Me 153

ACTA
POLYTECHNICA
SCANDINAVICA

MECHANICAL ENGINEERING SERIES No. 153

Effect of Lubricant on the Wear of Prosthetic Joint Materials

TIINA AHLROOS

Helsinki University of Technology
Laboratory of Machine Design
P.O. Box 4300
FIN-02015 HUT, Finland

Dissertation for the degree of Doctor of Science in Technology to be presented with due permission for public examination and debate in Auditorium K216 at Helsinki University of Technology (Espoo, Finland) on the 28th of November, 2001, at 12 o'clock noon.

ESPOO 2001

Ahlroos, T., **Effect of Lubricant on the Wear of Prosthetic Joint Materials.** Acta Polytechnica Scandinavica, Mechanical Engineering Series No. 153, Espoo 2001, 26 pp. Published by the Finnish Academies of Technology. ISBN 951-666-581-0. ISSN 0001-687X.

Keywords: prosthetic joint, hip joint, knee joint, lubricant, polyethylene, wear.

ABSTRACT

The wear of ultra-high molecular weight polyethylene (UHMWPE) in prosthetic hip and knee joints is a significant clinical problem. The wear particles cause inflammatory tissue reactions which may lead to osteolysis and loosening of the implant fixation. The effect of lubricant on the wear of polyethylene was studied with a reciprocating pin-on-flat (RPF) apparatus, uniaxial (HUT-2) and three-axis (HUT-3) hip joint simulators, circularly translating pin-on-disk (CTPOD) device, biaxial rocking motion (BRM-1 and BRM-2) hip wear simulators, and a three-axis ball-on-flat (BOF) knee wear simulator. The aim was to produce wear similar to that known to occur clinically. To accomplish this, the basic criteria for the lubricant were: 1) no polyethylene transfer layer should form on the metal counterface, 2) the bearing surface of the polyethylene should become burnished, 3) the wear particle size should be of the order of 1 μm, and 4) the wear factor should be of the order of 1×10^{-6} mm^3/Nm. The lubricants studied were human prosthetic joint fluid, bovine and calf serum, bovine albumin and gamma-globulin, soybean lecithin, dipalmitoylphosphatidylcholine (DPPC), soy protein, and distilled water. The counterfaces of polyethylene were CoCr, stainless steel, alumina, and diamondlike carbon (DLC). All the criteria were met by bovine and calf serum, albumin and gamma-globulin. Hence, albumin and gamma-globulin proved to be the crucial fractions of serum and synovial fluid with respect to producing clinically relevant wear of polyethylene. In conclusion, realistic wear was produced when the direction of sliding constantly changed relative to the polyethylene specimen, and a protein-based lubricant was used.

PREFACE

The study of biotribology, especially prosthetic joints, started at the Laboratory of Machine Design in the late 1980's. The work was started by V. Saikko, who did his master thesis and doctoral dissertation on the tribology of prosthetic joint materials and became a pioneer of this field in Finland and also one of the leading scientists in biotribology in the whole world. I started on this project as a researcher in 1995. This research area is very challenging and interesting because it is so interdisciplinary. I thank Prof. M. Kleimola for the opportinity to start the work. Prof. M. Airila is gratefully acknowledged for the guidance and support during the research work, which was done at the Laboratory of Machine Design. Dr V. Saikko has been my partner and supervisor during this work and I want to express my deepest gratitute to him. I want also thank my collegue Mr O.Calonius for conversations and partnership in the postgraduate studies.

The study was financed by the Academy of Finland, which I appreciate greatly. The Finnish Cultural Fund and Mrs E. Kolehmainen gave also financial support. I thank Prof. K. Holmberg for the opportunity to finish my postgraduate studies in the postgraduate school in the Research Field of Operational Reliability in VTT Manufacturing Technology. I would like to express my thanks to the pre-examiners Dr. J. Davidson and Dr. M. Lehto for their comments and to Mrs. E. Heap-Talvela for checking the English. I thank Mrs S. Vaahtera for all kind of help, Mr T. Salin for IT support, and Dr T. Paavilainen, Dr P. Ylinen and Dr S. Varjonen for teaching me orthopedics in the operating rooms of the Orthopaedic Hospital of the Invalid Foundation.

Finally, I want to thank my children, Lauri and Lotta, for their understanding during my postgraduate studies. Most of all, I want to thank my husband Vesa for all kind of support and help during these years.

Espoo, October 2001

Tiina Ahlroos

CONTENTS

LIST OF PUBLICATIONS

This dissertation consists of a summary and the following publications:

I Saikko, V., Ahlroos, T., Phospholipids as boundary lubricants in wear tests of prosthetic joint materials. Wear Vol. 207 (1997), p. 86–91.

II Ahlroos, T., Saikko, V., Wear of prosthetic joint materials in various lubricants. Wear Vol. 211 (1997), p. 113–119.

III Saikko, V., Ahlroos, T., Type of motion and lubricant in wear simulation of polyethylene acetabular cup. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine Vol. 213 (1999), p. 301–310.

IV Saikko, V., Ahlroos, T., Wear simulation of UHMWPE for total hip replacement with a multidirectional motion pin-on-disk device: Effects of counterface material, contact area, and lubricant. Journal of Biomedical Materials Research Vol. 49 (2000), p. 147–154.

V Saikko, V., Ahlroos, T., Calonius, O., Keränen, J., Wear simulation of total hip prostheses with polyethylene against CoCr, alumina and diamond-like carbon. Biomaterials Vol. 22 (2001), p. 1507–1514.

VI Saikko, V., Ahlroos, T., Calonius, O., A three-axis knee wear simulator with ball-on-flat contact. Wear Vol. 249 (2001), p. 310–315.

THE AUTHOR´S CONTRIBUTION

The author was responsible for the lubricant part of the publications.

1 INTRODUCTION

1.1 General

Joint replacement is a very efficient surgical treatment of severe joint diseases, and it has the best cost/benefit-ratio of all major surgical operations [6,7]. The total hip prosthesis is a ball-in-socket joint with three degrees of freedom: flexion-extension, abduction-adduction, and internal-external rotation. The wear of the acetabular cup (socket) made from ultra-high molecular weight polyethylene (UHMWPE) can limit the life of the implant, and may be a significant problem, if the surface of the femoral head (ball) is damaged. The knee prosthesis is a condylar joint and its principal motions are flexion-extension, anterior-posterior translation, and internal-external rotation. The wear of the polyethylene tibial component can also be a cause of failure. The wear debris resulting from the wear of the polyethylene components can cause inflammatory tissue reactions which can subsequently lead to the osteolysis of bone around the implant. Such bone lysis can lead to loosening of the fixation, which is the most frequent short-term failure mode of the prosthetic joints. A revision operation must then be performed, but the revision is more difficult and expensive than the primary operation, and the results are generally not as good. Quite often allogenic bone transplantation is required to fill the osteolytic cavities and hence the complete recovery from the operation takes longer time; 3 to 6 (12) months depending on the extent of bone bank material.

The aim of the tribological study of prosthetic joints is to aim at the development of joint couplings that minimize wear and friction in order to improve the long-term performance of these prostheses. To study the tribology of prosthetic joints in conditions similar to those prevailing in the human body, joint simulators are necessary. The simulator study should produce wear mechanisms, wear rates and wear debris similar to those seen clinically. The lubricant is a crucial parameter in the tribological studies of prosthetic joints, and is one consideration in the present study.

1.2 Natural joints

A natural, human joint is a complex mechanism with low friction. Joints allow movement and transmit large loads from bone to bone. The bone ends in the large joints are covered by articular cartilage, which is about 2 mm thick in healthy adults, but can be damaged and worn away in severely arthritic joints. Contact stresses can be of the order of 1 MPa. Joints are divided into two basic structural groups: diarthroses and synarthroses. Diarthroses are called synovial joints, in which synovial fluid is present, and synarthroses, in which there is no fluid. Synovial fluid (SF) is a dialysate of blood plasma containing electrolytes, cells, protein and mucopolysaccaride [3]. The volume of normal SF in the knee joint is estimated to be 0.5 to 2 ml [24]. SF has two tasks: lubrication and nutrition of the cartilage. The protein content of SF is about 20 mg/ml (2 %) and the proteins of SF are identical with the proteins of blood plasma. The principal proteins are albumin, gamma-globulin, transferrin and seromucin [3]. The lipid content of normal SF of the knee joint is about 2 mg/ml [12]. SF does not clot due to absence of fibrinogen and clotting factors. The lubricating ability of SF is important in joints. Hyaluronic acid is responsible for the viscosity of the SF. The normal healthy SF is highly non-newtonian, that is, the viscosity decreases greatly when the shear rate increases. Some diseases reduce the viscosity of the SF, and finally it becomes independent of the shear rate. This is caused by the reduced concentration of the hyaluronic acid in the pathological SF [24].

1.3 Prosthetic hip and knee joints

There are several types of prosthetic hip and knee joints. In Finland during the years 1980–1999, as many as 112 different designs of hip prostheses have been used [11]. The acetabular cup is usually made from ultra-high molecular weight polyethylene and the thickness of the cup is 6–12 mm. In prosthetic hip joints the head is metallic (CoCr, stainless steel, or Ti6Al4V) or ceramic (alumina Al_2O_3 or zirconia ZrO_2). Alumina-on-alumina and CoCr-on-CoCr combinations are also used. The surface of the head is polished to 0.005–0.05 μm R_a. Hall et al. made a retrieval study on 129 Charnley acetabular components after revision operation. They found that the mean penetration of the 316 stainless steel head into the high-density polyethylene was 0.20 mm/year, the mean volumetric wear rate was 55 mm^3/year, and calculated mean clinical wear factor k was 2.1×10^{-6} mm^3/Nm [4].

The tibial component of knee prostheses is also made of polyethylene and the femoral component generally made of CoCr alloy. The tibial component is relatively flat and the polyethylene bearing surface can be as thin as 4 mm. The femoral component is convex and, in many types of knee prostheses, the tibiofemoral contact is highly non-conforming. If the contact is non-conforming, it leads to high contact stresses, which can be above the strength of polyethylene. Typical findings of the tibial components removed from patients are burnishing, abrasion, scratching, embedded acrylic bone cement particles, pitting, delamination, surface deformation and cracking. In Finland during the years 1980–1999, a total of 91 different designs of knee prostheses were used [11].

1.4 Lubrication and wear mechanisms of prosthetic hip joints *in vitro* and *in vivo*

There are several theories of the lubrication mechanisms in natural joints. Boundary, hydrodynamic, weeping, elastohydrodynamic, squeeze-film, hyaluronate-protein gels, boosted, filtration, mixed, and fluid film have been presented [3]. The true lubrication mechanism in natural or prosthetic joints is still in dispute. The joint is surrounded by a joint capsule, in which the synovial bursae and membrane secrete SF to lubricate the joint. There is a pseudojoint cavity around the prosthetic joint filled with prosthetic joint fluid, but the quality of the fluid is different from that of SF in primary osteoarthritis (OA). The concentration of hyaluronate is lower in prosthetic hip joints than in OA hip joints, but the total protein concentration is relatively similar [13].

One theory about the lubrication of prosthetic hip joints is that the proteins of the SF act as a boundary lubricant by adsorbing to the metallic surface [16]. Wang et al. showed that soluble proteins are not an effective boundary lubricant and therefore claimed that there is no boundary lubrication in prosthetic hip joints *in vivo* [18,19]. The protein concentration in wear test lubricant should range from 20 mg/ml to 35 mg/ml, as in human synovial fluid [21]. If the protein concentration is too high, the proteins degrade faster, precipitate, and become a solid lubricant, which reduces wear in an abnormal way. If the protein concentration is too low, the polyethylene transfer layer will form [18]. The proteins of bovine serum in simulator tests seem to be responsible for the wear of polyethylene rather than preventing it [19]. The bovine serum should be diluted by at least 50 % for the simulator tests [23]. Wang et al. also studied the effect of protein concentration and lubricant volume on the wear of polyethylene. They found that the precipitate concentration decreased when the volume of the lubricant increased and the wear rate acted vice versa. The highest wear rate was achieved with the lowest protein concentration studied, 20 mg/ml, and it also had the lowest degradation index when the lubricant volume was constant at 400 ml. The regular bovine serum with 65 mg/ml protein concentration showed the highest degradation index and lowest wear rate [22]. The addition of 0.43 mg/ml hyaluronic acid to bovine serum containing 35 mg/ml proteins lowered slightly the wear rate of polyethylene [19].

The advantage of water lubrication is that it does not degrade during testing, but the wear rate is usually much below the clinical wear rate calculated from retrieved prostheses. In water lubrication, polyethylene transfer to the counterface is usually seen [1], but not always [14]. The transfer layer is not seen clinically in explanted prostheses or in wear tests if serum is used as a lubricant [17]. The proteins of the lubricants appear to be responsible for the absence of the transfer layer [1,2,8]. At present, serum is the most popular lubricant in wear testing of prosthetic joints and their materials because its composition is close to that of synovial fluid. The polyethylene particles isolated from the used serum lubricant of hip simulators tests [17] and from periprosthetic tissues [9] have been found to be similar, at 0.1–1 μm in size. The prosthetic joint fluid has been studied little and its properties are always different depending on the type of the prosthesis and the disease the patient has or is suffereing from.

The principal wear mechanisms in prosthetic hip joints are adhesive and abrasive. In knee prostheses, fatigue wear may also play a detrimental role. The adhesive wear mechanism is responsible for the production of an enormous number of polyethylene wear particles, and because of the adhesive wear, it seems that the lubrication is not very effective. Wang et al. proposed their theory of starved lubrication regime for conforming contact [18]. Earlier it was thought that the surface roughness of the femoral head is the crucial factor affecting the wear of polyethylene [1,2]. These tests were made with reciprocating wear testers in water lubrication. Wang et al. showed that reciprocators exaggerate the influence of counterface surface roughness on polyethylene wear [20]. They found that the wear factor in multidirectional motion serum-lubricated tests is approximately proportional to the square root of the femoral head roughness R_a [21].

1.5 Contribution

The aim of the present study was to search for new information about the wear of polyethylene with respect to the test lubricant and the type of motion, and load**.** The tests were done with a reciprocating pin-on-flat (RPF) apparatus, uniaxial (HUT-2) and three-axis (HUT-3) hip joint simulators, a circularly translating pin-on-disk (CTPOD) device, biaxial rocking motion (BRM-1 and BRM-2) hip wear simulators, and a three-axis ball-on-flat (BOF) knee wear simulator. The basic criteria for the lubricant are:

(a) No polyethylene transfer layer should form on the metal counterface
(b) The bearing surface of the polyethylene should become burnished
(c) The wear particles should be of the order of 1 μm and smaller in size as in the clinical situation
(d) The wear factor should be of the order of 1×10^{-6} mm^3/Nm

At first, phospholipid-water dispersions were studied. A transfer layer formed in some tests, but otherwise the wear was negligible (Publication I). The next stage was soybean lecithin and soy protein studies. Soy protein in salt solution showed excellent lubricating properties. Bovine serum and joint fluid aspirated from a prosthetic hip joint at revision operation were studied for comparison (Publication II). With a new circularly translating pin-on-disk (CTPOD) device, bovine serum, phosholipid (DPPC), and soy protein were studied. This simple device gave a realistic wear simulation with serum lubrication. Phospholipid and soy protein resulted in unrealistic wear (Publication III). Studies on albumin and gamma-globulin indicated that their effect on polyethylene wear is close to that of serum (Publication IV). The bovine serum was changed to calf serum, which was used without additives in the BRM-2 hip wear simulator. The wear behaviour and the size and shape of wear particles were similar to those seen in clinical studies (Publication V). In the ball-on-flat (BOF) knee wear simulator calf serum was used as a lubricant, and it functioned well in evaluating knee wear as well (Publication VI).

2 MATERIALS AND METHODS

In all tests, one counterface was ultra-high molecular weight polyethylene, the wear measurement was gravimetric, soak controls were used, and vacuum desiccation was done before weighing.

2.1 Publication I

Various phospholipid lubricants were studied in a reciprocating pin-on-flat device and in two hip joint simulators. The lubricants were dipalmitoylphosphatidylcholine (DPPC) 3 mg/ml in distilled water and in 0.1 M Na_2HPO_4-$NaPO_4$ phosphate buffer, pH 7.4, and soybean lecithin 1 mg/ml and 3 mg/ml in distilled water. The DPPC was 99 % pure P-0763 by Sigma Chemical Co. The soybean lecithin was Lipoid S 30 (Lipoid GmbH), which is a mixture of various phospholipids, the main component (32 %) being phosphatidylcholine. Phospholipids were dispersed by ultrasonication. The pH values of all but the buffer solution were about 5.5. Sodium azide (0.02 %) was added to all lubricants to retard microbial growth.

The pins were 2.5 Mrad gamma irradiated polyethylene, GUR 415. The diameter of the pins was 8.9 mm and the end was chamfered at an angle of 60º so that the initial diameter was 3 mm. The disks were CoCr alloy ASTM F 75 and they were disk-shaped, 35 mm in diameter, 10 mm thick and the R_a value was 0.006 ± 0.002 µm. The acetabular cups were of the same type gamma irradiated polyethylene and the thickness of the cups was 10.9 mm. The acetabular shells were made of titanium alloy. The femoral~~s~~ heads were wrought CoCr alloy ASTM F 799. The diameter of the heads was 28 mm and R_a value 0.014 ± 0.003 µm.

The reciprocating pin-on-flat (RPF) apparatus was a new design for friction and wear screening of prosthetic joint materials and their surface treatments, coatings and for lubricant studies. The pin was pressed against the disk with a constant force of 70.7 N, and the nominal contact pressure was 10 MPa (force divided by the contact area of the chamfered pin 7.065 mm^2) . The disk was repicrocated sinusoidally along horizontal linear bearings with a crank mechanism. The stroke length was 10 mm and cycle frequency 1.02 Hz, so the maximum sliding speed was 32 mm/s. The apparatus had 12 identical test stations. The hip joint simulator HUT-2 was uniaxial and it had flexion-extension (60°) motion about a horizontal axis, and the load axis was vertical. The apparatus had five identical test stations and the cycle frequency was 1.08 Hz. The three-axis hip joint simulator HUT-3 had flexion-extension (45º), abduction-adduction (12º), and internal-external rotation (12º). The load axis was at an angle of 12º to the vertical. It had one test station and the cycle frequency was 1.18 Hz. Both simulators simulated walking, the peak load was 3.5 kN and the loading was of the on-off type. The prostheses were upside down and there were also loaded control cups. The gravimetric wear measurement was done at about 0.5, 1, 2 and 3 million cycles, unless terminated earlier due to polyethylene transfer.

2.2 Publication II

Several different lubricants were studied in the RPF apparatus and in the three-axis hip simulator HUT-3. The lubricants in the RPF tests were Lipoid S 30 soybean lecithin 3 mg/ml in distilled water, pH 6.1, and in 0.1 M Ringer´s solution in phosphate buffer, pH 7.4. In the simulator test, Lipoid S 30 was in Ringer´s solution, pH 6.7. The soy protein lubricant was 20 mg/ml of Supro 595 in 0.15 M NaCl solution, pH 6.7, and in 0.1 M phosphate buffer, 0.15 M NaCl solution, pH 7.4. About 90 % of the proteins of Supro 595 were globulins and the rest was mostly albumin. The prosthetic joint fluid (4.5 ml) was aspirated at revision surgery from a CoCr-on-polyethylene prosthesis. The bovine serum was sterile filtered, adult bovine serum Sigma B-2771. Sodium azide was added to the lubricants to retard microbial growth.

The pins were made of 2.5 Mrad gamma irradiated polyethylene, GUR 415. The diameter of the pin was 8.9 mm and the end was chamfered at an angle of 60º and so the initial diameter was 3 mm. The disks were made of annealed stainless steel 316L, ASTM F 138. They were disk-shaped, 30 mm in diameter and 10 mm thick. The surface roughness R_a was 0.004–0.005 µm measured by a diamond stylus instrument, and 0.002–0.003 µm measured by atomic force microscopy.

In the 3 million cycle HUT-3 simulator test, a 28 mm CoCr ASTM F 799 head was articulated against a metal-backed polyethylene acetabular cup, the thickness of the polyethylene liner being 10.9 mm.

2.3 Publication III

Several lubricants and types of motion and were studied in three different devices. The phospholipid lubricant was 3 mg/ml of pure 16:0/16:0 dipalmitoylphosphatidylcholine dispersed in Ringer´s solution by sonication. The soy protein lubricant was 20 mg/ml of Supro 595 first vigorously mixed with distilled water and then 0.9 % NaCl was added. To phospholipid and soy protein lubricants, 0.02 % sodium azide was added. The serum was Sigma B-2771. Sodium azide (0.2 %) was added and the serum was diluted with distilled water 1:2 because the protein content of serum (60–85 mg/ml) was higher than that of joint fluid (20 mg/ml)

The polyethylene pins were GUR 415. They were used in previous tests and were remachined for the present test. They were 2.5 Mrad gamma irradiated in air seven years before the test. The nominal contact pressure was 10 MPa. The disks were of polished stainless steel (R_a 0.003 µm) and alumina (R_a 0.006 µm). The acetabular cups were made of Himont 1900T polyethylene and were gamma irradiated in air two years before the test. The cups were backed by a 52 mm outer diameter titanium alloy shell. The alumina and CoCr ASTM F 799 heads were of 28 mm diameter.

The new circularly translating pin-on-disk (CTPOD) apparatus was made from the old RPF apparatus. The idea of CTPOD was that the direction of sliding relative to the pin changes constantly. The polyethylene pin was loaded by a static 70.7 N force against the disk. The apparatus had twelve stations, and it was analogous to the biaxial rocking motion (BRM) simulator. In the HUT-3 simulator, the direction of the load was fixed relative to the cup. The direction of sliding rotated, but the angular velocity of its rotation varied during a cycle. Three different load cycles were used with one test joint. From 0 to 5 million cycles the load was 0–3.5 kN. From 5 to 8 million cycles the load was constant 0.35 kN, not zero, between toe-off and heel strike. From 8 to 11 million cycles the load was constant 1 kN throughout the cycle. The new biaxial rocking motion (BRM-1) simulator was built and the motion was identical to that of the existing BRM simulators. It had one test station, the load was static, 1 kN, and its direction was vertical. The cup was located horizontally above the head, and the load was fixed relative to the cup. The direction of sliding rotated at constant angular velocity (1 r/s) because of the motion of the head.

2.4 Publication IV

The wear of non-irradiated polyethylene was studied with the CTPOD device in different lubricants. The albumin lubricant was prepared by diluting Sigma A-7534 bovine albumin solution with 0.15 M NaCl solution so that the protein concentration became 40 mg/ml. The gamma-globulin lubricant was prepared by diluting Sigma G-4904 bovine gamma-globulin solution with 0.15 M NaCl solution so that the protein concentration became 10 mg/ml. Both Sigma solutions contained originally 8.5 mg/ml NaCl and 1 mg/ml sodium azide. The serum lubricant was Sigma B-2771, to which sodium azide was added to a concentration of 0.02 %.

The pins were ram extruded ultra-high molecular weight polyethylene Hostalen GUR 4150. In test 1, the wear end was chamfered so that the initial diameter was 3 mm. In test 2, the pins were simple cylinders with 8.9 mm diameter. The contact areas were 7 and 62 mm^2, and the nominal contact pressures 10 and 1.1 MPa, respectively, as the load was 70.7 N in both cases. The counterface was stainless steel in serum, albumin and gamma-globulin tests, and alumina in serum, each containing three identical specimens. The disks were identical to those of Publication III.

2.5 Publication V

The bovine serum was changed to triple 0.1 μm sterile filtered, low-protein, low-endotoxin HyClone Alpha Calf Fraction serum (catalogue number SH30076.03) in the next tests with the new three-station BRM-2 simulator. The serum was diluted 1:1 with distilled water so that the protein concentration became 20 mg/ml. There were no additives in the lubricant.

Three different 28 mm heads were studied: alumina, CoCr ASTM F 799 and DLC-coated CoCr. The alumina heads were Biolox Forte from CeramTec AG, Germany, and the others were from Industrias Quirúrgicas de Levante s.a., Spain. The DLC coating was done by INASMET, Spain, and it was 3 μm thick. The surface roughness was similar in all the heads, the R_a value was 0.010 ± 0.002 μm. The metal-backed polyethylene liners were from Industrias Quirúrgicas de Levante s.a, the thickness being 10.9 mm. The material was Perplas IMP 2000, Hostalen GUR 1050. All cups were from the same manufacture lot and were packed and gamma-irradiated by 2.5 Mrad in argon. Polyethylene wear particles were isolated from the used lubricant and analysed by scanning electron microscopy (SEM).

2.6 Publication VI

Diluted HyClone Alpha Calf Fraction serum, without additives, was used as a lubricant also in the new ball-on-flat (BOF) knee wear simulator. The ball was a 54 mm dia. CoCr ASTM F 799 head from a hip hemiprosthesis manufactured by Waldemar Link, Germany. The disks were machined from Perplas IMP-2000 ultra-high molecular weight polyethylene bar and their diameter was 40 mm. Four different disks were studied: thicknesses 5 and 10 mm with no irradiation and no aging, and thickness 10 mm with 2.5 Mrad irradiation in air and consequent aging in an air convection oven, and in O_2.

The motion consisted of flexion-extension (FE), anterior-posterior translation (APT), and inward-outward rotation (IOR). The frequency was 1.08 Hz and the loading was vertical, static 2 kN. Wear particles were studied as in Publication V.

3 RESULTS

3.1 Phospholipids

The DPPC lubricant (3 mg/ml in phosphate buffer) prevented the polyethylene transfer to the CoCr counterface in the RFP test. There was practically no debris and the disks looked practically unchanged in the microscopy, and the average coefficient of friction was 0.04. The wear of polyethylene was negligible and the polyethylene surfaces were polished. DPPC (3 mg/ml) in distilled water resulted in mild transfer (Table I) (Publication I). The DPPC Lipoid PC (3 mg/ml) in Ringer’s solution resulted in zero wear (Table II) in the CTPOD test. The polyethylene transfer was heavy in two disks and slight in one disk, and the average coefficient of friction was 0.07. The DPPC results were erratic (Publication III).

The soybean lecithin Lipoid S 30 (3 mg/ml) in distilled water prevented the polyethylene transfer to the CoCr counterface in the RPF test. The disks looked unchanged in the microscopy, and the average coefficient of friction was 0.07. The wear of polyethylene was negligible, and the polyethylene surfaces were polished. Lipoid S 30 in a concentration of 1 mg/ml resulted in mild polyethylene transfer and the average coefficient of friction was 0.10. When Lipoid S 30 in distilled water was used in hip simulators, heavy transfer occurred onto the CoCr heads and there were macroscopic shreds, flakes and threads in the lubricant, although the gravimetric wear was very low (Publication I). In the HUT-3 simulator test, Lipoid S 30 in Ringer´s solution prevented polyethylene transfer to the CoCr head. The wear factor was 1.1×10^{-8} mm^3/Nm, and the average coefficient of friction was 0.02. The cup was burnished and there were some macroscopic polyethylene flakes (Publication II).

3.2 Proteins

The soy protein Supro 595 with and without buffer prevented transfer and wear in the RPF tests against stainless steel. Machining marks were clearly visible on the pins after the test and average coefficient of friction was 0.06 in NaCl, and 0.03 in the buffer (Publication II). In the CTPOD test, however, Supro 595 resulted in heavy polyethylene transfer. The coefficient of friction was 0.15, and the wear factors k were 0.2×10^{-6}, 9.0×10^{-6} and 11×10^{-6} mm^3/Nm (Publication III).

In the CTPOD test with albumin and gamma-globulin, there was no polyethylene transfer on the disks. The wear was very low in test 1, but in test 2, the mean wear factor was 1.93×10^{-6} mm^3/Nm with albumin and 2.36×10^{-6} mm^3/Nm with gamma-globulin. There were no significant differences between the wear factors in the three lubricants, serum, albumin, and gamma-globulin. The mean coefficients of friction in test 2 were about 0.10 for albumin and gamma-globulin. In optical microscopy of the pins, micrometer-scale ripples and polyethylene wear particles were seen. In test 1, the disks were undamaged, but in test 2, slight scratches were seen. There was no correlation between the occurrence of scratches and the wear of the pin (Publication IV).

3.3 Prosthetic joint fluid

In the RPF test with polyethylene against stainless steel, the joint fluid from an artificial hip joint after implantation of the total hip prosthesis resulted in heavy transfer, and the wear factor was 1.2×10^{-6} mm^3/Nm. There were grooves in the sliding direction on both the pin and the disk, and macroscopic polyethylene shreds. The average coefficient of friction was 0.12 (Publication II).

3.4 Serum

In the RPF test with polyethylene against stainless steel, the bovine serum Sigma B-2771 prevented transfer. The coefficient of friction decreased gradually between the weighing stops. Machining marks of the pin were partly visible microscopically after the test and the disk remained undamaged. The average coefficient of friction was 0.02 (Publication II). The bovine serum was studied also in the CTPOD device and in the BRM-1 and the HUT-3 simulators. Wear was substantial in all three test devices, quite contrary to preliminary water lubricated tests. The heads and the disks were undamaged. In the CTPOD test, the polyethylene wear factor k against stainless steel and alumina was 8.6 and 4.8×10^{-6} mm^3/Nm, respectively. The wear was so high that the diameter of the wear surface increased and the contact pressure decreased. The wear particles were no longer macroscopic. In the HUT-3 simulator, three different load cycles were used during the 11 million cycle test with polyethylene against CoCr heads. When the load was 0–3.5 kN, the wear factor k was 1.4×10^{-6} mm^3/Nm and the coefficient of friction μ 0.05; when the load was 0.35–3.5 kN, k was 1.7×10^{-6} mm^3/Nm and μ 0.04; when the load was static 1 kN, k was 0.5×10^{-6} mm^3/Nm and μ 0.11. In the BRM-1 tests with polyethylene against CoCr and alumina, k was 0.7×10^{-6} mm^3/Nm in both cases (Publication III). In the CTPOD test with polyethylene against stainless steel and alumina, the mean wear factor was higher against stainless steel (2.26×10^{-6} mm^3/Nm) than against alumina (1.55×10^{-6} mm^3/Nm), and the difference was statistically significant. In visual examination, the surfaces of the pins were polished and there was no polyethylene transfer on the disks. In optical microscopy with low magnification, criss-cross scratches were seen on the pins. With higher magnification, ripples and wear particles in the micrometre scale were seen (Publication IV).

In the BRM-2 tests with HyClone calf serum, there was no transfer. The wear factors were $1.51–1.80 \times 10^{-6}$ mm^3/Nm, lowest with alumina heads and highest with DLC heads. All test cups were burnished, and the bearing surfaces showed a fringe-like appearance in SEM examination. The majority of the wear particles were 0.1–1 μm in diameter. The heads were practically unchanged (Publication V). There was no transfer in the BOF tests with the HyClone calf serum. The wear factors for the non-irradiated disks were 0.33×10^{-6}

mm^3/Nm (10 mm thick) and 0.29×10^{-6} mm^3/Nm (5 mm thick), and 0.30×10^{-6} mm^3/Nm for the irradiated, oven-aged disk, and 0.79×10^{-6} mm^3/Nm for the irradiated, O_2 aged disk. The wear zone was burnished in all tests. The majority of the wear particles were 0.1–1 μm in diameter. In addition, there were some larger flakes of 10 μm diameter. The coefficients of friction were 0.043–0.051, and the calculated maximum contact pressures at five million cycles were 13.1–17.7 MPa (Publication VI).

Table I. Criteria fulfilled by the lubricants

Lubricant	Test apparatus	Counterface	Criteria
DPPC			
3 mg/ml in water	RPF	CoCr	2
3 mg/ml in phosphate buffer	RPF	CoCr	1, 2
0.3 % in Ringer's solution	CTPOD	stainless steel	2
Lecithin			
1 mg/ml in water	RPF	CoCr	2
3 mg/ml in water	RPF	CoCr	1, 2
3 mg/ml in water	RPF	stainless steel	2
3 mg/ml in phosphate buffer	RPF	stainless steel	2
3 mg/ml in water	HUT-2	CoCr	2
3 mg/ml in water	HUT-3	CoCr	2
3 mg/ml in Ringer's solution	HUT-3	CoCr	1, 2
Soy protein			
2 % in NaCl	RPF	stainless steel	1, 2
2% in phosphate buffer	RPF	stainless steel	1, 2
2 % in water	CTPOD	stainless steel	4
Albumin	CTPOD	stainless steel	1, 2, 3, 4
Gamma-globulin	CTPOD	stainless steel	1, 2, 3, 4
Prosthetic joint fluid	RPF	stainless steel	4
Serum			
Sigma bovine serum	RPF	stainless steel	1, 2
Sigma bovine serum	CTPOD	stainless steel	1, 2, 3, 4
Sigma bovine serum	CTPOD	alumina	1, 2, 3, 4
Sigma bovine serum	CTPOD	stainless steel	1, 2, 3, 4
Sigma bovine serum	CTPOD	alumina	1, 2, 3, 4
Sigma bovine serum	HUT-3	CoCr	1, 2, 3, 4
Sigma bovine serum	BRM-1	CoCr	1, 2, 3, 4
Sigma bovine serum	BRM-1	alumina	1, 2, 3, 4
HyClone calf serum	BRM-2	alumina	1, 2, 3, 4
HyClone calf serum	BRM-2	CoCr	1, 2, 3, 4
HyClone calf serum	BRM-2	DLC	1, 2, 3, 4
HyClone calf serum	BOF	CoCr	1, 2, 3, 4

Criteria:
1. No polyethylene transfer layer should form on the metal counterface
2. The bearing surface of the polyethylene should become burnished
3. The wear particles should be of the order of 1 μm in size
4. The wear factor should be of the order of 1×10^{-6} mm^3/Nm

Table II. Average wear factors *k* of polyethylene in different tests

Device	Lubricant	Counterface	*k* (10^{-6} mm^3/Nm)	γ-irradiation
RPF	joint fluid	stainless steel	1.2	in air
CTPOD	DPPC	stainless steel	0.0	in air >7 a
CTPOD	soy protein	stainless steel	6.8	in air >7 a
CTPOD	albumin	stainless steel	1.9	no
CTPOD	gamma-globulin	stainless steel	2.4	no
CTPOD	bovine serum	stainless steel	8.6	in air >7 a
CTPOD	bovine serum	alumina	4.8	in air >7 a
CTPOD	bovine serum	stainless steel	2.3	no
CTPOD	bovine serum	alumina	1.6	no
HUT-3	lecithin	CoCr	0.0	in air
HUT-3	bovine serum	CoCr*	1.4	in air >2 a
		*	1.7	in air >2 a
		*	0.5	in air >2 a
BRM-1	bovine serum	CoCr	0.7	in air >2 a
BRM-1	bovine serum	alumina	0.7	in air >2 a
BRM-2	calf serum	alumina	1.5	in argon <1 a
BRM-2	calf serum	CoCr	1.8	in argon <1 a
BRM-2	calf serum	DLC	1.8	in argon <1 a
BOF	calf serum	CoCr	0.3	no
BOF	calf serum	CoCr	0.3	no
BOF	calf serum	CoCr	0.3	in air
BOF	calf serum	CoCr	0.8	in air
BOF	calf serum	CoCr	1.3	in air

*Three different load cycles: 0–3.5 kN, 0.35–3.5 kN, and static 1 kN

4 DISCUSSION

The wear with DPPC was erratic, since transfer did occur, but the net wear was still negligible. The result was the same as with distilled water as a lubricant. In some cases, the transfer layer was absent, but the wear was nevertheless much too low in comparison with typical clinical wear rates. In the boundary lubrication of natural joints, DPPC seems to have an important role [5]. However, the present tests indicated that DPPC is not important with respect to the wear of polyethylene in prosthetic joints.

The prosthetic joint fluid was aspirated at a total hip revision surgery. The lubricating properties of the fluid were surprisingly poor. There was heavy polyethylene transfer, and the wear and friction were high. The behaviour of the prosthetic joint fluid resembled that of distilled water, which seemed to be attributable to the degradation of the joint fluid.

The results with soy protein were contradictory. In the RPF tests, no transfer and no wear occurred, whereas in the CTPOD tests, heavy transfer and high wear occurred. Although soy protein resembles animal protein, the soy protein solution proved to be an unsuitable lubricant for the wear tests of prosthetic joint materials.

Albumin and gamma-globulin gave wear factors, wear mechanisms, and friction similar to those observed with serum. Hence, it can be concluded that albumin and gamma-globulin are the crucial fractions of serum and synovial fluid with respect to the wear of polyethylene. All the four criteria were met by bovine and calf serum, albumin and gamma-globulin.

The clinical fact that the increasing contact area increases wear was proved in the CTPOD tests. The excessive wear of polyethylene in some CTPOD tests was caused by a subsurface brittle region called the white band. The embrittlement results from sterilization by gamma irradation in air, which leads to oxidation over the years [15]. The embrittlement and the following high wear are seen in shelf-aged, retrieved polyethylene cups [10], and now it was reproduced in wear tests.

In the BOF tests, the wear rate and contact pressure of the non-irradiated polyethylene disks were insensitive to the disk thickness. The wear of the irradiated, artificially aged disks was higher than that of the non-irradiated disks, but the wear was sensitive to the aging method. The thickness dependence of wear seen *in vivo* appears to be caused by gamma-irradiation in air.

In the RPF tests, transfer layer was sometimes detected, but the wear was still negligible. This differs from clinical observations. The RPF tests may produce realistic wear rates if the counterface is damaged, but the wear mechanisms still differ from the clinical ones.

In conclusion, realistic wear was produced when an animal protein based lubricant was used, and when the direction of sliding constantly changed relative to polyethylene specimen, as in the CTPOD, HUT-3, BRM-1, BRM-2, and BOF simulators.

REFERENCES

1. Cooper, J.R., Dowson, D. and Fisher, J., The effect of transfer film and surface roughness on the wear of lubricated ultra-high molecular weight polyethylene. Clin Mater Vol. 14 (1993), p. 295–302.

2. Derbyshire, B., Fisher, J., Dowson, D., Hardaker, C.S. and Brummitt, K., Comparative study of the wear of UHMWPE with zirconia ceramic and stainless steel femoral heads in artificial hip joints. Med. Eng. Phys. Vol. 16 (1994), p. 229–236.

3. Dumbleton, J.H., Tribology of natural and artificial joints. Amsterdam, Elsevier, 1981.

4. Hall, R.M., Unsworth, A., Siney, P., Wroblewski, B.M., Wear in retrieved Charnley acetabular sockets. Proc Instn Mech Engrs, Part H, J Eng Med Vol. 210 (1996), p. 197–207.

5. Hills, B.A., Butler, B.D., Barrow, R.,E., Boundary lubrication imparted by pleural surfactants and their identification. J App Phys Vol. 53, (1982), p. 463–469.

6. Laupacis, A., Bourne, R., Rorabeck, C., Feeny, D., Wong, C., Tugwell, P., Leslie, K., Bulls, R., The effect of elective total hip replacement on health-related quality of life. J Bone Joint Surg Vol. 75A, (1993), p. 1619–1626.

7. Liang, M.H., Cullen, K.E., Larson, M.G., Thompson, M.S., Schwartz, J.A., Fossel, A.H., Roberts, W.N., Sledge, C.B., Cost-effectiveness of total joint arthroplasty in osteoarthritis. Arthr Rheum Vol. 29, (1986), p. 937–943.

8. McKellop, H.A., Clarke, I.C., Markolf, K.L. and Amstutz, H.C., Wear characteristics of UHMW polyethylene: A method for accurately measuring extremely low wear rates. J Biomed Mater Res Vol. 12 (1978), p. 895–927.

9. McKellop, H.A., Campbell, P., Park, S.-H., Schmalzried, T.P., Grigoris, P., Amstutz, H.C. and Sarmiento, A., The origin of submicron polyethylene wear debris in total hip arthroplasty. Clin Orthop Vol. 311 (1995), p. 3–20.

10. Muratoglu, O., Liu, A., Jasty, M., Bragdon, C.R., Elder, J.R., Harris, W.H., Oxidative degradation and embrittlement of ultrahigh molecular weight polyethylene: analysis of 107 components. Fifth World Biomaterials Congress, May-June 1996, Toronto, Canada, 1996.

11. Nevalainen, J., Hirvonen, A., Pulkkinen, P., The 1998–1999 implant yearbook on orthopaedic endoprostheses. Publications of the National Agency for Medicines 5/2000. Vantaa, 2000.

12. Rabinowitz, J.L., Gregg, J.R., Nixon, J.E., Schumacher, H.R., Lipid composition of the tissues of human knee joints. Clin Orthop Vol. 143 (1979), p. 260–265.

13. Saari, H., Santavirta, S., Nordström, D., Paavolainen, P. Konttinen Y., Hyaluronate in total hip replacement. J Rheum Vol. 20 (1993), p. 87–90.

14. Saikko, V.O., Paavolainen, P.O. and Slätis, P., Wear of the polyethylene acetabular cup. Metallic and ceramic heads compared in a hip simulator. Acta Orthop Scand Vol. 64 (1993), p. 391–402.

15. Sutula, L.C., Collier, J.P., Saum, K.A., Currier, B.H., Currier, J.H., Sanford, W.M., Mayor, M.B., Wooding, R.E., Sperling, D.K., Williams, I.R., Kasprzak, D.J., Impact of gamma sterilization on clinical performance of polyethylene in the hip. Clin Orthop Vol. 319 (1995), p. 28–40.

16. Walker, P.S. and Erkman, M.J., Metal-on-metal lubrication in artificial human joints. Wear Vol. 21 (1972), p. 377–392.

17. Wang, A., Sun, D.C., Stark, C. and Dumbleton, J.H., Wear mechanisms of UHMWPE in total joint replacements. Wear Vol. 181–183 (1995), p. 241–249.

18. Wang, A., Essner, A., Polineni, V.K., Sun, D.C. and Dumbleton, J.H., Lubrication and wear of ultra-high molecular weight polyethylene in total joint replacement. Tribology International Vol. 31 (1998), p. 17–33.

19. Wang, A., Polineni, V.K., Essner, A., Stark, C. and Dumbleton, J.H., Role of proteins and hyaluronic acid in the lubrication and wear of the UHMWPE acetabular cups. 24th Annual Meeting of the Society for Biomaterials, April 22–26, 1998, San Diego, California, 1998.

20. Wang, A., Polineni, V.K., Stark, C. and Dumbleton, J.H., True effect of femoral head surface roughness on the wear of UHMWPE acetabular cups. 44th Annual Meeting, Orthopaedic Research Society, March 16–19, 1998, New Orleans, Louisiana, 1998.

21. Wang, A., Polineni, V.K., Starck, C., Dumbleton, J.H., Effect of femoral head surface roughness on the wear of ultrahigh molecular weight polyethylene acetabular cups. J Arthrop Vol. 13 (1998), p. 615–620.

22. Wang, A., Polineni, V.K., Essner, A., Stark, C. and Dumbleton, J.H., Quantitative analysis of serum degradation and its effect on the outcome of hip joint simulator wear testing of UHMWPE. 25th Annual Meeting Transactions, Society for Biomaterials, 1999.

23. Wang, A., Polineni, V.K., Essner, A., Stark, C. and Dumbleton, J.H., The impact of lubricant protein concentration on the outcome of hip joint simulator wear testing. 25th Annual Meeting Transactions, Society for Biomaterials, 1999.

24 Yehia, S.R., Duncan, H., Synovial fluid analysis. Clin Orthop Vol. 107 (1975), p. 11–24.