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Research Article

The Effect of Clearance upon Friction of Large Diameter Hip Resurfacing Prostheses using Blood and Combinations of Bovine Serum with Aqueous Solutions of Cmc and Hyaluronic Acid as Lubricants

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Abstract

In real life, immediately after joint replacement, the artificial joint is actually bathed in blood instead of synovial fluid. Blood contains large molecules and cells of size ~ 5 to 20 micron suspended in plasma and considered to be a non-Newtonian (pseudoplastic) fluid with viscosity ~ 0.01 Pas at shear rates of 3000 s^{-1}. The effect of these properties on friction is not fully understood and, so far, hardly any studies have been carried out regarding friction of metal-on-metal bearings with various clearances in the presence of lubricants such as blood or a fluid containing macromolecules such as Hyaluronic Acid (HA) which is a major component of synovial fluid, increasing its viscosity and lubricating properties. In this work, therefore, the frictional behaviour of a group of Smith and Nephew Birmingham Hip Resurfacing devices with a nominal diameter of 50mm and diametral clearances in the range ~ 80 to 300µm, in the presence of blood (clotted and whole blood), a combination of Bovine Serum (BS) with Hyaluronic Acid (HA) and Carboxymethyl Cellulose (CMC) adjusted to a range of viscosities (~0.001-0.2 Pas), and bovine serum with CMC adjusted to a similar range of viscosities have been investigated.

The results suggest that reduced clearance bearings have the potential to generate high friction especially in the presence of blood which is indeed the *in vivo* lubricant in the early weeks after implantation. Friction factors in higher clearance bearings were found to be lower than those of the lower clearance bearings using blood as the lubricant.

Introduction

Metal on metal bearings have the potential to produce far less wear than conventional metal on polyethylene bearings and when the current generation of metal on metal devices were developed they were thought to have the potential for lower failure rates than other designs in the market. This optimism was mainly due to a remarkable improvement in the prosthetic design of metal-on-metal resurfacing devices including improved sphericity, excellent tolerances, the use of large diameter components to lower the risk of dislocation, good lubrication between the articulating surfaces, and high carbon and carbide content to reduce wear. The major objectives in the design of joint prostheses are to achieve stable articulations, low friction and wear, solid fixation to the bone, and normal range of motion. However, the demands presented by highly active patients with longer life expectancy have challenged the orthopaedic companies to improve both design and materials of joint implants. To improve the stability and osteointegration, some prostheses were modified to use a cemented or non-cemented femoral component and with a hydroxyapatite coated cup. With the development of these metals on metal devices, there was a strong trend towards their use but following recent well publicized high failure rates and complications, particularly the development of ALVAL, with some particular designs the popularity of metal on metal bearing couples has dropped dramatically. Data from the National Joint Registry however does not show uniform failure rates amongst the various metals on metal designs.

Hip replacement studies on postoperative implant migration have postulated that the stability and therefore one aspect of the long-term success of the implants may be predicted from the levels of migration within the first two years after implantation. Radiostereophotogrammetric Analysis (RSA) has therefore been used to measure the migration of the prosthesis with respect to the bone and its stability *in vivo*. RSA studies carried out on BHR devices have shown negligible migration of the implant [1-5] suggesting long-term stability *in vivo* for the hip resurfacing prosthesis. Another

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important feature of the hip resurfacing devices is the improved bony ingrowth or ongrowth due to their roughened backing via hydroxyapatite coating, resulting in improved rotational stability of the prosthesis. Also, use of mechanical fixations such as fins has been suggested for improving the initial rotational stability of the prosthesis in the early weeks and months after implantation [6].

Tribology theories and hip joint simulator studies have predicted that friction, lubrication and wear within these bearing systems are affected by several factors including load applied, material hardness, surface roughness, bearing diameter, sliding speed, radial clearance and the viscosity of the lubricant [7-16].

Traditional hip friction studies have employed bovine serum as the lubricant with added Carboxymethyl Cellulose (CMC), on the premise that this combination simulates the viscosity and other characteristics of the *in vivo* lubricant, i.e. synovial fluid [17]. This combination does not contain Hyaluronic Acid (HA) which is a lubricating substance with good shock absorption properties present as a major component of cartilage and the synovial fluid in joints and also distributed widely throughout connective, epithelial (skin), and neural tissues where it has a protective, structure stabilizing and also shock-absorbing role [18,19].

Hyaluronic acid, however, has large molecules of glucosaminoglycan (or special mucopolysacharide) and a high but variable molecular weight (in the range 10^4 - 10^7 Da) and viscosity. Immediately after joint implantation, the artificial joint is actually bathed in blood for couple of weeks or even months and not in synovial fluid. Blood also contains large molecules and cells of size ~ 5 to 20 micron and the effect of these on friction is not yet fully understood. To the authors knowledge, there are no studies on friction of metal-on-metal bearings with varying clearances in the presence of blood or a fluid containing macromolecules (e.g. both HA and blood) as lubricants.

Most modern cementless joints depend on a press fit primary fixation which stabilises the component in the early weeks. This allows bony ingrowth and ongrowth to occur which in turn provides durable long term fixation. Increased bearing friction in the early weeks and months after implantation can lead to micromotion and has the potential to prevent effective bony ingrowth from occurring. Therefore, friction in the early postoperative period can be critical to the long-term success of the fixation. This has been one of the concerns raised in a recent clinicoradiological study of metal-metal bearings with reduced and closely controlled diametral clearance of 100μm [20]. A progressive radiolucent line at the periphery of the socket component was evidenced in a few of these cases (8 out of 26) at follow-up, as shown in figure 1 [5,20], and raised the possibility that increased friction was affecting component fixation.

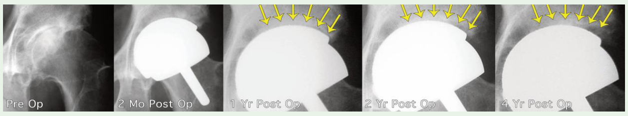

Figure 1: Radiographs of a patient with a low clearance Birmingham Hip Resurfacing, showing a progressive radiolucent line around zones 1 and 2 of the acetabular component, suggesting increased friction and micromotion resulting in poor fixation.

Therefore, the aim of this work was to investigate the frictional and lubrication behaviour of a group of S&N Birmingham Hip Resurfacing (BHR) devices with a nominal diameter of 50mm and diametral clearances in the range ~ 80μm to 300μm, using human whole blood, clotted blood, BS+CMC and BS+HA+CMC as lubricants of viscosities ~0.03-0.2Pas.

Materials and Methods

Five as cast high carbon Co-Cr-Mo MOM ‘Birmingham Hip Resurfacing (BHR) devices’ (supplied by Smith and Nephew Orthopaedics Ltd, Leamington Spa, UK) with a diameter of 50mm each and diametral clearances of 80, 135, 200, 243 and 306μm were used in this study. The initial surface roughness (Ra) was measured between 20-30nm using a Form-Talysurf 50 (Taylor Hobson, Leicester, UK), and the components were within BHR manufacturing tolerances.

Frictional measurements of all the joints were carried out at University of Bradford-Medical Engineering Department, using a Prosim Hip Joint Friction Simulator (Simulation Solutions Ltd, Stockport, UK). The acetabular cup was positioned in a fixed low-friction carriage below and the femoral head in a moving-frame above. The carriage sits on an externally pressurized hydrostatic bearings generating negligible friction compared to that generated between the articulating surfaces, also allowing for a self-centering mechanism as shown in figure 2. During the flexion-extension motion, the friction generated between the BHR devices causes the pressurized carriage to move. This movement (or rotation) is restricted by a sensitive Kistler piezoelectric force transducer which is calibrated to measure torque directly.

A pneumatic mechanism controlled by a microprocessor generates a dynamic loading cycle and the load is also measured by a piezoelectric force transducer. Friction measurements (friction factor results given in this paper) were made in the ‘stable’ part of the cycle at 2000N and to obtain accurate measurements for friction, the centre of rotation of the joint was aligned closely with the centre of rotation of the carriage. The loading cycle was set at maximum and minimum loads of 2000N and 100N, respectively. In the flexion/extension plane, an oscillatory harmonic motion of amplitude ±24° was applied to the femoral head with a frequency of 1Hz as shown schematically

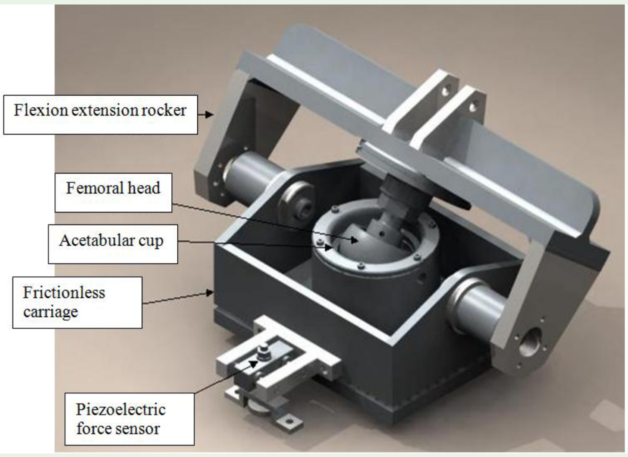

Figure 2: Hip joint friction simulator.

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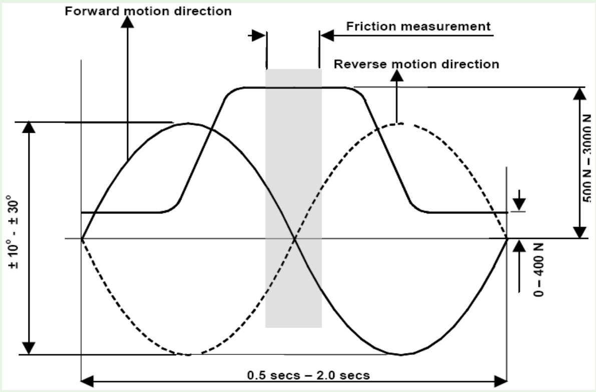

Figure 3: Schematic dynamic loading cycle applicable by the simulator indicating the forward and reverse motion directions and the friction measurement zone.

in figure 3. The load was therefore applied to the femoral head with the artificial hip joint in an inverted position, i.e. femoral head on top of the acetabular component, but with a 12° angle of loading between the two bearings as observed in human's body.

The angular displacement, frictional torque (T) and load (L) were recorded through each cycle. The frictional torque was then converted into friction factor (f) using equation 1, where r is the femoral head radius.

Equation 1: $f = T/rL$

An average of three independent runs (tests) was taken.

The tests were conducted using: (i) human whole blood (with Lithium heparin to prevent clotting), (ii) human clotted blood, (iii) Bovine serum (new born calf serum via Harlan Sera-Lab with a total protein content of 61.27 mg/ml which had been sterile filtered to 0.1mm) and aqueous solution of CMC, and (iv) with Hyaluronic Acid added to (iii) as the lubricants for each joint. The viscosity of the whole blood was found to be ~ 0.01 Pas and that of clotted blood was ~0.02 Pas at a shear rate of~3000 s^{-1} (Figures 4a and 4b). The test was then run with a combination of: (iii) Bovine serum and aqueous solutions of CMC to achieve viscosities of 0.0038, 0.0013, 0.0136, 0.0327, 0.105 and 0.19 Pas and (iv) Bovine serum (BS) and hyaluronic acid (Supartz® supplied by Smith and Nephew Orthopaedics Ltd) with or without CMC to achieve viscosities of 0.00145, 0.0035, 0.01324, 0.037 and 0.138 Pas. Note that all the viscosities were measured at a shear rate of 3000 s^{-1} using the Anton Paar Physica MCR 301 Viscometer; the content of the hyaluronic acid was equivalent to that of synovial fluid in a normal young adult subject (~3.1), and the bovine serum was diluted to 25%, i.e. the BS concentration was kept at 25% with aqueous solutions of CMC (75% distilled water+CMC). The CMC was used as a gelling agent or viscosity enhancer. The CMC fluids are shown [17] to have similar rheological properties (Figures 4c and 4d) to synovial fluid, but it is possible that they may not produce the shear stresses created by the presence of macromolecules in the lubricant. Also, 0.2% sodium azide was added to the solutions (1g per litre of serum) as an anti-bacterial/antibiotic agent (biostatic).

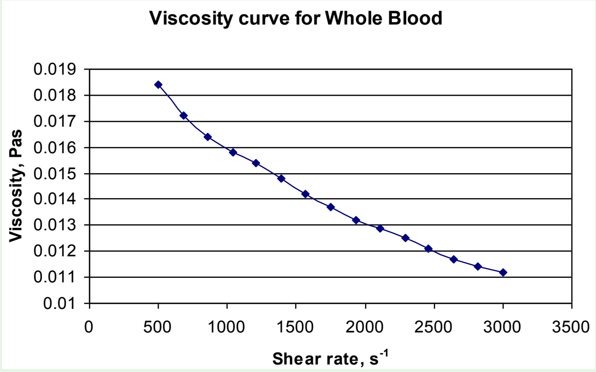

Figure 4a: Viscosity versus shear rate for whole blood.

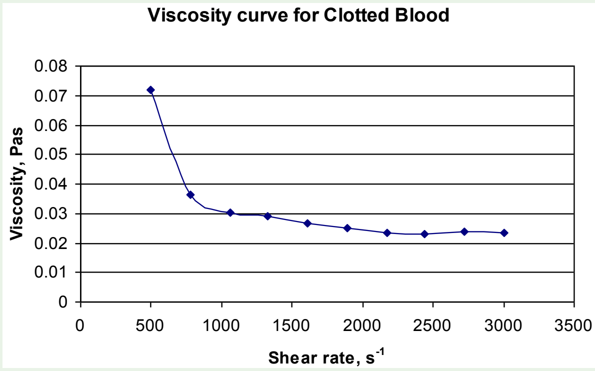

Figure 4b: Viscosity versus shear rate for clotted blood.

Results

The viscosity curves for blood and clotted blood in Figures 4a and 4b, respectively, show a pseudoplastic flow behaviour, i.e. a decrease in viscosity as shear rate increases, suggesting a shear thinning characteristic with the viscosity curve becoming asymptotic (leveling off) and remaining constant at high rates of shear >3000 s^{-1} (except for blood, see Figure 4a) implying that the lubricant becomes an incompressible isoviscous Newtonian fluid at these shear rates. This result, therefore, indicates typical viscosities for blood and clotted blood expected between the articulating surfaces after implantation and allows some comparison with other biological lubricants such as synovial fluids and bovine serum. From figure 4a, it can be seen that blood has a viscosity of ~ 0.01 Pas as compared to ~ 0.02 Pas for clotted blood (Figure 4b) at a shear rate of 3000 s^{-1}, suggesting higher

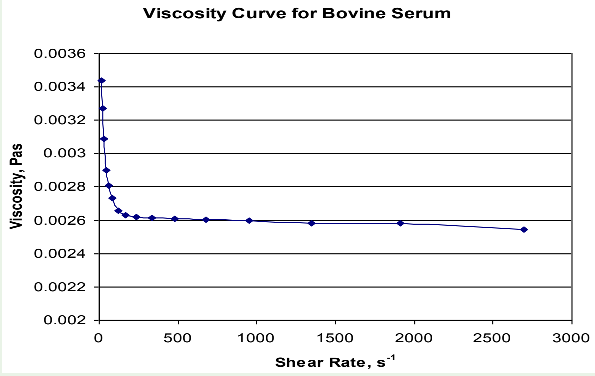

Figure 4c: Viscosity versus shear rate for 25 % bovine serum.

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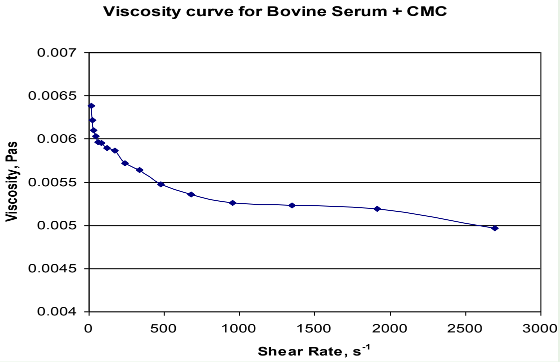

Figure 4d: Viscosity versus shear rate for 25 % bovine cerum with CMC.

friction at the articulating surfaces is expected depending on the diametral clearance when blood is the lubricating fluid. The bovine serum with or without CMC also exhibited non-Newtonian shear thinning characteristics, i.e. psuedoplastic flow behaviour, as can be seen from figures 4c and 4d, respectively.

Figure 5 is the graph of friction factor versus diametral clearance for all the five joints using whole blood (η=0.013 Pas), clotted blood (η=0.02 Pas), BS+CMC (η=0.0135 Pas) and BS+HA+CMC (η=0.0132 Pas) as lubricants. A significantly important finding is that the friction factors consistently decrease with increase in diametral clearance for both blood and clotted blood. This result clearly implies that blood and clotted blood as lubricants may cause higher friction at lower clearances, especially after joint implantation, as compared with other physiological body fluids. On the other hand, the BS+CMC lubricants with similar viscosities of ~ 0.013 Pas showed the opposite effect, i.e. caused an increase in friction factor with increase in diametral clearance (except for the 175μm clearance indicating optimum for the 50mm ϕ joint Figure 5). Also notable is that the friction factors are consistently higher for blood and clotted blood (0.15-0.2) as compared with those obtained for bovine serum with carboxymethyl cellulose and hyaluronic acid (~0.08-0.14). The higher friction factors for blood and clotted blood may be due to the presence of large molecules (blood cells of size ≥ 20μm) which may get entrained between the articulating surfaces raising the shearing forces and hence causing higher friction especially for lower clearances as seen in figure 5.

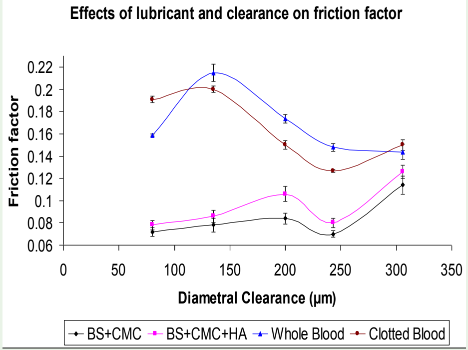

Figure 5: Friction factor versus diametral clearance using whole blood (η=0.013 Pas), clotted blood (η=0.02 Pas), BS+CMC (η=0.0135 Pas) and BS+CMC+HA (η=0.0132 Pas) as lubricants.

Discussion

The engineering issues surrounding optimal metal-on-metal prostheses have been the centre of much debate and research. Ongoing research into the in vitro wear performance of these bearings as a function of macrogeometry (bearing diameter, clearance and component thickness) and microgeometry (roundness and surface finish) is done in hip function simulators with lubricants that are believed to simulate the natural joint fluid in terms of viscosity. However, these lubricants have the limitation of being unable to simulate the friction effects of macromolecules.

So far, factors such as cellular and macromolecular shear that can affect friction in these bearings, *in vivo*, have not been specifically investigated in vitro. Progressive radiolucent lines that appeared in a few patients with low clearance bearings (Figure 1) prompted the need to study this issue of increased friction in these bearings. However, the current widespread concern about early failure of some metal on metal bearings raises the question of which factors may be of relevance in the early failure of resurfacing hips and total hip replacements using metal on metal bearing couples.

The results of this study suggest that reduced clearance MOM bearings have the potential to generate high friction especially in the early weeks after implantation when blood is indeed the *in vivo* lubricant. Friction factors in higher clearance bearings are much reduced in comparison. This higher friction in the low clearance bearings may produce micromotion and hamper bony ingrowth resulting in impaired fixation with long-term implications for survival.

It is well recognized that the selection of optimum diametral clearance between the femoral head and the acetabular cup is a critical factor for the success of MOM bearings and thus an important consideration for the design/manufacturing of MOM hip prostheses [21]. The current literature regarding the use of small clearances gives two different concluding remarks, i.e. for in vitro wear tests supported by theoretical studies it is claimed that smaller clearances reduce bedding-in wear and may improve lubrication conditions [22,23]. So far, clinical studies, has not provided any evidence that larger clearances can cause reduction in the life of the MOM hip prostheses.

The frictional studies in this work have shown that lower clearances do not necessarily reduce the friction factors to a level for the presence of full fluid film lubrication and that the friction factors decrease with increase in diametral clearance for high viscosity (0.01-0.02 Pas) fluids. It is to be noted that friction between the bearing surfaces is the combination of direct contact between the bearing surfaces and the internal friction of the lubricant. For a small clearance, the shear rate of the lubricant will be higher than the larger clearance, e.g. the shear rate for the 80 μm clearance would be higher than that of the larger 306 μm clearance which suggests that a high friction factor may be caused due to the internal friction of the lubricant, especially when the viscosity is high, as seen in this study [24-27]. This means that the friction force will then be dominated by the internal friction of the lubricant and for a smaller clearance, the bearing area can easily extend in the equatorial direction, which can result in higher contact stresses on the bearing surface near the equatorial area and hence cause a higher friction torque under the same load.

Although the early factor of blood in the joint may be more relevant to the occasional occurring of failure of bony ingrowth or ongrowth leading to early loosening of the prosthesis from bone such frictional factors may also be of relevance in initiating the process of bearing failure due to the development of third body wear, or fretting at morse tapers.

Conclusion

- It became clear that the friction factors decreased consistently with increase in diametral clearance for both blood and clotted blood with opposite effect for BS+CMC and BS+HA+CMC of similar viscosities (~0.013 Pas). This therefore suggested that higher clearances will lower the friction for these large diameter S&N BHR devices depending on the type of lubricant and viscosity.
- The friction factors were higher for both blood and clotted blood especially at lower clearances as compared to the other lubricants indicating that lower diametral clearances may increase the risk of micromotion during the early weeks/months after hip implantation which in turn may adversely affect the longevity of the implant.

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