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Research paper

Lubrication of metal-on-metal hip joints: The effect of protein content and load on film formation and wear

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ABSTRACT

Lubricant films were measured for a series of bovine serum and protein containing (albumin, globulin) saline solutions for CoCrMo femoral component sliding against a glass disc. Central film thickness was measured by optical interferometry as a function of time (constant mean speed: 0 and 10 mm/s) and variable mean speed (0–50 mm/s). The effect of load (5–20 N) on film thickness was also studied. The development of the wear scar on the CoCrMo surface was monitored by measuring the width of the contact zone during the film thickness tests. The results showed film thickness increased with time for both the static and sliding tests. Films formed in the static, loaded test were typically in the range of 3–40 nm. The globulin containing solutions formed the thickest films. In the sliding tests a wear scar rapidly formed on the implant component for the bovine serum and albumin fluids, negligible wear was observed for the globulin solutions. Film thickness increased with sliding time for all test solutions and was much greater than predicted by isoviscous EHL models. The film increase was found to correlate with increasing wear scar size and thus decreasing contact pressure. A new lubricating mechanism is proposed whereby during sliding the fluid undergoes bulk phase separation rheology, so that an elevated protein phase forms in the inlet zone. This protein phase is a high-viscosity biphasic matrix, which is periodically entrained into the contact forming a thick protective hydro-gel film. One of the main findings of this study is that film thickness was very sensitive to load; to a much greater extent than predicted by EHL models. Thus film formation in MoM hip joints is very susceptible to high contact pressures which might be due to implant misalignment and edge-loading.

1. Introduction: artificial joint lubrication

Artificial joint procedures and in particular the replacement of hips and knees continue to become more frequent. Recently the UK National Joint Registry (2010) reported a total of 71,021 primary hip and 8309 revision procedures for 2008/2010 in England alone. In addition there is increasing usage of larger femoral heads; in 2009 47% of hips had a head size of 32 mm or greater compared to 21% in 2006 and 6% in 2003 which is due in part to the greater use of LHMoM resurfacings (NJR 2010). However, concern over postoperative lesions (Revell et al., 1997) has prompted a re-evaluation of the performance of LHMoMs which culminated in the issue of a Medical Device Alert by the *Medicines and*

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Abbreviations

BCS	Bovine calf serum
CoCrMo	FS75 Cobalt–chromium–molybdenum alloy
CW_{start} CW_{end}	Effective contact width measured at the start and end of the test
CW_r	Relative effective contact width CW_{end}/CW_{start}
EHL	Elastohydrodynamic lubrication
LHMoM	Large head metal-on-metal
MoM	Metal-on-metal
SF	Synovial fluid
THR	Total hip replacement
UHMWPE	Ultra high molecular weight polyethylene

Healthcare products Regulatory Agency (MHRA, 2010) and the withdrawal of some brands from the market. The NJR (2010) reported overall revision rates of "2.9% *of the patients had a revision of their hip replacement within five years. The lowest revision rates were seen in patients who received a cemented prosthesis (five year revision rate of* 2.0%) *and the highest in those who had a LHMoM THR (five year revision rate of* 7.8%)". There are a number of underlying factors which contribute to high LHMoM failure, which include; design, surgeon and patient issues. The most usual explanation is that LHMoM hips are susceptible to non-optimum positioning particularly the inclination angle of the acetabular cup. High inclination angles are thought to contribute to edge-loading which is associated with high wear rates (Langton et al., 2008). The results from hip simulator tests (Smith et al., 2011) and fluid film modelling (Dowson, 2006) predict that the larger head size should significantly improve performance and implant life. However the revision rates belie this prediction and one possible explanation for this disparity is that the fundamental lubrication mechanisms are different and that patient synovial fluid chemistry plays a role.

Wear of artificial joints is controlled by the properties of the implant material and lubricating film. The effects of non-optimum implant position, patient gait, implant design and synovial fluid chemistry will be reflected in the lubricant film properties. The relevant properties include film thickness during articulation and chemical composition. Lubricating film formation over the gait cycle is usually ascribed to hydrodynamic mechanisms due to the effects of fluid entrainment and squeeze film (Dowson, 2006). The lubricant is modelled as a simple continuum fluid with a Newtonian rheology (Cooke et al., 1978; Dowson, 2006). An alternative mechanism is boundary lubrication due to surface films formed by phospholipids or proteins contained in the periprosthetic synovial fluid (Bell et al., 2001; Widmer et al., 2001).

In an earlier paper (Fan et al., 2011) we reported a new mechanism for film formation with protein containing solutions. The research showed model synovial fluid solutions formed much thicker films than expected which was attributed to protein-agglomeration close to the contact. This formed a reservoir of high-viscosity material in the inlet region which passed through the contact developing a relatively thick lubricant film. Post-test examination of the femoral head revealed the formation of gelatinous deposits close to the wear scar in the inlet region (Fan et al., 2011). There are a number of papers in the research literature reporting the formation of organic deposits on implant surfaces (Wimmer et al., 2003). The concentration and type of proteins in SF affect implant wear (Sawae et al., 2008; Wang et al., 2003) although the relationship is not clear and there is very little reported work for MoM implants. There are significant differences between healthy and periprosthetic SF (Delecrin et al., 1994; Kitano et al., 2001) and this might be a further factor determining premature joint failure.

Kitano et al. (2001) describe healthy and periprosthetic SF as containing a mixture of large and surface active molecules including proteins (albumin and γ-globulin), phospholids, hyaluronan. Kitano et al. (2001) go on to list the total protein content of healthy SF in the range 18–20 mg/ml, which increases in periprosthetic and diseased SF to 30–50 mg/ml. The most abundant protein is given as albumin, which is typically found with a concentration range of 20–39 mg/ml in periprosthetic SF and 7–18 mg/ml in healthy. The concentration of globulin also increases from 0.5–2.9 mg/ml in healthy and from 4.6–15.4 mg/ml in periprosthetic. Thus the concentration and protein composition changes in diseased and periprosthetic SF.

The aim of the current paper was to study the 'inlet aggregation' mechanism in more detail and to quantify the effect of protein content and load (pressure) on film formation and CoCrMo wear.

2. Experimental programme

In the current work the MoM hip contact was simulated by a commercial grade 'as-cast' CoCrMo femoral head loaded and rubbing against a glass disc. Central film thickness was measured for a range of speeds, loads (pressures) and lubricant properties (BCS and proteins). Two series of tests were carried out:

1. Film formation under cyclic loading (5 N) at 0 mm/s (720 s). The contact was loaded for ca 15 s while film thickness measurements were taken and then un-loaded for ca 45 s, this was repeated every minute. Fresh fluid was continuously supplied to the contact.
2. Film formation and wear measurements at constant entrainment speed (10 mm/s) for 720 s (14.4 m sliding distance). Film thickness was measured during the test and periodically the wear scar diameter was estimated from the dispersed image. The following tests were then carried out after this initial constant speed test:
   a. Effect of load (5–20 N) on film thickness at 10 mm/s.
   b. Film thickness as a function of speed at constant load (5 N): tests were carried out by slowly increasing and decreasing the sliding speed (0–55 mm/s).

Film thickness was measured by thin film optical interferometry using a femoral head/glass disc contact. The test device was supplied by PCS Instruments PLC, London. The optical measurement technique has been extensively reported in earlier papers (Cann et al., 1996; Johnston et al., 1991) and only a brief description will be given here. The technique uses optical interferometry to measure central film thickness in the glass/metal contact region, the measurement