, the number of particles produced in a metal-on-metal articulation may exceed the number of UHMWPE particles produced by a metal-on-UHMWPE articulation (0.1-0.5 μm, [77]) despite the low wear volume of the metal-on-metal prosthesis. Doorn et al. [74] isolated and characterised metal wear particles from the periprosthetic tissues from first and second-generation metal-on-metal prostheses. The particles were in the size range 51-116 nm, and were mainly round in shape. These authors estimated that between $6.7 \times 10^{12}$ and $2.5 \times 10^{14}$ particles would be produced each year. In addition there is concern over the distribution of these small ionic particles around the body and the biological effects that they may have on cells and tissues. Metal particles...
have been shown to be disseminated throughout the body and have been found in the
lymph nodes, liver, spleen and bone marrow [78-82]. Little is known about their
long-term systemic effects, although concerns about metal sensitivity and increased
incidence of haematological cancers, such as lymphoma and leukaemia have been
raised.

It is still not clear whether osteolysis occurs around metal-on-metal hip
prostheses. In general, the new generation metal-on-metal prostheses have not been
associated with particle-induced osteolysis. More recently a report by Beaule et al.
[83] described osteolysis in association with a metal-on-metal prosthesis induced by
joint fluid access to the effective joint space. In addition, the results of long-term
implantation are at present unknown. Schmalalzried et al. [84] studied a series of first
generation McKee-Farrar hips, some of which had been implanted for 30 years, and
found the incidence of osteolysis to be four per cent for the whole series. This
compared favourably with metal-on-UHMWPE hips, but indicated that metal-on-
metal prostheses may not eliminate osteolysis in the longer term.

Metal-on-metal bearings have not been applied to many joints other than the
hip. Most other joints require different designs to provide adequate function, and
therefore suffer from additional wear mechanisms for which metal-on-metal surfaces
have few advantages.

2.6.3 Metal on Polyethylene Bearings

The goal of finding new means of reducing wear degradation in polyethylene has lead
to some developments in this material in the last two decades. A substantial leap
forward was made with the discovery of the role of oxidation in the wear performance
of polyethylene [85]. Polyethylene components, like most medical devices, are
sterilised by exposure to gamma irradiation [86]. Unfortunately, the radiation, while
penetrating through the component, has sufficient energy to break the chains that form
the molecular backbone of the polymer. If the radiation exposure is performed while
the component is exposed to air, the broken ends can react with oxygen, causing
harmful changes, including a decrease in molecular weight, a dramatic loss of
ductility, and a decrease in strength. The combined effect may make the polyethylene
markedly more susceptible to wear. One important form of alternative bearing
surface has emerged simply by removing the chance that the polyethylene can oxidise
during the sterilisation process. Device manufacturers have accomplished this task in
two ways: (1) placing polyethylene joint replacement components into sealed packages that contain either a vacuum or an inert gas, such as nitrogen or argon, instead of air and (2) replacing radiation altogether, instead exposing polyethylene components to ethylene oxide or gas plasma, neither of which imparts sufficient energy to cause oxidation. Though these alterations in sterilization can eliminate degradation, they do not have the same beneficial impact on wear. Techniques that eliminate irradiation altogether also eliminate the benefit of the additional cross-linking between the molecular chains in the polymer.

The most significant alteration in polyethylene joint replacement components is the inclusion of elevated levels of radiation, beyond those required to simply sterilise the implant. The goal is to induce even higher levels of cross-linking that occur with the conventional sterilization dose (historically UHMWPE have received a dosage ranging between 25 to 40 kGy during sterilization [86]). Advantages of elevated cross-linking include significantly reduced wear [87, 88] resulting from the higher radiation dose. This increased wear resistance has also renewed interest in large femoral heads as a means of reducing the risk of dislocation. With a larger head size, sliding distance between the bearing surfaces and the resulting amount of wear are higher, so conventional metal-on-polyethylene bearings are typically small diameter (32mm or less). Larger head sizes are now available with matching larger diameter, highly crosslinked polyethylene acetabular components. But these components are thin (less than 5 mm in some cases) making the strength and toughness of highly crosslinked polyethylene important considerations.

However the use of this material in knee replacement is much more limited. The types of motion and wear that occur in knee replacement could lead to fracture or other failure of the highly crosslinked polyethylene in knees. In fact, changes in mechanical properties that accompany increased crosslinking may pose the biggest threat to the clinical effectiveness of these materials. The presence of the crosslinks adversely affects uniaxial ductility, and the uniaxial failure strain of UHMWPE decreases linearly with increasing radiation dosages [89]. Because of this concern, even newer forms of highly crosslinked polyethylene are being introduced to improve on this technology. These materials use alterations in the crosslinking and thermal treatment (annealing or remelting) processes to impart both increased wear resistance and improve toughness [90, 91]. During irradiation, the loss of ductility depends on the crystalline microstructure of the UHMWPE, because crosslinking occurs primarily
in the amorphous phase, where the molecular chains are in sufficient proximity such that a covalent bond can be created between adjacent polymer molecules by the applied energy. Un-irradiated UHMWPE typically has a crystallinity in the region of 50% [92], so some 50% of the material is amorphous content that can be crosslinked during irradiation. If the temperature of the UHMWPE changes during the crosslinking process, this can influence the distribution of crosslinking in the polymer, and, hence, influence its ability to accommodate large strains prior to failure [93, 94]. Second-generation highly cross-linked polyethylenes such as X3 (Stryker Orthopaedics, Mahwah, NJ) that uses a sequential annealing process to help saturate free radicals has been released. Clinical results with this second generation devices are not yet available. In the work reported here, the friction and lubrication of the X3 acetabular cup articulating against both a metallic and composite femoral components will be assessed.

2.6.4 Ceramic Bearings

Alumina and zirconia are used in TJRs specifically for the purpose of providing more wear resistant bearing surfaces. Because of their hardness, ceramics can be polished to a very smooth finish and remain relatively scratch resistant while in use as a bearing surface. The most significant disadvantage of ceramics is their brittle nature, making them susceptible to fracture [95]. As with the case of metal-on-metal bearings, where improvements in metallurgy have sparked renewed interest, improvements in ceramic quality have led to increased interest in ceramic bearings [96]. Increased chemical purity and reduced grain size have lead to increased strength [97] and a dramatic reduction in the number of fractures seen clinically [98]. Nonetheless, strength and toughness remain issues, where impingement of the femoral and acetabular components at extreme ranges of motion can lead to fracture.

Alumina and zirconia components have been used for decades, mostly as femoral heads in THRs. Alumina has the longest history of successful use in articulations with UHMWPE and against itself in ceramic-on-ceramic bearings. Recently, an oxidised zirconium material has been introduced into both hip and knee replacement components for use against polyethylene; few results are available with this material and clinical experience is short.

Ceramic-on-polyethylene bearings have been commercially available for some time as alternatives to metal-on-polyethylene. Although the clinical studies reported
[99-102] thus far in literature have been retrospective in nature, overall the research would suggest that ceramic heads do not substantially improve the wear rate of UHMWPE acetabular components. It may be that prospective, randomised trials with large numbers of patients will be necessary to detect the relatively small difference in wear rates with ceramic and metal femoral heads.

Alumina-on-alumina hip prostheses have been used clinically for over 25 years. In general, alumina-alumina joints have shown very low wear rates clinically, though the results are design dependent. Recent reports also show excellent wear resistance in young patients, with no measurable wear and no evidence of osteolysis even beyond a decade of follow-up [103]. Furthermore, very few implant fractures have been observed, even in this high demand patient population, lending further credence to the improved mechanical properties of alumina. While ceramic bearing have been used extensively in hips, the use of ceramic bearings in other joint replacements is much more limited. For joint designs such as the knee replacements that require bearings with non-conforming shapes to provide the patient with adequate function, the advantages of ceramic-on-ceramic bearings are unclear.

Developments in ceramic bearings are leading to new material formulations such as zirconia-toughened alumina and to new bearing couples such as ceramic-on-metal. Because it is unlikely that these ceramic bearings can be shown to further substantially reduce clinical production of wear debris, their adoption will depend on their capability of solving more pragmatic needs, such as large heads and thin shells [91]. An element of the study reported here will relate to the use of large diameter ceramic heads on thin carbon fibre reinforced (CFR) composites cups.

### 2.6.5 New Hip Bearing Designs

Contemporary hip bearings are supported by femoral stem and acetabular shells that are very stiff when compared to adjacent bone. In the acetabulum, it has been shown that the presence of a stiff shell can lead to retroacetabular bone loss in patient populations [104]. Recent finite analysis suggests that acetabular stress shielding and bone loss are inevitable with hemispherical acetabular shells and that stress shielding is not affected by the thickness of the cup wall [105]. Results with a horseshoe-shaped all polymer (polyethylene bearing surface, carbon fibre reinforced polybutyleneterphthalate shell, and hydroxylapatite coating) Cambridge Cup (Howmedica, Staines, UK) showed an early reduction in bone loss with this flexible
design and the recovery in bone density in the weight bearing region of the acetabulum at 2 years follow-up [106]. A second generation horseshoe shaped design, the so called MITCH™ PCR Cup (Stryker SA, Montreux, Switzerland), has both a structure and bearing surface of carbon reinforced fibre polyetheretherketone (CRF PEEK) composite and is fixed to bone with a hydroxyapatite coating. The femoral head is alumina ceramic. Finite element analyses of the MITCH™ PCR Cup in bone shows superior loading of the acetabular dome compared to a traditional hemispherical design. Clinical trials of the Mitch PCR now are underway. In this study, the friction and lubrication of these large diameter couplings will be assessed. The effect of diameter size on the lubrication regime acting within this novel hip system will be determined.

2.6.6 Compliant Layer Technology
Compliant or ‘cushion form’ bearings comprising layers of low elastic modulus materials are being investigated in this study for use in total replacement joints, as a technology that attempts to simulate the natural synovial joint. The low modulus lining on the bearing surface of the prosthesis is used to promote a continuous film of lubricant between the articulating surfaces and hence reduce both friction and wear. The promotion of a continuous film of lubricant may be attributed to conventional EHL and squeeze film effects, μEHL and local deformation of the low elastic modulus layers. The low elastic modulus layer may be considered to fulfil a similar function to that performed by cartilage in the natural joint. A reduction in friction will result in increased mobility, longer service life and a reduction in the discomfort of patients.

The literature on compliant layer technology is reviewed in the following sections. Most of it refers to its application in hip and knee replacements. Great interest is shown in polyurethanes as these materials exhibit many of the desired properties of natural cartilage.

2.6.6.1 Compliant Bearings for TJR- mathematical calculations of theoretical lubrication regimes, contact stresses and contact area.
The theory governing the function of compliant bearings is based on both contact mechanics and lubrication analysis and requires that both the Reynolds equation (which describes the flow of the lubricant) and the elasticity equations (which
describe the deformation of the contact) be solved simultaneously. Several groups have calculated the fluid film properties under a variety of loading regimes for compliant layer hip joints [107-110] and found that the thickness of the fluid film is dependent on the contact area, which can be controlled by (1) the elastic modulus of the thin layer, (2) the thickness of the layer, and (3) the radial clearance. Computational contact mechanics illustrated that it was important to optimise the contact area at maximum load so that the contact stresses and the pressure in the film of lubricant are minimised and fluid film thickness is maximised. A decrease in elastic modulus and an increase in layer thickness will increase the contact area, and as a result contact stresses are reduced and fluid film thickness is increased. Yao [111] demonstrated how the layer thickness needs to be increased with an increase in Young’s modulus of the layer in order to keep the contact radius unchanged. However, the elastic modulus should not be lower than necessary to produce effective μEHL as a further reduction in modulus will produce increased shear strains and vice versa for the layer interface [112]. Strozzi and Unsworth [113] proposed an optimum layer thickness for an acetabular cup of 2mm using Estane polyurethane grade 5714F1 (E= 8.5MPa).

Analysis of the theoretical lubrication regimes illustrated that compliant layer knee joints should operate under fluid film lubrication at physiological viscosities. Computational contact mechanics again illustrated that it was important to maximise the contact area subject to kinematic requirements in the natural knee joint so that the contact stresses and the pressure in the film of lubricant are minimised and fluid film thickness is maximised [114]. Steward et al. [115] showed that the magnitudes and locations of stresses within the compliant joint could be controlled by varying the compliant layer thickness and substrate modulus. They recommended a 4mm thick compliant layer with an elastic modulus of 20MPa and a 4mm thick structural support layer with an elastic modulus of 1000MPa.

One of the limiting factors of using compliant materials as bearing surfaces in artificial joints appears to be the strength of the interface between the soft layer and its support layer [116-119]. Mattewson [116] developed a theory for the indentation of a soft thin coating rigidly bonded to a semi-infinite rigid substrate using differential equations to describe the deformation of the coating. Using some basic assumptions, he found that the interfacial shear stress between the coating and the substrate was largest for incompressible materials, implying that these materials were more likely to
debond than others. A stress analysis study on compliant layers showed that the 
maximum shear stress occurred at the interface close to the edge of contact [117], and 
this was approximately 0.2 times the magnitude of the maximum normal compressive 
surface stress. Because of the direction of the compliant layer movement, the 
maximum interfacial radial shear stress would be of a similar value and at the same 
location as this maximum shear stress, indicating that failure by debonding would 
tend to initiate in this region. After testing several types of polyurethane (moduli in 
the range of 6-20 MPa) bonded to a metal plate in a knee simulator, Auger et al. [118] 
reported that fatigue in the bond between the compliant layer and substrate was of 
concern, with the lower modulus materials exhibiting the worst performance. A 
simulator study of compliant layer knees identified four mechanisms by which the 
fluid film could break down, whereby high frictional torque at the bearing interface, 
with consequential failure at the bonded interface with the support layer [119], was 
the consequential outcome. However, a recent study by Burgess et al. revealed strong 
interface bonds (using peel tests) between two polycarbonate urethanes, when 
moulded under optimum conditions [120].

2.6.6.2 Tribological Assessment of Compliant Bearings for THR

Frictional assessment of compliant layer polyurethanes were carried out by a number 
of different research centres. Carvaria et al. [121-123] and Jin et al. [124] analysed 
the friction of polyurethane and stainless steel using pin-on-disc experiments. These 
preliminary studies showed that the lowest friction was obtained when hard 
pins/indenters were sliding on polyurethane and that although the material 
combinations gave extremely low levels of friction during steady state, sliding start up 
friction was high. Overall they concluded that a fluid film readily forms under good 
conditions.

In vitro studies examining the friction of polyurethane acetabular cups against 
metal femoral balls in pendulum type simulators universally concluded that this hip 
joint operated under fluid film lubrication [118, 125-128]. It was also shown that a 
clearance of between 0.1 and 0.25mm was required to avoid impingement of the joint 
as a result of creep of the polyurethane [128]. In 1993 Auger et al. [118] designed 
and constructed two hip joints to be elastohydrodynamically equivalent producing 
approximately equal initial contact areas and theoretical film thicknesses. One was 
made from conventional UHMWPE (>1 GPa such that elastic deformation of the
surface asperities and μEHL were not effective) and the other was a cushion component which had a low modulus layer (20MPa such that μEHL was considered to be effective) introduced into the joint space. Friction measurements were carried out on the Leeds pendulum simulator apparatus and the two joints were compared. Values for the friction factor at peak loads and peak velocity in the cushion cup were much lower than in the UHMWPE cup. The enhanced lubrication of the cushion cup, compared to the elastohydrodynamically equivalent UHMWPE cup is consistent with μEHL theory.

Wear of polyurethane acetabular cups was assessed by gravimetric means yielding favourable yet unreliable results. Bigsby et al. [129] illustrated that the mean wear rate for polyurethane cups (10.08 ± 16.03mm³/million cycles) was much lower than UHMWPE cups. In another study Smith et al. [130] measured the volumetric wear rates of 5 polyurethane acetabular cups using a coordinate measuring machine and calculated an average wear rate for the cups as 14.1mg ± 9.63mm³/million cycles. Again the standard deviation was large for the calculated wear rates as with the results from Bigsby et al. and was attributed to creep rather than wear of the cups.

In vivo studies carried out by Carbone et al. [131-133] investigated the wear of compliant layer polyurethane bearing in a sheep total hip arthroplasty model for up to 4 years with excellent results. The major finding of this study, which has also been reported by Khan [134], was that there was no biodegradation of the polyurethane and no surface damage or deterioration in the wear performance of the compliant layer hip.

A number of conclusions can be made from the studies on compliant polyurethane bearings for use in THRs. It was shown that they can articulate with very low frictional torques which is indicative of fluid film lubrication whereby EHL and squeeze film action are the two main lubrication mechanisms present. During the stance phase EHL predominates, when pressure is generated in the lubricant by an entraining motion between the two joint surfaces. Squeeze film action predominates at heel strike in walking phase; the two surfaces move towards each other, squeezing the fluid out of the joint space. The squeeze film lubrication that is produced in these compliant joints actually improves the maintenance of the fluid film, which remains present for a longer period of time than it would do for hard bearing surfaces or conventional joints.
It was also shown that although bearing surface topography is a key parameter in fluid film formation and asperity contact, the design of the joint appears not to be particularly critical, with fluid film lubrication observed over a wide range of conformity, head size, and layer modulus. This is important, as the bearing geometry will change with time due to creep changing the effective equivalent radius and layer thickness.

Overall the suitability of compliant layer polyurethane hip joints is promising and will be investigated further in the work reported here.

2.6.6.3 Tribological Assessment of Compliant Bearing for TKR

The first published study on the in vitro wear and friction of compliant layer bearings was by Auger et al. in 1993 [110, 118, 135] who assessed the friction and wear of flat compliant layer polyurethane bearings articulating against a standard metallic condylar femoral components. Compliant bearings were designed and constructed to be elastohydrodynamically equivalent to a conventional UHMWPE joint, producing approximately equal initial contact area and theoretical film thicknesses. They consisted of an initially flat, soft layer of material on a relatively hard backing which imposed fewer biomechanical constraints and allowed a greater range of movement. The simple premise was that if effective fluid film lubrication could be established with such poor initial conformity, even greater effectiveness of lubricating film formation would be assured once the soft layer had bedded in as a result of creep, or by introducing appropriate profiled tibial surfaces. Friction measurements were carried out on the Leeds pendulum simulator apparatus. The UHMWPE tibial inserts were compared to a range of compliant layer tibial components with thicknesses varying from 0.25 to 5mm and elastic moduli from 5 to 20MPa. The results [118, 136] confirmed that a flat cushion tibial component performed better than a conventional UHMWPE joint replacement due to the allowance of larger areas of contact as a result of the deformation of the low modulus layer. The compliant knee joint operated within the mixed lubrication regime, but they benefited from a substantial measure of FFL and μEHL was effective in preserving low friction and thin but effective lubricating films.

In a wear and durability investigation of compliant layer knee joints by Auger et al. [135] it was demonstrated that a polyurethane with an elastic modulus of 6 MPa was not suitable as it did not possess adequate structural integrity. Also, when run
dry, high friction and rapid wear destroyed the compliant layer. However, the 20MPa compliant layer tibial inserts were tested with promising results up to 4 million cycles. There were a number of features visible on the surface of these compliant layer inserts which included [135]: (1) depressions due to creep deformation of the polyurethane material in the area under the femoral component (the creep stabilised after about 1 million cycles), (2) scratches/ tracks in the depressions in the polyurethane appeared in the anterior-posterior direction, (3) rippled and wavy lateral depressions, (4) tears, perpendicular to the direction of sliding, and (5) some debonding of the compliant layer from the rigid substrate was seen.

Stewart et al. [119] investigated the tribological conditions leading to fluid film breakdown in composite compliant layer polyurethane knee bearings such as sever cyclic loading, reduced sliding velocity, variable stroke length and start up friction after periods of loading. They believed that some contact between the surfaces is inevitable and the low modulus material must be able to withstand brief periods of contact and potentially high friction. The wear of these materials is a major concern when the conditions for fluid film lubrication are not optimised, such as start up or after a long stationary period of constant loading. Stewart et al. [119] confirmed that start up friction was high, although no apparent wear features were visible following these severe condition. They concluded that start up friction was found to peak after 60 seconds of stationary loading, which was in agreement with another study [121] that found that start up friction peaked after 80 seconds of static loading. They also demonstrated that in some of the cases severe kinematic conditions, mixed lubrication was evident as indicated by some light scratching of the polyurethane components. Finally, it was concluded that compliant layer knee replacement should be designed to operate with thick elastohydrodynamic fluid films to provide protection when tribological conditions are severe.

Pearcy [137] stated in his essay on “A new generation of artificial hip joints” that three points needed to be clarified in relation to compliant layer joints which are as follows:

1. Would compliant layer joints operate well with viscosities similar to the low viscosity synovial fluid found in arthritic joints?
2. Would compliant layer joints be damaged much faster than conventional joints in the presence of bone debris or bone cement debris?
3. Would the compliant layer be destroyed when running without any lubricant as expected immediately post surgery in vivo?

Essner and Wang [138] assessed Pearcy’s concerns regarding three body wear. They carried out wear studies, in the presence of crushed bone cement, on UHMWPE tibial inserts and PU tibial inserts, which have been described elsewhere [139]. They demonstrated that the compliant layer tibial inserts exhibited minimal surface roughness changes under wear testing for 9 million cycles compared to UHMWPE controls. Also it was shown that the femoral components articulating against the compliant layer components were slightly scratched while those articulating against the UHMWPE components were significantly scratched.

In a study by Ash et al. [139] the friction of UHMWPE and compliant layer standard conformity tibial inserts articulating against CoCr condylar femoral components was assessed following three body wear for 3 million cycles, using crushed bone cement. The frictional torque of both material combinations increased dramatically in the presence of bone debris but did not increase the wear rates. However, following three body wear testing the compliant bearings had a much lower friction than the UHMWPE bearings and still operated under fluid film lubrication. The volume of bone cement particles between each of the bearings and the resultant frictional torque both decreased over time. This occurred more quickly with the PE bearings but greater damage was caused to the surface of the PE bearing than the polyurethane.

The friction and wear of unicondylar compliant layer PU tibial inserts has recently been studied [140]. In this study, it was shown that the compliant layer joints operate under fluid film lubrication. However, the joint did appear to operate under a mixed lubrication regime when using bovine serum lubricant although it was postulated that this is due to protein-protein rubbing as a form of boundary lubricant.

Overall the suitability of compliant layer polyurethane knee joints is promising and will be investigated further in the work reported here.

2.6.6.4 Polyurethanes

As mentioned previously, the main potential materials proposed for use in compliant bearing arthroplasty are polyurethanes. Both Khan [141, 142] and Quigley [143, 144] present an in depth review of polyurethane in medical application. In general,
polyurethane has better abrasion and tear resistance than other plastics and silicones, while offering higher load bearing capacity. Compared to other polymers, polyurethanes offer superior impact resistance, while offering excellent wear properties and elastic memory. This ultra-tough material is used in many biomedical applications such as in pacemaker leads, ventricular assist devices, catheters, stents and many other biomedical devices due to its good biocompatibility and resistance to chemical attack. Polyurethanes have outstanding resistance to oxygen, and many other general weather conditions, but more importantly is resistant to chemical attack in the body. Since there is little chemical breakdown of these polyurethanes in the human body, their excellent mechanical and biocompatibility characteristics are not altered in any way.

Polyurethanes possess complex chemical structures that typically comprise three monomer components: a diisocyanate, a polyol (which is an oligomeric macromonomer) and a chain extender. These three ‘degrees of freedom’ allow thousands of combinations and permutations, yielding polyurethanes of vastly different physiochemical and mechanical properties. Due to its unique composition, the structure of polyurethanes is quite different from other polymers. Polyurethane elastomers typically show a two-phase structure in which hard segment micro-domains are dispersed in a matrix of soft segments. The hard segment micro-domains are composed mainly of the diisocyanate and the chain extender, while the soft segment is composed of a sequence of polyol groups. For this reason, polyurethanes are often referred to as segmented block copolymers. The predominant linkage in the soft segment identifies the type of polyurethane for example, polyester-urethanes incorporate ester linkages, polyether-urethanes incorporate ether linkages, and polycarbonate-urethanes incorporate carbonate linkages.

The main classes of polyurethanes considered for chronic implantation are thermoplastic polyurethanes based on polycarbonate soft segments. They currently have the most history and the most extensive documentation on file with the Food and Drug Administration (FDA). One such PU which has been tested extensively is Bionate®.

2.6.6.5 Bionate®
Bionate® is a polycarbonate-urethane, which was developed by the Corvita Corporation (Miami, USA) and patented for biomedical use in 1992 as Corethane.
The Polymer Technology Group Incorporated acquired the licence to manufacture this in 1996. Studies have shown Bionate® to be the most biocompatible of the polyurethane materials considered as candidates for potential use in compliant bearings due to their proven stability. Bionate® is considerably more resistance to biodegradation than conventional polyether-urethanes. Oxidative stability is achieved through a replacement of susceptible ether groups with carbonate linkages adjacent to the hydrocarbon groups. This makes these polymers very attractive in applications in which oxidation is a potential mode of degradation.

The three components which make up Bionate® are:

- **Hard Segment-** MDI- 4,4’-Methyl bisphenyl diisocyanate or Methylene Diisocyanate
- **Soft Segment-** PHEC- Poly(1,6-hexyl 1,2-ethyl carbonate)
- **Chain Extender-** BDO- 1,4-Butanediol

Their chemical structures are shown in Figure 2.10.

![Chemical structures of three components which make up Bionate®](image)

**Figure 2.10:** Chemical structures of three components which make up Bionate®.

Bionate® polycarbonate-urethanes are supplied as free-flowing spherical pellets and can be used for conventional injection moulding, extrusion and compression moulding techniques. Varying the total hard segment content of Bionate® during synthesis can produce a variety of Bionate® polymers with a wide range of hardness, modulus, tensile strength properties and elongation. Evaluations of the tribological and mechanical properties of Bionate® (Shore hardness 80A and 75D) have shown them to be suitable in joint replacement [46, 120, 145-147]. For compliant bearings in this study, a two layered bearing is used. A soft grade Bionate® 80A is used for the top layer and is backed with a harder grade Bionate® 75D. In order to achieve this
two layer bearing material, bonding of the soft layer to hard layer is required. Components are manufactured by a two-part injection moulding process, designed to permit control over compliant layer thickness and surface finish. The first step involves the moulding of the harder Bionate® 75 backing and the second involves the over-moulding of the Bionate® 80A soft complaint layer onto the backing. The overmould joint bond is excellent. It is not clear what precisely causes the excellent adhesion between the two materials but it is possible than an interpenetrating network of the soft polyurethane into the hard polymer is formed [148].

REFERENCES


Chapter 3

Experimental

In order to evaluate the performance of materials for use in total joint replacements, a variety of tests and techniques were employed and are described below under the different subject areas.

3.1 Material Characterisation

3.1.1 Dynamic Mechanical Thermal Analysis (DMTA)

Dynamic mechanical thermal analysis (DMTA) is an important technique capable of providing considerable information on the position of transitions and the mechanical properties of polymers. DMTA measures the storage modulus (\(E'\)) and the loss modulus (\(E''\)) as a function of temperature. A sinusoidal mode of deformation is applied to the sample, as the temperature is scanned from well below the glass transition temperature to the point when the sample becomes too soft to test in a given apparatus. DMTA provides information on first and second order transitions (\(T_m\) and \(T_g\), respectively), the degree of phase separation, crystallinity and crosslinking of the polymer, and the mechanical properties such as the glassy state and the rubbery plateau modulus.

In DMTA experiments (Figure 3.1), the applied force and the resulting deformation vary sinusoidally with time, at a rate specified by the frequency (f) in cycles/sec, or \(\omega = 2\pi f\) in radians/sec. For idealised elastic behaviour, the resultant strain will alternate exactly in phase with the applied stress. A completely viscous material will have a strain lagging 90° (out of phase) behind the applied stress. When a sinusoidal stress is applied to a viscoelastic material it will behave neither as a perfectly elastic nor a perfectly viscous body while the resultant stain will lag behind the stress by some angle (\(\delta\)), where \(\delta < 90°\). The magnitude of the loss angle is dependent upon the amount of internal motion occurring (damping).

The stress (\(\sigma\)) and strain (\(\varepsilon\)) can be expressed as follows:

\[
\sigma = \sigma_0 \sin(\omega t + \delta)
\]

\[
\varepsilon = \varepsilon_0 \sin(\omega t)
\]
Where $\omega$ is the angular frequency and $\delta$ is the phase angle. Then:
\[ \sigma = \sigma_0 (\sin \omega t) \cos(\delta) + \sigma_0 \cos(\omega t) \sin(\delta) \]

The stress may be considered to consist of two components, one in-phase with the strain ($\sigma_0 \cos \delta$) and the other $90^\circ$ out-of-phase ($\sigma_0 \sin \delta$). When these are divided by the strain, we can separate the modulus into an in-phase (real) and out-of-phase (imaginary) components. The corresponding relationships are:
\[ \sigma = \varepsilon_0 E' \sin(\omega t) + \varepsilon_0 E'' \cos(\omega t) \]

\[ E' = \left( \frac{\sigma_0}{\varepsilon_0} \right) \cos(\delta), \quad E'' = \left( \frac{\sigma_0}{\varepsilon_0} \right) \sin(\delta) \]

Where $E'$ is the real part of the modulus, and $E''$ is the imaginary part. Alternatively:

\[ E' = \frac{\text{Amplitude of the in phase component}}{\text{Strain amplitude}}, \quad E'' = \frac{\text{Amplitude of the out of phase component}}{\text{Strain amplitude}} \]

Complex representation of the modulus can be expressed as:
\[ \sigma = \sigma_0 \exp(it) \]
\[ \varepsilon = \varepsilon \exp(i(\omega t + \delta)) \]
\[ \frac{\sigma}{\varepsilon} = E^* = \text{Dynamic Young's Modulus} = E' + iE \]

The phase angle ($\delta$) is defined as:
\[ \tan \delta = \frac{E''}{E'} = \frac{\text{Loss Modulus}}{\text{Storage Modulus}} \]

The real components of the modulus $E'$ is termed the storage modulus because it is related to the storage of energy in potential form for subsequent release by periodic deformation. The imaginary part of the modulus $E''$ is termed the loss modulus and is associated with the dissipation of energy, primarily as heat, upon deformation. The loss tangent, $\tan \delta$, is described as the internal friction or damping. It corresponds to the ratio of energy dissipated per cycle to the maximum potential energy stored during the cycle. The separation of the two components describing two independent processes within the sample, elasticity (energy storage) and viscosity (energy dissipation), is a fundamental feature that yields sensitivity to both macroscopic and molecular relaxation processes.
Figure 3.1: Schematic of the DMTA.

Typical events discernible from a DMTA thermogram are displayed in Figure 3.2. From a low temperature, with constant heating rate, resonant induced localised motion of pendant groups can occur and manifests itself in small relative peaks in the damping curve. Correspondingly, there is a slight decrease in slope of the storage modulus (E’). Structural permutations offer additional possibilities that other side groups may vibrate, with local damping maxima and modulus variations. Frequently these are denoted as the γ and β transitions, respectively upon heating. Further heating effects an order of magnitude reduction in the storage modulus.

In the region of the inflexion point where the storage modulus decreases, the damping curve displays a prominent maximum, associated with Tg of the system. Frequently, this is termed the α transition. Additional melting of ordered or partially ordered phases can result in the storage modulus, with corresponding upturns in the damping behaviour. From this event onwards, the extra mobility conferred to the system results in an asymptotic decline in the storage modulus, effectively approaching zero with the advent of Tm. In this state, relative damping increases and reflects the increasing propensity towards viscous behaviour. Accordingly, dynamic mechanical thermal analysis was employed to determine the relative viscoelastic response of the materials over a wide temperature range. The morphology and
important second order events were resolved with this technique, enabling correlation with molecular processes.

**Figure 3.2**: Idealised DMTA behaviour for a viscoelastic material, in tension, for a fixed frequency.

A Polymer Laboratories mark II DMTA (189) with a torsion head was used to measure the torsional storage and loss moduli; $G'$, $G''$ and the torsional damping, tan $\delta$, of the material as a function of temperature. In this instrument the upper clamp is driven and the lower clamp is rigidly fixed, all enclosed in a temperature programmable environment chamber. The upper clamp is fixed to a torsion bar of adjustable free length, enabling the selection of the system’s natural frequency. Consequently materials of diverse moduli can be analysed.

Within this arrangement sample materials can be subjected to a small angle oscillation, driven by means of a DC coil. Depending upon material stiffness, the frequency of oscillation is selected between 0.01 and 100 Hz, with the ability to multiplex several frequencies. Additionally, longitudinal tensile or compressive loading can be superimposed during thermal scans.

In real time the resultant sample motion is monitored and resolved for moduli and damping calculations. Sub-ambient temperatures were achieved by circulating the liquid nitrogen through a cooling jacket. Due to instrument limitation, the gaseous environment of DMTA chamber was uncontrolled in that a nitrogen purge could not be used. Consequently atmospheric moisture was able to condense on sample
substrates upon heating from sub-ambient conditions. However given the relative nature of this technique, all samples were subjected to the same procedure.

### 3.1.2 Surface Profilometry

Surface topography plays a significant role in tribology. The accurate measurement of surface roughness parameters is used in determining the theoretical lubrication regimes acting within joints. Recorded values of surface roughness parameters before and after testing are also utilised in the illustration of friction and wear mechanisms during *in vitro* testing.

The Zygo NewView 100 is a general purpose, three-dimensional, imaging surface structure analyser; it provides both imaged surface details of test parts and accurate measurements to characterise these details. The NewView uses scanning white light interferometry to image and measure test part surfaces and provide surface structure without contacting the surface. Light from the microscope divides; one portion reflects from the test surface and another portion reflects from an internal, high quality reference surface. Both portions are then directed onto a solid-state camera. Interference between the two light wavefronts results in an image of light and dark bands, called fringes that indicate the surface structure of the part being tested. The test part is scanned by vertically moving the object with a piezoelectric transducer (PZT). As the objective scans, a video system captures intensities at each camera pixel. These intensities are converted into images by MetroPro software. In addition, surface images are displayed on a video monitor, which magnifies the objective image 20 times. Measurements are three-dimensional. Vertical measurements, normal to the surface, are performed interferometrically. Lateral measurements, in the plane of the surface, are performed by calculating the pixel size from the field of view of the objective in use. The NewView analyses and quantifies the surface topography of parts. Results are displaced on a colour display as solid images, plots, and numeric representations of the surface. The most frequently quoted roughness parameters are as follows:

- **Roughness average** $R_a$ is the arithmetic average of the absolute values of the surface height deviations from the best fitting plane.

$$R_a = \frac{1}{L} \int_0^L |Z(x)| \, dx$$
- Root mean square (RMS) roughness $R_q$ is the root mean square average of the roughness profile ordinates.

$$R_q = \sqrt{\frac{1}{L} \int_0^L Z^2(x) \, dx}$$

- $R_{sk}$, the skewness: is the “second moment” of the height distribution and is a measure of the skewness or symmetry of the surface.

$$R_{sk} = \frac{1}{M N \bar{S}_q^3} \sum_{j=1}^M \left( \sum_{i=1}^N \eta^3(x_i, y_j) \right)$$

$M$: is a number of points of per profile (scan line)

$N$: is the number of profiles

$\eta$: amplitude at $(x, y)$ point

A surface with predominately deep valleys will tend to have a negative skew, whereas a surface comprised predominately of peaks will have a positive skew.

- $R_p$, the maximum peak height: is the height of the highest point.

- $R_v$, the maximum valley: is the depth of the lowest point.

- $R_t$, the maximum height of the surface: is found from $R_p - R_v$.

### 3.2 Mechanical

#### 3.2.1 Creep Testing

Polymer materials exhibit time dependent behaviour, which is often referred to as viscoelasticity. Creep is time dependent deformation under load and is a major cause of failure in polymer products. In order to design parts that are subject to long-term loading, designers must use creep data in an effort to ensure that parts do not rupture, yield, craze, or simply deform excessively over their service life. The creep properties of polymers can be measured in experiments which subject the materials to
applied loads and measure the degree of deflection with time. This is static creep, whereas the samples in service experience a dynamic load.

Creep tests were carried out using a purpose built apparatus consisting of three creep stations. The creep stations were manufactured by ELE International (UK) and were originally built for consolidating soil samples but were adapted to provide an accurate method of creep assessment. One creep station is schematically illustrated in Figure 3.3. It features a loading beam (1) having three alternative points (2) for a weight hanger (3). These points provide lever arm ratios of 9:1, 10:1 and 11:1. Before sample set-up the load beam was raised by means of the supporting jack screw (4) until there was a gap of approximately 5mm between the upper surface of the beam and the underside of the slot in the frame (5). The sample discs were placed between two stainless steel 30mm diameter discs and positioned under the loading yoke (6) (Figure 3.4) on the machine base (7). To test the sample in a lubricant, a stainless steel immersion bath was placed on the machine base and the sample positioned in the bath rather than directly on the machine base. Using a spirit level the loading yoke was carefully aligned to the vertical and the locking nut (8) was tightened until it engaged closely in the recess on the top stainless steel disc. It was shown, using an S-type load cell, that a minimal pre-load (<50N) was placed on the samples by tightening the locking nut. Subsequently it was shown using a 6kN S-type load cell that the loads employed gave the required force to achieve the range of contact stresses to be used. A dial gauge (9), with an accuracy of 0.01mm, was attached to the arm (10) on the gauge pillar (11). The arm could travel vertically on the gauge pillar and was fixed in position using a locking screw (12) so that the height of the dial gauge is zero. The load was placed on the weight hanger and was fully carried by the support jack. In this way the desired temperature could be achieved first before loading the sample discs by means of carefully loosening the support jack. To achieve a temperature of 37°C, the three creep stations were enclosed in a Perspex heat chamber and exposed to 7 heat lamps attached to the inside of the chamber. The temperature of the inside of the chamber or lubricant was measured using a K-type thermocouple wire. The temperature was fed back to a controller and the temperature was adjusted to the set-point i.e. 37°C. Once testing began, the load was applied and the dial gauge readings were taken at various intervals for periods up to 400 hours. This time was far less than that proposed in the international standards for creep testing (1000Hrs); instead creep was carried out until the creep displacement curve
had levelled off. It was believed that creep testing up to this point provided an adequate indication of a “worst case scenario” creep of the material \textit{in vivo}. Analysis of creep data is explained in detail in Chapter 4.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig3.3}
\caption{Schematic of the creep testing apparatus.}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig3.4}
\caption{Schematic of the sample disc setup.}
\end{figure}

\[ \text{Beam Ratio} = \frac{A+B}{A} \]
\[ \text{Where } A = 2'' \pm 0.002'' \]
\[ (9:1) = 16'' \pm 0.002'' \]
\[ (10:1) = 18'' \pm 0.002'' \]
\[ (11:1) = 20'' \pm 0.002'' \]
3.3 Tribological

3.3.1 Friction Testing

3.1.1 Friction Simulator

Friction of various bearing combinations was examined using a TE89 friction simulator manufactured by Phoenix, Tribology, Newbury, UK. The friction simulator can be used for knee or hip joints and works in a similar way to the Durham Hip Function Simulator and Durham Friction Simulator II. It comprised a fixed, bench-mounted, main frame and a moving load frame into which the components if the joint are mounted (Figure 3.5). It consisted of a servo-hydraulic mechanism controlled by a personal computer via a microprocessor to dynamically load the knee joints as they oscillate through an adjustable pre-set angle in the anatomical position. Friction testing was carried out at room temperature.

The upper specimens were mounted onto the loadbeam which rotated about the joint centre. The simulator subjected the hip and knee joints to a simple harmonic oscillatory motion with a stroke of ± 32.5° and 25° respectively in the flexion/extension plane, with a frequency of 0.8Hz. This motion was applied to the joints by a scotch yoke mechanism connected to a motor to simulate a walking cycle.

The lower specimens were mounted in a sample holder inside a trunnion bath which allowed the samples to be fully covered with lubricant at all times. The trunnion bath was placed in the friction carriage. For the hip bearing, the acetabular carriage was supported by externally pressurized bearings which provided a self-centering mechanism. For the knee bearing, a screw adjustment at the front of the unit allowed the user to align the specimens accurately and then hold the joint in a fixed horizontal position. The trunnion bath pivots in low friction contra-rotating bearings about the centre-line of rotation of the femoral component. The carriage had very low friction, which allowed it to rotate solely due to frictional torque generated at the joint surfaces. The bath was restrained from rotation by a calibrated Kistler piezoelectric force transducer that allowed the frictional torque of the joint to be measured. The transducer was mounted vertically to de-couple the friction measurement from any horizontal movement of the assembly caused by misalignment, which could swamp the friction signal.
Using a linear solenoid and a 9:1 lever ratio, dynamic loading cycles of maximum and minimum loads 2000N and 100N respectively were applied. The load was measured with a piezo-electric load washer, and controlled using a thyristor drive and feedback from a ‘sample and hold’ facility in the controller. An initial run-in of 400 cycles was carried out on each joint to allow conditions to stabilize before taking any friction measurements. The friction was measured throughout the loading cycle. However, all the average values were calculated from within the high load phase of the cycle in which the frictional torques generated were the highest. To obtain accurate measurements of friction, it was necessary to have all the axes of rotation aligned, i.e. that of the upper and lower components, loadbeam and trunnion bath. The joint components were aligned and set-up so that the centre of rotation of the joint

Figure 3.5: Plint Friction Simulator.
coincided with the centre of rotation of the friction simulator. Any horizontal misalignment between the rotational axes of the lower components and trunnion bath which could be eliminated in situ, and hence would lead to an additional residual eccentric torque, was allowed for by performing two runs on each joint. One run in the forward direction with the load applied as the upper component oscillated forward and one in the reverse direction with the load applied as the upper component oscillated backwards. From these two runs, the true frictional torque, \( T \), was calculated. For perfect alignment, the oscillating motion of the femoral component was expected to generate a frictional torque, which was symmetrical around zero.

To obtain accurate measurements of friction, it was necessary to have all the axes of rotation aligned. The head was aligned by fitting stems of the correct height; the height was adjusted by raising or lowering the head within the jig prior to test. Any horizontal misalignment which could not be eliminated in situ, and hence would lead to an additional residual torque were accommodated by performing two runs on each joint, one run in the forward direction with the load applied whilst the upper component was moving forwards in the cycle and one in the reverse direction with the load applied whilst the upper component was moving backwards in the cycle. From these two runs the true frictional torque, \( T \), was calculated.

\[
T = \frac{|T_n| + |T_i|}{2}
\]

Where \( T_n \) is the frictional torque produced in the forward run (normal run) and \( T_i \) is the frictional torque produced in the reverse direction (inverse run). This frictional torque is then converted to friction factor (\( f \)) using the equation below.

\[
f = \frac{T}{rL}
\]

Where \( T \) is the frictional torque between the bearing surfaces, \( r \) is the radius of the femoral component and \( L \) is the axial load applied across the joint. Friction factor is similar to the coefficient of friction but varies slightly depending on the elastic contact of the joint. The frictional torque, load, and angular displacement are measured throughout the loading cycle and an average friction factor is taken from the high load, high velocity stage of the loading cycle (equivalent to the stance phase of walking). Since the friction factor is numerically of the same order as the average
kinetic coefficient of friction of the joint, Dowson [1] proposed that specific ranges of coefficients of friction could be used to assign the lubrication regime in which TJRs operate (Table 3.1).

Table 3.1: Broad ranges of coefficients of friction (μ) representative of various modes of lubrication in THRs.

<table>
<thead>
<tr>
<th>Mode of Lubrication</th>
<th>Representative μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry</td>
<td>0.1-2.0</td>
</tr>
<tr>
<td>Boundary</td>
<td>0.07-0.15</td>
</tr>
<tr>
<td>Mixed</td>
<td>0.01-0.1</td>
</tr>
<tr>
<td>Fluid film</td>
<td>0.001-0.02</td>
</tr>
</tbody>
</table>

3.1.1.2 Stribeck Analysis

Stribeck analysis was used to give an indication of the mode of lubrication, in which the friction factor was plotted against Sommerfeld number, \( z \), which is defined as:

\[
z = \frac{\eta u r}{L}
\]

Here \( \eta \) is the viscosity of the lubricant and \( u \) is the entraining velocity.

Changing the viscosity of the lubricant varies the Sommerfeld number for a given joint. A schematic representation of a Stribeck curve is given in Figure 3.6. If the friction factor is constant then boundary lubrication (BL) dominates. A decrease in the friction factor with an increase in the friction factor with an increase in Sommerfeld number (lubricant viscosity) is indicative of a mixed lubrication (ML) regime. An increase in the Sommerfeld number is indicative of fluid film lubrication (FFL) whereby asperities of the opposing bearing surfaces are separated by a thin fluid film. The “ideal” Stribeck plot for conventional TJRs, illustrating their operation in a mixed lubrication mode would be expected to display a decreasing trend in friction factor with increasing Sommerfeld number.
3.3.2 Wear Testing

3.3.2 The Shoulder Wear Simulator at University of Limerick

The shoulder simulator was manufactured in a joint collaboration between the University of Limerick and University College Dublin. It was originally built by Shine but has since been extensively rebuilt. A schematic of its key components are shown in Figure 3.7. The primary aim is to reproduce clinically significant wear mechanisms and debris. Validation of the simulator is based on repeatability and accuracy of the loading and motion profiles and the comparison of wear mechanisms with clinical findings.

3.3.2.1 Motion

The simulator has an upright swinging cradle simulating Abduction-Adduction (AA) and a drive shaft mounted centrally on the cradle to simulate the Internal-External Rotation (IER). The IER shaft is coupled in a 2:1 ratio to the cradle motion through a bevel gear box and pulley system. A servomotor with a 100:1 gearbox drives the cradle and the maximum ranges of motion are 20-120° AA and 10-60° IER. An optimal running frequency of 0.8 Hz as well as pre-programmed acceleration and deceleration are used to minimise vibration. The glenoid holder is free to translate in axes, allowing the component to engage the rotating head. This self-centering ability not only allows for minute misalignment, but also allows the line of action of the resultant load to shift depending on the geometries of the interacting components.

Figure 3.6: Strubeck plot.
3.3.2.2 Loading

While the motion is carried out through the humeral component, forces are applied to the glenoid holder using two pneumatic actuators, supplied through programmable valves. Each actuator is capable of applying forces up to 1kN. Two axes of loading are used: medial-lateral (ML) and superior-inferior (SI) loading. Simulating superiorly directed loading is important because it is characteristic of the problematic rheumatoid patient population. All of the activities of daily living examined by Anglin et al. [2] also resulted in superior loads. Observations on retrieved glenoid components consistently illustrate that the humeral head bores into the glenoid creating a new conforming articular facet centred superiorly [3]. Given that the intention is to maintain a constant load with respect to the glenoid, the line of action of the resultant force in the simulator is linked to the motion.

3.3.2.3 Lubrication

A temperature controlled water bath is used to heat a stainless steel beaker of bovine serum. A peristaltic pump allows the lubricant to be continuously circulated through the test chamber, where the temperature is maintained at 37°C +/- 1°C. The space between the humeral and glenoid components is sealed using a rubber gaiter, which flexes as the cradle cycles (Figure 3.8). This sealed enclosure isolates the test...
specimen, preventing third body contamination from the test machine and the atmosphere and also helps to prevent evaporation. The test chamber is filled from the bottom displacing any air through the upper port. The chamber holds approximately 200ml of lubricant, ensuring that the contact surfaces are completely immersed in the fluid test medium.

![Figure 3.8: Lubrication system.](image)

### 3.3.2.4 Component Fixation and Alignment

A complete humeral prosthesis, head and stem, is fixed into a humeral holder using PMMA bone cement. An alignment fixture is used to ensure that the humeral head is positioned at the point of cross section of the two rotational axes of the simulator, throughout the test. Once it has set, the cement is covered with a layer of silicon sealant to prevent any particles from entering the joint space. As the humeral head is mounted on an actual stem, the stiffness of the prostheses *in vivo* is closely simulated.

The glenoid components are mounted into prepared cylindrical polyurethane foam blocks. These are then press fitted into the glenoid holder and sealed with silicone to be water tight. The properties of the foam, which conforms to ASTM F1839 [4], are similar to those of cancellous bone. Standard implanting procedure [5] is used where a centering hole is first drilled into the foam, the surface is then reamed to fit the component backing and slots or holes are drilled as required for pegs or keels. The component is placed ensuring superiorly-inferiorly (SI) and anteriorly-posteriorly (AP) alignment. As mentioned earlier, the ability of the glenoid holder to slide on three mutually perpendicular slides not only allows the glenoid locate itself against
the humeral component, but compensates for small misalignments of the components. Easy and accurate mounting of the glenoid holder into the simulator allows removal of the component for wear analysis.

3.3.2.5 Control and Feedback

The machine is controlled by custom-made software programmed under Lab View FieldPoint real time. The simulator is equipped with all the necessary sensor controls to guarantee continuous monitoring of the wear simulator. Data retrieved includes the two applied forces and the glenoid displacements on three axes. A cycle counter and temperature is incorporated. Safety cut-out functions have also been incorporated for low lubricant level and opening of the Perspex safety cover.

REFERENCES

Chapter 4

Creep Measurement and Dynamic Mechanical Thermal Analysis of Polyurethane Materials for use in Compliant Layer Prostheses

Abstract
Based on the research previously mentioned [1-8], Bionate® polycarbonate-urethanes of Shore hardness 80A and 75D have been found to be the most suitable materials for use in compliant layer prostheses. In order to carry out a complete tribological evaluation of this joint type, key performance characteristics such as material’s response to creep, strain and temperature were assessed.

Dynamic mechanical thermal analysis (DMTA) highlighted the sensitivity of the modulus of Bionate® materials to temperature and the need for accurate temperature control during in vitro testing. In particular for Bionate® 75D it revealed the close proximity of its glass transition to 37°C. The structural difference between the two polymers was clearly evident by comparing their thermograms. Bionate® 80A, which has a lower hard segment content, displayed lower modulus and glass transition temperature than 75D. The plasticisation ability of Bionate® materials was also demonstrated as reductions in the moduli and damping behaviour for hydrated samples were observed. This behaviour was attributed to the actions of plasticisation by the absorbed solutions.

The compressive creep behaviour of Bionate® 80A and 75D was studied under relevant in vitro conditions. The non-linear viscoelastic behaviour of these materials was demonstrated and creep deformation was shown to increase with temperature and lubrication. Bionate® 80A was notably less creep resistant than 75D and both materials exhibited permanent deformation the degree of which was far greater in 75D.

Overall, the data presented here provide a comprehensive material characterisation of Bionate® 80A and 75D and highlights the suitability of these materials for orthopaedic applications. The creep data generated should essentially allow the development of improved designs in compliant layer technology.
4.1 Introduction

The objective of this work is to give a comprehensive material characterisation of polyurethanes, Bionate® 80A and 75D, relevant to orthopaedic device applications. Polyurethanes comprise three reactive components: (1) a diisocyanate, (2) a soft segment, which is an oligomeric macromonomer and (3) a chain extender. They typically show a two-phase structure in which hard segment microdomains are dispersed in a matrix of soft segments. The hard segment microdomains mainly comprise the diisocyanate and the chain extender [3]. The predominant linkage in the soft segment identifies the type of polyurethane. Bionate® is a polycarbonate-urethane as it incorporates carbonate linkages. It is commercially available in a range of different hardness values, as measured using a Shore Durometer procedure. Its hardness and stiffness is controlled through variation in the ratio of hard and soft segments in the polymer chain. The components of Bionate® are shown in Table 4.1.

Table 4.1: Chemical composition of Bionate®.

<table>
<thead>
<tr>
<th>Polyurethane</th>
<th>Type</th>
<th>Aromatic/Aliphatic</th>
<th>Soft Segment</th>
<th>Hard Segment</th>
<th>Chain Extender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bionate®</td>
<td>Polycarbonate-urethane</td>
<td>Aromatic</td>
<td>PHEC</td>
<td>MDI</td>
<td>BDO</td>
</tr>
</tbody>
</table>

Abbreviations:
PHEC- Poly(1,6-hexyl 1,2-ethyl carbonate)
MDI- 4,4'-Methyl bisphenyl diisocyanate or Methylene Diisocyanate
BDO- 1,4-Butanediol

Designs have now been developed [8, 9] for joint systems using these materials and extensive simulator and animal trials carried out [3, 4, 10]. Specifically Bionate® 75D, a harder material, is used to provide structural support to a softer and compliant bearing face layer of 80A. Components are made by a two-step injection moulding process in which the softer layer is over-moulded onto the harder backing to give a strong fusion bond between the two polymers. For such property critical applications, response of these materials to strain and heat is clearly of interest and is one of the main concerns of this study. The polymers are very hygroscopic [6] and will have to withstand heat and shear conditions throughout their lifespan in vivo. The first part of this study is therefore concerned with Dynamic Mechanical Thermal Analysis (DMTA) of Bionate® 80 and 75D. This test method will allow characterisation of
these materials in terms of their dynamic modulus, elasticity, viscosity, damping behaviour, and glass transition temperature, and the change of these with strain, strain rate, temperature, and oscillatory frequency.

A further concern with these materials is that under load they are easily deformable and may be susceptible to large amounts of creep, which may in turn adversely affect the tribological performance of the implants. The second part of this study therefore, assesses the compressive creep behaviour of Bionate® 80A and 75D at various stress levels, temperatures and environmental conditions that these materials are subjected to during service.

Creep is time dependent deformation under load and is a major cause of failure in polymer products. The creep properties of plastics can be measured in experiments which subject the material to applied loads and measure the degree of deflection with time. The various ways of presenting the resulting data and the inter-relationships are shown below.

![Figure 4.1: Creep curves.](image)

The creep curves shown on the left represent the increase in strain which occurs with time when the material is loaded to various stress levels A to D. Log time is used to allow compression of time periods from seconds to years onto one graph. This graph provides the basic information how the materials respond to stress over a period of time. The right hand plot is an isochronous stress-strain curve, where the stress needed to induce a particular level of strain in a specified time is shown. Each of the
curves is for a different time with $t_0$ being the isochronous response and $t_1, t_2$ etc. being curves for progressively longer times.

The compressive creep behaviour of compliant layer polyurethane hip and knee replacements has been assessed previously. Auger et al. [11] used a Dartec servo-hydraulic apparatus to apply a sinusoidal compressive load at a rate of 1Hz to flat compliant layer tibial inserts which were fully flooded in deionised water. The maximum load used was 2kN and the minimum load was 0kN. The creep was measured at regular intervals over 2.6 million loading cycles (~30 days) by measuring the maximum depression in the compliant layer using a Talycontour. They found that creep stabilised after approximately 1 million cycles of compressive loading with a maximum creep of approximately 0.9mm. Smith et al. [12] assessed the creep in polyurethane acetabular cups. The cups were submerged in distilled water, oriented anatomically inverted, and loaded under a constant 3kN force for up to 96 hours on a Hounsfield testing machine. The creep was measured as the vertical displacement of the femoral component and was recorded periodically throughout the creep tests. They showed that the amount of creep was relatively small at ambient temperature, ~0.3 mm, and that twice as much creep occurred at 37°C.

However these methods used by Auger et al. and Smith et al. are not true compressive creep tests as detailed by the relevant standards. Both studies take no account of the creep of the polyurethane at different stress levels and therefore, ignore the non-linear nature of viscoelasticity in plastics. In particular, Auger’s results take no account of recovery of the polyurethane in the period between removal of load and measurement of the depression. More recently, Flannery [13] carried out compressive creep tests on compliant layer polyurethane constructs under different stresses and in vitro conditions. To replicate the thickness of standard 10mm thick compliant layer tibial inserts, the polyurethane constructs consisted of three disks of Bionate® 75D bonded to one disk of 80A. He showed that the creep of polyurethane increased dramatically with increasing stress and also with temperature and lubrication. At the contact stress experienced by the compliant layer joint during wear testing, the creep was minimal and that over the test period creep rupture of the material did not occur even when subjected to a contact stress of 10.2MPa. In that same study, Flannery also compared the creep of polyurethanes with UHMWPE components and found much greater creep of the polyurethane using similar contact stresses. In this study, the compressive creep characteristics of Bionate® 80A independent of 75D, and vice
versa, will be studied. The effects of lubrication and varying loads and temperature will be examined.

4.2 Materials and Methods

4.2.1 DMTA

Samples of rectangular geometry of approximate dimensions: 15(w) * 2.5(T) * 40(l) were cut from irradiated injection moulded plaques of Bionate® 80A and 75D and were conditioned for at least 4 weeks prior to testing as follows:

- Immersion in distilled water at 37°C,
- Dried in vacuum oven at 60°,
- Immersion in buffer solution, pH = 4.01 (acid),
- Immersion in buffer solution, pH = 10.01 (base).

A polymer laboratories mark II DMTA in torsion bar mode was used. In this instrument the upper clamp is driven and the lower clamp is rigidly fixed. The test chamber is an enclosed, temperature programmable environment where sub-ambient temperatures are achieved by circulating liquid nitrogen through a cooling jacket. The instrument was operated in constant displacement mode with multiplexed frequencies of 0.1, 1 and 10 Hz. Thermal scans were conducted over temperature range -60°C to 80°C, and -60°C to 160°C, for Bionate® 80A and 75D respectively, at a heating rate dT/dt = 2°C min⁻¹.

4.2.2 Creep

Discs of 25mm diameter were punched from irradiated injection moulded plaques, approximately 2.5mm and 2.3mm thick, of Bionate® 80A and 75D respectively. Four discs of Bionate® 80A were bonded together using a small amount of tetra hydrofuran in order to replicate the thickness of a standard tibial insert (10mm) and similarly, four disks of Bionate® 75D were bonded together. The construct is illustrated in Figure 4.2.

Creep of the samples was assessed in the same method as Flannery, using the creep apparatus described earlier in the experimental chapter. The samples were assessed at ambient temperature and at 37°C, and also when fully flooded with 25% bovine calf serum (BCS) at 37°C to examine the effects of “in vivo” lubrication conditions on the creep.
Figure 4.2: The polyurethane construct set-up.

The knee joint is subjected to very high compressive stresses during most activities of daily living. Flannery [13] estimated the actual contact stresses experienced in vivo for congruent and flat polyurethane total knee replacements to be 1.29MPa and 2.5MPa respectively, using Hertzian contact theory [14]. Contact stresses of 1.3MPa, 4.5MPa and 7.2MPa are all within and above these ranges and are therefore suitable to use for the creep experiments in this study.

4.2.2.1 Creep Calculations

The % creep and creep strain of the materials were calculated from the deformation according to the following equations and the relevant creep curves plotted. The compressive creep strain ($\varepsilon_t$) is given by the equation:

$$\varepsilon_t = \frac{(\Delta L)_t}{L_0} = \frac{(L_0 - L_t)}{L_0}$$

Where $(\Delta L)_t$ is the creep deformation at time $t$, given by subtracting the sample thickness at time $t$ from the original thickness ($L_0$) and the compressive creep strain is calculated by dividing the deformation by the original sample thickness. The total creep is given by the change in thickness of the specimen as a result of compression over the test period beginning at time zero when the load is first applied. There the % creep is given by the equation:

$$\text{% Creep} = \frac{\text{Total Creep}}{L_0} \times 100$$
Where the % creep is calculated by dividing the total creep measured by the original thickness ($L_o$). The % creep is strictly a percentage calculation of the total creep of the samples in compression. It does not take into account any elastic deformation of the samples following removal of the compressive load.

The recovery of the sample discs was determined by measuring the thickness of the disks at nine points using a micrometer. The thickness was measured immediately after the load was removed and then at various time intervals. The samples were kept at the same conditions at which they were tested for the first 24 hours while their recovery was measured and kept in dry conditions at room temperature thereafter. The % creep recovery was calculated using the equation:

$$\% \text{ Creep Recovery} = \frac{(L_t - L_f)}{\text{Total Creep Deformation}} \times 100$$

Where $L_t$ is the sample thickness at a time $t$ after removing the load, $L_f$ is the final thickness after the creep testing ($L_f = L_o - \text{Total Creep Deformation}$). The residual deformation or permanent set remaining after the sample were compressed was taken as the difference between the final measured creep recovery and the original sample thickness as given in the equation:

$$\% \text{ Permanent Set} = \frac{(L_o - L_f)}{\text{Total Creep Deformation}} \times 100$$

Where $L_f$ is the final sample thickness measured when examining creep recovery.

### 4.3 Results and Discussion

#### 4.3.1 DMTA

Dynamical mechanical behaviour of the two polycarbonate-urethanes, Bionate® 80A and 75 D are shown in Figures 4.3 and 4.4. Excellent repeatability of the technique was shown, when multiple samples of the same material were tested. As discernible, the resultant thermograms may be considered as superimposed, as demonstrated in Figures 4.3 and 4.4.
Figure 4.3: Bionate® 80A, 3 samples (A, B, C) conditioned in distilled water at 37°C (1 Hz).

Figure 4.4: Bionate® 75D, 3 samples (A, B, C) conditioned in distilled water at 37°C (1 Hz).

Figures 4.5 and 4.6 show the DMTA profiles of Bionate® 80A and 75D tested at three different frequencies (10, 1 and 0.1 Hz). The profiles have similar shapes. The
storage modulus transformed from glassy (plateau region) at low temperatures to elastic and then rubbery as the polymer passes its glass transition temperature. Damping is expressed as tan δ and is related to viscoelastic properties. The glass transition temperature was identified by a drop in storage modulus (G’) and prominent peks in the tan δ. It was assumed that, as the hard segment diisocyanate content is increased, the modulus and the glass transition temperature also increased. Bionate® 75D, (which has higher hard segment content than 80A) displayed significantly higher storage modulus values and glass transition temperatures than 80A. The glass transition temperature of Bionate® 80A was approximately 67°C lower than of 75D. In addition, Bionate 80A had a broader drop in G’ and broader tan δ peaks as compared to 75D. The results are tabulated in Table 4.2. They are comparable with Geary et al. [10] who obtained glass transition temperatures of 17°C and 76°C for Bionate® 80A and 75D respectively, at a frequency of 5Hz. Quigley [5] presented similar results for Bionate 95A.

![Bionate® 80A conditioned in distilled water at 37°C](image)

**Figure 4.5:** Bionate® 80A, Conditioned in distilled water at 37°C (10, 1, 0.1 Hz).
Additional melting of ordered or partially ordered phases can result in further slope changes in the storage modulus, with corresponding upturns in the damping behaviour. However, there was no evidence of gross-phase separation of the hard and soft segments as two transitions were not exhibited. It is believed that phase separation is favoured by a higher number and size of copolymer’s blocks. For example, styrene-butadiene-styrene block copolymer readily displays phase separation and forms very regular structures. Large block lengths of styrene and butadiene, and their incompatible solubility parameters assist phase separation. In the aforementioned study done by Geary et al. [10] they too noted the damping curves did not show any secondary peaks evident of the 2-phase behaviour that would be
expected if there was significant phase separation of hard and soft segments. It is postulated, however, that micro-phase separation does occur and evidence of this has been demonstrated by the presence of a two-phase structure using electron microscopy [15, 16] and also in a study by Hsu et al. [17] who demonstrated that MDI-based polycarbonate-urethanes of four different soft segment contents, exhibited various degrees of micro-phase separation based on the rule of glass transition temperature values whereby phase mixing brings glass transition temperature up (i.e. micro-phase separation increased with increasing content of soft segment).

As the mechanical frequency was increased (0.1 < 1 < 10 Hz) the position of the glass-rubber transition moved to a higher temperature since the polymer chains needed more energy, i.e. the sample needed to be hotter to respond to the shorter timescale stresses imposed at higher frequencies. Thus higher frequency vibration or using a faster heating rate will shift transitions to higher temperatures as evident in Table 4.2. It was also noted that the glass transition temperature was broadened over a wider spread of temperature at higher frequencies than at lower frequencies.

Figures 4.7 and 4.8 show the combined DMTA profiles of Bionate® 80A and 75D respectively, and Tables 4.3 and 4.4 give the glass transition temperatures and storage modulus values at 37°C, after various conditionings. There was a significant increase in the modulus and glass transition temperature of the sample dried in the vacuum oven prior to testing compared to the sample that was immersed in distilled water. This depression of the glass transition temperature and modulus by water illustrates the material’s ability to be plasticised. Plasticisation is known to cause a broadening of the glass transition as well as a reduction in temperature. Samples were stored in buffer solutions with pH values of 4 and 10, to investigate their effect if any, on mechanical properties. It is evident from the thermograms that there was no discernible difference between the samples stored in an acidic or basic solution. The results however show similarities to the sample that was immersed in distilled water, and this was attributed to the actions of plasticisation by the absorbed buffer solution. Depression of modulus and glass transition temperature caused by plasticisers has been explained in terms of increased free volume, in which the contribution of the various constituents of the system is in proportion to their free volume [18]. In the study by Quigley [5] his data was related to hydrated samples as his DMTA runs were performed on samples immediately after their removal from solution. Consequently he reported reductions in the moduli and damping behaviour.
Figure 4.7: Bionate® 80A, combination of conditions (1 Hz).

Figure 4.8: Bionate® 75D, combination of conditions (1 Hz).
Table 4.3: Glass transition temperatures for Bionate® 80A and 75D (1Hz), under various conditions.

<table>
<thead>
<tr>
<th></th>
<th>Immersed in distilled water</th>
<th>pH=4.01</th>
<th>pH=10.01</th>
<th>Dried in vacuum oven</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bionate® 80A</td>
<td>5</td>
<td>5.2</td>
<td>5.6</td>
<td>7.6</td>
</tr>
<tr>
<td>Bionate® 75D</td>
<td>76</td>
<td>62</td>
<td>67.5</td>
<td>81.6</td>
</tr>
</tbody>
</table>

Table 4.4: Storage modulus at 37°C values for Bionate 80A® and 75D (1Hz), under various conditions.

<table>
<thead>
<tr>
<th></th>
<th>Immersed in distilled water</th>
<th>pH=4.01</th>
<th>pH=10.01</th>
<th>Dried in vacuum oven</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bionate® 80A</td>
<td>18</td>
<td>13</td>
<td>16</td>
<td>19</td>
</tr>
<tr>
<td>Bionate® 75D</td>
<td>616</td>
<td>541</td>
<td>380</td>
<td>840</td>
</tr>
</tbody>
</table>

A cause for concern is the close proximity of the glass transition temperature to the operating temperature of 37°C. This means that with both materials, mechanical properties are changing quite quickly with temperature and this was most notable with Bionate® 75D (rapid drop in modulus in and around this temperature). However frictional heating (breakdown of the fluid film lubrication) of Bionate® 75D is not likely and may be more significant with 80A which is intended to be used as the bearing face material. The sensitivity of the modulus to change in temperature around body temperature also highlights the need for accurate temperature control throughout in vitro testing.

4.3.2 Creep

Flat polyurethane constructs of Bionate® 80A and 75D were creep tested using three different applied stresses, at room temperature and at 37°C, under both dry and lubricated conditions for periods of up to 17 days (408 hours), with their creep recovery being monitored post creep testing.

The % creep and maximum deformation values are shown in Table 4.5. The results show that increasing the stress (1.3MPa < 4.2MPa < 7.2MPa) and temperature
(ambient < 37°C), had an increasing effect on the amount of creep observed in all creep specimens (both Bionate® 80A and 75D). It was also shown that these specimens experienced larger creep deformation when lubricated conditions were used (i.e. lubricated with BCS at 37°C versus dry at 37°C) and this is attributed to the very hydrosopic and plasticising nature of Bionate® 80A and 75D as evident from DMTA studies. The absorbed BCS had a plasticizing effect on the constructs which resulted in the polymers exhibiting elastic deformation and hence an increase in creep deformation.

**Table 4.5**: % Creep and maximum deformation values of Bionate® 80A (I) and 75D (II) samples, at the different test conditions after 400 hours.

<table>
<thead>
<tr>
<th>(I) Bionate® 80A</th>
<th>Stress Level (MPa)</th>
<th>% Creep</th>
<th>Maximum Deformation (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>37°C</td>
<td>Bovine calf serum at 37°C</td>
</tr>
<tr>
<td>1.3</td>
<td>10.46</td>
<td>12.11</td>
<td>13.17</td>
</tr>
<tr>
<td>4.5</td>
<td>32.69</td>
<td>39.03</td>
<td>41.99</td>
</tr>
<tr>
<td>7.2</td>
<td>57.67</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(II) Bionate® 75D</th>
<th>Stress Level (MPa)</th>
<th>% Creep</th>
<th>Maximum Deformation (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>37°C</td>
<td>Bovine calf serum at 37°C</td>
</tr>
<tr>
<td>1.3</td>
<td>1.89</td>
<td>2.44</td>
<td>2.75</td>
</tr>
<tr>
<td>4.5</td>
<td>5.61</td>
<td>6.98</td>
<td>7.95</td>
</tr>
<tr>
<td>7.2</td>
<td>9.50</td>
<td>13.62</td>
<td>15.12</td>
</tr>
</tbody>
</table>
The % creep and maximum deformation values found for Bionate® 75D samples were notably less than those found for Bionate® 80A samples. It was shown, that at room temperature using the maximum contact stress of 7.2MPa, minimal creep of the Bionate® 75D samples occurred (~10%), compared to that of the 80A samples (~58%). Although creep of 58% is considerably large, creep rupture did not occur over the testing period. It should be noted though, that due to the large deformation exhibited by Bionate® 80A using this contact stress (as seen in Figure 4.9), further testing using this contact stress were not investigated. Creep in excess of 70% is a likely estimate for Bionate® 80A samples at 37°C and lubricated at 37°C using 7.2MPa.

The Bionate® 75D samples exhibited significant lower strain values than 80A and this can be explained by a swelling effect, as 80A has the ability to absorb moisture more quickly than 75D. It has been proposed that the aromatic hard segment constituents may directly influence the chain mobility of adjacent soft segment microdomains resulting in reduced water absorption and increasing the glass transition temperature [3]. This increase was confirmed by DMTA in part 1 of this study. DMTA also verified that the modulus of Bionate® 75D is significantly higher than 80A due to the higher hard segment content and this higher modulus caused a lower initial deflection and a smaller change in deflection during the course of the creep experiments, compared to 80A.

**Figure 4.9:** Compressive creep displacement of Bionate® 80A tested at room temperature using a contact stress of 7.2MPa.

The variation of creep deformation was plotted as a function of time in Figures 4.10 and 4.11 for the various conditions and stresses used. The deformation increased rapidly at start of testing and then slowed. A steady state was reached after approximately 48 hours of testing. It should be noted, however, that an absolute
steady state had not been reached at the conclusion of testing and the samples were still subject to minor amounts of creep. The slope of the creep curves nevertheless decreased steadily throughout each test, which indicated that the deformation of the material was tapering off as Figures 4.10 and 4.11 illustrate.

**Figure 4.10:** Compressive creep displacement of Bionate\textsuperscript{®} 80A samples, under different environmental conditions and contact stresses plotted against time.

**Figure 4.11:** Compressive creep displacement of Bionate\textsuperscript{®} 75D samples, under different environmental conditions and contact stresses plotted against time.
Figures 4.12 and 4.13 show the characteristic creep curves for the constructs calculated from the deformation curves. The compressive creep strains were found to be linear and increased with respect to time on a logarithmic scale under each contact stress.

**Figure 4.12:** Creep curves of compressive creep strain of Bionate® 80A samples, under different environmental conditions and contact stresses plotted against time on a logarithmic scale.

**Figure 4.13:** Creep curves of compressive creep strain of Bionate® 75D samples, under different environmental conditions and contact stresses plotted against time on a logarithmic scale.
The graphs aforementioned provide the basic information about Bionate\textsuperscript{®} 80A and 75D responds to stress over a period of time. Because it is desirable to illustrate if the polycarbonate-urethane samples exhibit linear or non-linear viscoelastic properties, the creep data was replotted to give the isochronous stress-strain curves of the material at the three test conditions, where the stress needed to induce a particular level of strain in a specified time is shown. If a polymer is linear viscoelastic the isochronous stress/strain relationship is a straight line and therefore a creep curve at only one stress is necessary to characterise the material as it is assumed that the elastic deformation at equilibrium and the rate of viscous flow are directly proportional to stress. The isochronous curves were found to be linear up to certain stress and strain levels. Typical isochronous curves for polymers show linear behaviour at small strains and nonlinear response at large strains. It can be seen from the curvature of the isochronous curves (Figures 4.14 and 4.15) when all three contact stresses were employed that the samples tested in this study exhibited non-linear viscoelastic properties (i.e. creep compliance is a nonlinear function of load).

The isochronous curves show that in the whole range of testing times the total strains all increased with the increase of load, i.e. the higher the load is the greater the degree of increase. In addition they show that for each given level of load, the total strain increases with increase in testing time. Stress relaxation is a consequent phenomena to creep. If the deformation is constant, stress resisting that deformation will decrease with time. The physical mechanism that causes a plastic to undergo creep also applies to the phenomenon of stress relaxations. Figures 4.14 and 4.15 illustrate that at a fixed strain, the stress decreases with the elapsed time.

Although Bionate\textsuperscript{®} 75D was shown to be notably more creep resistant than 80A, both materials exhibited similar creep behaviour as evident from their similar shaped creep and isochronous curves.
Figure 4.14: Isochronous creep curves of Bionate® 80A samples, under different environmental conditions.
Figure 4.15: Isochronous creep curves of Bionate\textsuperscript{®} 75D samples, under different environmental conditions.
The average % creep recovery and permanent set values are shown in Table 4.6. There was an immediate recovery even before the disks could be measured and this was evident from the difference between the measured deformation and thickness before and after testing.

**Table 4.6:** % Creep recovery and permanent set values of Bionate® 80A and 75D samples, in different test environments and stresses after 96 hours.

<table>
<thead>
<tr>
<th>Stress Level (MPa)</th>
<th>Bionate® 80A</th>
<th>Bionate® 75D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Recovery/ % Permanent Set</td>
<td>% Recovery/ % Permanent Set</td>
</tr>
<tr>
<td></td>
<td>Ambient 37°C</td>
<td>Bovine calf serum at 37°C</td>
</tr>
<tr>
<td>1.3</td>
<td>96/4</td>
<td>94/6</td>
</tr>
<tr>
<td>4.5</td>
<td>82/18</td>
<td>81/19</td>
</tr>
<tr>
<td>7.2</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

* Creep recovery could not be measure as the discs de-bonded after the removal of the load.

Bionate® 80A and 75D both exhibited permanent deformation, the degree of which was far greater for 75D than 80A, and this finding has been reported elsewhere. The % recovery decreased with respect to temperature, from ambient to 37°C, and lubricated conditions, from dry to fully flooded with BCS. There was almost full recovery for the samples tested at ambient temperature at the lowest contact stress. Also as expected, the creep recovery was far greater for the samples tested at the lower contact stress than at the higher contact stresses.

To the knowledge of the author no previous attempt has been made to examine the compressive creep behaviour of Bionate® 80A independent of 75D, and visa versa, using physiologically relevant *in vivo* and *in vitro* contact stresses and environments. The creep results presented here were obtained using mouldings manufactured under processing conditions closely corresponding to those which would be used for production of orthopaedic components. The results therefore provide a very useful guide to the use of these materials in orthopaedic applications as
they will allow the creep of compliant layer prostheses of varying layer thickness to be estimated. This logic was explored by comparing data with Flannery [13] who as mentioned before, investigated the creep behaviour of polycarbonate-urethane constructs made from 1 ply of Bionate® 80A bonded to 3 ply of 75D, using the same experimental technique. Flannery reported an average of 3.20% creep strain for constructs tested using a contact stress of 1.3MPa at room temperature after 300 hours (Figure 4.16). Using the data presented in this study, a 4.01% creep strain value was estimated (values of creep strain at various time intervals were divided to generate a result for 1 ply, this data was subsequently applied for the appropriate construct, i.e. construct of 1 ply Bionate® 80A bonded to 3 ply 75D).

![Figure 4.16](image)

**Figure 4.16:** Creep curve of compressive creep strain of Bionate® 80 (1 ply) backed with 75D samples (3 ply), under 1.3MPa and at room temperature plotted against time on a logarithmic scale, as experimentally by Flannery [13]. Predicted values using data from this study are plotted on same chart for comparison.

### 4.4 Conclusions

To ensure a compliant layer joint retains fit, form and function over its lifetime, material characterisation techniques were employed. Although fracture of Bionate® materials *in vivo* is highly unlikely, excessive deformation is a possibility which may
well result in loss of joint stability, loosening of the component or breakdown of the bearing surface. If heat generated through cyclic loading or a breakdown in the lubricating film cannot be dissipated, the resultant temperature rise may be detrimental to this type of joint system. A drop in modulus owing to a rise in temperature could compromise the structural integrity of the compliant layer joint.

DMTA highlighted the sensitivity of the modulus of Bionate® materials to temperature; in particular for 75D it revealed the close proximity of its glass transition to 37°C. Frictional heating of 75D is not likely however as it is intended to be the backing material in compliant layer joints. Nonetheless, the DMTA data showed a strong need for accurate temperature control during in vitro testing. The plasticisation ability of Bionate® materials was also demonstrated from DMTA, as reductions in the moduli and damping behaviour for hydrated samples attributed to the actions of plasticisation by the absorbed solutions were seen.

Through a series of creep experiments, the non-linear viscoelastic behaviour of Bionate® materials was demonstrated. Essentially, creep testing was carried out for 17 days (408 hours), by which the creep displacement curve had levelled off. It was believed that creep testing up to this point provided an adequate indication of ‘worst case scenario’ (constant static load) creep of the material in vivo, since human knee joints undergo dynamic forces when loaded, allowing instantaneous recovery upon removal; furthermore they are subjected to very small loads (<200N) for substantial periods of time, at rest. Creep rupture was not observed over the test period, and sample deformation increased dramatically with increasing stress as well as temperature and lubrication.

Bionate® 75D displayed significantly lower creep strain than 80A. The structural and chemical nature of the samples strongly influences their mechanical behaviour, along with their propensity to absorb water. Aromatic hard segments (MDI) which have been shown to have few conformational isomers and non-planer configurations readily form ordered microdomains [3]. Such aromatic hard segment constituents may directly influence the chain mobility of adjacent soft segment microdomains, resulting in increased glass transition temperature, reduced water adsorption and higher modulus. The content of hard segments in Bionate® 80A is lower than 75D, and as a result 80A was notably less creep resistant. The reversal in strain was measured at various time intervals up to 96 hours after the stress was removed. Both Bionate® materials exhibited permanent deformation, the extent of
which was dependent on the environment and contact stress used. As expected, the % recovery decreased with respect to temperature and lubrication. The degree of permanent deformation experienced by Bionate® 75D was significantly greater than 80A.

In conclusion, the results presented in this chapter provide a comprehensive material characterisation of Bionate® 80A and 75D relevant to orthopaedic device applications. The creep data set should essentially allow the development of improved designs in compliant layer technology.

REFERENCES
5. Quigley, F.P., Selection and assessment of elastomeric materials for compliant-layered total hip arthroplasty, in Materials Science and Technology Department. 1999, University of Limerick: Limerick.


Chapter 5

In Vitro Friction and Lubrication of Conventional UHMWPE, Hard and Compliant Layer Total Hip Prostheses

Abstract

It is widely accepted that the principle cause of osteolysis and consequent loosening of the replacement hip joint is polyethylene wear debris. To avoid this, interest has been renewed in hard, smooth surface bearings such as ceramics, and more recently, the emphasis has been on compliant layer technology. In this study, using a specially developed friction simulator, the friction and lubrication properties of a conventional metal-on-UHMWPE, a ceramic-on-ceramic and a metal-on-polyurethane compliant layer joint were evaluated both experimentally using Stribeck analysis and theoretically using the theory of Hamrock and Dowson. It was found that employing a biological fluid such as bovine calf serum (BCS) increased the friction by varying degrees when compared with carboxymethyl cellulose (CMC) synthetic lubricants. Mixed lubrication was found to occur in the metal-on-UHMWPE joint with all lubricants. The ceramic-on-ceramic and metal-on-polyurethane compliant layer joints, however, exhibited fluid film lubrication with synthetic lubricants but mixed lubrication with the biological lubricant. The experimental results were compared with theoretical predictions of film thickness and lubrication modes and a strong correlation was observed when employing CMC fluids as the lubricant. With further optimization of the design of the compliant layer joint, full fluid film lubrication should be achieved.

5.1 Introduction

This study uses a specially developed friction simulator to determine and compare the friction and lubrication regimes of conventional metal-on-UHMWPE hip prostheses with the friction and lubrication regimes of ceramic-on-ceramic and metal-on-polyurethane compliant layer hip joints. Under ordinary conditions the healthy hip joint operates mainly in the full fluid film regime, where the opposing porous surfaces
of the joints are separated by a film of lubricant (synovial fluid) and any load is carried by the pressure generated within this lubricant, providing low wear and friction. The fluid film is achieved by a combination of elastohydrodynamic lubrication (EHL), microelastohydrodynamic lubrication (μEHL) and squeeze film lubrication [1]. When this natural bearing joint is damaged by injury or diseases such as osteoarthritis, a total hip replacement is the most common and successful method to ease pain and to improve mobility.

Unfortunately, conventional metal-on-UHMWPE joints function in the mixed lubrication regime, where the bearing surfaces are not totally separated and the contact unavoidably results in wear. When wear debris is formed by the implant, the fibrous tissue layer surrounding the implant will try to expel these foreign bodies. If it is not possible for the body to break down these particles, as is the case of UHMWPE, macrophages or multi-nucleated giant cells (MNGC) will surround the particles and release cytokines which directly stimulate osteoclastic activity leading to bone resorption and eventually to possible loosening of the hip implant [1]. A realistic alternative to the problem of wear in conventional metal-on-UHMWPE is the use of bearing surfaces which exhibit low wear that operate in the full fluid film lubrication regime, which may be achieved either through (a) the development of hard bearing surfaces or (b) compliant layer technology.

Hard surface bearing joints include metal-on-metal and ceramic-on-ceramic. Metal-on-metal joints were not considered in this study as they have been found to produce very high frictional torques [2-4], whereas, ceramic-on-ceramic joints have been shown to operate within the fluid film lubrication regime exhibiting remarkably low friction factors [5-9]. A 28mm diameter ceramic-on-ceramic hip joint is evaluated in this study, (Trident® alumina ceramic bearing).

Compliant layer technology has been proposed to offer the benefits of reduced wear and friction and prolonged lifespan of the artificial joints by maintaining a fluid film between the articulating surfaces. However, over thirty years since the first published papers on compliant layer joints, few publications have given details of in vitro assessments of compliant layer bearings. Predominantly, studies have concentrated on the suitability of polyurethane elastomers as the most suitable candidate material for the compliant layer as these materials exhibit many of the desired properties of natural cartilage and are more readily manufactured [10-12]. Initially, the research on compliant bearings focused attention on use in the human hip
joint via mathematical approaches calculating contact stresses and contact area [13-16], as well as in vitro assessment of friction and wear [17-22]. An in vivo assessment in an ovine model [23, 24] has also been reported. Overall, the studies concluded that a fluid film readily forms between the articulating counterfaces with promising levels of friction factors; therefore, one of the principle aims of this study is to further evaluate this phenomenon, using well established artificial bearings.

5.2 Materials and Methods

5.2.1 Total Hip Replacement Components

Table 5.1 and Figure 5.1 show the material combinations tested in this study. The joints were tested three times each and were cleaned thoroughly before each test.

<table>
<thead>
<tr>
<th>Femoral component</th>
<th>Acetabular component</th>
<th>Diameter (mm)</th>
<th>Radial clearance (mm)</th>
<th>Equivalent radius, $R_x$ (m)</th>
<th>Equivalent Elastic modulus, $E^\prime$ (Pa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoCrMo</td>
<td>UHMWPE</td>
<td>28</td>
<td>0.20</td>
<td>0.99</td>
<td>$4.7 \times 10^9$</td>
</tr>
<tr>
<td>CoCrMo</td>
<td>Polyurethane</td>
<td>28</td>
<td>0.25</td>
<td>1.04</td>
<td>n/a</td>
</tr>
<tr>
<td>Al$_2$O$_3$</td>
<td>Al$_2$O$_3$</td>
<td>28</td>
<td>0.03</td>
<td>6.10</td>
<td>$3.8 \times 10^{11}$</td>
</tr>
</tbody>
</table>

Figure 5.1: Material combinations tested.
5.2.2 Friction Testing
Friction of the bearing combinations was examined using a TE89 friction simulator manufactured by Phoenix Tribology, Newbury, UK, and is described in detail in Chapter 3. The simulator subjected the femoral head to a simple harmonic oscillatory motion with a stroke of ±24° in the flexion/extension plane, with a frequency of 0.8Hz. The acetabular cup was positioned in the friction carriage and the femoral head was fixed in an upper moving frame, therefore the prosthesis was inverted relative to its in vivo position. A dynamic load, with maximum and minimum loads of 2000N and 200N respectively, was applied.

5.2.3 Lubricants
Measurements of friction factors of the components were undertaken when the acetabular cups were fully lubricated using aqueous carboxymethyl cellulose (CMC) solutions (BHD, UK) with a range of viscosities from 0.001 – 0.18 Pa s with distilled water providing the viscosity of 0.001 Pa s. The joints were also tested using a 25% bovine calf serum (BCS) (Sigma Aldrich, Ireland), 75% deionised water and a 0.2wt% of sodium azide preservative.

5.2.4 Surface Characterisation
Before testing, the surface roughness of the components was measured on the Zygo NewView 100 non-contact profilometer. The 10x lens with 0.75x zoom was used, giving an area view of 0.96 mm x 0.72mm. Five measurements were taken at random within the presumed contact zone of both the femoral head and the acetabular cup of each material combination.

5.2.5 Theoretical Lubrication Regime
5.2.5.1 Analysis of Lubricating Film Thickness for Conventional Metal-on-UHMWPE and Ceramic-on-Ceramic Joints.
The theory of Hamrock and Dowson for low elastic modulus materials was used in predicting the minimum film thickness, $h_{\text{min}}$, for these two material combinations [25].
\[
\frac{h_{\text{min}}}{R} = 2.798 \left( \frac{\eta u}{E' R} \right)^{0.65} \left( \frac{L}{E'R^2} \right)^{-0.21}
\]

where \(E'\) is the equivalent elastic modulus of the material pairing given by:

\[
\frac{1}{E'} = 0.5 \left( \frac{1 - v_1^2}{E_1} \right) + \left( \frac{1 - v_2^2}{E_2} \right)
\]

5.2.5.2 Analysis of Lubricating Film Thickness for Metal-on-Compliant Layer Cup

The film thickness for the compliant layer joints were calculated from the theory of Dowson and Yao [26].

\[
h_{\text{min}} = 1.59R \left( \frac{\eta u}{E'' R} \right)^{0.56} \left( \frac{h_i E'''}{(E'' R)^{0.36}} \right) \left( \frac{L}{E'' R^2} \right)^{-0.20}
\]

The constrained column model, used to derive the above formula, is restricted to compliant materials with a Poisson’s ratio of less than 0.4, whereas polyurethanes used as the layer in compliant layer joints have a Poisson’s ratio approaching 0.5. In order to accommodate a layer of \(v_2 = 0.5\), Dowson et al. [13] indicated that an adjusted modulus, \(E_{\text{adj}}\), should be used thus allowing the film thickness equations based on the constraint column model to be applied to incompressible layers.

\[
E_{\text{adj}} = \frac{4LRH_i}{\pi a^4} \left\{ \frac{(1 + v_2)(1 - 2v_2)}{1 - v_2} \right\}
\]

where \(a\) is the contact radius given by:

\[
a = 0.94h_i^{0.38} \left( \frac{LR}{E_2} \right)^{0.21}
\]

where \(E_2\) is the elastic modulus of the compliant layer. The modulus terms \(E''\) and \(E'''\) are given by:

\[
\frac{1}{E''} = 1 - \frac{v_1^2}{E_{\text{adj}}}
\]

and

\[
\frac{1}{E'''} = \frac{(1 + v_2)(1 - 2v_2)}{(1 - v_2)E_{\text{adj}}}
\]

where \(v_2 = 0.4\) throughout.
5.2.5.3 Lambda Ratio

The predicted minimum film thickness, together with the recorded values of $R_{q1}$ and $R_{q2}$, the average root mean square roughness of the head and the cup respectively, were used to determine the dimensionless parameter $\lambda$ [27] and therefore lubrication regimes acting within the joints for all material combinations.

$$\lambda = \frac{h_{\text{min}}}{\left( (R_q^1)^2 + (R_q^2)^2 \right)^{1/4}}$$

Experimental observations show that if the ratio of the minimum film thickness to the combined surface roughness, $\lambda$, is less than three, then mixed lubrication is likely. If $\lambda > 3$ then a full fluid-film lubrication regime is predicted [27] where the asperities of the bearing surfaces are completely separated by the lubricant.

5.2.6 Representative Coefficients of Friction for Various Modes of Lubrication

Since the friction factor is numerically of the same order as the average coefficient of friction of the joint, Dowson [28, 29] proposed that broad ranges of coefficients of friction could be used to assign the lubrication regime in which total hip replacements operate, as indicated in Table 5.2. The friction, therefore, alone often indicates the mode of lubrication.

Table 5.2: Representative coefficients of friction values ($\mu$) for various modes of lubrication.

<table>
<thead>
<tr>
<th>Mode of lubrication</th>
<th>Representative $\mu$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry</td>
<td>0.1 - 2</td>
</tr>
<tr>
<td>Boundary</td>
<td>0.07 - 0.15</td>
</tr>
<tr>
<td>Mixed</td>
<td>0.01 - 0.1</td>
</tr>
<tr>
<td>Fluid film</td>
<td>0.001 - 0.02</td>
</tr>
</tbody>
</table>

5.3 Results and Discussion

5.3.1 Stribeck Assessment

Stribeck analyses were performed on all material combinations in this study. Each sample was tested three times and the average Stribeck plots generated are shown in Figure 5.2, where separators are used to distinguish between lubricants of different
make-up. The Stribeck curves for each test (x3) are shown in Appendix E. The friction factors produced when employing CMC fluids were in the ranges of 0.0012 - 0.0018, 0.019 - 0.037 and 0.007 - 0.013 for the ceramic-on-ceramic, metal-on-UHMWPE and metal-on-polyurethane compliant layer respectively.

The ceramic-on-ceramic joint exhibited extremely low friction. The friction factors were shown to increase slightly with rising Sommerfeld number, indicative of a fluid film lubrication regime. In full fluid film lubrication, the bearing surfaces are separated by the lubricant and the friction generated is due to the shearing of the lubricant film.

The general trend throughout the test on the conventional metal-on-UHMWPE joint was a falling friction factor with increasing Sommerfeld number, indicative of a mixed lubrication regime. The friction factors produced were significantly higher than the other material combinations examined.

The metal-on-polyurethane compliant layer joint showed relatively low friction factors and there was no apparent trend in the Stribeck plot generated, suggesting that this joint operated within a fluid film lubrication regime or at the very least very little surface to surface contact.

Figure 5.2: Average Stribeck plots of the conventional metal-on-UHMWPE, ceramic-on-ceramic and metal-on-polyurethane (PU) compliant layer total hip replacements assessed with aqueous CMC solutions and a 25% solution of BCS. Standard deviations are shown.
It is clear from Figure 5.2 that the level of friction factor encountered in all the material combinations depended on whether synthetic CMC fluids or biological BCS was used as the test lubricant. An increase in friction factor was found when BCS was used and was possibly due to proteins adsorbed onto the bearing surfaces being sheared. This increase was more pronounced for the ceramic-on-ceramic joint and a similar effect was found by Scholes et al. [6].

The scale of friction factors for the conventional joint combinations, employing both CMC fluids and BCS, were found to be of the same order as those reported in the studies mentioned in the introduction to this chapter.

### 5.3.2 Comparison of Friction Values with Theoretical Predictions

Table 5.3 shows the predicted lubrication modes for each material pairing. The $\lambda$ of the metal-on-UHMWPE, ceramic-on-ceramic and metal-on-polyurethane THR systems were calculated to be 0.060, 4.621 and 1.671 respectively. Theoretically this implied that the ceramic-on-ceramic joint would operate under fluid film conditions, since $\lambda$ was greater than 3, and the metal-on-UHMWPE and metal-on-polyurethane joint would operate under mixed lubrication conditions, since $\lambda$ was less than 3.

<table>
<thead>
<tr>
<th>Femoral component</th>
<th>Tibial component</th>
<th>Femoral, $R_{q1}$ (μm)</th>
<th>Tibial, $R_{q2}$ (μm)</th>
<th>Predicted minimum film thickness, $h_{min}$ (μm)</th>
<th>Lambda ratio, $\lambda$</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoCr</td>
<td>UHMWPE</td>
<td>0.038</td>
<td>1.301</td>
<td>0.0784</td>
<td>0.060 (&lt;3)</td>
</tr>
<tr>
<td>Al$_2$O$_3$</td>
<td>Al$_2$O$_3$</td>
<td>0.003</td>
<td>0.0095</td>
<td>0.0460</td>
<td>4.621 (&gt;3)</td>
</tr>
<tr>
<td>CoCr</td>
<td>Polyurethane</td>
<td>0.047</td>
<td>0.142</td>
<td>0.2504</td>
<td>1.671 (&lt;3)</td>
</tr>
</tbody>
</table>

The Stribeck plot for the conventional metal-on-UHMWPE joint with the $\lambda=3$ line, which is showed as the dashed line, is shown in Figure 5.3. All the points on this plot were to the left of the $\lambda=3$ line, suggesting a mixed lubrication regime. Because this
joint operated in the mixed lubrication regime wear will occur at the contacting asperities. It can be seen from Figure 5.3 that in order for these for this joint to undergo the transition from mixed to full fluid film lubrication, the Sommerfeld number at which the joint operates must be increased. As it is not possible to change the loads or the lubricant to which the joint is subjected, the only possible way to achieve full fluid film lubrication would be to increase the bearing diameter. However, under current operating conditions the diameter would have to increase dramatically and would be too large to be accommodated by the average human pelvis. It can be therefore assumed, that the conventional metal-on-UHMWPE operates in a mixed lubrication regime and asperity contact, and subsequent wear is to be expected.

![Figure 5.3: Average Striebeck plot of the conventional CoCr-on-UHMWPE total hip replacement with $\lambda=3$ line. Standard deviations are shown.](image)

The Striebeck plot for the ceramic-on-ceramic joint with the $\lambda=3$ line (dashed line) is shown in Figure 5.4. All the friction factors at the higher end of the viscosity range were to the right of the $\lambda=3$ line, suggesting a fluid film lubrication regime. The theoretical prediction of lubrication correlated well with experimental data. Hard bearing pairings rely on very smooth surfaces to increase the film thickness to
combined surface roughness ratio in order to attain full fluid film lubrication. Results from the ceramic-on-ceramic joint tested in this study supported this point.

![Ceramic-on-ceramic](chart.png)

**Figure 5.4:** Average Strubeck plot of the ceramic-on-ceramic total hip replacement with \( \lambda = 3 \) line. Standard deviations are shown.

The Strubeck plot for the metal-on-polyurethane compliant layer joint with the \( \lambda = 3 \) line (dashed line) is shown in Figure 5.5. In this examination, full fluid film was achieved at the higher viscosities; friction factors right of the \( \lambda = 3 \) line. Theoretically, for this joint the transition from mixed lubrication to full fluid film should occur at a viscosity of 0.028 Pa s. A typical value for the viscosity of pathological synovial fluid is 0.01 Pa s at 3000 s\(^{-1}\), therefore a minor increase in the bearing radius of this type of joint would result in higher entraining velocities and therefore the transition from mixed to full fluid film lubrication would occur at viscosities similar to those found in the body which may in turn lead to very low clinical wear rates.
Figure 5.5: Average Striebeck plot of the CoCr-on-PU compliant layer total hip replacement with $\lambda=3$ line. Standard deviations are shown.

5.4 Conclusions

Both the compliant layer joint and the ceramic-on-ceramic joint tested in this study gave significantly lower friction than the conventional metal-on-UHMWPE joint. The level of friction factor encountered was shown to depend on the lubricant make-up; proteins in the BCS had an increasing effect on the friction of all bearings. For the synthetic lubricant, the theoretical predictions correlated well with experimental data. These predictions were less appropriate however with BCS as the lubricant, as adsorbed films of protein will affect the viscosity and hence the lubricating conditions.

At the lower lubricant viscosities (those close to the viscosity of synovial fluid) all the joint combinations operated in the mixed lubrication regime and therefore wear of varying degrees will occur. The design of the compliant layer joint and the hard bearing surface joint must therefore be optimized to encourage these joints to work in the full fluid film lubrication regime and hence avoid the problem of wear.
NOTATION:

- $a$: contact radius
- $E_{adj}$: adjusted elastic modulus for layer of $v_2 > 0.4$
- $E'$: equivalent elastic modulus
- $E''$: elastic modulus term
- $E'''$: elastic modulus term
- $E_1$: modulus of elasticity of femoral head component
- $E_2$: modulus of elasticity of the acetabular cup
- $f$: friction factor
- $h_{min}$: minimum film thickness
- $ht$: layer thickness
- $L$: applied load
- $r$: equivalent radius for a ball on plane model
- $R_c$: radius of acetabular cup
- $R_x$: equivalent radius of the material pairing
- $R_{Q_1}$: r.m.s roughness of femoral head component
- $R_{Q_2}$: r.m.s. roughness of acetabular cup
- $T$: frictional torque
- $u$: entraining velocity
- $z$: Sommerfeld no
- $\eta$: lubricant viscosity
- $\mu$: coefficient of friction
- $\lambda$: Lambda ratio (surface separation ratio)
- $v_1$: Poisson’s ratio of the femoral head component
- $v_2$: Poisson’s ratio of the acetabular cup component

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Chapter 6

In Vitro Friction and Lubrication of Conventional UHMWPE and Compliant Layer Total Knee Prostheses

Abstract
Compliant layer technology, in which a soft polymer mimics the performance of natural cartilage, may offer advantages compared with conventional metal-on-plastic joints. In this study the friction and lubrication properties of a conventional metal-on-UHMWPE prosthesis and a metal-on-polyurethane compliant layer joint were evaluated both experimentally using Stribeck analysis and theoretically using the theory of Hamrock and Dowson. Mixed lubrication was found to occur in the metal-on-UHMWPE joint with all the lubricants; (the biological fluid 25% bovine calf serum (BCS) solution gave a slightly higher friction factor). The metal-on-compliant layer polyurethane joint, however, exhibited full fluid film lubrication with the synthetic lubricants but mixed lubrication with the biological fluid. A strong correlation was observed between experiment and theory when employing carboxymethyl cellulose (CMC) fluids as the lubricant for both joints assessed.

Overall the friction and lubrication results demonstrated the ability of compliant layer joints to operate with fluid film lubrication and consequential lower frictional torque during the walking cycle.

6.1 Introduction
This study uses a friction simulator to determine and compare the friction and lubrication regimes of metal-on-polyurethane compliant layer knee joints with the friction and lubrication regimes of conventional metal-on-UHMWPE knee prostheses. Unlike natural, healthy synovial joints, conventional metal-on-UHMWPE knee joints have been found to operate in the mixed lubrication regime. Mixed lubrication occurs when there is significant asperity-asperity contact between the bearing surfaces and the load is carried by both the asperity contact and the pressure generated within the fluid.
The introduction of artificial joints incorporating polyurethane compliant layer surfaces has led to the possibility of increasing artificial knee joint life. Polyurethane is a polymer whose compliance can be customised by the mixture of hard and soft segments [1]. Frictional tests have shown that low modulus polyurethane performs well in total hip replacements (THRs) [2-6], however the kinematics of the knee joint are far more complex than the hip, and frictional assessment should be accomplished with a joint simulator which includes both sliding and rolling motion in an oscillatory contact. Until recently there have been fewer laboratory studies that report on polyurethanes use and performance in TKR. Auger et al. [7] showed that the friction coefficients of flat compliant layer bearings were between 0.05 and 0.001 depending on the elastic modulus and thickness of the compliant layer. Ash [8] has shown that compliant bearing knee systems exhibited friction factors below 0.01 and proposed that the compliant inserts operated with some degree of fluid film lubrication. Scholes et al. [1] performed lubrication studies on polyurethane unicondylar knee prostheses and concluded that the joints were operating close to fluid film lubrication with friction factors in the range of 0.05-0.004. More recently, Flannery [9] showed that compliant layer polyurethane TKRs operate with fluid film lubrication where elastohydrodynamic lubrication (EHL) and micro-elastohydrodynamic lubrication (μEHL) flatten and polish the asperities on the surface of the compliant layer (friction factors 0.03-0.001).

In this study, the friction and lubrication regimes of metal-on- (1) compliant layer polyurethane and (2) UHMWPE, knee prostheses are determined using a friction simulator. The intention of the compliant polyurethane bearing was to mimic the natural joint by more closely simulating the elastic properties of artificial cartilage and hence the fluid film lubrication it promotes.

6.2 Materials and Methods
6.2.1 Total Knee Replacement Components
6.2.1.1 UHMWPE Tibial Components
A 10mm thick UHMWPE Interax® Duration® tibial bearing insert manufactured by Stryker, Orthopaedics, Limerick was used in this study (Figure 6.1). The insert were sterilised by 25kGrays gamma irradiation in an inert nitrogen atmosphere. Prior to testing the insert was conditioned by immersing in distilled water for a minimum period of four weeks to ensure equilibrium fluid absorption.
6.2.1.2 Compliant Layer Polyurethane Tibial Components
A congruent polyurethane tibial insert based on the standard Interax® design, manufactured by Stryker Orthopaedics, Limerick was used in this study (Figure 6.1). The component was made up of a backing layer of 10mm Bionate® 75D and a 2mm surface layer of Bionate® 80A. The insert was sterilised by 25kGrays gamma irradiation in an inert nitrogen atmosphere, before being conditioned prior to testing by immersion in distilled water for three months.

6.2.1.3 Cobalt Chrome Femoral Components
The femoral components used were standard left side Interax® Midi 600 cobalt chrome (CoCr) femoral components also manufactured by Stryker Orthopaedics, Limerick and corresponded to the UHMWPE tibial insert used (Figure 6.1).

![Material combinations tested.](image)

**Figure 6.1:** Material combinations tested.

6.2.2 Friction Testing
Friction of the bearing combinations was examined using a TE89 friction simulator manufactured by Phoenix Tribology, Newbury, UK. The simulator subjected the femoral components to a simple harmonic oscillatory motion with a stroke of ±32.5° in the flexion/extension plane. The tibial inserts were a press-fitted into an Interax Midi 2 base plate and a dynamic load was applied with maximum and minimum loads of 2000N and 200N respectively. Each sample was tested three times.
6.2.3 Lubricants
Measurements of friction factors of the components were undertaken when the tibial inserts were fully lubricated using aqueous carboxymethyl cellulose (CMC) solutions (BHD, UK) with a range of viscosities from 0.001 – 0.18 Pa s with distilled water providing the viscosity of 0.001 Pa s. The joints were also tested using a 25% bovine calf serum (BCS) (Sigma Aldrich, Ireland), 75% deionised water and a 0.2wt% of sodium azide preservative.

6.2.4 Surface Characterisation
Before testing, the surface roughness of the components was measured on the Zygo NewView 100 non-contact profilometer. The 10x lens with 0.75x zoom was used, giving an area view of 0.96 mm x 0.72 mm. Five measurements were taken on each component. These surface roughness measurements were performed on all the bearing surfaces, both the femoral condyles and tibial components.

6.2.5 Theoretical Lubrication Regime
There are a number of engineering formulations that allow the prediction of the lubrication regime of a bearing system for a given set of conditions provided the roughness of the bearing surfaces are known. The lubricating film thickness was derived mathematically for the UHMWPE and complaint layer inserts using the following theoretical analysis. See notation at end of chapter for explanation of parameters.

6.2.5.1 Analysis of the Lubricating Film Thickness of UHMWPE Inserts
The central and minimum fluid film thickness was estimated for the UHMWPE insert using the following analysis, which was carried out according to the same protocol as Auger et al. [7]. Hertzian contact theory was used to calculate the contact half width, b, for the UHMWPE inserts:

\[
b = \left( \frac{8F'R}{\pi E'f} \right)^{1/2}
\]

Where R is the reduced radius given by:

\[
\frac{1}{R} = \frac{1}{R_1} - \frac{1}{R_2}
\]
And \( E' \) is the reduced modulus:

\[
\frac{1}{E'} = \frac{1}{2}\left(\frac{1-v_1^2}{E_1} + \frac{1-v_2^2}{E_2}\right)
\]

The elastohydrodynamic film thickness for the UHMWPE joint was estimated from the Hamrock and Dowson formula [10] which was used in its line contact form:

\[
\frac{h_{\text{min}}}{R} = 7.43 \left(\frac{\eta u}{E' R}\right)^{0.65} \left(\frac{F'}{E' R}\right)^{-0.21} \left(\frac{R}{L}\right)^{0.21}
\]

And the central film thickness was estimated from the Hamrock and Dowson relation [10]:

\[
\frac{h_{\text{cen}}}{R} = 7.32 \left(\frac{\eta u}{E' R}\right)^{0.64} \left(\frac{F'}{E' R}\right)^{-0.22} \left(\frac{R}{L}\right)^{0.22}
\]

### 6.2.5.2 Analysis of the Lubricating Film Thickness of Compliant Layer Inserts

The central and minimum film thickness was estimated for the compliant layer insert using the following analysis, which was carried out according to the same protocol as Auger et al. [7]. The full elasticity solutions produced by Meijers [11] were used to determine the contact half-width for the compliant layer insert:

\[
\frac{4F' R (1-v^2)}{\pi E_2 b^2} = \left(\frac{b}{t_h}\right)^2 f\left(\frac{b}{t_h}, \nu\right)
\]

where \( f\left(\frac{b}{t_h}, \nu\right) \) is a function defined by Meijers and \( t_h \) is the compliant layer thickness.

The elastohydrodynamic film thickness for the compliant layer insert was estimated from the line contact formulae given by Medley et al. [12]:

\[
\frac{h_{\text{min}}}{R} = 1.159 \left(\frac{b}{t_h}\right)^{-0.4875} \left(\frac{2 \eta u}{E_2 R}\right)^{0.6} \left(\frac{F'}{E_2 R}\right)^{-0.2} \text{ for } \frac{b}{t_h} \geq 2
\]
\[
\frac{h_{\text{min}}}{R} = 1.335 \exp^{-0.2394 \left( \frac{b}{t_h} \right)} \left( \frac{2 \eta u}{E_2 R} \right)^{0.6} \left( \frac{F'}{E_2 R} \right)^{-0.2} \text{for } \frac{b}{t_h} < 2
\]

The central film thickness was calculated from the relation given by Hooke [13]:

\[
h_{\text{cen}} = \frac{h_{\text{min}}}{0.8}
\]

### 6.2.5.3 Lambda Ratio

The predicted minimum film thickness, together with the measured composite root mean square roughness were used to determine the dimensionless parameter \( \lambda \) [14] (known as the surface separation or lambda ratio), and therefore the theoretical lubrication regimes acting within the joint:

\[
\lambda = \frac{h_{\text{min}}}{\left( \left( R^1_q \right)^2 + \left( R^2_q \right)^2 \right)^{1/2}}
\]

If \( \lambda \) is equal or less than 1, boundary lubrication prevails. If \( \lambda \) exceeds 3, effective separation and fluid film lubrication can be achieved. At \( 1 < \lambda \) varying degrees of mixed lubrication result [14]. The mathematically predicted modes of lubrication can be compared to those observed experimentally.

### 6.3 Results and Discussion

#### 6.3.1 Stribeck Assessment

**6.3.1.1 CoCr-on-UHMWPE**

Friction of this bearing combination was tested three times and the Stribeck plots generated is shown in Figure 6.2. There is no apparent trend in the Stribeck plot, although at high values of Sommerfeld number, the friction starts to fall slightly. An ideal Stribeck plot would illustrate a distinctive decreasing trend in friction factor with increasing Sommerfeld number (CMC viscosity); however, this was not observed for this joint. The friction factors measured were in the average range of 0.022 - 0.014 when using CMC fluids as the lubricant. This range of friction factors and the weak general trend of decreasing friction factors with increasing Sommerfeld number indicated that the joint was operating under a mixed lubrication regime and that asperity contact determines the frictional torque.
The friction factors produced, however, depended on whether CMC fluids or bovine
calf serum was used as the lubricant. An increase in friction factor was found when
bovine serum was used (0.032). This increase is possibly be due to proteins adsorbed
onto the bearing surfaces being sheared and not due to more asperity contact. This
has been seen in joints of other material combinations [15]. The results from the tests
performed were similar to those found by Flannery et al. [9, 16] for conventional
metal-on-UHMWPE knee joints and to those found by Unsworth [17] and Scholes et
al. [15] for conventional metal-on-UHMWPE hip joints. The evidence shows that these
joints operated under a mixed lubrication regime.

**Figure 6.2:** Stribeck plot of the CoCr-on-UHMWPE TKR assessed with aqueous
CMC solutions and a 25% solution of BCS. Standard deviations are shown.

### 6.3.1.2 CoCr-on-Compliant Layer Polyurethane

Friction of this bearing combination was tested three times and the Stribeck plots
generated are shown in Figure 6.3. An ideal Stribeck curve indicative of fluid film
lubrication would show the friction factor increasing with increasing Sommerfeld
number. A minimum point is reached which is recognised as the demarcation
between fluid film lubrication and some asperity interaction (mixed lubrication).
After this, increasing viscosity results in an increase in friction factor and implies
fluid film lubrication. In full fluid film lubrication, the bearing surfaces are separated by the lubricant and the friction generated is due solely to the shearing of the lubricant film. A slight increasing trend, although not uniform was observed in the Stribeck plot whereby the friction increased with increasing Sommerfeld number. The average friction factors produced were remarkably low (0.009 – 0.006), an order of magnitude lower than the CoCr-on-UHMWPE joint. At this level of friction and with a slightly rising Stribeck curve, this looks very much like fluid film lubrication.

Similar to the effect seen with the UHMWPE insert, the 25% bovine calf serum lubricant caused an increase in friction factor (0.0245) relative to the friction observed using CMC solutions. This value was at least double the values produced with CMC fluids alone. Again in the same way as the CoCr-on-UHMWPE total knee replacement, it is proposed that the increase in friction was caused by the rubbing of proteins, which had adsorbed onto the polyurethane and CoCr bearing surfaces. The results from these tests were similar to those found by Scholes et al. [18], Auger et al. [7], Flannery et al. [9, 16] and Ash et al. [8].

**Figure 6.3:** Stribeck plot of the CoCr-on-polyurethane TKR assessed with aqueous CMC solutions and a 25% solution of BCS. Standard deviations are shown.
6.3.1.3 Comparison of Friction Values with Theoretical Predictions

Table 6.1 on the next page lists the values of the various design and input parameters used in the following analysis. Table 6.2 shows the predicted lubrication modes for each material pairing. The $\lambda$ of the UHMWPE and the polyurethane compliant layer TKR systems were calculated to be 0.136 and 3.552 respectively. Theoretically, this implied that the metal-on-UHMWPE joint would operate under mixed lubrication conditions, since $\lambda$ was less than three, and the metal-on-polyurethane joint would operate under fluid film lubrication conditions since $\lambda$ was greater than three.

**Table 6.1:** Total knee joint design parameters and input conditions.

<table>
<thead>
<tr>
<th>Description</th>
<th>Parameter</th>
<th>Notation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral component (CoCr)</td>
<td>Modulus</td>
<td>$E_1$</td>
<td>2.1 x 105 MPa</td>
</tr>
<tr>
<td></td>
<td>Poisson’s ratio</td>
<td>$\nu_1$</td>
<td>0.300</td>
</tr>
<tr>
<td></td>
<td>Radius of curvature</td>
<td>$R_1$</td>
<td>39.39 mm</td>
</tr>
<tr>
<td></td>
<td>Bearing length</td>
<td>$L_1$</td>
<td>75.58</td>
</tr>
<tr>
<td>Tibial component (UHMWPE)</td>
<td>Modulus</td>
<td>$E_2$</td>
<td>779 MPa</td>
</tr>
<tr>
<td>or</td>
<td>Poisson’s ratio</td>
<td>$\nu_2$</td>
<td>0.486</td>
</tr>
<tr>
<td>Tibial component (PU compliant layer)</td>
<td>Modulus</td>
<td>$E_2$</td>
<td>6.83 MPa</td>
</tr>
<tr>
<td></td>
<td>Poisson’s ratio</td>
<td>$\nu_2$</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Radius of curvature</td>
<td>$R_2$</td>
<td>53.8 mm</td>
</tr>
<tr>
<td></td>
<td>Contact half width</td>
<td>$b$</td>
<td>6.125 mm</td>
</tr>
<tr>
<td>Input conditions</td>
<td>Applied load</td>
<td>$F$</td>
<td>2200N</td>
</tr>
<tr>
<td></td>
<td>Entrainment velocity</td>
<td>$u$</td>
<td>0.031 m/s</td>
</tr>
<tr>
<td></td>
<td>Lubricant viscosity</td>
<td>$\eta$</td>
<td>0.00341 Pa s</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(25% BCS viscosity)</td>
</tr>
</tbody>
</table>

**Table 6.2:** Predicted lubrication modes ($\eta = 0.001$ Pa s) (standard deviations are given in parentheses).

<table>
<thead>
<tr>
<th>Femoral component</th>
<th>Tibial component</th>
<th>Femoral, $R_{q1}$ (μm)</th>
<th>Tibial, $R_{q2}$ (μm)</th>
<th>Predicted minimum film thickness, $h_{\text{min}}$ (μm)</th>
<th>Predicted central film thickness, $h_{\text{cen}}$ (μm)</th>
<th>Lambda ratio, $\lambda$</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoCr</td>
<td>UHMWPE</td>
<td>0.0842 (0.033)</td>
<td>0.7456 (0.095)</td>
<td>0.070</td>
<td>0.102</td>
<td>0.136 (&lt;1)</td>
</tr>
<tr>
<td>CoCr</td>
<td>Polyurethane</td>
<td>0.0754 (0.0056)</td>
<td>0.0456 (0.0164)</td>
<td>0.313</td>
<td>0.391</td>
<td>3.552 (&gt;3)</td>
</tr>
</tbody>
</table>
The Stribeck curve for the metal-on-UHMWPE joint with the $\lambda=3$ line, which is shown as the dashed line, is shown in Figure 6.4. All the points on this curve are to the left of the $\lambda=3$ line, suggesting a mixed lubrication regime. Theoretically, for these joints, the transition from mixed lubrication to full fluid film should occur at a viscosity of 0.702 Pa s. A typical value for the viscosity of pathological synovial fluid is 0.01 Pa s at 3000s$^{-1}$. The theoretical prediction of lubrication mode correlates well with experimental data.

![Stribeck Curve](image)

**Figure 6.4:** Average Stribeck plot of the CoCr-on-UHMWPE TKR with $\lambda=3$ line. Standard deviations are shown.

From Figure 6.4, it can be seen that in order for this joint to undergo the transition from mixed lubrication to full fluid film the Sommerfeld number at which these joints operate must be increased. It is not possible to change significantly the load to which the joint is subjected nor is it possible to increase the viscosity of the lubricant *in vivo*. Apart from the Sommerfeld number, it is also unlikely that the surface roughness of the components will be further much improved. Therefore, it is to be expected that this joint is destined to work in the mixed lubrication regime and that wear is a certainty.

The Stribeck curve for the metal-on-polyurethane joint with the $\lambda=3$ line (which is shown as the dashed line) is shown in Figure 6.5. All the friction factors at
the higher end of the viscosity range are to the right of the $\lambda=3$ line, suggesting a fluid film lubrication regime. Theory would suggest that the transition from mixed to fluid film lubrication should occur at a viscosity of 0.0026 Pa s, a value much lower than that of the conventional UHMWPE joint. For compliant layers to work well they must operate within the full fluid film lubrication regime through the effects of EHL and $\mu_{\text{EHL}}$ in order to reduce both the wear and friction by eliminating the asperity contact between the bearing surfaces [19]. In this study, full fluid film was achieved at the higher viscosities and excellent correlation between the experimental data and the theoretically predicted mode of lubrication was observed.

![Figure 6.5: Average Streibek plot of the CoCr-on-Polyurethane TKR with $\lambda=3$ line. Standard deviations are shown.](image)

6.4 Conclusions
The friction tests on metal-on-polyurethane compliant layer TKR provided encouraging results and the joint was found to work within the full fluid film regime at the higher end of the viscosity range. The friction factors produced were extremely low and significantly lower than those obtained for the conventional metal-on-UHMWPE joint.

The conventional metal-on-UHMWPE TKR was shown to operate within a mixed lubrication regime with the majority of the friction produced at the bearing surfaces, due to shearing of the UHMWPE component asperities.
It was clear that the level of friction factor encountered in artificial knee joints depended on the lubricant; proteins in the biological BCS had an increasing effect on the friction of these bearings. For the synthetic lubricants (CMC fluids), the theoretical predictions of lubrication modes correlated well with experimental data. However these predictions were less appropriate when BCS was employed as the lubricants, as adsorbed proteins as well as the viscosity affect the lubricating conditions.

**NOTATION:**

- $\eta$: lubricant viscosity
- $\mu$: coefficient of friction
- $\lambda$: Lambda ratio (surface separation ratio)
- $b$: contact half width
- $f$: friction factor
- $z$: Sommerfeld no.
- $E'$: reduced elastic modulus
- $E_1$: modulus of elasticity of femoral component
- $E_2$: modulus of elasticity of the tibial insert
- $F$: applied load
- $F'$: applied line load = $F/L_1$
- $L_1$: bearing length
- $R$: reduced radius
- $R_1$: radius of femoral component
- $R_2$: radius of tibial component
- $v_1$: Poisson’s ratio of the femoral component
- $v_2$: Poisson’s ratio of the tibial component
- $u$: entraining velocity
- $t_h$: thickness of the compliant low modulus layer
- $T$: frictional torque
- $h_{\text{min}}$: minimum film thickness
- $h_{\text{cen}}$: central film thickness
- $Rq_1$: r.m.s roughness of femoral component
- $Rq_2$: r.m.s. roughness of tibial component

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Chapter 7

In Vitro Friction and Lubrication of Large Bearing Hip Prostheses

Abstract
New material combinations and designs of artificial hip implants are being introduced in an effort to improve proprioception and functional longevity. Larger joints in particular are being developed to improve joint stability, and it is thought that these larger implants will be more satisfactory for younger and more physically active patients. The study detailed here used a hip friction simulator to assess the friction and lubrication properties of large diameter hip bearings of metal-on-metal and ceramic-on-reinforced polymer couplings. Joints of different diameters were evaluated to determine what effect, if any, bearing diameter has on lubrication.

The frictional studies showed that the metal-on-metal joints worked under the mixed lubrication regime, producing similar friction factor values to each other. The addition of proteins in the form of bovine calf serum (BCS) reduced the friction. The ceramic-on-(reinforced-polymer) samples were shown to operate with high friction factors and mixed lubrication. When tested with BCS, the larger diameter bearings showed a decrease in friction compared to the smaller size bearings. The addition of proteins resulted in an increase in friction, unlike the metal-on-metal system.

This study demonstrated that the component's diameter had little or no influence on the lubrication and friction of the large bearing combinations tested.

7.1 Introduction
This study uses a friction simulator to determine and compare the friction and lubrication regimes of large bearing hip prostheses, of varying diameter. The majority of hip prostheses in use today are of the metal-on-ultrahigh molecular weight polyethylene (UHMWPE) type, with the replacement femoral head being much smaller than the normal healthy femoral head found in the human body. This hard-on-soft configuration was pioneered by Charnley [1], and it is believed that the most common causes for failure of this implant type are prosthetic dislocation, and aseptic loosening due to osteolysis which is induced by polyethylene (PE) wear debris.
Additionally, it has been suggested that this conventional hip replacement system is not satisfactory for younger patients primarily due to their higher activity levels [2]. Smaller diameter prostheses may result in reduced joint stability and increased dislocation rates with respect to the normal hip joint [3, 4]. It is proposed that larger diameter prostheses would offer better proprioception and provide a greater range of motion [5], in addition to, a more natural transfer of loads and possible preservation of bone mineral density [6]. In an effort to eliminate the wear problems of PE and improve the implant’s proprioception and limited survivorship, research has been directed at the use of alternative materials and designs. The first part of this paper is concerned with the use of large diameter hard-on-hard configurations, specifically metal-on-metal implants.

Metal-on-Metal hip replacements were first introduced by McKee and Watson-Farrar [7] in the 1950s, but were neglected for several years due to early failures by loosening owing to high frictional torque, as well as the rapid increase in popularity of the Charnley arthroplasty. Although many of these metal-on-metal implants yielded variable early results, some successful implants had long life-times (in excess of 20 years) with very low wear rates [8-11]. Recent improvements in manufacturing techniques and better knowledge of factors that influence wear i.e. interplay of metals, macro-geometry (diameter and clearance), micro-geometry (surface topography) and lubrication, have led to a revival in the use of metal-on-metal bearings and it is now considered that equatorial binding contributed to the high-friction torque and loosening evident in many of the early metal-on-metal implants. There is also renewed interest in resurfacing arthroplasty using metal-on-metal bearings, which should allow bone stock preservation [12].

Many studies have been done to characterise the wear properties of metal-on-metal implants and it has been determined that the volume of wear in these hard-on-hard bearings is typically two orders of magnitude lower than that of the PE recorded for the metal-on-UHMWPE implants [13, 14]. Two distinctive regions of wear have been widely reported from hip simulator studies: at first, the femoral head and acetabular components show a reasonably quick but decreasing wear rate over the first 1-2 million cycles and this region is commonly referred to a “bedding-in” or a “running-in” period. Once this process has been completed, the rate of wear becomes relatively steady and generally relatively small and this region is normally referred to as a “steady-state wear” period. Both the initial bedding-in and steady-state wear
have been found to be influenced by head diameter and clearance [15]. It has been shown [14, 16] that the head diameter plays a major role in determining the lubrication regime and hence the volumetric wear and wear rate in metal-on-metal hip replacements tested. As the diameter was increased the volumetric wear rate was much higher. The effect of clearance was also shown to control the wear behaviour of metal-on-metal implants [14].

While much work has been done to characterise the wear properties (and the effect of diameter and clearance on wear), much work still remains to be done to characterise the frictional properties of metal-on-metal implants. Cipera and Medley [17] conducted a friction study of cobalt based alloys for metal-on-metal hip implants, using a linear reciprocating pin-on-flat device. The friction factors produced were found to be 0.2 and 0.14 using 30% bovine serum (BS) and distilled water respectively. Scholes and Unsworth [18] found, using a friction simulator, that metal-on-metal joints produced the highest friction out of a range of material combinations (metal-on-metal, ceramic-on-ceramic, and conventional metal-on-UHMWPE, all of 28mm), regardless of the lubricant used, and found friction factors of 0.28 using carboxymethyl cellulose (CMC) fluids as the lubricant. A simple resistivity technique, whereby direct measurement of the separation between the two articulating surfaces, has also been employed. Dowson et al. [19] showed that, for artificial joints of 36mm, the mode of lubrication is likely to be mixed lubrication with some periods of effective surface separation. Smith et al. [14] also used this technique and assessed different diameter bearings, and for the largest joint diameter they looked at the effect of radial clearance. Smaller joints showed no surface separation. The larger joints mainly operated in the mixed lubrication regime; however the smaller clearances provided more surface separation per cycles, which suggests the smaller clearances gave better lubrication.

A study done by Unsworth et al. [20] examined the friction of a 50mm hip resurfacing device prior to- and during- wear testing. At zero cycles of wear, the joint appeared to operate within the boundary lubrication mode, by one million cycles a classical Stribeck curve indicative of mixed lubrication was observed and by two million cycles friction factors of about 0.015 were produced; at this level of friction, full fluid film lubrication prevailed. They concluded that the implant appeared to be subjected to fluid film lubrication as its surface topography modified with wear time (asperities smoothed and skewness moved from positive to negative). In another
study carried out by Scholes et al. [21] on the lubrication regime in large diameter metal-on-metal hip joints, friction factors of 0.015 – 0.03 were found and they concluded that the joints were operating within the mixed lubrication regime but with lower friction factors than other metal-on-metal combinations published elsewhere.

More recent studies have been done by Brockett et al. [3, 22] and Wimmer et al. [23]. Brockett et al. [3] compared the friction in 28mm conventional and 55mm resurfacing metal-on-metal hip replacements using a pendulum machine. The friction factor was found to be lower for the resurfacing implant (0.098 v 0.121), though this was reported as not being statistically significant. In the other study by Brockett et al. [22] the lubrication and friction of large diameter metal-on-metal hip replacements was examined, with diametral clearances of 53, 94 and 194 μm. Friction factors in the range of 0.07-0.23 were obtained, with the small and mid range clearance bearings having similar friction factors in all test conditions, whereas the largest clearance joint resulted in a significant increase in friction with 25% serum conditions, again illustrating the influence of clearance on the friction in metal-on-metal bearings. Wimmer et al. [23] investigated stick phenomena in metal-on-metal hip joints after resting periods, using a pin-on-ball testing unit, and assumed a similar friction factor for all bearing with different diameters.

It should be noted though, that the studies above, employed dissimilar components and a variety of friction testing techniques (simulator, electrical resistivity, and pendulum), therefore it is difficult to draw comparisons and establish an exact lubrication regime for metal-on-metal hip implants. The first aim of this study, therefore, was to investigate the friction and lubrication of ‘new’, un-implanted, large diameter metal-on-metal hip resurfacing implants, using a friction simulator (that accurately matches both the loading and motion profiles encountered by the body during the walking cycle) and to determine what, if any, effect diameter size has on the lubrication regime acting within this all-metal system.

An alternative attempt to prolong the life of hip prostheses is to improve the mechanical properties and wear resistance of the polymer. Mechanical properties of polymers can be tailored, for example by preparing carbon fibre reinforced (CFR) composites with varying fibre length and orientation. The second element of this paper is concerned with the use of large diameter ceramic-on-CFR-PEEK couplings.
Carbon-fibre-reinforced poly(ether-ether-ketone) (CFR-PEEK) has been reported as a more wear-resistant material than UHMWPE. In a study by Scholes and Unsworth [24], they reported that the wear produced by CFR-PEEK articulating against ceramic, assessed on a multidirectional pin-on-plate machine, was much lower than the wear produced by conventional joint material (metal-on-PE) and metal-on-metal combinations, indicating that these ceramic - CFR-composites combinations may perform well in joint applications. Recent studies by Scholes et al. [25] and Latif et al. [26] investigating the wear and friction of a flexible and anatomically shaped CFR-PEEK acetabular cup gave encouraging results. Their wear data (low wear rate was sustained over 25 x 10⁶ cycles, the equivalent of up to approximately 25 years in vivo) clearly indicates that this novel cup design will provide improved long-term component wear. Although the wear performance was very promising, additional friction tests should be carried out on this system to determine the precise lubrication regime under which will they operate in vivo, and allow a full tribological analysis to be executed. Therefore, the second aim of this study was to investigate the friction and lubrication of ‘new’, un-implanted, large diameter alumina-on-CFR-PEEK hip implants, using a friction simulator and to determine what if any effect diameter size has on the lubrication regime acting within this novel hip replacement system.

7.2 Materials and Methods

7.2.1 Components
One set of MITCH TRH™ metal-on-metal hip systems of 38, 42, 48, 52 and 58 mm nominal diameter, and one set of ceramic-on-CFR-PEEK hip systems of 38, 42, 52 and 60 mm nominal diameter, were used. The MITCH TRH™ is a total hip femoral head resurfacing system manufactured by Finsbury orthopaedics exclusively for Stryker and is currently in clinical use. The reinforced polymer hip systems comprised of thin-walled horseshoe-shaped CFR-PEEK (pitch based) cups articulating against ceramic femoral heads. The cups were designed and manufactured as flexible components in an attempt to prevent stress shielding within the adjacent bone when implanted in the body [27].

7.2.2 Geometric and Surface Characterisation
Geometric and surface parameter data of the metal-on-metal implants were measured prior to testing using a coordinate measuring machine (Mitutoyo Crysta Apex C
and a non-contacting surface profilometer (Zygo, NewView), respectively. The clearances of the CFR-PEEK systems were estimated by measuring the gap between the surfaces at the equator, while the surface topography was measured using a contacting profilometer (Form Talysurf Series, Taylor-Hobson). All sample types were manufactured to the same surface finish with very close tolerances.

7.2.3 Friction Testing
Friction of the bearing combinations was examined at room temperature using a TE89 friction simulator manufactured by Phoenix Tribology, Newbury, UK, which has been described elsewhere [28]. The simulator subjected the components to a simple harmonic oscillatory motion with a stroke of ±24° in the flexion/extension plane with a frequency of 0.8Hz. Each hip implant was tested twice in each lubricant and the results averaged to build up the Stribeck curve.

The bearings were arranged in an inverted position with respect to in vivo and the friction carriage was self-aligning, to ensure correct positioning of the implant during testing. The acetabular cups of the metal prostheses were not angled, and were cemented in sample holders using Simplex bone cement, whereas the acetabular components of the CFR-PEEK systems were press-fitted into specially designed and manufactured UHMWPE holders (Figure 7.1), oriented at 33° to the horizontal to ensure that the dynamic loads were applied to the same direction in the simulator as they are in vivo. The “arms” of the cups were relieved, ensuring that the internal geometry of the cups was not altered.

Initial studies to determine the sensitivity of the simulator and the repeatability of the data were performed prior to this study. The sensitivity was assessed by measuring the friction of a low-friction, ceramic-on-ceramic hip bearing. To examine, the repeatability, a conventional metal-on-UHMWPE hip implant was tested a total of three times. Results from these investigations are shown in section 3.1.
7.2.4 Lubricants

Measurements of friction factors of the components were undertaken when the acetabular cups were fully lubricated using aqueous carboxymethyl cellulose (CMC) solutions (BHD, UK) with a range of viscosities from 0.001 – 0.18 Pa s, with distilled water providing the viscosity of 0.001 Pa s. The joints were also tested using 100% bovine calf serum (BCS) (Sigma Aldrich, Ireland) and a 25% BCS, 75% deionised water and a 0.2wt% of sodium azide preservative. The CMC fluids were compared with the tests using BCS as the lubricant to assess the effects of proteins on the lubrication of these joints. To prevent damage to the joint, the highest viscosities were tested first. The measurements with the lower range of viscosities were then completed. The joints were cleaned thoroughly between tests by removing any surplus lubricant and then wiped down with isopropanol. An estimation of the lubricating film thickness, $h_{\text{min}}$, in the metal-on-metal implants can be obtained using the Hamrock and Dowson formula as shown on the next page:

$$
\frac{h_{\text{min}}}{R} = 2.798 \left( \frac{\eta \mu}{E' R} \right)^{0.65} \left( \frac{L}{E' R^2} \right)^{-0.21}
$$

where $E'$ is the equivalent elastic modulus of the material pairing given by:
The predicted minimum film thickness, together with the recorded values of $R_{q1}$ and $R_{q2}$, the average root mean square roughness of the head and the cup respectively, were used to predict the lambda ratio and therefore lubrication regimes acting within the joints [29].

$$\lambda = \frac{h_{\text{min}}}{\left((R_q^1)^2 + (R_q^2)^2\right)^{1/2}}$$

It has been shown that a lambda ratio value of greater than 3 indicates fluid-film lubrication; a value below 1 indicates that boundary lubrication prevails and a value between 1 and 3 indicates that the bearing is operating in a mixed lubrication regime [30].

7.3 Results and Discussion

7.3.1 Strubeck assessment of (a) ceramic-on-ceramic and (b) conventional metal-on-UHMWPE, hip implants of 28mm diameter.

The Strubeck plots for these hip joints are shown in Figure 7.2. Figure 7.3 illustrates the repeated friction testing results (x3) using the conventional implant, with each test representing the average Strubeck curves having tested the joint twice in each lubricant. A slight increasing trend, whereby the friction increased with increasing Sommerfeld number was observed in the Strubeck plot for the all-ceramic implant tested with CMC fluids, (linear correlation value 0.71). The average friction factor was remarkably low (0.0015), and this have been the lowest friction measured using this simulator. A distinctive decreasing trend, (linear correlation value -0.96), was seen in the Strubeck plot for the conventional joint with CMC fluids, indicative of a mixed lubrication regime. The results found here are similar to results found by others [18, 31-33]. With these levels of friction and distinctive Strubeck plots, it is evident that the friction simulator is capable of defining lubrication regimes. Excellent repeatability of the simulator is clearly demonstrated in Figure 7.3, with only very minor variations in friction factor results between the three tests.
Figure 7.2: Strubeck plots for (a) ceramic-on-ceramic and (b) conventional metal-on-UHMWPE, hip implants of 28 mm nominal diameter, tested with CMC fluids, showing correlation lines and standard deviations.

Figure 7.3: Strubeck plots for conventional metal-on-UHMWPE hip implant tested three times using CMC fluids only. Standard deviations are indicated.
7.3.2  Stribeck Assessment of Metal-on-Metal Large Diameter Hip Bearings

The Stribeck plots for the metal-on-metal hip resurfacing implants are shown in Figure 7.4. No apparent trends (decrease/increase in friction factor with increase in Sommerfeld number) were seen for any of the joints, and the friction factors produced were relatively high ranging from 0.25-0.11. These friction factors are similar to those found by Williams et al. [34], Cipera et al. [17] and Brockett et al. [3] who each assumed a mixed lubrication regime. Compared with results from a 28mm metal-on-metal implant as found by Scholes [18], these friction factors are notably lower, indicating improved lubrication. The mode of lubrication in this study was therefore likely to be mixed lubrication, in which the load is carried in part by the contact between the asperities of the bearing surfaces and also by the pressure generated within the lubricant. The severity of direct metal-to-metal contact was evident from the visible scratching present on both the acetabular and femoral components, in the direction of motion, at the polar contact, Figure 7.5 and 7.6.

![Stribeck Plots: Metal-on-Metal Hip Resurfacing Systems](image)

**Figure 7.4:** Stribeck plots for the metal-on-metal hip resurfacing systems of 58, 52, 48, 42 and 38 mm nominal diameter, tested with CMC fluids, distilled water and solutions of BCS. Separators are used to distinguish between lubricants of different make-up. Standard deviations are shown.
Figure 7.5: Visible scratching on CoCr femoral head of 58mm nominal diameter with the direction of articulation indicated.

![Image of visible scratching on CoCr femoral head]

$Ra = 0.06\mu m$, $Rsk = -1.999$, $PV = 2.339\mu m$, $Valley = -1.40\mu m$, $Peak = 0.94\mu m$

Figure 7.6: Surface topography of a typical CoCr femoral head of 58mm nominal diameter showing scratching in the articulation direction.

$Ra = 0.06\mu m$, $Rsk = -1.999$, $PV = 2.339\mu m$, $Valley = -1.40\mu m$, $Peak = 0.94\mu m$

It has been reported that friction testing of worn components after the running-in period has shown improved lubrication. Unsworth et al. [20] have shown the progression from boundary lubrication to mixed lubrication and then to full fluid film lubrication as running-in progressed in a 50mm diameter metal-on-metal hip resurfacing replacement. They also observed that although the composite roughness of the surface did not change much during running-in, the skewness changed from positive to negative over the first three million cycles indicating that the peaks had been smoothed and the valleys deepened. For the samples tested in this study, it would be expected that if their tribological conditions became more favourable (at
steady state), then an increased proportion of the applied load would be carried by fluid film action rather than asperity contact. For comparative purposes, the mean friction factor values generated by each bearing diameter, tested with CMC fluids, and solution of BCS are shown in Figure 7.7. The mean friction factors in CMC fluids were 0.136 (± 0.023), 0.143 (± 0.022), 0.192 (± 0.017), 0.214 (± 0.015), and 0.191 (± 0.022), for the 58, 52, 48, 42, and 38 mm diameter bearings respectively. While the larger bearings exhibited slightly lower friction factors, the differences are negligible, therefore a similar friction factor for each diameter bearing was assumed. This influence of bearing diameter on tribology appears to correlate well with a study done by Wimmer et al. who also obtained a similar friction factor for metal-on-metal bearings with different diameters. As only a limited number of joints were available a statistical evaluation of friction results could not be performed, but it is considered that the results found with the samples tested provide a good indication of this system’s friction and lubrication properties. Additional samples were beyond this project’s expenditure limit.

![Metal-on-Metal Hip Resurfacing Systems](image)

**Figure 7.7:** Friction factor values with standard deviations for the metal-on-metal hip resurfacing systems of 58, 52, 48, 42 and 38 mm nominal diameter, tested with CMC fluids, distilled water and solutions of BCS.
It is evident from Figure 7.7 that the addition of proteins in the form of BCS had a significant decreasing effect on the friction factors and this phenomenon has been found by other workers [3, 35, 36]. It is possible that proteins in the biological serum adhere to the surface of the metal bearings, for example it has been shown [37] in pin-on-disc testing that most worn surfaces, notably UHMWPE and metal, have a residual albumin coating. These adsorbed proteins can act as solid phase lubrications and reduce the adhesive forces between the metal-on-metal contacts, hence reducing the friction. In the work reported here the presumed protein concentration, however, has little effect on the scale of friction factors produced, an observation which is consistent with an adsorption mechanism.

Theoretical analysis shown in Table 7.1, show that all the bearing diameters had a lambda ratio of greater than three, suggesting a fluid film lubrication regime. Although the theoretical analyses would suggest a fluid film lubrication regime for the joints, the experiments showed that they operated within the mixed mode of lubrication with some periods of effective lubrication.

<table>
<thead>
<tr>
<th>Bearing Diameter (mm)</th>
<th>Radial Clearance (mm)</th>
<th>Predicted minimum film thickness, $h_{min}$ (μm)</th>
<th>Lambda ratio, $\lambda$</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>0.075</td>
<td>0.087</td>
<td>$&gt;3$</td>
</tr>
<tr>
<td>52</td>
<td>0.072</td>
<td>0.084</td>
<td>$&gt;3$</td>
</tr>
<tr>
<td>48</td>
<td>0.062</td>
<td>0.072</td>
<td>$&gt;3$</td>
</tr>
<tr>
<td>42</td>
<td>0.057</td>
<td>0.066</td>
<td>$&gt;3$</td>
</tr>
<tr>
<td>38</td>
<td>0.050</td>
<td>0.058</td>
<td>$&gt;3$</td>
</tr>
</tbody>
</table>

7.3.3 Stribeck Assessment of Ceramic-on-CFR-PEEK Large Diameter Hip Bearings
The friction of alumina-on-CFR-PEEK hip systems of 38 and 42mm nominal diameter were examined using maximum loads of 1000 and 500N, and their resulting Stribeck plots are shown in Figure 7.8. The friction factors produced using both maximum loads were very similar, and surprisingly in some cases, the 500N load
yielded slightly higher values. A similar effect was reported in a study done by Scholes et al. [25].

![Graph](image)

**Figure 7.8:** Friction factor values and standard deviations for the alumina-on-CFR-PEEK hip systems of 42 & 38mm nominal diameter, tested with max. loads of 500 and 1000N. Separators are used to distinguish between lubricants of different make-up.

The Stribeck plots for each of the ceramic-on-CFR-PEEK joints (500N, max. load) are shown in Figure 7.9 and their mean friction factors are illustrated in Figure 7.10. Similar to the metal-on-metal hips, neither a rising nor a falling trend was observed in the Stribeck plots using CMC fluids and distilled water, with constant friction factors of about 0.217 generated by each bearing. These friction factors were significantly higher than those produced by the all-metal resurfacing hips and similar results were found by Scholes et al. [25] although a maximum load of 2800N was used in that study.

The influence of bearing size on friction could be seen when BCS solutions were employed as the test lubricants. An increase in the component’s nominal diameter resulted in lower friction factors values: 0.336 (±0.007), 0.314 (±0.005), 0.296 (±0.005) and 0.282 (±0.005) for the 38, 42, 52 and 60mm diameter respectively (using a 25% solution of BCS).
Figure 7.9: Striebeck plots for the alumina-on-CFR-PEEK hips of 60, 52, 42 and 38 mm nominal diameter, tested with CMC fluids, distilled water and solutions of BCS. Separators are used to distinguish between lubricants of different make-up. Standard deviations are shown.

Unlike the metal-on-metal hip systems, the addition of proteins resulted in an increase in friction, with friction factor values found in the range of 0.336-0.282 using BCS solutions. The effect of increasing friction with BCS has been reported in other material combinations, but most notably in all-ceramic hip joints [18] and it has been suggested [38] that this is because albumin is not absorbed onto alumina surfaces and does not therefore provide the continuous protecting film. In the case of the CFR-PEEK joints studied here consideration must also be given to the possibility if local heating denaturing the proteins [37]. These joints operated in a high friction regime, indicating the dissipation of large amounts of energy at the articulating surfaces. There are two possible outcomes from this, local heating or generation of new surfaces and debris by wear.
Figure 7.10: Friction factor values with standard deviations for the alumina-on-CFR-PEEK hips of 60, 52, 42 and 38 mm nominal diameter, tested with CMC fluids, distilled water and solutions of BCS.

These tests have revealed either boundary lubrication or severe mixed lubrication, close to boundary lubrication, regime for the alumina-on-CFR-PEEK joints. In addition, friction tests without any lubrication were attempted, but the resultant frictional torques were extremely high and over the limit of measurements of the machine, thus implying that during the lubricated experiments there was some hydrodynamic action which lowered the friction within the simulator’s limits.

The large clearances of these bearings (Table 7.2) are believed to be the fundamental cause of the very high frictional torques found in this study. Clearance is one of the main factors that influence wear and friction, as it implicates the amount and type of lubrication. Larger clearances reduce the contact area, resulting in a loss of effective lubrication and more rapid wear. The clearance of each bearing was too large and resulted in ‘spot contact’ whereas polar contact is preferred. The design and flexibility of this type of acetabular cup allows for easy modification of the clearance parameter. The minimum clearance that is required to ensure polar contact can be achieved by effectively pinching the arms of the acetabular cup.
Table 7.2: Geometrical parameters for ceramic-on-composite implants.

<table>
<thead>
<tr>
<th>Nominal diameter (mm)</th>
<th>Mean diametral clearance (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>0.80</td>
</tr>
<tr>
<td>52</td>
<td>0.86</td>
</tr>
<tr>
<td>42</td>
<td>0.87</td>
</tr>
<tr>
<td>38</td>
<td>0.91</td>
</tr>
</tbody>
</table>

7.4 Conclusions

In this study, the metal-on-metal joints have shown similar friction factors and illustrated mild mixed lubrication. Compared to a conventional size metal-on-metal joint of similar clearance, the larger bearings exhibited lower friction factors, illustrating improved lubrication. New unworn samples were tested for short periods, hence the influence of wear and wear-related geometric and surface changes were not considered. It is proposed that at steady state wear, these samples would operate with full fluid film lubrication. The level of friction factor encountered in this joint system depended on the lubricant; bovine calf serum had a decreasing effect on the friction of all bearings. This study found no correlation between theoretical predictions and the experimental data.

Tests on the alumina-on-CFR-PEEK coupling of different diameters revealed severe mixed lubrication, and this was probably due to the large diametral clearances of the bearings. It is possible that a reduction in friction and improved lubrication would be observed if the clearances were reduced. The design and flexibility of CFR-PEEK acetabular cup should allow for easy modification of its internal geometry, thus altering the bearing’s clearance. BCS fluids showed significantly higher friction factors than the CMC tests and this may be due to adsorbed proteins shearing. The size of the components had an effect on the magnitude of friction factors produced using BCS solutions. It was shown that the larger diameter bearing exhibited lower friction than the smaller diameter bearings.

The question of the role of the lubricants remains open. It is clear from the results presented here, and from the results of others for example [3, 28, 31, 35], that the material couple-lubricant relationship is important and warrants further investigation. The generation of adsorption isotherms for the various combinations
for example may be a helpful first step and could allow more informed speculation about provide further insight into the tribology micro-mechanisms.

NOTATION:

- $\text{E}'$ equivalent elastic modulus
- $E_1$ modulus of elasticity of femoral head component
- $E_2$ modulus of elasticity of the tibial insert
- $f$ friction factor
- $h_{\text{min}}$ minimum film thickness
- $L$ applied load
- $\eta$ lubricant viscosity
- $R$ reduced radius
- $R_1$ or $r$ radius of the femoral component
- $R_2$ radius of the tibial inserts
- $R_{\text{q1}}$ r.m.s roughness of femoral head component
- $R_{\text{q2}}$ r.m.s. roughness of acetabular cup
- $T$ frictional torque
- $u$ entraining velocity
- $\mu$ coefficient of friction
- $v_1$ Poisson’s ratio of the femoral head component
- $v_2$ Poisson’s ratio of the acetabular cup component
- $z$ Sommerfeld no.
- $\lambda$ Lambda ratio (surface separation ratio)

REFERENCES


Chapter 8

In Vitro Wear Performance of a Glenoid Component Using Compliant Layer Technology for use in Total Shoulder Arthroplasty

Abstract
Results from wear testing suggest that a compliant layer glenoid may be more robust compared to the conventional ultra-high molecular weight polyethylene (UHMWPE) glenoid. Impingement wear on the compliant layer surface was a frequent finding and was caused from repeated contact between the rim of the hemispherical humeral component and the articular surface of the glenoid, under a constant load. In an attempt to address this problem, a full ball humeral component was incorporated into the system. The absence of wear features suggest that this new system functioned well under a full fluid film lubrication regime.

8.1 Introduction
As part of a general investigation into the validity of compliant layer technology as a method of dealing with some of the challenges of orthopaedic device development a project was initiated to design a compliant layer glenoid system. An appropriate design was arrived at but not fully validated in that project. It was therefore considered appropriate to validate the wear performance of the developed compliant layer glenoid system as part of this work as it usefully incorporates many of the ideas being evaluated as part of this work.

In a total shoulder arthroplasty (TSA) both the articular surfaces of the glenohumeral joint are replaced to address problems such as such as debilitating pain or unacceptable loss of function of the shoulder caused by disease or trauma. Similar to total hip arthroplasty (THA) and total knee arthroplasty (TKA), conventional TSA surgery today generally incorporates a hard metal or ceramic humeral head component articulating against an ultra-high molecular weight polyethylene (UHMWPE) glenoid component. In general this joint type is effective in reducing or removing pain and restoring function to the shoulder by restoring strength and movement, however time in service affects the continued effectiveness of the
procedure and survivorship in the best of cases is over 85% at 15 years [1]. Glenoid loosening is noted as the major reason for failure of this joint type [2-6] and is caused by a combination of factors such as joint instability and wear to the UHMWPE components. Loss of active stabilisation of the joint can increase the amount of translation of the humeral head on the glenoid and the resultant intermittent loading can lead to rocking of the glenoid component and subsequent loosening [2]. Polyethylene wear debris has been widely accepted as the principle cause of osteolysis leading to aseptic loosening in THA and TKA and this association has been reported in TSA as part of a clinical series [3, 4], as part of a study of negative outcomes [5], as part of studies examining retrievals [6-8], and as part of studies examining wear debris [9, 10]. Retrieval studies showed a combination of abrasive and fatigue wear mechanisms at work, and the damage modes were similar to those seen in knee components i.e. scratching, abrasion, pitting, delamination, deformation, embedded wear debris and burnishing.

Compliant layer joints are designed to operate in a similar way to the natural synovial joint in that they incorporate a ‘compliant’ soft layer as the bearing surface, thus promoting the joint to enjoy full fluid film lubrication using both elastohydrodynamic lubrication (EHL) and microelastohydrodynamic lubrication (μEHL) [11]. Laboratory studies [15-19] and animal trials [12-14] have indicated that with good design and material selection, hip and knee prostheses incorporating compliant layer technology, can show superior friction and wear characteristics than the standard metal against UHMWPE systems. Compared with the hip or knee, the glenohumeral joint is subject to lower intermittent stresses, higher velocities and longer stroke lengths making it even more conducive to lubrication. To that end, Geary [15] designed and developed a novel compliant layer glenoid component employing two grades of Bionate® polycarbonate-urethanes of shore hardness 80A and 75D (Figure 8.1). As illustrated in Figure 8.1, components were produced using a two-part injection moulding process whereby the hard bearing (75D) was moulded first and then used as an insert with the softer layer (80A) over-moulded. Figure 8.2 shows an actual component which has been implanted in a shoulder replica. A full description can be found elsewhere [15-17].
It is postulated that this compliant layer glenoid component will exhibit low wear in addition to improving joint stability. In the study by Geary [15], the loosening and stability performance of this particular joint system was evaluated using a purpose built fixture based on biaxial test apparatus recommended in ASTM F2028-05 [18]. Superior stability and resistance to loosening over the standard UHMWPE glenoid was demonstrated. Some limited wear testing was also carried out in that study and while results appear promising, a full assessment was not available. The purpose of this study therefore was to evaluate fully the in vitro wear performance of this compliant glenoid layer system, as an example of the practical application of compliant layer technology in a joint designed ab initio for its utilisation.
8.2 Materials and Methods

8.2.1 Components

The wear characteristics of compliant layer glenoid components designed by Geary and manufactured by Stryker Orthopaedics, Limerick, were assessed against standard 44mm diameter CoCrMo humeral heads (Stryker Cat. No. 6949-2-442). The glenoid employed two grades of polycarbonate-urethane (Bionate® 80A and 75D - DSM PTG Inc., California) and had a bearing surface diameter of 48mm. A 2mm radial mismatch is employed as standard on these Stryker components. Before testing, each glenoid was sterilised by a minimum of 25kGy gamma irradiation in nitrogen atmosphere, before being conditioned by immersion in distilled water for twelve weeks to ensure equilibrium fluid absorption before testing.

8.2.2 Wear testing

Wear testing was carried out on a single station wear simulator (Figure 8.3) which was built in a joint collaboration between the University of Limerick and University College Dublin [19]. The wear simulator was validated by Geary [15] by comparing the wear of standard UHMWPE glenoid (Stryker Cat. No. 6949-3-044) and humeral (Stryker Cat. No. 6949-2-442) components with clinical retrievals.

![Figure 8.3: Shoulder wear simulator.](image-url)
A schematic of the key components of the shoulder wear simulator is provided in Figure 8.4 and a detailed description can be found in Chapter 3 of this thesis. A complete humeral prosthesis, head and stem, was mounted upside-down onto the upright swinging cradle with the humeral head positioned at the point of cross section of the two rotational axes of the simulator. Glenoid components were mounted into polyurethane foam blocks and these blocks were press fitted into the glenoid holder. Three mutually perpendicular linear bearings allowed the glenoid holder to translate freely on three axes, thus allowing the glenoid component to engage the femoral head. The space between the humeral and glenoid components was sealed using a rubber gaitor thus creating a flexible test chamber and ensuring that the contact surfaces were completely immersed in the test lubricant. The lubricant used was 30% bovine calf serum (Sigma Aldrich Ireland Ltd.), 70% deionised water and a 0.1wt% sodium azide preservative. This was maintained at 37±2°C and circulated continuously into the test chamber using a peristaltic pump. While all motion was carried out through the humeral head, forces were applied to the glenoid holder using pneumatic actuators, supplied through programmable valves. Each joint was tested for at least 1x10⁶ cycles at approximately 0.8 Hz and was cycled from 50-120° abduction - adduction with 25-60° internal - external rotation. This simulated arm abduction in the scapular plane. The joint was loaded to 750N in the medial direction and a 150N load was applied in the superior direction to simulate subluxation of the humerus, as is often reported in revision TSA [20]. Wear of the components was analysed every 0.5 million cycles and the lubricant was replaced.

**Figure 8.4:** Schematic of key components of the shoulder wear simulator.
8.2.3 Wear Analysis Methods
Gravimetric wear analysis i.e. the change in weight of the component after wear testing is equal to the amount of wear, was not employed in this study. Weight gain of compliant layer bearings has been reported previously [15, 21-23] and it is thought that the hydrophilic nature of polyurethanes contributed to this phenomenon. Instead, wear of the glenoid components was assessed qualitatively by visual inspection and quantitatively by penetration depth, surface profilometry and using shadowgraph measurements of change in curvature. Digital photography (Nikon D40) and Scanning Electron Microscopy (SEM) were used to record visible wear patterns. Data acquisition from the three sensors mounted onto the glenoid holder recorded the kinematic interaction of the glenoid with the reciprocating humeral component, and in particular data from the medial-lateral sensor allowed the penetration depth of the humeral component into the glenoid component to be estimated. Non-contact profilometry was carried out using a Zygo NewView 100 scanning white-light interferometer to measure the surface topography of the glenoid components, while contact profilometry (Form Talysurf Series, Taylor-Hobson) was employed for the humeral components. Silicone replicas were taken of the glenoid bearing surface using RepTech Moldsil and a shadowgraph was used to measure geometrical changes in component diameter.

8.3 Results and Discussion
Four compliant layer glenoid components (sample aliases: 1, 2, 3 and 4) were examined under the conditions described and their performances are outlined below. Because of a misalignment in the articulation system, sample 1 was discontinued after approximately 0.85 million cycles (Mc). The remainder samples were tested to 1 Mc.

8.3.1 Macroscopic Observations
Digital photographs showing a selection of the glenoid components taken before and following wear testing can be seen in Figure 8.5. Impingement wear of the compliant layer was a frequent finding in components 2, 3 and 4, and is thought to be as a direct result of contact between the hard-edged portion of the humeral head and the polymer surface. Visual examination after 0.5 Mc revealed that this region of contact was almost instantly affected by the stress and thermal conditions arising at the contact points due to sliding. It is believed that significant frictional heating occurred and as
illustrated from the DMTA studies in Chapter 4, a slight rise in temperature can change the mechanical properties of the polymer. Friction heat generated at the interface due to abrasive forces along with other processes such as creep caused loss of dimension from plastic deformation in this contact zone. Plowing material was displaced to the side resulting in the formation of grooves but there was no removal of material evident (Figure 8.5b). Encouragingly, despite this abnormal wear condition, the integrity of the compliant layer was not compromised and the articular surfaces as a whole were in excellent condition suggesting there was good joint function over the testing period and a mild mixed (close to fluid film) lubrication regime governed.

In contrast, glenoid sample 1 revealed severe abrasive subsurface wear, whereby damage to the glenoid was far deeper into the material than only at the surface (Figure 8.5a). This damage and loss of material was caused through an unforeseen misalignment in the bearing system circa 0.75 Mc. At this point, excessive movement of the joint was witnessed which consequently caused the simulator to shut down, owing to an over-torque of the cradle during swinging. Before this point however, it is thought the joint may have operated with a mild mixed lubrication regime and visual examination at 0.5 Mc revealed wear features similar to the other components. Following that, the rate of removal of material was very quick and therefore suggests that a boundary lubrication regime governed at that time. The results highlight how conformity i.e. the interrelationship of the humeral head articular surface to the glenoid, is essential and this has ramifications for wear.

The findings cited here are comparable to the results found by Geary [15], who too reported impingements or “ripples” of varying depths, in the compliant bearing surface which were attributed to point contact between the rim of the hemispherical humeral head and the compliant bearing. A possible solution to this problem of wear was to use a rounded ball as an alternative humeral head component. Two sets of this type of articulation system (sample aliases A and B) featuring a “full” CoCr ball with a diameter of 44mm (MITCH TRH™ manufactured by Finsbury orthopaedics exclusively for Stryker) were tested under the same conditions. As no physical degradation of the glenoid surface was observed after 0.5 and 1 Mc, the components were tested for a further 1 Mc. The resultant articular surfaces were in excellent condition after 2 Mc suggesting improved conformity between prosthetic components. It was therefore assumed that these joints operated with a full fluid film lubrication regime, whereby the bearing surfaces were separated by the test lubricant.
Chapter 8

[A] Component 1: post-wear 0.85Mc

[B] Component 3: post-wear 1Mc

[C] Component: pre-wear

[D] Component A: post-wear 2Mc

Figure 8.5: Digital photographs of complaint layer glenoids.
No significant humeral component damage was seen, with the polished surface preserved throughout wear testing, except for sample 1 where scratching and gouging (abrasive wear) were present.

### 8.3.2 Microscopic Observations

Typical examples of SEM surface images taken prior to testing are shown in Figure 8.6. These are the as-moulded surfaces and show few defects. Representative images for glenoid components 2, 3 and 4 and images of glenoid component 1, following wear testing, are shown in Figures 8.7 and 8.8 respectively. Figure 8.7 [a] and [b] reveal slight polishing of the compliant layer surface in the low load-bearing regions since many of the asperities, apparent on the unused glenoid surface, appear to be flattened or no longer present. A similar effect was observed by Flannery et al. [24] in a study examining the wear performance of compliant layer tibial inserts for use in TKA. In the high load-bearing region (Figure 8.7 [c]-[f]), lengthy grooves caused by humeral edge impingement were observed in the direction of sliding. Dragging of the material and thermal effects due to interfacial fiction energy dissipation are also evident. In comparison, microscopic examination revealed severe damage to the surface of component 1 as shown in Figure 8.8 [a]-[d]. Deep and wide scratches, displaced or transferred material, and third body gouge features indicate both abrasive and adhesive wear mechanisms.

Representative SEM images for glenoid components A and B are shown in Figure 8.9. These images reveal no significant damage and show areas of the surface that have similar appearance to the pre-wear components. As-moulded asperities were still present over large areas of the surfaces, suggesting a fluid-film lubrication regime governed.

![Figure 8.6](image-url)

**Figure 8.6:** SEM images of the compliant layer surface prior to wear testing.
Figure 8.7: SEM images post-wear testing.
8.3.3 Sensor Feedback

As mentioned earlier, the glenoid holder has the ability to slide on three mutually perpendicular slides (Figure 8.10). This allows the glenoid to locate itself against the humeral head and also compensates for any small misalignments of the components.
Each axis is equipped with a sensor which observes the position of the glenoid holder and is controlled by custom-made software programmed under LabView FieldPoint real time. Feedback from the sensors was captured at various intervals throughout testing and the data retrieved was converted to displacement which specifies the change in position of the glenoid in reference to a previous position (i.e. the difference between the initial position and the final position). Feedback from the sensors showing the change in position of the glenoids over time is presented in Figure 8.11.

Figure 8.10: Movement of glenoid holder on three axes.
(ML= Medial lateral, AP= Anterior Posterior, SI= Superior Inferior)

The notable jumps in the displacement plots at 0.5 million cycles are as a result of component removal and remounting. Apart from these variable shifts, the results in general illustrate that the components ran smoothly with minor variation. This is best appreciated by the sharp spikes observed in the displacement plots for sample 1. This point in the cycle corresponds to the accidental shift in the glenoid component’s position and as mentioned earlier, this misalignment between the articulating components lead to excessive rocking of the joint and severe wear damage to the complaint layer surface.
Figure 8.11: Average displacement plots for compliant glenoids.
Figure 8.11 (continued): Average displacement plots for compliant glenoids.
The M-L displacement is a measure of the penetration of the humeral head into the glenoid component and rate of penetration can be estimated from the slope of the displacement average vs. cycles plot. For best results, the penetration rate was estimated from two sequential runs (every 0.5Mc) and the data is shown in Table 8.1.

<table>
<thead>
<tr>
<th>Glenoid Component</th>
<th>Average Penetration Rate (mm/Mc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.88 *</td>
</tr>
<tr>
<td>2</td>
<td>0.29 ± 0.09</td>
</tr>
<tr>
<td>3</td>
<td>0.48 ± 0.62</td>
</tr>
<tr>
<td>4</td>
<td>0.65 ± 0.13</td>
</tr>
<tr>
<td>A</td>
<td>0.57 ± 0.07</td>
</tr>
<tr>
<td>B</td>
<td>0.50 ± 0.15</td>
</tr>
</tbody>
</table>

* estimated from the entire M-L curve.

Since each component exhibited minimal wear (with the exception of sample 1), the penetration rates highlight the ability of the compliant Bionate® 80A layer to deform and thus improve conformity between the joint components. This is an important feature as it permits the joint to enjoy fluid film lubrication using both elastohydrodynamic lubrication (EHL) and microelastohydrodynamic lubrication (μEHL). In the study by Geary [15], an average penetration rate of 0.16-0.35 mm/Mc and 0.12mm/Mc was found for the UHMWPE and compliant layer glenoids respectively. Putting these rates side by side Geary suggested that the wear performance of the compliant layer design compared favourably to the “gold standard” UHMWPE glenoid. However while this may be true, no reference was made to the creep response of these bearing materials. Deformation of the bearing surfaces under load would have seemed to be a likely factor for the extent of penetration of the humeral component into the bearing surface. Furthermore it was also suggested in that study [15], that the penetration rate of the polyethylene glenoid correlated with wear depth measurements estimated by both Swieszkowski et al.[25]
of 0.2mm/year using 3D contact analysis, and Hopkins et al. [26] of 0.3mm/Mc using finite element modelling. However, wear depth and penetration rate measurements are separate entities and therefore cannot be compared. Wear depth implicates removal of material (i.e. wear), whereas penetration rate implicates gross deformation and recoverable creep.

8.3.4 Surface Profilometry

Non-contacting profilometry was carried out before and after wear testing to observe on a microscale, surface roughness and topographical features present on the glenoid components. A 20x magnification lens was used, set at 0.5x zoom and gave a field view of ~550µm x 750µm. Eight measurements with z-axis accuracy of ±5nm were made at random points on the wear surface and were averaged for each component. Measurements were made at random points in the wear areas with some emphasis on specific areas exhibiting more macroscopic wear post-wear testing.

The average surface roughness (Ra) data are shown in Figure 8.11 and Figure 8.12 shows some of the typical surface topographical maps. In general, there was varied agreement between the Ra results and the observed wear as described earlier. In the areas of impingement wear, the surface displayed a textured or grooved surface large enough to be perceived by the unaided eye. Surface topography results indicated an increase in Ra at these areas. Similarly, at areas where there was no evidence of macroscopic wear, no surface topographical changes were reported. However, the strength of association between the surface roughness and the wear of glenoid component 1 was poor. The roughness parameters were unable to describe the damaging features of the surface adequately. Furthermore, areas with substantial wear marks were not possible to view on the Zygo NewView 100 due to the lack of reflectivity of the surfaces and the apparent high PV values of the damaged surfaces. This demonstrates that this surface characterisation technique should be coupled with SEM or other visualisation techniques.

The humeral components showed similar surface roughness values both before and after the wear test with the exception of component 1. These are shown in Table 8.2.
Table 8.2: Average surface roughness for the humeral components.

<table>
<thead>
<tr>
<th>Stage in wear test</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>0.0140</td>
<td>0.0163</td>
<td>0.0176</td>
<td>0.0192</td>
<td>0.0140</td>
<td>0.0161</td>
</tr>
<tr>
<td>After</td>
<td>0.1466</td>
<td>0.0247</td>
<td>0.0339</td>
<td>0.0283</td>
<td>0.0197</td>
<td>0.0239</td>
</tr>
</tbody>
</table>

Figure 8.12: The average surface roughness (Ra), measured before and after wear testing of the compliant layer glenoid components. Eight measurements were made on the wear surface and the average is plotted with standard deviations illustrated as Y-error bars.
Figure 8.13: Selection of surface topography plots representative of the following areas: (a) pre-wear, (b) low wear (visual analysis showed no surface damage), (c) & (d) impingement wear.
8.3.4 Shadowgraph Measurements

Silicone replicas were taken of the glenoid bearing surfaces at various intervals using RepTech Moldsil and a shadowgraph was used to measure changes in component diameter, the results of which are presented in Figure 8.14. The results show the deformation of the components caused by implantation, as a special clamping device was used to flex the pegs of the glenoid in order to locate them in the prepared holes of the foam (Figure 8.15). It has been proposed that this method of fixation should allow ease of implantation in vivo [27] and while it resulted in a slight change in the curvature of the samples, damage to the compliant layer surface was prevented and any deformation which occurred was recovered by 0.5 million cycles. It can be assumed from Figure 8.14 (and from creep studies of Bionate® materials in Chapter 4) that the amount of permanent deformation of the glenoid components after wear testing was negligible. The premise of a compliant layer shoulder joint is the same as for the hip and knee joint whereby a low elastic modulus layer has the potential to deform and increase the contact area, and as a result contact stresses are reduced and fluid film thickness is increased. The results reported in this study provide further evidence that the complaint layer deformed during simulation, thus improving joint conformity and promoting fluid film lubrication.

![Change in Glenoid Curvature](image)

**Figure 8.14:** Shadowgraph results of compliant layer glenoid components.
8.4 Conclusions

The wear performance of a compliant layer glenoid system for use in TSA was evaluated in this study. This particular joint system was designed *ab initio* by Geary *et al.* [15-17] to use compliant bearing technology and was not a modification of an existing design. The behaviour of a bearing material is greatly dependent on the surface of the material, surface contact area and the environment under which the material must operate. The results from visual and surface profilometry analysis, revealed impingement wear of the compliant layer after 1Mc, caused by repeated contact between the rim of the humeral component and the glenoid surface, under a constant load. This is an example of two body abrasion where asperities of the harder surface press into the softer surface, with plastic flow of the softer surface occurring around the harder asperities. Despite this, there was no removal of material and the integrity of the compliant layer surface was not compromised. Results obtained from the displacement sensors outputs and shadowgraph studies, confirmed the ability of the compliant layer to deform and increase the contact area between the prosthetic components. Conformity is the interrelationship of the humeral head articular surface to the glenoid, and is an important concept with ramifications for both wear and loosening. Poor conformity observed in sample 1 (due to misalignment of the articular components) lead to severe abrasive and adhesive wear of the glenoid component. In an attempt to improve conformity and eliminate the factor which leads to impingement wear, a full CoCr ball was substituted for the hemispherical humeral component. Results from wear testing examining this joint combination revealed a more conforming system with no macroscopic evidence of deformation of the compliant layer material after 2Mc. The evidence suggests that these joints operated close to full-fluid film lubrication providing exceptional low wear. Conventional
metal-on-UHMWPE shoulder joints tested under similar condition and on the same simulator [15] showed inferior wear performance. It would therefore appear that this compliant layer glenoid system may be an excellent option for shoulder replacement.

While it was desirable to measure the friction in this glenoid system in this study, it was not possible to do so using the friction simulator at the University of Limerick, as the humeral head cannot be fitted within the swinging cradle of the test machine.

REFERENCES

Chapter 9

In Vitro Friction and Lubrication of Vitamin E- Blended Polyurethanes for use in Compliant Layer Prostheses

Abstract
Orthopaedic implants made of compliant polycarbonate-urethane materials are being investigated in this thesis, as an alternative bearing solution in hip, knee and shoulder replacements. Polycarbonate-urethanes are widely used in the medical device industry because of their combination of outstanding physical properties and in vivo biostability and biocompatibility. However it is now thought that this class of polyurethanes may be vulnerable to some oxidation if not stabilised. It is postulated that the mechanism of chemical degradation involves oxidative attack on the polycarbonate urethane soft segment due to the reactive oxygen species released from adherent macrophages and foreign body giant cells. It is therefore necessary to stabilise polycarbonate-urethane against oxidation. Synthetic antioxidants are often satisfactory; however, particularly for biomedical applications, it is of interest to use the natural antioxidant Vitamin E (α-tocopherol). However seeing as these implants are designed to operate with low friction and enhanced lubrication, it is necessary to examine the effect of this additive on their friction and lubrication properties. Vitamin E was blended to the polycarbonate-urethanes at 1% by weight and acetabular components with and without Vitamin E were tested in vitro using a friction simulator (against a metallic coupling). It was found that the addition of Vitamin E had no effect on friction and it was postulated therefore, that these joints will retain their frictional and lubrication properties in vivo.

9.1 Introduction
This study uses a friction simulator to examine the effect of Vitamin E on the frictional characteristics of compliant layer bearings. Bionate®, (commercial polycarbonate-urethanes, The Polymer Technology Group, Inc.) with Shore hardness 75D and 80A comprise the compliant layer components being investigated in this thesis for hip, knee and shoulder replacement implants Bionate® is formed with a
MDI (4, 4’- methylene biphenyl diisocyanate) hard segment, chain extended with BDO (1, 4- butanediol) and a PHEC (1, 6-hexyl 1, 2-ethyl carbonate) soft segment. The structure of Bionate® 80A is shown in Figure 9.1 [1]. While the carbonate linkages adjacent to hydrocarbon groups give this class of polyurethane improved oxidative stability compared to polyester and polyether urethanes, Bionate® may be vulnerable to some in vivo oxidation if not stabilised. Data from several in vitro and early in vivo studies examining the biostability and biocompatibility of polycarbonate urethanes are available and are summarised in the following section.

![Polycarbonate urethane, Bionate® 80A](image)

**Figure 9.1:** Chemical structures of Bionate® 80A [1].

A comprehensive four year sheep hip study by Khan *et al* [2] using a two-layer Bionate® acetabular cup showed that the “Bionate® 80A functioned well with the bearing surfaces of the retrieved hip cups showing no significant evidence of biodegradation or wear damage”. Christenson *et al.* [3] reported evidence of surface degradation of polycarbonate urethane rods that were explanted from rabbits after 15 months in vivo. In a follow up in vitro study, [4] they examined polycarbonate-urethane films treated with an oxidative solution that mimicked the microenvironment at the adherent cell-material interface. Results from their cage implant studies and cell culture experiments indicated that “monocytes, adhere, differentiate to macrophages and fuse to form foreign body giant cells on the polycarbonate-urethane”. More recently, case reports from a human clinical study of a 10.5 and 12 month retrieved polycarbonate urethane cups with shore hardness 80A (TriboFit system manufactured by Active Implants Corp, Memphis, Tennessee) are available after revision surgeries were performed for “pain of unknown origin” [5, 6]. Histology and synovial fluid analysis “found sparse evidence of particulate debris and no synovitis” and overall it was reported that “the surgical findings, data, and images collected were encouraging and similar to those found in sheep [7]” and “confirmed
the preclinically determined low wear articulation and biocompatibility of polycarbonate-urethane as a weight bearing material”.

While the findings in the aforementioned studies [2-7] provide mostly compelling evidence for the biostability of polycarbonate-urethanes, with detection of degradation reported in most case as ‘minimal’, the hypothesis that this class of material is susceptible to oxidation by adherent cells warrants considerable investigation. A possible mechanism of chemical degradation involving oxidative attack on the polycarbonate-urethane soft segment is depicted in Figure 9.2 [4].

**Figure 9.2:** Oxidative mechanism of soft segment degradation [4].

The straight chain hydrocarbon compounds in the soft segment can be considered to be a simple paraffinic hydrocarbon and is therefore susceptible to oxidation. It is thought that oxygen radicals abstract an α-methylene hydrogen atom (α position relative to the oxygen) and form a chain radical. A portion of the chain radicals combine with other chain radical resulting in crosslinking while combination of the chain radical with a hydroxyl radical forms a hemiacetal, followed by chain scission and formation of alcohol and aldehyde end groups. The overall result is a reduction in the polymer’s mechanical properties as caused by the solubilisation and extraction of low-molecular-weight degradation products. For that reason stabilisation of the soft segment against *in vivo* oxidation is of interest.
Oxidative mechanisms of degradation can be inhibited by additives (antioxidants) that capture free radicals that would otherwise cause polyurethane chain scission and crosslinking. The antioxidants conventionally used in biomedical polyurethanes are synthetic compounds such as Santowhite® and Irganox®. These hindered phenolic antioxidants have been shown to be effective at inhibiting polyether-urethane biodegradation and stress cracking [8] and later found similar success for polycarbonate-urethane [3, 4]. Synthetic antioxidants, however, may not be appropriate for biomedical applications - for example, if they sacrifice biocompatibility when too concentrated [9] or if their oxidative degradation products have undesirable toxicology effects. Therefore, to avoid possible deficiencies of synthetic antioxidants, use of a biological hindered phenol antioxidant, Vitamin E (α-tocopherol), has been proposed as its transformation products are known and safe [10-12] and it is already ‘Generally Recognised As a Safe’ (GRAS) substance by the FDA. During the past decade, there has been an explosion of interest in the development of Vitamin E as an antioxidant for medical grade UHMWPE and active commercialisation of Vitamin E in UHMWPE soon followed. E-Poly HXLPE (Biomet, Inc.) was given FDA clearance for clinical use in total hip replacements in 2007 and in total knee replacements in 2008 [13]. This material has been reported to be oxidatively stable, although clinical results are not yet available [13]. The addition of Vitamin E in polyurethanes, however, has not been as extensively studied and to the knowledge of the author, there are no reports examining polycarbonate-urethanes/Vitamin E to date. Schubert et al. and Anderson et al. [14, 15] analysed the influence of Vitamin E on polyether-urethane urea’s biostability in an in vivo cage implant system and it was concluded that the antioxidant properties of Vitamin E prevented oxidation and enhanced biostability of the polymer.

![Chemical structure of α-tocopherol, Vitamin E. (Chromanol rings with hydroxyl groups can donate a hydrogen atom to reduce free radicals i.e. interception of the oxidation radical chain process).](image)

**Figure 9.3:** Chemical structure of α-tocopherol, Vitamin E. (Chromanol rings with hydroxyl groups can donate a hydrogen atom to reduce free radicals i.e. interception of the oxidation radical chain process).
The premise of Polycarbonate-urethane/Vitamin E is to improve in vivo oxidation stability. As the compliant layer implants in this study are designed specifically to operate with low friction and fluid film lubrication, it is important that any addition to the polymer does not change this property. This study therefore, uses a friction simulator to determine and compare the tribological properties of a metal-on-compliant layer polycarbonate-urethane with and without Vitamin E in a total hip replacement system. The objective here is not to study oxidation in Bionate® per se; rather it is to examine the effect of an established bio-acceptable antioxidant on the friction characteristics of the material. Compatibility of polymer additives is always an important question. Some additives, for example anti-static agents, are designed to bloom to the surface for maximum effect. Others, for example most stabilizers, are designed to be homogenously dispersed throughout the material. If the stabilisers bloom to the surface it is possible that this may have consequences for the frictional characteristics. There is no published information on the compatibility of Vitamin E in polyurethanes and so an investigation into the stabilised compounded materials surface properties is appropriate.

9.2 Materials and Methods
9.2.1 Components
Polycarbonate-urethane acetabular cups of 32mm diameter (Stryker Orthopaedics), with and without Vitamin E, were tested against a Cobalt Chrome (CoCr) femoral component. The α-tocopherol form of Vitamin E was added at 1% by weight to Bionate® and was thermally blended prior to consolidation. Before testing the acetabular components were conditioned by immersing in distilled water to ensure equilibrium fluid absorption. Furthermore, in order to investigate the effect of radiation on acetabular components containing Vitamin E, one component was sterilised by 25kGrays gamma-ray irradiation in an inert nitrogen atmosphere prior to testing.

Much of the work described in this chapter was dependent upon the supply of materials and samples from an industrial source (Stryker Orthopaedics) and are part of that companies ongoing proprietary research effort. In consequence of this, confidentiality issues limited the amount of information available at the time of testing.
9.2.2 Friction Testing

The friction of the bearing combinations was examined using a TE89 friction simulator. Like previous testing, the simulator subjected the femoral head to a simple harmonic oscillatory motion with a stroke of ±24° in the flexion/extension plane at a frequency of 0.8Hz. A dynamic load of 2000N and 200N was applied. Aqueous solutions of CMC (viscosity range 0.001 – 0.018 Pa s), distilled water and a 25% BCS solution were employed as the test lubricants.

9.2.3 X-ray Photoelectron Spectroscopy

The surface elemental conditions of polycarbonate-urethane with and without Vitamin E were analysed using highly sensitive X-ray photoelectron spectroscopy (XPS). The XPS spectra were obtained using an XPS spectrophotometer (AXIS 165) with a 15kV Mg-Kα radiation source at the anode. Further equipment details can be found in Appendix F.

9.3 Results and Discussion

9.3.1 Striebeck Assessment

Figure 9.4 shows the Striebeck curves for the metal-on-polycarbonate-urethane, metal-on-polycarbonate urethane containing antioxidant Vitamin E, and metal-on-polycarbonate-urethane containing Vitamin E after gamma-ray irradiation. Separators are used to distinguish between lubricants of different make-up. There was little difference between the results and no apparent trends (decrease/increase in friction factor with increase in Sommerfeld number) were seen. The friction factors produced were extremely low (range 0.01-0.001 using CMC fluids) and were much lower that that for a conventional UHMWPE joint. They were similar, however, to results for a 28mm ceramic-on-ceramic hip joint tested in an earlier study (Chapter 5) using the same friction simulator and operating conditions (results from this study are shown in Figure 9.5). Other researchers who established that this all-ceramic joint operates under fluid film lubrication conditions, have reported similar friction factors [16, 17].

Frictional measurements of a metal-on-polycarbonate-urethane hip joint of 28mm diameter were carried out in a previous study (Chapter 5) and after experimental testing and theoretical calculations, it was concluded that “a minor increase in the bearing radius of this joint would result in higher entraining velocities and therefore the transition from mixed to full fluid film lubrication would occur”.

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Data from this current study confirmed this statement; the friction factors produced for the 32mm hip were slightly lower than those obtained for the 28mm hip (0.007-0.013 for CMC/distilled water, and 0.033 for BCS). This indicates improved lubrication in the 32mm versus 28mm diameter compliant layer joints, i.e. the joints in this study operated within a full fluid film lubrication regime.

Again, as seen with previous testing, the scale of friction depended on whether synthetic CMC fluid or biological BCS was employed as the test lubrication, whereby an increase in friction was found when BCS was used.

**Figure 9.4**: Striebeck plots for the metal-on-polycarbonate urethane hips, with and without antioxidant, tested with CMC fluids, distilled water and 25% solution of BCS. Separators are used to distinguish between lubricants of different makeup. Standard deviations are indicated.
Figure 9.5: Stribeck plots for the 32mm metal-on-polycarbonate urethane hips, with and without antioxidant, and a 28mm ceramic-on-ceramic hip, tested with CMC fluids, distilled water and 25% solution of BCS. Separators are used to distinguish between lubricants of different makeup. Standard deviations are indicated.

9.3.2 XPS Analysis

The elemental composition of the samples was revealed by high resolution XPS spectra from the surfaces. This test procedure is destructive to the samples. Because of the small numbers of samples available from the industrial source, some samples were precluded (i.e. acetabular components prior to friction testing). Nevertheless it was possible to obtain some useful comparative data and this is detailed in the following sections.

Elemental compositions of the polycarbonate-urethane acetabular components with and without antioxidant Vitamin E, after friction testing, are shown in Table 9.1. There was a significant difference in the data; the total oxygen decreased and total carbon increased at the surface of the sample without Vitamin E. Antioxidants do not eliminate oxygen from a polymer system; rather they redirect reactions within the material towards directions that do result in loss of material properties. Thus it may be possible that higher surface oxygen content observed here is consistent with the
action of a chain breaking antioxidant forming non-damaging oxidised products. A substantial increase in the C 1s peak corresponding to C-O, C-OH (~286.5eV) and the related O1s peaks for C-O-C (532eV) and Ph-OH (533.8eV) suggest the presence of an antioxidant (Ph = benzene ring).

**Table 9.1:** Surface elemental composition (%) of Polycarbonate-urethane acetabular cups with and without Vitamin E after friction testing.

<table>
<thead>
<tr>
<th>Name</th>
<th>Polycarbonate-urethane acetabular cup (after friction)</th>
<th>Polycarbonate-urethane with Vitamin E acetabular cup (after friction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Position</td>
<td>% Conc.</td>
</tr>
<tr>
<td>O 1s</td>
<td>532.0</td>
<td>18.1</td>
</tr>
<tr>
<td>N 1s</td>
<td>400.1</td>
<td>1.2</td>
</tr>
<tr>
<td>C 1s</td>
<td>284.8</td>
<td>80.6</td>
</tr>
<tr>
<td>O 1s_1</td>
<td>532.0</td>
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<tr>
<td>O 1s_2</td>
<td>533.7</td>
<td>4.4</td>
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<tr>
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</tr>
<tr>
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</tr>
<tr>
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</tr>
<tr>
<td>C 1s_4</td>
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<td>2.2</td>
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<tr>
<td>C 1s_5</td>
<td>289.0</td>
<td>1.7</td>
</tr>
<tr>
<td>C 1s_6</td>
<td>290.4</td>
<td>2.3</td>
</tr>
</tbody>
</table>

The XPS survey scans can be found in Appendix D (I & II).

The nitrogen levels increased on the surface of the polycarbonate urethane sample containing Vitamin E. As nitrogen is only present in the hard segment, this raises the possibility that hard segment concentration has increased on the surface due to segmental rearrangement of the polyurethanes chains. (It is also possible that small amounts of protein on the surface of friction tested specimens may have contributed to the increased content on the surface of these materials, albumin found in BCS contains nitrogen).

There is some silicate contamination in both samples which can contribute to the O1s peaks appearing at 532-533 eV. The presence of silicone on the surface of Bionate 55D has been reported in a study by Simmons *et al.* [18], which they related to the moulding process during manufacturing.
For comparison, XPS analysis was also performed on a sample of Bionate® 80A, cut from an injected moulded plaque which was manufactured under processing conditions that closely correspond to those which would be used for the production of the acetabular components. Table 9.2 summarises the surface elemental composition of this ‘non-friction tested’ sample.

**Table 9.2:** Surface elemental composition (%) of Bionate 80A (polycarbonate-urethane) before friction testing. XPS survey scans in Appendix G (I & II).

<table>
<thead>
<tr>
<th>Name</th>
<th>Bionate® 80A injection moulded plaque (Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Position</td>
</tr>
<tr>
<td>O 1s</td>
<td>532.2</td>
</tr>
<tr>
<td>N 1s</td>
<td>399.9</td>
</tr>
<tr>
<td>C 1s</td>
<td>284.8</td>
</tr>
<tr>
<td>O 1s_1</td>
<td>532.2</td>
</tr>
<tr>
<td>O 1s_2</td>
<td>533.7</td>
</tr>
<tr>
<td>C 1s_1</td>
<td>284.7</td>
</tr>
<tr>
<td>C 1s_2</td>
<td>285.4</td>
</tr>
<tr>
<td>C 1s_3</td>
<td>286.6</td>
</tr>
<tr>
<td>C 1s_4</td>
<td>288.1</td>
</tr>
<tr>
<td>C 1s_5</td>
<td>289.1</td>
</tr>
<tr>
<td>C 1s_6</td>
<td>290.5</td>
</tr>
</tbody>
</table>

The data indicated similar carbon, oxygen and nitrogen compositions for the control - as moulded, and Vitamin E - after friction, samples.

### 9.4 Conclusions

In summary, the rationale behind stabilising the residual free radicals in polycarbonate-urethane compliant bearings with antioxidant Vitamin E (α-tocopherol) is to provide long term oxidation resistance without sacrificing the low frictional properties of this joint type. In this study the *in vitro* friction and lubrication properties of compliant layer bearings blended with Vitamin E were examined. Furthermore, the effect of gamma-ray irradiation on components blended with Vitamin E was investigated. It was shown that the addition of the antioxidant had no effect on the frictional properties. All the joints gave low friction with no comparable
differences in the range of friction factors produced. It was established that these joints operated within a full fluid film lubrication regime. While it is not yet clear how much the longevity of Vitamin E-blended polyurethane implants will be improved clinically, based on this information attained from this study it is postulated that these joints will retain their frictional and lubrication properties in vivo.

REFERENCES


Chapter 10

In Vitro Friction and Lubrication of Artificial Hip Joints with Poly(2-methacryloyloxyethyl phosphorylcholine) Grafted Polyethylene

Abstract
Stryker Orthopaedic, have developed the X3® advanced bearing technology, which is the first highly crosslinked polyethylene that is sequentially irradiated annealed (i.e. the temperature is kept below the melt point following irradiation). This means it does not need to be "re-melted" and thus, the polyethylene is not weakened, which increases the wear resistance of the material while maintaining its strength. While Stryker’s X3® is now available for implantation, other important strategies, such as surface modification techniques using newly designed polymeric materials, are being developed to further improve the wear resistance and biocompatibility of the implant. One of the most effective polymers for this is a phospholipid polymer, 2-methacryloyloxyethyl phosphorylcholine (MPC).

The study detailed here used a friction simulator to assess the friction and lubrication properties of X3® acetabular cups, with and without surface grafting with MPC. The friction studies showed that both the unmodified- and grafted MPC-X3® components tested against a metallic and polymer counterpart operated with mixed lubrication with higher friction factors found when the polymer femoral head was used. It was also demonstrated that MPC grafting on the polyethylene liner increased the friction regardless of the difference in femoral head materials. It was postulated that the phospholipids acted as boundary lubricants within a mixed lubrication regime.

While both systems operated with mixed lubrication, it is thought that development of this technique could improve the in vivo performance and longevity of this joint replacement.

10.1 Introduction
This study uses a friction simulator to examine the effect of MPC grafting on the friction characteristics of highly crosslinked polyethylene. As a material for
prostheses, polyethylene has been the key to the success of total joint replacements since it was first used by Sir John Charnley (1961). However, as mentioned frequently throughout this thesis, the production of UHMWPE debris at the articulating surfaces of joint replacements plays a central role in initiating osteolysis and as a result, research efforts have focused increasingly on improving the performance of UHMWPE.

During the late 1990s, it was realised that irradiation above the typical sterilisation dose range of 25 to 40kGy could substantially improve the wear performance of UHMWPE [1]. Irradiation causes the radiolytic scission of the molecular chains by cleavage of the C-C and C-H bonds, generating radicals within the material. In the amorphous region, the mobility of the free radicals is higher than in the crystalline region and they can recombine (leading to crosslinking, branching and the formation of double bonds), stabilise or react with either incoming oxygen or oxygen that is already present [2]. Hip joint simulator studies indicated more than 90% reduction in wear for a dose of 100kGy [3] (doses higher than 100kGy offered diminished returns in terms of additional wear reduction).

The disadvantage of irradiation is material degradation through an oxidative process (interaction between the free radicals in the material and the surrounding oxygen); the result of which is polyethylene embrittlement which jeopardized the assumption of wear reduction. To control subsequent oxidation of the material, changes in the material production based on temperature were devised. In the ‘first-generation’ of commercial crosslinked polyethylenes, the residual free radicals after crosslinking by irradiation were originally controlled by different thermal treatments.

These stabilisation methods can be classified into two groups, depending on whether the stabilisation temperature falls below (annealing) or above (remelting) the melt-transition temperature of the polymer, which is around 137°C. Heating above the melting temperature destroys the crystalline regions of the material thus making the free radicals that were in the crystals available for crosslinking. The disadvantage of melting is the reduction in crystal size and in material yield and ultimate strength that ensues. A compromise solution is to heat the material to just below the melting temperature. This solution preserves the original crystal structure, retains mechanical properties, and makes more free radicals available for crosslinking than would be available without thermal treatment while still retaining some free radicals in the crystal domains. Typically annealing is carried out at 130°C.
As both methods introduce changes in the microstructure particularity in the crystalline content and lamellar size (more pronounced after remelting than annealing), this generates negative effects on the capability of the polymer to absorb energy before fracture (toughness) and even on fatigue resistance. Thus, recent research efforts have been placed on securing a better post-treatment that would permit the elimination of free radicals while maintaining key mechanical properties. Attempts have been made to develop ‘second-generation’ highly crosslinked UHMWPE, addressing in particular the use of sequential annealing steps where each step includes an irradiation process at 30kGy followed by annealing at 130°C for 8 hours. This method maintains the suitable mechanical properties observed in annealed highly crosslinked polyethylenes while improving the oxidative resistance by a free radical reduction in each cycle. The X3® advanced bearing technology (Stryker Orthopaedics), is the first highly crosslinked polyethylene that is sequentially irradiated annealed (process has three sequential irradiation/annealing steps to help saturate free radicals has been released). Stryker Orthopaedics report that their X3® bearing technology is the first highly crosslinked polyethylene to offer 1) structural fatigue strength better than conventional polyethylene, 2) 97 per cent wear reduction over conventional PE; greater than first-generation highly crosslinked polyethylene and 3) oxidation resistance similar to virgin UHMWPE [4-7]. Clinical studies for use of X3® in both the hip and knee [8] are underway but clinical results are not yet available. A retrieval study [9] conducted by Kurtz et al. is the first study to report an analysis of retrieved X3® liners. They examined whether or not highly crosslinked UHMWPE formulations, including X3® sequentially annealed UHMWPE would have lower oxidation and oxidation potential than historical gamma-air and conventional gamma-insert sterilized liners. Elevated rim oxidation was not observed in the X3® group with oxidation and hydroperoxide levels being significantly lower. They concluded that the X3® liners had zero-to-low levels of oxidation following their brief in vivo period [9].

While much work has been done to characterise the wear properties of highly crosslinked UHMWPE implants, much work still remains to be done to characterise their friction properties, and to the knowledge of the author there are no published studies to date. The first aim of this study, therefore, was to investigate the friction and lubrication properties of ‘new’, un-implanted, 32mm diameter X3® acetabular implants against metal and polyether-ether-ketone (PEEK) femoral heads, using a
friction simulator. Results from this study can be combined with wear data to complete a full tribological assessment of these joint types.

Innovations and developments in the field of highly crosslinked UHMWPE are still far from over. While sequential annealing is now available for implantation, other important strategies are being developed such as the addition of oxygen scavengers—mainly Vitamin E [10]. Surface modifications are being investigated using different ion implantation techniques with N, He, C + H, C + H + Ar, or diamond like coating (DLC) in an attempt to obtain harder and more resistance surfaces [2]. Another nanoscale modification uses photo-induced polymerisation of radicals to graft 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer onto the polyethylene surface and this system is evaluated in this work.

Ishihara et al. (inspired by the natural phospholipids of biomembranes) have recently developed a novel artificial joint system with MPC polymer grafted onto the surface of cross-linked polyethylene aiming to reduce wear and avoid bone resorption (Figure 10.1) [11]. MPC is a methacrylate monomer that has a phospholipid polar side group in a side chain and can be a good polymer biomaterial owing to reduction of protein absorption and cell adhesion [12]. MPC grafting onto the surface of medical devices has already been shown to suppress biological reactions even when they are in contact with living organisms, and is now clinically used on the surfaces of intravascular stents, intravascular guide wires, soft contact lenses and the oxygenator (artificial lung) under the authorisation of the FDA of the United States [11, 13-16].

**Figure 10.1:** MPC is bound to the PE liner by the covalent bond with a photoinduced graft polymerisation technique [11].
Mechanical studies by Ishihara *et al.* [11, 17-20] revealed that MPC grafting on polyethylene liners dramatically decreased the amount of wear compared to untreated liners (tests were performed on a hip joint wear simulator under conditions recommended by ISO standards). Also, from these studies, they reported a significant decrease in friction with MPC grafting. However, the coefficient of friction was measured using a ball-on-plate machine with a load of 0.98N, and a tensile test device; experimental methods that do not simulate the loading and motion of a hip *in vivo*. The second purpose of this study, therefore, was to investigate the *in vitro* friction and lubrication properties of X₃® acetabular components surface grafted with MPC (MPC_X₃), using a friction simulator that closely matches the *in vivo* loading and motion cycles.

### 10.2 Materials and Methods

Much of the work described in this chapter was dependent upon the supply of materials and samples from an industrial source (Stryker Orthopaedics) and are part of that companies ongoing proprietary research effort. In consequence of this, not all combinations of tests and samples types were tested. Confidentiality issues also limited the amount of information that was available at the time of testing. Some of the test procedures used were destructive to the samples supplied and again because of the small numbers of samples available, some combinations of test procedures were precluded. Nevertheless it was possible to obtain some useful comparative data and this is detailed in the ensuing pages.

#### 10.2.1 Components

Highly crosslinked polyethylene acetabular cups of 32mm diameter (X₃®, Stryker Orthopaedics), with and without nano-grafting of MPC onto the articulating surface (MPC_X₃) were examined against CoCr and PEEK femoral heads. Worn components of MPC_X₃ (after 2x 10⁶ cycles in a hip wear simulator) were also examined. Medical devices are normally sterilised prior to implantation and in particular gamma-ray irradiation is the method typically used for the UHMWPE components of artificial joints. Therefore, in order to investigate the effect of this radiation, a MPC_X₃ component was sterilised by 25kGrays gamma-ray irradiation in an inert nitrogen atmosphere prior to testing.
MPC was industrially synthesised using the method by Ishihara et al. [21] and the photo-induced graft polymerisation on the X3® surface (50 - 100 nm thick) was carried out with an ultraviolet irradiation of 5mW/cm² at 60°C for 90 minutes using a filter to pass only ultraviolet light with a wavelength of 350 ± 50nm (Stryker Orthopaedics, Mahwah, NJ, USA). This technique grafts MPC directly onto the crosslinked polyethylene, forming C-C covalent bonds between the polyethylene and the MPC polymer.

### 10.2.2 Friction Testing
The friction of the bearing combinations was examined using a TE89 friction simulator. Like previous testing, the simulator subjected the femoral head to a simple harmonic oscillatory motion with a stroke of ±24° in the flexion/extension plane at a frequency of 0.8Hz. A dynamic load of 2000N and 200N was applied. Aqueous solutions of CMC (viscosity range 0.001 – 0.018 Pa s), distilled water and a 25% BCS solution were employed as the test lubricants.

### 10.2.3 X-ray Photoelectron Spectroscopy
The surface elemental conditions of X3 before and after MPC grafting were analysed using highly sensitive X-ray photoelectron spectroscopy (XPS). The XPS spectra were obtained using an XPS spectrophotometer (AXIS 165) with a 15kV Mg-Kα radiation source at the anode. Samples were examined before and after friction testing. Further equipment details can be found in Appendix F.

### 10.2.4 Scanning Electron Microscope - Energy Dispersive X-ray Spectroscopy (SEM-EDS)
The surface and cross-section of the acetabular components were observed using a scanning electron microscope (SEM, Hitachi SU-70) and analysed (composition measured) using energy dispersive X-ray spectroscopy (EDS, Oxford Instruments).

### 10.3 Results and Discussion
#### 10.3.1 Stribeck Assessment of CoCr-on-X3 and PEEK-on-X3
The Stribeck plots for these hip joints are shown in Figure 10.2. There was a significant difference between the results for the two different femoral head materials with the friction factors for the metal head being lower than those with the PEEK
head. The reduction in friction with the metal counterface may be due to better surface finish of the metallic surface. This is in agreement with work done by Flannery [22] and Scholes [23] when examining the friction of PEEK-on-UHMWPE knee implant.

The level of friction factors produced for both joints are indicative of a mixed lubrication regime however it is thought that an increased portion of the load in the PEEK-on-X3 joint was carried asperity contact rather than fluid film. The friction factors produced for the metal-on-X3 are very comparable to that of the conventional metal-on-UHMWPE 28mm diameter hip joint tested in Chapter 5 (0.02-0.036 for CMC, 0.037 for distilled water, 0.044 for BCS). Similarly, the level of friction factor encountered in both material combinations depended on whether CMC fluids or BCS was used as the lubricant, with an increase in friction factor found when BCS was used due to proteins being sheared.

**Figure 10.2:** Stribeck plots for new and unworn metal and PEEK - on - X3, tested with CMC fluids, distilled water and 25% solution of BCS. Separators are used to distinguish between lubricants of different makeup. Standard deviations are indicated.

### 10.3.2 Stribeck Assessment of MPC grafting on X3®

The Stribeck plots for the grafted MPC_X3 tested against CoCr and PEEK femoral heads are shown in Figure 10.3 (for comparison, results from the untreated X3®
implant systems are plotted on the same figure). Unlike the studies by Ishihara et al., [11, 18, 19] MPC grafting was shown to cause an increase in friction for joints tested; the increase being more pronounced with the PEEK counterpart.

Because phospholipids themselves are known to work as effective boundary lubricants [24, 25] this increase in friction was likely to have arisen from the layer that is formed by MPC grafting. In the study by Moro et al. [11] the friction coefficients using a tensile test device on the MPC-polyethylene plate were about one seventh of those on the non-grafted polyethylene plate. From the other studies using a ball-on-plate machine [18, 19], lower friction with MPC grafting was also demonstrated (tests were carried out under a constant load of 0.98N, unlike a physiological loading cycle, and with a sliding distance of 25mm). These studies supposedly provided evidence that MPC grafting on polyethylene greatly increases lubricity. However, it is thought that the low friction resulting from these experiments would be destroyed by features which are present in a hip joint friction simulator i.e. motion- which involves some relative rotation rather than purely sliding, closely conforming surfaces and bearing pressure. Ball-on-plate, similar to pin-on-disk, is essentially a materials tribology test used to screen materials rather than whole total hip replacement systems.

Figure 10.3: Striebeck plots for new and unworn metal and PEEK -on- X3 (with and without MPC surface grating), tested with CMC fluids, distilled water and 25% solution of BCS. Separators are used to distinguish between lubricants of different makeup. Standard deviations are indicated.
Although the MPC grafted X3® cups exhibited slight higher friction than the untreated X3® components, both sets operated with a mixed lubrication regime. Because these joints operate in the mixed lubrication regime wear will occur at the contacting asperities.

10.3.3 Strieber Assessment of MPC grafting on X3®, (effect of wear testing and gamma irradiation)

Strieber analyses were performed on two worn and one irradiated (new) X3® cups with MPC surface modification (tested against CoCr femoral heads) and the Strieber plots are shown in Figure 10.4.

![Figure 10.4](image)

**Figure 10.4:** Strieber plots for new, irradiated and worn metal-on-X3 with and without MPC surface grafting, tested with CMC fluids, distilled water and 25% solution of BCS. Separators are used to distinguish between lubricants of different makeup. Standard deviations are indicated.

There was very little difference between the results for the MPC_X3 components post wear testing for 2 million cycles. The magnitudes of the friction factors produced by both joints are indicative of a mixed lubrication regime and are lower than those for the new (unworn) samples. As the worn components were free of scratches and surface damage, it was expected that more of the load was carried by the fluid film
due to flattening of surface asperities; whereas, normally the majority of the friction produced at the bearing surfaces is due to shearing of the polyethylene component asperities.

The gamma-ray sterilised MPC_X3 cup exhibited lower friction than the non-sterilised component. It is possible that energy from the gamma-ray irradiation may have had a damaging effect on the MPC layer and therefore friction factors similar to those found for the metal-on-X3 without MPC surface grafting are expected. The results as seen in Figure 10.4 seem to suggest this. As mentioned in the introduction, gamma-ray sterilisation is known to influence the properties of UHMWPE components (severs the C-C and C-H bonds and then produces crosslinking) and it has been reported that gamma-ray sterilised UHMWPE sometimes exhibits improved wear resistance due to the formation of many cross-links. Several investigators have also reported that wear resistance is better in gamma-ray sterilised UHMWPE than in ethylene oxide sterilised UHMWPE [26-28].

10.3.4 XPS Analysis
Table 10.1 summarizes the elemental compositions of the untreated X3® and MPC grafted X3® surfaces prior to friction testing. In the case of the untreated X3® surface, a strong intensity at 284.8 eV was observed. This is attributed to carbon atoms in the methylene chain. A small peak at 532.2 eV was also observed. This peak is attributed to oxygen atoms and may come from oxidation or contamination of the polyethylene surface. After MPC grafting on the X3® surface, the XPS dramatically changed. In the carbon atom region, XPS peaks at 286.4 eV and 288.7 eV were observed on the MPC-X3 surface. These peaks are attributed to the ether bond (-C-O-C-) and carbonyl group, respectively. XPS peaks near 400 eV were attributed to the nitrogen atom. Moreover, phosphorous peaks observed at 133.2 eV and 134.2 eV were attributed to the phosphorylcholine group in the MPC units. These results can confirm successful photoinduced graft polymerisation of MPC on highly crosslinked polyethylene, X3®.
Table 10.1: Surface elemental composition (%) of X3 and MPC_X3 samples before friction testing.

<table>
<thead>
<tr>
<th>Name</th>
<th>X3 (before friction)</th>
<th>MPC_X3 (before friction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Position (eV)</td>
<td>% Conc.</td>
</tr>
<tr>
<td>O 1s</td>
<td>532.2</td>
<td>6.8</td>
</tr>
<tr>
<td>C 1s</td>
<td>284.8</td>
<td>91.7</td>
</tr>
<tr>
<td>N 1s</td>
<td>399.8</td>
<td>0.8</td>
</tr>
<tr>
<td>P 2p</td>
<td>133.3</td>
<td>2.5</td>
</tr>
</tbody>
</table>

The XPS survey scans can be found in Appendix H (I & II).

Table 10.2 summarises the elemental compositions of the untreated X3®, MPC grafted X3® and gamma-ray sterilised MPC grafted X3® surfaces, after friction testing. In the case of the untreated X3® surface, the valence spectra resemble that of characteristic polyethylene and the level of oxidation was found to be slightly higher after friction testing. The atomic concentration of nitrogen and phosphorous at similar binding energies as for MPC layer have decreased to ~ 0.1%, thus it can be assumed that most of MPC layer was removed as a result of friction testing.

In the case of the gamma-ray sterilised MPC grafted X3® surface, carbon is present as C-C/C-H corresponding to polyethylene. The results are similar to the untreated X3 cup before friction testing; the amount of oxidation and concentration of nitrogen and phosphorous specific to the phosphorylcholine group in MPC have decreased.

Table 10.2: Surface elemental composition (%) of X3, MPC_X3, MPC_X3 irradiated samples after friction testing.

<table>
<thead>
<tr>
<th>Name</th>
<th>X3 (after friction)</th>
<th>MPC_X3 (after friction)</th>
<th>MPC_X3 IRRADIATED (after friction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Position (eV)</td>
<td>% Conc.</td>
<td>Position (eV)</td>
</tr>
<tr>
<td>O 1s</td>
<td>532.2</td>
<td>10.6</td>
<td>532.2</td>
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<td>C 1s</td>
<td>284.8</td>
<td>88.0</td>
<td>284.7</td>
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<tr>
<td>N 1s</td>
<td>400.2</td>
<td>2.5</td>
<td>399.9</td>
</tr>
<tr>
<td>P 2p</td>
<td>131.5</td>
<td>0.1</td>
<td>131.5</td>
</tr>
</tbody>
</table>

The XPS survey scans can be found in Appendix H (I & II).
10.3.5 SEM-EDS Analysis

To investigate the presence and adhesion of the MPC layer on the surface of the polyethylene components, cross-sections of the MPC_X3 component before friction testing were examined using SEM (scanning electron microscope). An untreated X3® sample was also studied and served as a control. As evident from the SEM images in Figure 10.5, a MPC layer could not be clearly observed on the surface of the polyethylene substrate (B).

Figure 10.5: Cross-sectional SEM images of (A) untreated X3 and (B) MPC_X3

Using SEM-EDS (scanning electron microscope - energy dispersive x-ray spectroscopy), the experimental composition of the MPC_X3 specimen was determined. Nitrogen (atomic no. 7) was not detected, as EDS cannot detect the lightest elements, typically below the atomic number of Na which is 11. However phosphorous which has an atomic number of 15 was also not detected. The surface of the MPC_X3 sample, (i.e. MPC layer) was also analysed and the EDS spectrum is shown in Figure 10.6. Surprisingly no phosphorous was detected and results from this technique can not confirm successful grafting of MPC on X3®.
EDS is less sensitive than XPS. The penetration depth (interaction area) is also dependent on the accelerating voltage. The MPC layer was estimated to be approximately 50 - 100 nm thick was therefore not a problem for the XPS as it looks at the top 10 nm. The SEM though was operated between 5-7 kV and the polymer is low in density so a penetration depth of at least 0.5 - 1 μm was estimated. According to results from XPS there is only 3.5 atomic % of phosphorous. This might explain why a phosphorous peak is not observed as the signal in the SEM would be depleted further with over 90% of the EDS signal coming from the background that would have no phosphorous.

10.4 Conclusions

In this study the friction of commercially available highly crosslinked polyethylene X3® acetabular implants against a metal (CoCr) and a polymer (PEEK) counterpart were investigated. It was shown experimentally, using Stribeck assessment that these joints operated within a mixed lubrication regime and produced friction factors similar to a conventional metal-on-UHMWPE hip.

The effect of photo-induced graft polymerisation of biocompatible phospholipid polymer- MPC onto the X3® acetabular implant surface, with respect to friction, was also examined. Friction simulator studies revealed that the MPC grafting
slightly increased the friction. It was postulated that the phospholipids acted as boundary lubricants within a mixed lubrication regime.

Various factors such as type of bearing material, surface roughness, homogeneity of the surface and chemical composition affect the lubricity of an artificial joint. It was shown in this study that MPC grafted components after 2 million cycles in a wear simulator, markedly decreased the friction compared with new ‘unworn’ samples. This decrease in friction was attributed to an improvement in the component’s surface roughness i.e. asperities flattening- as a result of motion and loading. It was also shown that gamma-ray sterilisation of the MPC grafted X3® resulted in a decrease in friction, with similar friction factors obtained to those of the unmodified X3® implant.

Ishihara et al. [19] have reported results which are contrary to the observations made here, that is they see a slight increase in friction of MPC grafted polyethylene after gamma-ray irradiation whereas in this work a decrease in friction was observed after irradiation. Similarly Ishihara et al. [11, 17, 29] report a significant decrease in friction when the MPC coating is grafted whereas here an increase was observed. Several reasons can be put forward to explain these differences.

First, the procedure reported by Ishihara and co-workers to graft the MPC onto the polyethylene is questionable and proof of grafting appears to depend upon XPS evidence of phosphorous and nitrogen after washing the samples. If grafting has not occurred then it is possible that the MPC is simply functioning as a mobile lubricant. Ishihara proposes that one of the methods by which MPC works is by binding water, although Ishihara describes this as “free water” and the mechanism will apply regardless of whether the MPC is grafted or simply absorbed. Irradiation will result in structural degradation of the MPC regardless of its state of grafting or adsorption and so friction would be likely to increase. However a critical consideration is the load applied to the articulating surfaces. A high applied load could be expected to more rapidly remove a weakly adhering layer of MPC. This would lead to dispersion of MPC in the lubricant fluid with a consequence increase in friction as observed.

Because the joints in this study were shown to operate in the mixed lubrication regime, wear will occur at the contacting asperities. From the biological advantages shown in other studies [16, 30, 31], Moro et al. [11] believed that if particles were produced by friction, they would be biologically inert with respect to phagocytosis by macrophages and subsequent bone resorptive responses. However, this may not be
the case as the aforementioned studies [16, 30, 31] are related to coated coronary stents and not artificial joint systems.

Data from in vitro testing have confirmed the excellent wear properties of X3® [4-7, 32]. This, along with the excellent results from MPC grafted polyethylene wear studies [11, 14, 18-20] and the proven history of MPC polymer as a biomaterial means that development of this technique could improve the quality of care of patients having this type of joint replacement.

REFERENCES


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<th>Reference</th>
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Chapter 11

Conclusions and Recommendations for Future Work

11.1 Introduction
As outlined in the introduction, the aim of this project was to evaluate experimentally, new materials and designs being suggested as ways of improving artificial implants’ wear performance, longevity and proprioception. Presented in this chapter is a summary of the research work completed. First, a comprehensive review of literature was completed and included as Chapter 2; a short review of relevant literature was also presented at the beginning of each chapter. While individualised conclusions were made at the end of each result chapter, the main overall highlights of the thesis are summarized below.

11.1.1 Highlights of Thesis
Further knowledge was added to the field of compliant layer technology. A comprehensive database of Bionate® 80A and 75D, in terms of their creep performance and their mechanical properties relevant to orthopaedic device applications, was generated. This information was not previously available.

The friction performance of these materials using well established joint types was measured and compared to conventional hip and knee implants. Results from friction testing demonstrated that fluid film lubrication conditions, and ‘close-to’ fluid film lubrication conditions, were generated, with friction levels comparable to those of healthy human joints. For the most part, the bearing surfaces remaining separate from one another. Parallel work, investigating the addition of a polymer stabiliser, Vitamin E, showed that the low frictional properties of this joint type were not compromised. The wear performance of a compliant layer glenoid designed ab initio was established. Impingement wear, caused from repeated contact between the rim of the humeral head and articular surface of the glenoid, was the finding. The absence of wear features, when a full ball was employed as the humeral component, makes this a more appropriate system and further confirms the validity of the compliant bearing system.
The friction and lubrication properties of large diameter hip bearings were determined. To the knowledge of the author, there was no published information examining the effect of diameter on the frictional properties of ‘new and unworn’ hip implants, although there was a school of thought in the industry that larger bearings should give better frictional characteristics. The study demonstrated that the component’s diameter had little or no influence on the lubrication and friction of the large bearing combinations tested. The presumption that large diameter metal-on-metal hip bearings exhibit fluid film lubrication was also found to be invalid.

Friction studies revealed that MPC grafting on highly crosslinked polyethylene liners increased the amount of friction compared to untreated liners. This is contrary to results reported by other authors. A criticism of their studies is their method of friction assessment. ‘Ball-on-plate’ is essentially a tribology test used to screen materials and it is thought that the low friction observed by these workers is strongly associated with the method of assessment used and will not carry through into the more severe conditions of a real joint. It was concluded from this work, that the phospholipids acted as boundary lubricants within a mixed lubrication regime.

11.2 Future Work

The question of the role of the lubricants and the relationships between in vitro testing and in vivo performance remains open. It is clear from the results presented here and from the results of others, that the material couple-lubricant relationship is important and warrants further investigation. The generation of adsorption isotherms for the various combinations for example may be a helpful first step and could allow more informed speculation about provide further insight into the tribology micro-mechanisms, thus allowing the refinement of test procedures.

Additional creep experiments of polyurethane constructs of varying thicknesses would be of use for the development of improved designs in compliant layer technology. Furthermore, the relationship between dynamic and static creep warrants further investigation.

Knowledge in the public domain, regarding MPC coatings and Vitamin E stabilisers, for artificial joint implants remains in its infancy. Long-term wear testing of these systems is necessary. Also, as in the case of all joint implants, their clinical
performance and whether they will prolong the longevity of joint implants will be best determined by prospective clinical studies.

In compliant layer bearings, the interface between the two polyurethane materials is formed by fusion bonding, and is consequently an inherent weakness in the system. The weakness is most noticeable at the edges, as when the material is loaded and the soft layer deforms, the displaced materials exerts a shear force at the interface. Polyurethane is not porous, but can develop full fluid film lubrication if the conditions are correct. Structural modification to compliant bearing surfaces i.e. holes or channels in the surface, similar to Figure 11.1, could be investigated to determine whether these features can be used to modify lubrication retention and creep effects. The rationale is outlined below:

- In the contact area of the articulation, holes or channels may act as sumps to retain and release lubrication through the action of contact pressure and movement.
- In the peripheries of both acetabular cups and tibial inserts, such peripheral features could control the effects of creep resulting from loading of compliant, incompressible materials.
- The extent of creep could be reconciled with the voidage created by hole or channel inclusion.

Such a system would be biomimetic in that natural cartilage secretes lubricant under stress.

**Figure 11.1:** Laser drilled holes (periphery- 500μm, area of articulation- 300μm) in the surface of a compliant layer knee insert (medial and lateral components).

This design was presented at a workshop on ‘mathematical modelling in industrial problems’ (62nd European Study Group with Industry), held by MACSI (Mathematics Applications Consortium for Science and Industry) at the University of Limerick. The report produced from the study group is shown in Appendix I. Furthermore, preliminary laser trials were carried out in the National Centre for Laser Applications...
(NCLA), National University of Ireland, to establish the laser’s ability to work with Bionate® 80A, its efficiency and most importantly the quality of the hole fabricated. A selection of SEM and optical microscopic images of the fabricated holes are shown in Appendix J. It is hoped that this idea may be taken further as a refinement of compliant layer technology.

11.3 Publications


These papers can be found in Appendix K. A review paper based on Chapter 2 is also in preparation and will be submitted to ‘Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine’ when completed. It is the hope of the author, that widespread adoption of these results into the orthopaedic community, will aid joint development in the future.
### Bionate® Polycarbonate-Urethane: Material Data Sheet

<table>
<thead>
<tr>
<th>Property</th>
<th>Procedure</th>
<th>Bionate® PCU</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ASTM</td>
<td>80A 90A 55D 65D 75D</td>
</tr>
<tr>
<td>Colour</td>
<td>NA</td>
<td>Clear, colourless to slightly yellow</td>
</tr>
<tr>
<td>Hardness, Durometer</td>
<td>D-2240</td>
<td>83A 91A 56D 66D 73D</td>
</tr>
<tr>
<td>Density, g/cm³</td>
<td>D-792</td>
<td>1.19 1.2 1.21 1.22 1.22</td>
</tr>
<tr>
<td>Tear Strength, Die 'C', pli</td>
<td>D-624</td>
<td>370 550 780 NA 1350</td>
</tr>
<tr>
<td>Ultimate Tensile Strength (psi)</td>
<td>D1708</td>
<td>6765 7993 8782 9015 9171</td>
</tr>
<tr>
<td>Ultimate Elongation (%)</td>
<td>D1708</td>
<td>531 406 365 281 241</td>
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<tr>
<td>Tensile Stress at 50% (psi)</td>
<td>D1708</td>
<td>634 1159 1772 3683 5188</td>
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<td>100% (psi)</td>
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<td>871 1604 2467 4601 5825</td>
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<tr>
<td>300% (psi)</td>
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<td>2453 5345 6963 NA NA</td>
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<tr>
<td>Flexural Modulus, psi 1% Secant Modulus</td>
<td>D790</td>
<td>4160 6030 7000 NA 260,000</td>
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<tr>
<td>Flexural Stress, psi at 5% Deflection</td>
<td>D790</td>
<td>180 275 300 NA 10,200</td>
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<td>Water Absorption (%)</td>
<td>D-750</td>
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<td>Dielectric Strength (V/mil)</td>
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<tr>
<td>Dielectric Constant, k', 60 hz</td>
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<tr>
<td>Coefficient of Friction (Kinetic)</td>
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<td>1.52 NA 0.81 NA 0.64</td>
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<tr>
<td>Taber Abrasion, 1000g wt. Wear Index, mg/1000 cycles</td>
<td>D1044</td>
<td>5.7 9.1 7.4 NA 31</td>
</tr>
<tr>
<td>Vicat Softening Temp.</td>
<td>D-1525</td>
<td>78 88 98 NA 56</td>
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<tr>
<td>°C</td>
<td>173</td>
<td>190 208 NA 133</td>
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<tr>
<td>°F</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coefficient of Linear Thermal Expansion</td>
<td>E-831</td>
<td>160.2 160.7 137.1 NA 93.2</td>
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<td>x 10-6/°C</td>
<td>E-1545</td>
<td>89 89.3 76.2 NA 51.8</td>
</tr>
<tr>
<td>x 10-6/°F</td>
<td>D-1238</td>
<td>(1200g) (1200g) (2160g) (2160) (5000g)</td>
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<td>Approximate Melt Index g/10 min at 224°C</td>
<td>D-955</td>
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<td>1.2 1.2 1.2 NA 1.2</td>
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<tr>
<td>Flame Bar</td>
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<td>0-3.0 0-3.0 0.5-2.0 NA 0.5-2.0</td>
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<tr>
<td>Optimum Extrusion Conditions</td>
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<td>°F</td>
<td></td>
<td>410 410 428 428 190-232</td>
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<tr>
<td>°C</td>
<td></td>
<td>180- 180- 190- 190- 190-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>210 210 220 220</td>
</tr>
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</table>

*Note: Typical physical property values are not to be construed as sales specifications.*
Representative Biological Test Results
The scope of Bionate® PCU's tests-encapsulating Histology, Carcinogenicity, Biostability, and Tripartite Biocompatibility Guidance for Medical Devices-reassures medical device and implant manufacturers of the material's biocompatibility. Below is a representative summary.

<table>
<thead>
<tr>
<th>Biological test</th>
<th>Results</th>
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<tbody>
<tr>
<td>Ames Mutagenicity</td>
<td>Non-mutagenic</td>
</tr>
<tr>
<td>Chronic Toxicity: USP Muscle Implantation</td>
<td>Macroscopic reaction not significant</td>
</tr>
<tr>
<td>Compliment Activation</td>
<td>Less activation of the compliment system than ePTFE</td>
</tr>
<tr>
<td>USP Cytotoxicity (MEM Elution)</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>Non-hemolytic</td>
</tr>
<tr>
<td>Humoral Immunological Study</td>
<td>No humoral (serological) immune response</td>
</tr>
<tr>
<td>USP Pyrogenicity</td>
<td>Non-pyrogenic</td>
</tr>
<tr>
<td>Platelet Deposition (ex vivo shunt)</td>
<td>No difference in thrombogenicity when compared to ePTFE control</td>
</tr>
<tr>
<td>Sensitization: Magnusson and Kligman</td>
<td>No dermal sensitization</td>
</tr>
<tr>
<td>Acute Systemic Toxicity</td>
<td>No significant systemic toxicity</td>
</tr>
<tr>
<td>USP Implantation Test: 7 days in rabbits</td>
<td>Macroscopic reaction not significant</td>
</tr>
<tr>
<td>Intracutaneous Toxicity</td>
<td>No significant irritation or toxicity</td>
</tr>
<tr>
<td>Carcinogenicity: 2 years in rats</td>
<td>Non-carcinogenic</td>
</tr>
</tbody>
</table>
**Bionate® 80A: Certificate of Analysis**

**CERTIFICATE OF ANALYSIS**

To UNIVERSITY OF IRELAND GOODS INWARDS
ATTN: RECEIVING UNIVERSITY OF LIMERICK LIMERICK, IRELAND
PO Number: 6226459

<table>
<thead>
<tr>
<th>Lot Number</th>
<th>PTG Part Number</th>
<th>Qty. (lbs)</th>
<th>Description</th>
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<td>FP70063</td>
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<td>Bionate® 80A UR Thermoplastic Polycarbonate-urethane</td>
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<tr>
<th>Characteristic</th>
<th>Test Method</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness</td>
<td>QCT005</td>
<td>80 ± 5 A</td>
<td>84</td>
</tr>
<tr>
<td>Tensile Strength at Break</td>
<td>QCP043</td>
<td>≥ 5,000 psi</td>
<td>6,843</td>
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<tr>
<td>Weight Average Molecular Weight (Mw)</td>
<td>QCP039</td>
<td>≥ 200,000 Daltons</td>
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<td>Molecular Weight Distribution (Mw/Mn)</td>
<td>QCP039</td>
<td>2.0 ± 0.5</td>
<td>2.1</td>
</tr>
<tr>
<td>FT-IR Spectrum</td>
<td>QCP024</td>
<td>Conforms to Standard</td>
<td>Pass</td>
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</tbody>
</table>

Authorized Signature: Mimi Tran  
PTG Medical LLC  
Date: January 23, 2008
Bionate® 75D: Certificate of Analysis

CERTIFICATE OF ANALYSIS

To: UNIVERSITY OF IRELAND GOODS
   INWARD
   ATTN: RECEIVING
   UNIVERSITY OF LIMERICK
   LIMERICK, IRELAND
   PO Number: 6226459

<table>
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<th>Lot Number</th>
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<table>
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<th>Test Method</th>
<th>Specification</th>
<th>Result</th>
</tr>
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<tr>
<td>Hardness (Shore)</td>
<td>QCT005</td>
<td>75 ± 5 D</td>
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<tr>
<td>Tensile Strength at Break</td>
<td>QCP043</td>
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<td>Weight Average Molecular Weight (Mw)</td>
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<td>Molecular Weight Distribution</td>
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<tr>
<td>FT-IR Spectrum</td>
<td>QCP024</td>
<td>Conforms to Standard</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Authorized Signature: Mimi Tran  
Date: January 17, 2008
# Bovine Calf Serum: Certificate of Analysis

**Certificate of Analysis**

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Origin</td>
<td>United States</td>
<td>United States</td>
</tr>
<tr>
<td>Staphylococcus [staph]</td>
<td>None Detected</td>
<td>Pass</td>
</tr>
<tr>
<td>Bovine Cholera [bov]</td>
<td>None Detected</td>
<td>Pass</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>3.9 mg/ml</td>
<td>3.9 mg/ml</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>&gt; 20 mg/dL</td>
<td>&gt; 20 mg/dL</td>
</tr>
<tr>
<td>Appearance</td>
<td>Contains Clumping Agent</td>
<td>Pass</td>
</tr>
<tr>
<td>pH</td>
<td>7.2 - 7.4</td>
<td>7.2 - 7.4</td>
</tr>
<tr>
<td>Conductivity</td>
<td>240 - 350 mS/cm</td>
<td>300 mS/cm</td>
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</tbody>
</table>

**Certificate of Analysis**

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein Fraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bovine Factor X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&amp; Factor VIII</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor IX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor XII</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor XIII</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor V</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor VIII</td>
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</table>

**Certificate of Analysis**

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotting Tests</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Cell Culture</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Lipid Analysis</td>
<td>Pass</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Information**

- Lots are tested for the following seven proteins: Bovine Factor X, Factor VIII, Factor IX, Factor XII, Factor IX, Factor VIII, Factor XIII, Factor VII.
- All results meet or exceed Sigma's quality control standards.
- The certificate includes a complete list of all components and their concentrations.
- The certificate also includes a detailed description of the test methods used, ensuring the accuracy and reliability of the results.
Individual Strubeck Plots for the hip implants tested in Chapter 5.

**Ceramic-on-ceramic**

**Metal-on-UHMWPE**
Appendix E

Metal-on-compliant layer polyurethane

![Graph showing friction factor vs. Sommerfeld number for different tests](image)

- Test 1
- Test 2
- Test 3
XPS: Equipment Details

The Kratos AXIS 165 spectrometer was used for measurements with the following parameters:

Sample Temperature: 20-30 °C  
X-Ray Gun: 150 W (10 mA, 15kV), mono Al K$_\alpha$ 1486.58 eV  
Pass Energy: 160 eV for survey spectra and 20 eV for narrow regions  
Step: 1 eV (survey), 0.05 eV (regions)  
Dwell: 50ms (survey), 100 ms (regions)  
Sweeps: survey (3), narrow regions (5-20)  
Calibration: C 1s line of hydrocarbon (C-C/C-H) at a binding energy of 284.8 eV was used for charge reference  
Other: spectra were collected in the normal to the surface direction. XPS detection limit is estimated to be 0.1-0.5 at%.  
Data processing: Construction and peak fitting of synthetic peaks in narrow region spectra used a Shirely type background and the synthetic peaks were of a mixed Gaussian-Lorenzian type. Relative sensitivity factors used are from CasaXPS library containing Scofield cross-sections. RSF values used for individual peaks is given in the excel sheets.  
Sample preparation: Powder was dusted onto double sided adhesive tape for measurements
XPS Survey Scans - Chapter 9

1. PU After Friction Testing
2. Vitamin E Blended PU After Friction Testing

Survey_2/8

<table>
<thead>
<tr>
<th>Name</th>
<th>Pos</th>
<th>FWHM</th>
<th>Area</th>
<th>At%</th>
</tr>
</thead>
<tbody>
<tr>
<td>O 1s</td>
<td>532.42</td>
<td>3.240</td>
<td>3149.1</td>
<td>28.285</td>
</tr>
<tr>
<td>C 1s</td>
<td>284.42</td>
<td>3.090</td>
<td>2350.8</td>
<td>62.886</td>
</tr>
<tr>
<td>N 1s</td>
<td>399.42</td>
<td>2.520</td>
<td>1623.9</td>
<td>2.380</td>
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<td>Na 1s</td>
<td>1069.42</td>
<td>3.174</td>
<td>1096.8</td>
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<td>Si 2p</td>
<td>102.42</td>
<td>3.058</td>
<td>1655.6</td>
<td>5.345</td>
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<tr>
<td>Mg 2s</td>
<td>89.42</td>
<td>3.219</td>
<td>210.3</td>
<td>0.965</td>
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</table>

Binding Energy (eV)

CPS

Survey_2/8
3. PU 80A Before Friction Testing

<table>
<thead>
<tr>
<th>Name</th>
<th>Pos. (eV)</th>
<th>FWHM</th>
<th>Area</th>
<th>At%</th>
</tr>
</thead>
<tbody>
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<td>3.29</td>
<td>2957.0</td>
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<tr>
<td>C 1s</td>
<td>284.66</td>
<td>3.20</td>
<td>2458.4</td>
<td>63.53</td>
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<tr>
<td>N 1s</td>
<td>399.64</td>
<td>2.62</td>
<td>2600.7</td>
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<tr>
<td>Si 2p</td>
<td>101.46</td>
<td>2.75</td>
<td>2071.0</td>
<td>6.55</td>
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</tbody>
</table>

Survey_3/2
### Appendix G (II)

#### XPS Quantification of High Resolution Spectra - Chapter 9

**Sample 1: PU**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<th>R.S.F.</th>
<th>Area</th>
<th>% Conc.</th>
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<td>2.7</td>
<td>2.93</td>
<td>461.2</td>
<td>18.1</td>
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<td>N 1s</td>
<td>400.1</td>
<td>1.1</td>
<td>1.8</td>
<td>19.5</td>
<td>1.2</td>
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<tr>
<td>C 1s</td>
<td>284.8</td>
<td>1.1</td>
<td>1</td>
<td>700.7</td>
<td>80.6</td>
</tr>
</tbody>
</table>

N in Ph-N-CO2-

| O 1s   | 532.0    | 1.8  | 2.93   | 347.6 | 13.8    |
| O 1s   | 533.7    | 1.3  | 2.93   | 110.1 | 4.4     |
| C 1s   | 284.8    | 1.0  | 1      | 495.5 | 57.4    |
| C 1s   | 285.3    | 1.1  | 1      | 56.5  | 6.5     |
| C 1s   | 286.5    | 1.1  | 1      | 90.8  | 10.5    |
| C 1s   | 288.2    | 1.1  | 1      | 18.8  | 2.2     |
| C 1s   | 289.0    | 1.1  | 1      | 14.6  | 1.7     |
| C 1s   | 290.4    | 0.8  | 1      | 20.1  | 2.3     |

| O 1s   | 532.2    | 2.5  | 2.93   | 722.4 | 26.8    |
| N 1s   | 399.9    | 1.2  | 1.8    | 41    | 2.5     |
| C 1s   | 284.8    | 1.2  | 1      | 651.4 | 70.7    |
| O 1s   | 532.2    | 1.6  | 2.93   | 477.8 | 18.1    |
| O 1s   | 533.7    | 1.3  | 2.93   | 230.8 | 8.7     |
| C 1s   | 284.7    | 1.0  | 1      | 393.7 | 43.0    |
| C 1s   | 285.4    | 1.1  | 1      | 51.6  | 5.6     |
| C 1s   | 286.6    | 1.2  | 1      | 146.8 | 16.0    |
| C 1s   | 288.1    | 0.8  | 1      | 9.7   | 1.1     |
| C 1s   | 289.1    | 1.0  | 1      | 13.6  | 1.5     |
| C 1s   | 290.5    | 0.8  | 1      | 31.7  | 3.5     |

**Sample 2: PU treated with vit E**

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**Sample 3: PU before friction**

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XPS Survey Scans - Chapter 10

1. X3 Before Friction Testing

![XPS Survey Scan](image)
2. MPC_X3 Before Friction Testing

![XPS Spectrum](image.png)

- O 1s
- C 1s
- N 1s
- Na 1s
- P 2p
- Si 2p
- Ca 2p

Survey_MPCB/22

Binding Energy (eV)

CPS

1400 1200 1000 800 600 400 200 0

$10^4$
3. X3 Before Friction Testing (red), MPC_X3 Before Friction Testing (pink), MPC_X3 After Friction Testing (gold) MPC_X3 Irradiated After Friction Testing (blue).

Survey_X3B/3
XPS Quantification of High Resolution Spectra - Chapter 10

### X3- before friction (X3B)

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- O from phosphates, etc
- O from organic
- C-C, C-H
- C-O
- O=C-O
- N+ in an organic matrix
- 2p3/2: phosphate
- 2p1/2
- O from organics
- Oxidation
- Oxidation
- XPS Quantification of High Resolution Spectra- Chapter 10
### MPC-X3-after friction (MPCA)

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| C 1s | 284.8 | 0.9 | 1    | 23598.9 | 1201.81 | 33.05 | 714 | 75.5 |
| C 1s | 286   | 1.1 | 1    | 3015.1 | 1200.57 | 33.05 | 91.2 | 9.7 |
| C 1s | 288.8 | 1.4 | 1    | 658.9 | 1197.79 | 33.05 | 23.1 | 2.4 |
| N 1s | 399.9 | 1.3 | 1.8  | 207.6 | 1086.68 | 29.5 | 3.9 | 0.4 |
| N 1s | 402.4 | 1.6 | 1.8  | 52.4 | 1084.2 | 29.5 | 1 | 0.1 |
| P 2p | 133.5 | 2.1 | 1.19 | 45.9 | 1353.13 | 31.55 | 1.2 | 0.1 |

**Notes:**
- O from organics
- C-C, C-H
- C-O
- O=C-O
- N
- N+ in an organic matrix
- Phosphate

### MPC-X3-after friction-irradiated (MPCA_I)

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**Notes:**
- O from organics
- C-C, C-H

748.1
The appendix herein contains the report from MACSI on the inclusion of holes/channels in a compliant layer knee joint.
Stryker Osteonics:
Prosthetic Knee Joint

P.G. Hjorth,*
    J. King †
A. Korobeinikov‡
    J. Mason§
S. McKee ¶
S. Wilson ∥

Problem Presented by:
C. Birkinshaw, S. Flanagan,
University of Limerick

---

*Technical University of Denmark.
†University of Nottingham
‡University of Limerick
§Bristol University
¶University of Strathclyde
∥University of Strathclyde
1 The Problem

The human knee is a hinge-type joint comprising two major bones, the femur and the tibia. The bone is end capped with a soft compliant substance cartilage, which acts as a low friction bearing. Lubrication is added by the cartilage synovial fluid, which ensures that the bearing works with full fluid film lubrication.

As the knee articulates, fluid is drawn through the joint space, ensuring that the two opposing cartilage surfaces do not come into contact. The load applied to the knee depends upon the activity, and can be as much as 8 times body weight. The cartilage also acts as a shock absorber, dampening the excessive loads applied and protecting the bones from shock. Synovial fluid is non-Newtonian, and when the joint is stationary, the fluid is almost gel-like. The cartilage is porous, and never dries out in the healthy knee.

In the diseased knee cartilage breaks down, and the articulation tends to a bone-on-bone bearing. This is painful, and can be operated on to replace the diseased joint with a prosthetic joint. See figure 2.
The material properties of the prosthetic joint do not simulate cartilage in general. However, a new type of material is being considered polyurethane (PU), which simulates cartilage more closely than the conventional materials used in joint replacement. The system being considered is a PU tibial bearing articulating against a metal femoral bearing.

The PU is not porous, but can develop full fluid film lubrication if the conditions are correct. Many mathematical approaches ([2]-[11]) have been adopted to explore the nature and tribology of lubrication between poroelastic surfaces. The entire lubrication process is complex and involves the simultaneous solution of the equations of fluid dynamics with the equations of Hertian contact mechanics.

In the joints manufactured, it is necessary to have a soft, compliant PU as the bearing material. Under load, this material is easily deformable, and as the load increases so the contact area increases, thereby lowering the contact stress. The soft PU bearing is supported by a harder PU backing. The interface between the two materials is formed by fusion bonding, and is consequently an inherent weakness in the system. The weakness is most noticeable at the edges; when the material is loaded and the soft PU deforms, the displaced material exerts a shear force at the interface.

The Study Group was asked
(1) To investigate the inclusion of holes / channels in the loaded area of bearing to determine whether these features can: entrap fluid and thus simulate a porous surface, and can release fluid when the bearing is articulated to maximise the development of a fluid film.

(2) To investigate if holes around the periphery of the bearing can reduce the shear stress at the interface.

2 Thin Film Lubrication Theory

In thin film lubrication theory (see e.g., [1]), one considers a 2-D model of two surfaces in relative motion, and a thin layer of fluid in between.

Let $U_R$ be the relative velocity of the two surfaces (here given to the upper surface), and $h(x)$ the $x$-dependent separation of the surfaces. See figure 3.
Figure 3: Thin film model. The fluid forms a thin layer of width $h(x)$ between the femur (top) and the tibia (bottom) surfaces. The curvature relative to other distances is exaggerated. The top surface moves with a velocity $U_R$.

The horizontal velocity field in the film is approximately given ([1]) by

$$
u(x, z) = \left[ \frac{U_R}{h} - \frac{z}{2\mu} p_x \right] (h - z)$$

(1)

where $\mu$ is the fluid viscosity, and $p_x$ is the $x$-derivative of the pressure $p$. 

The overpressure $p - p_0$ (which in the joint supports the vertical load) is connected to the width function $h(x)$, by:

$$\frac{p - p_0}{6\mu} = U_R \int_x^{x} \frac{1}{h^2(s)} \mathrm{d}s - 2Q \int_x^{x} \frac{1}{h^3(s)} \mathrm{d}s$$

(2)

where $U_R$ is the relative velocity, and $Q$ is the volume flux related to $U_R$ by:

$$Q = \int_0^{h(z)} u \, \mathrm{d}z = \frac{1}{2} U_R h - \frac{h^3}{12\mu} p_x$$

(3)

3 A Surface cavity

Even from the lowest order equations (2) and (3) one can estimate the effect of changes in the height function $h(x)$. Suppose a small hole is drilled into the PU tibia surface, as in figure 4 (b).

The small hole will be filled with fluid, since the large pressure forces in the joint are much greater than the subtle effects like capillary forces.
The hole causes a new height function $h_2(x)$ of the fluid. The pressure will, for a fixed contact surface area, always adjust itself to the constant body weight and thus be a constant. Since the hole introduces a local increase in $h$, the new $h_2(x)$ will have lower values in the region where there is no hole, keeping the integral over the $1/h^2(x)$ terms in the pressure integrals equation (2) constant.

Since thin-film theory predicts that the pressure is of order $\mu UL/h^2$ while the tangential stresses are of order $\mu U/h$, horizontal forces in this model are smaller than vertical forces by a factor of order $h/L$.

Thus, a hole (and even more a collection of small holes) will lead to a smaller minimal value of $h(x)$. A smaller $h$ means less tangential stress, in other words less friction in the bearing. On the other hand, a too small value of $h$ brings the hard surfaces even closer to undesired contact.

4 Poroelasticy

A number of studies of the properties of poroelastic systems like the knee joint has been performed; see e.g., recent works [10] and [11], where a simplified model of joint articulation in the presence of both a non-Newtonian synovial fluid and poroelastic surfaces have been studied.
Even though a PU surface is not porous, it is interesting to compare the conclusion of the previous section with results from more complex calculations involving poroelastic surfaces with varying degrees of roughness.

We therefore briefly outline, following [11], an extension of the model to a poroelastic system, albeit without the feature of a couple-stress synovial fluid. The properties of such a fluid seems nevertheless relevant for the system and should be considered in further studies.

In figure 5, the tibia base is now poroelastic, meaning that the material has elastic properties as well as the ability to entrain fluid in a microscopic structure of canals, so that one should consider both a material displacement field \( U \), and the average fluid field \( V \) inside the poroelastic in addition to the ‘real’ fluid field \( (u, v) \) outside the poroelastic.

![Figure 5: A poroelastic problem.](image)

The distance function \( h \) now consists of two terms, \( h(x) = h_0(x) + h_s \), where \( h_s \) describes a random variable with zero mean and a deviation which characterizes the roughness of the surface.

Using a statistical average, and scaling with the natural length scale \( L \), one can obtain a dimensionless quantity \( C \) which is a measure of the relative roughness of the poroelastic surface.

The fluid field is considered to be incompressible:

\[
\frac{\partial u}{\partial x} + \frac{\partial v}{\partial y} = 0
\]

as well as satisfying

\[
\mu \frac{\partial^2 u}{\partial y^2} = \frac{\partial p}{\partial x} \quad \text{and for the pressure } p \quad \frac{\partial p}{\partial y} = 0
\]
In the poroelastic region, the material displacement field \( U \)

\[
\rho_m \frac{\partial^2 U}{\partial t^2} = \text{div}\sigma_m - \frac{\mu}{k} \left( \frac{\partial U}{\partial t} - V \right)
\]

In the fluid region, we \( U, \text{Fluid field } V \)

\[
\rho_f \frac{\partial^2 V}{\partial t^2} = \text{div}\sigma_f + \frac{\mu}{k} \left( \frac{\partial U}{\partial t} - V \right)
\]

where \( \sigma_m \) and \( \sigma_f \) are stress tensors. The pressure \( P \) in the pores will satisfy

\[
\nabla^2 P = 0
\]

Boundary conditions for the velocity field will be that at \( z = 0 \):

\[
u = 0, \quad v = -v_n, \quad \frac{\partial^2 u}{\partial z^2} = 0
\]

At \( z = h_0 \):

\[
u = 0, \quad v = -v_n - \frac{dh_0}{dt}, \quad \frac{\partial^2 u}{\partial z^2} = 0
\] (4)

In [11], it is found that such a system has a spatial pressure distribution which depends on the roughness parameter \( C \). See figure 6.

Figure 6: Dimensionless overpressure \( \bar{p} - p_0 \) across the joint for small and large values of the dimensionless roughness parameter \( C \).

A load-carrying capacity may be defined as

\[
\bar{W} = \int_0^L \bar{p} - p_0 \, dx
\] (5)
It is established in [11] that the load capacity is an increasing function of the roughness parameter $C$. It is established in [11] that the load capacity is an increasing function of the roughness parameter $C$.

5 Conclusion

We have examined, within a simple bearing model of a knee joint, the effect on the fluid film properties of the presence of a small vertical hole in the load area. The calculations indicates that

Fluid is entrapped in such a hole (in a porous medium, fluid can also be released, and may thus be ‘pumped’ in and out, so the porous layer can act as a reservoir of fluid).

In a simple model, the presence of the hole will, for constant load, cause a smaller minimal film separation of the two surfaces. This will lower the horizontal friction, but may also bring about surface contact in high load situations.

We note that this result, that small holes gives better lubrication is consistent with [11] and also with recent results examining both slide and roll [12].

The model is incomplete in that it consideres pure sliding, not the combined effect of sliding and rolling, and also does not consider the elastic deformation of the PU surface. Also, we did not consider the second question of the effect of holes to reduce sheer stresses at the soft PU - hard PU interface.
References


Selection of SEM and optical microscope images, showing the surface and cross sections of laser drilled holes fabricated in polyurethane Bionate® 80A.

Φ 50 μm

_Percussion drilling: 1 kHz, 0.16 W, 2 shots/10 ms delay_

Holes examined labelled 1-6

SEM images examining the surface of these holes are shown below and on the next page:

No.1: 700X  
No.2: 700X
Appendix J

No.3: 1800X

No. 4: 1300X

No. 5: 1300X

No.6: 1500X

Φ 500 μm
X-hatch trepanning; 1 kHz, 0.16 W, 10 μm spacing, 20 mm/s

Holes examined labelled (1-4)

SEM images examining the surface of these holes are shown on the next page:
Note that No.2 100X image did not save correctly!
Appendix J

Φ 500 μm

X-hatch trepanning; 1 kHz, 0.16 W, 10 μm spacing, 20 mm/s

Holes examined labelled (1-3)

SEM images examining the cross section of these holes are shown below and on the next page:

No. 2 & 3: 30X

No. 3: 75X (top section)
Optical microscopic images examining the cross section of these holes are shown on the next page:
Appendix J

No. 2: 5X

No. 2: 10X (base section)

No. 2: 10X (top section)

No. 3: 5X (base section)

No. 3: 5X (top section)
The appendix herein contains papers that have been (A) submitted and (B) in-press, in peer reviewed journals.
In vitro friction and lubrication of large bearing hip prostheses

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Abstract: New material combinations and designs of artificial hip implants are being introduced in an effort to improve proprioception and functional longevity. Larger joints in particular are being developed to improve joint stability, and it is thought that these larger implants will be more satisfactory for younger and more physically active patients. The study detailed here used a hip friction simulator to assess the friction and lubrication properties of large-diameter hip bearings of metal-on-metal and ceramic-on-reinforced-polymer couplings. Joints of different diameters were evaluated to determine what effect, if any, bearing diameter had on lubrication. In addition, the effects of lubricant type are considered, using carboxymethyl cellulose and bovine calf serum, and the physiological lubricant is shown to be considerably more effective at reducing friction.

The frictional studies showed that the metal-on-metal joints worked under a mixed lubrication regime, producing similar friction factor values to each other. The addition of bovine calf serum (BCS) reduced the friction. The ceramic-on-reinforced-polymer samples were shown to operate with high friction factors and mixed lubrication. When tested with BCS, the larger-diameter bearings showed a decrease in friction compared with the smaller-size bearings, and the addition of BCS resulted in an increase in friction, unlike the metal-on-metal system.

The study demonstrated that the component’s diameter had little or no influence on the lubrication and friction of the large bearing combinations tested.

Keywords:

1 INTRODUCTION

The majority of hip prostheses in use today are metal on ultrahigh-molecular-weight polyethylene (UHMWPE), with the replacement femoral head being much smaller than the normal healthy femoral head found in the human body. This hard-on-soft configuration was pioneered by Charnley [1], and it is believed that the most common causes of failure of this implant type are prosthetic dislocation and aseptic loosening due to osteolysis, which is induced by polyethylene (PE) wear debris. Additionally, it has been suggested that this conventional hip replacement system is not satisfactory for younger patients, primarily owing to their higher activity levels [2]. Smaller-diameter prostheses may result in reduced joint stability and increased dislocation rates with respect to the normal hip joint [3, 4], and it is proposed that larger-diameter prostheses would offer better proprioception and provide a greater range of motion [5], in addition to a more natural transfer of loads and possible preservation of bone mineral density [6]. In an effort to eliminate the wear problems of PE and improve the implant’s proprioception and limited survivorship, research has been directed at the use of alternative materials and designs. The first part of this paper is concerned with the use of large-diameter hard-on-hard configurations, specifically metal-on-metal implants.

Metal-on-metal hip replacements were first introduced by McKee and Watson-Farrar [7] in the 1950s, but were neglected for several years because of early
failures by loosening owing to high frictional torque, as well as the rapid increase in popularity of the Charnley arthroplasty. Although many of these metal-on-metal implants yielded variable early results, some successful implants had long lifetimes (in excess of 20 years) with very low wear rates [8–11]. Recent improvements in manufacturing techniques and better knowledge of factors that influence wear, i.e., interplay of metals, macrogeometry (diameter and clearance), microgeometry (surface topography), and lubrication, have led to a revival in the use of metal-on-metal bearings, and it is now considered that equatorial binding contributed to the high-friction torque and loosening evident in many of the early metal-on-metal implants. There is also renewed interest in resurfacing arthroplasty using metal-on-metal bearings, which should allow bone stock preservation [12].

Many studies have been carried out to characterize the wear properties of metal-on-metal implants, and it has been determined that the volume of wear in these hard-on-hard bearings is typically two orders of magnitude lower than that of conventional (i.e. not highly crosslinked) PE recorded for the metal-on-UHMWPE implants [13, 14]. Two distinctive regions of wear have been widely reported from hip simulator studies: at first, the femoral head and acetabular components show a reasonably high but decreasing wear rate over the first 1–2 million cycles, and this region is commonly referred to as the ‘bedding-in’ or ‘running-in’ period. Once this process has been completed, the rate of wear becomes relatively steady and generally relatively small, and this region is normally referred to as the ‘steady-state wear’ period. Both the initial bedding-in and steady-state wear have been found to be influenced by head diameter and clearance [15]. It has been shown [14, 16] that the head diameter plays a major role in determining the lubrication regime and hence the volumetric wear and wear rate in metal-on-metal hip replacements. As the diameter was increased, the volumetric wear rate became much higher. The effect of clearance was also shown to control the wear behaviour of metal-on-metal implants [14].

While much work has been done to characterize the wear properties (and the effect of diameter and clearance on wear), further work is necessary to characterize the frictional properties of metal-on-metal implants. Cipera and Medley [17] conducted a friction study of cobalt-based alloys for metal-on-metal hip implants, using a linear reciprocating pin-on-flat device. The friction factors produced were found to be 0.2 and 0.14 using 30 per cent bovine serum (BS) and distilled water respectively. Scholes and Unsworth [18] found, using a friction simulator, that metal-on-metal joints produced the highest friction (0.28 using carboxymethyl cellulose (CMC) fluids as the lubricant) when evaluating a range of material combinations that included metal-on-metal, ceramic-on-ceramic, and conventional metal-on-UHMWPE, all of 28 mm, regardless of the lubricant used. A simple resistivity technique, with direct measurement of the separation between the two articulating surfaces, has also been employed. Dowson et al. [19] showed that, for artificial joints of 36 mm, the mode of lubrication is likely to be mixed lubrication with some periods of effective surface separation. Smith et al. [14] also used this technique to monitor the effect of radial clearance for different-diameter bearings. Smaller joints showed no surface separation. The larger joints mainly operated in a mixed lubrication regime; however, a smaller clearance provided more surface separation per cycle, which suggests that smaller clearances gave better lubrication.

A study carried out by Unsworth et al. [20] examined the friction of a 50 mm hip resurfacing device prior to and during wear testing. At zero cycles of wear, the joint appeared to operate within the boundary lubrication mode, by 1 million cycles a classical Strubeck curve indicative of mixed lubrication was observed, and by 2 million cycles friction factors of about 0.015 were produced; at this level of friction, full fluid film lubrication prevailed. They concluded that the implant appeared to be subjected to fluid film lubrication as its surface topography modified with wear time (asperities smoothed and skewness moved from positive to negative). In another study carried out by Scholes et al. [21] on the lubrication regime in large-diameter metal-on-metal hip joints, friction factors of 0.015–0.03 were found, and they concluded that the joints were operating within a mixed lubrication regime but with lower friction factors than other metal-on-metal combinations published elsewhere.

More recent studies have been carried out by Brockett et al. [3, 22] and Wimmer et al. [23]. Brockett et al. [3] compared the friction in 28 mm conventional and 55 mm resurfacing metal-on-metal hip replacements using a pendulum machine. The friction factor was found to be lower for the resurfacing implant (0.098 versus 0.121), although this was reported as not being statistically significant. In a second study by Brockett et al. [22], the lubrication and friction of large-diameter metal-on-metal hip replacements were examined, with dia-
metral clearances of 53, 94, and 194 μm. Friction factors in the range 0.07–0.23 were obtained, with the small and mid-range clearance bearings having similar friction factors in all test conditions, whereas the largest clearance joint resulted in a significant increase in friction with 25 per cent serum conditions, again illustrating the influence of clearance on the friction in metal-on-metal bearings. Wimmer et al. \[23\] investigated stick phenomena in metal-on-metal hip joints after resting periods, using a pin-on-ball testing unit. A similar friction factor was attained for bearings with different diameters.

It should be noted, though, that the above studies employed dissimilar components and a variety of friction testing techniques (simulator, electrical resistivity, and pendulum), and therefore it is difficult to draw comparisons and establish an exact lubrication regime for metal-on-metal hip implants. The first aim of this study, therefore, was to investigate the friction and lubrication of ‘new’, unimplanted, large-diameter metal-on-metal hip resurfacing implants, using a friction simulator (that more realistically matches both the loading and motion profiles encountered by the body during the walking cycle), and to determine what effect, if any, diameter has on the lubrication regime acting within this all-metal system.

An alternative approach to prolonging the life of hip prostheses is to improve the mechanical properties and wear resistance of the polymer. Mechanical properties of polymers can be tailored, for example, by preparing carbon-fibre-reinforced (CFR) composites with varying fibre length and orientation. The second element of this paper is concerned with the use of large-diameter ceramic-on-CFR composites, specifically alumina-on-CFR-PEEK couplings.

Carbon-fibre-reinforced poly(ether ether ketone) (CFR-PEEK) has been reported as a more wear-resistant material than UHMWPE. Scholes and Unsworth [24] reported that the wear produced by CFR-PEEK articulating against ceramic, assessed on a multidirectional pin-on-plate machine, was much lower than the wear produced by conventional joint material (metal-on-PE) and metal-on-metal combinations, indicating that these ceramic–CFR composite combinations may perform well in joint applications. Recent studies by Scholes et al. [25] and Latif et al. [26], investigating the wear and friction of a flexible and anatomically shaped CFR-PEEK acetabular cup, gave encouraging results. Their wear data (low wear rate was sustained over $25 \times 10^6$ cycles, the equivalent of up to approximately 25 years in vivo) clearly indicates that this novel cup design will provide improved long-term component wear. Although the wear performance was very promising, additional friction tests should be carried out on this system to determine the precise lubrication regime under which they will operate in vivo, and to allow a full tribological analysis to be executed. Therefore, the second aim of this study was to investigate the friction and lubrication of ‘new’, unimplanted, large-diameter alumina-on-CFR-PEEK hip implants, using a friction simulator, and to determine what effect, if any, diameter size has on the lubrication regime acting within this novel hip replacement system.

2 MATERIALS AND METHODS

2.1 Components

One set of a proprietary metal-on-metal hip system, of 38, 42, 48, 52, and 58 mm nominal diameter, and one set of a ceramic-on-CFR-PEEK hip system, of 38, 42, 52, and 60 mm nominal diameter, were used. The reinforced polymer hip systems comprised thin-walled horseshoe-shaped CFR-PEEK (pitch-based) cups articulating against ceramic femoral heads. The cups were designed and manufactured as flexible components in an attempt to prevent stress shielding within the adjacent bone when implanted in the body [27].

2.2 Geometric and surface characterization

Geometric and surface parameter data of the metal-on-metal implants were measured prior to testing using a coordinate measuring machine (Mitutoyo Crysta Apex C (544)) and a non-contacting surface profilometer (Zygo, NewView) respectively. The clearances of the CFR-PEEK systems were estimated by measuring the gap between the surfaces at the equator, while the surface topography was measured using a contacting profilometer (Form TalySurf Series, Taylor-Hobson). All sample types were manufactured to the same surface finish with very close tolerances.

2.3 Friction testing

Friction of the bearing combinations was examined at room temperature using a TE89 friction simulator manufactured by Phoenix Tribology, Newbury, UK, which has been described elsewhere [28]. The simulator subjected the components to a simple
harmonic oscillatory motion with a stroke of ±24° in the flexion/extension plane with a frequency of 0.8 Hz. The bearings were arranged in an inverted position with respect to in vivo, and the friction carriage was self-aligning, to ensure correct positioning of the implant during testing. The acetabular cups of the metal prostheses were not angled, and were cemented in sample holders using Simplex bone cement, whereas the acetabular components of the CFR-PEEK systems were press-fitted into specially designed and manufactured UHMWPE holders (Fig. 1), oriented at 33° to the horizontal to ensure that the dynamic loads were applied to the same direction in the simulator as they are in vivo. The ‘arms’ of the cups were relieved, ensuring that the internal geometry of the cups was not altered.

A calibrated Kistler piezoelectric force transducer allowed the frictional torque of the joint to be measured. The frictional properties are represented by a non-dimensional friction factor \( f \), which is defined by the equation

\[
f = \frac{T}{rL}
\]

where \( r \) is the radius of the femoral component and \( L \) is the applied load. The friction factor is numerically of the same order as the average kinetic coefficient of friction of the joint \([29, 30]\). To determine the mode of lubrication, the friction factor was plotted against the Sommerfeld number, \( z \), in a Striebeck plot \([31–33]\). The Sommerfeld number is defined by the equation

\[
z = \frac{\eta u r}{L}
\]

where \( u \) is the entraining velocity and \( \eta \) is the viscosity of the lubricant. Each hip implant was tested twice in each lubricant, and the results were averaged to build up the Striebeck curve.

Initial studies to determine the sensitivity of the simulator and the repeatability of the data were performed prior to this study. The sensitivity was assessed by measuring the friction of a low-friction, ceramic-on-ceramic hip bearing. To examine the repeatability, a conventional metal-on-UHMWPE hip implant was tested a total of 3 times. Results from these investigations are shown in section 3.1.

### 2.4 Lubricants

Measurements of friction factors of the components were undertaken when the acetabular cups were fully lubricated using aqueous carboxymethyl cellulose (CMC) solutions (BHD, UK) with viscosities ranging from 0.001 to 0.18 Pa s, with distilled water providing a viscosity of 0.001 Pa s. The joints were also tested using 100 per cent bovine calf serum (BCS) (Sigma Aldrich, Ireland) and 25 per cent BCS, 75 per cent deionized water, and 0.2 wt % of sodium azide preservative. Table 1 gives the supplier’s analysis of the serum.

The CMC fluids were compared with the tests using BCS as the lubricant to assess the effects of proteins and other physiological materials on the lubrication of these joints. To prevent damage to the joint, the highest viscosities were tested first. The measurements with the lower range of viscosities were then completed. The joints were cleaned thoroughly between tests by removing any surplus lubricant, and then wiped down with isopropanol.

An estimation of the lubricating film thickness, \( h_{\text{min}} \), in the metal-on-metal implants can be obtained using the Hamrock and Dowson formula \([34]\)

![Fig. 1 UHMWPE acetabular cup holder specially designed and manufactured to hold a horseshoe-shaped CFR-PEEK acetabular cup](image)

Table 1  Bovine serum analysis

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification (wt%)</th>
<th>Results (wt%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein electrophoresis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total protein</td>
<td>5.5–7.5</td>
<td>6.6</td>
</tr>
<tr>
<td>Albumin</td>
<td>—</td>
<td>3.6</td>
</tr>
<tr>
<td>Globulin</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>alpha</td>
<td>—</td>
<td>1.1</td>
</tr>
<tr>
<td>beta</td>
<td>—</td>
<td>0.8</td>
</tr>
<tr>
<td>gamma</td>
<td>—</td>
<td>1.1</td>
</tr>
</tbody>
</table>

—, no specification established.
This equation has been used to calculate the minimum lubricating film thickness in joints of various construction types. In equation (3), \( \eta \) is the viscosity of the lubricant, \( u \) is the entraining velocity, \( L \) is the load applied to the joint, \( R \) is the equivalent radius, and \( E' \) is the equivalent elastic modulus of the bearing material combination, defined by the equation

\[
\frac{1}{E'} = 0.5 \left( \frac{1-v_1^2}{E_1} + \frac{1-v_2^2}{E_2} \right)
\]

where \( v_1 \) and \( v_2 \) are the Poisson’s ratio of the head and cup respectively.

The predicted minimum film thickness, together with the recorded values of \( R_1^q \) and \( R_2^q \), the average root-mean-square roughness of the head and the cup respectively, were used to predict the lambda ratio, \( \lambda \), and thereby the lubrication regimes acting within the joints, as noted in the equation [35]

\[
\lambda = \frac{h_{min}}{ \left( R_1^2 Q_1^2 + R_2^2 Q_2^2 \right)^{1/2}}
\]

It has been shown that a lambda ratio value greater than 3 indicates fluid film lubrication, a value below 1 indicates that boundary lubrication prevails, and a value between 1 and 3 indicates that the bearing is operating in a mixed lubrication regime [36].

3 RESULTS AND DISCUSSION

3.1 Strubeck assessment of (a) ceramic-on-ceramic and (b) conventional metal-on-UHMWPE hip implants of 28 mm diameter

The Strubeck plots for the hip joints tested are shown in Fig. 2. Figure 3 illustrates the repeated friction testing results (\( \times 3 \)) using the conventional implant, with each test representing the average Strubeck curves having tested the joint twice in each lubricant. A slight trend, whereby the friction increased with increasing Sommerfeld number, was observed in the Strubeck plot for the all-ceramic implant tested with CMC fluids (linear correlation value 0.71). The average friction factor was remarkably low (0.0015) – the lowest friction measured using this simulator. A clearly apparent decreasing trend (linear correlation value \(-0.96\)) was seen in the Strubeck plot for a metal/PE joint with CMC fluids, indicative of a mixed lubrication regime. The results found here are similar to results reported by others [18, 37–39]. With these levels of friction and distinctive Strubeck plots, it is evident that the friction simulator is capable of defining lubrication regimes. Excellent repeatability of the simulator is clearly demonstrated in Fig. 3, with only very minor variations in friction factor results between the three tests.
3.2 Stribeck assessment of metal-on-metal large-diameter hip bearings

The Stribeck plots for the metal-on-metal hip resurfacing implants are shown in Fig. 4. No apparent trends (decrease/increase in friction factor with increase in Sommerfeld number) were seen for any of the joints, and the friction factors produced were relatively high, ranging from 0.25 to 0.11. These friction factors are similar to those found by Williams et al. [40], Cipera and Medley [17], and Brockett et al. [3], who each assumed a mixed lubrication regime. Compared with results from a 28 mm metal-on-metal implant, as found by Scholes and Unsworth [18] (0.16–0.3 using CMC fluids), these friction factors are notably lower, indicating improved lubrication. The mode of lubrication in this study was therefore likely to be mixed lubrication, in which the load is carried in part by the contact between the asperities of the bearing.

![Stribeck plots for a conventional metal-on-UHMWPE hip implant tested 3 times using CMC fluids only. Standard deviations are indicated](image1)

![Stribeck plots for metal-on-metal hip resurfacing systems of 58, 52, 48, 42, and 38 mm nominal diameter, tested with CMC fluids, distilled water, and solutions of BCS. Separators are used to distinguish between lubricants of different make-up. Standard deviations are shown](image2)
surfaces and also by the pressure generated within the lubricant. The severity of direct metal-to-metal contact was evident from the visible scratching present on both the acetabular and femoral components, in the direction of motion, at the polar contact (Figs 5 and 6).

It has been reported that friction testing of worn components after the running-in period has shown improved lubrication. Unsworth et al. [20] have shown the progression from boundary lubrication to mixed lubrication and then to full fluid film lubrication as running-in progressed in a 50 mm diameter metal-on-metal hip resurfacing replacement. They also observed that, although the composite roughness of the surface did not change much during running-in, the skewness changed from positive to negative over the first 3 million cycles, indicating that the peaks had been smoothed and the valleys deepened. For the samples tested in this study, it would be expected that, if their tribological conditions became more favourable (at steady state), then an increased proportion of the applied load would be carried by fluid film action rather than asperity contact.

For comparative purposes, the mean friction factor values generated by each bearing diameter, tested with CMC fluids, and solution of BCS are shown in Fig. 7. The mean friction factors in CMC fluids were $0.136 \pm 0.023$, $0.143 \pm 0.022$, $0.192 \pm 0.017$, $0.214 \pm 0.015$, and $0.191 \pm 0.022$ for the 58, 52, 48, 42, and 38 mm diameter bearings respectively. While the larger bearings exhibited slightly lower friction factors, the differences were negligible, and therefore a similar friction factor for each diameter bearing was assumed. This influence of bearing diameter on tribology appears to correlate well with a study done by Wimmer et al. [23], who also obtained a similar friction factor for metal-on-metal bearings with different diameters. As only a limited number of joints were available for analysis, a statistical evaluation of friction results could not be performed, but it is considered that the results found with the samples tested provide a good indication of this system’s friction and lubrication properties.

It is evident from Fig. 7 that the addition of BCS had a significant effect in decreasing the friction factors, and this phenomenon has been observed by other workers [3, 41, 42]. It is possible that proteins in the biological serum adhere to the surface of the metal bearings; for example, it has been shown [43] in pin-on-disc testing that most worn surfaces, notably UHMWPE and metal, have a residual albumin coating. These adsorbed proteins can act as solid-phase lubrications and reduce the adhesive forces between the metal-on-metal contacts, hence

**Fig. 5** Visible scratching on a CoCr femoral head of 58 mm nominal diameter, with the direction of articulation indicated

**Fig. 6** Surface topography of a CoCr femoral head of 58 mm nominal diameter, showing scratching in the articulating direction ($R_s = 0.06 \mu m$, $R_{sk} = -1.999$, maximum height difference between peaks and valleys = $2.339 \mu m$, valley = $-1.40 \mu m$, peak = $0.94 \mu m$)
reducing the friction. In the work reported here, however, the presumed protein concentration has little affect on the scale of friction factors produced, an observation that is consistent with an adsorption mechanism.

Theoretical analysis (Table 2) was carried out, using equations (3) and (5) to determine the minimum film thickness and the lambda ratio, and showed that all the bearing diameters had a lambda ratio of greater than 3, suggesting a fluid film lubrication regime. Although this result would suggest a fluid film lubrication regime for the joints, the experiments actually showed that they operated within a mixed mode of lubrication with some periods of effective lubrication.

3.3 Stribeck assessment of ceramic-on-CFR-PEEK large-diameter hip bearings

The friction of alumina-on-CFR-PEEK hip systems of 38 and 42 mm nominal diameter was examined using maximum loads of 1000 and 500 N, and the resulting Stribeck plots are shown in Fig. 8. The friction factors produced using both maximum loads were very similar, and in some cases, surprisingly, the 500 N load yielded slightly higher values. A similar effect was reported in a study done by Scholes et al. [25].

The Stribeck plots for each of the ceramic-on-CFR-PEEK joints (500 N maximum load) are shown in Fig. 9, and their mean friction factors are illustrated in Fig. 10. There was no macroscopic evidence of damage to the component surfaces. Similar to the metal-on-metal hips, neither a rising nor a falling trend was observed in the Stribeck plots using CMC fluids and distilled water, with constant friction factors of about 0.217 generated by each bearing. These friction factors were significantly higher than those produced by the all-metal resurfacing hips, and similar results were found by Scholes.

### Table 2  Geometrical parameters and theoretical minimum film predictions

<table>
<thead>
<tr>
<th>Bearing diameter (mm)</th>
<th>Radial clearance (mm)</th>
<th>Predicted minimum film thickness $h_{min}$ (µm)</th>
<th>Lambda ratio $\lambda$</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>0.075</td>
<td>0.087</td>
<td>&gt;3</td>
</tr>
<tr>
<td>52</td>
<td>0.072</td>
<td>0.084</td>
<td>&gt;3</td>
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<tr>
<td>48</td>
<td>0.062</td>
<td>0.072</td>
<td>&gt;3</td>
</tr>
<tr>
<td>42</td>
<td>0.057</td>
<td>0.066</td>
<td>&gt;3</td>
</tr>
<tr>
<td>38</td>
<td>0.050</td>
<td>0.058</td>
<td>&gt;3</td>
</tr>
</tbody>
</table>

Fig. 7  Friction factor values with standard deviations for the metal-on-metal hip resurfacing systems of 58, 52, 48, 42, and 38 mm nominal diameter, tested with CMC fluids, distilled water, and solutions of BCS

Fig. 8  Friction factor values and standard deviations for alumina-on-CFR-PEEK hip systems of 42 and 38 mm nominal diameter, tested with maximum loads of 500 and 1000 N. Separators are used to distinguish between lubricants of different make-up

Fig. 9  Stribeck plots for alumina-on-CFR-PEEK hips of 60, 52, 42, and 38 mm nominal diameter, tested with CMC fluids, distilled water, and solutions of BCS. Separators are used to distinguish between lubricants of different make-up. Standard deviations are shown.
et al. [25], although a maximum load of 2800 N was used in that study.

The influence of bearing size on friction could be seen when BCS solutions were employed as the test lubricants. An increase in the component’s nominal diameter resulted in lower friction factor values: 0.336 ± 0.007, 0.314 ± 0.005, 0.296 ± 0.005, and 0.282 ± 0.005 for the 38, 42, 52, and 60 mm diameters respectively (using a 25 per cent solution of BCS).

Unlike the metal-on-metal hip systems, the use of BCS resulted in an increase in friction, with friction factor values in the range 0.336–0.282 using BCS solutions. This effect of increasing friction with BCS has been reported in other material combinations, but most notably in all-ceramic hip joints [18], and it has been suggested [44] that this is because albumin is not adsorbed onto alumina surfaces and does not therefore provide a continuous protecting film. In the case of the CFR-PEEK joints studied here, consideration must also be given to the possibility of local heating denaturing the proteins [43]. These joints operated in a high friction regime, indicating the dissipation of large amounts of energy at the articulating surfaces. There are two possible outcomes from this: local heating or generation of new surfaces and debris by wear.

These tests have revealed either a boundary lubrication or a severe mixed lubrication regime (close to boundary lubrication) for the alumina-on-CFR-PEEK joints. In addition, friction tests without any lubrication were attempted, but the resultant frictional torques were extremely high and above the limit of measurements of the machine, thus implying that, in the lubrication experiments, there was some hydrodynamic action that lowered the friction to within the simulator’s limits.

The large clearances of these bearings (Table 3) are believed to be a significant factor in the high frictional torque values determined in this study. Clearance is one of the main factors that influence wear and friction, as it is one of the determining factors of the type of lubrication. Larger clearances reduce the contact area (and increase the contact stress), resulting in a loss of effective lubrication. The clearance of each bearing appeared to be too large and resulted in ‘spot contact’, whereas polar contact is preferred. The design and flexibility of this type of acetabular cup allow for easy modification of the clearance parameter. The minimum clearance that is required should ensure near-polar contact, with the proviso that the arms of the acetabular cup do not pinch the ball when the cup is slightly compressed and properly seated.

4 CONCLUSIONS

In this study, the metal-on-metal joints have shown similar friction factors and illustrated mild mixed lubrication. Compared with a conventional-size metal-on-metal joint of similar clearance, the larger bearings exhibited lower friction factors, illustrating improved lubrication. New unworn samples were tested for short periods, and hence the influence of wear and wear-related geometric and surface changes were not considered. It is proposed that, at steady-state wear, these samples would operate with full fluid film lubrication. The level of the friction factor encountered in this joint system depended on the lubricant; bovine calf serum had a decreasing effect on the friction of all bearings. This study found no correlation between theoretical predictions and experimental data.

Tests on alumina-on-CFR-PEEK couplings of different diameters revealed severe mixed lubrication, and this was probably due to the large diametral clearances of the bearings. It is possible that a reduction in friction and improved lubrication would be observed if the clearances were reduced.

<table>
<thead>
<tr>
<th>Nominal diameter (mm)</th>
<th>Mean diametral clearance (mm)</th>
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</thead>
<tbody>
<tr>
<td>60</td>
<td>0.80</td>
</tr>
<tr>
<td>52</td>
<td>0.86</td>
</tr>
<tr>
<td>42</td>
<td>0.87</td>
</tr>
<tr>
<td>38</td>
<td>0.91</td>
</tr>
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</table>
The design and flexibility of CFR-PEEK acetabular cup should allow for easy modification of its internal geometry, thus altering the bearing’s clearance. BCS fluids showed significantly higher friction factors than the CMC tests, which may be due to adsorbed protein shearing. The size of the components had an effect on the magnitude of the friction factors produced using BCS solutions. It was shown that the larger-diameter bearings exhibited lower friction than the smaller-diameter bearings.

The question of the role of the lubricants remains open. It is clear from the results presented here, and from the results of others [3, 28, 37, 41], that the material couple–lubricant relationship is important and warrants further investigation. The generation of adsorption isotherms for the various combinations, for example, may be a helpful first step and could allow more informed speculation and provide further insight into the tribology micromechanisms.

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In vitro friction and lubrication of large bearing hip prostheses

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APPENDIX

Notation

- $E'$ equivalent elastic modulus
- $E_1$ modulus of elasticity of the femoral head component
- $E_2$ modulus of elasticity of the tibial insert
- $f$ friction factor
- $h_{\text{min}}$ minimum film thickness
- $L$ applied load
- $R$ reduced radius
- $R_1$ or $r$ radius of the femoral component
- $R_2$ radius of the tibial inserts
\r_{q}^{1}\quad \text{r.m.s roughness of the femoral head component} \\
\r_{q}^{2}\quad \text{r.m.s. roughness of the acetabular cup} \\
T\quad \text{frictional torque} \\
u\quad \text{entraining velocity} \\
\zeta\quad \text{Sommerfeld number} \\
\eta\quad \text{lubricant viscosity} \\
\lambda\quad \text{lambda ratio (surface separation ratio)} \\
\mu\quad \text{coefficient of friction} \\
u_{1}\quad \text{Poisson's ratio of the femoral head component} \\
u_{2}\quad \text{Poisson's ratio of the acetabular cup component}
Compliant layer knee bearings
Part I: Friction and lubrication

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ABSTRACT

Compliant layer technology, in which a soft polymer mimics the performance of natural cartilage, potentially represents a resolution to the wear and associated longevity coupled with conventional metal-on-plastic joints. In this two-part study, the friction and wear of compliant layer polyurethane (PU) tibial inserts articulating against metal femoral components were investigated as part of a preliminary in vitro screening.

In Part I the friction and lubrication regimes were evaluated both experimentally using Stribeck analysis and theoretically using the theory of Hamrock and Dowson to investigate the joints ability to operate within a fluid film lubrication regime. Using aqueous carboxymethyl cellulose (CMC) fluids as the lubricant the joints were shown to operate with low friction and specifically, in some individual joints, with friction factors equivalent to ceramic-on-ceramic bearings as observed in hip bearings. Protein containing lubricants caused an increase in friction relative to the CMC solutions and it is proposed that this results from the shearing of interfacial protein layers adsorbed onto the articulating surfaces.

Overall, the friction and lubrication results demonstrated the ability of compliant layer joints to operate with fluid film lubrication and consequential lower frictional torque during the walking cycle. In Part II of this study the wear performance of this articulation system will be investigated.

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1. Introduction

Compliant layer technology may offer the benefits of reduced wear and friction and prolonged functionality in artificial joints by maintaining a fluid film between the articulating surfaces. However, over thirty years since the first published papers on compliant layer joints [1–3], few publications have described in vitro assessments of compliant bearing performance.

In 1977 Rybicki introduced the “compliant bearing model” for human joint lubrication showing that joints operated with fluid film lubrication under most conditions [1]. This led to the development of the compliant layer or “cushion form” bearing, a method first suggested by Unsworth et al. in 1981 [2], intended to mimic natural joints. The term ‘cushion bearings’, first introduced by Dowsen in 1989 [3], refers to thin layers of low elastic modulus materials that are used as a biomimetic surface in total joint replacements. These compliant layers allow the hard, smooth femoral component to sink into the soft acetabulum or tibial bearing to create higher conformity and the appropriate conditions for fluid film lubrication and hence reduce both friction and wear [4]. The entire compliant bearing concept is modelled on the natural synovial joint and the low elastic modulus layer may be considered to fulfil a similar function to that performed by cartilage in the natural joint.

Recent studies have concentrated predominantly on the suitability of polyurethane (PU) elastomers, as the most suitable candidate material for the compliant layer as these are durable materials exhibiting many of the desired properties of natural cartilage, and are readily commercially manufactured as biomaterials [5–7]. Initial research focused on use in the human hip joint using mathematical approaches aimed at calculating theoretical lubrication regimes, contact stresses and contact area [8]. In vitro assessment of friction and wear [9–12], and in vivo assessment in an ovine model have also been described [13,14]. Overall, the studies concluded that a fluid film readily forms between the compliant layer polyurethane and hard counterpart with low levels of friction under favourable lubrication conditions.

The premise of compliant layer knee joints is the same as for the hip joint whereby a low elastic modulus layer has the potential to allow microscopic elastic deformation of the surface asperities, micro elastohydrodynamic lubrication (µEHL) and preservation of a protective fluid film. The first published study on the in vitro wear and friction of compliant layer bearings in the knee was by Auger et al. in 1993 [4,15] and remains the standard for comparative
assessments of compliant bearing knee joints. Auger et al. assessed the friction and wear of flat compliant layer PU bearings articulating against a standard metallic condylar femoral component and showed that the compliant layer joints operated within the mixed lubrication regime, but that they benefited from a substantial measure of fluid film lubrication, had the potential for generating very low friction values and performed better than an equivalent UHMWPE joint. Auger et al. showed that the friction coefficients of flat compliant layer bearings were between 0.05 and 0.001 depending on the compliant layer thickness and elastic modulus of the PU.

Other studies have investigated the tribological conditions leading to fluid film breakdown in compliant bearings, such as severe cyclic loading, reduced sliding velocity, third body debris and start-up friction. Stewart et al. [16] confirmed that although start-up friction was high, no apparent wear features were evident in their composite compliant layer polyurethane knee bearings as fluid was quickly drawn into the joint space (within a few cycles). They also demonstrated that in some severe kinematic conditions, a mixed lubrication mode was indicated as observed by some light scratching of the PU components. Ash et al. [17] carried out friction and wear studies, in the presence of crushed bone cement, on both UHMWPE and PU tibial inserts and demonstrated that the PU inserts exhibited minimal surface roughness changes under wear testing for 5 million cycles, compared to UHMWPE controls that showed severely scratched surfaces. More recently the friction and wear of unicompartmental compliant layer PU tibial inserts has been studied [18,19] and it has been shown that the compliant layer joints operate under near fluid film lubrication with friction factors in the range of 0.004–0.05 using carbomethyl cellulose (CMC) solutions. However, the joints did appear to operate under a mixed lubrication regime when using bovine serum lubricant with friction factors ranging from 0.04 to 0.1, although it was postulated that this was due to protein–protein rubbing.

Overall the behaviour of compliant layer PU knee joints as reported in the literature appears promising and is investigated further in the work reported here. Initially, the friction of flat and congruent PU tibial inserts will be assessed to clarify their theoretical and in vitro mode of lubrication. Subsequently, the total knee replacements (TKRs) will be tested on a knee wear simulator for 2 million cycles and their wear behaviour monitored using a variety of techniques (Part II). The ultimate aim of the work reported in Part I of this study was to build on the work of Auger et al. [4,15] and examine the friction of flat and standard conformity compliant layer PU bearings of practical designs and biomaterials.

### 2. Materials and methods

#### 2.1. Total knee replacement components

Two sets of flat polyurethane inserts (Sets A and B) and four sets of congruent inserts (Sets 1, 2, 3, and 4) were assessed. Each set consisted of two components (medial and lateral). The flat components were made up of a 2 mm Bionate® 80A compliant surface layer and an 8 mm hard backing layer, composed of 75% Bionate® 75D and 25% hydroxyapatite. The Bionate® 75D and hydroxyapatite hard backing was being investigated in a separate, unpublished, study examining the effect of this material combination on bone in-growth. The congruent components were made up of a backing layer of 10 mm Bionate® 75D and a 2 mm surface layer of Bionate® 80A and were based on the standard Interax® design to allow comparison with other studies to determine equivalency between these and conventional UHMWPE joints [20,21]. The tibial bearings were produced using an injection moulding procedure whereby the soft bearing was moulded first and then used as an insert with the harder layer overmoulded. The interface achieved has been demonstrated [22] to be robust under friction and wear testing. Each set was sterilised by a minimum of 25 kGy gamma irradiation in nitrogen atmosphere, before being conditioned by immersion in distilled water for 12 weeks to ensure equilibrium fluid absorption before testing. It is noted that the flat and congruent bearings are made up of different backing materials and hence it will not be possible to directly compare their tribological properties.

The femoral components used were standard left side Interax® Midi 600 cobalt chrome (CoCr) femoral components manufactured by Stryker Orthopaedics, Limerick, which correspond to the standard UHMWPE Interax® Duration® tibial bearing inserts.

#### 2.2. Friction testing

Friction of the bearing combinations was examined at room temperature using a TE89 friction simulator (Phoenix Tribology, Newbury, UK) which has been described in detail elsewhere [21]. Each knee joint was tested twice in each lubricant and the results averaged to build up the Stribeck curve/plot, which is described below. Also, to examine the friction simulators repeatability Set 1 was tested three times and the Stribeck curves compared.

The simulator subjected the femoral components to a simple harmonic oscillatory motion with a stroke of ±32.5° in the flexion/extension plane with a frequency of 0.8 Hz. The tibial inserts were press-fit into an Interax® Midi 2 base plate and a dynamic load applied with maximum and minimum loads of 2000 and 200 N, respectively. The inserts were mounted in a stainless steel bath inside a trunnion bath, which allowed them to be fully covered with lubricant at all times. The trunnion bath pivots in low friction contra-rotating bearings about the centre-line of rotation of the femoral component, allowing the bath to oscillate solely due to the frictional torque generated at the joint surface. The bath was restrained from oscillation by a calibrated Kistler piezoelectric force transducer that allowed the frictional torque of the joint to be measured.

The frictional properties of the TKRs are represented by a non-dimensional “friction factor” (f) which is defined as:

\[
    f = \frac{T}{rL}
\]

where r is the radius of the femoral component, T is the frictional torque and L is the applied load. The friction factor is numerically...
of the same order as the average kinetic coefficient of friction of the joint [23,24]. In order to determine the mode of lubrication, the friction factor was plotted against the Sommerfeld number (z) as a Stribeck plot [25–27]. The Sommerfeld number is defined as:

\[ z = \frac{\eta u r}{F} \]  

(B)

where \( u \) is the entraining velocity and \( \eta \) is the viscosity of the lubricant. Altering the viscosity of the lubricant varies the Sommerfeld number for a given joint. If the friction factor is constant as the Sommerfeld number (lubricant viscosity) increases boundary lubrication dominates. However, a decrease in the friction factor with an increase in the Sommerfeld number is indicative of a mixed lubrication regime while an increase in the Sommerfeld number and increase in friction factor is indicative of FFL whereby asperities of the opposing bearing surfaces are separated by the lubricant.

2.3. Lubricants

Measurements of friction factors of the components were undertaken when the tibial inserts were fully lubricated using aqueous carboxymethyl cellulose (CMC) solutions (BDH, UK) with a range of viscosities from 0.001–0.180 Pa.s, with distilled water providing the viscosity of 0.001 Pa.s. The joints were also tested using a 25% bovine calf serum (BCS) (Sigma–Aldrich, Ireland) water diluted solution, with 0.2 wt% of sodium azide added as preservative to minimise denaturing of the protein in the serum. The joints were briefly soaked (<10 min) in the BCS prior to testing. The pure CMC solutions and 25% BCS were measured using a Brookfield DV-II viscometer at room temperature. The viscosities of the CMC solutions and 25% BCS were measured a range of viscosities from 0.001–0.180 Pa.s, with distilled water.

2.4. Theoretical mode of lubrication

The central and minimum fluid film thickness was estimated for the compliant layer inserts using the following analysis, which was carried out according to the same protocol as Auger et al. [4]. The full elasticity solutions produced by Meijers [28] were used to determine the contact half width for the compliant layer inserts:

\[ \frac{4FR}{\pi E_2 b^2} \left(1 - \frac{v^2}{u^2}\right) = \left(\frac{b}{h_0}\right)^2 \frac{1}{\frac{1}{R_1} + \frac{1}{R_2}} \]  

(C)

where \( R \) is the reduced radius given by:

\[ \frac{1}{R} = \frac{1}{R_1} + \frac{1}{R_2} \]  

(D)

and \( f(b/h_0, v) \) is a function defined by Meijers.

Subsequently, \( (b/h_0, v) \) was calculated to be >2 and therefore, the elastohydrodynamic film thickness for the compliant layer TKRs was estimated from the line contact formulae given by Medley et al. [29]:

\[ h_{\text{min}} \left(\frac{R}{R} \right) = 1.159 \left(\frac{h_0}{b}\right)^{0.4875} \left(\frac{2\eta u/E_2 R^{0.6}}{F'/(E_2 R)^{0.2}}\right) \text{ for } b/h_0 \geq 2 \]  

(E)

Finally, the lambda ratio (Eq. (G)) was used to calculate the theoretical lubrication regime acting within the joint by dividing the predicted minimum film thickness by the measured composite root mean square surface roughness [31]:

\[ \lambda = \frac{h_{\text{min}}}{((R_{11})^2 + (R_{11})^2)^{1/2}} \]  

(G)

The central film thickness was calculated from the relation given by Hooke [30]:

\[ h_{\text{cen}} = \frac{h_{\text{min}}}{0.894} \]

(F)

where \( h_{\text{cen}} \) is a surface separation value and depending on its magnitude is indicative of the mode of lubrication between two bearings. If \( \lambda < 1 \), boundary lubrication prevails. If \( \lambda > 3 \), effective separation and fluid film lubrication can be achieved. At \( 1 < \lambda < 3 \), varying degrees of mixed lubrication result [32]. The mathematically predicted modes of lubrication can be compared to those observed experimentally.

2.5. Surface profilometry

Surface profilometry was used to measure the root mean square roughness (Rq) of the TKRs prior to testing. Surface roughness of the femoral components was measured using a Form Talysurf 120 stylus profiler (Taylor Hobson) with a cut-off length of 0.08 mm. Four traces 10 mm in length were carried out on each side of the components: two in the medial–lateral (M–L) direction and two in the anterior–posterior (A–P) direction. All traces were taken in the bearing area and were averaged.

Owing to the compliant nature of the PU bearing, stylus contact profilometry was found to be unsuitable; therefore, surface roughness was measured using a non-contact surface profilometer (Zygo New-view 100 scanning white-light interferometer, NUIG, Ireland). A 20× magnification lens was used, set at 0.5× zoom giving a field of view of 200 μm × 300 μm. Six measurements with z-axis accuracy of ±5 nm were made at random points within the presumed wear zone and were averaged for each tibial insert.

3. Results and discussion

3.1. Stribeck assessment of flat bearings

The Stribeck plots generated for Sets A and B when assessed using CMC fluids and a 25% solution of BCS are shown in Fig. 1. The classical Stribeck curve indicative of fluid film lubrication, whereby the friction increased with increasing Sommerfeld number was not
observed uniformly. Although the friction factors showed some fluctuation, no trend was apparent. The average friction factors produced were extremely low and are equivalent to friction factors obtained in an unpublished study by the same author, for a 28 mm ceramic-on-ceramic hip joint using the same friction simulator and operating conditions, as shown in the figure. The magnitude of the friction factors is also comparable to that reported by other researchers for alumina-on-alumina total hip replacements who established that this joint combination operated under fluid film lubrication conditions [18,33,34].

The friction factors generated depended on whether synthetic CMC fluid or biological BCS was used. An increase was found at physiological viscosities when BCS was used rather than the CMC solutions (0.008 and 0.014 compared to 0.003 and 0.004 for Sets A and B, respectively). It is proposed that the increase in friction was caused by rubbing of proteins, which had adsorbed onto the CoCr and PU bearing surfaces as reported previously by Scholes and Unsworth [18]. It is considered that the higher friction factor observed when using the BCS for the ceramic joint arises from the low clearance between the articulating surfaces facilitating greater protein interaction.

### 3.2. Stribeck assessment of congruent bearings

Fig. 2 illustrates the repeated friction testing for Set 1. It is evident from the figure that there were only very minor variations in friction factor results between the three tests demonstrating the repeatability of the friction simulator.

The average of these three tests with the CMC solutions are plotted in Fig. 3 and for comparative purposes, results generated from a conventional CoCr-on-UHMWPE (Interax®) TKR, are also plotted. A slight increasing trend, as illustrated by a Pearson’s correlation value of 0.81, whereby the friction increased with increasing Sommerfeld number was observed in the Stribeck plot for the compliant joint. The average friction factors produced were remarkably low (0.006–0.009) and as such were considerably lower than the CoCr-on-UHMWPE joint. The superior lubricating characteristics of the compliant layer joint compared with the conventional joint are clearly evident from Fig. 3. At this level of friction and with an increasing Stribeck curve this appears to follow the classical curve that defines fluid film lubrication at the higher viscosities.

The Stribeck plots generated from Sets 2, 3 and 4 are shown in Fig. 4. The results are similar to Set 1 with average friction factors in the range of 0.007–0.009 with CMC fluids. The effect seen with the congruent inserts with BCS lubricant is similar to that seen earlier for the flat bearings, in that an increase in friction factor resulted relative to the friction produced with CMC fluids alone.

### 3.3. Comparison of friction values with theoretical predictions

Table 1 lists the values of the various design and input parameters used in the following analysis. It should be noted that the value for the Poisson’s ratio for the compliant joint is an assumption and is inaccurate as it is strain related. However, this assumption is incorporated in this simplistic model and does not detract from the overall observations regarding the mode of lubrication. Using Eq. (E) the minimum lubricating film thickness for the flat and congruent knee joints were calculated to be 0.148 and 0.298 \(\mu\)m, respectively.

The root mean square surface roughness (\(R_q\)) values of the femoral and tibial components are shown in Table 2. These val-
ues along with the predicted minimum film thickness were used with Eq. (G) to calculate $\lambda$ for each set and, therefore, the theoretical lubrication regimes acting within each set. The $\lambda$ value of the flat TKR systems was calculated to be 1.44 and 1.63 for Sets A and B, respectively. Theoretically, this implies that these joints would operate under mixed lubrication conditions since $\lambda$ is between 1 and 3. However, these $\lambda$ values are considerably larger than those obtained for conventional CoCr-on-UHMWPE joints ($\sim0.20$) as predicted in a previous study [21]. Therefore, it is believed that these flat compliant layer joints may operate closer to fluid film lubrication than conventional joints.

The calculated $\lambda$ values for all the congruent CoCr-on-PU knee joints were an order of magnitude lower than those reported earlier [21] for conventional UHMWPE-CoCr TKRs and therefore illustrated the superior frictional properties of these biomimetic joints.

The Striebeck plots for Sets A and B with the $\lambda = 3$ line (which is shown as the dashed line) are shown in Fig. 5. Initially, Eq. (G) was used to calculate $h_{\text{min}}$ which was subsequently substituted into Eq. (E) from which the lubricant viscosity was derived. Finally, the Sommerfeld number at which $\lambda = 3$ was determined. The $\lambda = 3$ line theoretically represents the transition from mixed lubrication to fluid film lubrication for the flat knee joints, although, it is seen that the friction factors remain relatively constant after the transition line. A possible explanation for the inconsistency with fluid film Striebeck theory is the inherent experimental limitations when measuring such extremely low friction factors.

The Striebeck plots for Sets 1, 2, 3 and 4 with the $\lambda = 3$ line are shown in Fig. 6. All the friction factors at the higher end of the viscosity range are to the right of the $\lambda = 3$ line, suggesting a fluid film lubrication regime at these viscosities.

Overall, the frictional assessment of compliant layer knee joints confirmed the predicted fluid film lubrication mode. It was shown that when operating under conditions simulating those found in vivo with a suitable lubricant, similar kinematics and a dynamic load, albeit at ambient temperatures, that the joints operated with FFL. Importantly, it can be seen that some of these friction factors were an order of magnitude lower than those reported earlier [21] for conventional UHMWPE-CoCr TKRs and therefore illustrated the superior frictional properties of these biomimetic joints.

### 4. Conclusions

In pre-wear testing, *in vitro* frictional assessments have shown that both flat and congruent compliant layer polyurethane TKRs operate with low friction giving FFL where EHL and $\mu$EHL flatten and polish the asperities on the surface of the compliant layer. In a previous study [21] similarly designed UHMWPE bearings were shown to operate in the mixed lubrication mode with asperity contact.

It is clear that the level of friction factor encountered depends on the lubricant; proteins in the BCS had an increasing effect on the friction of all the bearings tested. The theoretical predictions were less appropriate with BCS as the lubricant, as adsorbed proteins on the surface of the compliant layer may have affected the frictional properties. The use of a suitable lubricant with similar kinematics and a dynamic load, although at ambient temperatures, that the joints operated with FFL. Importantly, it can be seen that some of these friction factors were an order of magnitude lower than those reported earlier [21] for conventional UHMWPE-CoCr TKRs and therefore illustrated the superior frictional properties of these biomimetic joints.

### Table 1

Total knee joint design parameters and input conditions.

<table>
<thead>
<tr>
<th>Description</th>
<th>Parameter</th>
<th>Notation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
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<td>Femoral component (CoCr)</td>
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<td>$E_1$</td>
<td>$2.1 \times 10^5 \text{ MPa}$</td>
</tr>
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<td>Poisson’s ratio</td>
<td>$\nu_1$</td>
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</tr>
<tr>
<td></td>
<td>Radius of curvature</td>
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<td></td>
<td>Bearing length</td>
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<td>$E_2$</td>
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<td>Poisson’s ratio</td>
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<tr>
<td></td>
<td>Radius of curvature</td>
<td>$R_2$</td>
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<td></td>
<td>Contact half width</td>
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<tr>
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<td>Minimum film thickness</td>
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<td>0.148 $\mu$m</td>
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<tr>
<td></td>
<td>Central film thickness</td>
<td>$h_{\text{cen}}$</td>
<td>0.166 $\mu$m</td>
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<tr>
<td>Tibial component (PU congruent compliant layer)</td>
<td>Modulus</td>
<td>$E_3$</td>
<td>6.83 MPa [35]</td>
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<td>Central film thickness</td>
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</table>

### Table 2

Predicted lubrication modes.

| Input conditions | Applied load | $F$ | 2200 N |
| | Entrainment velocity | $u$ | 0.031 m/s |
| | Lubricant viscosity | $\eta$ | 0.00341 Pa s (25% BCS viscosity$^a$) |

**Notes:**

$^a$ It should be noted that the BCS viscosity is close to that expected for pathological synovial fluid.
cation regime conflicted for the flat and congruent joints, their frictional performance was unambiguous as both joints clearly exhibited FFL characteristics. Striebeck analysis clearly pointed towards superior wear performance of a compliant bearing knee joint over a conventional UHMWPE joint. This potential for superior wear performance will be investigated in Part II of this study.

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References