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Design, Development and Applications of Hip Joint Simulators

by

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Submitted for the degree of Doctor of Philosophy

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August, 1999

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Abstract

The five station AB Automation simulator combined motion in the flexion/extension and internal/external rotation axes, with load actuators that moved with the femoral component in the flexion/extension plane to reproduce a clinical load vector. PTFE and UHMWPE cups were used to evaluate the simulator against similar simulator and clinical studies. The motion cycles were successful in reproducing tunnelling of the femoral head into the acetabular cup as seen *in vivo*, but inconsistent loading between stations and with test duration was undesirable. Lubricant choice was restricted principally to water or saline, ultimately limiting application of the simulator.

The Mk.I Durham simulator used the same motion as the AB simulator, but a redesigned loading control system provided consistency between five articulating and one creep station. Zirconia and CoCrMo femoral heads were wear tested against UHMWPE cups in bovine serum, using gravimetric and volumetric techniques to measure cup wear. No statistically significant difference in wear rates was found between the two techniques, and two distinct linear wear phases were identified for all cups by both methods. A high wear rate up to two million cycles was shown to be due to wearing-in of the acetabular cups, compared with a lower wear rate from two to five million cycles. Cup wear rate was lower against zirconia than CoCrMo heads, due to the superior surface finish of the zirconia heads. This lower wear rate may be preserved *in vivo* as the zirconia heads also exhibited better scratch resistance over the duration of the wear testing. The surface topography of the femoral and acetabular components was consistent with clinical observations, and simulator wear debris size distribution was similar to that of *ex-vivo* debris.

Uni-axial simulator motion was found to be an unacceptable simplification to simulator design, but simplified loading, of the type studied, made no significant difference to cup wear rate compared with physiological loading. The Mk.II Durham simulator therefore featured simplified loading and sinusoidal motion in two axes phased to produce an elliptical wear path over the acetabular cup surface. Using motion cycles of physiological magnitude, acetabular cup wear rates showed excellent agreement with both simulator and clinical studies, giving confidence in the use of the simulator as a tool to test prosthetic designs prior to clinical trials.

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Abbreviations

Al	Aluminium
ASTM	American Society for Testing Materials
AFM	Atomic force microscope
BS	British Standard
CAM	Characterisation of Advanced Materials
CMC	Carboxy-Methyl-Cellulose
CMM	Co-ordinate Measuring Machine
Co	Cobalt
CoCrMo	Cobalt Chromium Molybdenum
Cr	Chromium
ISO	International Standards Organisation
LALLS	Low Angle Laser Light Scattering
MINT	Motion Interpreter language
Mk.	Mark
MNGC	Multi-nuclear giant-cell
Ni	Nickel
PC	Personal Computer
PMMA	Polymethylmethacrylate
POP	Pin-On-Plate
PTFE	Polytetrafluroethylene
S.D.	Standard Deviation
S.E.	Standard Error
SEM	Scanning Electron Microscope
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
Ti	Titanium
TJR	Total Joint Replacement
UHMWPE	Ultra High Molecular Weight Polyethylene
V	Vanadium
2-D	Two-Dimensional
3-D	Three-Dimensional

Nomenclature

ε_u	Elongation at failure found from a tensile test
f	friction factor
σ_u	Ultimate tensile strength
μ	coefficient of friction
ρ	Spearman's coefficient
a	pole height - interface height
H	Hardness
k	Wear factor
L	Load
m/v	mass/volume
N	Number of cycles
nchnc	new CoCrMo head new cup
nchwc	new CoCrMo head worn cup
wchnc	worn CoCrMo head new cup
wchwc	worn CoCrMo head worn cup
nzhnc	new zirconia head new cup
nzhwc	new zirconia head worn cup
wzhnc	worn zirconia head new cup
wzhwc	worn zirconia head worn cup
R, r	radius of the acetabular cup, femoral head
Ra	Arithmetic surface roughness
Rk	Roughness, core roughness depth
Rmax	Roughness, maximum peak height
Rrms	Roughness, root mean square
Rpk	Roughness, reduced peak height
Rpm	Mean levelling depth of 5 consecutive sampling lengths
Rsk	Roughness, skew
R^2	Coefficient of determination
S	Sliding distance

T	true frictional Torque
T_b	Torque measured on backward run
T_f	Torque measured on forward run
ΔV	Wear
V1	Material filled profile peak volume
V2	Void volume
Wa	Waviness, arithmetic average
Wmax	Waviness, maximum peak
Z	Sommerfeld parameter

Chapter 1. Introduction

John Charnley (1961) described his new hip arthroplasty and stated,

> *'Objectives must be reasonable. Neither surgeons nor engineers will ever make an artificial hip-joint which will last thirty years and at some time in this period enable the patient to play football.'*

A review in 1999 of twenty to thirty year results from 320 implants of the Charnley hip arthroplasty found that only 5.3% of the implants had been revised, and 93.9% patients had either no pain or only minor discomfort, (Wroblewski *et al*, 1999). Whilst this success has made total hip replacement a common operation, the demands to operate on younger patients has meant *in vivo* durations must be increased. Furthermore, the UK population over 65 years of age is almost 50% greater than it was thirty years ago (Dunn, 1999), and this trend will continue putting ever greater demands on surgeons and engineers to extend prosthetic life.

To develop new prosthetic designs intended to extend *in vivo* durations, various hip simulators have been built. It has long been recognised that testing the performance of prostheses prior to clinical trials is desirable. Wright and Scales declared in 1977 that although it was not mandatory, it was inexcusable to use THR *in vivo* before adequate laboratory testing. In the same year, Swanson (Swanson, 1977) reviewed the published literature to date and identified 49 different prosthetic designs, only 9 of which had been tested in a simulator. Furthermore, only one of these designs had been modified as a result of testing. He considered that the proportion of untested designs was unfortunately likely to increase.

It is still not mandatory to conduct wear tests, but the use of laboratory machines has been widespread. Unfortunately, standard testing procedures have not been adopted although the need for standardisation has long been recognised (Clarke, 1981, Paul, 1997). A reason for this is perhaps that most simulator studies have been studies of prosthetic design as opposed to studies of simulator design or testing protocol. As a result, scientific understanding of simulator design and test protocol had not progressed to a stage where standards could be confidently defined. An accurate replication of *in vivo* motion and loading can be achieved in the laboratory using a hip simulator incorporating three axes of motion and loading, (Dowson and Jobbins,

1988). However, the capital and running costs of this type of machine restricts the number of test stations and hence the significance of the test results. Therefore, there is a need to develop more cost effective, multiple station hip simulators with a balance between complexity and accuracy of simulation.

Biological response to foreign bodies has been reviewed in this thesis to understand the primary cause of prosthetic failure as we understand it today; loosening (Kusaba and Kuroki, 1997) through osteolysis induced by particulate debris (Willert and Buchhorn, 1993). Through understanding the importance in reducing particulate debris, wear measurement techniques could be reviewed critically. Gravimetric and volumetric wear measurement were then compared within this study, with additional work examining gravimetric wear measurement protocol.

The relationship between femoral surface topography and wear rate was also reviewed and studied. New zirconia and CoCrMo femoral heads, and explanted CoCrMo femoral heads have been wear tested against new UHMWPE acetabular cups in a hip simulator. With the benefit of understanding the need to reduce the rate of particulate debris production, observations were made in this study which had important clinical implications to the possible *in vivo* durations of the types of new femoral heads that were tested. Additionally, a relationship between wear rate and root mean square surface roughness, Rrms, was found which also has clinical and manufacturing implications.

Simulator design was reviewed and considered from the published literature prior to the evaluation of three hip wear simulators. The simulators that were evaluated within this thesis attempted to reproduce clinical acetabular cup wear through two fundamentally different philosophies of simulator motion and loading. The first two simulators used motion and loading cycles to reproduce a clinical wear vector in the acetabular cup. The third simulator was designed as a result of the study of simplification of simulator design. Simplified motion and loading cycles were used to reproduce clinical wear using an elliptical wear path in the acetabular cup.

Chapter 2. Literature Review

2.0 Introduction

A review of biological response to foreign bodies is presented initially to focus on osteolysis which is currently believed to be the primary cause of prosthetic failure. Having gained an understanding of the importance of reducing particulate debris, the tribology of conventional artificial joints, (metal or ceramic against polyethylene), and the generation of wear particles is reviewed. The measurement of the rate of polyethylene wear is then presented with relevance to the use of hip simulators. The design of hip simulators is then discussed with respect to replicating the *in vivo* environment, motions and loads. Finally, a review of wear rates of 22 and 28mm diameter prostheses worn both *in vitro* and *in vivo* was undertaken for comparison with the wear test results of this study.

2.1 Biological response to foreign bodies

2.1.1 Osteolysis due to polyethylene wear debris

John Charnley attributed the failure of metal on metal prostheses in the 1950's to excessive friction between the femoral and acetabular components, and believed low friction arthroplasty was the solution. The clinical failure of his first low friction prostheses using a small 7/8" femoral head to reduce frictional torque, coupled to a low friction polytetrafluorethylene (PTFE) acetabular cup, is well documented (Charnley *et al*, 1969, Dowson and Wallbridge, 1985). His subsequent design using a polyethylene cup did indeed reduce friction over the previous metal-on-metal designs, but the problem of joint failure was still not fully addressed. Charnley attributed loosening to sepsis despite being unable to culture bacteria from the lesions (Charnley *et al*, 1968).

Allergic reactions to methyl methacrylate monomer by handlers was documented (Fries *et al*, 1975) but Charnley believed bone cement to induce only a mild tissue response which would not progress whilst the joint components had sound mechanical fixation (Charnley, 1979). However, extensive localised bone resorption in four rigidly anchored cemented total hip replacements was later reported by Jasty *et al* (1986). Pathological examination of tissue from the regions of osteolysis revealed abundant methylmethacrylate particulate debris and a little polyethylene. Jones and Hungerford (1987) made similar observations and attributed prosthetic loosening to 'cement disease', subsequently advocating cementless implants (Hungerford and Jones, 1993). As scientific knowledge grew on the cellular biology and biomechanical mechanism of bone resorption (Vaes, 1988), progress could be made in understanding the osteolytic response induced by implants.

Some studies supported, or appeared to support, the theory of 'cement disease' causing bone lysis. Barth *et al* (1991) showed *in vitro* that particles of polymethylmethacrylate (PMMA) could activate macrophages and Bos *et al* (1995) found histiocytes from autopsies mainly contained wear particles of bone cement with polyethylene in less abundance. In a biomechanical and histological study of bone lysis around cemented components with sound fixation, Maloney *et al* (1990) observed that focal (localised) lysis occurred around either fractures in the cement mantle, or in an area of very thin cement. Histology showed a histocytic reaction with evidence of particles of polymethylmethacrylate whilst no polyethylene was observed. Similarly, Anthony *et al* (1990) radiographically observed focal bone lysis in fixed prostheses in regions near defects in the cement mantle.

However, although PMMA can contribute to osteolysis, a body of evidence was growing implicating polyethylene wear debris as the main offender. Willert *et al* (1989) observed polyethylene induced bone resorption distant from the joint, in the absence of particles of PMMA, in patients with cemented implants with large UHMWPE femoral heads. Bone resorption was found to occur in studies of both cemented and cementless prostheses (Schmalzried *et al*, 1992, Kim *et al,* 1993, Zicat *et al*, 1995) and studies solely of cementless hip replacements (Maloney *et al*, 1995, Learmonth *et al*, 1997) proving that cement was not solely responsible for osteolysis. Schmalzried *et al* (1992) observed that bone lysis was associated with macrophages

laden with polyethylene debris and the number of macrophages present had a direct relationship with the amount of bone resorption. The authors also believed that the effective joint space was any point that the debris-laden joint fluid could reach. The bone lysis observed around defects in the cement mantle by Maloney *et al* (1990) and Anthony *et al* (1990) would tend to support this theory, and not 'cement disease' induced osteolysis, by providing a site for the joint fluid to contact the surrounding bone.

Histological studies of tissues from around prostheses shed more light on how osteolysis was induced. Santavirta *et al* (1990) observed numerous macrophages in periprosthetic lesions, but only minimal numbers of fibroblasts and lymphocyctes. Similarly, Schmalzried *et al* (1992) also noted the absence of lymphocytes following histological studies of periprosthetic tissue. (Lymphocytes are a type of white blood cell forming part of the body's immune system and respond to matter recognised as invasive by producing anti-bodies or by attacking foreign proteins.) These observations led to studies which confirmed wear debris prompted a foreign-body response as opposed to an immunological reaction (Santavirta *et al*, 1993).

Polyethylene particles induce a macrophage response, whilst larger particles, or clusters of small particles, induce a multi-nuclear giant-cell (MNGC) reaction, (Howie *et al*, 1993a,b), and the number of these cells is directly proportional to the type and amount of debris present (Schmalzried *et al*, 1992). Macrophages form part of the body's natural cellular defence system, and ingest, then digest, bacteria, dead cells and foreign matter. The ingestion process is called phagocytosis, during which the macrophage encapsulates the 'invader' with pseudopodia. Once encapsulated, the macrophage attempts to digest the 'invader' using lysomes. However, the lysomes have no effect on polyethylene and polyethylene particles will reside in the macrophage cytoplasm indefinitely whilst the macrophage will continue to phagocytose further matter. MNGC's are essentially large macrophages formed from fusion of new and ageing macrophages, or macrophage mitosis in the absence of cytogenesis.

As the wear debris accumulates within each macrophage, the macrophage exhibits various cellular responses which have been shown to vary with particle size and morphology (Shanbang *et al*, 1994a), as well as the debris material (Murray and

Rushton, 1990). Theories abound on exactly how osteolysis then results, but the cytokines produced by the distressed macrophage stimulate osteoclast production and inhibit osteoblast creation with a net result of bone lysis (Haynes *et al*, 1997). It has also been suggested that the macrophages may themselves resorb bone directly (Murray and Rushton, 1990) or differentiate into lacunar bone resorbing cells (Pandey *et al*, 1996).

Biological response to particle size has been investigated over many years. It has long been recognised that although large pieces of foreign material may be functionally chemically inert causing no untoward tissue response, the same cannot be said of small particles of the same material (Bullough *et al*, 1988). Early work showed that a relationship between particle size and biological response existed to the extent that particles of the order of 1.0 to 2.0μm might precipitate the most phagocytic response (Tabata and Ikada, 1988). Later work suggested that submicron sized particles were likely to be the most damaging due to the likelihood that they were produced in numbers of billions (Harris, 1994), yet many researchers had failed to observe these particles by using light microscopy. More recently, high magnification microscopic techniques have been employed, such as scanning electron microscopy (SEM) and atomic force microscopy (ATM), to observe these sub-micron particles and it is indeed the very high numbers of small particles that are primarily responsible for osteolysis (Wang A *et al*, 1996, Revell *et al*, 1997). Despite all these observations, research has still persisted using bulky material implants in animal studies in an attempt to observe macrophage response (Rosengren *et al*, 1998).

2.1.2 Biological response to metal and ceramic particles

Metal ion levels in people professionally exposed to metals such as Titanium, Cobalt, Chromium and Molybdenum metals is well documented, which naturally led to research in patients with THR's. Pazzaglia *et al* (1986) investigated the levels of metal ions in plasma and urine. The study carefully examined patient occupation and residency to eliminate exposure to these metals through other sources. Fifteen of the patients selected had prostheses with CoCrMo femoral heads articulating against

polyethylene acetabular cups and two patients had CoCrMo metal on metal McKee-Farrar prostheses. The patients showed an increase in metal ion levels in urine and plasma over controls but no cases of skin sensitivity was observed. Surprisingly, the levels of metal ions in the patients with metal on metal prostheses was similar to those with metal on polyethylene prostheses. (A later hip simulator study by Saikko *et al* (1998) investigated the release of Co, Cr and Ni into the bovine serum using atomic absorption microscopy. CoCr against CoCr, CoCr against polyethylene, and alumina against polyethylene prostheses were tested and the results were not of similar magnitude for each pairing.) The levels of metal ions were considerably lower than that observed in groups professionally exposed to these metals. The authors therefore concluded that the observed levels of metal ions should not represent a toxic hazard.

An attempt to establish a link between THR and cancer was made in New Zealand. Gillespie *et al* (1988) searched Morbidity Records, the Register of Deaths, Cancer Registry, electoral rolls and data from the New Zealand Statistics Centre. From the data they were able to study 1358 THA patients over a period amounting to a total of 14,286 years of implantation and identified significantly higher incidence of lymphatic and haemopoietic system cancers over the general population. However, for the same group, the incidence of cancer in the breast, colon and rectum was significantly lower than for the general populace. The authors discussed other possible causes to implants for the observations made, implicating drug therapy for osteoarthritis prior to surgery as a possible source of difference over the general population. In conclusion, they did not think their findings should detract from the potential benefits of THR as the higher incidence of certain cancers was still relatively small and somewhat offset by lower incidence of other particular cancers. They also drew attention to the need for more detailed studies into the biological effects of implants and drugs relating to arthritic patients.

Histological examinations were conducted by Agins *et al* (1988) on tissues collected from around failed prostheses. Nine patients were selected for the study all with Ti-6Al-4V on polyethylene prostheses. The tissues immediately adjacent to the prostheses were stained dark by the metallic debris and this observation was common to other histological studies. High levels of the metal ions were measured over

controls and the authors concluded that this could be locally irritating and possibly toxic. However, they were unable to demonstrate that this contributed to loosening.

From a group of forty-six patients with prostheses utilising titanium and CoCr femoral heads, and designed for cemented and cementless fixation, Dorr *et al* (1990) conducted histological, biochemical and ion analysis of retrieved tissues and fluids. This authors observed that the synovial fluid showed high ion content with both loose and fixed stems, but only elevated blood ion content with loose stems for both prosthetic fixation types. They concluded that systemic elevation of ion levels only occurred as a result of stem loosening due to a mechanical cause, and recommended early revision of implants suspected of being loose.

Examining primary synovium and lymphatic nodes in only two patients, Langkamer *et al* (1992) found metallic debris both local to the prostheses and distant in the lymphoreticular tissues albeit in much lower concentrations. The authors strongly stressed the carcinogenic, co-carcenogenic and toxic nature of the metals found but admitted it was still a matter of contention whether THR was carcinogenic. A post-mortem study by Case *et al* (1994) investigated the extent and effect of disseminated wear debris from stainless steel and CoCr implants. The cadaveric samples exhibited debris both local to the implants and distant in lymph nodes, liver, spleen and bone marrow even when the prostheses were visually unworn. In cases of loose prostheses the levels of debris were elevated and necrosis of lymph nodes was observed but the association between disease and implant was not confirmed. Furthermore, they cautioned against cementless prostheses using new alloys and porous coatings which increased the surface area exposed to corrosion and the formation of wear debris.

These studies showed that implants did lead to a rise in metal ion levels in patients, in many parts of the body, and that loose prostheses saw further elevation in metal ion levels. However, these levels were much lower than levels seen in people professionally exposed to these metals and the claim that THR's were carcinogenic or led to skin sensitivity could not be definitely established. In addition to research into the aforementioned problems brought on by metal ions, research into establishing a link between metal ions and osteolysis was conducted.

Haynes *et al* (1993) conducted an *in vitro* study using milled CoCr alloy and Ti-Al-V particles of similar size and concentration to that previously observed *in vivo*. The

study investigated the relationship between toxicity of metal particles and their ability to stimulate the release of cytokines implicated in bone resorption. Ti-Al-V showed little toxicity whilst CoCrMo particles were highly toxic but the Ti-Al-V particles caused a significant increase in the production of cytokines over CoCrMo. The results were similar for a wide range of concentrations for similarly sized particles of different metal alloys leading to the conclusion that CoCrMo was less likely to cause a severe release of inflammatory mediators associated with osteolysis, despite being more toxic than Ti-Al-V.

Limited necrosis around metal-on-metal prostheses and few MNGC's were observed in comparison with metal-on-polyethylene prostheses by Doorn *et al* (1996). They concluded that metal-on-metal caused a less intense periprosthetic reaction than metal-on-polyethylene joints and that the intensity of the reaction did not play an important role for the metal-on-metal prostheses investigated.

Human synoviocytes propagated *in vitro* by Bendall *et al* (1996) showed a dose dependent relationship between Ti, CoCr and PMMA debris and release of inflammatory cytokines. This showed metallic debris to be cytotoxic to human synoviocytes due to the release of the cytokines, and therefore played a role in mediating inflammation and osteolysis. Wang J Y *et al* (1996) also conducted an *in vitro* study into how Ti, Co and Cr ions interfered with human osteoblast function. They similarly found that metal ions affected the release of cytokines and consequently osteoblast function leading to osteolysis.

Clearly, the metallic components of an implant pose potential health risks to the patient as shown in the studies above. However, the biological response to the metal ions may be considered to be within acceptable levels provided a prosthesis is revised before loosening occurs. With particular regard to the ability of metal ions to induce osteolysis, it seems that polyethylene presents the far greater problem by virtue of the quantity of wear debris produced. The osteolytic potential of ceramic particles seems similarly low in comparison to polyethylene, when considering the following studies.

Biopsies of dense alumina-alumina THR's from two patients at six months and twelve years were studied by Boutin *et al* (1988). Even after twelve years no necrosis was identified despite numerous, yellowish clusters of small alumina particles (<5 μm) in the synovial capsule. The particles were often encapsulated by macrophages and small

amounts of other inflammatory cells were identified such as lymphocyctes in further biopsies from loose implants. No MNGC's were identified or indeed large alumina particles even from the loose implant biopsies.

In another study of alumnia-alumina THR in patients under 50 years of age, Sedel *et al* (1994) noted that in over twenty years of use of alumina in Europe no problems related to either carcinogenesis or aluminium release had been reported. However, no histological studies were conducted and the rigor with which this observation was researched is not discussed. Boehler *et al* (1994) conducted histological examinations from seven alumina-alumina, cementless implants and found a chronic inflammatory response in only two cases. The biological response to the ceramic particles was restricted mainly to macrophages, and no MNGC's were observed.

Henessge *et al* (1994) conducted histological examinations of tissues from 14 patients with a mixture of ceramic-on-ceramic, ceramic-on-polyethylene, and metal-on-metal prostheses. The inflammatory response to the ceramic-on-ceramic pairings was less than those pairings with polyethylene, as was the amount of necrosis. They found little difference in biological response to bone cement between the different types of prostheses, as Lerouge *et al* (1997) also found. However, the origin of the observed response was markedly different in this latter histological study of 12 ceramic-on-ceramic and 18 metal-on-polyethylene prostheses. Unsurprisingly, polyethylene wear debris was the precursor for cellular reaction for the metal on polyethylene group. For the ceramic-on-ceramic group, six times as many zirconia oxide particles, from the bone cement, were isolated and characterised compared with alumina particles. A mean particle size of 0.28 μm was measured which would support the histological observations of Boutin *et al* (1998) and Boehler *et al* (1994) of no MNGC's. Similarly, using a SEM, Yoon *et al* (1998) measured a mean particle size of 0.71 μm from ceramic-on-ceramic implants. Their histological examination of ten tissue samples from the acetabular-bone interface and three from the femoral-bone interface observed a macrophage response similar to that observed with polyethylene debris.

2.1.3 Loosening attributed to other mechanisms

Aspenberg and Herbertsson (1996) investigated periprosthetic bone resorption due to particles and movement. Using a rat model, polyethylene particles were placed between bone and a titanium implant which caused no fibrous membrane to develop or bone resorption to occur. Subsequent sliding of the implant against the bone caused a fibrous membrane to develop thus shielding the bone from the implant. Addition of polyethylene particles at this point in time caused little change to the fibrous membrane. Once sliding of the implant was stopped, the bone to implant contact was re-established. However, if after the cessation of sliding polyethylene particles were added, the fibrous membrane was maintained. The conclusion drawn by the authors was that mechanical stimuli in implants is of primary importance to implant failure. In the later stages of loosening, particles also played a part in moderating the loosening process. The application of the polyethylene particles using a fine artist's brush makes it impossible to quantify the number of particles added but the observations made are interesting in the absence of other similar experiments.

Further work by Aspenberg with van der Vis (1998) was to observe pseudojoints and periprosthetic membranes to have high local pressures during motion. The authors used an animal model where bone was subjected to elevated fluid pressures which induced osteocyte death and bone resorption in the model.

Wroblewski (1997) put forward an intriguing argument for TJR failure caused primarily by loosening and secondarily by polyethylene wear particles. He based his argument on the basic statement of Wolff dating back to 1892 that 'bone responds to function' and cited changes in bone to age, time, load and trauma. He discussed cavitation and osteolysis, cavitation being the natural response of living tissues to any process where changes in volume and pressure occur over a period of time. In TJR a change in volume and pressure to the skeleton is noticed in operation leading to cavitation and circulation of bursal fluid to all areas of the cavity, both acetabular and femoral. He therefore argued that dispersion of the wear debris is inevitable and that these are the effects but not the cause of the TJR failure.

Maloney *et al* (1989) had previously shown through biomechanical testing of femurs retrieved at autopsy, that marked stress shielding in the proximal medial femoral

cortex was still evident many years after insertion of the stem. Adaptive bone remodelling had been studied by Jacobs *et al* (1993) who commented that a better understanding of the relationship between stem stiffness and bone remodelling was required.

Taylor and Tanner (1997) suggested implant migration and loosening was caused through fatigue failure of cancellous bone. Their finite element studies showed high levels of stress in cancellous bone around implants for which they knew migration and survivorship details. These stresses exceeded measured *in vitro* fatigue strength values of cancellous bone which they suggested would lead to collapse of the bone with time and hence migration leading to eventual failure.

2.2 Friction and Wear

2.2.1 Friction

Sir John Charnley's pioneering work on total hip replacements was undertaken with the intention of minimising frictional torque as he believed large frictional torques would lead to joint loosening and failure (Charnley, 1961). As we have seen, joint failure is primarily attributable to osteolysis induced by polyethylene wear debris and not frictional torque. However, Charnley's design has become the template for modern day conventional artificial joints and his work was ultimately extremely successful in extending prosthetic life over the previous designs.

Despite not eliminating joint failure, Charnley did achieve low frictional torques with his design. Anderson *et al* (1972) showed that a torque of 100 Nm was required to remove a well-fixed socket from an acetabulum. Hall *et al* (1994) found that frictional torques developed in both new and explanted Charnley prostheses were very much lower than this value even when considering start-up friction which can approach twice that observed in steady-state dynamic motion (Simon *et al*, 1975). Despite higher frictional torques, some designs of joints exhibit longer *in vivo* durations than similar designs with lower frictional torques. In a study of the Tharies hip replacement, Mai *et al* (1996) found that survivorship for larger diameter prostheses was significantly better than for smaller prostheses, in bilateral replacements of two different size prostheses. In a comprehensive study of eighty-eight explanted Charnley prostheses, Hall *et al* (1997a) found that friction had a minimal role to play in the loosening of the acetabular component.

Tribological studies of natural synovial joints have shown that such joints benefit from fluid film lubrication (Unsworth *et al,* 1974), where the load is carried by the pressure in the lubricating fluid. Most modern conventional total hip replacements are composed of two hard material couples, typically metals or ceramic against UHMWPE. Unsworth (1978) and O'Kelly *et al* (1979) showed experimentally that conventional joint implants experience mixed lubrication, in which the load is carried partly by the fluid pressure and partly by the contact of asperities on the two articulating surfaces leading to wear. Frictional torque of the prosthesis, whilst not the

primary cause of loosening, may accelerate loosening and failure of a prosthesis with a compromised joint/bone interface. For prostheses with excessive wear and penetration of the femoral head into the acetabular cup, 'neck impingement' can occur. This leads to eccentric loading due to the resultant force being changed and ligaments and tendons realigning (Hall *et al*, 1993).

As new designs of replacement joints are developed, friction testing of the prostheses gives an understanding of the lubrication mechanism likely to be prevalent *in vivo*. Friction testing of metal on metal hip joints showed that they have higher friction factors than metal on plastic joints (Unsworth *et al*, 1988) and that surface contact alignment of the two components is important (Walker and Gold, 1973). Ceramic on ceramic replacement hip joints were friction tested by Scholes *et al* (1997) and found to operate with extremely low friction under certain conditions. A novel concept of compliant layer hip joints has been developed which has been shown to operate with full fluid lubrication (Unsworth *et al*, 1987) and have minimal wear in simulator wear testing (Bigsby *et al*, 1998, Smith *et al*, 1999a). However, although some compliant layer hip joints designs have given encouraging results, not all of the designs are successful in achieving full fluid film lubrication and have failed during wear testing (Smith *et al*, 1998a).

The measurement of friction generated between the bearing surfaces of artificial joints is important as it provides an insight into the type of lubrication occurring in the joints. Analysis of the variation of the coefficient of friction with the Sommerfeld parameter (viscosity x velocity x radius / load) can distinguish between mixed lubrication (where the load across the prosthesis is carried partly by asperity contact and partly by the joint lubricant), and full fluid film lubrication (where the load across the prosthesis is carried entirely by the joint lubricant). The type of lubrication has an impact on the wear rates of the prostheses and prosthetic life as osteolysis, generated by wear debris, leads to prosthetic loosening and subsequent failure as we have seen.

2.2.2 Wear

Friction testing a prosthesis gives an indication of the lubrication regime likely to be prevalent in the joint *in vivo*. The interaction between the bearing surfaces leads to wear of the surfaces either immediately or as consequence of multiple articulations. Wear can be divided into two main types, cohesive or interfacial (Lancaster, 1990), whilst the introduction of a third body between the bearing surfaces can contribute to an acceleration of these mechanisms.

Abrasive wear (Brown *et al*, 1976) is a type of cohesive wear. Surface asperities of the harder bearing material plough grooves into the surface of the softer material leading to the release of wear debris. A further type of cohesive wear is caused by interaction of asperities of each bearing surface. When the asperities come into contact during relative motion they must be deformed in order to pass each other. Over a number of articulations the repeated deformation leads to the production of wear debris through fatigue wear (Brown *et al*, 1976). Cohesive wear is mainly governed by the cohesive strength of the polymer, in a conventional artificial hip joint, and is not restricted to the surface of the polymer.

Interfacial wear arises as a result of either adhesion or fatigue (Arnell, 1991). Adhesion of the two bearing materials may result in immediate detachment of the softer material. In addition to immediate detachment, repeated cyclic stresses of the asperity as the joint is articulated can result in fatigue and detachment of the asperity, known as fatigue wear.

Clearly, in the case of conventional hip joints, the material properties of the polymer have implications on how the joint will wear and Wang *et al* (1995) suggested that ultimate tensile strength and breaking elongation were the best indicators. Load and sliding distance are also important wear indicators. For conventional artificial joints, the interaction between the two surfaces may be assumed to be ideally plastic-elastic to derive the following relationship:-

$$\Delta V = \frac{LS}{H}$$

in which wear (ΔV) is proportional to load (L) and sliding distance (S), and inversely proportional to hardness (H) (Archard 1953). Increasing load above the bulk yield stress will increase wear dramatically. The surface roughness of the hard femoral

component, in conventional artificial joints, has an influence on the wear of the softer polymer against which it articulates, due to asperity contact. Early work by Dowson *et al* (1985) using a simple reciprocating pin-on-disc model led to the relationship:-

$$k = a(R_a)^b$$

where k is the wear factor, and Ra is the arithmetic surface roughness as defined in appendix A. Using stainless steel pins against UHMWPE plates in distilled water, Dowson *et al* found $a=4x10^{-5}$ and b=1.2.

A theoretical wear model based on microasperity contact was developed by Wang *et al* (1995) which attempted to combine material properties of the soft polymer, load and surface roughness of the hard femoral component:-

$$\frac{\Delta V}{N} \propto L^{1.5} R_a{}^{1.5} \frac{1}{\sigma_u^{1.5} \varepsilon_u}$$

where N is the number of articulating cycles, σ_u is the ultimate tensile strength, and ε_u is the elongation at failure found from a tensile test. The authors reanalysed work by other groups to support different parts of their proposed model. A study by Rose *et al* (1982) into the effect of load on the wear of UHMWPE in serum revealed wear rate was proportional to load raised to the power of 1.41. Similarly, work by Weightman and Light (1986) on the wear of UHMWPE against alumina and stainless steel with different surface finishes showed wear rate proportional to $Ra^{1.4}$.

Hall *et al* (1996a) established a relationship between clinical wear factor and surface roughness in an explant study of 129 explanted Charnley sockets, 99 paired with the explanted femoral head. Wear of the acetabular components was measured with a shadowgraph technique, and roughness of the femoral heads using a non-contacting Rodenstock RM 600 laser profilometer. The results indicated that clinical wear factor was proportional to Ra raised to the power 0.54. Another paper by Hall *et al* (1997b) on 35 paired Charnley explanted heads and sockets measured using the same techniques gave clinical wear factor proportional to Ra raised to the power 0.5.

An explant study by Kusaba and Kuroki (1997) included 149 femoral heads of 22, 28 and 32 mm diameter manufactured from alumina and CoCrMo, with 105 heads paired with the retrieved acetabular cup. Femoral roughness was measured using a stylus-type machine, cup wear was measured shadowgraphically, and a selection of new heads were also measured for comparison. Polyethylene wear was weakly linked to roughness in a series of linear relationships.

The microasperity model devised by Wang *et al* (1995) was not found to hold true when wear rate and roughness were studied in a hip simulator (Wang *et al*, 1998). The authors found what they considered a linear relationship between wear factor and arithmetic surface roughness, Ra. However, they also performed analysis with power functions for comparison with the work by Hall *et al* (1996a) and found wear factor proportional to $Ra^{0.42}$ which was lower than the findings of Hall *et al*. The simulator study used 32 mm diameter CoCrMo femoral heads roughened with graded SiC to produce multi-directional scratching which the authors considered representative of *in vivo* scratched heads. The tests were of one million cycles duration which as discussed later explains the smaller value in the power relationship.

Three body wear can contribute an additional wear mechanism which can lead to elevated wear rates even after the third body has evacuated the contact area of the joint. The third body must be at least as hard as the soft polymer, and when captured between the articulating surfaces can significantly increase the abrasion process. In addition to the immediate impact on wear of the polymer, the third body can damage the hard femoral component leading to long term elevated wear rates. Clinically, bone and bone cement present possible sources of third body particles, but metal debris from a number of parts of the implant can contribute third bodies (Learmonth and Cunningham, 1997). Metallic debris can be produced by fretting at the tapered femoral head to stem interface and any other metal to metal interface such as where screws retain acetabular shells. Surface coatings on the femoral head can cause significant third body damage when pieces become detached, as can detached metal beads often used for bony ingrowth in cementless implants.

2.2.3 Gravimetric measurement of wear

Gravimetric measurement is generally restricted to measuring wear in acetabular cups worn *in vitro*. This is principally because UHMWPE has been shown to gain mass with time due to its mildly hydrophilic nature (Clarke *et al*, 1985) which must be compensated for in order to calculate the amount of wear. The precise initial mass of retrieved acetabular cups is unknown, and obviously no soak control will have been maintained to compensate for fluid uptake. Retrieved acetabular cups also often exhibit damage caused during the retrieval which cannot be accounted for. However, Hashimoto *et al* (1995) used a gravimetric technique to measure volumetric wear in retrieved acetabular components. The retrieved liners were filled with ethanol and the mass of the fluid required was weighed. Using a new acetabular cup of the same design, the mass of fluid required to fill an unworn cup was established. The mass of fluid due to wear was then divided by the density of ethanol to calculate the worn volume, and subsequently volumetric wear rate was calculated from implant duration. The authors made no mention of how they compensated for cup tolerances, evaporation of the ethanol or any other experimental difficulties. Furthermore, they acknowledged lateral wear vectors were observed but made no reference to how this may have caused problems in being able to fill the component to its original level.

Two main types of gravimetric techniques have been used to measure the wear of polyethylene acetabular cups worn *in vitro*. Wear debris was collected by Greer (1979) by filtering it from the lubricant, desiccating it, then weighing the debris to determine the cup wear rates. The AB Automation simulator, discussed later, was originally designed to use a similar technique, but the peristaltic pump was not powerful enough to circulate the lubricant with the filters in place. This type of gravimetric method has further problems to the power of the lubricant pump. Not all the debris can be confidently collected from the lubricant as the debris may adhere to any surface it comes into contact with. Depending on the design of the lubricant system, the debris could float on the surface of the lubricant (UHMWPE density 930 kg/m^3) in a storage bath, or become trapped within any sediment in the bath and escape filtering. As a consequence of these errors, the measured acetabular cup wear rates are likely to be lower than the true wear rates.

The generally accepted gravimetric technique to measure the wear of UHMWPE acetabular cups is to weigh the cups directly following a cleaning and drying protocol. A soak control cup must be maintained in the same lubricant as the prostheses in the simulator to compensate for moisture absorption by the UHMWPE. The mass gain due to moisture absorption must be measured and subtracted from the mass loss of the articulating cups due to wear in order to calculate the true mass loss of the cups. Saikko *et al* (1992) suggested that UHMWPE acetabular cups absorb moisture at different rates when either loaded or unloaded, and therefore the soak control should be subject to the same loading cycle as the articulating cups. Bragdon *et al* (1996) built a 12 station hip simulator and each of the twelve articulating stations had a complimentary loaded, soak control station for gravimetric measurements. However, most research groups employing gravimetric measurements maintain only unloaded soak controls (McKellop *et al*, 1995a, Wang A *et al*, 1996, Medley *et al*, 1996, Clarke *et al*, 1997) which is also advocated, or likely to be advocated, by standards bodies (ASTM Ref. F732 - 82, ASTM Draft Standard, ISO 14242-2,).

Prior to beginning a wear test, some research groups and standards bodies recommend conditioning the UHMWPE in a fluid. This is due to the rate of fluid absorption by the polyethylene being greater in the first 30 days than thereafter (Clarke *et al*, 1985). However, the lubricant, temperature and duration used to condition the UHMWPE, suggested by the various groups differs. Many researchers do not specify in the literature whether they condition the acetabular cups, and Saikko *et al* (1993) specify that conditioning of the cups is not required. The reason given by Saikko *et al* for this is that the mass deviation was relatively small compared with the mass loss due to wear. As the work by Clarke *et al* showed UHMWPE cups to gain approximately 4 to 5 mg of mass over the initial 30 days of conditioning, this argument seems contradictory to Saikko *et al*'s (1992) insistence on using loaded soak controls, as opposed to unloaded, due to the difference in moisture absorption.

The cleaning and drying protocols used, or advocated, by the research groups and standards bodies varies. No work has been published on how cleaning and drying may effect the accuracy of the measurements which is perhaps surprising given the documented hydrophilic nature of UHMWPE. The differences between various cleaning and drying protocols are summarized in Table 2.1.

Author	Solvent	Immersion time	Drying technique	Drying time
Saikko *et al* (1993)	Ethanol	'Cleaned'	Vacuum	30 mins
Bragdon *et al* (1996)	Ethanol	10 mins	Laminar flow	30 mins
Burgess (1996)	Acetone	1 min	Air dry	30 mins
Good *et al* (1996)	Ethanol	10 mins	Vacuum	30 mins
Medley *et al* (1996)	Ethanol	'Rinsed'	Air dry	70 mins
ASTM F 732 - 82	Methanol	3 mins	Air dry	30 mins
ISO 14242-2	Iso-propanol	5 mins	Vacuum	30 mins

Table 2.1 Principle differences in the cleaning and drying protocols used for simulator testing.

2.2.4 Volumetric measurement of simulator wear

Acetabular cups worn *in vitro* and *in vivo* can be measured with volumetric techniques. For cups worn *in vitro* using a simulator, the first volumetric measurement work involved the use of a shadowgraph technique also employed for measuring the wear of *ex-vivo* acetabular cups. The initial part of the method requires taking a cast of the acetabular cup using a dental cement. Atkinson *et al* (1985a) then machined the cast away in 1mm thick sections tracing the magnified image of the remaining cast each time and measuring the trace. From these measurements the volumetric wear was calculated. Alternatively, the magnified profile of the cast in the worn plane can be recorded, and the centre of the femoral head determined for the unworn and worn regions of the trace using a stencil. The angle of penetration relative to the open face of the cup, and the wear depth, can then be calculated from these two points (Hall *et al*, 1995).

Concerns over contamination or modification of the acetabular cup surface by the casting material led researchers to explore alternative means of measuring simulator cup wear. A Talyrond was used by Scales *et al* (1985) for direct measurements using an unworn area of the cup as a reference datum. However, the sensitivity of this technique with cups exhibiting low wear was problematic. A combined Talyrond and

co-ordinate measuring machine (CMM) technique was used by Wroblewski *et al* (1996) to improve the accuracy of the measurements.

An indirect CMM technique used by Burgess (1996) involved taking a cast of the cup and then measuring the cast with a CMM. This technique demonstrated an accuracy of ±0.01mm for the prosthetic diameter, but showed a significant difference ($p=0.011$) between direct and indirect CMM measurements. A systematic error of approximately 0.2% under-estimation was later identified and attributed to cast shrinkage and deformation by the CMM probe.

As the availability of co-ordinate measuring machines has become more widespread, direct measurement of *in vitro* volumetric wear using a CMM has been employed by a number of researchers (Derbyshire *et al*, 1994a, Brummitt and Hardaker, 1996, Bigsby *et al*, 1998a, Goldsmith and Dowson, 1999). Hall *et al* (1995) also used a CMM to measure wear in retrieved cups. However, the technique is reliant on a relatively undamaged reference plane, usually taken to be the open face rim of the cup, which is not always available with retrieved specimens. A study by Derbyshire *et al* (1994b) investigated the accuracy of acetabular cup dimensional measurements using two different co-ordinate measuring machines. A repeatability error was observed which was attributed to very small misalignments of the datum axis system prior to measurements. However, calculated volume was insensitive to this error and a volume repeatability error of $\pm 1.8mm^3$ could be expected. Therefore, a simulator test may require several million cycles to minimise this error for low acetabular cup wear rates.

Twenty eight standard explanted Charnley sockets were measured by Hall *et al* (1995) using three measurement methods to compare different measurement techniques. A co-ordinate measuring machine (CMM) was used when an undamaged reference surface was available on the cup, and the results compared with data from the shadowgraph technique (which did not require a reference plane). Penetration depth was also measured radiographically from pre-revision X-rays and used for comparison. (In later work, Hall *et al* examined discrepancies between shadowgraphic and radiographic measurements of penetration depths (1998a) and penetration rates (1998b).) The authors concluded that penetration depth, as measured by the three techniques, varied by ±0.5mm, but showed no significant statistical discrepancy

between the shadowgraph and CMM measurements. The low and imprecise results from the radiographic measurements were thought to be as a result of radiographs being in the coronal rather than the worn plane. (A later study by Smith P N *et al* (1999) showed the influence of weight-bearing on radiographic measurements to be highly significant and that linear wear was significantly underestimated when patients were supine.) The calculation of wear volume by the shadowgraphic and radiographic methods was considered to be imprecise compared with direct measurement using a CMM. However, the use of different formulae to calculate wear volumes from the shadowgraph measurements did bring better agreement with the direct CMM measurements albeit with wide limits. Hall *et al* concluded that confidence could be taken in the shadowgraph technique provided sufficient penetration existed to make errors in the technique negligible.

Just as gravimetric measurements require a soak control, volumetric measurements have historically required a 'creep' control. Creep is the deformation of the polymer of the acetabular cup and is a function of material, geometry, temperature and loading (Clarke, 1981). Variation of results, from a number of centres, measuring wear of polymers using wear-screening devices led Dumbelton (1978) to advocate the use of a creep control. A creep control is a specimen which is subjected to the same loading regime as the wear specimens, but without the applied motion. Using the measurements of the creep control, a creep curve could be produced which then allowed compensation of the wear specimen measurements, which combine wear and creep, to give true dimensional changes.

Dowson and Jobbins (1988) built a three station hip simulator and investigated wear and creep. The importance they placed on understanding creep is perhaps best summarised in how they described the three stations of the simulator as one creep station and two 'wear + creep' stations. Indeed, they concluded from a 3 million cycle wear test using shadowgraphic measurements that creep was responsible for 60% of the total penetration in polyethylene cups over that duration of testing. Using the same simulator but with more accurate CMM measurements at one million cycle intervals, Derbyshire *et al* (1994a) identified that most creep occurred within the first million cycles. In a separate study, Derbyshire *et al* (1994b) measured acetabular cup creep relaxation and the results indicated that the rate of relaxation, and hence volume

change, was negligible after approximately 100 hours. This prompted Bigsby *et al* (1997) to use the same simulator and CMM, but take measurements every half a million cycles allowing 100 hours creep relaxation time before taking measurements. This research showed that most creep occurred in the first half a million cycles of the wear test, after which it remained relatively static. These finding resulted in researchers using CMM's to calculate wear from measurements taken at approximately 0.5 to 1 million cycles duration onwards (Besong *et al*, 1998a, Barbour *et al*, 1999a,b).

One further volumetric wear measurement technique, fluid displacement, was used to measure *ex-vivo* wear by Jasty *et al* (1997). An appropriately-sized femoral head was inserted into the acetabular cup and aligned with the remaining original radius of the cup. (A section of un-worn, original radius is a pre-condition of this technique.) Oil was then used to fill the remainder of the cup with the measured volume of oil required revealing the worn volume of the acetabular cup. To counter criticism of the technique the authors took multiple measurements of forty worn and ten new acetabular cups, and evaluated interobserver and intraobservor error. The interobserver error between three technicians was 10%, as was the intraobserver error for multiple measurements. Accuracy of the technique was measured by machining a 'known' volume from an acetabular cup and measuring it with the fluid displacement method. The accuracy was quoted as being within 10% for the 95% confidence interval. This type of technique could conceivably be used to measure cup wear during the course of a simulator test. However, the accuracy of a CMM is superior to this method, and does not contaminate the articulating surface.

2.2.5 Surface topography

We have seen that a number of wear models have been proposed which include surface roughness, Ra, as a parameter influencing wear rate. Therefore, the surface roughness of the femoral heads must be measured before wear testing. Measuring surface roughness and other surface parameters before and after testing can also quantify roughening of the heads over a wear test, thereby giving an indication of the

scratch resistance of a material or surface treatment. Measurement of acetabular cup topography is also interesting, but the size and shape of a cup often prevents measurement of the surface until the cup is cut into sections to allow access for measuring devices at the end of a wear test.

The topography of a surface is composed of three main elements; form, waviness and roughness (Stout and Blunt, 1995). Form represents the overall shape of the surface, for example, spherical in the case of a femoral head. Errors in form of THR bearing surfaces are often due to a lack of rigidity during a machining process of usually either the component or tool mounting. Other form errors can arise through strain caused by heating or excessive surface residual stresses. Waviness features are often repetitive, typically arising from a machining process as the tool feeds along the components surface. Roughness represents the final deviation from an ideal surface.

Surface topography measurement can be sub-divided into contacting and non-contacting techniques. Contacting techniques usually involve dragging a stylus over the surface being measured which can cause a small degree of damage to the surface which has been observed to be extremely detrimental to the results of a wear test (Saikko, 1996). The resolution of these techniques is limited by the size of the stylus which can also 'bounce' and miss some surface features if dragged too quickly. Contact profilometry is a 2-D technique giving a profile of the surface, although recently the technique has been developed to give 3-D topographical measurements using motorised tables. This is perhaps ill advised prior to wear testing given the potential damage to the surface. A number of non-contacting techniques exist including optical focus detection, optical interferometry, light scattering, capacitance and electron tunnelling. Although some difficulties can be encountered in measuring surfaces of low reflectivity with some of these techniques, the resolution offered can be sub-nanometer or even sub-ångström.

The parameters originating from the development of 2-D profilometry are numerous and varied, often chosen for ease of measurement, for example the maximum peak to valley height taken from only two extreme points. The choice of some parameters was driven by the measurement instrumentation or the demands of a particular application. The different 3-D measurement systems available, coupled with the computing power now available to consider complex statistical parameters have led researchers to

define set parameters to prevent the 'parameter rash' (Dong *et al*, 1994) seen with 2-D profilometry. The suggested parameters have been intended to provide links to current 2-D standards, describe only a range of topographical features, and have a sound mathematical or statistical basis. However, despite international recognition that 3-D parameter rash should be avoided, some researchers have questioned the parameters selected by international committees. Furthermore, even if an agreed set of parameters is reached and widely accepted, the computing power available has already led to suggestions of new analytical techniques for these parameters (Jiang *et al*, 99). This could potentially develop into a similar, if more subtle, form of parameter rash.

The surface topography parameters used in this study have been selected following evaluation of the literature and are presented in Appendix A. Three-dimensional optical interference profilometry has been used which offers vertical resolution of sub-nanometers, and a number of points have been taken from any measured surface to overcome problems associated with spatial topographical differences.

The surface roughness of femoral heads manufactured from different materials has been investigated in a number of studies, some of which are summarised in Table 2.2. Surface roughness values for new femoral heads and heads worn both *in vitro* and *in vivo* are reported. Different measurement tools and protocols have been used, as well as some differences in the parameter quoted, which makes comparisons difficult. Some studies on similar head materials exist, but differences in prosthetic design such as surface finish of components will lead to discrepancies between studies. For the explanted femoral heads, patient differences such as mass and activity levels may affect how the heads roughen with time, as indeed will the prosthetic design such as cemented versus cementless fixation. Similarly for heads worn in a simulator, the motions and loads applied, combined with test duration will effect roughening. However, a review of the studies in Table 2.2 indicates two things. Firstly, that it is possible to rank approximately which materials are more scratch resistant than others, and secondly that the current British Standard (BS 7251 : 1990) for femoral head surface roughness, Ra, of 0.05 μm measured using a contacting stylus is hopelessly out of date.

Other studies into femoral head surface roughness have been described previously in the section on 'Wear'. In addition to those, Hall *et al* (1996b) measured 36 explanted

and 5 new Charnley femoral heads using a non-contacting Rodenstock RM 600 laser profilometer and examined them using a Joel-JSM-IC848 SEM. The median values of all measured surface parameters, except skewness, were significantly different between the new and explanted heads. For example, Ra for the explants was 0.06 μm and 0.02 μm for the new heads, whilst skewness was -0.27 and -0.46 respectively. The new heads used in the study may have had a superior surface finish to those of the explanted heads when first implanted due to improved manufacturing techniques. However, the authors considered any such difference not sufficiently large as to impact on the significance of their findings. Furthermore, no significant difference was found between measurements taken in the anterior/posterior and medial/lateral directions. As most motion of the hip occurs in the flexion/extension axis, scratches may have been expected to be anterior/posterior orientated. This would lead to larger surface roughness measurements taken in the medial/lateral direction. The authors thought this possibly due to the largest joint reaction force occurring not during a primarily flexion/extension portion of motion, and considered this observation to be of particular relevance to the design of hip simulators.

Also in the review of 'Wear', two explant studies by Hall *et al* (1996a, 1997b) were described which established a relationship between clinical wear factor and surface roughness. In the latter study, the authors found only Ra and skewness significantly linked to wear factor, and called for more work investigating the suitability of surface parameters for correlating heads roughness and wear. The advantages of establishing such a link would prove valuable.

Author	Femoral head material	Cohort (for mean reported here)	Measurement method	Mean Surface Roughness, Ra (unless specified otherwise)
Drabu *et al*, 1994	Ti alloy	7 explants, 3 new	Talysurf, 0.8mm cutoff	new = 0.024±0.002μm, worn = 0.040±0.017μm
Brummitt *et al*, 1996	Ti alloy	2 explants	Talysurf & interferometer	worn = 0.087μm (talysurf) worn = 0.096μm (interferometer)
Wroblewski *et al*, 1992	Stainless Steel	4 explants, 5 new	Talysurf	new = 0.019μm, worn = 0.034±0.021μm
Derbyshire *et al*, 1994a	Stainless Steel	2 worn in simulator for 2 million cycles	Talysurf, 0.8mm cutoff	new = 0.027±0.005μm, worn = 0.076±0.045μm
Minakawa *et al*, 1998	Stainless Steel	10 explants	Talysurf & Laser profilometry	Mean Rpm = 0.7555μm in damaged areas
McKellop *et al*, 1995b	CoCrMo	3 worn in simulator for 5 million cycles	Laser profilometry	new = 0.07μm, worn = 0.073±0.005μm
Brummitt *et al*, 1996	CoCrMo	2 explants	Talysurf & interferometer	worn = 0.028μm (talysurf) worn = 0.011μm (interferometer)
Minakawa *et al*, 1998	CoCrMo	5 explants	Talysurf & Laser profilometry	Mean Rpm = 0.9864μm in damaged areas
Kusaba & Kuroki, 1997	CoCrMo	36 explants	Stylus machine, 0.25mm cutoff	worn = 0.030±0.020μm
Derbyshire *et al*, 1994a	Zirconia	2 worn in simulator for 2 million cycles	Talysurf, 0.8mm cutoff	new = 0.013±0.005μm, worn = 0.039±0.009μm
Sugano *et al*, 1995	Alumina	3 explants	SEM	worn = 0.01 μm
Kusaba & Kuroki, 1997	Alumina	54 explants	Stylus machine, 0.25mm cutoff	worn = 0.015±0.012 μm
Minakawa *et al*, 1998	Alumina	5 explants	Talysurf & Laser profilometry	Mean Rpm = 0.0238μm. No damage evident.

Table 2.2 Surface topography studies of new and worn femoral heads of different materials.

2.2.6 Wear debris

The varying amount of biological response to different sizes of particle has been discussed earlier. It is therefore beneficial to establish the size and morphology of the debris since these influence biological response. For example, a new prosthetic design producing a similar mass wear rate as previous designs may extend prosthetic life if the size of the debris produced incites a lesser biological reaction. Similarly, in order to assess whether a simulator effectively reproduces the *in vivo* situation, not only must the acetabular cup wear rates be comparable with those observed *in vivo,* but the size and shape distributions of the wear debris produced must also be similar.

There has been a number of studies into techniques to isolate wear debris from tissue, blood, and bovine serum (Campbell *et al*, 1994, Margevicius *et al*, 1994, Fisher *et al*, 1997, Hansen *et al*, 1998, Elfick *et al*, 1999a). This area of THR research is still in its infancy and a number of problems must be overcome before credibility can be given to the findings of such a study. For example, early studies used light microscopy to view the polyethylene debris (Lee *et al*, 1992) which is regarded as not being visible below 2 μm diameter (Revell *et al*, 1997) other than as a diffuse birefringence (Schmalzried *et al*, 1994). Filtration of the supernatant fluid obtained from ultra-centrifugation may also have a strong bearing on the observed debris size. This is perhaps best illustrated by the work of Hirakawa *et al* (1996) and Tipper *et al* (1997) using sequential filtering pore sizes of 10 μm and then 0.4 μm and 10 μm followed by 0.1 μm respectively. Hirakawa *et al* observed a modal size of 0.8 μm and Tipper *et al* of 0.1 - 0.5 μm, which may be due to Hirakawa losing a significant number of smaller wear particles to the filtrate.

The definitions used to describe the morphology of wear debris particles are many and varied. McKellop *et al* (1995b) attempted to define four types of particle but showed inconsistencies within their own piece of work. The first group of particles they defined as 'granules'; smooth and round, but promptly added 'unless flattened' to their definition. Having defined the four groups of particles they subsequently described large needle-like particles and flake-shaped particles. Nevertheless, these definitions would serve researchers well if only they were universally adopted as researchers define seemingly similar particles in a multitude of ways. Granules;

smooth and round (unless flattened!), in the size range 0.1 to 1.0 μm, and the most common type of particle observed in retrieved tissue samples from around THR. Beads; round but grainy in texture with a size range of <1 μm to several microns. Fibrils; elongated particles as long as 4 μm and less than 0.2 μm wide, often featuring a rounded head with a tapered tail. Shreds; elongated particles as long as 10 μm and several microns at the widest point, generally larger and more irregular than fibrils, seldom featuring a head. Large needle-like particles and flake-like particles have also been observed by a number of different researchers although they account for only a small number of particles. These particles, although few in number, may possibly account for a significant portion of the total mass of debris.

Perhaps one of the biggest criticisms of most types of wear debris analysis are the numbers of particles counted. The most common method of counting particles combines a SEM with a graphical analysis package and the number of particles counted is often as little as a hundred (Maloney *et al*, 1995, Campbell *et al*, 1996, Kobayashi *et al*, 1997). Occasionally the number of particles counted is not specified (Shanbhag *et al*, 1994b), and the largest stated cohort using this technique is two thousand particles (Besong et al, 1998b). These numbers of particles represent a tiny fraction of the thousands of billions of particles produced during the life of a THR which raises the obvious question of whether such a technique can accurately predict the true size and morphology of the wear debris. Subsequent predictions of mass distributions are similarly flawed with the added difficulty of weighing the debris on a filter paper which has been shown to be problematic (Elfick, 1999b).

Alternative methods of counting particles exist which can count far greater numbers of particles when suspended in liquid. A popular technique is to use an automated particle analyser using electrical impedance technology. This technique does have its limitations in so far as the device is designed with a small aperture so that only one particle passes the electrodes at a time. Studies have used apertures which can only count particles from above 0.5 μm (Maloney *et al*, 1995, Hirakawa *et al*, 1996) and 0.58 μm (Margevicius *et al*, 1994) diameter respectively. The technique becomes inaccurate for larger particles so the fluid must be reanalysed with a larger aperture to give confidence to the measurements. As the earlier comparison between the studies of Hirakawa *et al* (1996) and Tipper *et al* (1997) using sequential filtering pore sizes

of 0.4 μm 0.1 μm showed, 0.4 μm is still too large and the smaller particles are omitted from the study.

Another type of automated particle counter counting particles suspended in fluid, are the Low Angle Laser Light Scattering (LALLS) particle analysers. These devices can count of the order of one hundred thousand particles per sample, giving confidence that the results of the analysed sample are representative of the tissue or fluid from which it was taken. As the technique does not require filtration and drying, unwanted artefacts and agglomeration of debris are avoided. Also, as the technique is non-destructive the counted sample could subsequently be used in cellular response studies. Finally, these devices are capable of quantifying debris within the size range 0.05 μm to 1000 μm, which represents a significant improvement over all other techniques as shown by Elfick *et al* (1999a).

Despite all the problems highlighted above, for techniques other than those using LALLS particle analysers, researchers have tried to relate numbers of particles per gram of tissue to various parameters such as prosthetic size and design (Maloney *et al*, 1995). The difficulties in making such observations are then often compounded by using very small cohorts which mix prosthetic size (Huk *et al*, 1994), material (Campbell *et al*, 1996) and so forth. Many studies fail to stipulate from where the tissue originates, femur or acetabula, or the tissue type. It is quite conceivable that differences between polyethylenes, sterilization techniques and femoral head surface topography may influence the morphology of the wear debris produced. The tissue harvest site may be linked to the quantity and type of debris observed.

Having given a multitude of reasons to discredit most wear debris studies to date, wear debris analysis remains an important area of THR research and these are the studies to which we are forced to draw comparison. The evidence points to most particles being smaller than the resolution of light microscopy, of the order of one micron in size. Consequently, mass distributions of particle size are subject to considerable leverage from larger particles as shown by the mass distributions of Fisher *et al* (1997) and Tipper *et al* (1997). Table 2.3 summarizes debris size from a number of studies of tissue from THR patients, and from hip simulator studies.

Author	Wear debris source, sample size & THR type	Measurement Technique	Wear Debris Size and Distribution
Lee *et al*, 1992	*ex-vivo* tissue - 10 Ti, 10 CoCr, 10 St.Steel	Light microscopy & digital image analysis	Fibrils : 2 to 4 μm x 8 to 13 μm
Shanbhag *et al*, 1994b	*ex-vivo* tissue 11 Ti alloy uncemented	Direct from SEM image	92% of debris - granules, mean size 0.53 ± 0.3μm
Margevicius *et al*, 1994	*ex-vivo* tissue 5 (1 ceramic head)	SEM for morphology, Elec. res. particle counter	modal diameter 0.69 ± 0.1μm
Schmalzried *et al*, 1994	*ex-vivo* tissue 24 (7 different designs)	polarized light microscopy & semiquantitative grading	majority < 1 μm, some >10μm and >20μm rare
McKellop *et al*, 1995	3 CoCr *ex-vivo* tissue 3 CoCr simulator samples	SEM & digital image analysis	*ex-vivo* : 75% of rounds 0.2 to 0.8μm, most elongates 0.5 to 4.0μm Simulator : 95% of rounds ≤ 0.2μm, most elongates 0.5 to 2.5μm
Campbell *et al*, 1995	*ex-vivo* tissue 3 Ti, 6 CoCr	SEM & digital image analysis	granules & beads : mean dia. 0.38 ± 0.32μm Fibrils and shreds : 2.19 ± 1.26 μm
Maloney *et al*, 1995b	*ex-vivo* tissue 35 (various designs)	SEM for morphology, Elec. res. particle counter	90% < 0.95 μm mean : 0.63 ± 0.27 μm mode : 0.49 3 μm
Kobayashi *et al*, 1997	*ex-vivo* tissue 3 Charnley THR	SEM & digital image analysis	Equivalent Circle Diameter 0.91 ± 0.09 μm Aspect ratio 2.06 ± 0.07 μm, Roundness 3.05 ± 0.85 μm
Revell *et al*, 1997	*ex-vivo* tissue 18 samples	Direct from SEM image	Equivalent Circle Diameter median = 0.82μm
Fisher *et al*, 1997	*ex-vivo* tissue 4 samples	Direct from SEM image, mass by filter paper weighing	Modal size of particles 0.1 to 0.5 μm 5 to 82% of mass distribution ≤ 10μm
Tipper *et al*, 1997	*ex-vivo* tissue 19 Charnleys	Direct from SEM image, mass by filter paper weighing	Modal size of particles 0.1 to 0.5 μm 18 to 96% of mass distribution ≤ 10μm
Ingham *et al*, 1998	Simulator - 1 Zirconia head	SEM & digital image analysis	No. distribution 85% 0.1-0.5μm, 11% 0.5-1.0μm, 3% 1-5μm Mass 33% 0.1-0.5μm, 20% 0.5-1.0μm, 18% 1-5μm, 29% >10μm

Table 2.3 UHMWPE wear debris size from THR *ex-vivo* tissue studies, and from hip simulator serum studies.

2.3 Hip Simulator Design

In 1970 Dowson *et al* claimed that all hip simulators to date were unsatisfactory and then described their new single station hip simulator design. Over a decade later Clarke (1981) would give an overview of simulators to date and their relevance, concluding that simulators must be multi-station which had been the major limitation of all previous studies. The debate on simulator design still rages today through both practical and theoretical studies (Medley *et al*, 1997, Barbour *et al*, 1999a).

2.3.1 Lubricant

The use of synovial fluid to replicate the *in vivo* lubricant exactly in wear simulators is not viable due to the cost and difficulty in obtaining the quantities required for testing. Keeping the synovial fluid sterile and to a standard specification would also impose severe difficulties. Indeed, the issue of defining a standard specification would itself probably cause an intense debate. Would it be better to use low viscosity synovial fluid typical of an arthritic joint, or more viscous synovial fluid from a healthy joint? Perhaps the synovial fluid should be changed during the course of the test to replicate recovery from trauma following THR?

De-ionised water was a popular lubricant for simulator studies since it is inherently consistent, but several problems have emerged from wear testing rendering it largely redundant. Saline solution has been used as a substitute for synovial fluid but suffers from similar drawbacks to water. A number of other lubricants have also been proposed such as sodium carboxymethyl cellulose fluids, silicone fluids, mineral oils and gelatine-based lubricants, mainly for their rheological properties. Any lubricant that is to prove a worthy substitute for synovial fluid should prevent the formation of transfer films as these are not observed clinically, and should also contain proteins to promote boundary lubrication. Most of the aforementioned lubricants fail in either one or both of these respects.

Bovine serum has a comparable viscosity (Cooke *et al*, 1978) and protein make-up to synovial fluid. It is also readily available to consistent specifications. Good *et al* (1996) and Bigsby *et al* (1997) both made comparative simulator studies between water and bovine serum lubricated wear tests. The bovine serum in both studies prevented the formation of transfer films and reduced the variability in results from as much as over ±70% with water to only ±3% with serum (Good *et al*, 1996).

Unidirectional tri-pin-on-disc tests were conducted by Besong *et al* (1999) to compare the morphology of polyethylene wear debris generated in water and in serum. The morphology of the wear debris produced in water was observed to be different to that produced in serum. The debris produced in serum was comparable to *ex-vivo* debris isolated from tissue samples taken at revision operations.

The concentration of bovine serum and the volume used in each station (Wang *et al*, 1999) is also now being researched. The frequency with which the lubricant is replaced and the importance of the prostheses orientation is also recognised (Wang *et al*, 1999, McKellop *et al*, 1999) although not yet quantified for polyethylene joints. The work by Wang *et al*, suggests that reducing the mass of proteins per unit volume, increasing the volume of lubricant in each station, and anatomically mounting the prostheses are all preferential when testing.

2.3.2 Temperature

The temperature at which wear tests should be conducted has been debated less than other test protocol as nominal body temperature of 37°C is an obvious choice to replicate *in vivo* conditions. However, wear tests are often conducted at ambient temperature rather than 37°C.

Prostheses material properties may change between ambient and body temperature which would strengthen the case for using 37°C. The viscosity of the lubricant may differ between the two temperatures as well, but whether this makes the lubricant more or less representative of synovial fluid would depend on the lubricant. If all testing was conducted at 37°C one variable would be removed when comparing research from different centres. Testing at ambient temperature would induce some

variability in conditions between tests conducted in such diverse places as Helsinki, Durham and Califiornia. However, as the ambient temperature of a laboratory is likely to be controlled by air-conditioning and central-heating systems to make it a comfortable working environment, the variability in ambient temperature may not be great. Maintaining 37°C has cost and complexity implications to the simulator in capital and running costs over testing at ambient temperature, but it is perhaps practical test issues that have dictated whether ambient or 37°C is used.

Most early simulator wear tests were conducted in recirculating distilled water with a central lubricant bath common to multiple stations. This allowed relatively easy control of temperature at 37°C usually with a single thermocouple-controlled immersion heater in the lubricant storage bath. More recently wear tests have used bovine serum as a lubricant and have used additives such as sodium azide to reduce biological degradation of the proteins in the serum. For a similar reason the majority of these tests have been conducted at ambient temperature as the proteins will degrade more rapidly at 37°C (presuming ambient temperature is below 37°C). It is also now recognised that individual stations should be kept separate to prevent contamination of wear debris from one station to another which means alternative methods of temperature control are required to that of a single thermocouple-controlled immersion heater. Most of these later tests conducted at ambient temperature have recorded said temperature which may prove useful if research shows discrepancies between tests conducted at ambient and 37°C.

2.3.3 Simulator Loading

The most widely adopted loading profile is that defined in a classical paper by Paul (1967). In his study, Paul combined three measurement techniques to establish the loading profile during normal gait. Sixteen, young, adult subjects with no obvious abnormalities were fitted with electrodes to the major muscle groups which measured muscle activity during walking. Markers on the skin of each subject were used to measure movement through the use of cinematic film, whilst a force plate on the floor measured ground to foot forces. Having obtained all this information, equilibrium

equations were used to calculate forces and moments at the joint, taking account of gravity and accelerations. Peak values of hip joint force were 3.9 times body weight at the second of two load peaks in the gait cycle. Although most simulator studies have applied the Paul loading cycle, the magnitude varies depending on the theoretical mass of the patient. Load studies subsequent to Paul's work, using various measurement (English and Kilvington, 1979, Bergmann *et al*, 1993) and analytical techniques (Seireg and Arvikar, 1975) have not suggested any radically different loading profile, merely emphasizing the variations in gait from one subject to another. The use of the Paul loading cycle therefore is as representative of a 'typical' loading cycle in a 'typical' patient as any other loading study.

Those studies that have not adopted the Paul loading cycle include a study by Young *et al* (1979) on hydraulic loading control intended for incorporation later into a simulator design. This study used the loading curve presented by Seireg and Advicar (1975) with a maximum force of 5.4 times body weight. A simplified Crowninshield *et al* (1978) loading cycle was used in a five station hip simulator by Saikko *et al* (1992, 1993, 1995). This simulator had only one axis of motion in the flexion/extension plane which this thesis will demonstrate later is an over-simplification of simulator design. (Saikko (1996) later built a three-axis, single station hip joint simulator which also used a simplified Crowninshield *et al* loading cycle).

The Shore Western Manufacturing (SWM, Monrovia, California, USA) simulators used at the Loma Linda University Medical Centre, California have used a sinusoidal load profile (Clarke *et al*, 1993, Good *et al*, 1996) which in a later study was stated as not being synchronised to the motion cycles (Clarke *et al*, 1997). Simplification of loading and motion cycles had been discussed by Viceconti *et al* (1996), and although motion cycles may approximate to sinusoidal profiles, the vertical loading cycle most closely resembles a square wave and not a sinusoidal profile. Furthermore, not synchronising loading to the motion cycles simply cannot attempt to replicate clinical motion and loading patterns over the duration of a wear test.

Simplification of loading has been investigated at the University of Leeds over two studies. Besong *et al* (1998a) used the Leeds PA1 simulator, capable of three axes of motion and three axes of loading, to compare cup wear rates with 3 axes of loading with 1 axis of loading. A 32 mm diameter zirconia femoral head articulating against an

UHMWPE cup was used for the first test with 3 load axes, and a 28 mm diameter zirconia head against an UHMWPE cup in the second test with 1 load axis. The cup wear rates were 30.0 and 32.1 $mm^3/10^6$ cycles respectively which the authors found not to be statistically significantly different. With such little data it is dangerous to draw such conclusions particularly considering the discrepancy in prosthetic size over the two tests. A number of studies have shown wear rate to rise with increases in femoral diameter (McKellop *et al*, 1995a, Hall *et al*, 1998c, Oonishi *et al*, 1998, Elfick *et al*, 1998a) so it is surprising that the second test with a smaller prostheses has a higher wear rate. The second study by Barbour *et al* (1998, 1999a) studied both simplification of motion and simplification of loading. Both elements of the study were considerable departures from previous physiological cycles. The simplified loading profile used in their study extended for only half of each gait cycle which is shorter than that described by Paul (1967). Phasing of the loading with the simplified motion cycles was different from that proposed by Viceconti *et al* (1996) and measured clinically by Johnston and Smidt (1969). The results suggested that these motion and loading cycles gave cup wear rates that were not statistically significant from physiological motion and loading. This may be true for the combined simplification of motion and loading cycles, but the individual effect of simplifying either motion or load was not demonstrated. In a later study, Barbour *et al* (1999b) described a similar loading cycle that extended for 65% of each gait cycle, perhaps recognising the over-simplification of the original simplified cycle.

The number of loading axes required for successful simulator testing, and the positioning of load actuators on each axis was discussed by Dumbelton (1978). He hypothesised that simulator loading should be physiological and be capable of physiological variations, and that the vertical loading axis should be offset at an angle similar to that *in vivo*. Viceconti *et al* (1996) also discussed the design of hip simulators and used a computer model to predict the optimum simulator design with a balance between complexity and cost. With regard to the optimum number of loading axes and the applied loading profiles, the computer predicted that square wave vertical loading offset by 15° combined with sinusoidal anterior/posterior loading would be best. The angular offset represents the average angular displacement of the resultant force acting on the hip during a normal walking cycle.

Many multi-station simulators being used currently have a single axis of vertical loading (Bragdon *et al*, 1996, Clarke *et al*, 1997, Medley *et al*, 1997, Barbour *et al*, 1999a,b, McKellop *et al*, 1999, Wang *et al*, 1999) which represents simplification over that of the optimum model produced by Viceconti *et al*. The multi-station simulators described by Brummitt and Hardaker (1996), Goldsmith and Dowson (1999), and the simulators described within this thesis all use load actuators that swing in the flexion/extension plane with the femoral component. This achieves more sophisticated loading than otherwise can be achieved with a single stationary loading actuator per station. Unfortunately, Viceconti *et al* did not perform an analysis of this type of simulator to allow a theoretical comparison with other simulator designs.

2.3.4 Simulator motion

The multi-station simulators with load actuators that swing in the flexion/extension plane were originally designed so that the combination of motion and loading cycles reproduced the three-dimensional locus of the load vector over the acetabular component as seen *in vivo* (Paul, 1967). Results from these machines have shown that the femoral head tunnels into the acetabular component (Brummitt and Hardaker, 1996, Smith *et al*, 1997, 1999b) as observed *ex vivo* (Atkinson *et al*, 1985a,b, Kabo *et al*, 1993) giving confidence in the ability of these simulator designs to replicate motion of the physiological load vector. To do this with two axes of motion as opposed to three, required modification to the motion cycles. This philosophy contrasts with simulators which apply motion cycles in each axis as observed *in vivo*, and therefore with only one or two axes of motion the physiological load vector will not be correctly reproduced. Many of these machines present a further simplified model by applying non-physiological motion cycles which are only of a similar magnitude to that observed *in vivo*. An example of such a simulator (Saikko *et al*, 1992) applied motion to the prostheses in the flexion/extension axis only with an approximately sinusoidal waveform. The range of motion in this axis amounted to that which would be observed in each axis *in vivo* (Johnston and Smidt, 1969) summed together.

Bragdon *et al* (1996) designed a simulator initially with two linked axis of motion, flexion/extension and internal/external rotation, but wear testing of prostheses produced negligible amounts of acetabular cup wear. Using a computer program, the authors traced the wear paths on the acetabular component by twenty separate points on the femoral head. This revealed linear reciprocating tracks on the acetabular component. Reanalysing the wear paths using physiological motion (Johnston and Smidt, 1969) revealed open quasi-elliptical wear paths. The simulator was redesigned with three axes of motion using physiological motion in each axis and acetabular cup wear rates rose to 26.7 $mm^3/10^6$ cycles. Bragdon *et al*'s study highlighted the importance of multidirectional motion in simulator studies, whilst another study by Wang A *et al* (1996) used a reciprocating pin-on-plate machine and hip simulator to reach the same conclusion.

The choice of motion cycles and the effect on the wear path traced in the acetabular cup by points on the femoral head was investigated further by Barbour *et al* (1999a). The Leeds PA2 simulator was used with sinusoidal motion in the flexion/extension plane from +30° to -15°. Motion in the internal/external axis was also sinusoidal with a magnitude of ±10° but synchronisation of the two motions was varied over the course of a wear test. For the first five million cycles the two profiles were in phase, but for the following four million cycles the profiles were 90° out of phase. When the motion cycles were in phase the wear path was linear and the cup wear rate was approximately 28 $mm^3/10^6$ cycles. Once the motion cycles were out of phase the wear rate rose to approximately 38 $mm^3/10^6$ cycles and the wear path was elliptical. The initial result with a linear wear path is surprisingly comparable with Bragdon *et al*'s result using physiological motion, as the latter study had found almost zero wear with a linear wear path. The cup wear rate with the elliptical path is more comparable with other simulator studies (Clarke *et al*, 1993, McKellop *et al*, 1995a) and the lower end of clinical findings (Livermore *et al*, 1990, Cates *et al*, 1993) using similarly sized prostheses. This result is encouraging as it suggests that simplifying simulator design to two axes of motion with simplified motion cycles designed to produce an elliptical wear path, can reproduce clinical wear rates. However, the study also used a simplified loading profile which was not validated independently making it impossible to separate the effects of simplifying load and motion on the resulting cup wear rates.

The inadequacies of this simplified loading profile were discussed in the previous section as being incorrectly synchronised and of too short a duration in the gait cycle, subsequently extended to a more physiological duration in a later study (Barbour *et al*, 1999b). Barbour *et al*'s study made visual inspection of the acetabular cup surfaces only, and as such a comprehensive comparison between acetabular surface topography from their study and that found clinically was not made. Finally, whilst the magnitude of the flexion/extension motion was similar to that measured clinically, the magnitude of the internal/external rotation was approaching double the measured clinical value (Johnston and Smidt, 1969, Gore, 1980).

A number of commercially available hip simulators (MATCO, MTS, SWM) usually apply a dynamic load, stationary relative to the femoral head whilst the cup is rotated with a 23° biaxial rocking motion. This type of design has been criticised for having unidirectional motion of constant velocity, and not reciprocating at changing velocities as *in vivo* (Saikko *et al*, 1993). Further criticism has focused on how wear is spread over a larger area of the cup than that observed in retrieval studies, and consequently being unable to reproduce tunnelling of the femoral head into the acetabular cup (Brummitt and Hardaker, 1996). In a finite element study of an MTS simulator motion and loading compared with clinical motion and load, Maxian *et al* (1996) found marked differences between the resultant load vectors as they were traced around the acetabular cup surface. This consequently caused discrepancies in the duty cycle stress. Peak stress magnitudes in the simulator approximated to those of human gait, but the contact region extended far greater. In a kinematic study of the MATCO simulator, Medley *et al* (1997) found the length of the *in vivo* wear path was less than the circular wear path in the simulator. The calculated contact areas in the simulator were also much larger than those *in vivo*, which agrees with the work by Maxian *et al*. Furthermore, femoral head wear was considered to be even less similar to clinical wear compared with that of cup wear, which has possible implications for femoral roughness studies using these types of simulator.

As mentioned previously, the loading profile described by Paul (1967) has been widely adopted as a representative physiological profile. The path of the load vector described by Paul has also been adopted in some simulator studies (Brummitt and Hardaker, 1996, Goldsmith and Dowson, 1999). The motion cycles in the

flexion/extension, internal/external rotation, and abduction/adduction axes described by Johnston and Smidt (1969) have also found favour in a number of studies (Saikko *et al*, 1992, 1993, 1998, Bragdon *et al*, 1996, Viceconti *et al*, 1996). Johnston and Smidt (1969) used an electrogoniometric method to determine the magnitude and pattern of continuous hip joint motion, and joint loading. This study was the first of its type applied to 3 planes of hip motion. Continuous motion was studied in 33 patients which was a significant advance over previous small-scale studies. A problem with this method included misalignment of the goniometers with the exact location of the hip joint, but the authors used a mathematical matrix method of correction for this problem. The goniometers were held in place by belts and some slippage occurred of both belt and soft tissue relative to the joint, but the motion of a subject with a fused hip was used to compensate for this error. Similar gait analysis with electrogoniometers was conducted by Gore (1980) but extended to cover a variety of patient groups and activities. For young, healthy adults of either sex, Gore identified very similar motion cycles to those identified by Johnston and Smidt.

2.3.5 Other aspects of simulator design

The speed of simulation should be approximately 1 Hz, that of the natural cadence of walking. A five million cycle test at 1 Hz represents just short of sixty days, or over eight weeks, continuous testing. Total test duration however will be longer due to periodic stopping to change lubricant, clean and measure the specimens, maintain the simulator, and so on. There is a temptation to increase the speed of simulation in order to complete wear tests quicker. However, it must be kept in mind that hip simulator wear tests are already accelerated tests compared with clinical or animal studies. Increasing the speed of testing may well impact on the results of the wear test through changes in temperature at the joint interface, or lubrication of the joint. As the author has demonstrated experimentally, both with simple configuration friction tests and full prostheses friction simulator tests (Smith *et al*, 1998b, 1999c), increasing the entraining velocity reduces the coefficient of friction. Most of the simulator tests already referenced have been conducted at approximately 1Hz with the

notable exception of Bragdon *et al* (1996) who tested at both 1 and 2 Hz claiming no adverse effects either as a serum temperature rise, or wear surface topography discrepancies. Although this may be true when testing polyethylene joints, it may not be true for other joint designs and as such replication of clinical conditions should be maintained.

Simulators should be designed with the capability to fixate prostheses as intended clinically. It may not always be necessary to secure the prostheses in such a manner, and indeed this can present problems, but the capability should exist. Difficulties were experienced in this study in making accurate gravimetric measurements of cemented acetabular cups. However, in a later study by the author this problem was overcome as well as the notoriously difficult problem of moisture absorption in polyurethane in a wear test of compliant layer hip joints (Smith and Unsworth, 1999a, Smith *et al*, 1999a). Many studies do not mount prostheses anatomically. The problems associated with wear debris entrapment at the articulating interface for metal-on-metal prostheses have been recognised (McKellop *et al*, 1999), as indeed they have for lubricant precipitate (Wang *et al*, 1999). The major objection to anatomical mounting is entrapment of air within the joint space. Expulsion of air prior to starting, or re-starting an anatomical wear test should be a sufficient protocol to address these criticisms. Air generated *in vitro* through joint articulation may also occur *in vivo* and be trapped in the joint space until such a time as the patient attains a position for the air to evacuate the joint space. Testing anatomically inverted therefore would not allow any air produced through articulation to become entrapped and ironically would not be representative of clinical conditions.

As mentioned previously, Clarke (1981) considered that simulators needed to be multi-station, which would allow the possibility of more statistically relevant results (Dumbleton, 1978). However, in order to reduce both capital and running costs, a balance between simulator complexity and cost needs to be realised. As Clarke and Kabo (1991) commented, the more complex the simulator the more incapable the machine is of running numerous tests for millions of cycles.

Safeguards to stop the wear test may be incorporated into the simulator design if test conditions fall outside specified limits. This has another function in protecting the simulator from possibly expensive damage once problems occur. It is possible

however to design and operate a simulator in such a way that expensive safeguards may not be required as malfunctions do not cause further damage to the simulator. This philosophy was adopted when designing the mk.II Durham hip joint wear simulator.

The simulator must be designed to allow easy removal of the test prostheses from the machine for cleaning and measurement. Lubricant changes should also be easily undertaken, and the need for a water-tight design is obvious but not always successfully incorporated into simulator design. Wherever possible, the number of parts coming into contact with the lubricant, and consequently interfaces to keep water-tight, should be minimised. The difficulty of cleaning said parts and interfaces should also be considered, and the need for anti-corrosion materials should not be underestimated.

Each station of a simulator should be fitted with a self-alignment feature as misalignment of the femoral head with the acetabular cup could lead to excessive wear. This excessive wear due to misalignment may also be seen on the loading and motion systems leading to possible changes in test conditions over the wear test and expensive reconditioning of components.

2.4 Acetabular cup wear rates

The wear tests conducted within this study used only 22.25 and 28 mm prostheses. A review of both simulator and clinical studies of similar sized prostheses has therefore been undertaken. For the smaller head size, both UHMWPE and PTFE acetabular cups were used, whereas the 28 mm diameter cups were all made from UHMWPE. CoCrMo and zirconia ceramic femoral heads were used in the wear tests, but due to the limited number of similar studies other femoral head material types have been reported.

2.4.1 Polytetrafluroethylene (PTFE) 22.25 mm diameter acetabular cup wear studies

The clinical failure within three years of PTFE cups due to high wear (Charnley *et al*, 1969) led to the use of polyethylene because of its superior wear characteristics. Limited PTFE clinical data is therefore available with which to draw comparison but is included in Table 2.4 along with simulator tests that have also used PTFE acetabular cups. The AB Automation validation exercise used both PTFE and UHMWPE acetabular cups to investigate the ability of the simulator to rank material wear rates as observed clinically.

The work by Good *et al* (1996) has already been commented on when discussing the choice of lubricant for wear testing. The authors found that tests conducted in water gave results which varied by in excess of ±70% compared with only ±3% in bovine serum. Acetabular cup wear rates in water, despite variability, were also very much lower than in serum. Therefore, the results of the PTFE wear test in this thesis should be compared with those of Good *et al* conducted using water, Charnley *et al*'s (1968) clinical findings, and ranked against tests using UHMWPE.

It is worth noting that all of the simulator tests in Table 2.4 are of exceptionally short durations. Indeed, Good *et al* (1996) conducted the longest test and reported three wear phases for the PTFE. The three wear phases had diminishing wear rates with increased duration of the wear test. This perhaps indicates that the cups had not fully

worn-in and that the tests should have been extended. The wear rates reported by Clarke (1981) were part of a validation exercise which included UHMWPE cups and he observed that with only 0.06 million cycles the UHMWPE cups showed insufficient wear for accurate measurement.

2.4.2 UHMWPE 22.25 mm diameter acetabular cup wear studies

Simulator studies using 22.25 mm diameter UHMWPE cups are shown in Table 2.5. As discussed previously, several groups have compared wear in water with wear in serum and found higher wear rates in serum. General agreement with those observations can be seen in Table 2.5, and as this thesis wear tested similar prostheses in water only, these are the studies with which comparisons should be drawn. However, the results of Saikko *et al* (1992, 1993) are several times the magnitude of all the other studies. The simulator used by Saikko *et al* in these studies has already been discussed and criticised for its over simplification to only one axis of motion, rendering it little more than a wear screening device.

The simulator studies are of longer durations than the PTFE wear tests, but are perhaps still too short with the exception of Brummitt and Hardaker (1996). Dowson and Jobbins (1988) found that penetration rates were too low to be accurately measured using a shadowgraph technique over only two million cycles duration. They concluded that in future tests further attention should be given to the measurement technique, and the duration of the test should be extended to perhaps five million cycles. The results also showed that creep accounted for sixty percent of the total penetration rate over their test. The suggestions and observations by Dowson and Jobbins were perhaps not sufficiently heeded by Derbyshire *et al* (1994a) who subsequently used the same simulator. Their shorter two million cycle test but with an improved measurement technique merely confirmed most of the penetration was due to creep in the first million cycles of the wear test.

Clinical studies of similar prostheses are shown in Table 2.6. The reported studies, bar one, use either radiographic or shadowgraphic means to measure penetration or wear. Radiographic studies of *in vivo* prostheses measure mainly well-functioning

prostheses. The difficulties associated with making accurate measurements using this technique are widely recognised (Charnley and Halley, 1975, Hall *et al*, 1995, Smith P N *et al*, 1999).

Direct measurement of retrieved *ex-vivo* cups, using a shadowgraphic technique in these studies, often results in higher wear rates than *in vivo* studies. This may be due to a skewed data-set as many of the prostheses will be revised for loosening through osteolysis due to high wear. This problem could possibly be overcome by retrieving well-functioning joints at post-mortem. A study of this type has been undertaken to compare results with a conventional retrieval study (Sychterz *et al*, 1996) and wear rates were 45 to 69 per cent less from post-mortem retrievals. Even a post-mortem study has a possible criticism that the data-set may be skewed towards lower-wear as the patients may have had reduced mobility prior to death. This could be countered by checking patient history, but as the number of post-mortem subjects is limited this would further reduce the cohort of such a study.

Author	Femoral head material	*Ex-vivo cohort,* or, Duration of test (10^6 cys)	Lubricant	Wear rate (mm^3 / 10^6 cys)	Penetration rate (*mm / yr*) or (mm / 10^6 cys)
Charnley *et al* (1969)	Stainless Steel	*39*	Synovial fluid		*2.26* *(0.91 to 6.04)*
Good *et al*, 1996	CoCrMo	0.53	Water	247 to 342	0.63 to 0.88*
Clarke, 1981	Stainless Steel	0.06	Bovine serum		3.4*
Good *et al*, 1996	CoCrMo	0.15	Bovine serum	2949 ± 3%	7.58*
Clarke *et al*, 1997	CoCrMo	0.115	Bovine serum	2952	7.59*

Table 2.4 22.25 mm diameter PTFE acetabular cup wear rates from simulator and clinical studies.

* Penetration rate calculated from the weight loss results using the density of the acetabular cup material by assuming that the femoral head bores a cylinder into the acetabular cup.

Author	Femoral head material	Lubricant	Measurement technique	Duration of test (10^6 cys)	Wear rate (mm^3 / 10^6 cys)	Penetration rate (mm / 10^6 cys)
Dowson & Jobbins, 1988	Stainless Steel	Water	Shadowgraph	3.1		0.054
Saikko *et al*, 1992, 1993	Stainless Steel	Water	Gravimetric	3.0	49, 55, 67$^+$	0.15*
Derbyshire *et al*, 1994a	Stainless Steel	Water	CMM	1.97	9	
Derbyshire *et al*, 1994a	Zirconia ceramic	Water	CMM	1.97	6	
Brummitt & Hardaker, 1996	CoCrMo	Water	CMM	6.75	6	
Wroblewski *et al*, 1996	Alumina ceramic (XLP cup)	Water	Talysurf & CMM	7.3		0.05
Clarke *et al*, 1993	Alumina ceramic	Bovine serum	Gravimetric	1.6	25$^+$	
McKellop *et al*, 1995a	Stainless Steel	Bovine serum	Gravimetric	3.0	41$^+$	
Maxian *et al*, 1997	Stainless Steel	Bovine serum	Gravimetric	3.0	39$^+$	
Bragdon *et al*, 1998	CoCrMo	Bovine serum	CMM	4.0	20.8 ± 2.5	0.10
Goldsmith & Dowson, 1999	Zirconia ceramic	Bovine serum	CMM	7.27	6.28	

Table 2.5 22.25 mm diameter UHMWPE acetabular cup wear rates from simulator studies.

$^+$ Wear rate in mg/10^6 cys converted to $mm^3/10^6$ cys by dividing by the relative density of the UHMWPE used.
* Penetration rate calculated from the weight loss results using the density of the acetabular cup material by assuming that the femoral head bores a cylinder into the acetabular cup.

Author	Femoral head material	Cohort	Measurement technique	Wear rate (mm^3 / yr)	Penetration rate (mm / yr)	Total wear vol., or, *creep component*
Charnley & Hayley, 1975	Stainless Steel	63	Radiographic		0.15	
Atkinson *et al*, 1985a	Stainless Steel	25	Shadowgraph		0.18 (0.005 to 0.6)	580 mm^3
Wroblewski, 1985	Stainless Steel (HDP cup)	22	Shadowgraph		0.19 (0.017 to 0.52)	
Livermore *et al*, 1990	CoCrMo	227	Radiographic	47.5 ± 36.2 (0 to 147)	0.13 ± 0.1 (0 to 0.39)	513 ± 393 mm^3 (0 to 1617)
Kabo *et al*, 1993	Stainless Steel	5	Shadowgraph	25.9	0.127	
Pederson *et al*, 1995	Stainless Steel	210 for 22 & 28mm dia. hips	Radiographic	41.2 ± 25.8 (at 15 yrs)	0.11± 0.07 (at 15 yrs)	
Hall *et al*, 1996a	Stainless Steel	129	Shadowgraph	55 (SE=5)	0.20 (SE=0.08)	508 mm^3 *10 (SE=18) mm^3*
Issac *et al*, 1996	Stainless Steel	87	Shadowgraph		0.181[+] (0.005 to 0.6)	*0.158 mm*
Jasty *et al*, 1997	CoCrMo	17	Gravimetric (fluid displacement)	37.2 ± 30.6		
Kesteris *et al*, 1996	CoCrMo	33	Radiographic	57 (2 to 117)	0.15 (0.01 to 0.31)	420 mm^3
Wroblewski *et al*, 1996	Alumina ceramic (XLP cups)	19	Radiographic		0.005 (-0.029 to 0.031)	

Table 2.6 22.25 mm diameter UHMWPE acetabular cup wear rates from clinical studies.

[+] Rate obtained from weighted regression analysis.

2.4.3 28 mm diameter UHMWPE acetabular cup wear rates

Simulator studies of 28 mm diameter prostheses are presented in Table 2.7. The wear tests by Greer (1979) and Saikko (1995) were conducted in water and as such should not be used for comparison with the bovine serum lubricated 28 mm tests of this thesis.

Despite his own advice on the subject (Clarke, 1981), Clarke *et al* (1993) performed a single specimen wear test. Cohort size for each of the tests should be considered to give more reliance on the quoted wear rate. Also, the duration of many of the tests should be considered as again many are too short. In the case of some of Barbour *et al*'s work (1999b), the study was of seven million cycles duration split into two parts of five million cycles plus two million cycles. This is an acceptable form of study as once the acetabular cups have worn-in they represent the mature joint *in vivo*. Subsequent changes in test conditions can be immediately measured without any other influencing variables. McKellop *et al* (1985a) made a similar change from the titanium femoral heads after two million cycles duration to the explanted titanium heads for a further one million cycles. As this thesis will demonstrate, the initial duration should have been extended to ensure measurements were made of the mature joint against the new titanium heads, to allow a true comparison with the explanted heads.

Wear tests using alumina or zirconia ceramic femoral heads generally show lower acetabular cup wear rates than studies with metallic femoral heads. It is difficult to notice any discrepancies between measurement techniques, for example, if we compare the results of Clarke *et al* (1993) and Besong *et al* (1998a). These studies used gravimetric and volumetric measurement respectively for ceramic against polyethylene joints finding similar wear rates of 35 and 32 $mm^3/10^6$ cys. Acetabular cup wear rates also tend to be higher against either explanted or deliberately scratched femoral heads, as would be expected with a roughened femoral counterface.

It is generally considered that simulator wear tests produce wear rates below those for similar prostheses worn *in vivo* (Clarke, 1981). Simulator wear tests do not use bone for fixation which prevents one form of contamination of the joint space which is often observed clinically (Learnmonth and Cunningham, 1997). Many simulator tests do not use cement fixation removing the possibility of a further contaminant. Those

studies that do use cement have advantages over the clinical environment in easy access when initially cementing the joint, and periodic inspection of the cement mantle during testing. UHMWPE acetabular cups tested *in vitro* have frequently had less post irradiation ageing than cups which have been implanted. The motion and loading cycles applied by simulators are generally smooth, continuous walking patterns without the extremes seen clinically when a patient may run, climb or descend stairs, rise from a chair, or even trip and possibly fall. Table 2.8 presents clinical studies of 28 mm diameter prostheses and can it can be seen that the wear rates generally are indeed higher than simulator study wear rates. As with the simulator studies, the clinical studies of ceramic femoral heads generally show lower acetabular cup wear and penetration rates than studies with metallic femoral heads.

It is worth noting in the review of clinical studies (Tables 2.6 and 2.8) that total wear volume is often quoted. There is growing clinical evidence to suggest that a threshold value for total volumetric debris may exist beyond which osteolysis will be induced. If this is true, then the rate at which an acetabular cup wears will determine how long the implant will last. Furthermore, once a volumetric threshold value is established, volumetric wear rates may be converted to a value for 'implant duration to failure' giving a striking comparison of one design to another.

Author	Femoral head material	Lubricant	Measurement technique	Duration of test (10^6 cys)	Cohort	Wear rate (mm^3 / 10^6 cys)
Greer, 1979	Metal	Water	Gravimetric (debris collection)	3 to 4	?	25.1^+
Saikko, 1995	Zirconia ceramic	Water	Gravimetric	3.0	6	0 to 23.2^+
Saikko, 1995	CoCrMo	Water	Gravimetric	3.0	6	55.2 to 88.3^+
Clarke *et al*, 1993	Alumina ceramic	Bovine serum	Gravimetric	1.6	1	35^+
McKellop *et al*, 1995a	Stainless Steel	Bovine serum	Gravimetric	3.0	3	55^+
McKellop *et al*, 1995a	Titanium	Bovine serum	Gravimetric	2.0	3	39^+
McKellop *et al*, 1995a	Titanium explants	Bovine serum	Gravimetric	1.0	3	50^+
Besong *et al*, 1998a	Zirconia ceramic	Bovine serum	CMM	4.0	1	32.1 ± 3.4
Maxian *et al*, 1997	Stainless Steel	Bovine serum	Gravimetric	3.0	3	51.1^+

Table 2.7 28 mm diameter UHMWPE acetabular cup wear rates from simulator studies (continued overleaf).

$^+$ Wear rate in mg/10^6 cys converted to $mm^3/10^6$ cys by dividing by the relative density of the UHMWPE used.

Author	Femoral head material	Lubricant	Measurement technique	Duration of test (10^6 cys)	Cohort	Wear rate (mm^3 / 10^6 cys)
Barbour *et al*, 1999a	Zirconia ceramic	Bovine serum	CMM	4.0	2	30.0 ± 2.3
Barbour *et al*, 1999a	CoCrMo	Bovine serum	CMM	4.0	2	41.6 ± 5.3
Barbour *et al*, 1999b	Zirconia ceramic	Bovine serum	CMM	5.0	5	41.2 ± 1.3
Barbour *et al*, 1999b	CoCrMo	Bovine serum	CMM	5.0	5	46.6 ± 5.6
Barbour *et al*, 1999b	CoCrMo (left unscratched)	Bovine serum	CMM	2.0	4	47.0 ± 0.7
Barbour *et al*, 1999b	CoCrMo (bead scratched)	Bovine serum	CMM	2.0	3	55.6 ± 4.1
Barbour *et al*, 1999b	CoCrMo (diamond scratched)	Bovine serum	CMM	2.0	3	113.1 ± 17.0

Table 2.7 28 mm diameter UHMWPE acetabular cup wear rates from simulator studies (continued).

Author	Femoral head material	Cohort	Measurement technique	Wear rate (mm^3 / yr)	Penetration rate (mm / yr)	Total wear vol., or, *creep component*
Livermore *et al*, 1990	CoCrMo	98	Radiographic	47.5 ± 36.2 (0 to 147)	0.13 ± 0.1 (0 to 0.39)	521 ± 463 mm^3 (0 to 2249)
Cates *et al*, 1993	Titanium	134 (cups in shells) 99 (no shells)	Radiographic	66.1 ± 33.3 48.2 ± 38.1	0.107 ± 0.054 0.078 ± 0.062	395 ± 214 mm^3 330 ± 268 mm^3
Kabo *et al*, 1993	Stainless Steel	23	Shadowgraph	75.6	0.234	
Hernandez *et al*, 1994	Titanium alloy	66 (cemented) 66 (uncemented)	Radiographic		0.14 0.22	cemented=259 mm^3 no cement=455 mm^3
Woolson & Murphy, 1995	CoCrMo	80	Radiographic		0.14 ± 0.09 (0 to 0.35)	
Pederson *et al*, 1995	CoCrMo	210 for 22 & 28mm dia. hips	Radiographic	70.9 ± 59.6 (at 10 yrs)	0.12± 0.10 (at 10 yrs)	
Sugano *et al*, 1995	Alumina	61	Radiographic		0.10 (0 to 0.31)	
Jasty *et al*, 1997	CoCrMo	12	Gravimetric (fluid displacement)	64.6 ± 30.1		
Devane *et al*, 1997	Titanium	69 (cemented) 70 (uncemented)	3D Radiographic	98.5 155.1		
Sychterz *et al*, 1998	CoCrMo & Ceramic	45 (Hylamer cup) 86 (Enduron cup)	Radiographic		0.12± 0.13 0.23± 0.29	
Hall *et al*, 1998a	Metal	1	Shadowgraph	32	0.08	
Oonishi *et al*, 1998	Alumina	50	Radiographic	51.0	0.08	

Table 2.8 28 mm diameter UHMWPE acetabular cup wear rates from clinical studies.

2.5 Summary

Polyethylene wear debris is the greatest cause of osteolysis from a conventional prosthesis. This is due to the fact that the majority of debris produced is polyethylene as opposed to metal, ceramic or cement. It is therefore the quantity of polyethylene debris produced that should be the main focus of simulator measurements.

Measurement methods should maintain control specimens relevant to both the measurement technique and the material being tested. Long term wear tests should include sufficient specimens to allow statistical analysis of results and run for a long period, perhaps 5 million cycles. This allows both the acetabular component to wear-in representing a mature joint *in vivo*, and enables sufficient wear to occur to allow accurate wear measurement. Femoral topography should also be measured before and after the wear test to relate femoral roughness to cup wear rate. This can also give an indication of the scratch resistance of the femoral material or surface treatment.

Hip simulators should be multi-station and feature at least two axes of motion with dynamic loading. The motion and loading cycles should reproduce a physiological load vector. Alternatively, the motion cycles should produce an open wear path with motion in each axis of physiological magnitude. Loading should be comparable to physiological loading in terms of magnitude, duration and synchronisation with the motion cycles. The lubricant should prevent the formation of transfer films on the femoral component and contain proteins to promote boundary lubrication. The most suitable lubricant at present is bovine serum.

Chapter 3. Apparatus

3.0 Introduction

The first hip simulator used at Durham University was an AB Automation Limited machine designed to use water as a lubricant during wear testing. Subsequently, it became apparent that such a machine was rapidly becoming obsolete as bovine serum was becoming the standard lubricant for wear testing (Good *et al*, 1996, Wang *et al*, 1996, Bigsby *et al*, 1997). Therefore, following a validation exercise (Smith *et al*, 1997, 1999b) and a wear test of compliant layer joints (Smith *et al*, 1998a) the AB Automation machine was redesigned to use bovine serum as a lubricant. At the same time several problems of the original design were addressed. The modified machine was renamed the Mk.I Durham hip joint simulator (Smith and Unsworth, 1999b).
Through research discussed later in this thesis (Smith and Unsworth, 1999c,d), and from work conducted at Leeds University as part of the joint CAM 1 project for the Department of Trade and Industry (Barbour *et al*, 1999a), acceptable simplifications to simulator motion and loading were established. This allowed the Mk. II Durham hip joint simulator to be designed with the intention of building a simpler, more reliable machine whilst maintaining a realistic simulation (Smith and Unsworth, 1999e).

3.1 AB Automation hip joint simulator

3.1.1 Description

The AB Automation simulator was delivered to Durham University incomplete and inoperative by creditors of AB Automation Limited who went into liquidation. Considerable work was therefore required to commission the hip simulator prior to beginning the validation exercise and subsequent long term wear testing. The

simulator was completely rewired at Durham following delivery and minor electrical faults continued to delay commissioning for some time.

The AB Automation simulator as shown in figure 3.1 was a five station simulator in which the joints were mounted anatomically and subjected to a dynamic loading cycle (Paul, 1967). Motion was applied in such a way as to produce the three dimensional locus of the load vector in the acetabular component as seen *in vivo* and used by Brummitt and Hardaker (1996).

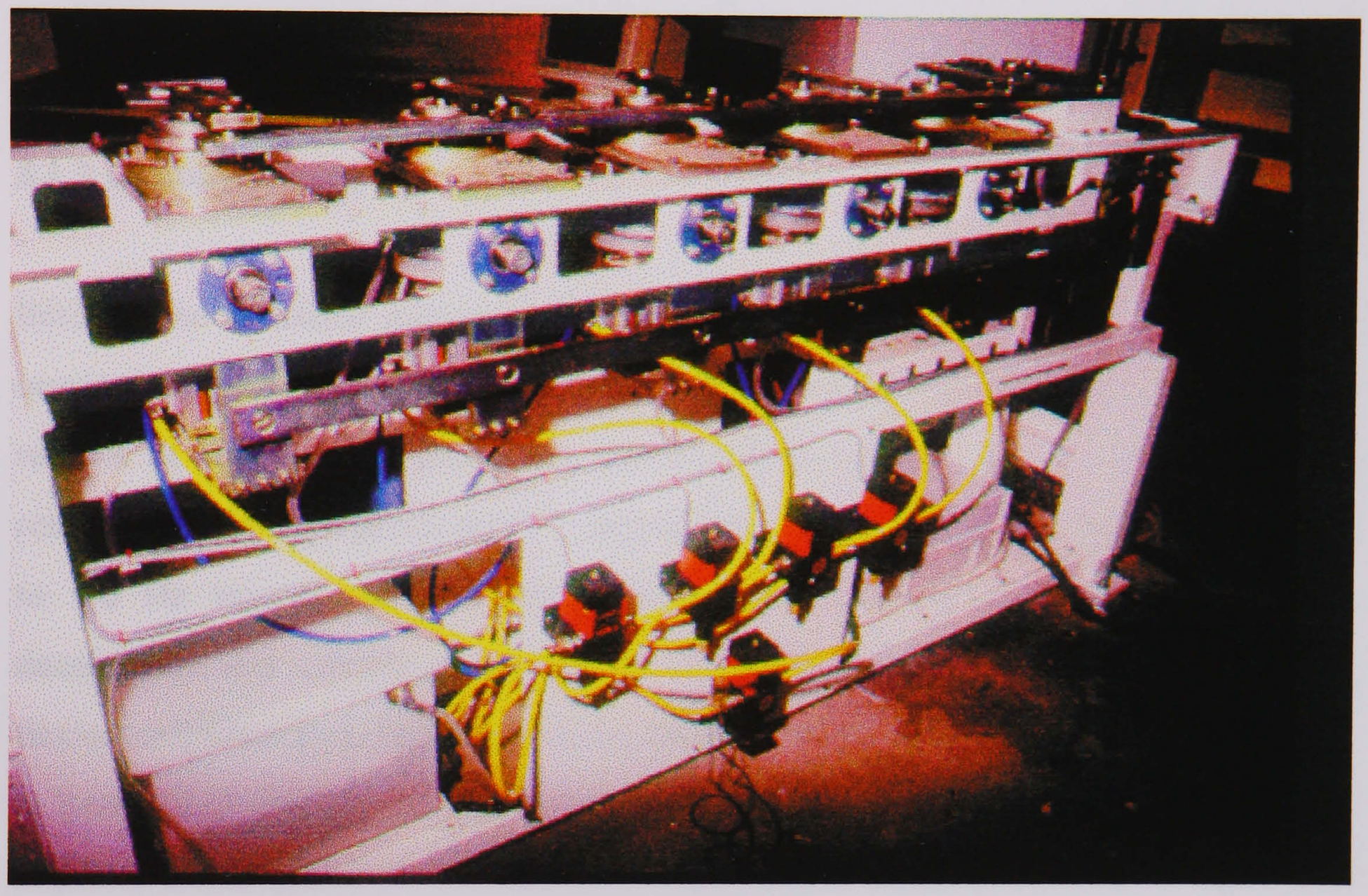


Figure 3.1 : The AB Automation hip simulator

The physiological motion was achieved with two axes of motion. The side axis represented the flexion/extension of the femur, and the top axis represented internal/external rotation of the hip joint. Motion was provided by a Harmonic Drive d.c. stepper motor and gearbox on each axis driving all five articulating stations identically via long drive bars. Encoders fitted to the end of the motors allowed the accuracy of the motion of the motors, and consequently the prostheses, to be assessed. The load was applied pneumatically to the femoral components, using one Hoerbiger pneumatic actuator and one Hoerbiger pneumatic proportional control

valve per station. The control signals to the motors and pneumatic proportional valves came from a Harmonic Drive EuroSystem/EuroStep Servo/Stepper positioning system programmed in Motion Interpreter (MINT) language using a PC. Distilled water was used as a lubricant recirculating in a pressurised system heated to 37°C. The AB Automation design featured filters in the recirculating system intended to capture wear debris from which wear rates could be calculated gravimetrically. However, the peristaltic pump was not powerful enough to circulate the lubricant when the filters were fitted so alternative wear measurement methods were employed.

3.1.2 Commissioning

Initially, the simulator motion operated at 0.65 Hz rather than 1.0 Hz which is the nominal frequency for walking. The actual motion of the prostheses against the request at 0.65 Hz, is shown for the flexion/extension axis and internal/external rotation axis in Figures 3.2 and 3.5 respectively. To increase the speed of the motion to 1.0 Hz several software modifications were required to change acceleration, deceleration and velocity characteristics of the d.c. stepper motors. Considering the flexion/extension axis, figure 3.3 shows the response at 1.0 Hz and it can be seen that in comparison to 0.65 Hz the response has deteriorated. Software modifications to improve the response at 1.0 Hz were implemented included altering the gain and making a phase shift to compensate for the motor lag. Optimising the motor characteristics gave satisfactory prosthesis motion as shown in Figure 3.4 for the flexion/extension axis. A similar procedure was applied to the internal/external rotation axis, and the initial performance at 0.65 Hz shown in Figure 3.5 can be compared with the final optimised performance at 1.0 Hz, as shown in Figure 3.6.

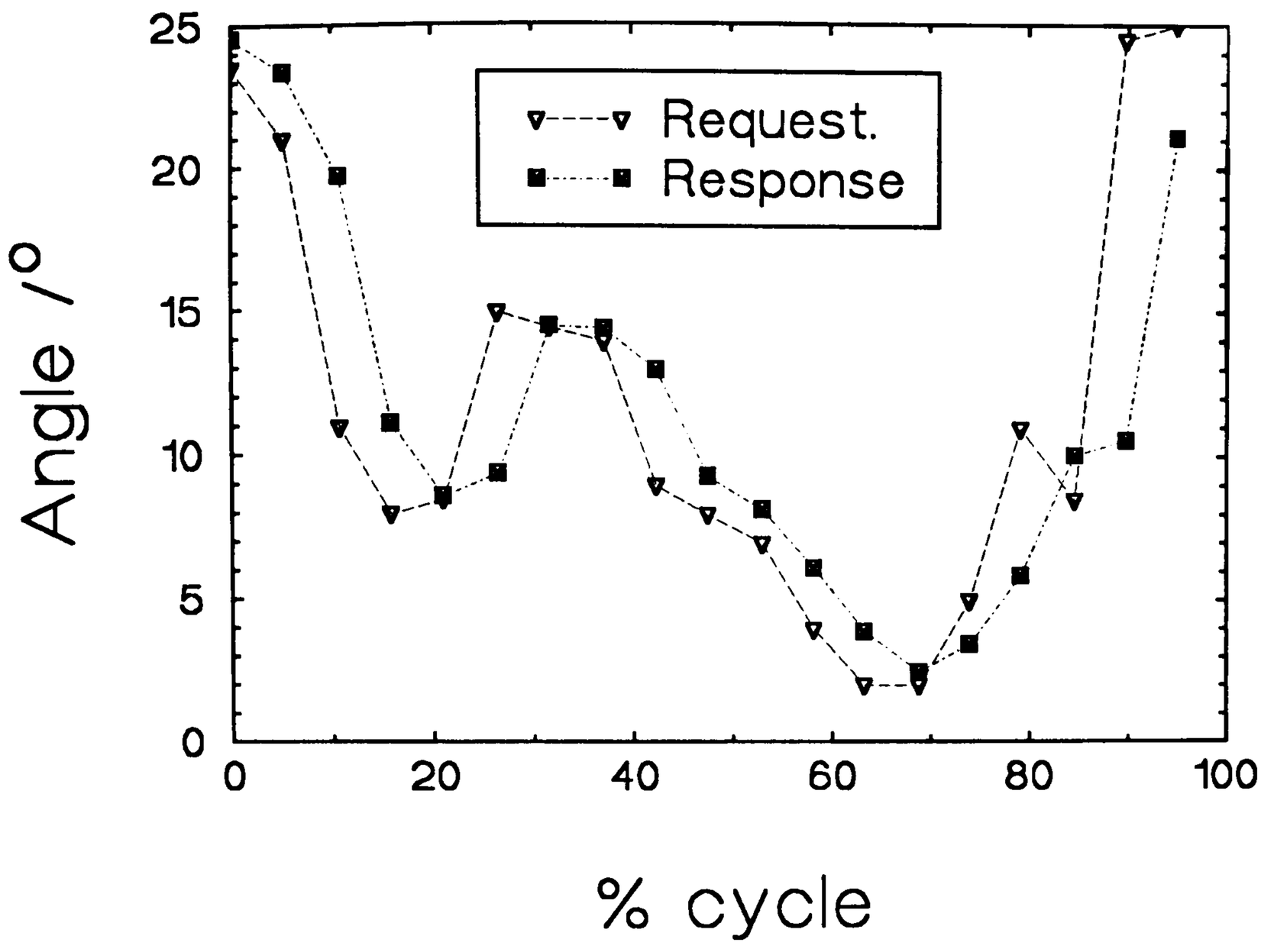


Figure 3.2 : Motion simulation on the flexion/extension axis at 0.65 Hz.

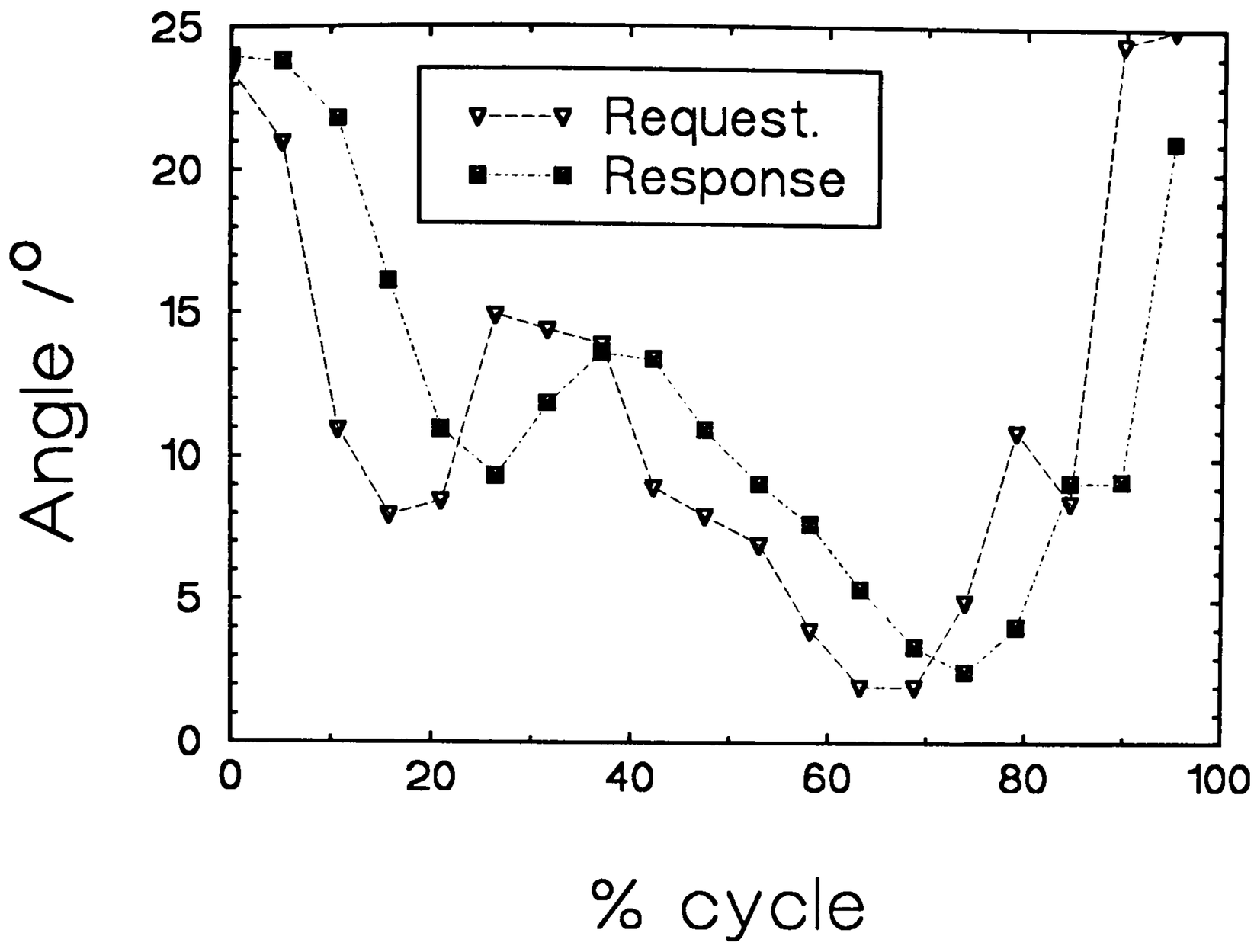


Figure 3.3 : Motion simulation on the flexion/extension axis at 1 Hz.

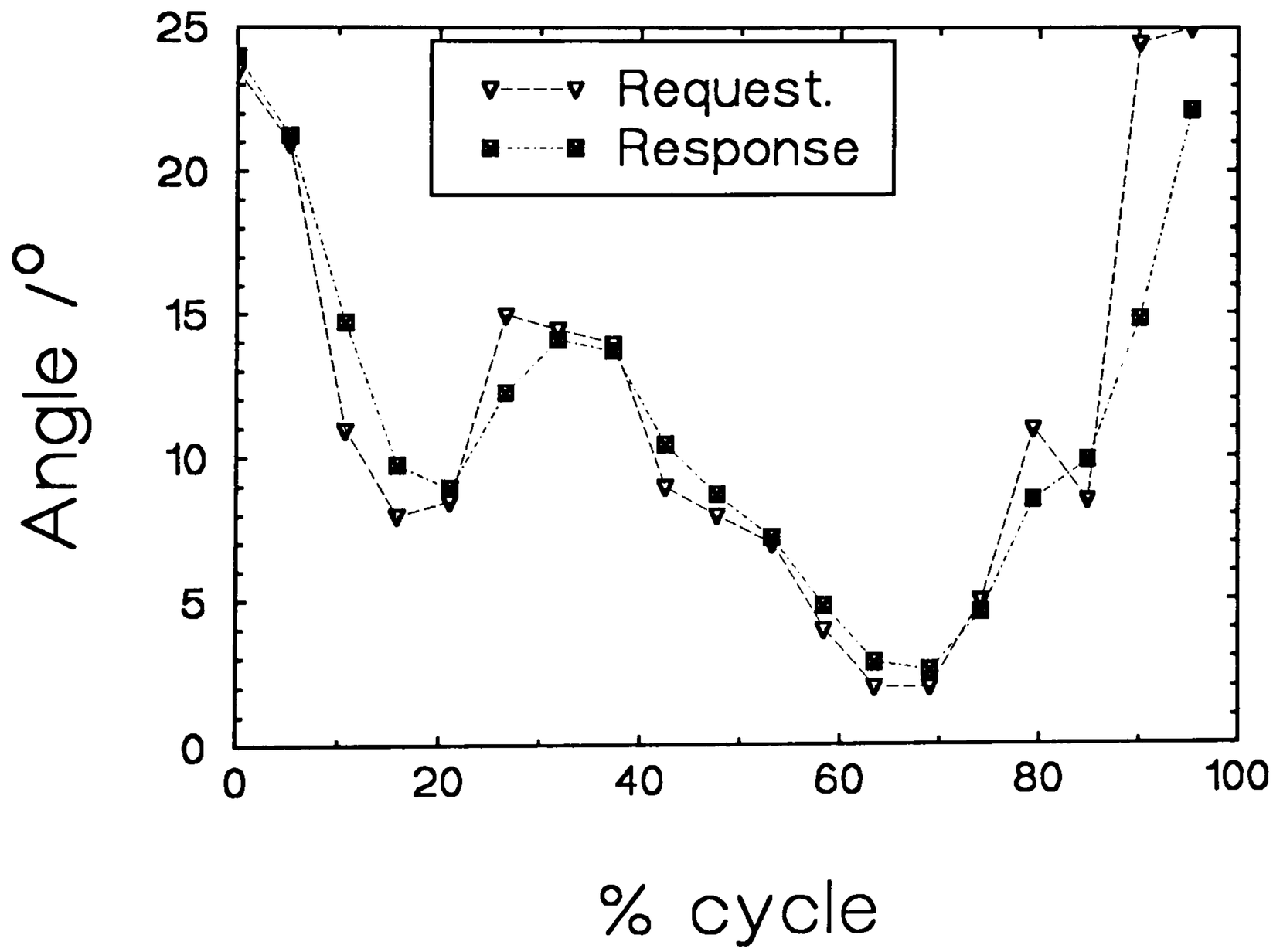


Figure 3.4 : Optimised simulator motion on the flexion/extension axis at 1 Hz.

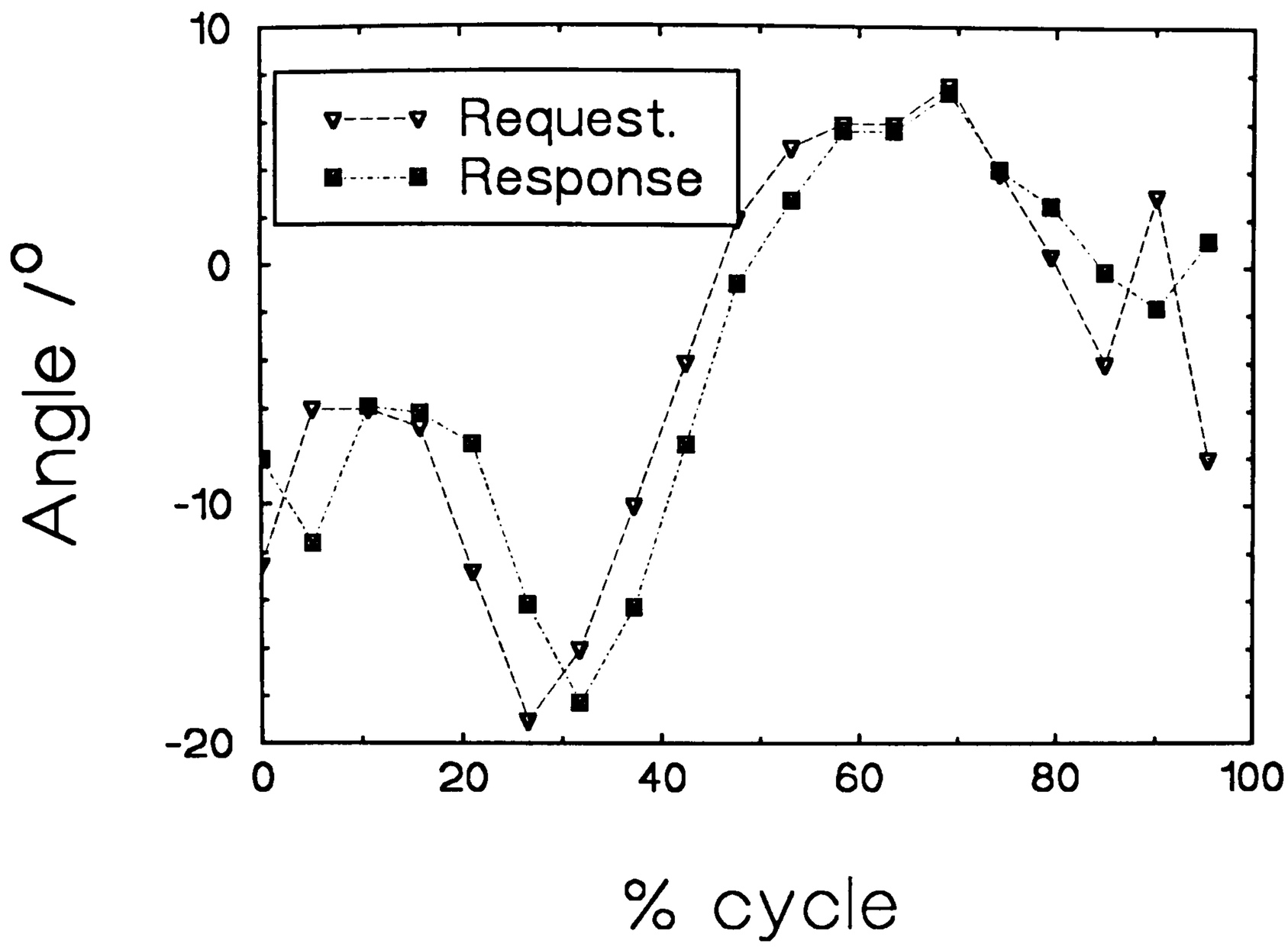


Figure 3.5 : Motion simulation on the internal/external rotation axis at 0.65 Hz.

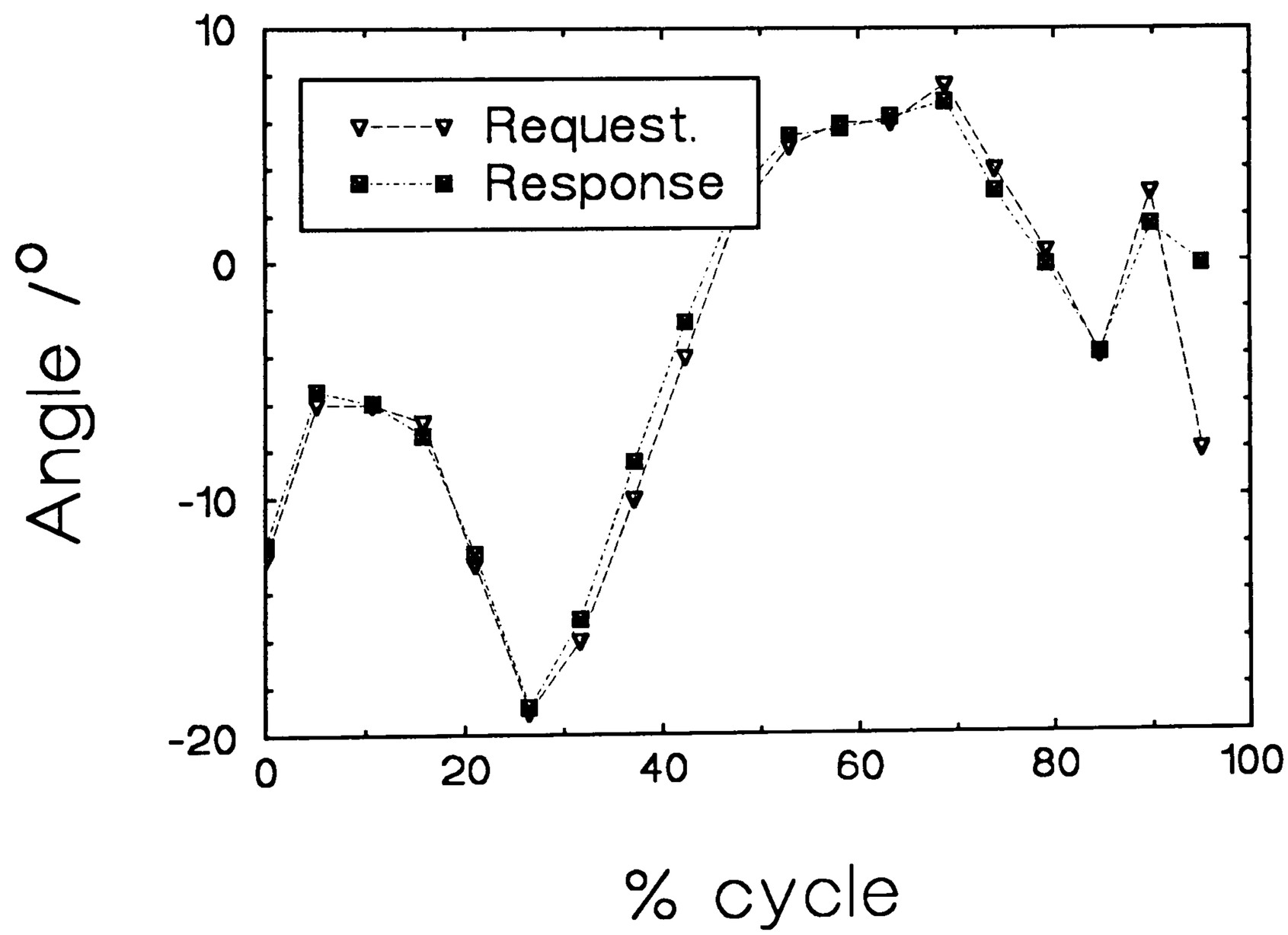


Figure 3.6 : Optimised simulator motion on the internal/external rotation axis at 1 Hz.

Prior to the authors work on the simulator, the best performance of this pneumatic loading system was achieved at 0.77 Hz but the operating frequency of the pneumatic system was now required to be 1 Hz. Thus, re-calibration of the pneumatic proportional valves was required. Analysis was performed on the effect of dead volume, supply and back pressure on the performance of the pneumatic system. The optimum performance of each station is given in Figures 3.7 to 3.11. The supply pressure was 11.0 bar and back pressure was 2.1 bar. Examination of the valves indicated that Stations 1 to 4 were driven with a Hoerbiger XRES11-15 proportional valve, whereas Station 5 was driven by a lower specification XRE11-15 valve hence the poor performance by comparison.

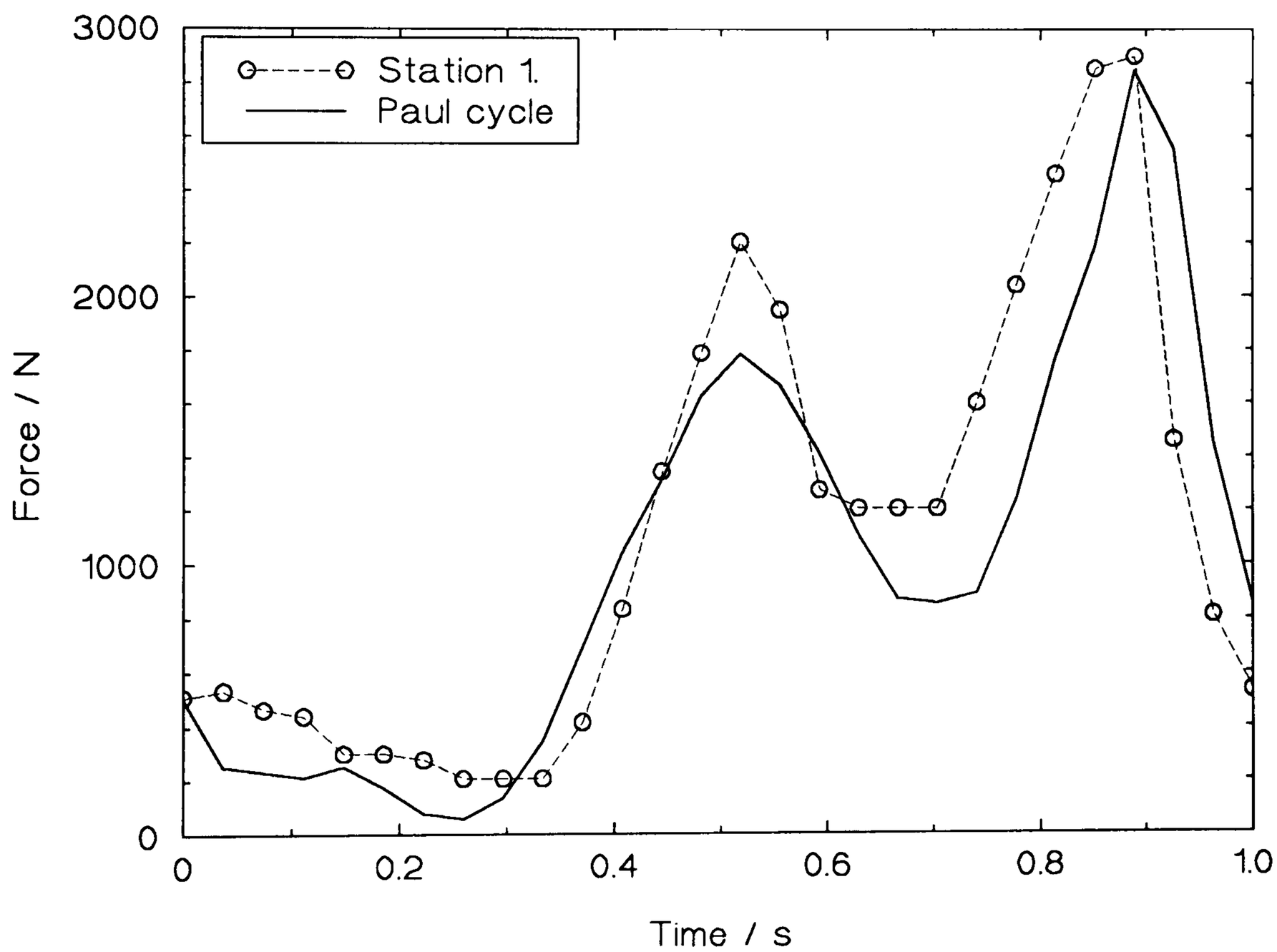


Figure 3.7 : Load simulation on Station 1.

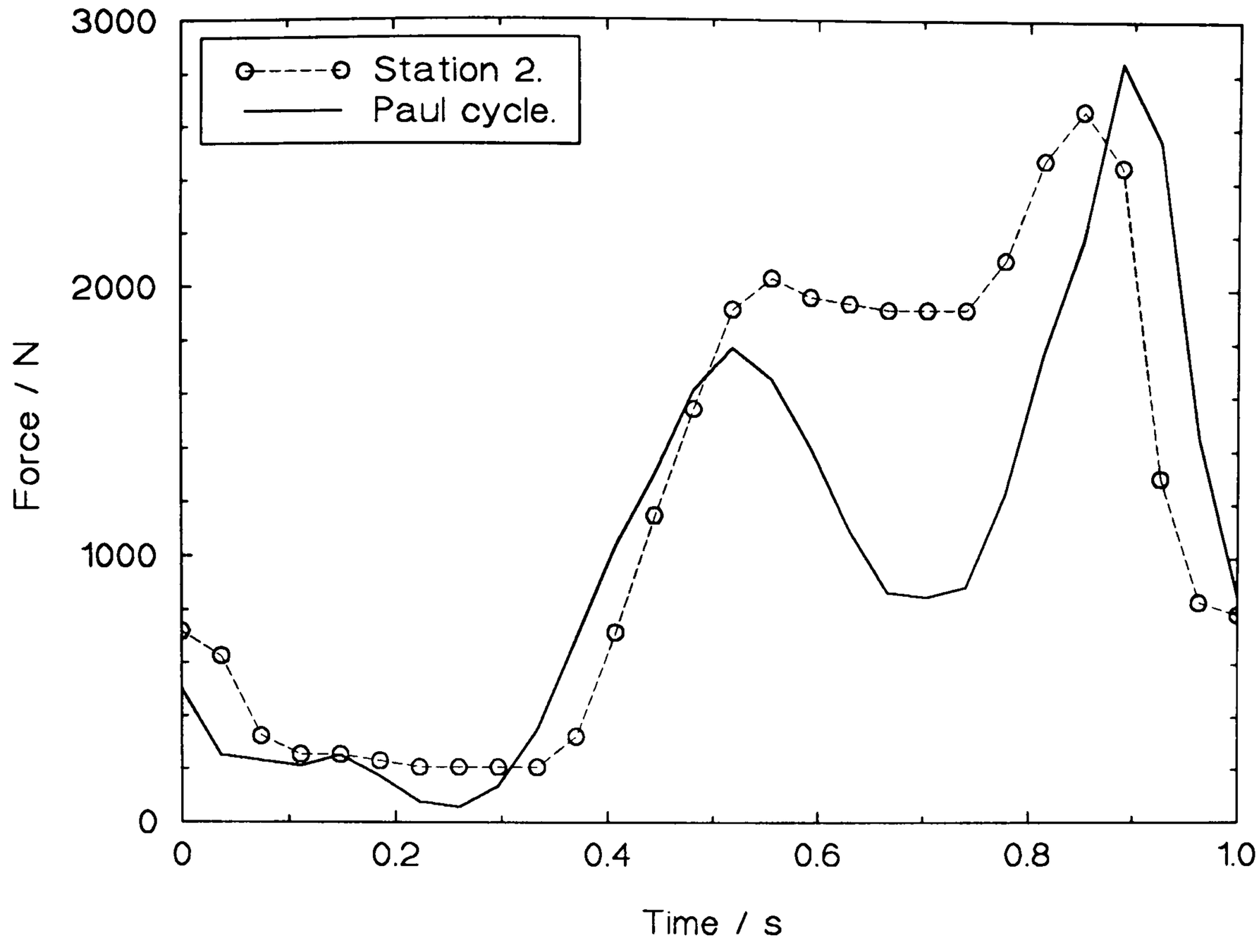


Figure 3.8 : Load simulation on Station 2.

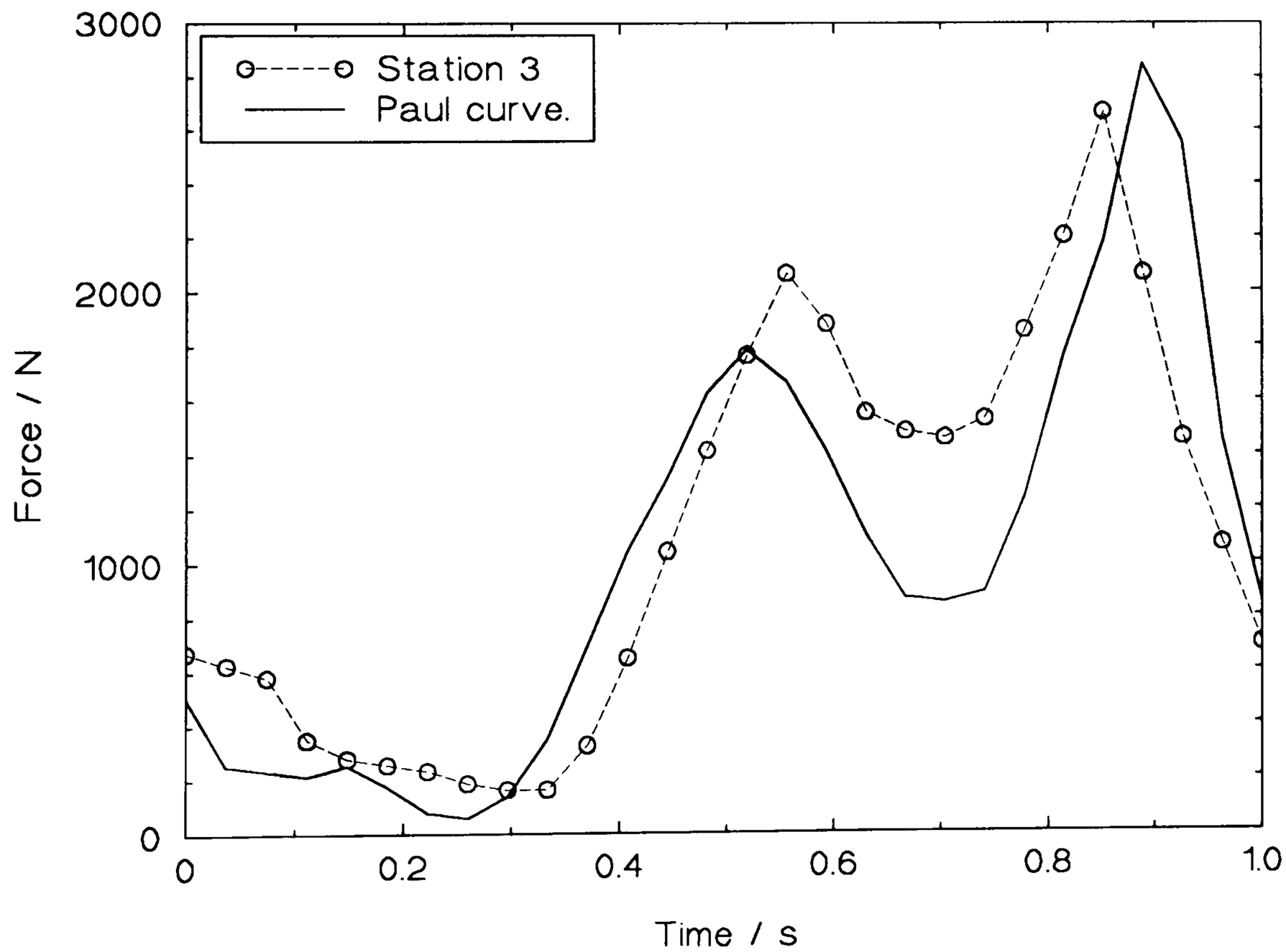


Figure 3.9 : Load simulation on Station 3.

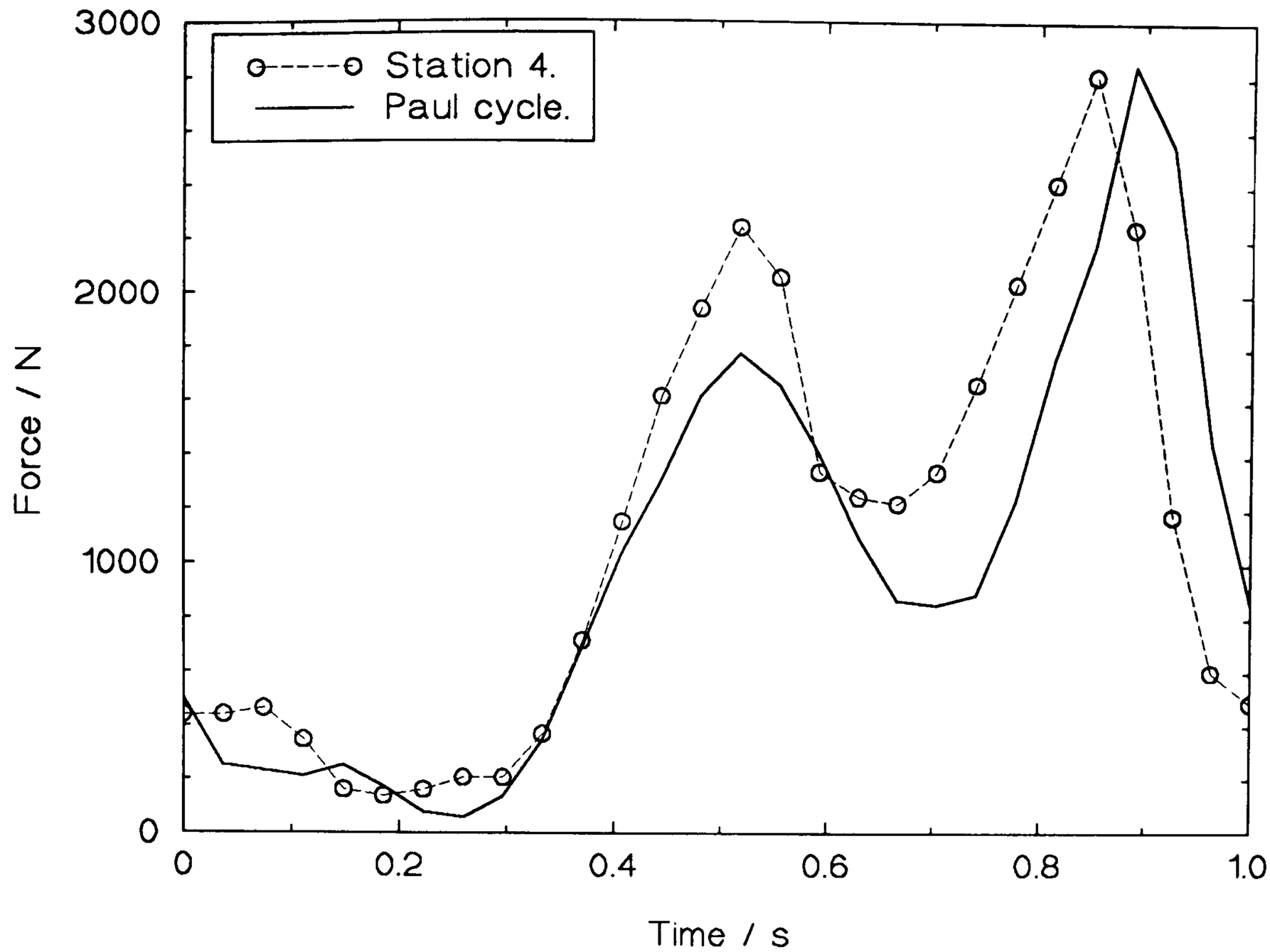


Figure 3.10 : Load simulation on Station 4.

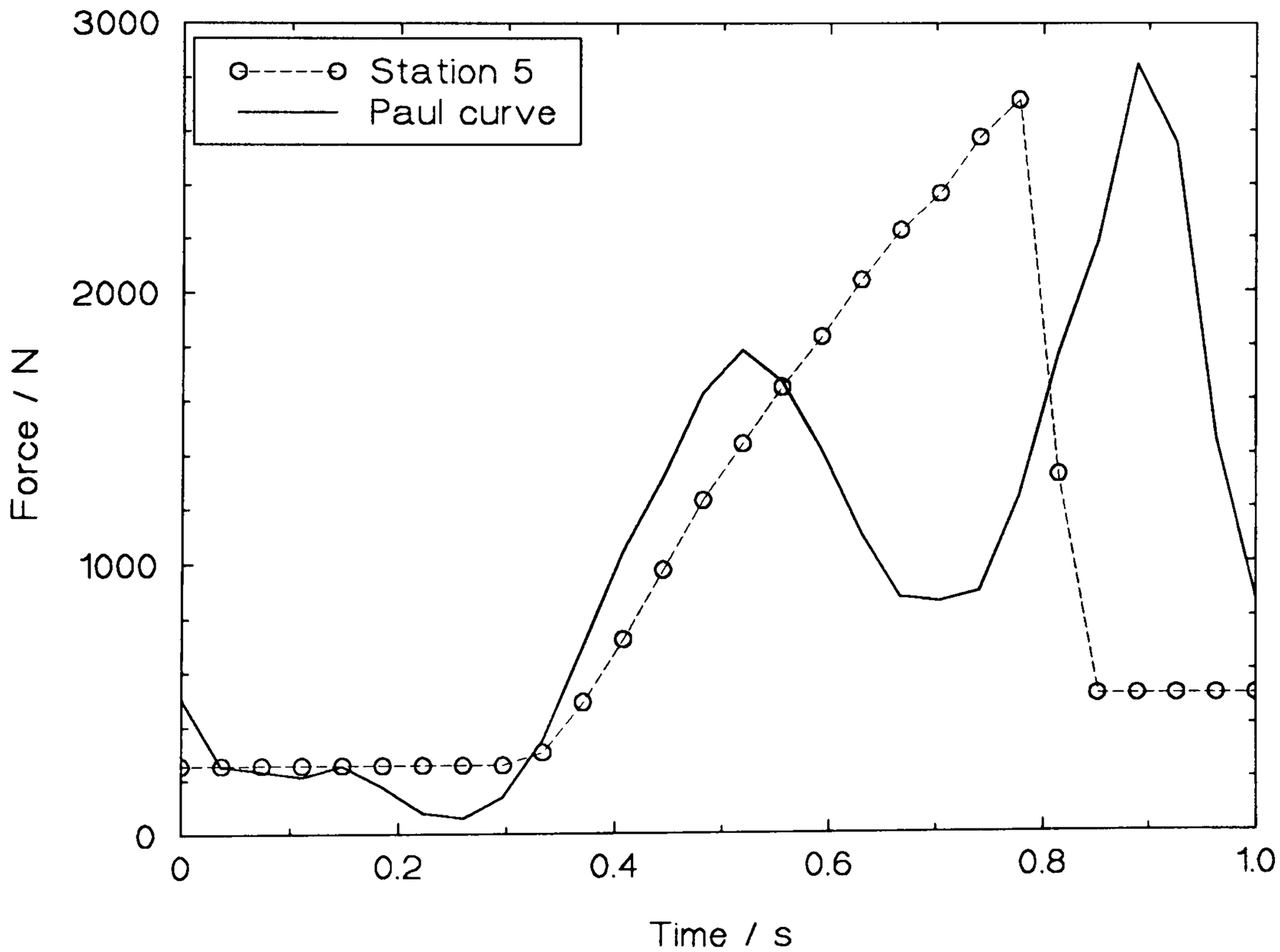


Figure 3.11 : Load simulation on Station 5.

The AB Automation simulator featured several safeguards to protect the prostheses under test should a fault occur. These safeguards included limit-switches on the extremes of motion on the internal/external rotation axis, and on one extreme of the flexion/extension axis. A further limit switch was therefore added to the flexion/extension axis to complete the motion safety system. The software was also programmed to stop the test if a fault were detected with lubricant level, lubricant flow, or low air pressure. Additional electrical safeguards to these were implemented on the machine to safeguard both the prostheses in the event of a machine failure, and the simulator from further damage as a result of the original failure. For example, a leak in the lubrication system was detected by a lubricant level sensor in the heated lubricant bath. This initiated the software to stop the wear test and display an error message. However, the electrical heater in the bath and peristaltic lubricant pump were not switched off at this point, and further loss of lubricant could have resulted in a fire if the exposed heating element had come into contact with the plastic lubricant storage bath. Therefore, an extra level sensor was added to cut the power to both the lubricant heater and the peristaltic lubricant pump to prevent consequent damage. The drive shaft, lever arm and link arm assembly of the flexion/extension axis were redesigned and manufactured to incorporate more substantial keyways, bearings and link pins. This was completed prior to the validation exercise due to several failures of these components during commissioning. The simulator control electronics were prone to overheating, but ducting within the cabinet and an additional cooling fan eliminated this problem.

It was necessary to establish protocols prior to the validation exercise to ensure consistent simulator performance and test methodology. Protocols had been established from earlier work and this was assessed and modified as necessary. A protocol existed for setting the femoral head and acetabular cup positions in each station. However, examination of the technique showed it to be fundamentally flawed by allowing the femoral head position to move out of alignment with the centre of rotation of the simulator stations. The revised procedure given in Appendix B ensured the femoral component was aligned with the centre of rotation, as well as allowing the pneumatic actuator to operate at part-stroke to reduce dead volume in the pneumatic system. Further protocols were established, including calibration checks on simulator

motion and loading, and the frequency with which the calibration checks should be made. Motion calibration was checked by examining the encoder output. Load calibration involved calibrating each station using a load cell and recording the loading cycle, as well as recording the output from the pneumatic proportional valve pressure transducer. The output from the pressure transducer was then monitored and compared with the calibrated recording to check loading performance on a regular basis. The tubes on the peristaltic pump system tended to fail which loosened the pump rotor and rollers leading to pump motor failure due to wear. A maintenance schedule was implemented to prevent unplanned stoppages caused by the pump which included replacement of the peristaltic tubing, checks on rotor and roller assembly, and regular cleaning of the motor. Ultimately, failure of the peristaltic pump instigated the redesign of the AB Automation simulator.

3.2 The Mk.I Durham hip joint simulator

The need to modify the AB Automation simulator to allow the use of bovine serum, combined with poor loading performance and unreliability, led to development of the Mk.I Durham hip joint simulator. This simulator (figure 3.12) maintained the five articulating stations driven by the Harmonic Drive d.c. stepper motors and the physiological motion cycles. The pressurised, recirculating, heated lubricant system of the AB simulator was replaced with a new joint cell design. A dynamically loaded, stationary creep station was added to the simulator, and the loading system was redesigned.

Figure 3.12 : The Mk.I Durham hip joint simulator.

The new cell design, as shown schematically in figure 3.13, required only 520ml of fluid to fill each separate cell. This allowed the economic use of bovine serum as a lubricant and prevented contamination of one cell from another as was possible with the previous recirculating design. Air was expelled from the joint space by inverting the assembled cell prior to insertion into the simulator. This was not possible with the previous design. The acetabular component was also mounted directly into a polyethylene holder and clamped by a stainless steel ring. This removed the necessity for cement in the cell and thus reduced the possibility of third body contamination. It also improved the accuracy of the gravimetric wear measurements. However, cemented and other types of fixation were still feasible with the new design if required. The number of parts that came into contact with the lubricant was significantly reduced, which allowed simple thorough cleaning of each cell and reduced the risk of lubricant leaks.

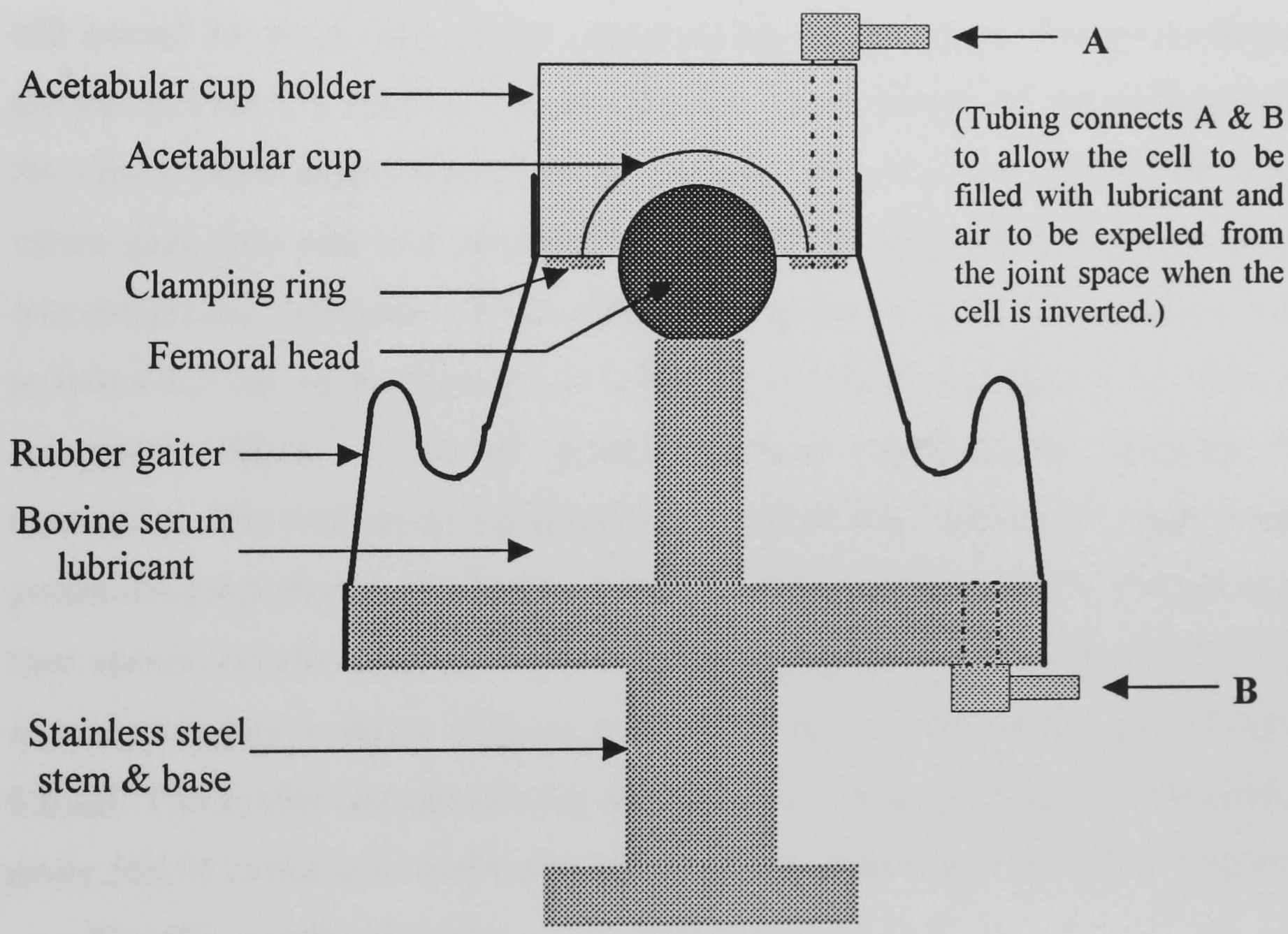


Figure 3.13 - Schematic view of the joint cell.

Most of the components used in the drive system on each axis were redesigned. The link pins were increased in diameter and stress raising features such as undercuts and steps in diameter were eliminated where possible. The drive bars, keys and keyways were also all increased in size. Many of the roller bearings in the AB Automation drive system were prone to failure probably because they were only reciprocating through a small arc and receiving high forces at the same point repeatedly within this motion. These bearings were replaced with phosphor-bronze plain bearings. Grease nipples, feed holes and grooves in the bearing surface ensured good distribution of grease to the bearing surface. A strict maintenance schedule was observed during testing including twice weekly greasing of all plain bearings. The simulator was serviced between wear tests which included disassembly, cleaning and regreasing of the gearboxes and all bearings. No bearing failures were subsequently observed.

The pneumatic loading system on the AB Automation design featured one control valve for each actuator. Therefore, despite regular calibration of the valves, potential still existed for the loading of one station to vary from another. The performance of the valves from one cycle to the next was also inconsistent, and the performance of the valves would rapidly decline as they became dirty with use. Finally, the original valves gave their optimum performance at 11 bar which could only be provided by one compressor within the School of Engineering. By reducing the working pressure to below 8.5 bar, more options were available to provide a supply in the event of a compressor failure. Trials of several different manufacturers products were undertaken. The final design pneumatically amplifies the output of a single Norgren pneumatic proportional valve using a SMC pneumatic booster valve. The pressure is then applied equally to all six stations through a manifold. The loading profile of an individual station is shown in figure 3.14 which was achieved at a supply pressure of 8.0 bar. This profile was identical for all stations. Loading performance was measured every 500,00 cycles and recalibration of the proportional valve was never required in over 20 million cycles of testing.

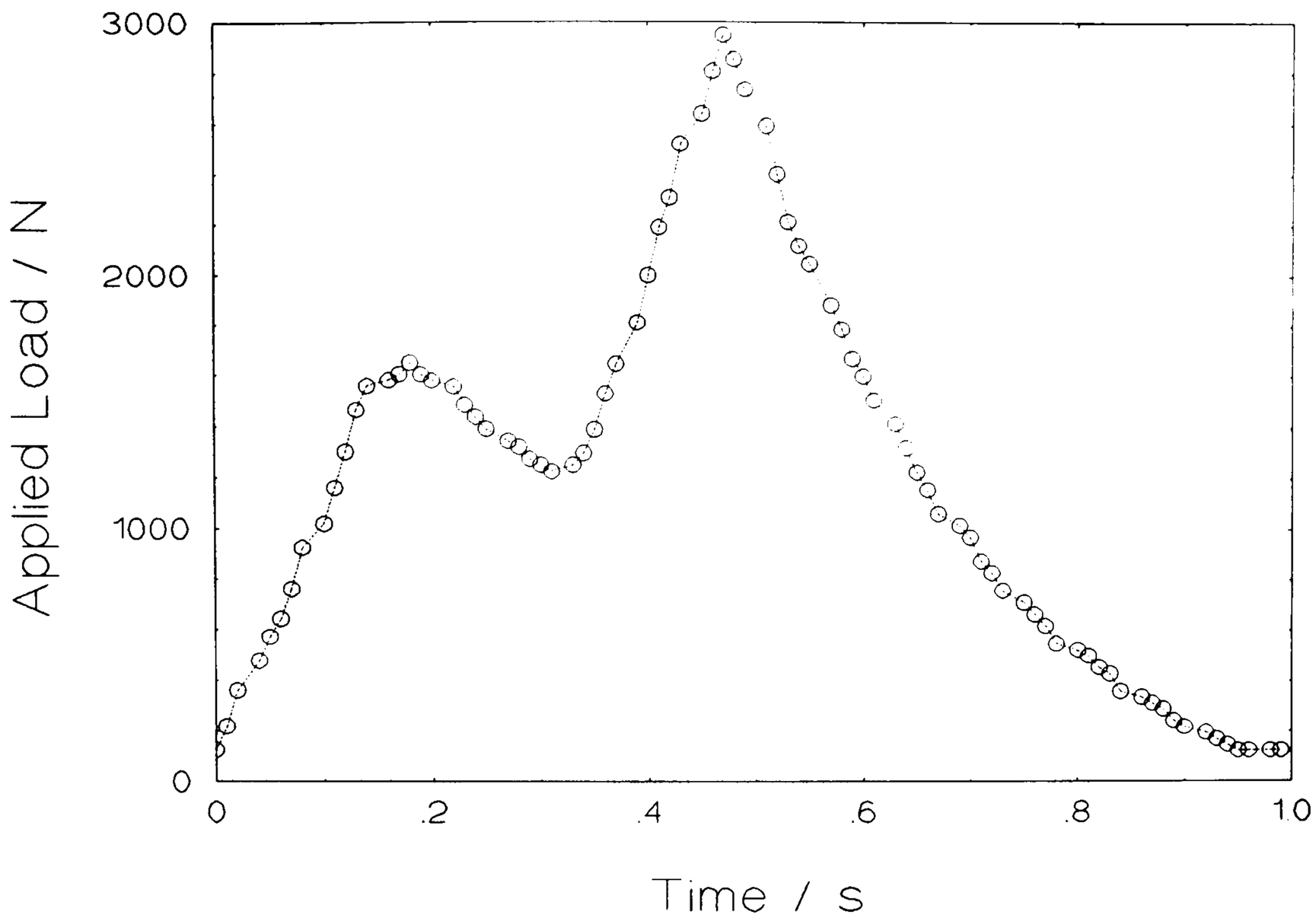


Figure 3.14 : Physiological loading cycle.

3.3 The Mk.II Durham hip joint simulator

The Mk.II Durham hip joint simulator shown in figure 3.15 has five articulating stations and a creep station of similar design to the previous simulator. However, the drive system to the long drive bars connecting each articulating station on the two axes was fundamentally different and the control system for the pneumatic loading system was also a completely new design.

Figure 3.15 : The Mk.II Durham hip joint simulator

An a.c. motor and gearbox drove an output shaft at 1 Hz on which a timing belt pulley and crank arrangement was mounted. The crank arrangement drove the flexion/extension drive bar directly and oscillated the femoral components with approximate sinusoidal motion through +30° to -15° in the flexion/extension plane. The timing belt pulley allowed the drive to pass through a timing belt to a similar pulley mounted on a shaft parallel to, but above the motor and gearbox output shaft. On the end of this shaft was another crank arrangement which directly drove the internal/external rotation drive bar. This caused the acetabular components to be oscillated with approximate sinusoidal motion in the internal/external rotation plane. The magnitude of the motion in this axis was initially ±10° to allow comparison with other studies (Barbour *et al*, 1999a,b), then reduced to a physiological magnitude of ±5° (Johnston and Smidt, 1969, Gore, 1980). The timing belt and slots on the internal/external rotation crank fastenings allowed a phase difference of 90° between the two motion cycles (see figure 3.16) to be accurately set.

On the centre of the top shaft, a slotted disc was used to activate three optoswitches for controlling the loading cycle. Rotating the slotted disc position relative to the internal/external rotation crank position on the top shaft allowed the loading cycle to be synchronised with the motion cycles. The optoswitches controlled a Norgren pneumatic proportional valve via a Programmable Interface Controller (PIC 16F84) and applied the loading cycle shown in figure 3.17. This loading cycle was derived from work on physiological motion with simplified loading discussed later in this thesis (Smith and Unsworth, 1999c,d). The output from the Norgren proportional valve was amplified pneumatically using a SMC booster valve. A manifold then supplied pressure equally to a Hoerbiger pneumatic actuator in each of the six stations.

A non-contacting Hall effect counter logged rotations of the top shaft and consequently numbers of internal/external rotation cycles. A similar counter was used to count cycles of the flexion/extension axis. In the event of a drive failure on one of the axes, the number of cycles elapsed until the fault had been discovered could also be identified.

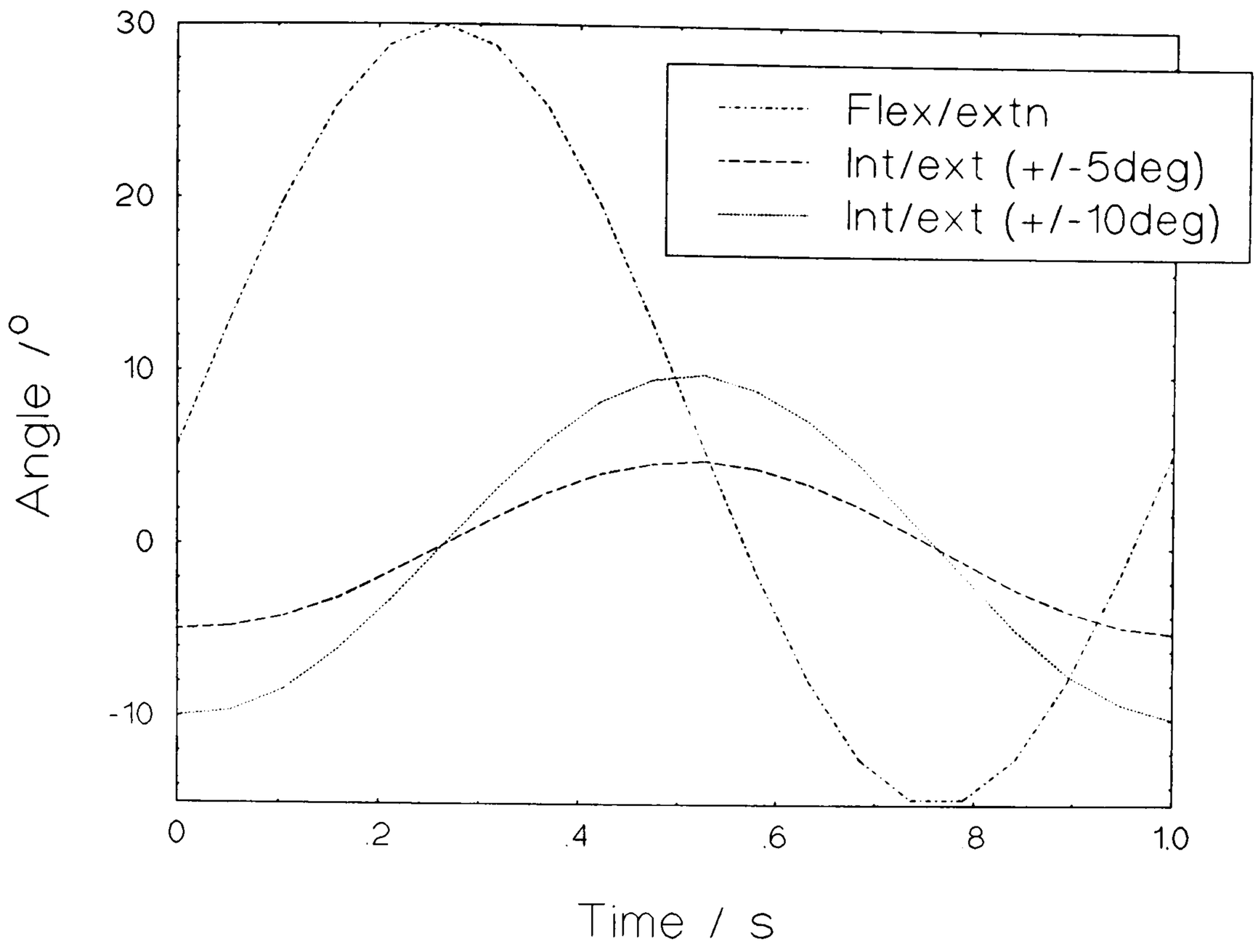


Figure 3.16 : The motion cycles used on the Mk.II Durham simulator.

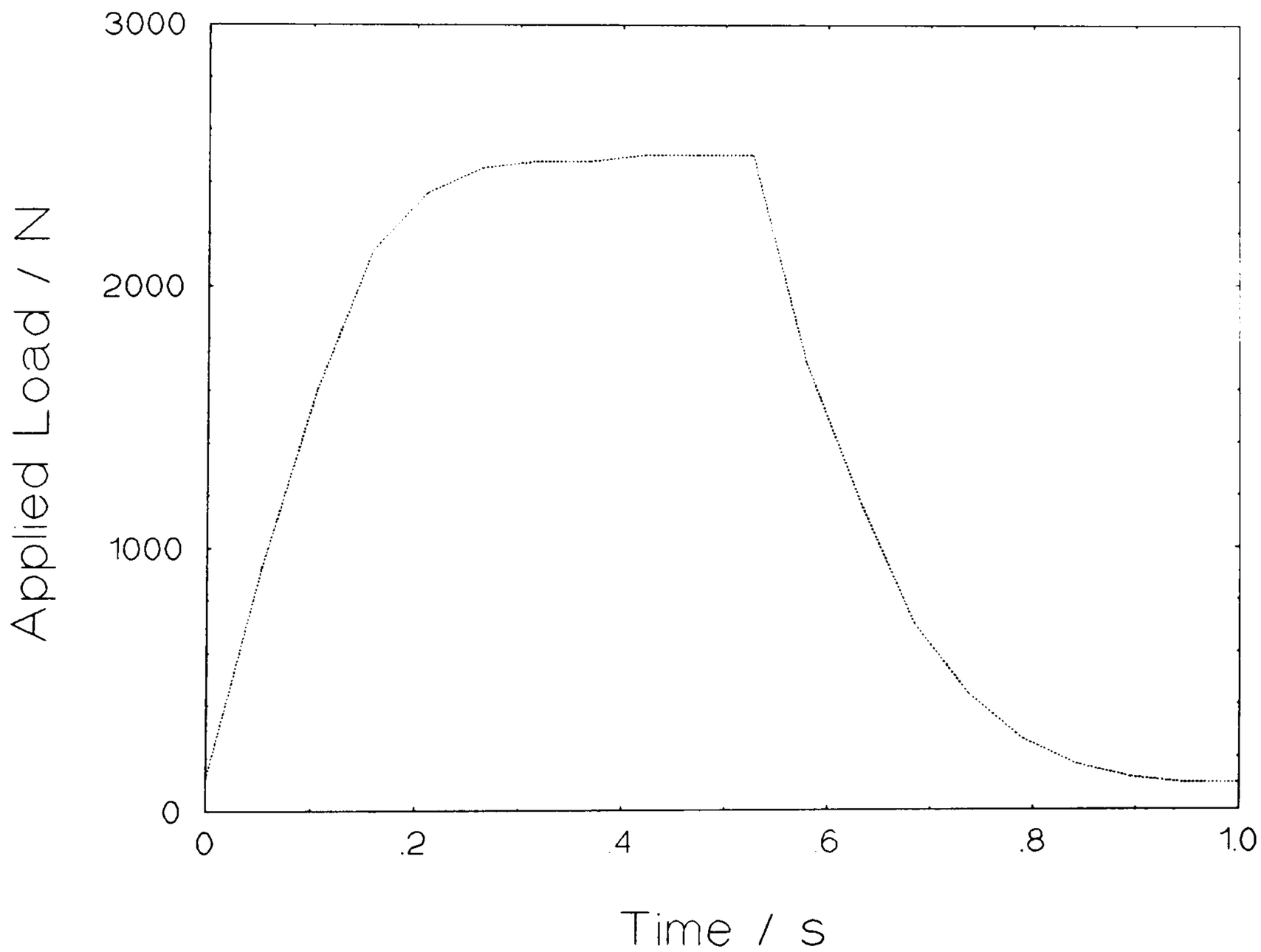


Figure 3.17 : The loading cycle applied on the Mk.II Durham simulator.

3.4 The Mk.II Durham hip function friction simulator

Friction experiments were undertaken on the Mk.II Durham hip function friction simulator (Hall *et al*, 1994, Burgess, 1996) as shown in figure 3.18. The simulator consisted of a fixed main frame with an upper oscillating frame to provide the motion cycle. Control of the simulator was by a Motorola 68020-based microcomputer via a PC.

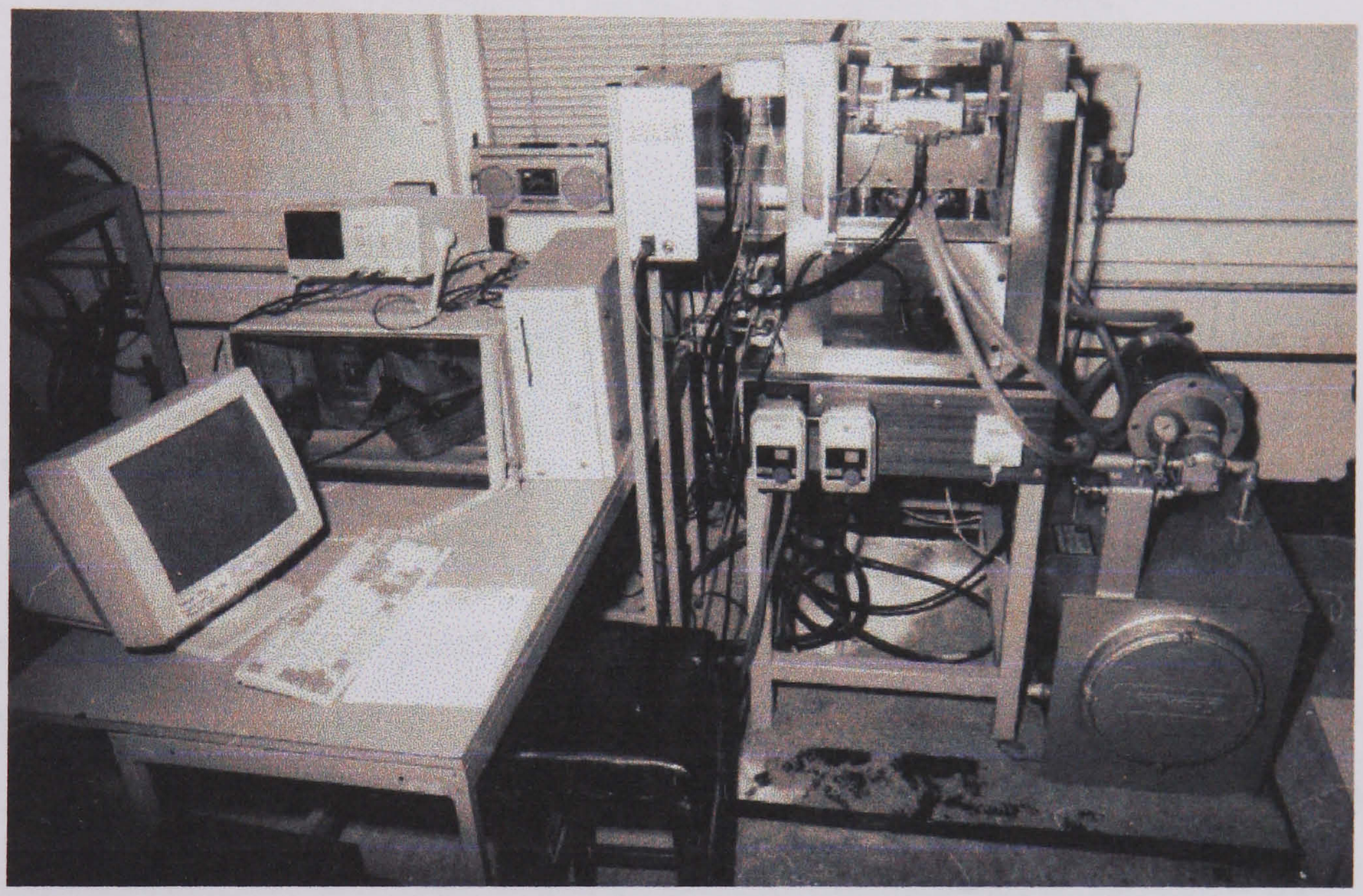


Figure 3.18 : The Mk. II Durham hip function friction simulator.

The prostheses were mounted anatomically inverted with the femoral component mounted in the upper oscillating frame and the acetabular component mounted below in a friction measuring carriage. The friction measuring carriage was mounted on externally pressurised bearings to provide both a 'self-centering' mechanism and a low friction axis about which the friction measuring carriage could rotate. The coefficient of friction of these bearings was at least an order of magnitude lower than that found in the measurement of the prostheses and enabled the frictional torque of a joint to be measured without undue influence from the supporting system. Rotation caused by frictional torque developed in the prostheses was resisted by a Kistler piezoelectric force transducer calibrated to measure frictional torque. Figure 3.19 is a

view of the transducer and the friction carriage containing an inverted prostheses with the femoral head above the acetabular cup.

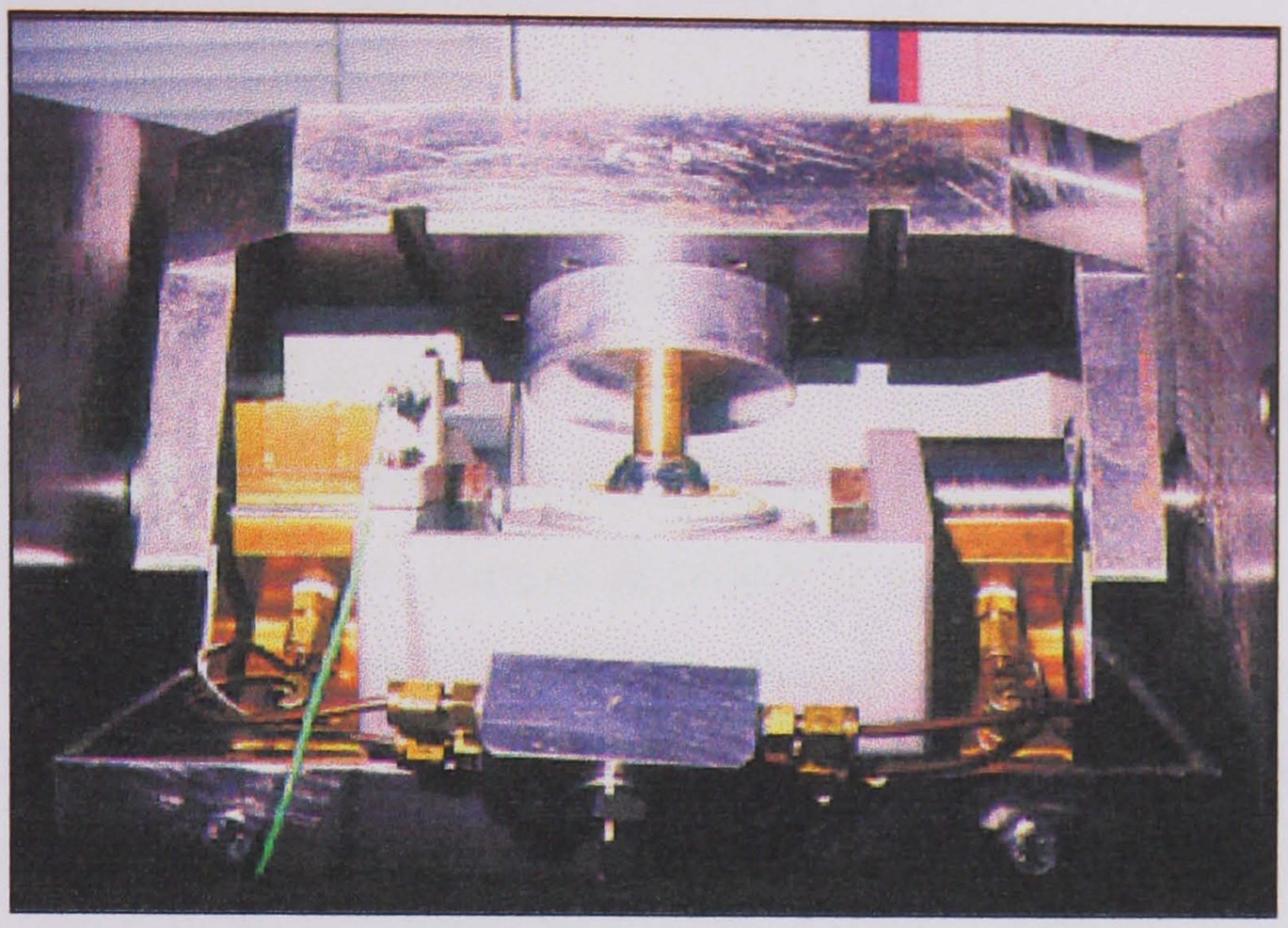


Figure 3.19 : View of the piezoelectric force transducer and friction carriage carrying an inverted prosthesis.

The vertical load was applied to the low friction bearings using a servo-hydraulic system with closed loop feedback control provided by four miniature load cells to measure the applied load. The applied loading cycle (English and Kilvington, 1979) had a minimum of 100N and a maximum of 2000N load, as shown in figure 4.1. Near sinusoidal motion was imposed on the femoral component in the flexion/extension plane with a nominal amplitude of ±25°. The cycle frequency was 0.833 Hz giving a cycle duration of 1.2 seconds during which load, frictional torque and angular displacement were measured 128 times each.

Chapter 4. Materials & Methods

4.1 AB Automation hip simulator validation test

Having commissioned the AB Automation simulator so that it operated at 1Hz, a validation exercise was undertaken. The objective of the test was to assess reliability over extended periods of time, and to demonstrate wear rates comparable to other *in vitro* wear tests conducted in water and below those of *ex vivo* wear studies.

The validation test was conducted in recirculating, distilled water at 37°C for 4.8 million cycles, using three UHMWPE (annealed GUR415, non-irradiated) and two PTFE (Grade FP307985, non-irradiated) acetabular cups articulating against 22 mm diameter CoCrMo femoral heads. UHMWPE and PTFE soak control cups were maintained in the lubricant bath and measurements were taken every half a million cycles.

The gravimetric wear measurement technique employed in this wear test differed from the protocol used in all the other wear tests and is given in Appendix C.I. A different protocol was used as the acetabular cups had to be cemented into the cup holders using PMMA bone cement. The consequences of using cement were that acetone could no longer be used in the cleaning protocol as it reacts with bone cement, and the porosity of the cement required drying the cups overnight prior to measurement. The true mass loss of a worn cup was obtained by subtracting the mass gain of the soak control due to moisture absorption, from the measured mass of the worn cup. The result was the true mass loss which was plotted against the number of cycles of the wear test. A straight line was then fitted to the curve using the method of least squares, to give the rate of mass loss. Penetration rate was calculated from the mass loss rate by coverting the wear rates in $mg/10^6$ cycles to $mm^3/10^6$ cycles by dividing by the density of the polymer (PE=2160 kg/m^3, UHMWPE=930 kg/m^3) and assuming the femoral head had bored a cylinder into the acetabular cup.

In addition to the gravimetric method, replicas of the bearing surface were also taken so that penetration depth rate was assessed using a shadowgraph technique (Hall *et al.* 1995).

4.2 Mk.I and Mk.II Durham hip simulator wear testing materials and methods

Standard materials and methods were used in all the wear tests on the Mk.I and Mk.II Durham hip simulators unless specified otherwise.

The prostheses used in the wear tests were 28mm diameter Howmedica products. The femoral heads were either zirconia or CoCrMo and all the acetabular cups came from the same batch at manufacture and sterilization. (Zirconia femoral heads Ref: 4653-40, CoCrMo femoral heads Ref 4653-01, UHMWPE acetabular cups Ref 4840-2856 Lot T241633, Sterilised May 1995 Lot 55301). Prior to wear testing the UHMWPE cups were conditioned in Ringers solution at 37°C for at least thirty days. The tests were conducted in a lubricant of 25% newborn calf serum with 0.1% m/v sodium azide to retard bacterial growth. The bovine serum used in all the wear tests was from the same supplier and batch. (Harlan Sera-Lab Ltd., Batch 6030207). Temperature of the lubricant was recorded using a Pico Technology TC08 multi-channel temperature logger which monitored the temperature of eight Type K thermocouples. This allowed room temperature and the temperature of the soak control, creep control, and each of the five articulating stations to be monitored.

Wear measurement of the acetabular cups was by the gravimetric method outlined in section 4.3.1. Wear and surface topography measurements were analysed using the Stata 4.0 statistical analysis package (Statacorp, 1995). Normality of the data was tested by applying Shapiro-Wilk and Shapiro-Francia tests, and equality of means was tested using *t* tests when the distribution was normal. For non-normal distributions Wilcoxon rank-sum tests were used to examine the equality of medians, and Spearman's rank correlation tests applied to assess the significance of independence.

4.3 Gravimetric versus volumetric wear measurement

Two wear tests were conducted using the Mk.I Durham hip joint simulator to compare gravimetric with volumetric wear measurement. The wear tests were each of a duration of 5 million cycles. The first test had two articulating zirconia femoral heads, three articulating CoCrMo femoral heads, and a zirconia femoral head was used in the creep station. The second test had three articulating zirconia femoral heads, two articulating CoCrMo femoral heads, and a CoCrMo femoral head was used in the creep station. This allowed data to be gathered on five articulating zirconia and five CoCrMo femoral heads spread over two wear tests. Wear rates of the acetabular cups were measured using both gravimetric and volumetric techniques using a Mettler balance and Kemco co-ordinate measuring machine (CMM) by directly measuring the same acetabular cups using both methods. This allowed a comparison between gravimetric and volumetric measurement techniques.

4.3.1 Gravimetric technique

The gravimetric technique required the maintenance of a soak control to allow for water absorption in the cups due to the hydrophilic nature of UHMWPE. However, subsequent testing revealed that a loaded soak control was necessary and this was provided by the creep control. Gravimetric measurements were taken every 0.5 million cycles. All the cups were removed from the simulator, cleaned, dried and weighed using the protocol shown in appendix C.II. The true mass loss of a worn cup was obtained by subtracting the mass gain of the loaded soak (creep) control due to moisture absorption, from the measured mass of the worn cup. The result was the true mass loss which was plotted against the number of cycles of the wear test. A straight line was then fitted to different regions of the curve using the method of least squares, to give the rate of mass loss over that region. The wear rates in $mg/10^6$ cycles was converted to $mm^3/10^6$ cycles by dividing by the density of the polyethylene ($930\ kg/m^3$). This allowed a direct comparison to be made with the volumetric results.

4.3.2 Volumetric technique

Volumetric measurements were taken using a Kemco 400 Coordinate Measuring Machine (Derbyshire, 1994b) at the University of Leeds. The cups were allowed to relax and equilibrate for at least 48 hours in the temperature controlled environment of a metrology laboratory where the CMM was sited, before taking measurements. Measurements were taken at 0.5, 1.5, 4.0 and 5.0 million cycles for the first wear test. An initial measurement was taken before the second wear test began, followed by measurements at 0.5, 1.0, 2.0 and 5.0 million cycles during the second wear test. The creep station provided a control cup to measure the creep of the UHMWPE due to loading. A straight line was fitted to the data over different durations of the wear test using the method of least squares, to give the rate of volumetric change over that region.

4.3.3 Femoral head surface topography

The surface topography of each of the femoral heads was measured before and after wear testing using a Zygo NewView 100 non-contacting optical interference profilometer. (Detailed protocol given in Appendix A.I). Images were taken using 400 times magnification giving a coverage of 180μm by 135μm. The horizontal resolution was consequently 0.56μm/pixel and the vertical resolution was sub-nanometres. Prior to calculation of the surface parameters, the spherical form of the femoral head was removed mathematically. When measuring the new femoral heads, both before and after wear testing, 26 points on each head were measured with the points arranged on the pole and then on annuli at 5°, 10°, 15°, 20° and 25° around the pole. The mean value of each surface parameter was calculated from all 26 points for each head.

4.3.4 Friction measurement

Frictional changes with new and worn prosthetic components were investigated. Initially, new CoCrMo and zirconia femoral heads were articulated against a new acetabular cup and the friction measured. The same new femoral heads were then articulated against a worn acetabular cup and the friction measured. (The worn acetabular cup was taken from the first wear test having completed 5 million cycles. The new acetabular cup was the soak control sample from the same test.)

Worn CoCrMo and zirconia femoral heads (also obtained from the first simulator wear test having completed 5 million cycles) were then friction tested against the new acetabular cup. The last part of the study involved both the worn CoCrMo and zirconia femoral heads articulating against the worn acetabular cup.

For a given set of test conditions, two experimental runs were required in order to derive friction factor for the test conditions. The load was initially applied in one direction of femoral component motion and then in the reverse direction, as shown in figure 4.1, to eliminate any possible small alignment errors.

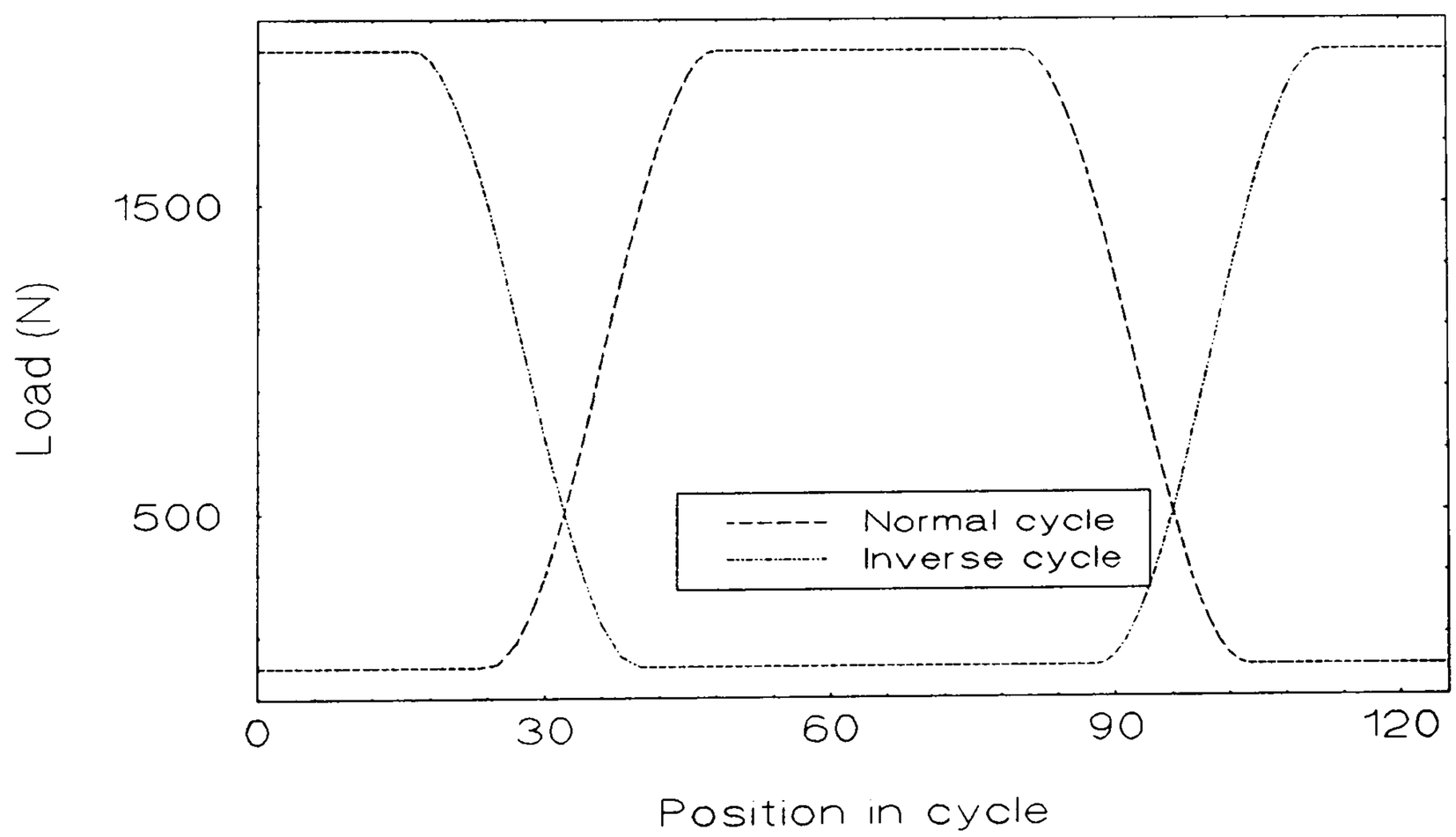


Figure 4.1 : Normal & inverse loading cycles to eliminate alignment errors.

Each experimental run produced a torque, T_f and T_b, as measured by the piezoelectric transducer, from which true frictional torque, T was calculated.

$$T = \frac{|T_b - T_f|}{2}$$

Analysis of the results took the form of a Stribeck curve by plotting friction factor, f, against Sommerfeld parameter, Z. Work by Unsworth (1978) and Gore *et al* (1981) encouraged the use of friction factor, f, rather than the coefficient of friction, μ, as strictly speaking the pressure distribution is unknown. However, one can assume that for a reasonable pressure distribution, friction factor is approximately equal to the coefficient of friction. Friction factor was therefore used to characterise the frictional properties of the prosthesis and is defined as torque divided by the product of radius of the femoral head and load across the prosthesis.

$$f = \frac{T}{r \, . \, L}$$

Sommerfeld parameter is the product of the entraining velocity, viscosity of the lubricant, and radius of the head, divided by the load across the prosthesis.

$$Z = \frac{v \, . \, r \, . \, \eta}{L}$$

Figure 4.2 is an idealised Stribeck curve. A falling trend, that is decreasing friction factor with increasing Sommerfeld parameter indicates a mixed lubrication regime in which load across the joint is carried partly by the lubricant and partly by contacting asperities. Contact of asperities is the primary reason for high friction in replacement hip joints. Full fluid film lubrication is indicated by a rising trend in the Stribeck curve, and at this point the load across the joint is supported entirely by the lubricant film. The rising trend is now indicating the rise in shear stress of the lubricant.

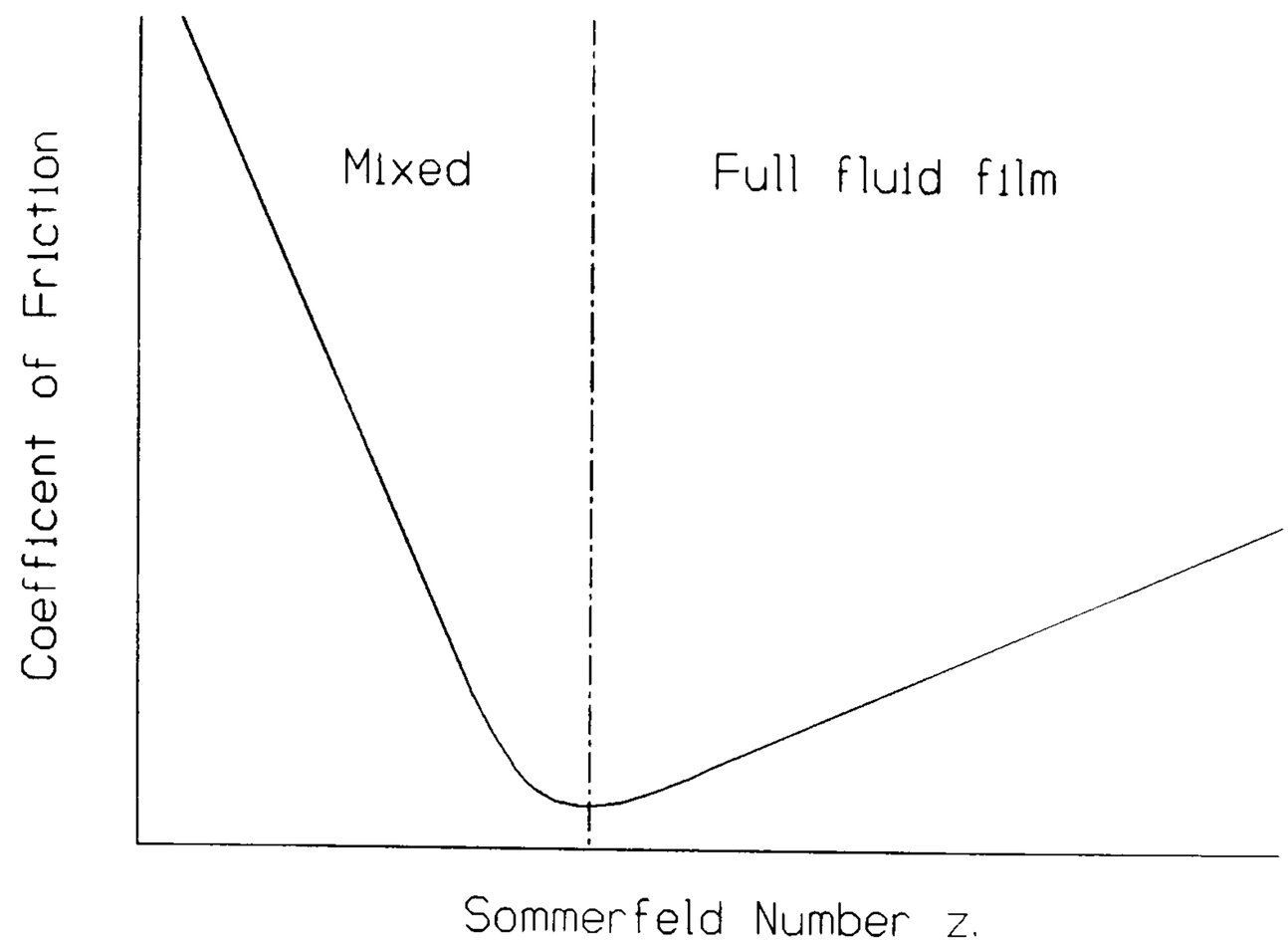


Figure 4.2 : Idealised Stribeck plot.

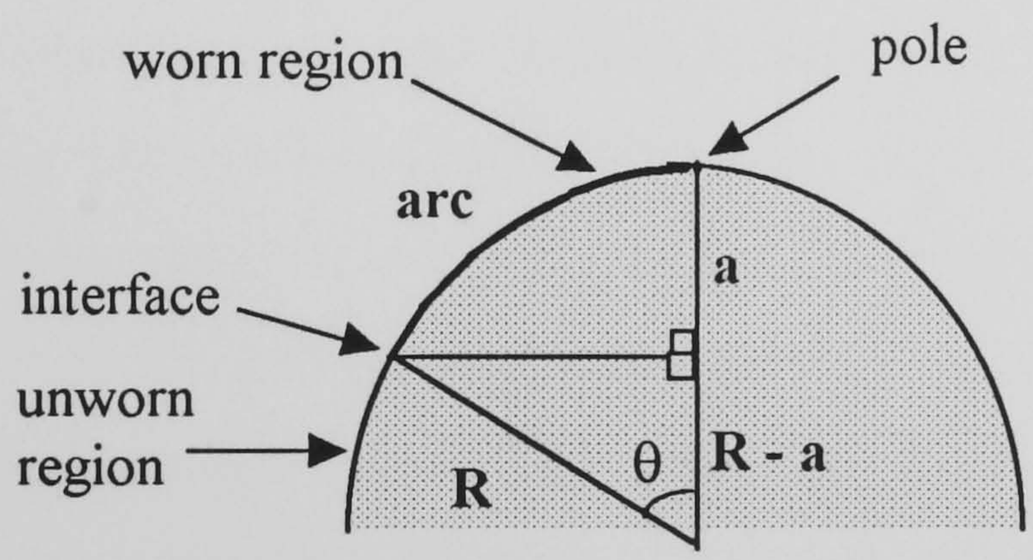
Water and aqueous solutions of carboxy-methyl-cellulose (CMC) were used as lubricants in the friction tests. For a given prosthetic component combination, load and entraining velocity, by changing the viscosity, a Stribeck plot could be produced. Carboxy-methyl-cellulose solutions have similar rheological properties to those of synovial fluid (Cooke *et al*, 1978). A Ferranti-Shirley cone-on-plate viscometer was used to measure a range of viscosities from 10^{-3} to 10^{-1} Pa s.

4.3.5 Area of worn acetabular region

The area of the worn acetabular region versus number of cycles was studied to see if the development of the worn region would relate to changes in wear rate of the UHMWPE acetabular during a wear test. Replicas of the acetabular cups were taken immediately following gravimetric measurements during the second wear test. Provil MCD (Bayer, UK) was used as the casting agent which is a polyvinylsiloxane used in dentistry. This material cures within a minute with 0.04% linear shrinkage and has been shown by Burgess (1996) to be acceptable for indirect CMM measurements of acetabular cups. The orientation of the cast was marked prior to removal from the acetabular cup. One acetabular cup was chosen at random (station one articulating

against a zirconia femoral head) and the replicas taken at a 0.5, 1.5, 2.0, 2.6, 3.1, 3.6, 4.2 and 5.0 million cycles were studied. The replicas were each placed on a graduated table and revolved through 360° in 22.5° increments. The interface between the original machining marks and worn region was clearly visible to the naked eye on the replicas. At each angular position as the cast was rotated, the height of the machining marks to worn region interface from the graduated table was measured using a vernier height gauge. The height at the pole of each cast was also recorded.

The vertical height from the pole to the interface between the worn and unworn regions was then calculated for each angular position. Cup radius then allowed the length of the arc from the pole of the cast to the interface between the worn and unworn regions to be calculated for each separate angular position. See figure 4.3.



a = pole height - interface height

R = cup radius

$\cos \theta = (R - a) / R$

arc = $R \times \theta$

Figure 4.3 : Schematic section through a replica to demonstrate how the arc length from the pole of the replica to the interface is calculated.

Having established the length of the arc at each angular position around the cast, the area of a triangle formed by a pair of arcs connected at the pole was calculated. Figure 4.4 represents the construction of a single triangle. The total area of the worn region was then calculated by summing the area of all the triangles. The total worn area was then plotted against number of cycles in order to assess changes in the size of the worn area with number of cycles.

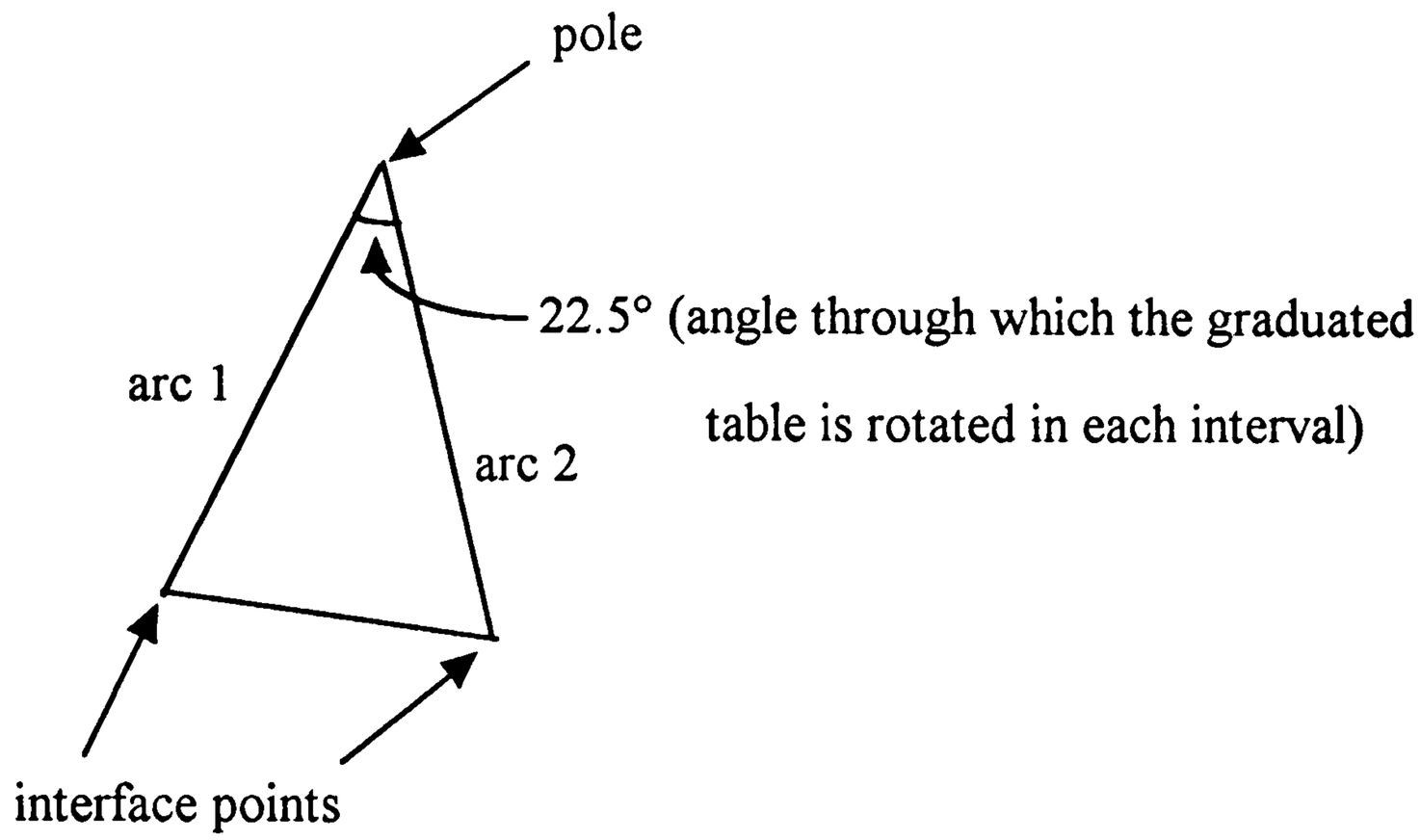


Figure 4.4 : Diagram showing a triangle formed from two arcs meeting at the pole of the replica and joined together at the interfacial points with a line.

4.4 Simplified loading and motion

The effect of simplifying either loading or motion, on the wear of UHMWPE acetabular cups normally subjected to full physiological motion and loading was compared in these studies. The wear rates of the acetabular cups were measured and the surface topography of the worn acetabular cups studied to evaluate the validity of either simplified loading or motion.

4.4.1 Wear test with simplified loading

The second wear test of the gravimetric versus volumetric study was extended to 7.1 million cycles to investigate the effect of simplified loading on the wear of UHMWPE acetabular cups. The simplified loading wear test used only the gravimetric data for the three zirconia and two CoCrMo femoral heads used in the second wear test. Furthermore, only data from two million cycles was used due to the high wear rates of the acetabular cups from zero to two million cycles (discussed later).

Physiological motion was applied to the prostheses for the full 7.1 million cycles. By reprogramming the Harmonic Drive control unit, physiological or simplified loading was achieved as shown in figure 4.5. For the first 5 million cycles of the wear test physiological loading, approximating to that defined by Paul (1969), was applied across the prostheses. A simplified loading profile approximating to a square wave, was applied across the prostheses for the final 2.1 million cycles of the wear test.

4.4.2 Wear test with uni-axial motion

A simplified motion wear test was conducted for a duration of 5.0 million cycles using the Mk.I Durham hip joint simulator. Physiological loading was applied across the prostheses but articulation was in the flexion/extension plane only by disconnecting the internal/external rotation drive bars. Two zirconia femoral heads were used in the articulating stations and a CoCrMo femoral head was used in the creep station. (The

three remaining stations were used for the explanted femoral head test described later.)

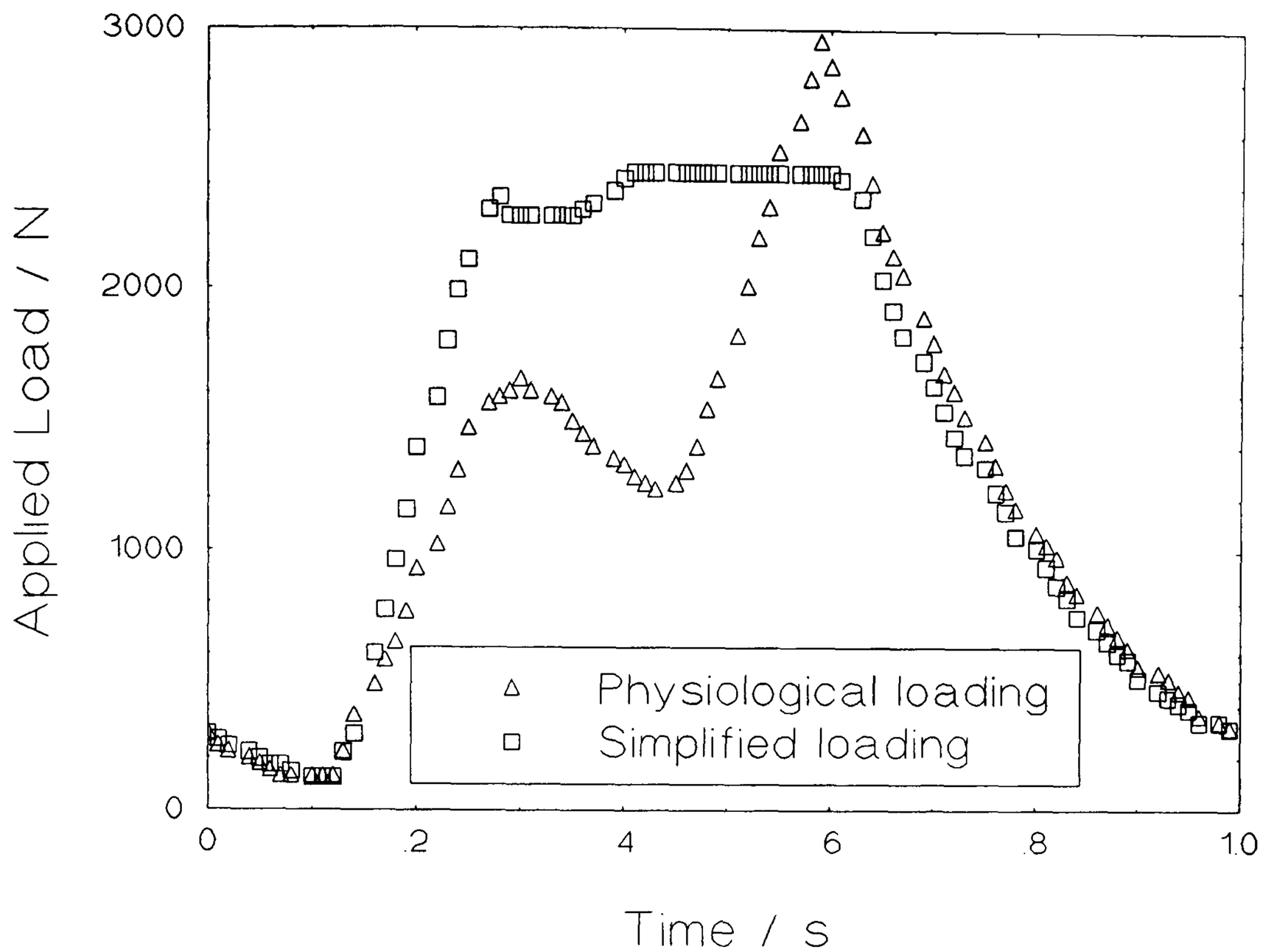


Figure 4.5 : Physiological and simplified 'square wave' loading wave forms.

4.4.3 Acetabular cup surface topography

Upon completion of the simplified motion and loading wear tests, the seven acetabular cups were cut into quarters to allow the surface topography to be examined in a number of ways. In addition to these cups, five cups that had been subjected to full physiological motion and load for five million cycles, three cups articulated against explanted heads in the simulator, and three 28mm diameter cementless explants were also examined.

Gross examination was followed by measurement using a Zygo 'New View 100' non-contacting optical profilometer. (Detailed protocol given in Appendix A.II). Six images were taken in the worn region and three in the unworn region at 10 times magnification giving a surface area coverage of 730 by 550 μm. Further examination

of the surfaces utilised a Zeiss Axiotech reflected light microscope fitted with differential interference contrast, and a JOEL JSM - IC848 scanning electron microscope (SEM).

4.5 Explanted femoral head wear test

4.5.1 Wear test

Three explanted femoral heads were wear tested in the Mk.I Durham hip joint simulator for 5 million cycles with full physiological motion and loading. (The two remaining articulating stations were used for the uni-axial motion study.) The three 28mm diameter explanted CoCrMo femoral heads used in the wear test were retrieved during revision surgery by Mr. Ian I.M. Pinder at the Freeman hospital, Newcastle-Upon-Tyne. The explanted joint and patient details are summarized in table 4.1. All three heads exhibited surgical damage from retrieval. However, in all cases the damage was sufficiently distant from the area of contact with the acetabular cup. The heads were articulated against new 28mm diameter UHMWPE acetabular cups and a new CoCrMo femoral head was used in the creep cell.

Case	Gender	Age at Primary / years	Reason for Primary	Mass / kg	Implant Duration / months	Joint Type
A	f	55	CDH	55	39	PCA, Howmedica
B	f	51	CDH	51	62	PCA, Howmedica
C	m	59	RA	59	16	Ultima, J & J

Table 4.1 : Patient and explanted joint type details.

4.5.2 Explanted femoral head surface topography

The surface topography of the femoral heads was measured before and after wear testing using a Zygo profilometer at 400 times magnification. (Detailed protocol given in Appendix A.III). When measuring the surface topography of the explanted heads 10 points were selected from the worn region followed by 4 points from the peripheral region. The median value of each surface parameter was calculated from the 10 points measured in the worn region.

4.6 The Mk.II Durham hip joint simulator validation exercise

4.6.1 Wear test

Five zirconia 28mm diameter femoral heads were articulated against UHMWPE acetabular cups for 5 million cycles. A CoCrMo femoral head was used in the creep station. The femoral components were oscillated with approximately sinusoidal motion through +30° to -15° in the flexion/extension plane. The acetabular components were oscillated with approximately sinusoidal motion through ±10° in the internal/external rotation for the first three million cycles of the wear test. From three to five million cycles the internal/external rotation was reduced to ±5°. The motion cycles are shown in figure 3.16 and were 90° out of phase. The loading cycle used throughout the wear test was the simplified loading cycle shown in figure 3.17. The surface topography of the femoral heads and acetabular cups were measured and assessed using the methods employed in Appendix A.I and A.II respectively.

The acetabular cups were the same type as used previously and also manufactured and sterlized in May 1995 but they were from a different batch (Lot 242677 as opposed to Lot 55301). Similarly, the lubricant was 25% newborn calf serum with 0.1% m/v sodium azide as used in the other wear test. The serum was obtained from the same supplier (Harlan Sera-Lab) but was from a later batch (No. 8030901) to the same specification.

4.6.2 Wear path analysis

A number of points on the femoral head were chosen and the wear paths followed by the points relative to the acetabular cup were analysed. Nineteen points per gait cycle were recorded by the motor encoders on the Mk.I Durham simulator and consequently the analysis per cycle was similarly for nineteen points. The analysis was performed for sinusoidal motion cycles applied to each axis on the Mk.II Durham simulator for both internal/external rotation magnitudes, and for the physiological motion cycles used on the Mk.I Durham simulator. The wear path of each point was

calculated from angular data using standard transformation matrices into Cartesian co-ordinates. The Cartesian co-ordinate system used aligned the anterior/posterior axis with the x-axis, the medial/lateral axis with the y-axis, and the superior/inferior axis with the z-axis. Abduction/adduction was set to zero due to the simulator designs, so flexion/extension and internal/external rotation about the hip were therefore generated by rotation about the y and z-axis respectively.

4.6.3 Femoral and acetabular cup surface topography

The surface topography of the zirconia heads was measured before and after wear testing using a Zygo non-contacting profilometer using the protocol used previously for new femoral heads in the gravimetric versus volumetric study. (See Appendix C.I). Following the wear test, the surface topography of the acetabular cup was examined as in section 4.4.3. Gross examination was followed by measurement using a Zygo non-contacting profilometer, (see Appendix C.II). Further examination of the surfaces utilised a Zeiss Axiotech reflected light microscope fitted with differential interference contrast, and a JOEL JSM - IC848 scanning electron microscope (SEM).

4.7 Cleaning & drying protocol

Seven UHMWPE (DePuy Charnley, Ref. 9651-22-047) cups were used as the specimens in the experiments. UHMWPE is mildly hydrophilic in nature and with time will absorb water from solution. During the first thirty days of exposure to water, moisture absorption is at its highest (Clarke *et al*, 1985) so the specimens were conditioned in Ringers solution for thirty days prior to the start of the test. All gravimetric measurements were made on a Mettler AE200 balance sensitive to 0.1mg. Non-dusted latex gloves were worn during handling, and clean, dry compressed air was used to remove any dust from the specimens. All experiments involved an initial cleaning protocol of washing the cups in tap water to remove bulk contaminants followed by cleaning them in a 1% Neutracon solution for 30 mins in an ultrasonic bath at 40°C. The cups were then rinsed in tap water, followed by distilled water, before absorbing most of the surface water from them with lint-free tissue.

The first series of experiments investigated the effect of then immersing the cups in a solvent for a measured time period. This was followed by absorbing most of the solvent from the cups with lint-free tissue, and air drying. The solvents chosen for the experiments were acetone, iso-proponol, methanol and ethanol, with cup immersion times of two, five, three and ten minutes respectively. The second series of experiments investigated the effect of drying the cups in air, in a laminar flow cabinet, and in a vacuum. For both series of experiments, measurements were taken periodically over three hours. The mean and standard deviation of mass change at each measurement was then plotted against time, assuming that at the final measurement the cups had equilibrated.

4.8 Wear debris analysis

A sample of distilled water lubricant containing PTFE and UHMWPE wear debris from the AB Automation validation exercise was stored for wear debris analysis. For all subsequent tests on the Mk. I and Mk II Durham hip joint simulators, samples of used bovine serum lubricant were stored from the soak controls and all articulating and creep stations. Unfortunately, only a single sample from the first wear test of the gravimetric versus volumetric measurement study has had the wear debris analysed to date. The sample was from a station in which a zirconia femoral head had articulated against a worn-in UHMWPE acetabular cup for approximately 0.5 million cycles. The serum was digested using the protocol in Appendix D devised by Tipper *et al* (1997). This work was undertaken by a colleague within the Centre for Biomedical Engineering at the University of Durham.

A Malvern Mastersizer laser diffraction particle analyser was used to measure the wear debris for both the sample from the AB Automation simulator validation exercise and the serum sample. The size and number of particles were measured and counted then compared with five retrieved tissue samples from three patients with THR's. A further comparison was made with a sample from a reciprocating pin-on-plate (POP) wear test of polyethylene against stainless steel measured using the same method. Background samples were required so that the analyser could compensate for the refractive index of the solution. The background sample for the PTFE and UHMWPE sample was distilled water obtained from the same source as that used as the lubricant. The background sample for the UHMWPE wear debris separated from serum, was sourced from the creep station sample taken at the same time and digested using the same protocol.

Chapter 5. Results

5.1 AB Automation simulator validation exercise

The mean acetabular cup wear rates for the PTFE and UHMWPE cups as determined by the gravimetric method were 236 and 11.5 mg/10^6 cycles respectively. Using the shadowgraph technique the mean penetration rate for the PTFE cups was 0.32 mm/10^6 cycles with 0.48 mm of penetration due to creep in the first million cycles. Similar mean penetration rate and creep for the UHMWPE cups were 0.04 mm/10^6 cycles and 0.09 mm. The individual results for all the cups are presented in table 5.1 for both measurement techniques.

The mass change of the PTFE cups and soak control cup are shown in figure 5.1 and for the UHMWPE cups and control in figure 5.2. The shadowgraph results are presented in Figures 5.3 and 5.4 for the PTFE and UHMWPE acetabular cups respectively. Straight lines were fitted to the data from one million cycles onwards to allow both the wear rate over the duration of the test, and the penetration due to creep in the first million cycles, to be calculated from the gradient and intercept of the line respectively.

		PTFE #1	PTFE #2	UHMWPE #1	UHMWPE #2	UHMWPE #3
Gravimetric Results	Mass Wear Rate (mg/10^6cycles)	104	368	9.72	5.35	19.5
	Penetration Rate (mm/10^6cycles)	0.12	0.44	0.027	0.015	0.054
Shadowgraph Results	Creep Component (mm)	0.421	0.540	0.113	0.124	0.027
	Penetration Rate (mm/10^6cycles)	0.148	0.490	0.045	0.026	0.051

Table 5.1 Results from the AB Automation simulator validation exercise.

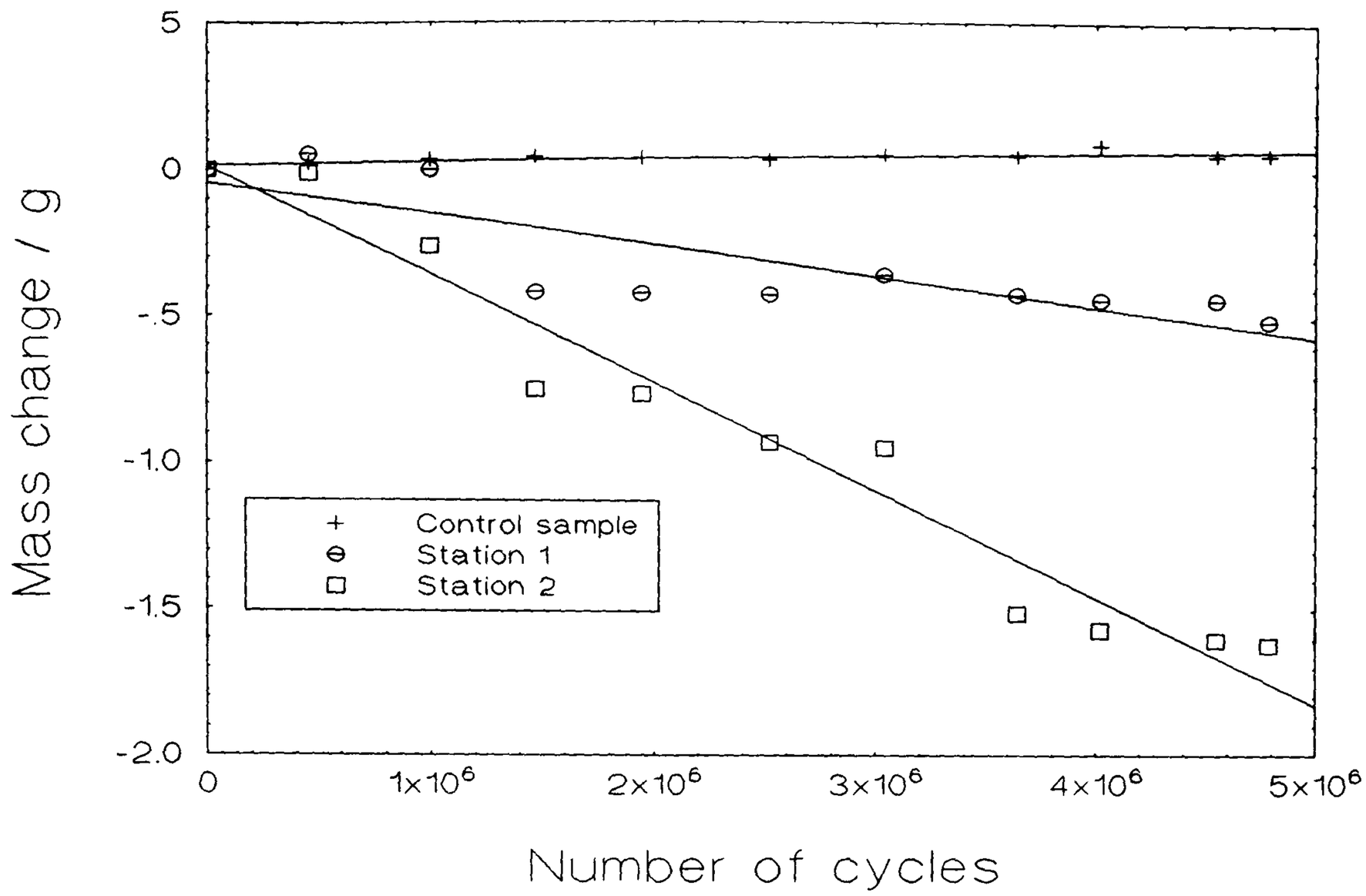


Figure 5.1 PTFE acetabular cups mass change with test duration.

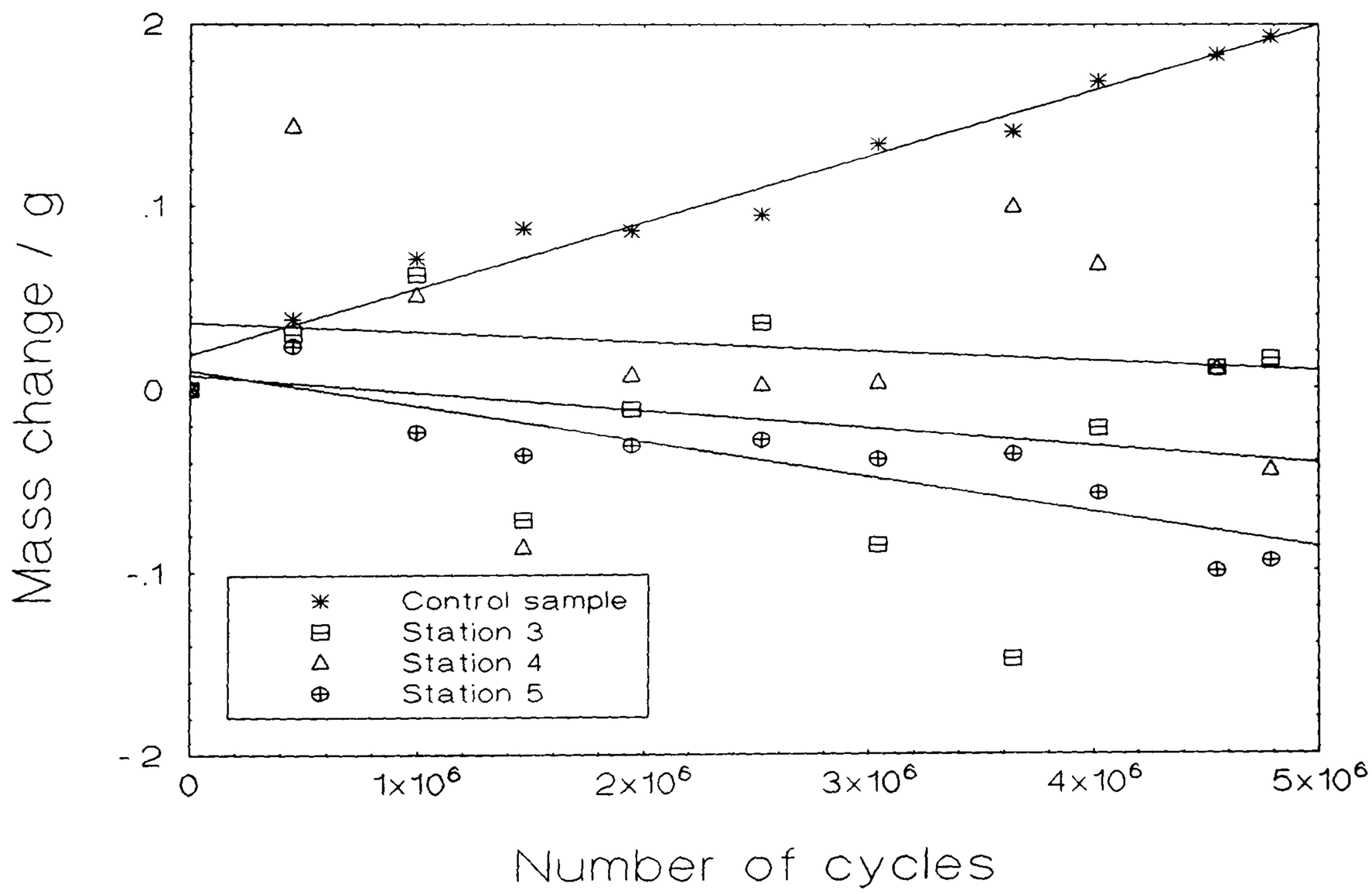


Figure 5.2 UHMWPE acetabular cups mass change with test duration.

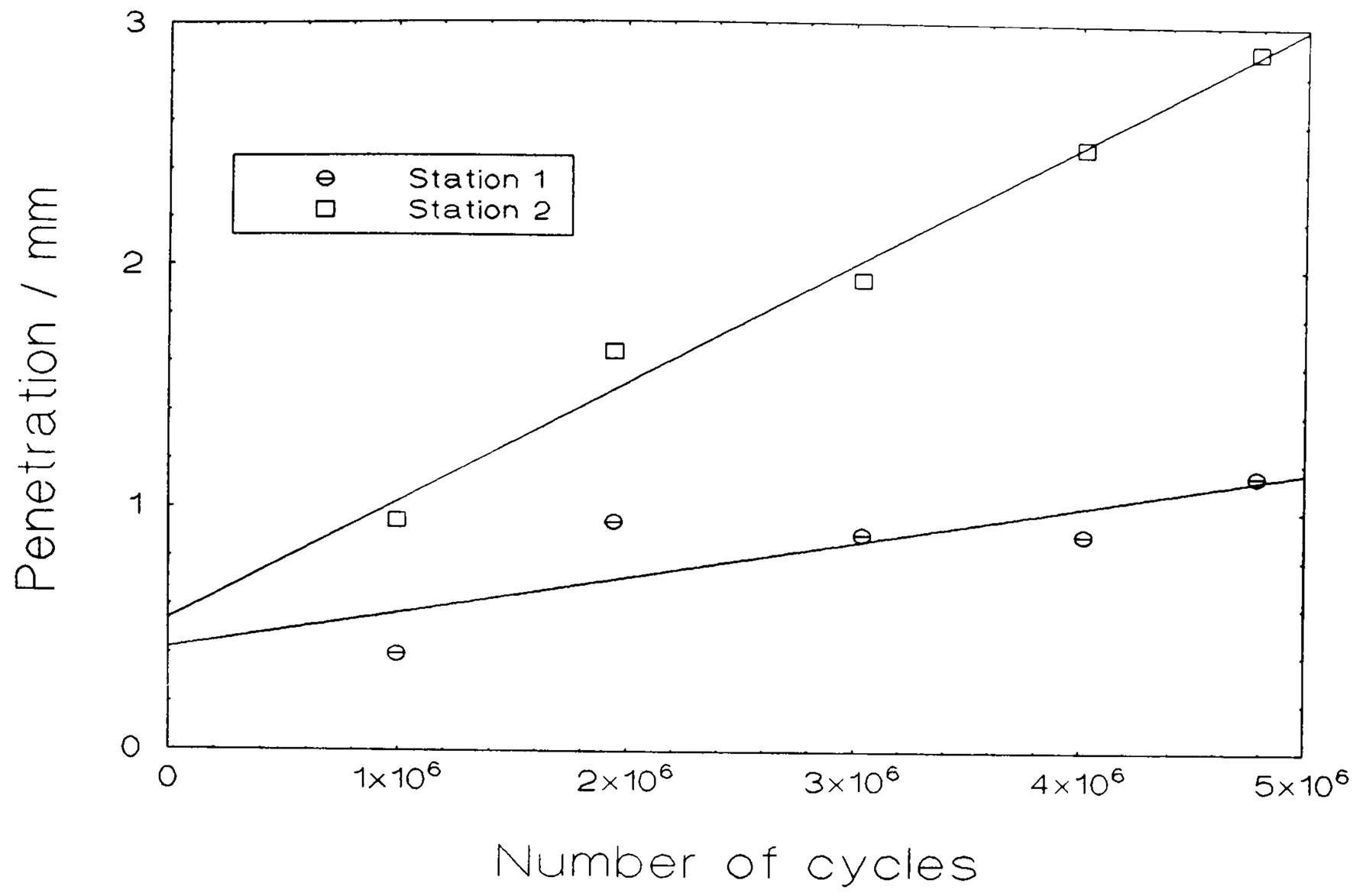


Figure 5.3 PTFE acetabular cups shadowgraph results.

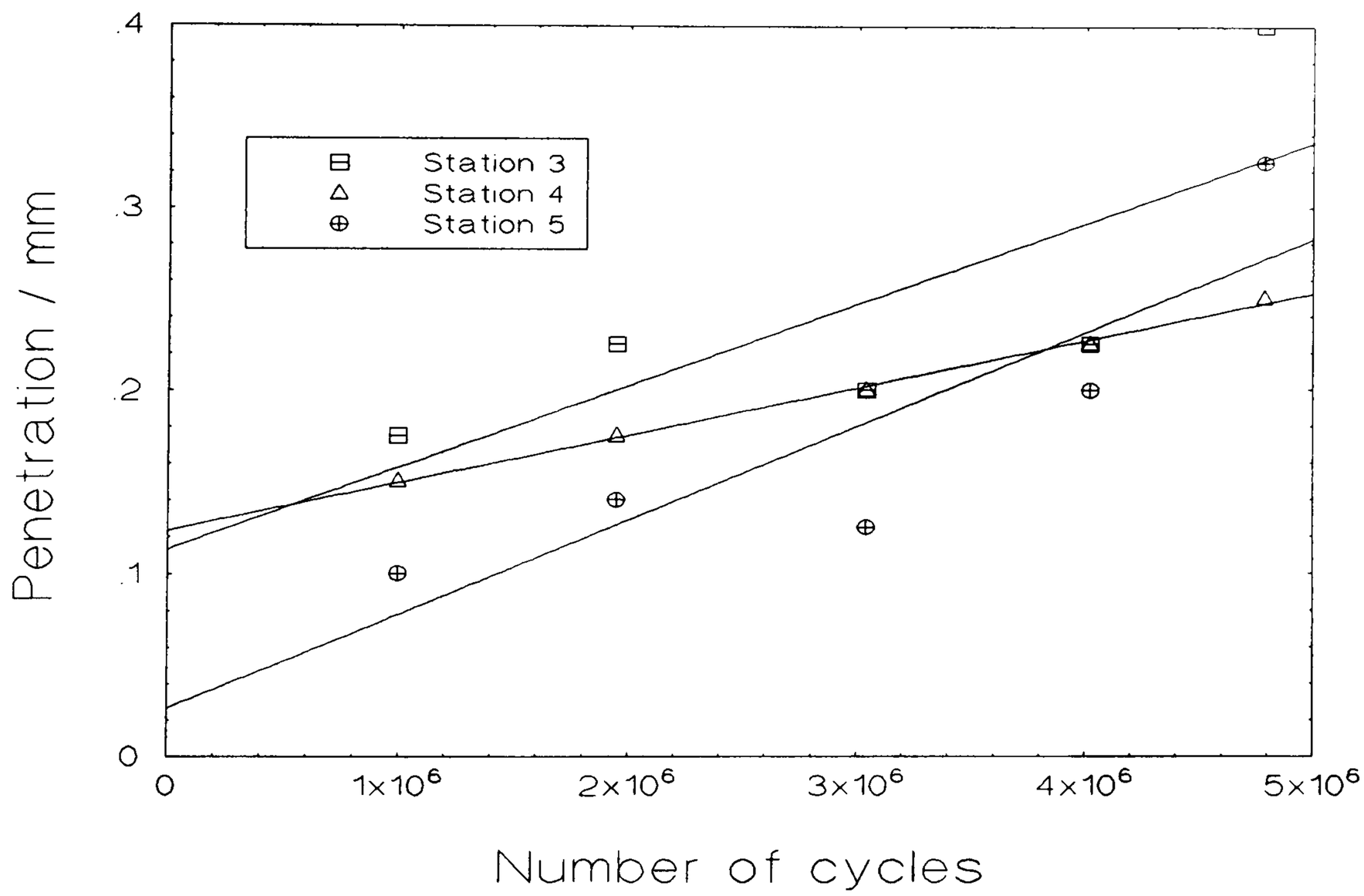


Figure 5.4 UHMWPE acetabular cups shadowgraph results.

5.2 Gravimetric versus volumetric wear measurement

5.2.1 Gravimetric measurements

The mass gain due to water absorption was greater for the dynamically loaded acetabular cups in the creep cell than for the unloaded soak controls in both wear tests. The mass gain for the creep and soak controls from the first wear test are shown in figure 5.5. Mass gain due to water absorption was therefore compensated for using the creep control sample for each wear test.

Figure 5.6 is a plot of the true mass loss of an acetabular cup over the duration of a wear test (wear test 1, station 5, against a CoCrMo femoral). Two lines have been fitted to the data by the method of least squares from zero to two million cycles and from two million to five million cycles duration. It can be clearly observed that from zero to two million cycles of the wear test the wear rate is higher than for the remaining duration of the wear test. Subsequent analysis of the wear data confirmed that all ten cups had a high initial linear wear rate from zero to two million cycles and a lower linear wear rate from two million to five million cycles. The wear rates for the two phases were significantly different ($p=0.0012$) for all the cups.

Figure 5.7 presents the mean wear rates and standard errors for cups articulating against zirconia and CoCrMo femoral heads for the initial wear phase up to 2 million cycles, the second phase from 2 to 5 million cycles, and an overall average wear rate covering the full duration of the test. The wear rates for cups articulating against zirconia heads were lower than those articulating against CoCrMo femoral heads for the full duration of the wear test ($p=0.096$).

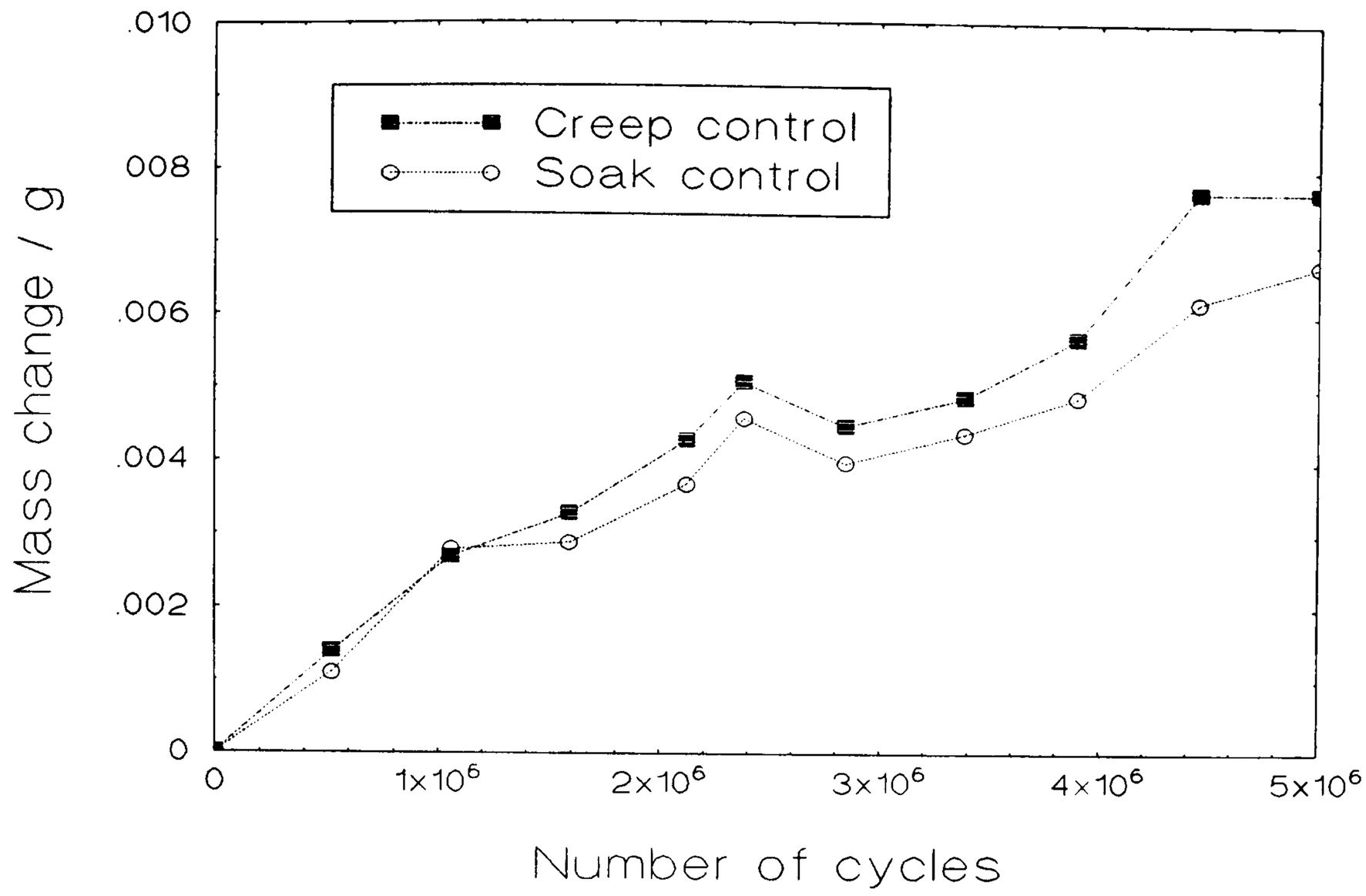


Figure 5.5 Mass gain due to water absorption for the soak and creep controls in the first wear test.

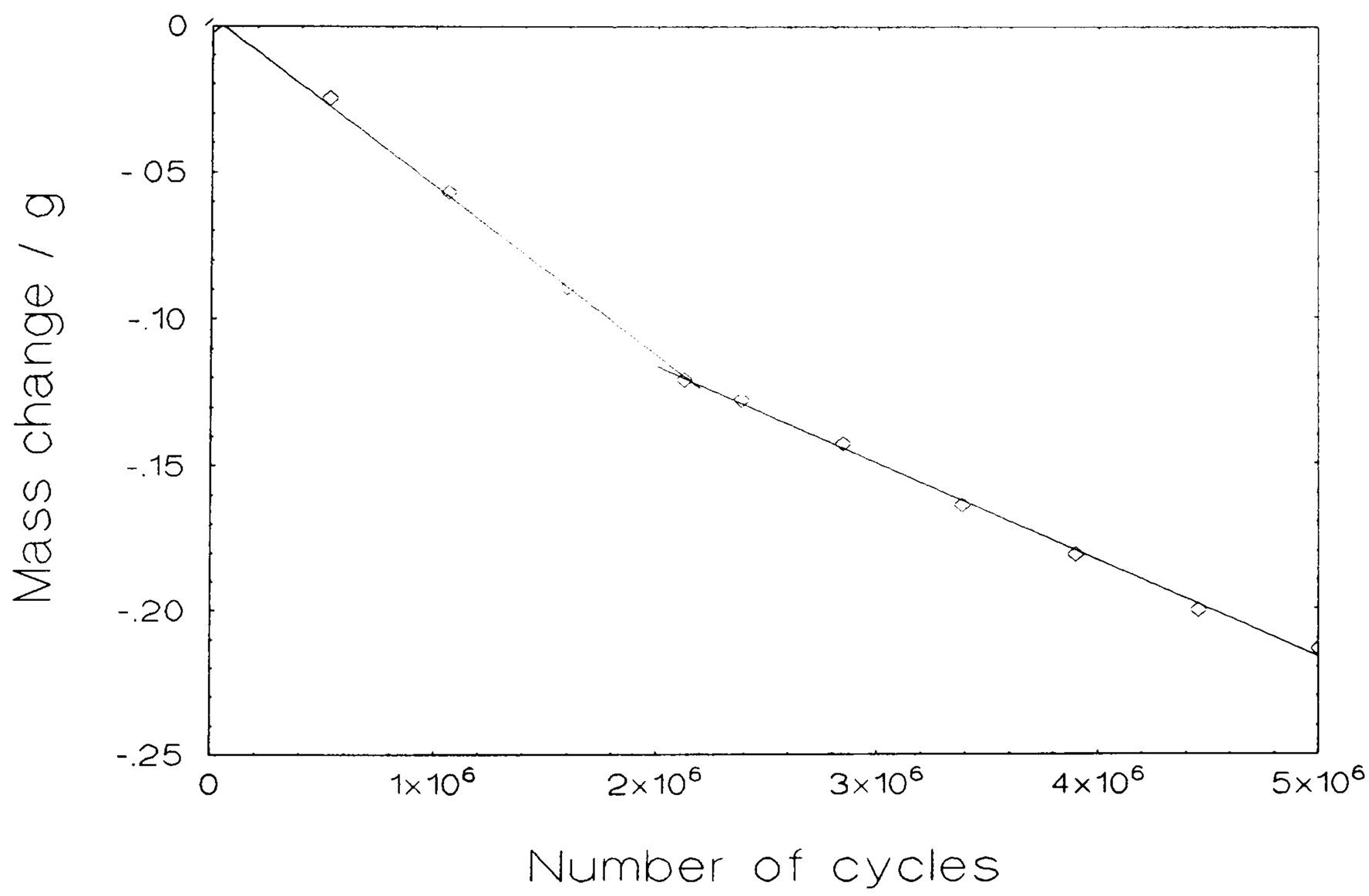


Figure 5.6 Mass change of an acetabular cup with test duration.

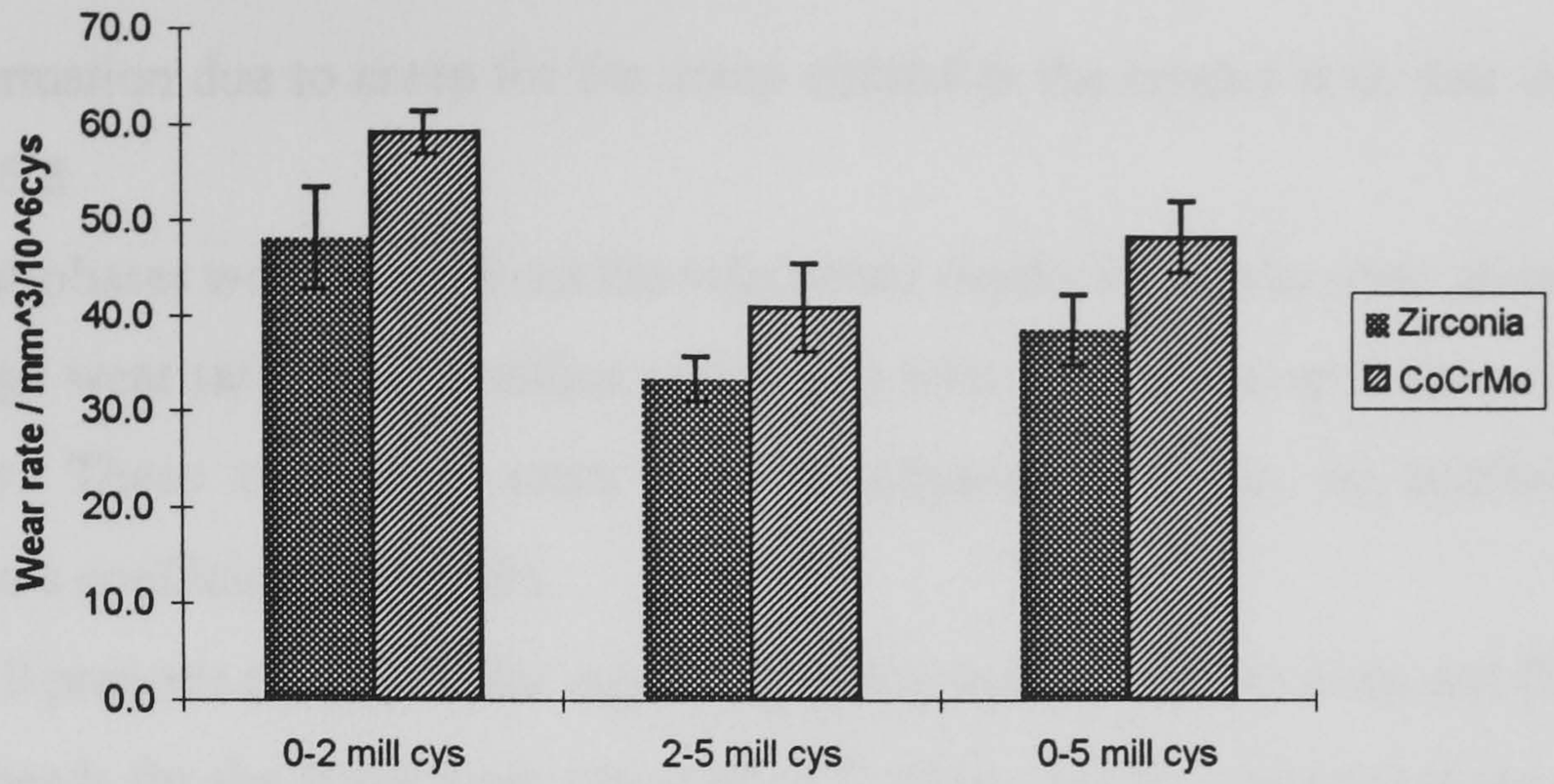


Figure 5.7 Gravimetric wear results for cups articulating against zirconia and CoCrMo femoral heads over different durations of the wear test.

5.2.2 Volumetric measurements

The deformation due to creep for the creep control in the second wear test is shown in figure 5.8.

Two wear phases were found from the volumetric results for all the wear samples. An initial, high wear rate up to 2 million cycles was followed by a lower linear wear rate thereafter. These two wear rates were significantly different as confirmed by Spearman's coefficient, ρ=-0.091.

Figure 5.9 presents the results for cups articulating against both zirconia and CoCrMo femoral heads for the initial wear phase up to 2 million cycles, the second phase from 2 to 5 million cycles, and an overall wear rate covering the full duration of the test. The wear rates for cups articulating against zirconia heads were significantly different (p=0.031) from those articulating against CoCrMo femoral heads for the full duration of the wear test.

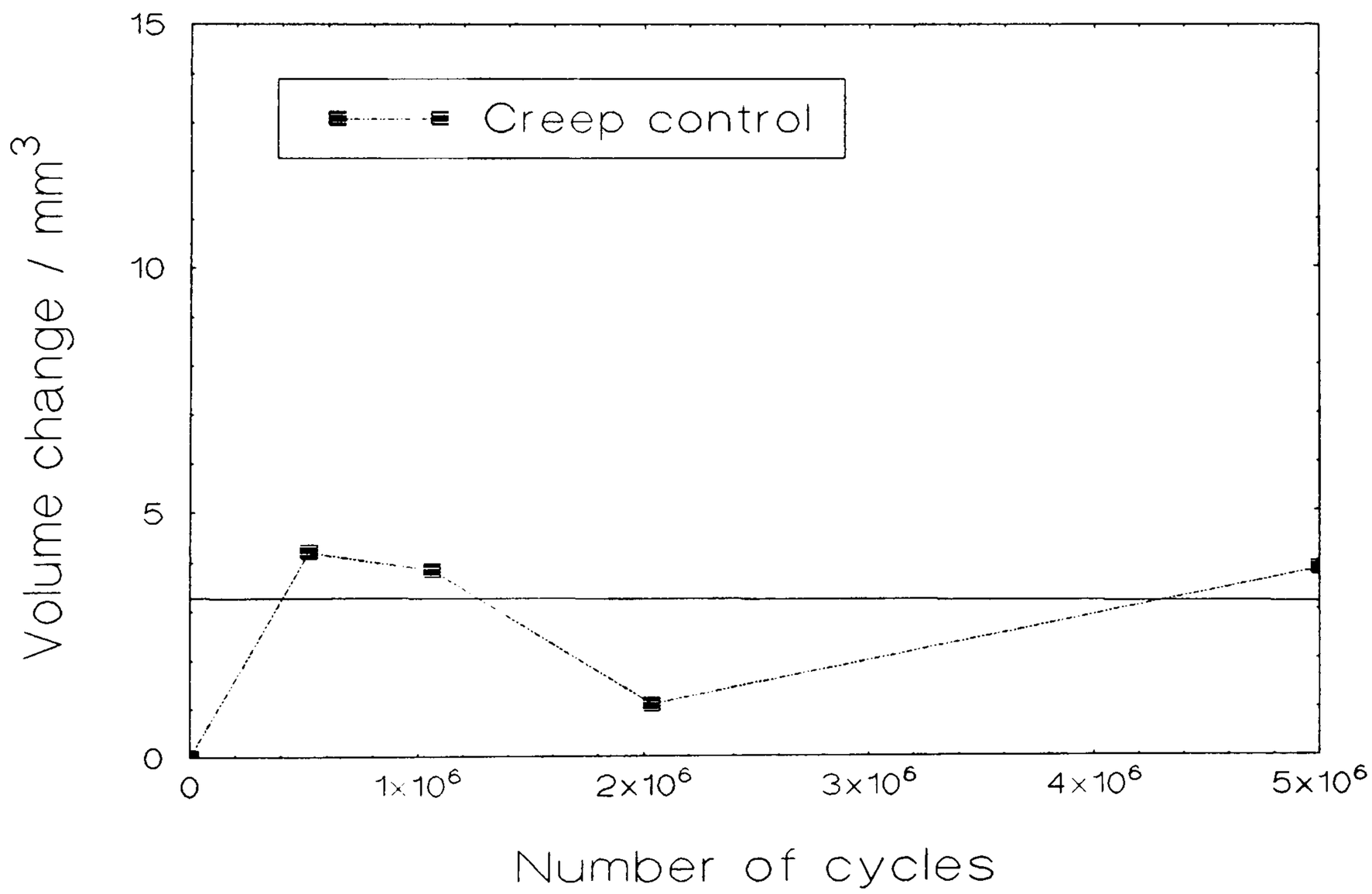


Figure 5.8 Volumetric change due to creep for the 28mm UHMWPE cup in the second wear test.

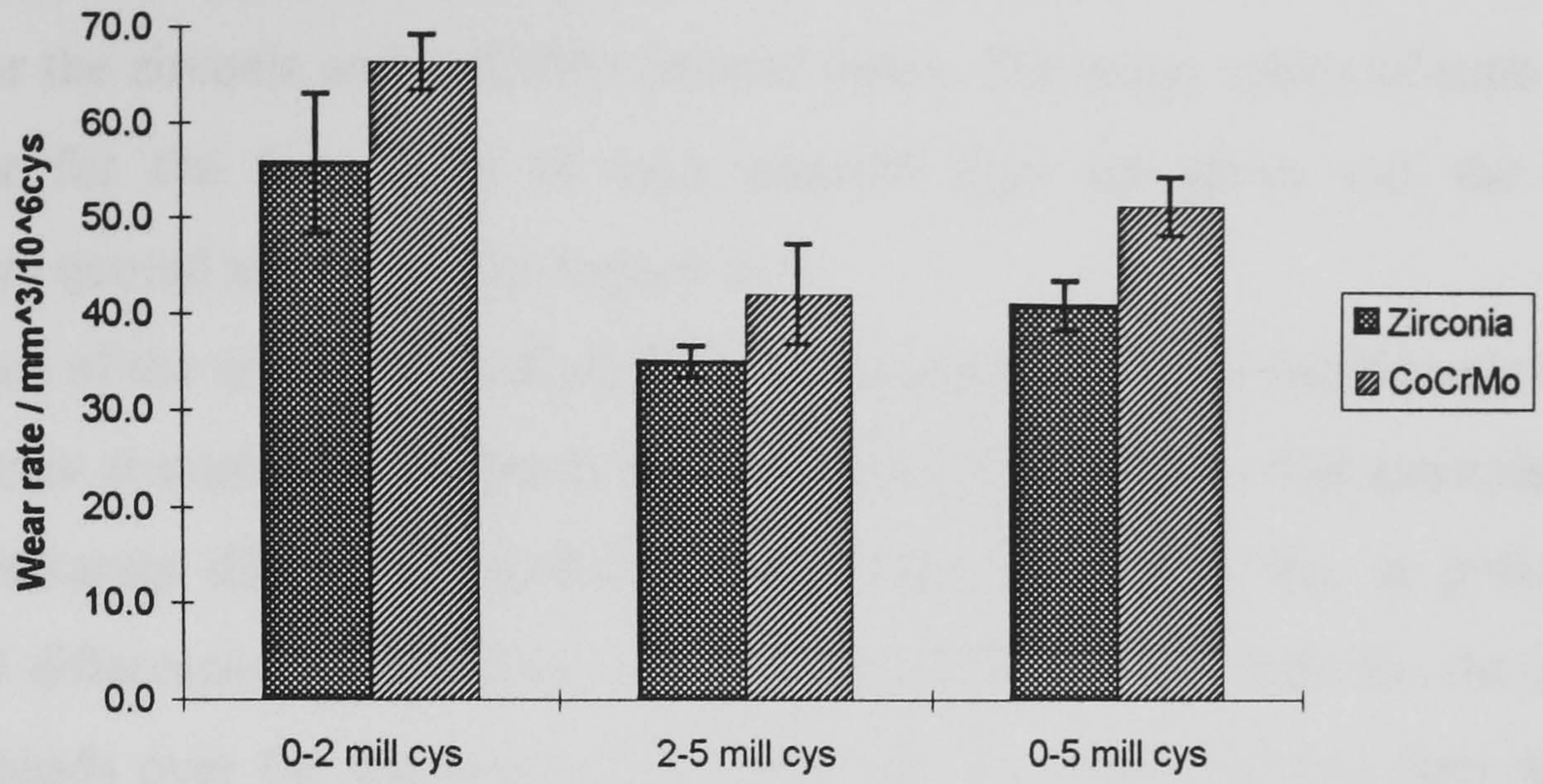


Figure 5.9 Volumetric wear results for cups articulating against zirconia and CoCrMo femoral heads over different durations of the wear test.

5.2.3 Femoral head surface topography

Table 5.2 shows some of the measured surface parameters before and after wear testing for the zirconia and CoCrMo femoral heads. The mean values of each surface parameter for the five heads of each material type are given and the surface parameters quoted are defined in Appendix A.

At the start of the wear test the CoCrMo heads were statistically significantly rougher than the new zirconia femoral heads for most surface parameters. For example, Rmax was significantly different at p=0.009 and surface roughness, Ra, at p=0.02. No statistical difference was observed in any of the surface parameters for the zirconia femoral heads over the duration of the wear test. The new CoCrMo femoral heads roughened over the wear test and this was confirmed as being statistically significant for all surface parameters except skewness. For example, Rpk was significantly different at p=0.0018 over the wear test and Rmax at p=0.0078.

Head type	No. of cycles	Ra (nm)	Rmax (nm)	Rpk (nm)	Rk (nm)	V1 (cu μm)	Rsk
zirconia	zero	3.1	56	3.3	9.7	3.6	-0.4
	$5x10^6$	3.0	95	3.6	9.4	4.1	-0.8
CoCrMo	zero	4.6	180	5.2	13.2	6.1	-2.5
	$5x10^6$	10.5	571	18.1	22.1	26.9	-1.3

Table 5.2 Mean surface topography measurements, before and after wear testing, for the five zirconia and five CoCrMo femoral heads.

5.2.4 Friction measurement

Stribeck plots of new CoCrMo and zirconia femoral heads friction tested against both new and worn acetabular cups are shown in figure 5.10. The dashed lines represent the results against a new acetabular cup and it can be clearly seen that for both femoral head materials the friction is higher than when friction testing against a worn acetabular cup as shown by solid lines. (N.B. In figures 5.10 to 5.13 the legend format follows this example: **nzhwc** - **n**ew **z**irconia **h**ead **w**orn **c**up)

The friction results for worn CoCrMo and zirconia femoral heads tested against both new and worn acetabular cups are shown as Stribeck curves in figure 5.11. The results against worn cups are similarly represented as solid lines and again friction is generally lower against worn cups than against new cups shown by dashed lines. However, the difference in friction factor between new and worn acetabular cups is not as great with worn femoral heads compared with new femoral heads.

Stribeck curves for a new acetabular cup against which new and worn femoral heads of both CoCrMo and zirconia have been friction tested are shown in figure 5.12. Figure 5.13 shows Stribeck curves for a worn acetabular cup against the same femoral heads. In both figures it can be seen that new femoral heads of both materials gave lower friction factors than worn femoral heads. This observation is more pronounced with worn acetabular cups.

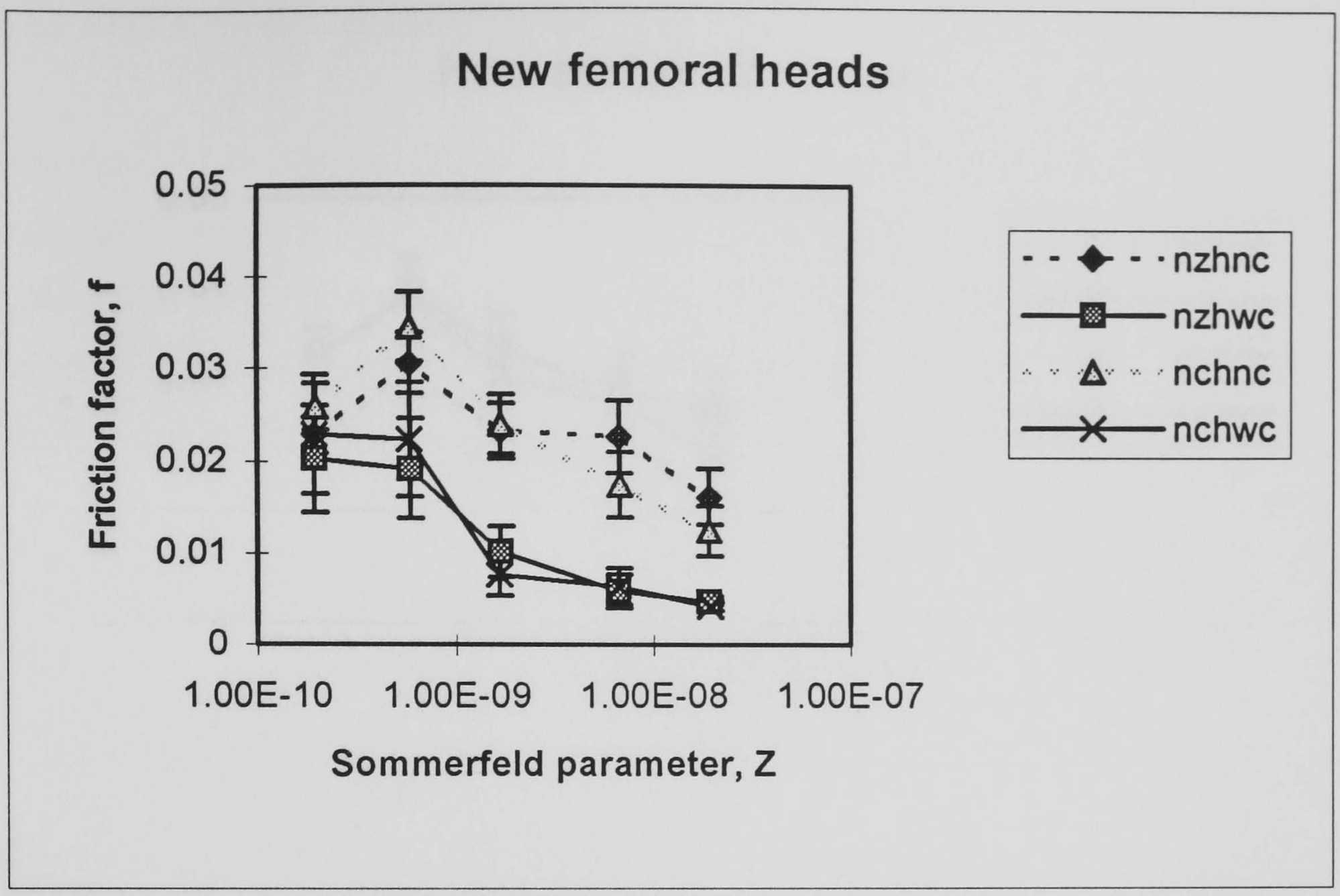


Figure 5.10 Friction results of new zirconia and CoCrMo femoral heads tested against both new and worn acetabular cups.

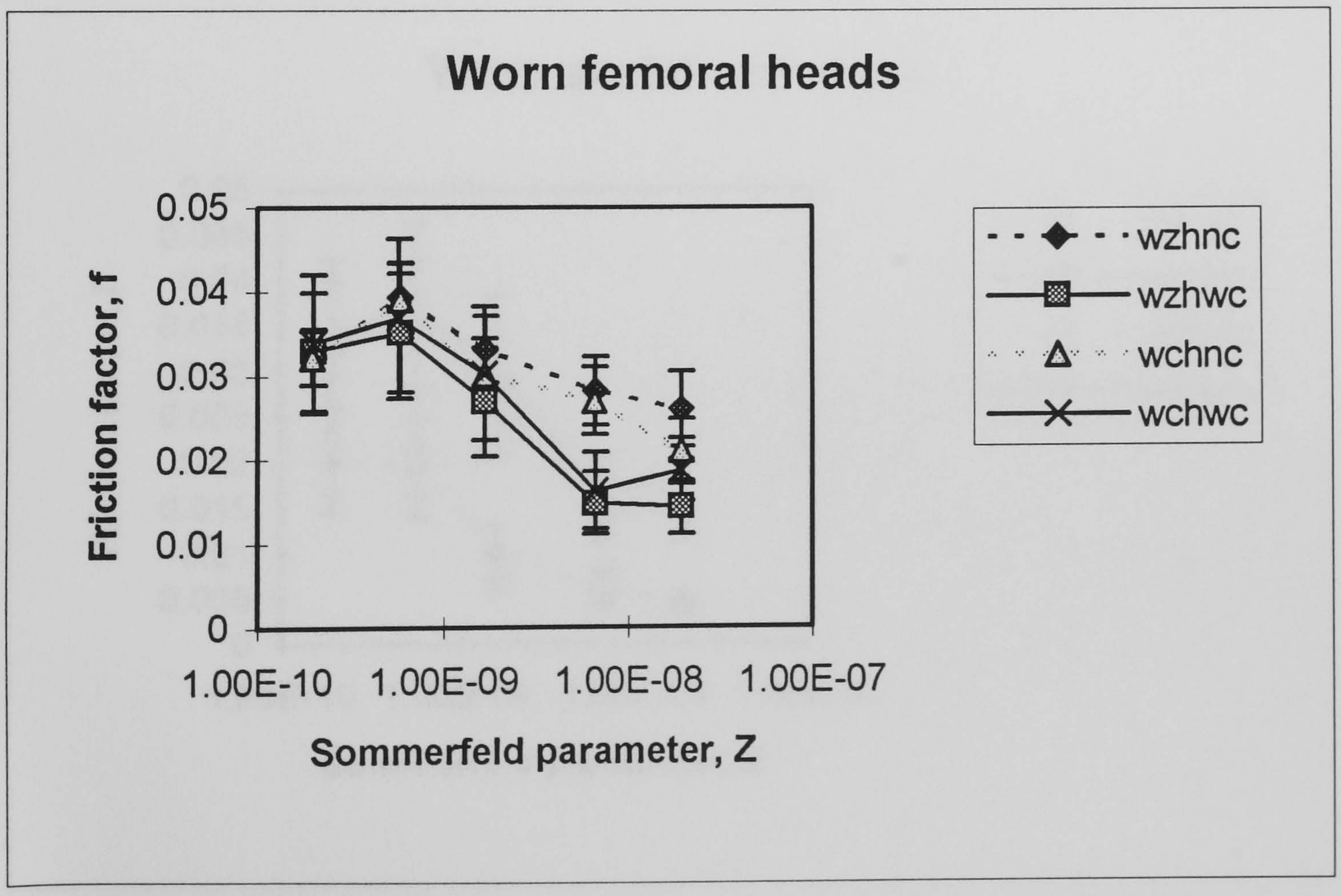


Figure 5.11 Friction results of worn zirconia and CoCrMo femoral heads tested against both new and worn acetabular cups.

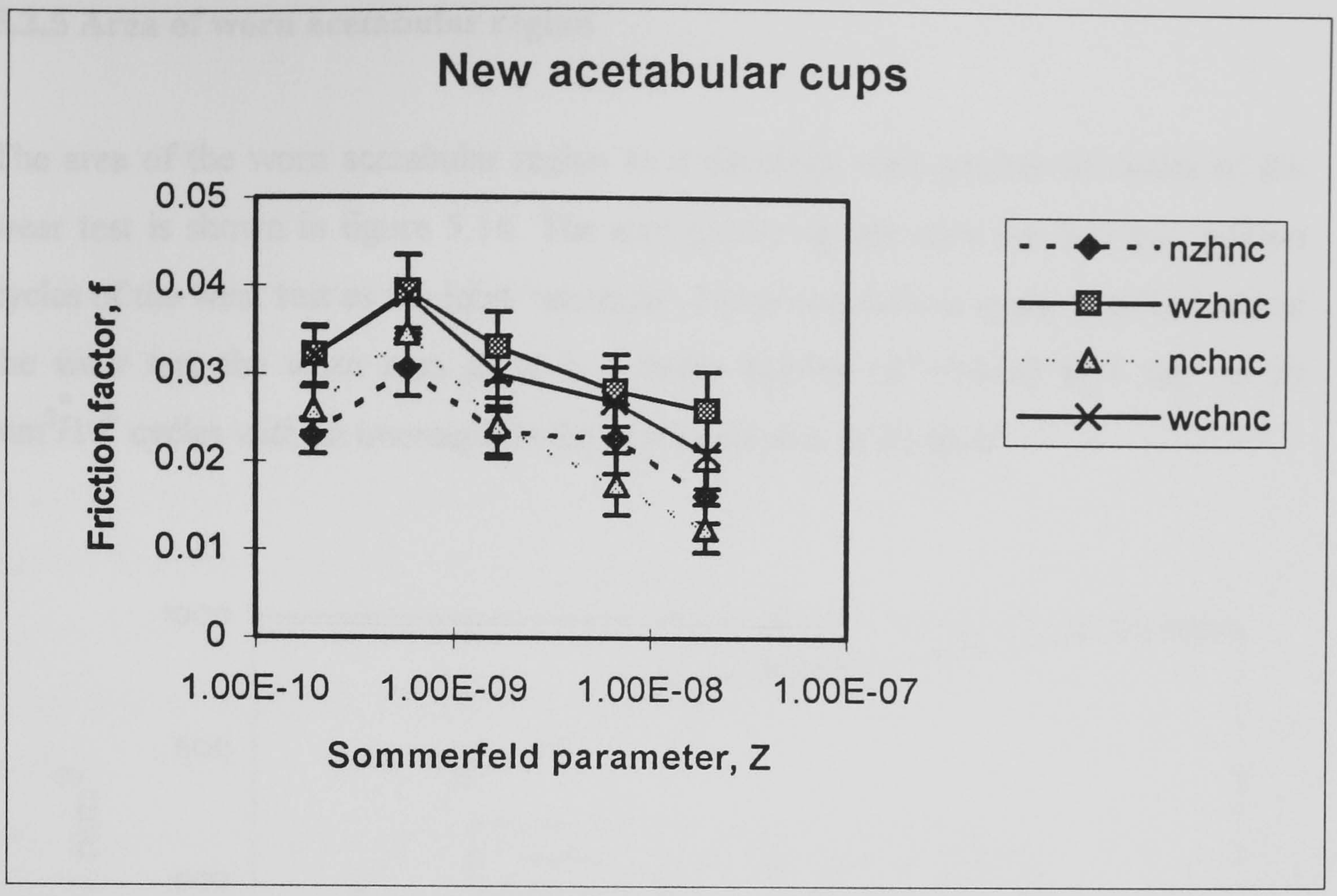


Figure 5.12 Friction results of a new acetabular cup tested against both new and worn zirconia and CoCrMo femoral heads.

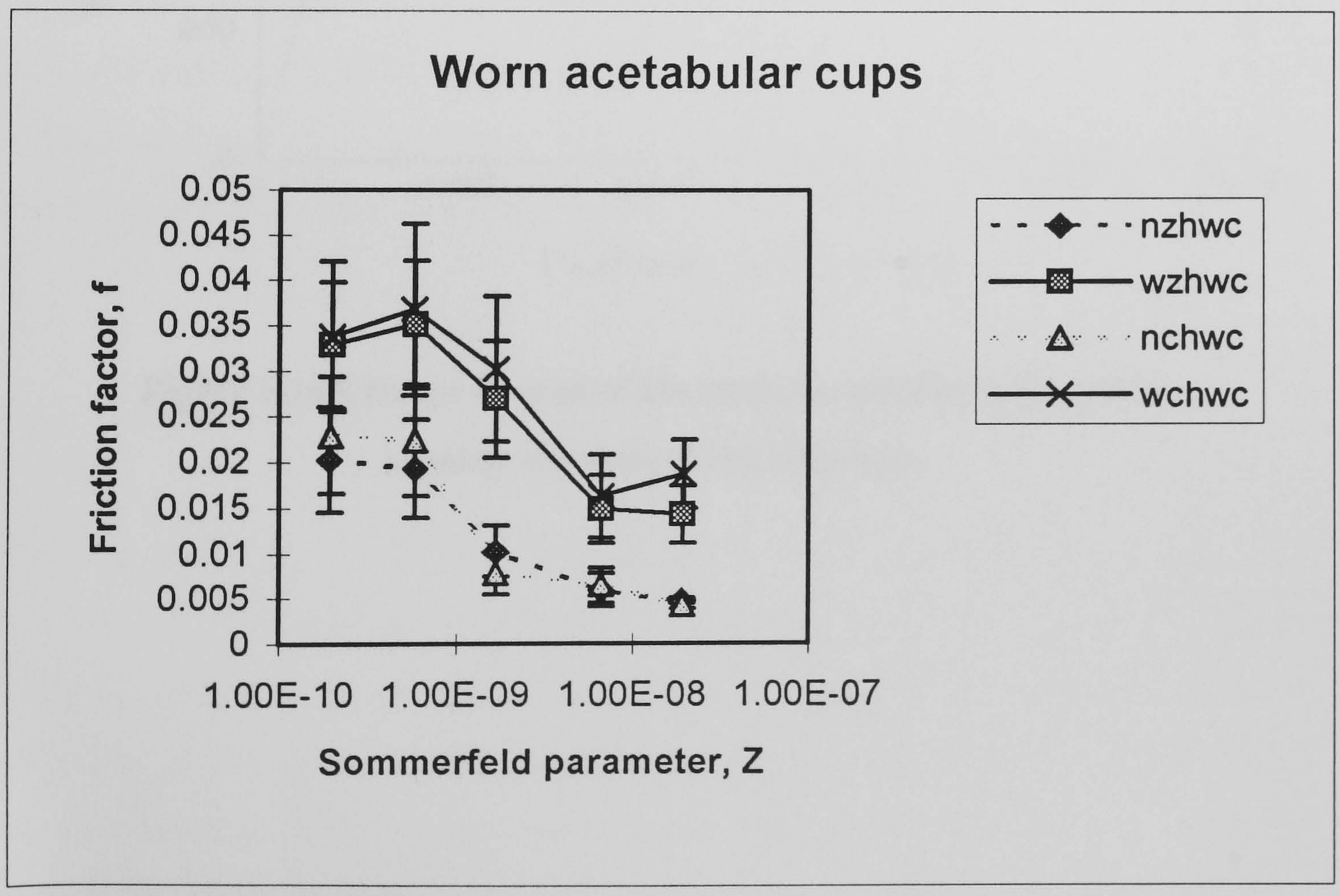


Figure 5.13 Friction results of a worn acetabular cup tested against both new and worn zirconia and CoCrMo femoral heads.

5.2.5 Area of worn acetabular region

The area of the worn acetabular region as it develops with number of cycles of the wear test is shown in figure 5.14. The area grows rapidly over the first two million cycles of the wear test as the joint 'wears in'. From two million cycles until the end of the wear test the worn area grew in a linear fashion (R^2=0.868) at a rate of 30 $mm^2/10^6$ cycles with an intercept on the worn area axis of 834mm^2.

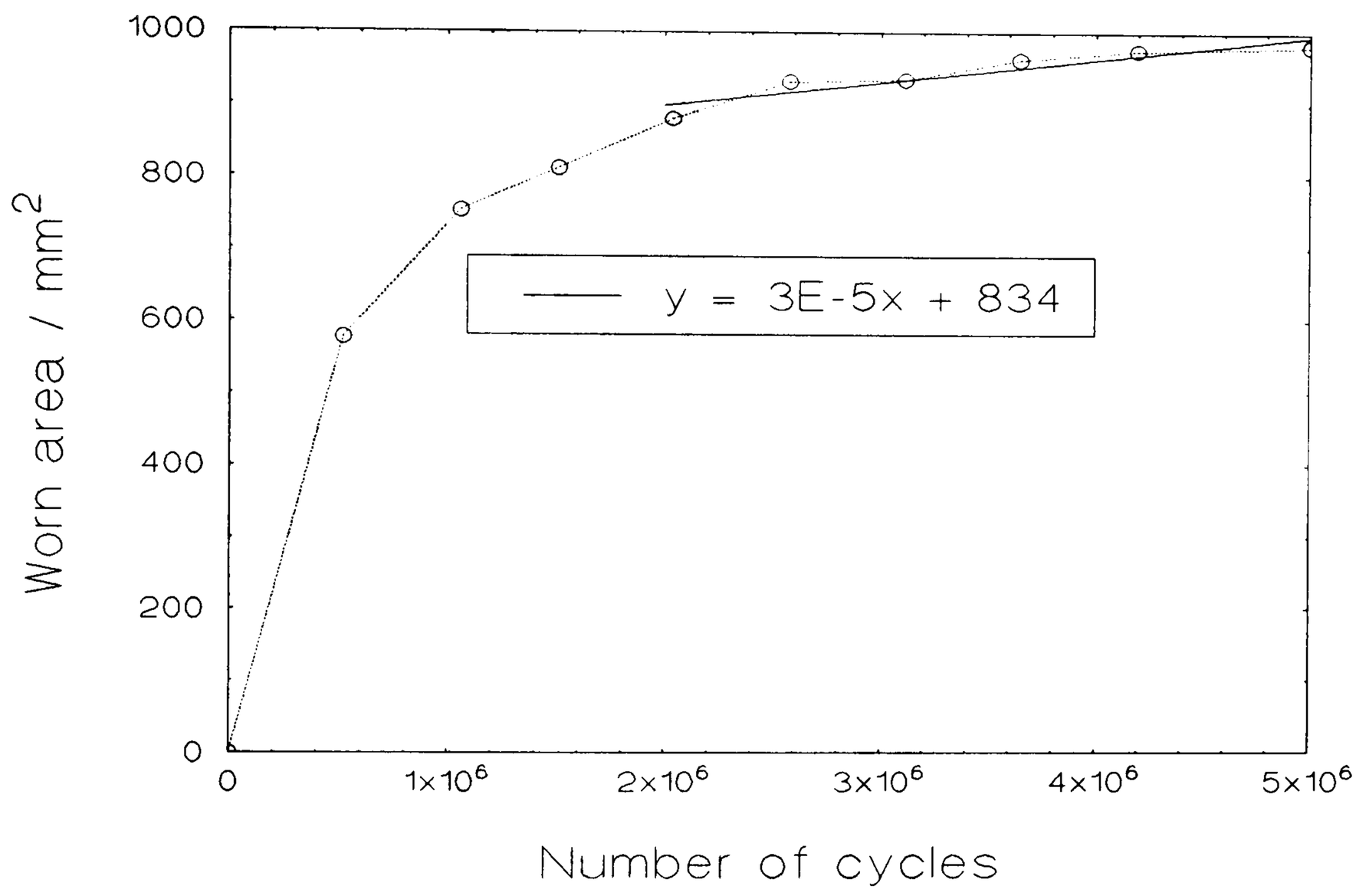


Figure 5.14 Change in area of the worn acetabular region with number of cycles of the wear test.

5.3 Simplified motion & loading

5.3.1 Simplified loading wear test

The wear of UHMWPE acetabular cups against 28mm diameter zirconia and CoCrMo femoral heads was shown to change after about two million cycles in the gravimetric versus volumetric wear measurement study. A high initial linear wear rate occurs up to 2 million cycles, followed by a lower linear wear rate from 2 million cycles. Therefore, the wear rate for physiological loading was calculated over the region 2 million cycles to 5 million cycles to eliminate the initial high wear rate. The wear rate for simplified loading was calculated from 5 million cycles to 7.1 million cycles.

The mean wear rates and standard deviations for the acetabular cups articulating against zirconia and CoCrMo femoral heads were 32.2±6.8 and 51.7±1.2 $mm^3/10^6$cys respectively with physiological loading. When subjected to square wave loading the cup wear rates were 30.1±9.9 and 49.2±1.3 $mm^3/10^6$cys against zirconia and CoCrMo respectively. The UHMWPE acetabular cups wear rates were lower against zirconia femoral heads than CoCrMo femoral heads for both loading regimes ($p=0.08$ for both loading regimes). No significant difference was found between the results for physiological loading and simplified loading.

5.3.2 Uni-axial motion

The wear rates for the two UHMWPE acetabular cups were very similar at 0.202 and 0.192 $mm^3/10^6$ when subject to simplified motion. These wear rates are approximately 150 times lower than wear rates for cups articulating against zirconia femoral heads subject to physiological loading and two axes of physiological motion. Furthermore, the net mass change of the cups over the wear test showed an increase in cup mass. This can be attributed to the mass gain of the cups due to moisture absorption being greater than the mass loss due to wear.

5.3.3 Acetabular cup surface topography

Gross inspection of the quartered acetabular cups worn with physiological motion and simplified loading revealed no notable difference with cups subjected to full physiological motion and loading. A further comparison was made with explanted cementless cups and also with acetabular cups worn against explanted femoral heads from the explanted femoral head wear test. Visual inspection using an optical microscope and a SEM also showed no differences between these cups types. Figure 5.15 shows the typical multi-directional scratching observed using optical microscopy at ten times magnification and figure 5.16 is a typical observation at 5000 times magnification using a SEM.

3-D measurements of various surface parameters were taken in the worn and unworn regions of the acetabular cups using a Zygo non-contacting profilometer, as shown in Table 5.3. This was undertaken for all the cups previously examined and also the cups subject to uni-axial motion. For all cup types there was a statistically significant difference between the unworn region and the smoother worn region for all surface parameters. When comparing the surface parameters for the worn region, no statistically different trends between any of these cup types was observed. However, visual inspection of the uni-axially worn cups highlighted differences with all the other cup types. The area of the worn region was very much smaller and concentrated near the pole of the cup. Initial impressions using the optical microscope were of scratched lines dominant in two orientations. Further inspection revealed that one series of the lines were the remains of the machining marks from manufacture and the other from the femoral head articulation. At 5000 times magnification on the scanning electron microscope parallel ripples in the surface of the polyethylene approximately 1μm apart could be seen as shown in figure 5.17.

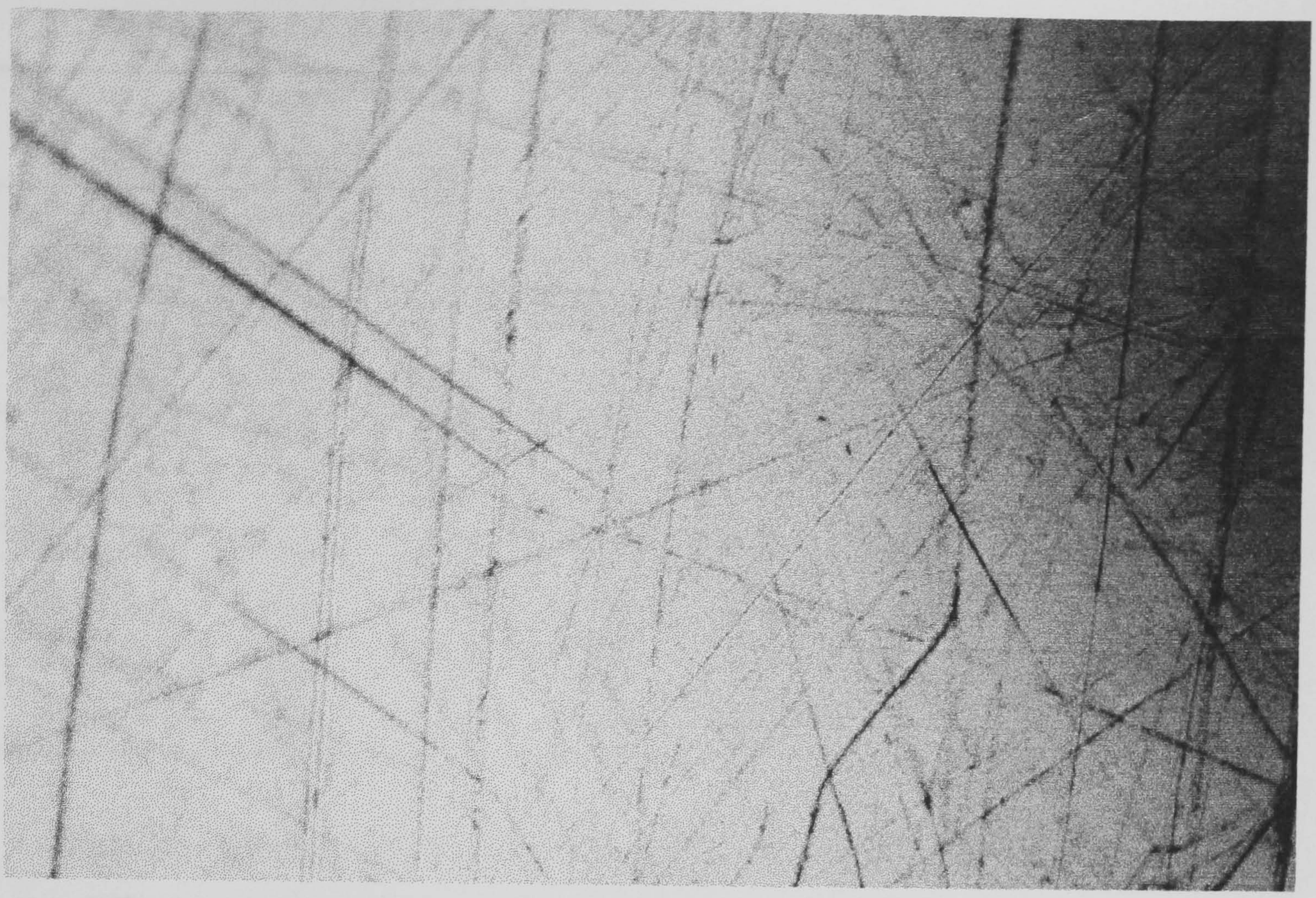


Figure 5.15 Optical microscopy image at ten times magnification of the surface of an acetabular cup subject to physiological motion and loading.

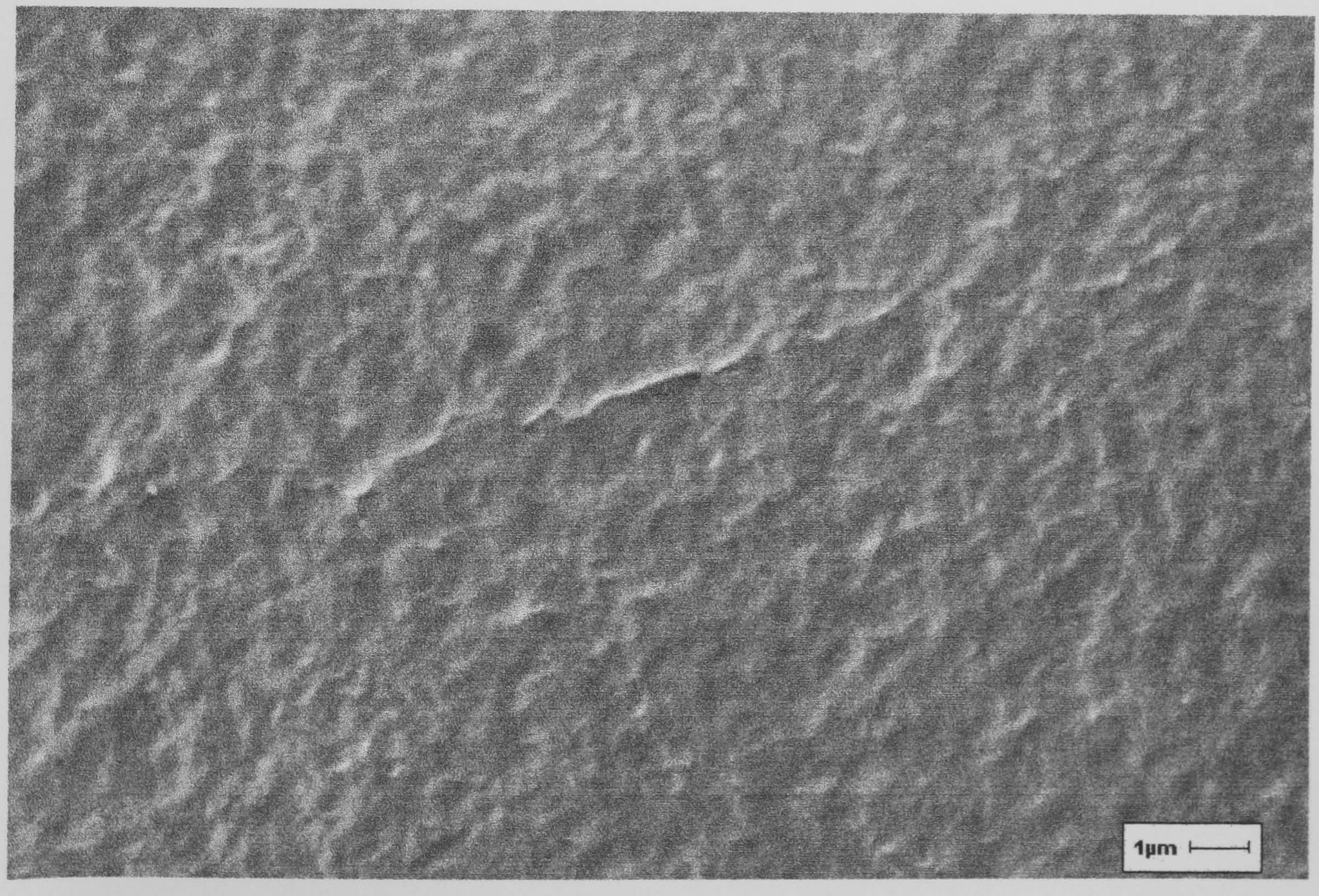


Figure 5.16 SEM image at 5000 times magnification of the surface of an acetabular cup subject to physiological motion and simplified loading.

Cup type	Region	Ra (μm)	Rmax (μm)	Rpk (μm)	Rsk	Wa (μm)	Wmax (μm)
Full phys	unworn	0.264	13.96	0.434	-0.46	0.698	4.87
mot & load	worn	0.053	2.48	0.184	1.83	0.052	0.59
Simplified	unworn	0.274	13.95	0.440	-0.96	0.719	4.69
loading	worn	0.023	1.41	0.077	2.42	0.046	0.42
Uni-axial	unworn	0.153	13.64	0.330	-2.00	0.737	5.44
motion	worn	0.030	2.44	0.095	0.41	0.079	1.08
Explanted	unworn	0.168	12.91	0.363	-0.48	0.579	4.49
head test	worn	0.022	1.41	0.060	-0.09	0.048	0.43
Explanted	unworn	0.982	40.53	1.803	-3.86	1.873	10.494
cups	worn	0.024	1.38	0.090	1.78	0.059	0.64

Table 5.3 Median values of various surface parameters for each of the four different cup types measured using a Zygo non-contacting profilometer.

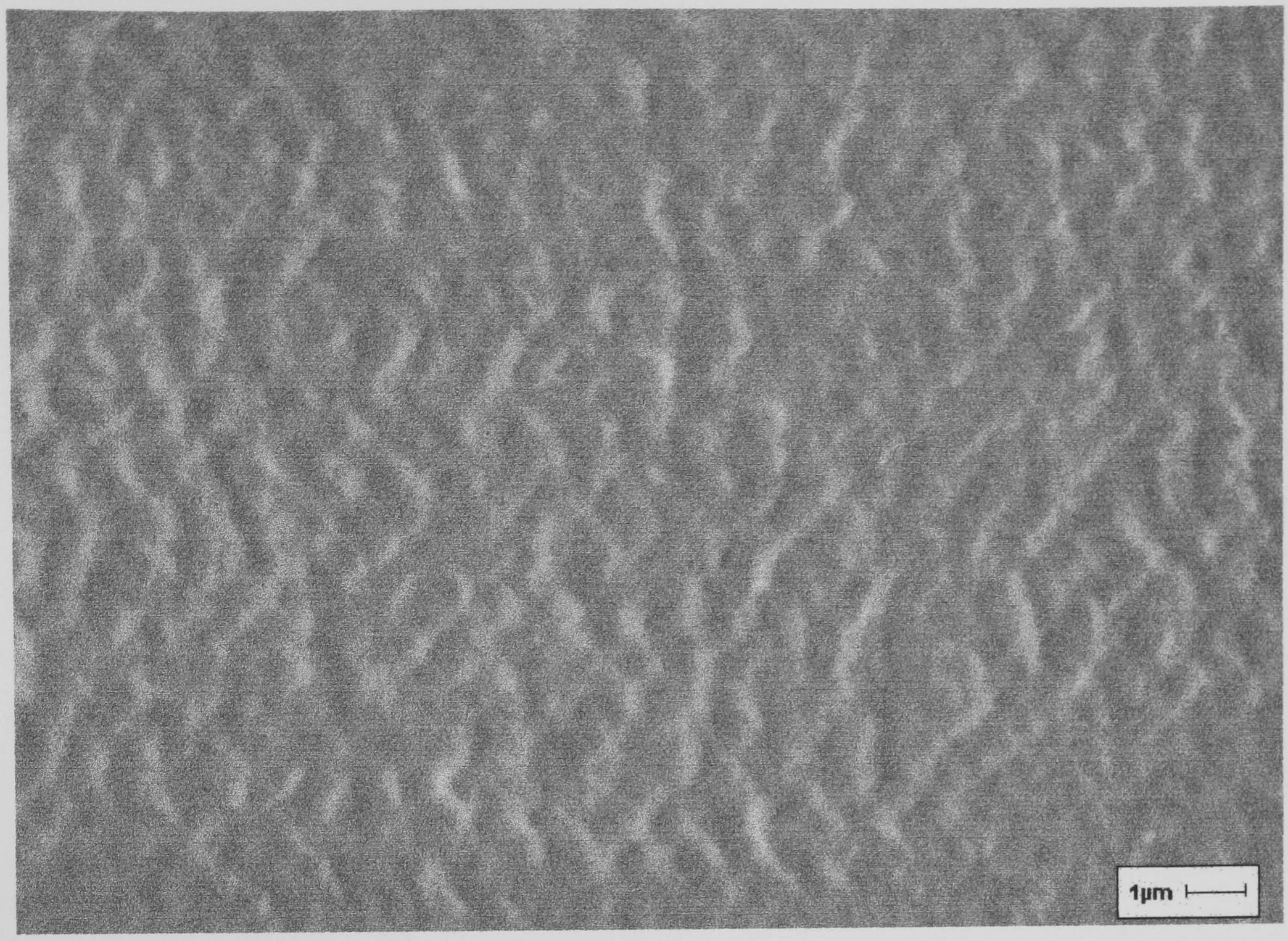


Figure 5.17 SEM image at 5000 times magnification of the surface of an acetabular cup subject to linear motion showing parallel ripples in the surface of the polyethylene approximately 1μm apart.

5.4 Explanted femoral head wear test

5.4.1 Wear test

The acetabular cup wear rates against the three explanted femoral heads, cases A, B and C, were 103.7, 149.5 and 120.4 $mm^3/10^6$ cys respectively. (Patient details and joint types shown in table 4.1). Due to the high acetabular cup wear rates against the explanted heads no wear-in period was evident as it was so rapid. Statistical examination of the data confirmed this observation.

For comparison, from the gravimetric study from two to five million cycles, thus representing the mature joint *in-vivo*, the cup wear rates (mean±S.D.) against zirconia and CoCrMo femoral heads were 33.3±5.1 and 40.8±10.3 $mm^3/10^6$ cycles respectively.

5.4.2 Explanted femoral head surface topography

A number of the measured surface parameters for each of the explanted femoral heads are shown in table 5.4. (For comparison the mean values of the five zirconia and five CoCrMo femoral heads from the gravimetric versus volumetric study are included.) It can be noted for the explanted heads that the parameters vary before and after wear testing. However, there was no statistical difference in any of the parameters over the duration of the wear test indicating no surface damage or improvement of the explanted heads caused by the tests. The variations in the surface parameters can be attributed to sampling errors due to spatial topographic differences. The numerous points taken on each femoral head gives confidence in the resulting surface parameter values and statistics performed using them.

Acetabular cup wear rate was plotted against each of the femoral roughness surface parameters for the explanted heads and mean values for the zirconia and CoCrMo heads from the gravimetric versus volumetric study. Root mean square surface roughness, Rrms, gave the strongest correlation with a coefficient of determination, R^2, of 0.951, (figure 5.18), and wear rate was proportional to $Rrms^{0.552}$.

Head	no. of cycles	Ra (nm)	Rmax (nm)	Rpk (nm)	Rrms (nm)	V1 (cu μm)	Rsk
A	zero	19	807	11	47	15	-5.9
	$5x10^6$	17	1401	14	48	15	-5.8
B	zero	55	1800	133	88	200	-0.3
	$5x10^6$	49	2129	110	96	139	-0.9
C	zero	24	1037	22	57	25	-4.9
	$5x10^6$	20	1458	30	45	32	-4.8
zirconia	zero	3.1	56	3.3	4.0	3.6	-0.4
	$5x10^6$	3.0	95	3.6	4.2	4.1	-0.8
CoCrMo	zero	4.6	180	5.2	7.0	6.1	-2.5
	$5x10^6$	10.5	571	18.1	15.4	26.9	-1.3

Table 5.4 Median values for various surface parameter of the three explanted femoral heads, before and after wear testing.

Mean values for the five zirconia and five CoCrMo heads used in the gravimetric versus volumetric study have been included for comparison.

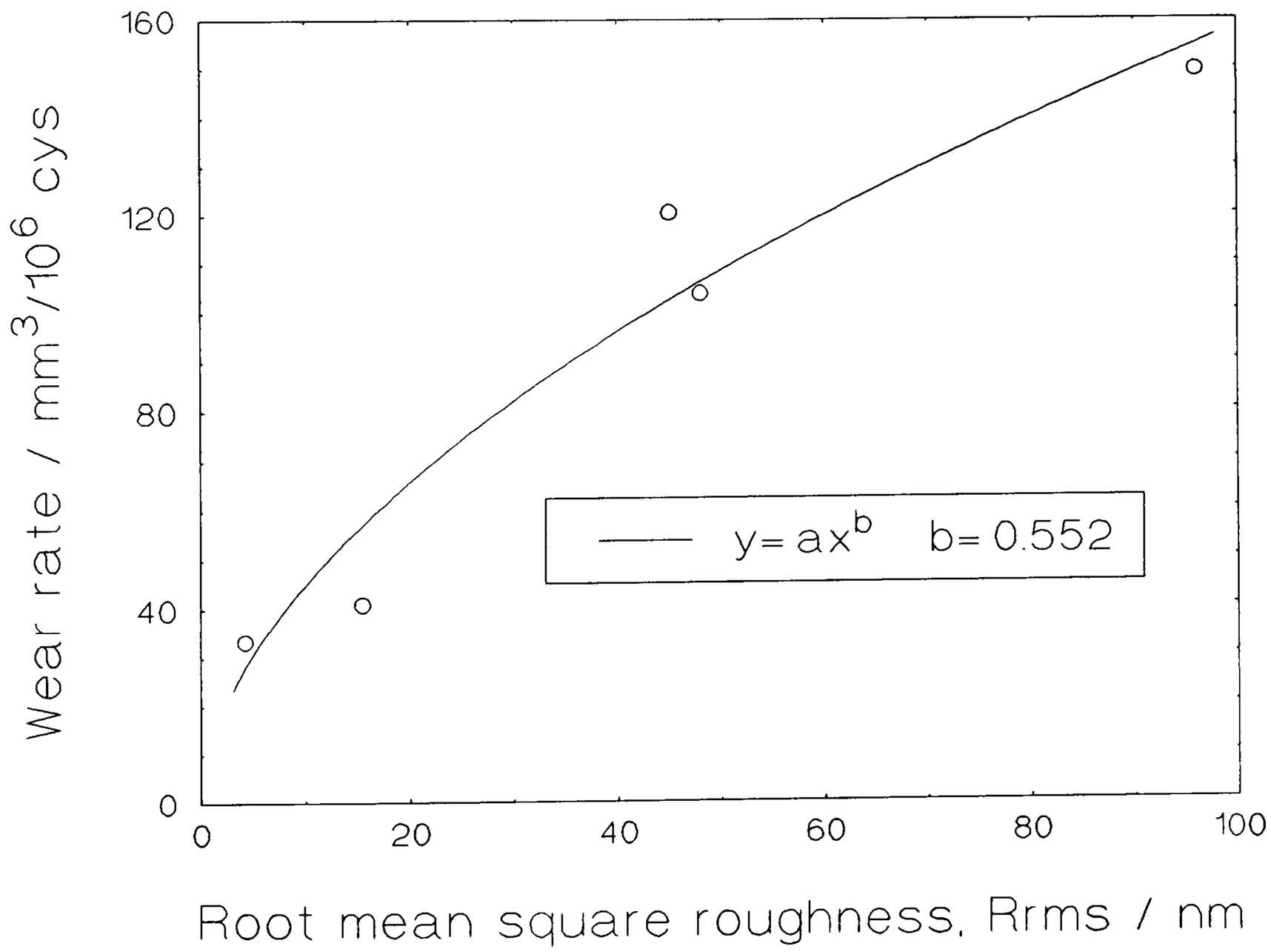


Figure 5.18 Cup wear rate versus femoral root mean square surface roughness, Rrms.

5.5 The Mk.II Durham hip simulator validation exercise

5.5.1 Wear test

From zero to one million cycles of the wear test a high, linear rate of wear was observed, attributed to the acetabular cups wearing-in, with a mean ± S.D. value of 101.8±24.8 $mm^3/10^6$ cycles. Wear from one to five million cycles therefore represented the mature joint *in vivo* as the cups had worn-in. With ±10° internal/external rotation, from one to three million cycles, the mean wear rate was 67.2±11.9 $mm^3/10^6$ cycles. When the internal/external rotation was reduced to ±5°, from three to five million cycles, the wear rate also reduced to 52.2±7.4 $mm^3/10^6$ cycles. This was statistically significantly lower than the wear from one to three million cycles ($p=0.05$).

5.5.2 Wear path analysis

Figure 5.19 shows the wear path of a single point on the femoral head relative to the acetabular cup as it moves through a gait cycle for the physiological motion applied on the Mk.I Durham simulator. (The point on the surface of the femoral head lies 8.083 mm along the adduction/abduction axis and 8.083mm along the flexion/extension axis.) Selecting another point for analysis reveals that there is a change in the wear path although the same basic shape is still evident as shown in figure 5.20. (The second point analysed lies 4.000 mm along the adduction/abduction axis and 4.000 mm along the flexion/extension axis.) Re-analysis of this second point for the simplified motion used for the Mk.II Durham simulator from zero to three million cycles with ±10° internal/external rotation, is shown in figure 5.21. An elliptical wear path is observed with this motion, and the ellipse tightens when the internal/external rotation is reduced to ±5° from three to five million cycles, as shown in figure 5.22.

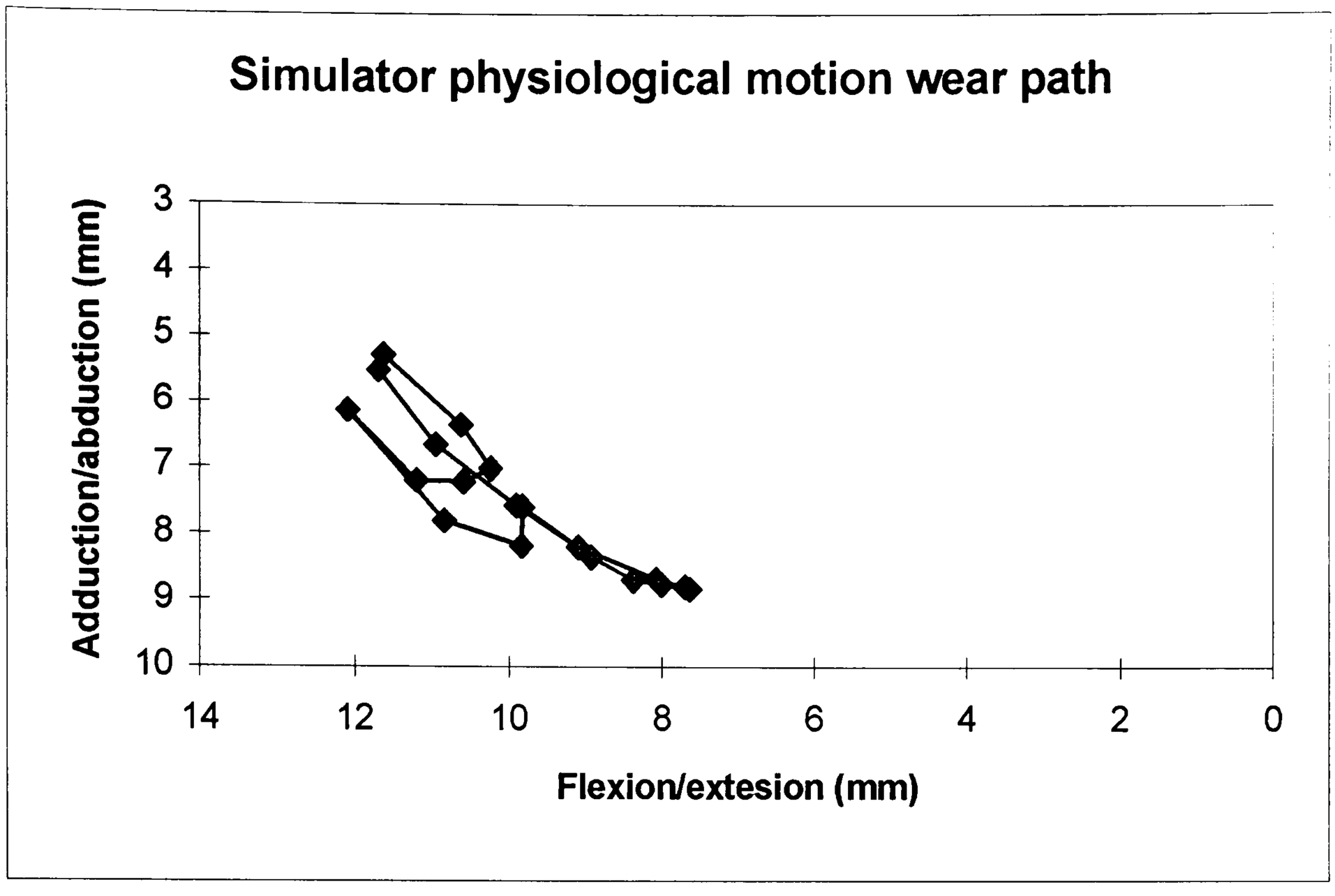


Figure 5.19 Wear path analysis of a point subjected to the physiological motion of the Mk. I Durham simulator.

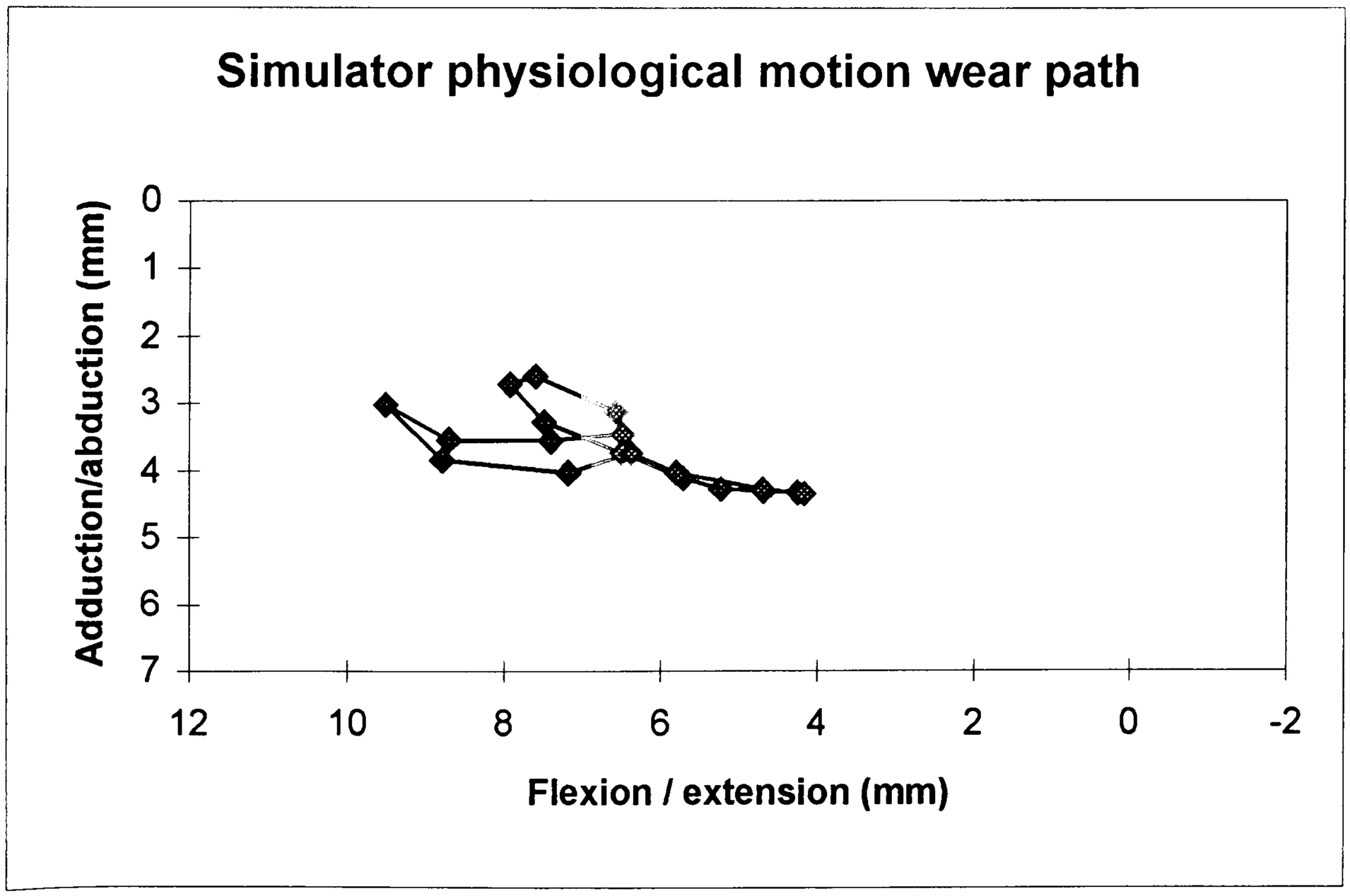


Figure 5.20 Wear path analysis of a second point subjected to the physiological motion of the Mk. I Durham simulator.

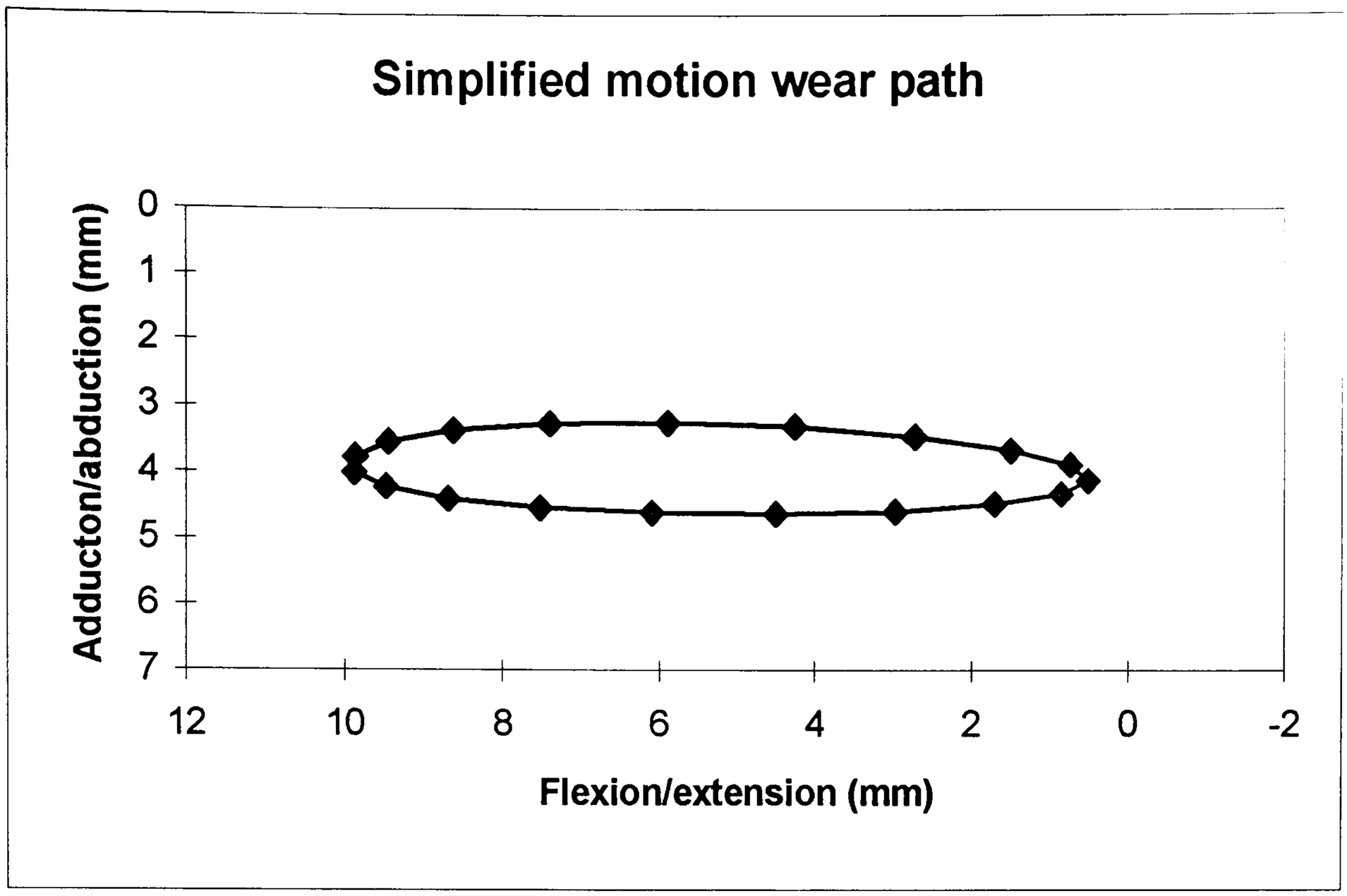


Figure 5.21 Wear path analysis of the same point as selected in figure 5.20 but subjected to the simplified motion of the Mk. II Durham simulator with ±10° internal/external rotation.

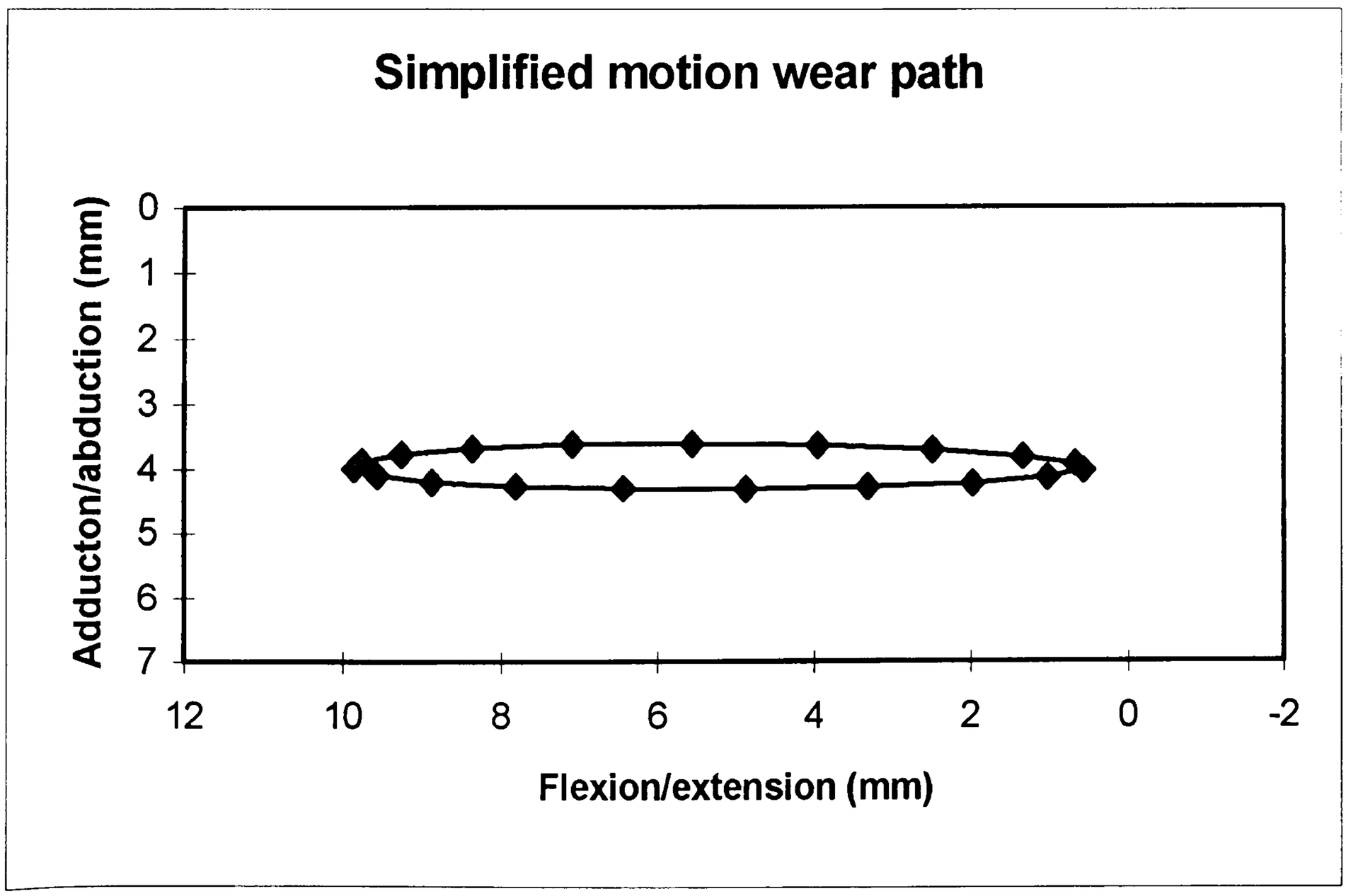


Figure 5.22 Wear path analysis of the same point but with the simplified motion reduced to ±5° internal/external rotation.

5.5.2 Femoral and acetabular surface topography

Table 5.5 shows some of the measured surface parameters before and after wear testing for the zirconia femoral heads worn with simplified motion and loading in the Mk.II Durham simulator. For comparison, the results for the zirconia heads worn with physiological motion and loading using the Mk.I Durham simulator in the gravimetric versus volumetric study are also given. No statistical difference was observed in any of the surface parameters for either set of zirconia heads over the duration of the wear tests.

Gross inspection of the quartered acetabular cups worn in the Mk.II Durham simulator with simplified motion and loading bore close resemblance to cups worn in the Mk.I Durham simulator with physiological motion and loading. Visual inspection using an optical microscope and a SEM also showed no differences between these cups types. Figure 5.23 shows the typical multi-directional scratching observed in an intensity map from the Zygo non-contacting optical interferance profilometer. The 3-D measurements of various surface parameters taken in the worn and unworn regions of the acetabular cups using the profilometer, are shown in Table 5.5. For both cup types there was a statistically significant difference between the unworn region and the smoother worn region for all surface parameters. When comparing the surface parameters for the worn region, no statistically different trends between the cup types was observed.

Simulator	no. of cycles	Ra (nm)	Rmax (nm)	Rpk (nm)	Rk (nm)	V1 (cu μm)	Rsk
Mk.II	zero	2.5	49	2.8	7.9	3.0	-0.5
	$5x10^6$	2.8	60	3.2	8.8	3.7	-0.2
Mk.I	zero	3.1	56	3.3	9.7	3.6	-0.4
	$5x10^6$	3.0	95	3.6	9.4	4.1	-0.8

Table 5.5 Mean values for various surface parameters, before and after wear testing, for the five zirconia heads worn with simplified motion and loading in the Mk.II Durham simulator. The five zirconia heads worn with physiological motion and loading in the Mk.I Durham simulator are included for comparison.

Figure 5.23 An intensity map taken of a cup worn in the Mk.II Durham simulator with simplified motion and loading, using a Zygo non-contacting profilometer at 40x magnification, showing multi-directional scratching.

Cup type	Region	Ra (μm)	Rmax (μm)	Rpk (μm)	Rsk	Wa (μm)	Wmax (μm)
Mk.II Durham	unworn	0.253	13.23	0.447	-0.42	0.677	4.87
simulator	worn	0.021	1.32	0.172	0.57	0.065	0.68
Full phys	unworn	0.264	13.96	0.434	-0.46	0.698	4.87
mot & load	worn	0.053	2.48	0.184	1.83	0.052	0.59
Explanted	unworn	0.982	40.53	1.803	-3.86	1.873	10.49
liners	worn	0.024	1.38	0.090	1.78	0.059	0.64

Table 5.6 Median surface parameters for the cups worn in the Mk.II Durham simulator with simplified motion and loading. Measurements from cups worn with full physiological motion and loading in the Mk.I Durham simulator and explanted cementless cups are included for comparison.

5.6 Cleaning & drying protocol

The results for the first part of the experiment which examined the effect of immersing the cups in different solvents are shown in figure 5.24. The first point to note is that for all the solvents used, the cups actually gain mass during the 'drying' period. The second point to note is the rapid mass change of the cups during the first hour of 'drying'. All the solvents had approached the equilibrium position with diminshed errors within two and a half hours. Immersion in ethanol for ten minutes performs best as a protocol in this experiment by approaching the equilibrium region fastest, in only an hour, with diminished errors bars.

The results for the second part of the experiment which examined the effect of cup drying techniques are shown in figure 5.25. The vacuum drying technique allowed the cups mass to approach equilibrium by the first measurement after 15 minutes drying time. However, differences of only several millibars from the nominally 600mbar vacuum caused relatively large deviations from the equilibrium in the subsequent measurement. Drying the cups in a laminar flow cabinet revealed that a drying time of 120 minutes resulted in near equilibrium measurements with diminished errors. The air drying experiment was ended after 180 minutes and an assumption made that the cups had reached an equilibrium mass that would be sustained if maintained in that environment. The results suggest that for air drying the true equilibrium may not have been reached.

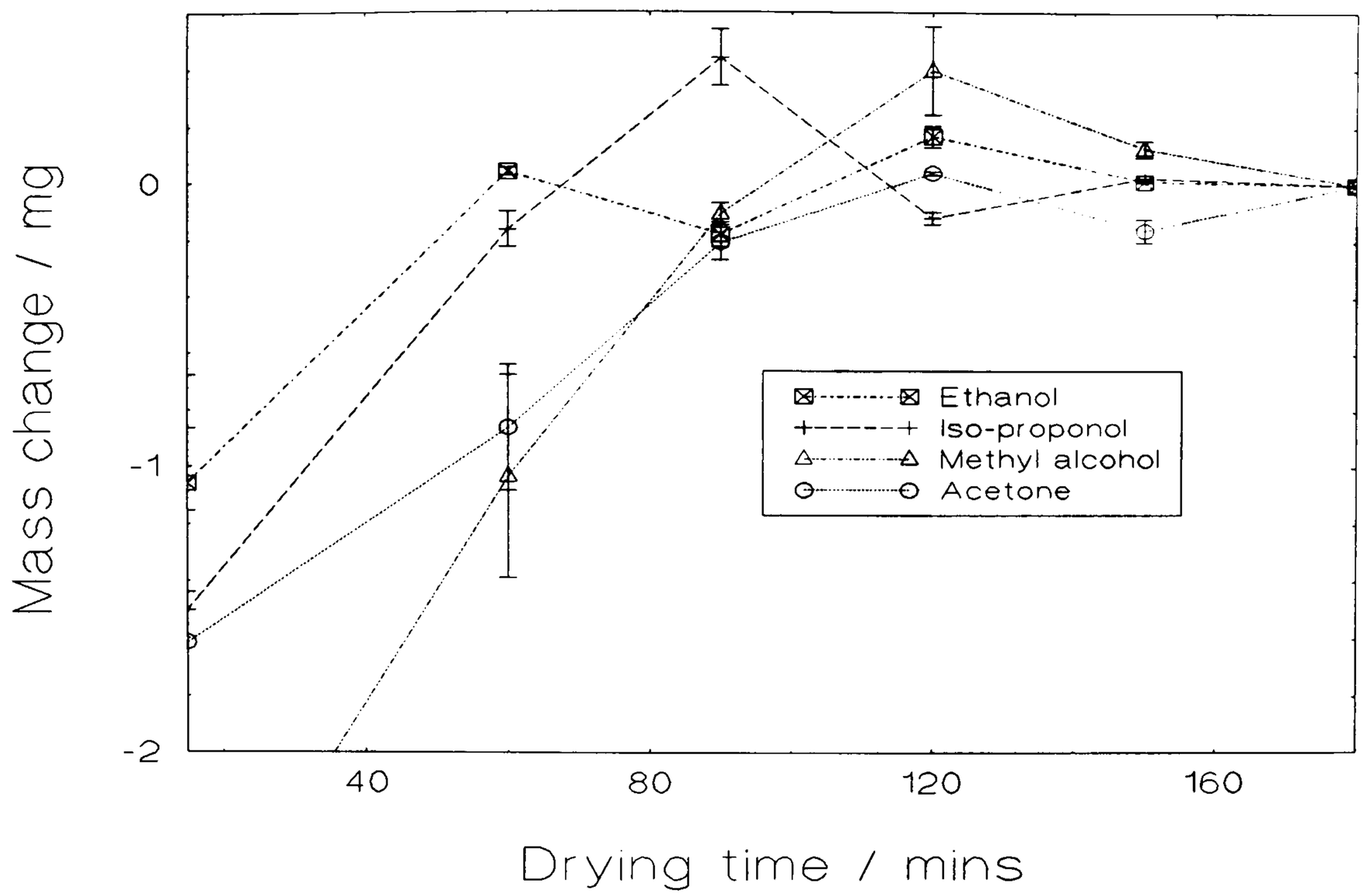


Figure 5.24 Mass change versus drying time following various protocols for cup immersion in a solvent.

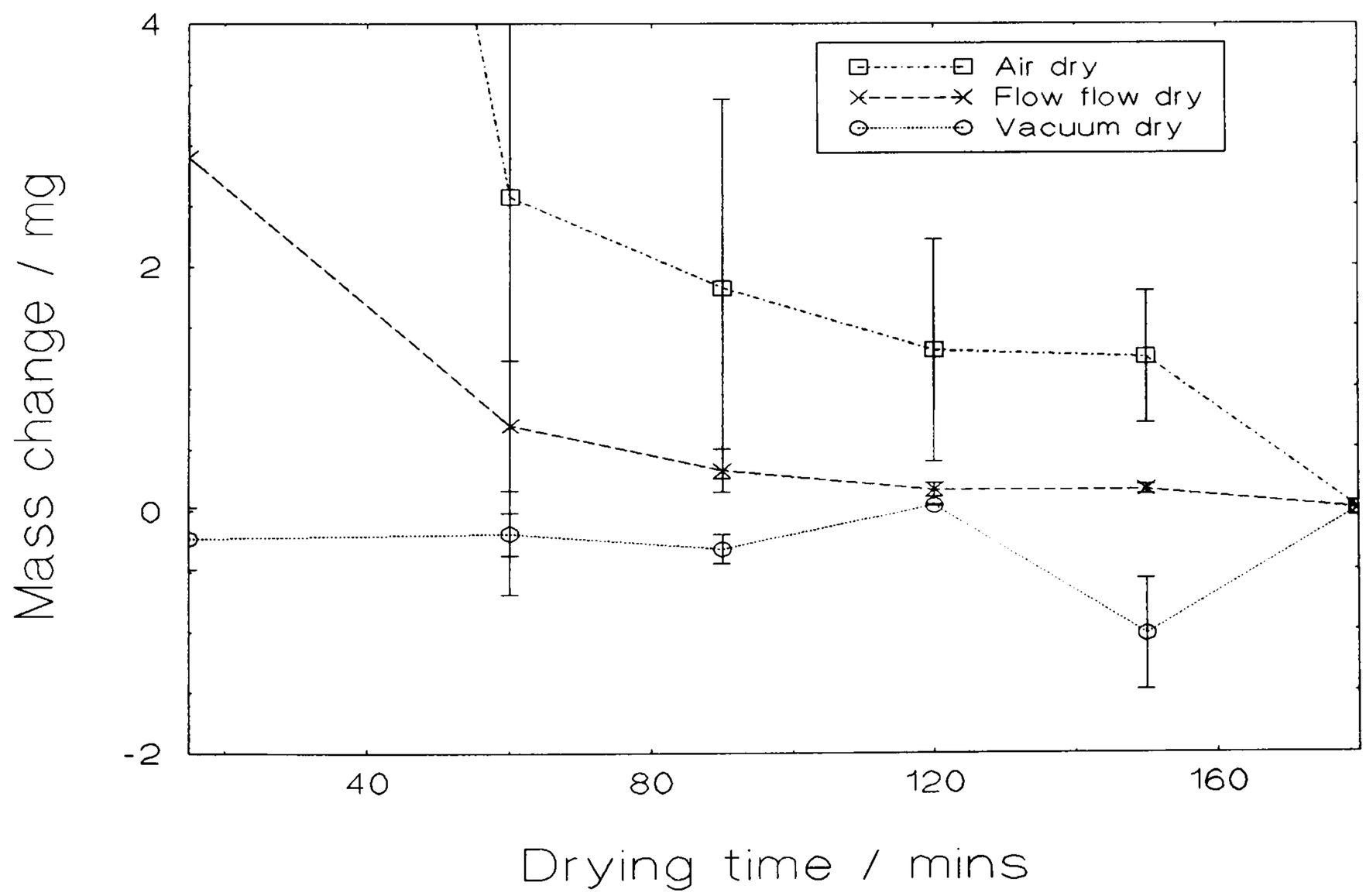


Figure 5.25 Mass change versus drying time investigating three cup drying techniques.

5.7 Wear debris analysis

The wear debris samples from the simulator were quantified in terms of particle diameter by percentage for both volume distribution and number distribution. In order to establish if the wear debris produced from the simulator was consistent with *ex-vivo* samples, five explanted tissue samples from three patients with THR's were used as a comparison. A sample from a reciprocating pin-on-plate (POP) test of polyethylene against stainless steel was also used for comparison.

The simulator sample from the AB Automation validation exercise conducted in distilled water for both PTFE and UHMWPE acetabular cups was analysed. Due to the design of the recirculating lubrication system a large reservoir meant that debris was diluted in a large volume of lubricant. Consequently, the particle analyser registered the presence of particles but there were insufficent particles to give any confidence in the result of the analysis.

The simulator sample from the gravimetric versus volumetric study conducted in bovine serum contained large quantites of debris lending confidence to the result. Figure 5.26 shows the volume distribution analysis for the simulator and reciprocating POP data, as well as the mean and standard deviation error bars for the *ex-vivo* data. It can be seen that the simulator is not too dissimilar from the *ex-vivo* data and the same can also be said for the POP test albeit with a markedly large peak near the 100 microns particle diameter size and little variation from that. A few large particles can skew the volume distribution considerably if the sample is composed primarily of small particles requiring the number distribution analysis to provide further information.

Figure 5.27 shows the number distribution by percentage of the different particle sizes. It can now be clearly seen that most of the POP particles are approximately 100 microns in diameter. The results for the simulator and *ex-vivo* samples are similar and are two magnitudes smaller than the POP results being concentrated around one micron diameter in size.

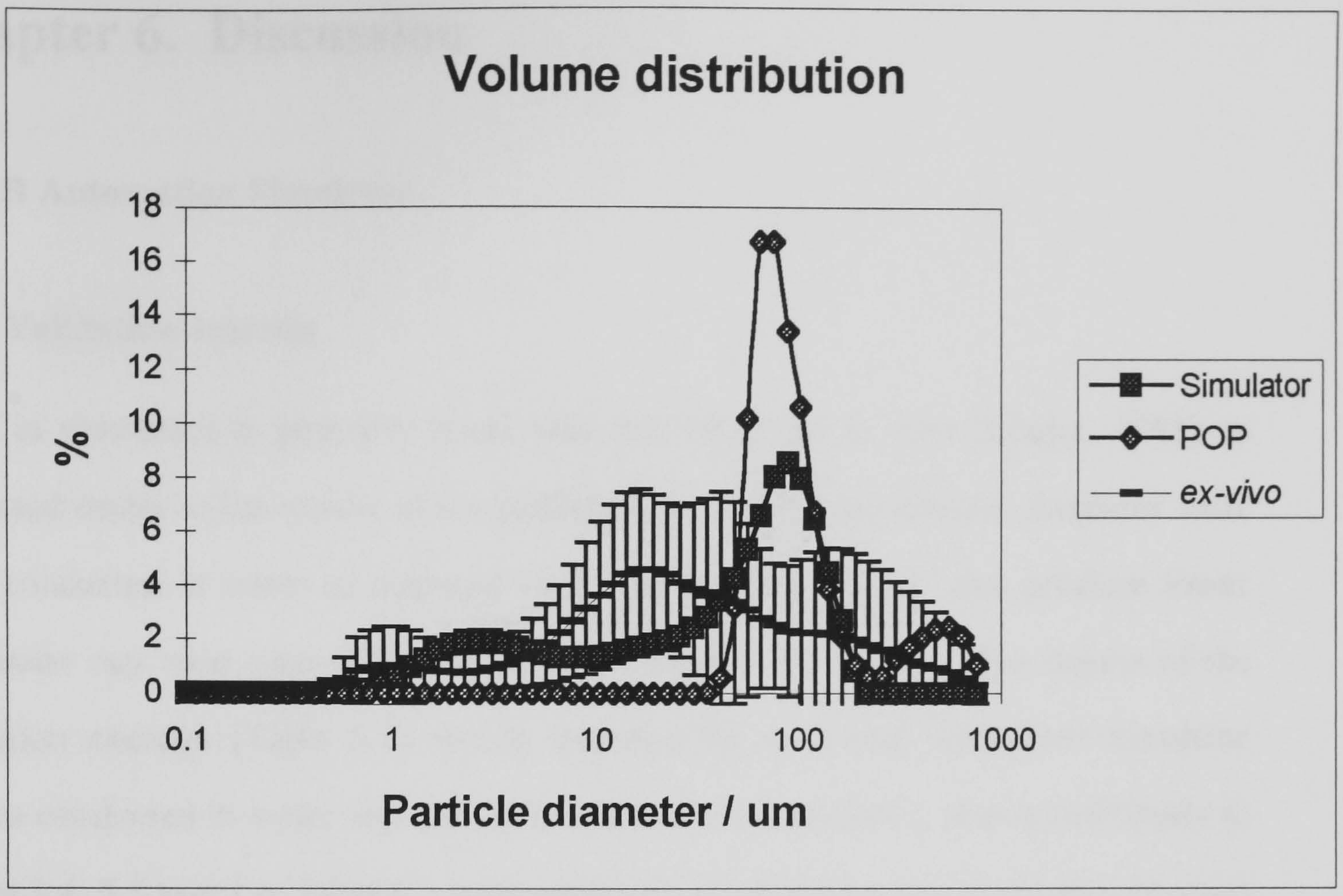


Figure 5.26 Wear debris particle size in terms of volume distribution by percentage of simulator, pin-on-plate and *ex-vivo* samples.

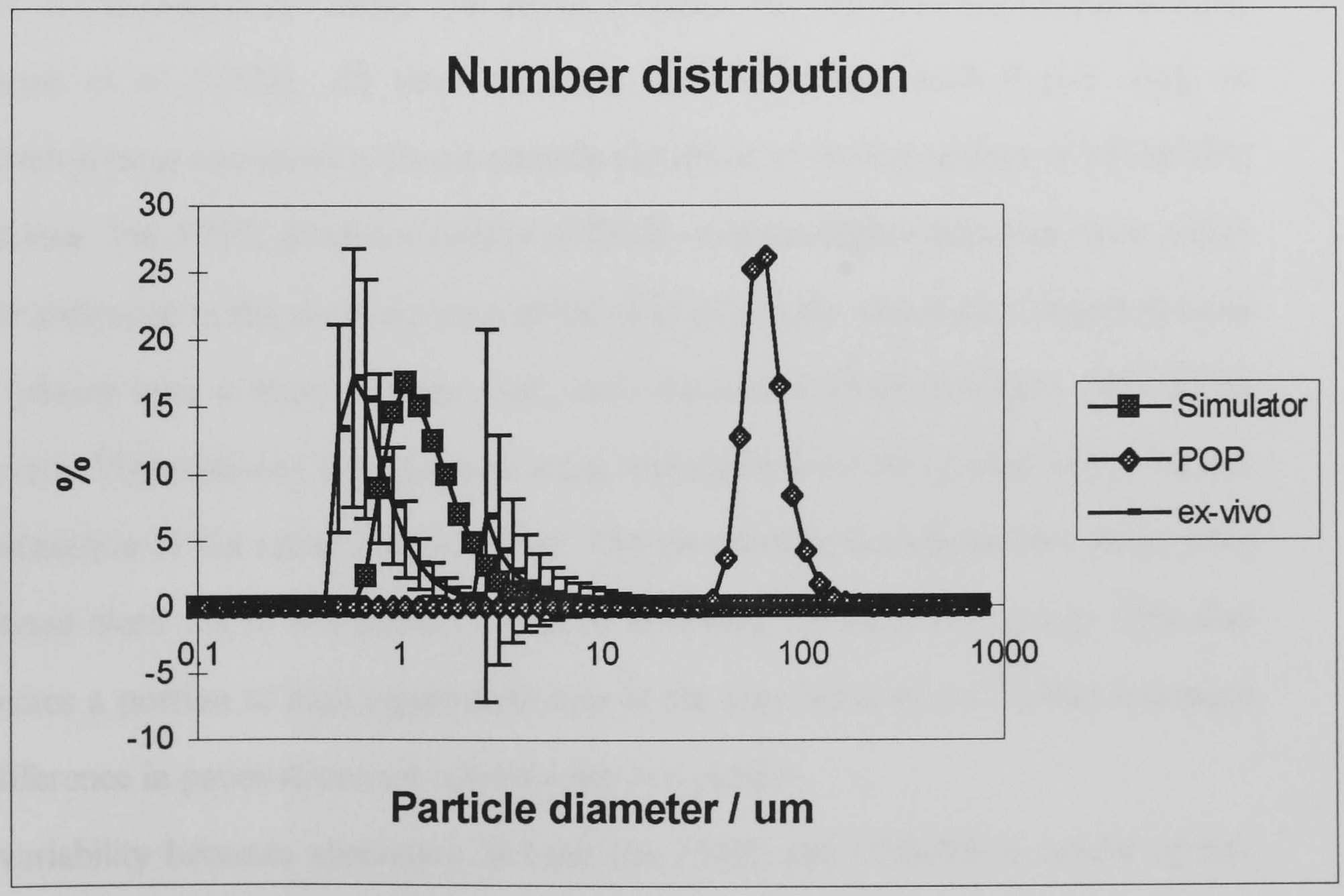


Figure 5.27 Wear debris particle size in terms of number distribution by percentage of simulator, pin-on-plate and *ex-vivo* samples.

Chapter 6. Discussion

6.1 AB Automation Simulator

6.1.1 Validation exercise

Wear in simulators is generally lower than that observed *in vivo* (Clarke, 1981) as discussed earlier in the review of the published literature. Furthermore, simulator wear tests conducted in water as opposed to bovine serum lubricant also produce lower acetabular cup wear rates (Good *et al*, 1996, Bigsby *et al*, 1997). The results of the validation exercise (Table 5.1) should therefore be compared with other simulator studies conducted in water and the limited clinical data available, shown previously in Tables 2.4, 2.5 and 2.6. Table 6.1 summarizes the results from this study and the most relevant studies from the three separate earlier tables.

The results for the PTFE cups from this study compare favourably with the clinical results of Charnley *et al* (1969), and are of a similar magnitude to the simulator study of Good *et al* (1996). All three of these studies feature much higher wear or penetration rates compared with comparable simulator or clinical studies of UHMWPE prostheses. The PTFE simulator results of Good *et al* are higher than this study which can be attributed to the short duration of Good *et al*'s study. Good *et al* reported three wear phases over a short duration test, each successive phase having a diminishing wear rate. This indicates that the cups were wearing-in over this period and were not representative of the mature joint *in-vivo*. The penetration rates from this study were calculated from 1.0 to 4.8 million cycles to eliminate the effects of creep. This also eliminates a portion of high penetration rate as the cups wear-in and further increases the difference in penetration rate between the two studies.

The variability between specimens in both the PTFE and UHMWPE results of this study has also been seen by Good *et al* (1996) and Saikko *et al* (1993). Good *et al* (1996) found that when wear testing in water the resulting wear rate precision varied between ±26% and ±70%. Saikko *et al* (1993) reported up to a twenty-nine times

difference between similar cups, with a mean difference of 6·3. The results for the UHMWPE cups from this study compare favourably with other simulator studies, except those of Saikko *et al* (1992, 1993). Furthermore, the UHMWPE results from this study are lower than clinical studies by a comparable magnitude to the PTFE results. Examination of all the acetabular cup replicas used in the shadowgraphic technique showed that the femoral component was tunnelling into the cup as observed *in vivo* (Atkinson *et al*, 1985a, Kabo *et al*, 1993).

6.1.2 Evaluation of the AB Automation simulator

The AB Automation simulator used a combination of load and motion cycles intended to reproduce a clinical load vector over the surface of the acetabular cup. The wear test results and the observation of the femoral heads tunnelling into the cups indicated that this was successful. However, the restriction to water and saline lubricants ultimately limited the relevance of the AB Automation simulator as a tool to test prostheses. Other protocol related problems with the simulator included the difficulty in confidently expelling air from the joint space prior to testing, and maintaining accurate and consistent loading in all stations over the full duration of the wear test. Difficulties with gravimetric wear measurement were also experienced as the acetabular cups could not be mounted without cement. Finally, the simulator was unreliable in a number of ways and the large number of parts and interfaces in the cell design made it difficult to maintain a water-tight system. It also presented cleaning difficulties.

This evaluation prompted the redesign of the AB Automation simulator to allow the use of bovine serum lubricant and anatomical mounting with a method of expelling air from the joint space prior to wear testing. The pneumatic system was also redesigned to improve performance, and reliability of the simulator generally was addressed.

Author	Prostheses	Measurement technique	Test duration (10^6 cys) or *ex-vivo cohort*	Wear rate ($mm^3/10^6$ cys) or *(mm^3/yr)*	Penetration rate ($mm^3/10^6$ cys) or *(mm^3/yr)*
This study	CoCrMo / PTFE	Gravimetric & Shadowgraphic	4.8	104, 368	0.148, 0.490
Good *et al,* 1996	CoCrMo / PTFE	Gravimetric	0.5	247 to 342$^+$	0.63 to 0.88*
Charnley *et al,* 1969	St. Steel / PTFE	*ex-vivo* cups sectioned & measured directly	*39*		*2.26 (0.91 to 6.04)*
This study	CoCrMo / UHMWPE	Gravimetric & Shadowgraphic	4.7	5.35, 9.72, 19.5	0.026, 0.045, 0.051
Dowson & Jobbins, 1988	St. Steel / UHMWPE	Shadowgraph	3.1		0.054
Saikko *et al*, 1992, 1993	St. Steel / UHMWPE	Gravimetric	3.0	49, 55, 67$^+$	0.15*
Derbyshire *et al*, 1994a	St. Steel / UHMWPE	CMM	2.0	9	
Brummitt & Hardaker, 1996	CoCrMo / UHMWPE	CMM	6.8	6	
Charnley & Hayley, 1975	St. Steel / UHMWPE	Radiographic	*63*		*0.15*
Livermore *et al*, 1990	CoCrMo / UHMWPE	Radiographic	*227*	*47.5 ± 36.2 (0 to 147)*	*0.13 ± 0.1 (0 to 0.39)*
Hall *et al*, 1996b	St. Steel / UHMWPE	Shadowgraph	*129*	*55 (SE=5)*	*0.20 (SE=0.08)*
Kesteris *et al*, 1996	CoCrMo / UHMWPE	Radiographic	*33*	*57 (2 to 117)*	*0.15 (0.01 to 0.31)*

Table 6.1 22.25 mm diameter PTFE and UHMWPE acetabular cup wear rates from simulator and clinical studies.

$^+$ Wear rate in $mg/10^6$ cys converted to $mm^3/10^6$ cys by dividing by the relative density of the acetabular cup material.

* Penetration rate calculated from the wear rate by assuming that the femoral head bores a cylinder into the acetabular cup.

6.2 Gravimetric versus volumetric wear measurement

6.2.1 Gravimetric versus volumetric measurement

The observation by Saikko *et al* (1992) that loaded controls gained more mass due to water absorption than unloaded soak controls was seen in both wear tests. Consequently, true mass loss calculations of the wear samples took into account the mass uptake of the loaded samples. Wear testing using gravimetric measurement therefore should incorporate a creep station to account more accurately for the moisture absorbed by the wear samples.

The deformation due to creep with test duration shown in figure 5.8 is consistent in form with that found by Bigsby *et al* (1997). Several other studies also report creep reaching a maximum in the first half a million (Goldsmith and Dowson, 1999) or million cycles (Brummitt and Hardaker, 1996, Derbyshire *et al*, 1994a). The amount of creep measured in various simulator and clinical studies varies, as indeed it will depending on material, geometry and load. However, the magnitude of the creep between the various studies is surprisingly similar, between 5 and 15 mm^3, for most simulator and clinical studies (Hall *et al*, 1996a). Exclusion of the volumetric data from the initial part of the wear test to allow creep to stabilise, when calculating volumetric wear rates, is also consistent with other authors (Bigsby *et al,* 1997, Barbour *et al*, 1999a,b, Goldsmith and Dowson, 1999).

Table 6.2 compares the wear results of this present study with other comparable *in vitro* studies of 28mm diameter prostheses. The wear rates quoted for this study are the overall wear rates for the full test duration to allow comparison with the other published results which generally use this method. This study showed that UHMWPE acetabular cup wear rates were higher against CoCrMo femoral heads than against zirconia femoral heads. Generally, tests with ceramic femoral heads gave lower wear rates than metallic heads (Clarke *et al*, 1993, McKellop *et al*, 1995a, Clarke *et al*, 1997, Barbour *et al*, 1999a,b). This study showed good agreement with published acetabular cup wear rate studies conducted in bovine serum. Interestingly, the later tests by Barbour et al (1999b) show even closer agreement than his earlier test did (1999a), both tests using the same type of prostheses and lubricant. This is most

probably attributable to two reasons. One reason may be the use of a Prosim simulator in the later tests which features loading actuators which swing with the femoral component, as does the simulator used in this study. Secondly, as discussed earlier, the loading cycle was extended in the later test which will cause more wear.

Table 6.3 gives the wear results from this study and compares them with clinical results for 28mm diameter prostheses. It can be seen that the results compare favourably as *in vitro* wear is generally less than *in vivo* wear. In a simulator, it is highly unlikely that bone or cement particles could contaminate the joint space causing possible damage to both the femoral head and acetabular cup whereas in the body this is a distinct possibility. The UHMWPE acetabular cups tested *in vitro* have frequently had shorter post irradiation ageing than cups which have been implanted. The motion and loading cycles applied by simulators are generally smooth, continuous walking patterns without the extremes seen clinically when a patient may run, climb or descend stairs, rise from a chair, or even trip and possibly fall.

As discussed in the literature review, wear measurement of *in vivo* prostheses is principally restricted to radiographic measurements. The difficulties associated with making accurate measurements using this technique are widely recognised (Charnley and Halley, 1975, Hall *et al*, 1995, Smith P N *et al*, 1997). Accurate *ex-vivo* wear measurements are possible by a number of methods. However, most *ex-vivo* studies use prostheses retrieved at revision surgery which are therefore more likely to show excessive wear. Sychterz *et al* (1996) retrieved 32mm diameter prostheses from cadavers, and found the *ex-vivo* wear rate to be 45 to 69 per cent less than that of comparable 32mm diameter prostheses retrieved at revision. Applying the same logic and ratio to the 28mm diameter prostheses results of Kabo *et al* (1993), who based their study on revision operation retrievals, would gave a wear rate of 23.4 to 41.6 $mm^3/10^6$cys. These values are clearly comparable to the *in vitro* results of this study.

The two wear phases shown by all prostheses were identified by both measurement techniques. The difference in acetabular cup wear rates against the different femoral head materials was also identified with both measurement techniques. The biphasal wear observed in this study has been noted by other authors, (Dumbleton, 1978, Wroblewski *et al,* 1996, Goldsmith and Dowson, 1999). Jasty *et al* (1997) found a statistically significant relationship between the duration the implant had been *in situ*

and the acetabular cup wear rate. Cups that had been *in situ* for short durations had significantly higher wear rates than cups *in situ* longer.

No statistically significant difference was found between the wear rates measured using gravimetric and volumetric methods for any of the wear test intervals analysed. In Table 6.2 it is difficult to notice any discrepancies between gravimetric and volumetric measurement results. For example, if we compare the results of Clarke *et al* (1993) and Besong *et al* (1998a) using gravimetric and volumetric measurement respectively for ceramic against polyethylene joints, similar wear rates of 35 and 32 $mm^3/10^6$ cys were measured. Bragdon *et al* (1998) used gravimetric and volumetric wear measurement in a study of 22, 26 and 32mm diameter femoral heads. The CMM was used principally to identify where most of the wear had occurred in the cups, but volumetric wear rates were quoted. This can be compared against gravimetric wear rates calculated using the density of UHMWPE. For example, for the 22mm diameter results the wear rates were 18.9±2.9 and 20.8±2.5 $mm^3/10^6$ cys for the gravimetric and volumetric methods respectively. No statistical difference between the measurement methods was found for each head size.

The gravimetric versus volumetric study formed part of a larger collaborative research project for the Department of Trade and Industry CAM 1 project entitled, 'Accelerated Test Methods to Predict the Durability of Materials and Surface Treatments Employed for Total Hip Replacements'. At the start of this project a testing protocol was discussed and established to ensure consistency in the project between tasks and research groups. One of the protocols established was to use prostheses of the same design, from the same manufacturer, manufactured at the same time. Consequently, there has been inevitable ageing of the irradiated polyethylene components which has been shown to have an adverse effect on the wear performance of the material (Besong *et al*, 1998b). Statistical analysis of the wear rates revealed no statistical difference between the two wear tests of the gravimetric versus volumetric study. However, when conducting a series of wear tests over an extended period of time it may be advisable to use polyethylene components of the same age from test to test rather than from the same original batch.

The concentration of bovine serum and the volume used in each station (Wang *et al*, 1999) has been researched. The frequency with which the lubricant is replaced during a wear test is probably similarly important. The importance of the prostheses

orientations was recognised (Wang *et al*, 1999, McKellop *et al*, 1999) although not yet quantified for polyethylene joints. The work by Wang *et al*, suggested that reducing the mass of proteins per unit volume, increasing the volume of lubricant in each station, and anatomically mounting the prostheses are all preferential when testing. This study tested anatomically mounted prostheses in 520 ml of calf serum in each station with 52 mg/ml of protein prior to dilution. This compares with a maximum of 400 ml per station with initially 65 mg/ml of protein calf serum from Wang *et al*'s study using anatomically inverted prostheses, which may be considered a reasonable protocol. Therefore, in the absence of further research on the subject, at present, the protocol adopted in this thesis does not look unreasonable.

Author	Femoral head material	Lubricant	Measurement technique	Duration of test (10^6 cys)	Cohort	Wear rate (mm^3 / 10^6 cys)
Gravimetric versus volumetric study	Zirconia ceramic	Bovine serum	Gravimetric	5.0	5	$38.6 \pm 3.6^+$
Gravimetric versus volumetric study	CoCrMo	Bovine serum	Gravimetric	5.0	5	$48.2 \pm 3.7^+$
Gravimetric versus volumetric study	Zirconia ceramic	Bovine serum	CMM	5.0	5	41.0 ± 2.6
Gravimetric versus volumetric study	CoCrMo	Bovine serum	CMM	5.0	5	51.4 ± 3.0
Clarke *et al*, 1993	Alumina ceramic	Bovine serum	Gravimetric	1.6	1	35^+
McKellop *et al*, 1995a	Stainless Steel	Bovine serum	Gravimetric	3.0	3	55^+
Besong *et al*, 1998a	Zirconia ceramic	Bovine serum	CMM	4.0	1	32.1 ± 3.4
Maxian *et al*, 1997	Stainless Steel	Bovine serum	Gravimetric	3.0	3	51.1^+
Barbour *et al*, 1999a	Zirconia ceramic	Bovine serum	CMM	4.0	2	30.0 ± 2.3
Barbour *et al*, 1999a	CoCrMo	Bovine serum	CMM	4.0	2	41.6 ± 5.3
Barbour *et al*, 1999b	Zirconia ceramic	Bovine serum	CMM	5.0	5	41.2 ± 1.3
Barbour *et al*, 1999b	CoCrMo	Bovine serum	CMM	5.0	5	46.6 ± 5.6

Table 6.2 28 mm diameter UHMWPE acetabular cup wear rates from this study and other simulator studies.

$^+$ Wear rate in $mg/10^6$ cys converted to $mm^3/10^6$ cys by dividing by the relative density of the UHMWPE used.

Author	Femoral head material	Cohort	Measurement technique	Wear rate (mm^3 / yr)	Penetration rate (mm / yr)	Total wear volume
Gravimetric versus volumetric study	Zirconia ceramic	5	Gravimetric CMM	$38.6 \pm 3.6^+$ 41.0 ± 2.6		
Gravimetric versus volumetric study	CoCrMo	5	Gravimetric CMM	$48.2 \pm 3.7^+$ 51.4 ± 3.0		
Livermore *et al*, 1990	CoCrMo	98	Radiographic	47.5 ± 36.2 (0 to 147)	0.13 ± 0.1 (0 to 0.39)	521 ± 463 mm^3 (0 to 2249)
Cates *et al*, 1993	Titanium	134 (cups in shells) 99 (no shells)	Radiographic	66.1 ± 33.3 48.2 ± 38.1	0.107 ± 0.054 0.078 ± 0.062	395 ± 214 mm^3 330 ± 268 mm^3
Kabo *et al*, 1993	Stainless Steel	23	Shadowgraph	75.6	0.234	
Woolson & Murphy, 1995	CoCrMo	80	Radiographic		0.14 ± 0.09 (0 to 0.35)	
Pederson *et al*, 1995	CoCrMo	210 for 22 & 28mm dia. hips	Radiographic	70.9 ± 59.6 (at 10 yrs)	0.12 ± 0.10 (at 10 yrs)	
Sugano *et al*, 1995	Alumina	61	Radiographic		0.10 (0 to 0.31)	
Jasty *et al*, 1997	CoCrMo	12	Gravimetric (fluid displacement)	64.6 ± 30.1		
Devane *et al*, 1997	Titanium	69 (cemented) 70 (uncemented)	3D Radiographic	98.5 155.1		
Sychterz *et al*, 1998	CoCrMo & Ceramic	45 (Hylamer cup) 86 (Enduron cup)	Radiographic		0.12 ± 0.13 0.23 ± 0.29	
Oonishi *et al*, 1998	Alumina	50	Radiographic	51.0	0.08	

Table 6.3 28 mm diameter UHMWPE acetabular cup wear rates from this and clinical studies.

$^+$ Wear rate in $mg/10^6$ cys converted to $mm^3/10^6$ cys by dividing by the relative density of the UHMWPE used.

6.2.2 Femoral surface topography

Once the acetabular cups had worn-in, thus representing the mature joint *in-vivo*, the zirconia femoral heads generated 33.3 $mm^3/10^6$ cys of UHMWPE wear debris whilst the CoCrMo heads produced 40.8 $mm^3/10^6$ cys under identical conditions. This was statistically significant ($p=0.03$). For all surface parameters, except skewness, the zirconia femoral heads were smoother than the CoCrMo femoral heads prior to wear testing. Skewness is a statistical term describing the shape of the amplitude distribution and low negative values are indicative of a good bearing surface. It is therefore unsurprising that there is no statistical difference in skewness between the femoral heads as they are excellent bearing surfaces. Therefore, since the standard production surface finish of the zirconia femoral heads is superior to the CoCrMo heads, this gives a significant reduction in UHMWPE acetabular cup wear rate.

Over the duration of the wear test there were no statistically significant changes in any of the surface parameters for the zirconia heads. The CoCrMo femoral heads roughened to an extent that was statistically significant for most surface parameters. Zirconia femoral heads therefore showed improved scratch resistance over CoCrMo femoral heads which is likely to lead to longer life than joints with CoCrMo femoral head components. These results support the suggestion of Pulliam and Trousdale (1997) that ceramic femoral heads should be preferred to metallic heads in primary arthroplasty because of their improved surface roughness and scratch resistance, although the authors had not quantified this statement.

The results from this study are summarized with some other surface topography studies in Table 6.4. Very few studies have used the latest generation of non-contacting optical interference profilometers as used in this study. However, Brummitt *et al* (1996) made use of both an optical interferometer and a Talysurf stylus machine. Using the interferometer to measure two explanted CoCrMo heads, the surface roughness values were very similar to the values from this study for the worn CoCrMo heads. Using the Talysurf to measure the same heads the surface roughness values were much higher. This indicates that surface roughness values of the same heads using different techniques can lead to substantially different values.

Kusaba and Kuroki (1997) also measured similar surface roughnesses to Brummit *et al* using a stylus type machine to measure 36 explanted CoCrMo heads.

Derbyshire *et al* (1994a) measured much larger surface roughnesses than found in this study for zirconia femoral heads, but as the authors used a Talysurf this may be expected. What Derbyshire *et al*'s and other studies indicate is that both new and worn ceramic heads are often substantially smoother than equivalent CoCrMo heads, as found in this study. An example of the superior scratch resistance of ceramic heads over metallic femoral heads was demonstrated by Minakawa *et al* (1998) who could find no obvious damage to alumina explants compared to CoCrMo explants.

The femoral heads in this study were mapped and measured using 26 points on the pole of the cup and then on annuli at 5°, 10°, 15°, 20° and 25°. The mapped area revealed no obvious pattern in the distribution of scratches or damage to the femoral heads following wear testing. The scratches were multi-directional and clearly not aligned to any particular orientation. These observations were consistent with a study of explanted CoCrMo femoral heads by Jasty *et al*, (1994) using optical and scanning electron microscopy. Hall *et al* (1996b) used a SEM to make similar observation to Jasty *et al* for a series of stainless steel Charnley explants. The authors also used a Rodenstock laser profilometer and found no significant difference between surface parameters measured in either the anterior/posterior and the medial/lateral directions which also agrees with the findings of this study.

Author	Femoral head material	Cohort (for mean reported here)	Measurement method	Mean Surface Roughness, Ra (unless specified otherwise)
Gravimetric versus volumetric study	CoCrMo	5 worn in simulator for 5 million cycles	Optical Interference Profilometer	new = 0.005μm, worn= 0.011μm
Gravimetric versus volumetric study	Zirconia	5 worn in simulator for 5 million cycles	Optical Interference Profilometer	new = 0.003μm, worn= 0.003μm
Brummitt *et al*, 1996	CoCrMo	2 explants	Talysurf & interferometer	worn = 0.011μm (interferometer) worn = 0.028μm (talysurf)
Kusaba & Kuroki, 1997	CoCrMo	36 explants	Stylus machine	worn = 0.023μm
Derbyshire *et al*, 1994a	Zirconia	2 worn in simulator for 2 million cycles	Talysurf	new = 0.013μm, worn = 0.039μm
Kusaba & Kuroki, 1997	Alumina	54 explants	Stylus machine	worn = 0.015 μm
Minakawa *et al*, 1998	CoCrMo	5 explants	Talysurf & Laser profilometry	Mean Rpm = 0.9864μm in damaged areas
Minakawa *et al*, 1998	Alumina	5 explants	Talysurf & Laser profilometry	Mean Rpm = 0.0238μm. No damage evident.

Table 6.4 This and other surface topography studies of new and worn femoral heads of various materials.

6.2.4 Friction measurement

It is difficult to observe any difference in friction factor between zirconia and CoCrMo when friction testing new heads. This is shown in figure 5.10 for new femoral heads tested against both new and worn acetabular cups. This is expected as both materials are considerably harder than UHMWPE so when operating in a mixed lubrication regime, friction will be due partly to shearing of the lubricant and partly the asperities of the UHMWPE in contact with the much harder femoral material. The frictional properties of fifty-four new prostheses of various designs has been investigated over two separate studies, (Saikko, 1992, Unsworth *et al*, 1994). The joint designs were of various sizes and femoral materials, but all featured an UHMWPE acetabular cup. No significant differences in the coefficient of friction was observed between the various designs.

The worn heads gave higher friction than the new heads, as shown in figure 5.13 when new and worn heads were friction tested against a worn acetabular cup. The same observation was less pronounced in figure 5.12 when friction testing against a new acetabular cup. In a study using a larger population, friction of worn heads against worn acetabular cups was not statistically significant from new heads and cups (Elfick *et al*, 1998b).

The worn acetabular cup gave lower friction than the new acetabular cup. This was true against both femoral head materials and was particularly marked against new femoral heads (see figure 5.10). This observation is particularly interesting in light of the two wear phases observed in the wear testing. The wear phase from 2 to 5 million cycles was significantly lower than the initial wear phase up to 2 million cycles, attributed to wearing-in of the acetabular cup. Measurements of the acetabular cups worn regions (Table 5.3) showed that the worn region of a cup was significantly smoother than the unworn region, for this series of cups. The reduction in surface roughness of the acetabular cup reduces the number of contact asperities between the acetabular and femoral components. This results in a greater portion of the load across the joint being carried by the fluid in the joint space and hence reduces friction.

6.2.5 Area of worn acetabular region

Whilst the wear rate measurements, for both gravimetric and volumetric techniques, very clearly showed two distinct wear phases suggesting wearing-in of the acetabular cups, scientific evidence of this was desirable. The friction tests showed lower friction in the worn acetabular cups, which was attributed to the worn region of the acetabular cups being significantly smoother than the unworn region. However, both the friction and acetabular cup surface topography measurements only compared the cups before and after 5 million cycles of wear testing and not about the crucial two million cycle point. Replicas of the acetabular cups allowed the area of the worn region to be measured so that the growth of its development over the wear test could be analysed. The worn region grew extremely rapidly over the first two million cycles of the test. From two to five million cycles of the test the worn region grew in a linear fashion at only $30mm^2/10^6$ cys. This small growth in the area can be attributed to the femoral head tunnelling into the acetabular cup. The intercept of the linear regression line indicated an area of $834mm^2$ that had developed as a result of the cup wearing-in, rather than a portion of wear that could otherwise be attributable to femoral tunnelling. This shows that the acetabular cups were wearing-in over the first two million cycles of the wear test, and that the high wear phase existed until the full worn region area had developed.

6.2.6 Evaluation of the Mk.I Durham hip joint simulator

The Mk.I Durham simulator proved to be extremely reliable during wear testing which is essential to completing multiple wear tests over the course of a study such as that reported in this thesis. The acetabular cup wear rates measured by either gravimetric or volumetric measurement showed excellent agreement with both simulator and clinical studies. Measurement and inspection of the femoral heads surface topography was entirely consistent with clinical findings and provided a useful indication of differences in scratch resistance between zirconia and CoCrMo femoral heads. Visual inspection of the acetabular cups surface topography was made with optical microscopy, non-

contacting profilometry and SEM, as discussed later. No notable difference between the cups worn with physiological motion and loading in this study, and a sample of retrieved liners from cementless implants was found. For example, multi-directional scratching was observed at ten times magnification using optical microscopy. Wear debris from the simulator was also similar to debris from retrieved tissue samples for both mass and volume particle size distributions (discussed later).

As with the earlier AB Automation simulator, the choice of motion and loading cycles were such that the clinical wear vector was reproduced in the acetabular cup. However, in contrast to the older simulator, the new pneumatic system of the Mk. I Durham simulator provided totally consistent performance over the duration of all the testing, and was common to all stations including the creep station. Air could be confidently expelled from the joint space prior to testing, which allowed anatomical testing without the risk of running the joints dry. The ability to mount acetabular cups without cement allowed accurate gravimetric measurement, to the extent that two very distinct wear phases were identified for every prosthesis tested in the gravimetric versus volumetric study.

In addition to the ability to test prostheses, the programmable motion and loading cycles and mechanical design of the Mk.I Durham simulator allowed research into simulator design. This work was subsequently undertaken and is discussed later, leading to understanding the limits of simplification of simulator design.

6.3 Simplified motion and loading

6.3.1 Simplified loading wear test

The UHMWPE acetabular cup wear rates against either zirconia or CoCrMo femoral heads with physiological motion and loading are comparable with a number of simulator and explant studies of 28mm diameter prostheses. The mean wear rate of the cups against zirconia ceramic heads was 32.2 $mm^3/10^6$ cys which compares favourably with simulator wear rates of 35.0 and 32.8 $mm^3/10^6$ cys found by Clarke *et al* (1993, 1997) conducted in bovine serum using alumina ceramic femoral heads.

A mean wear rate of 51.7 $mm^3/10^6$ cys for cups articulating against CoCrMo femoral heads was found in this study. McKellop *et al* (1995a) measured a cup wear rate of 55 $mm^3/10^6$ cys against 316 stainless steel heads in a simulator study conducted in bovine serum. An *in vivo* radiographic study by Livermore *et al* (1990) found a mean cup wear rate of 48.4 mm^3/ yr against CoCrMo femoral heads. Another radiographic study by Cates *et al* (1993) found mean cup wear rates between 48.2 to 61.6 mm^3/ yr against titanium femoral heads.

As discussed in the literature review, a study by Besong *et al* (1998a) investigated the simplification of three axes of loading to a single axis of loading during hip simulator wear testing. No significant difference was found in the wear rates and the conclusion drawn was that simplification to one axis of loading was acceptable when wear testing prostheses. Further simplification of the loading profile from a double peak waveform to a waveform approaching a square wave was investigated in this study. The shape of the simplified waveform as shown in figure 4.5 has rises and falls in load similar to the double peak cycle with a high load plateau replacing the double peak waveform. No significant difference was found between the UHMWPE acetabular cup wear rates using the double peak waveform and the simplified waveform against either zirconia or CoCrMo femoral heads.

Visual inspection of the surface of the cups worn with simplified loading using three optical methods revealed no notable differences with cups worn either *in vivo*, or with physiological motion and loading. This provides confidence that the wear mechanisms prevalent with simplified loading are similar to those with physiological loading and *in*

vivo. These findings suggest that the use of a simplified waveform, of the type tested in this study, is valid when wear testing.

6.3.2 Uni-axial motion

Barbour *et al* (1999a) continued the work of Besong *et al* (1998a) and simplified the simulator motion from three axes of motion to the flexion/extension and internal/external rotation axes only, as discussed previously. The simplification to two axes of motion was combined with simplification of the motion cycles to sinusoidal waveforms. Simplification of motion from three axes to only two axes was found to be acceptable provided that the simplified SHM cycles were 90° out of phase. A study by Bragdon *et al* (1996) found minimal UHMWPE acetabular cup wear rates using two axes of motion in a hip simulator when the combination of motion of the two axes were linked. Decoupling the two axes and applying physiological motion produced an open wear path and an average wear rate of 26.7 $mm^3/10^6$ cys. Wang A *et al* (1996) also observed similar variations in the wear performance of UHMWPE when subject to simple, linear reciprocating motion in a pin on wheel rig or multi-directional motion in a hip simulator.

The simplification of physiological simulator motion from two axes to one axis of motion produced extremely low acetabular cup wear. The area of the worn region in the acetabular cups was, by visual inspection, very much smaller than in cups subjected to two axes of motion. The worn region produced from simplified motion was concentrated near the pole of the cup whereas two axes of motion were shown to cause tunnelling of the femoral head into the cup in the AB Automation validation exercise (Smith *et al*, 1997, 1999b) and as seen *in vivo* (Atkinson *et al*, 1985a, Kabo *et al*, 1993). Using the scanning electron microscope at 5000 times magnification, parallel ripples were seen on the surface of the cups (figure 5.17) as observed by Bragdon *et al* (1996) and Wang A *et al* (1996). Therefore, the simplification of hip joint wear simulators to only one axis of motion would give unrepresentative wear rates whilst two axes of motion are acceptable provided that the motion of the two axes produce an open wear path (Barbour *et al*, 1999a, Bragdon *et al*, 1996).

6.3.3 Evaluation of simplification of simulator design

The simplified loading study showed that simplification to the loading cycle, of the type studied, was an acceptable simplification to simulator design. A control system designed to produce the simplified loading using the pneumatic system on the Durham simulator would be extremely simple as only three voltage changes per cycle are needed to control the pneumatic proportional valve. This would represent a large saving in capital expense on a new simulator over the complex control system used on the Mk.I. Durham simulator to reproduce a physiological loading.

Simplification to one axis of motion of simulator design was found to be unacceptable. However, the work by Barbour *et al* (1999a) was encouraging and suggested that a simplified simulator could be designed that used sinusoidal motion cycles to produce an elliptical wear path. Approximately sinusoidal motion can be reproduced mechanically using a crank arrangement with a sufficiently long conrod. This would allow a single motor to drive both axes with only start/stop control features. Another large saving in capital expense over programmable control systems and stepper motors could then also be made.

As discussed earlier in the review of the published literature, Barbour *et al*'s study used a simplified loading profile which was not validated independently making it impossible to separate the effects of simplifying load and motion on the resulting cup wear rates. The simplified loading profile was incorrectly synchronised and of too short a duration in the gait cycle, subsequently extended to a more physiological duration in a later study (Barbour *et al*, 1999b). In addition, the magnitude of the flexion/extension motion was similar to that measured clinically, but the magnitude of the internal/external rotation was approaching double the measured clinical rotation (Johnston and Smidt, 1969, Gore, 1980). Visual inspection only of the acetabular cup surfaces was insufficient to make a comprehensive comparison between cup topography from their study and that found clinically. Any new simulator design and study needed to address these issues before confidence could be taken in the wear rate results.

6.4 Explanted femoral head wear test

6.4.1 Wear Test

Simulator wear tests generally produce lower wear rates than those for similar prostheses worn *in vivo,* as has been discussed. One reason given for this it that bone or cement particles could not contaminate the joint space in a simulator whereas *in vivo* this can occur causing possible damage to both the femoral head and acetabular cup. However, two of the explanted heads tested here were cementless which eliminated the possibility of cement contaminating the joint space and damaging either component. Despite simulator wear rate results being generally lower than clinical wear rates, the explanted femoral heads tested against new UHMWPE cups gave very high wear rates. The wear rates were alarmingly high, particularly when considering that all three explanted heads fell within the current British Standard surface roughness value of 50nm for new femoral heads. The wear rates are far higher than many radiographic studies shown in Table 6.3, and even exceed 28mm diameter explant studies such as that of Kabo *et al* (1993) who found a wear rate of 75.6 mm^3/ yr.
In contrast to the earlier gravimetric versus volumetric measurement study, no initially high wear rate phase attributable to wearing-in of the acetabular cup was observed. This observation was confirmed statistically and was due to the very high acetabular cup wear rates against the explanted femoral heads. This caused the duration of wearing-in period to be so short as to be indistinct from the wear rate thereafter, which was representative of the mature joint *in vivo.*

6.4.2 Explanted femoral head surface topography

In the review of published literature on wear, several studies linked femoral head surface roughness to acetabular cup wear rate. Hall *et al* (1996a) established a relationship between clinical wear factor and surface roughness in an explant study of 129 explanted Charnley sockets, 99 paired with the explanted femoral head. Clinical wear factor was found to be proportional to surface roughness, Ra, raised to the

power 0.54. Hall *et al*'s power relationship is very close to the relationship found in this study in which root mean square roughness, Rrms, is proportional to wear rate raised to the power 0.552. This study has a limited number of data points and further testing is required to elucidate the relationship further. However, the similarity in results between these studies, indicates that the relationship is unlikely to be significantly different.

The microasperity model devised by Wang *et al* (1995) was revised when they studied wear rate and roughness in a hip simulator (Wang *et al*, 1998). The authors found what they considered a linear relationship between wear factor and arithmetic surface roughness, Ra. However, they also performed analysis with power functions for comparison with the work by Hall *et al* (1996a) and found wear factor proportional to $Ra^{0.42}$. The simulator study used 32 mm diameter CoCrMo femoral heads roughened with graded SiC to produce multi-directional scratching which the authors considered representative of *in vivo* scratched heads. The tests were of one million cycles duration which was shown here in the gravimetric and volumetric study to be of too short a duration to represent the mature joint *in vivo*. Consequently, at low surface roughnesses wear rates would be higher than in the mature joint, impacting on the relationship between surface roughness and wear rate. If the tests had been conducted over a longer duration the magnitude of the power relationship would increase bringing the result closer to that found by this study and Hall *et al*.

It has been proposed by a number of studies that loosening of an implant is related to the total volume of wear debris, as shown in Tables 2.6 and 2.8. This study has shown, using explanted femoral components, that once the femoral head becomes roughened the acetabular cup wear rate rises substantially. Loosening through osteolysis induced by wear debris will consequently be induced far quicker and the implant will fail prematurely. The benefits of improving production surface finish and scratch resistance have already been observed in the study of new zirconia and CoCrMo femoral heads. The relationship developed here adds further weight to those arguments.

A relationship between surface roughness and wear rate can be of further use in prostheses manufacturing. By knowing the relationship between surface roughness and wear rate, the balance between the cost of improving surface finish and benefits in longevity of implants can be optimised.

6.5 Mk.II Durham hip simulator validation exercise

6.5.1 Wear Test

Three separate linear wear phases were identified over the course of the wear test. The first wear phase from zero to one million cycles gave the highest wear rate and can be attributed to the acetabular cup wearing-in. The wear rates thereafter represented the mature joint and allowed direct comparison with other studies and between changes to the simulator motion.

From one to three million cycles the mean acetabular cup wear rate was 67.2 $mm^3/10^6$ cys. This can be compared with the 30.0 $mm^3/10^6$ cys wear rate from Barbour *et al*'s (1999a) study using the same motion, prostheses and lubricant, but a different type of simplified loading. The simplified loading used in this study has previously been validated against physiological loading in the simplified loading study and made no significant difference to the wear rates. The simplified loading in Barbour *et al*'s study, as discussed previously, was not validated independently. Their simplified loading profile was incorrectly synchronised and of too short a duration in the gait cycle (Paul, 1967). The substantial difference in wear rates between the studies implies that the simplified loading of Barbour *et al* (1999a) which extends for only half the gait cycle is an unacceptable simplification of the physiological cycle.

The magnitude of the flexion/extension motion used in this study and that by Barbour *et al* (1999a,b) was similar to that measured clinically. However, the magnitude of the internal/external rotation used by Barbour *et al* was approaching double the measured clinical value (Johnston and Smidt, 1969, Gore, 1980). From three to five million cycles the magnitude of the internal/external rotation motion in this study was reduced so that it was representative of that measured clinically. Mean acetabular cup wear rate subsequently reduced to 52.2±3.3 $mm^3/10^6$ cys which bears close comparison with several clinical studies. For example, in radiographic studies, Livermore *et al* (1990) and Cates *et al* (1993) found wear rates of 47.5±36.2 mm^3/yr and 48.2±38.1 mm^3/yr respectively. A ceramic study by Oonishi *et al* (1998) found a mean wear rate of 51.0 mm^3/yr, whilst explant studies of Jasty *et al* (1997) and Kabo *et al* (1993) found wear rates of 64.6±30.1 mm^3/yr and 75.6 mm^3/yr respectively.

6.5.2 Femoral and acetabular surface topography

The femoral head surface parameters measured for the five zirconia heads tested did not change significantly over the course of the wear. This observation is entirely in agreement with the findings of the five zirconia femoral heads tested in the Mk.I Durham simulator with physiological motion and loading in the gravimetric versus volumetric measurement study. The acetabular cup surface topography was also consistent both with *ex-vivo* cementless cups and cups worn with physiological motion and loading on the Mk.I Durham simulator, using optical microscopy, non-contacting profilometry and SEM methods.

6.5.3 Wear path analysis

The choice of motion cycles from zero to three million cycles was the same as used by Barbour *et al* (1999a,b). Using these motion cycles, a point taken on the femoral head traced an open elliptical wear path in the acetabular cup. Once the acetabular cups had worn-in, the mean acetabular cup wear rate was 67.2 $mm^3/10^6$ cys. This can be compared with the 33.3 $mm^3/10^6$ cys for five zirconia femoral heads tested in the Mk.I Durham simulator with full physiological motion and loading once the cups had worn-in. The Mk.II Durham simulator used a simplified loading cycle, that was validated in the simplified loading study and did not cause a significant difference to acetabular cup wear rates. Therefore, the large difference in wear rates can be attributed to the difference in motion cycles as the prostheses, lubricant and protocol were all similar.

In the literature review on 'wear', theory predicted that wear is directly proportional to sliding distance (Archard, 1953). Therefore, the ratio between wear rates due to the elliptical and physiological wear paths should be in the same ratio as the length of the wear paths according to theory. The mean wear rates for the elliptical and physiological motions cycles were 67.2 $mm^3/10^6$ cys and 33.3 $mm^3/10^6$ cys respectively, that is in a ratio of 2.02 to one. The length of the wear paths traced by the same point on the femoral head for the elliptical and physiological motions cycles was 21.56 mm and 16.24 mm respectively, or 1.33 to one as a ratio.

This discrepancy may be attributed to that portion of the physiological wear path which is effectively linear and as such produces negligible wear as found in the uni-axial study. Two portions of the wear path shown in figure 5.19 are effectively linear and when the length of the wear path excludes these the physiological wear path length is 10.51 mm. The elliptical wear path is 2.05 times longer than this, a similar ratio to the wear rates as predicted by theory.

This analysis can now be applied to the tighter ellipse caused by the reduction in internal/external rotation, from three to five million cycles, and compared with the physiological cycle. The ratio between wear rates of 52.2 $mm^3/10^6$ cys and 33.3 $mm^3/10^6$ cys is 1.57 to one. The ratio between wear path lengths of 20.98 mm and 10.51 mm is 2.00 to one. This discrepancy may be due to the aspect ratio of the tighter ellipse being such that motion at the end portions of the ellipse are effectively linear and as such produce negligible wear. However, further testing would be required to confirm, or otherwise, this theory and identify at which point the aspect ratio causes a sufficiently tight ellipse to cause effectively linear motion over part of each cycle.

6.5.4 Evaluation of the Mk.II Durham hip joint simulator

The initial choice of internal/external rotation magnitudes was to allow direct comparison with the work of Barbour *et al* (1999a) and hence a comparison of two different simplified loading cycles. The subsequent change in internal/external rotation magnitude allowed a comparison of the effect of simplified motion cycles on acetabular cup wear rate. Although designed as a tool to test prostheses, the simulator does have limited capabilities for testing motion and loading cycles.

The final choice of internal/external rotation was to make the magnitude of motion comparable with that found from clinical studies (Johnston and Smidt, 1969, Gore, 1980). The fact that the combination of motion cycles may produce an ellipse sufficiently tight to cause an element of linear motion, only serves to give the wear path more comparable features with the clinical wear path. It may be the case that a portion of linear motion may have significant clinical implications on the wear of new materials or treatments, which an open ellipse may not identify.

With simplified loading and simplified motion cycles of clinical magnitudes, the acetabular cup wear rates compared closely with many clinical studies. Examination of both femoral and acetabular surface topography also suggested that the wear mechanisms were common to those both *in vivo* and in hip simulators reproducing the clinical wear vector. The Mk.II Durham hip joint simulator used simplified motion and loading to achieve a realistic clinical simulation in a machine that was manufactured at a fraction of the cost to manufacture a simulator capable of reproducing a clinical wear vector. The simulator proved to be totally reliable but used, where possible, standard components which could be sourced extremely quickly in the event of a breakdown. The Mk.II Durham hip joint simulator represents a realistic, cost-effective alternative to most hip simulators currently available, as a tool for prosthetic testing.

6.6 Cleaning & drying protocol

When considering the effects of solvent type, it can be seen in figure 5.24 that the cups were initially gaining mass with time. UHMWPE is hydrophilic and the mass gain of the cups can be attributed to them rehydrating. The solvents therefore remove water from both the surface and the body of the UHMWPE cups, requiring time for the cups to reabsorb moisture from the atmosphere before reaching a steady state. Cups that had been immersed in ethanol approached the steady state equilibrium quickest, in approximately sixty minutes, with diminished standard deviations. Table 2.1 described the cleaning and drying protocols used by a number of research groups and advocated by standards. In all except one case, the drying time was of only thirty minutes duration which this study suggests is insufficient 'drying time' in most instances. This introduces errors into the gravimetric measurements of multiple specimens as the mass of the specimens will be changing rapidly over the several minutes it takes to weigh all the samples.

The study showed that following immersion of the cups in acetone for two minutes, two hours drying time would be sufficient to minimise errors due to rehydration. The gravimetric protocol used in this thesis, (except for the AB Automation validation exercise), employed this method successfully having validated it prior to wear testing. On the evidence of this study, immersion in ethanol for ten minutes followed by only one hour of drying would have been a preferable technique due to the reduction in drying time. However, it is advisable not to change protocol during the course of testing so the method using acetone was retained. In the case of the AB Automation exercise, the protocol involved immersion in methyl alcohol for three minutes followed by air drying overnight. The long drying time was necessary due to the porosity of the bone cement. This study showed that for cups without a cement backing, a drying time of approximately 150 minutes would be required following immersion in methyl alcohol.

The drying technique comparisons revealed that laminar flow cabinet drying was preferable to air drying because it reduced the length of time before measurements could be taken with reduced errors. As a result of this, in a wear test of polyurethane cups mounted in cement (Smith *et al*, 1999a), laminar flow cabinet drying was used in

preference to air drying to reduce the time required to take measurements. However, laminar flow drying and air drying are both satisfactory drying methods.

Vacuum drying reached the region of equilibrium by the first measurement at 15 minutes, but showed significant deviations over the course of the experiment due to the difficulties in obtaining a steady and consistent vacuum (figure 5.25). This finding has significant implications for studies using vacuum drying as part of their gravimetric protocol. It is highly unlikely that exactly the same vacuum can be pulled from measurement to measurement over the course of a multi-million cycle wear test. This will introduce an error into the gravimetric measurements. Furthermore, an important observation from the earlier part of the study into solvents and drying time was that UHMWPE cups that had been immersed in a solvent actually have to be exposed to atmosphere to allow them to rehydrate to a steady state. Obviously, following immersion in a solvent cups that are placed in a vacuum are not able to rehydrate. Therefore, once the cups are removed from the vacuum to be weighed on a balance they will immediately begin to rapidly gain mass as they rehydrate thus introducing more errors into the gravimetric measurements. A review of Table 2.1 shows that unfortunately vacuum drying has been widely used, often following immersion or cleaning in a solvent.

This study has shown that a number of protocols for cleaning and drying acetabular cups are acceptable in gravimetric measurement. The study also shows that adequate research into protocol is required before commencing a wear test to reduce the risk of introducing possible errors into the gravimetric method.

6.7 Wear debris analysis

The literature review of wear debris analysis highlighted problems with many of the published studies. This study used a digestion method followed by a particle analyser (Elfick *et al*, 1999a) to count significantly more particles than other studies and therefore give confidence to the results. Despite the use of the particle analyser, lubricant from the AB Automation validation exercise contained insufficient wear particles to give confidence in the results. This was due to the low acetabular cup wear rates in water producing limited debris which was then widely dispersed within the large volume of water in the lubrication system. However, the sample taken from the gravimetric versus volumetric study did contain large quantities of particles for analysis. This was compared with data from both *ex-vivo* tissue samples taken from around failed THR's, and lubricant from pin-on-plate (POP) testing of polyethylene against a stainless steel counterface. Although this comparison uses a small number of samples overall, and only one simulator sample, observations can be made between the *in vitro* and *ex-vivo* samples.

The volume distribution in figure 5.26 shows that the simulator and *ex-vivo* samples distributions spread over a range of particle diameters. This contrasts with the POP results which are concentrated around a particle diameter size of approximately 100 μm. Although the simulator volume distribution results are spread over a range of particle diameters like the *ex-vivo* samples, they also peak in the same region as the other *in vitro* POP results at approximately 100 μm.

Volume distribution can however be skewed considerably by the presence of relatively few large particles. The number distribution is therefore useful in elucidating which particles are the most common. Figure 5.27 clearly shows considerable difference between the POP results and both the simulator and *ex-vivo* results. The POP particles are mostly of approximately 100 μm diameter, as suggested by the narrow distribution of the volume distribution but only confirmed by the number distribution. The simulator volume distribution had a similar peak to the POP results at a particle size of approximately 100 μm diameter, but the spread of results was more comparable to the *ex-vivo* samples. In contrast to the POP results, the number distribution of the

simulator results was concentrated around 1 μm in diameter, similar to the *ex-vivo* results.

Although this study used only one simulator sample, one POP sample and only five tissue samples, notable differences between the particle sizes were noticed between the POP and the other samples. The simulator results are not too dissimilar from the tissue samples and the findings of other studies as shown in table 2.3 which lends further confidence in the ability of the simulators to reproduce clinical wear *in vitro*.

Chapter 7. Conclusion

No statistically significant differences were found between either gravimetric or volumetric measurement methods when measuring wear of UHMWPE acetabular cups. The gravimetric technique required loaded soak controls to compensate for moisture absorption due to the mildly hydrophilic nature of the UHMWPE. For the volumetric technique, only measurements taken after the first half a million cycles were used to allow creep of the polyethylene to stabilise.

A study of cleaning and drying protocol showed that following immersion in a solvent, UHMWPE acetabular cups needed exposure to atmosphere to allow rehydration to a steady state. The use of solvents followed by vacuum drying was therefore considered unsuitable as a gravimetric protocol. Depending on the solvent used, the period of air drying required varied before the cups reached a steady state at which gravimetric measurements could be taken. This period of time can be reduced through the use of a laminar flow cabinet.

In the gravimetric versus volumetric study, both measurement techniques identified two distinct, statistically significantly different, linear wear phases for all the acetabular cups. An initial high wear rate was observed from zero to two million cycles, followed by a lower wear rate from two to five million cycles. Friction testing of new and worn prostheses revealed lower coefficients of friction with worn prostheses as opposed to new prostheses. This was attributed to the acetabular cups being significantly smoother once worn. Growth of the area of the worn region in the acetabular cups was measured and found to grow rapidly over the first two million cycles. Thereafter, the worn region grew at a small linear rate caused by tunnelling of the femoral head into the acetabular cup. The significant difference in wear rates about two million cycles was therefore attributed to the acetabular cups wearing-in.

Mean acetabular cup wear rate was higher against CoCrMo femoral heads compared with zirconia femoral heads, as measured with both gravimetric and volumetric measurement techniques. This was attributed to the superior production surface finish of the zirconia femoral heads measured using a 3-D non-contacting optical interference profilometer. Over the course of the wear test the zirconia femoral heads showed no significant difference in their surface roughness, whereas the CoCrMo heads got

statistically significantly rougher over the wear test. Therefore, the zirconia femoral heads were more scratch resistant than the CoCrMo heads. Clinically, *in vivo* durations should be longer with zirconia femoral heads compared with CoCrMo due to the superior production surface finish and scratch resistance of the zirconia heads.

The wear rates of new acetabular cups against three explanted CoCrMo femoral heads were also investigated in this thesis. The measured cups wear rates against the explanted heads were two to three times higher than against new CoCrMo femoral heads. Acetabular cup wear rate was plotted against various surface parameters for the explanted heads and both new zirconia and CoCrMo heads. Root mean square deviation from the mean plane, Rrms, gave the strongest correlation of the various surface parameters, and wear rate was found to be proportional to Rrms raised to the power of 0.552.

Simplified loading, of the type studied, was found to be an acceptable simplification to simulator design. When simplified loading was compared with physiological loading no significant difference in acetabular cup wear rates or surface topography was found. Simulator capital cost savings could therefore be made due to the simplicity of the loading control system required for simplified loading. Simplifying simulator design to one axis of motion, (flexion/extension), was found to be unacceptable. Acetabular cup wear rates became negligible and acetabular surface topography was notably different from cups worn with full physiological motion and loading.

The AB Automation simulator used a combination of load and motion cycles intended to reproduce a clinical load vector over the surface of the acetabular cup. The wear test results were comparable with other studies in water, and tunnelling of the femoral heads into the cups was observed. This indicated that the philosophy of the load vector was successful, but variations in loading between stations and over the course of the wear test required improvement. The restriction to water and saline lubricants, as opposed to bovine serum, severely limited the relevance of the AB Automation Simulator as a tool to test prostheses.

The path of the load vector in the Mk.I Durham hip joint simulator was the same as that used in the AB Automation simulator. However, the loading between stations, including a creep station, over the duration of each wear test was consistent. Acetabular cup wear rates against new zirconia ceramic and CoCrMo femoral heads in

bovine serum using the Mk.I Durham simulator were comparable with a number of other studies. The surface topography of the femoral and acetabular components was examined using optical microscopy, non-contacting profilometry and SEM, and was consistent with clinical observations. Similarly, both mass and volume simulator wear debris particle size distribution was similar to that of a number of *ex-vivo* debris samples. In addition to the ability to test prostheses, the programmable motion and loading cycles and mechanical design of the Mk.I Durham simulator allowed research of simulator design.

The Mk.II Durham hip joint simulator used simplified loading and a combination of simplified motion cycles which reproduced an elliptical wear path over the surface of the acetabular cup. Using motion cycles of clinical magnitude, acetabular cup wear rates gave excellent agreement with simulator and clinical studies. Examination of both femoral and acetabular surface topography also suggested that the wear mechanisms were common to those both *in vivo* and in the Mk.I Durham simulator reproducing the clinical wear vector. The Mk.II Durham hip joint simulator used simplified motion and loading to achieve a realistic clinical simulation and can be used as a tool for prosthetic testing. The simulator was manufactured at a fraction of the cost to manufacture a simulator capable of reproducing a clinical wear vector and represents a realistic, cost-effective alternative to currently available commercial hip simulators.

Chapter 8. Future work

This study has examined many aspects of wear study protocols. Lubricant type was considered during the evaluation of the AB Automation simulator and bovine serum was subsequently used in the evaluation of the Mk.I and Mk.II Durham simulators. However, further work on lubricant type, composition, volume, frequency of renewal and so on, to that already studied, (Wang *et al*, 1999, McKellop *et al*, 1999), would be of further benefit to understanding wear test protocol. Similarly, the temperature at which tests are conducted could also be studied.

The relationship between wear rate and various surface topography parameters could be investigated further. This was investigated within this study for ten new femoral heads and three explanted femoral heads, but more data is required to give greater confidence in the findings. The CoCrMo femoral heads worn in the gravimetric versus volumetric study got statistically significantly rougher over the course of the wear testing and could be re-tested. In addition, more explanted femoral heads of various roughnesses could help develop regions of the curve currently without data points.

The programmable control system for motion and loading cycles on the Mk.I Durham simulator could be used to investigate alternative activities to level walking. Activities such as walking up and down stairs, sitting down and rising from a chair, entering and exiting an automobile, standing and shuffling in a queue, could be studied. Studies of both the frequency with which these activities are undertaken (Schmalzried *et al*, 1998, Morlock *et al*, 1999, Ma *et al*, 1999), and the associated gait analysis (Andriacchi *et al*, 1980, Kerr *et al*, 1991, Hutchinson *et al*, 1994, Bergmann *et al*, 1995) could be used to design a 'day-in-the-life' wear test.

Elliptical wear path aspect ratio could be researched using the Mk.II Durham simulator. The hypothesis that as the elliptical wear path narrows beyond a certain aspect ratio effectively linear motion is realised over part of the wear path could be the focus of such a study. However, the Mk.II Durham hip joint simulator was designed as a tool to test and develop new prosthetic designs prior to clinical designs, and this should be the main purpose of the simulator for future work.

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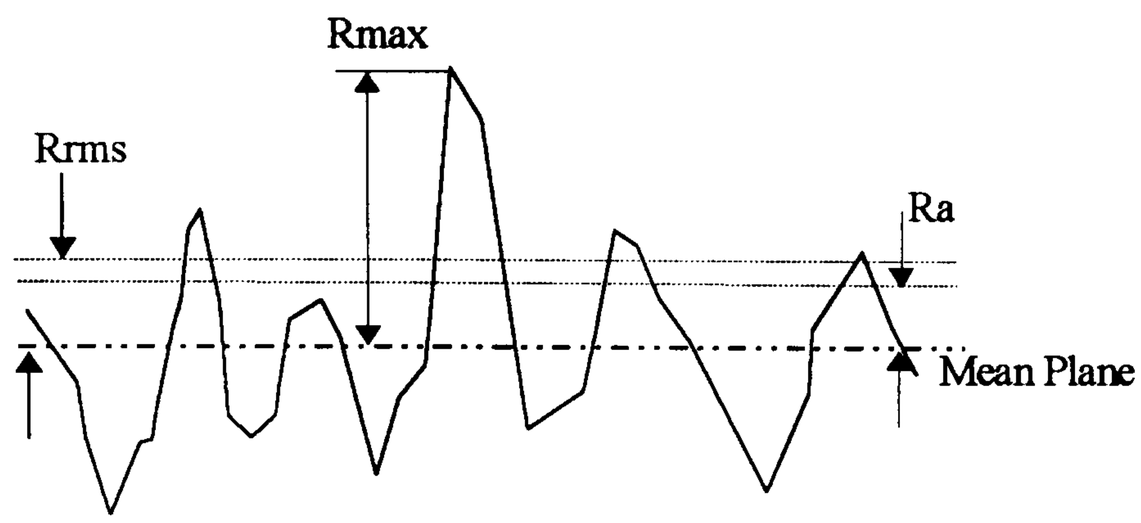
Appendix A. Surface topography

Texture Parameter Definitions



Rmax : Highest peak height. The height from the mean plane to the highest peak.

Ra : Arithmetic average deviation from the mean plane.

$$Ra = \frac{1}{L}\int_0^L |z| dx$$

Rrms : Root mean square deviation from the mean plane.

$$Rq = \sqrt{\frac{1}{L}\int_0^L z^2 dx}$$

Rsk : Skewness. The measure of the asymmetry of deviations about the mean plane. A statistical term which describes the shape of the amplitude distibution such that low negative values are indicative of good bearing surfaces.

$$R_{sk} = \frac{1}{R_q^{\,3}}\int_{-\infty}^{\infty}\int_{-\infty}^{\infty} h^3(x,z)p(h)dxdy$$

Rku : Kurtosis. Presented in conjunction with the skewness to describe the shape of the topography height distribution.

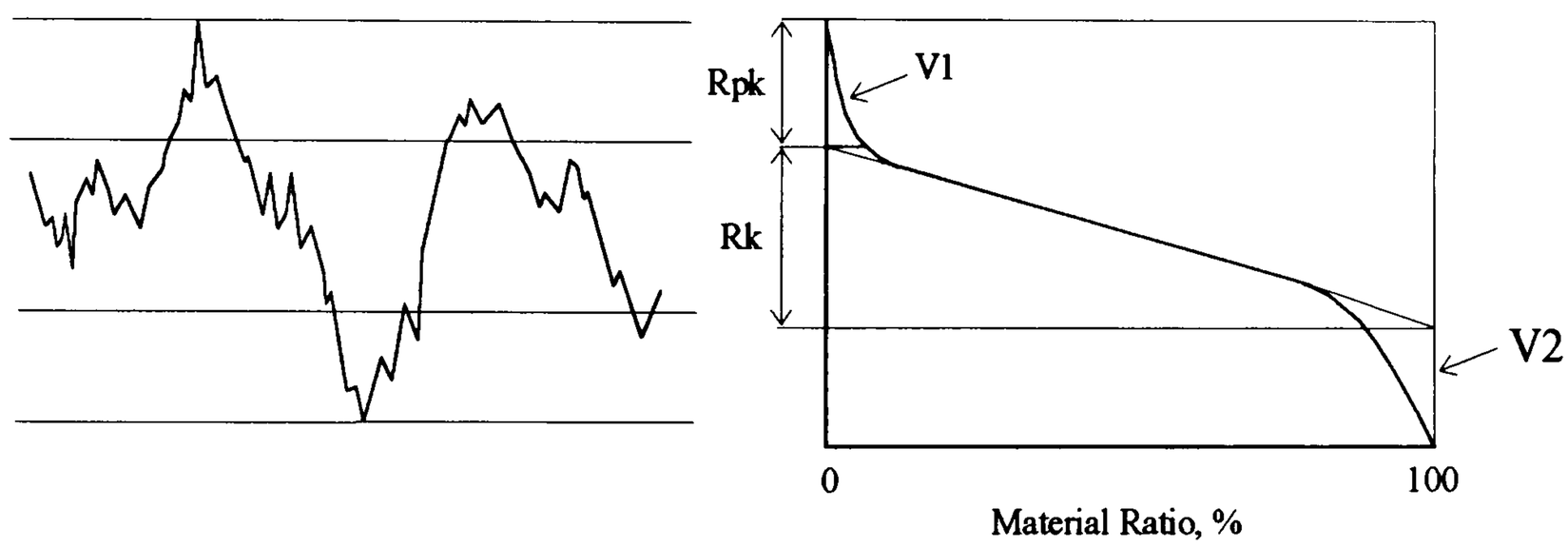
$$R_{ku} = \frac{1}{R_q^{\,4}} \int_{-\infty}^{\infty}\int_{-\infty}^{\infty} h^4(x,z)p(h)dxdy$$

Wa : Arithmetic average deviation of the filtered waviness data about the mean plane.

Wrms : Root mean square deviation of the filtered waviness data about the mean plane.

Wmax : The height of the highest waviness peak above the mean plane.

Abbott-Firestone Curve



Rk : Core Roughness Depth. The depth of the roughness profile excluding prominent peaks and grooves.

Rpk : Reduced peak height. The top portion of the surface exceeding the core height.

V1 : Material filled profile peak volume. The volume of the peaks exceeding the core height.

V2 : Void volume. The volume of the voids beneath the core.

Appendix A.I

New femoral head measurement protocol

General

x40 objective

no zoom

26 measurements taken on pole and on annuli of 5°, 10°, 15°, 20° and 25°

Each measurement of 180 x 135 μm

Advanced texture application

Filter:	OFF		
	remove spikes:	ON	(spike height 7.5xRMS)
	remove form:	sphere	

Parameters

Rmax Ra Rrms Rsk Rku Rk Rpk V1 V2

Appendix A.II

Acetabular cup measurement protocol

General

x10 objective

no zoom

6 images in worn, 3 images in unworn

Each measurement of 730 x 550 μm

Advanced texture application

Filter:	wavelength	50μm	
	frequency	20 mm^{-1}	
	remove spikes	ON	(spike height 7.5xRMS)
	remove form	Cylinder	

Parameters

Rmax Ra Rrms Rsk Rku Rk Rpk Wmax Wa Wq

Appendix A.III

Explanted femoral head measurement protocol

General

x40 objective

no zoom

10 worn images, 4 peripheral images

Each measurement of 180 x 135 μm

Advanced texture application

Filter: OFF

remove spikes:	ON	(spike height 7.5xRMS)
remove form:	sphere	

Parameters

Rmax Ra Rrms Rsk Rku Rk Rpk V1 V2

Appendix B. Component alignment protocol

Method for setting a joint specimen

1. The femoral head/stem assembly can now be screwed into the femoral component holder and the holder put in position above the pneumatic cylinder taking care to ensure it is sat correctly and the pneumatic cyclinder is at the start of its stroke.
2. Using a spirit level to ensure the femoral assembly mechanism is in the vertical position, the gimble mechanism must be levelled. This can be achieved by using the gimble levelling tools.
3. The height from the top surface of the base plate supporting the gimble, to the top of the femoral head can now be set to (229.6mm + R_{head}) using a spirit level and depth gauge. A dial gauge should now be put on the femoral head and when the femoral is in the correct position no head movement will occur when the flex/extension axis is moved. Tighten the M16 locking nut once the femoral head is correctly set. Recheck.
4. Screw down the acetabular cup assembly until the cup and head are just touching. Lock the acetabular component in this position using the M80 locking ring.

N.B. Fix the acetabular cup in the tapered mount using PMMA cement and aligning using the centralisation rig. (AB Automation simulator only.)

5. Loosen the femoral head locking nut, drop the height of the femoral head by approximately 3mm, tighten the M16 locking nut. (This allows the pneumatic cylinder to function part-stroke and the femoral component to position at the centre of rotation on the acetabular component.)

Appendix C.I

AB Automation simulator weighing protocol (PTFE & UHMWPE cups)

The procedure applies to all stations and control cups simultaneously.

1. Remove the cup holders from each station and the lubricant bath of the hip-joint simulator, and carefully remove the acetabular cup from the polyethylene cup holder.
2. Rinse the acetabular cups with tap water to remove bulk contaminants.
3. Place the cups in a jar filled with distilled water and Neutracon and place in a sonic bath for 15 mins at 40°C after 5 mins degas.
4. Rinse the cups in a stream of distilled water.
5. Ultrasonic clean the cups in distilled water for 5 mins.
6. Rinse the cups again in a stream of distilled water.

Do not touch the specimen directly from this point on to avoid contamination.

7. Dry with lint-free tissue.
8. Immerse the cups in methyl alcohol for 3 mins.
9. Dry with lint-free tissue.
10. Air dry the cups in a dust-free environment at room temperature overnight.
11. Blast clean with dry, clean, compressed air.
12. Weigh each acetabular cup in turn.
13. Repeat weighing until the readings are consistent within a narrow range.
14. Replace the cups in the cup holders and replace in the stations and lubricant bath as appropriate.

Appendix C.II

Mk.I and Mk.II Durham simulator weighing protocol (UHMWPE cups)

1. Stop the simulator, recording information on the data record sheet.
2. Remove the prostheses from the simulator by unbolting the shoulder screws from the pneumatic actuators, winding the dowels up from the cup holders, then sliding the cell assembly out from the rig.
3. Decant and freeze the lubricant in individual bottles labelling station number, prostheses and test description, test duration, and date.
4. Disassemble each cup from the gaiter and mount, then wash cups and soak control in tap water to remove bulk contaminants.
5. Immerse the cups in a 1% solution of Neutracon in an ultrasonic bath for 30 mins at 40°C, to remove other contaminants.

Do not touch the specimen directly from this point on to avoid contamination.

6. Rinse the cups under tap water, and then under a stream of distilled water, before drying with lint-free tissue. Finally immerse the cups in acetone for 2 minutes to remove water from the surface. Dry with lint-free tissue.
7. Air dry the cups for two hours, with the articulating surface exposed to atmosphere.
8. Meanwhile, prepare fresh 4000ml of lubricant. (Two mixes of 500 ml of filtered newborn calf bovine serum to 1500ml of distilled water and 2.00g of sodium azide.) Warm up and de-gas using the ultrasonic bath at 40°C for 30 minutes.
9. Clean the rest of the cell assembly by immersing in a warm 1% solution of Neutracon and brushing lightly.
10. Measure the weight loss or gain of the cups using the Mettler AE200 balance, to 0.1 mg, taking an average of at least three readings.

(Wear non-dusted rubber gloves, removing any dust on the cups using dry compressed air.)

11. Reassemble the cells matching the cups, heads, and holders correctly.
12. Fill each cell with lubricant (520ml) expelling any air from the articulating surface of the cup by inverting the cell and allowing air to pass through the bleed pipe.

13. Slide each cell into the correct station maintaining the correct orientation, wind the dowels down into the cup holder and screw the base to the actuator.
14. With the creep cell and four articulating cells in position, check the loading calibration using a load cell in the free station. Repeat this operation for each station and creep station.
14. Record information on the data sheet and re-start the simulator.

Appendix D. Wear debris protocol

Wear Debris Retrieval Protocol (Tipper *et al*, 1997)

1. Day One

   Hydrolysis of proteins using 12M KOH solution:

   For tissue samples prepare solution then add to sample

   For serum etc add correct weight of solid KOH direct to liquid

   * Note: $$\text{Molarity} = \frac{\text{weight of KOH}}{\text{molecular weight} \times \text{volume}}$$

   Leave for 24 hours

2. Day Two

i. Add equal volume of ethanol to KOH solution to achieve *at least* a 50/50 mix

ii. The resulting mix should be decanted in a glass screw-top jar (with top screwed on lightly).

iii. Place onto magnetic stirrer at a moderate speed and leave for 24hours.

3. Day Three

i. Pour liqour into glass beaker

ii. Wash out stirrer jar with ethanol

iii. Decant into centrifuge tubes (as PE particles float on top of liquid)

iv. Balance centrifuge tubes in pairs

v. Place tubes in opposing centrifuge buckets

vi. Centrifuge for 2 hours @ 3000 rpm

vii. Decant supernatant fluid into glass beaker

viii. Resuspend pellet by adding 5ml filtered water and using pipette suck up pellet & fluid to break it up

ix. Centrifuge resuspended fluid for a further 2 hours @ 3000 rpm

x. Decant supernatant fluid into beaker with that from first centrifuge run (label & retain any residual pellet for possible future use)

xi. Filtration Procedure

a. Dilute spun liquor with filtered water to <0.5M KOH soln.

b. Pass through filtration rig (ensure adequate washing of beaker and reservoir sides)

xii. Store filter in petri dish

General

1. Triple wash all glassware with filtered water prior to use.

Appendix D. List of Publications

Smith S L, Burgess I C, Unsworth A. (1997) Validation of a hip joint wear simulator. *JBJS*, **79-B**, Supp IV, 457-458.

Smith S L, Burgess I C, Unsworth A. (1998) Friction and wear testing of compliant layer hip joints on hip simulators. *JBJS*, **80-B**, Supp II, 180.

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Smith S L, Unsworth A. (1999) Low wear compliant layer hip joints. Presented at *BORS Autumn Meeting 1999.*

Smith S L, Ash H E, Unsworth A. (1999) A tribological study of UHMWPE acetbular cups and polyurethane compliant layer acetabular cups. Submitted to *Journal of Biomedical Materials Research (Applied Biomaterials).*

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TOPOGRAPHICAL VARIATIONS IN THE CARTILAGE THICKNESS OF HUMAN ANKLE AND KNEE JOINTS

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Introduction: The primary function of articular cartilage is load-bearing. It is well known that mechanical properties of articular cartilage vary topographically across the articular surfaces of the synovial joint. Previous studies carried out in our laboratory have revealed a significant correlation between the compressive modulus of the cartilage and the prevalent mechanical stress it is subjected to. A mechanical conditioning hypothesis that cartilage properties may be conditioned by the prevalent mechanical stress was advanced. In the present study, we examine topographical variations in the cartilage thickness and attempt to establish whether there are significant correlation between the cartilage thickness, its mechanical properties and the prevalent stress it is subjected to.

Materials & Methods: Fifteen pairs (male: 9; female: 6) of ipsilateral human ankle and knee joints were obtained at post-mortem. The ages, heights and weights of the donors were 61(13 years, 1.75 ± 0.09 m and 64 ± 11 Kg, respectively. Methods of measurement were described in details elsewhere (Yao and Seedhom 1993, Br. J. Rheum., vol.32, pp.956-965).

Results: The topographical variation in the cartilage thickness

The values of the cartilage thickness within various load-bearing areas vary topographically. Furthermore, articular cartilage of the ankle tibial and talar surfaces is significantly thinner ($p < 0.001$) than that of the tibial surface covered by menisci and the femoral condylar surfaces. The latter is significantly thinner
($p < 0.05$) than cartilage of the patellar surface of the femur and the tibial surfaces not covered by menisci.

The correlation between the cartilage thickness and its compressive modulus

There is a good correlation between the values of the cartilage compressive modulus in each of the various load-bearing areas and those of the cartilage thickness ($r = -0.99$) at $p < 0.001$ level of significance.

The correlation between the cartilage thickness and the prevalent stress it is subjected to

Again, a good correlation exists between the values of the prevalent stress acting on cartilage in these load-bearing areas and those of the cartilage thickness ($r = -0.93$) at $p < 0.01$ level of significance.

Conclusions: a. The cartilage thickness varies significantly across articular surfaces.

b. Stiffer cartilage tends to be thinner than softer cartilage.

c. Cartilage subjected to a higher prevalent stress tends to be thinner than that to a lower prevalent stress.

A NEW METHOD FOR ASSESSING PATIENTS AFTER ANTERIOR CERVICAL SPINE FUSION

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Anterior cervical spine fusion is one of the common surgical treatments for cervical spinal disorders. However, post-fusion reassessment relies mainly on plain radiographs, which are often inadequate. The aim of this study was to investigate the clinical application of videofluoroscopy in monitoring the progress of patients following fusion. Fourteen patients participated, including six males and eight females, their age was 49 ± 11 (mean ± SD). All the patients were due to undergo anterior cervical spine fusion. During the measurement the patients were asked to perform active flexion/extension movement and their cervical spine motion was assessed, using an electrogoniometer and a videofluoroscopy unit simultaneously. The patient were also asked to score their discomfort with a simple visual analogous pain scale rating from zero to ten. The videofluoroscopy images were then digitised in 10° intervals from 40° of flexion to 40° of extension and analysed with an image analysis system. The vertebral corners of each cervical segment were identified and intervertebral flexion/extension was calculated. A new parameter, *mobility potential*, was devised, defined as the ratio of the change in intervertebral flexion/extension to the change of flexion/extension of the head and neck. The average mobility potential in each cervical segmental level was then calculated and plotted with various angles of flexion/extension, forming a mobility potential map. All the patients were then reassessed with the same procedures at three months post-fusion and the changes in the mobility potential were assessed using paired t-test. Most of the patients had undergone Smith and Robinson's anterior fusion, whilst two patients had Cloward's procedures. Three patients had a single level fusion at C3/4, C5/6 and C6/7 respectively. The rest of the patients received a double level fusion, including one patient with a C3/4-C4/5 fusion, one patient with a C4/5-C5/6 fusion and nine patients with C5/6-C6/7 fusion. In flexion, the mobility potential was found to be decreased at C6/7 and a slight increase of the potential at C5/6 was found in the first 10° to 20°. All the mobility potentials at C5/6 decreased at C3/4 and C4/5, with a variation at C3/4 in the first 10°. The mobility potential generally increased at C2/3 while decreased at C1/2. However, no statistically significant differences were found. In extension, a statistically significant decrease in the mobility potential was found at C6/7 in the first -30° ($p < 0.05$). Statistically significant decreases in the mobility potential was found at C5/6 in the first -20° and -40 ($p < 0.05$). Despite a sharp rise in the mobility potential at C4/5 in the first -10°, a statistically significant decrease in the mobility potential was found in the first -30° at this level. All the mobility potential measurements decreased at C2/3 and C3/4 post-operatively. However, a statistically significant increase in the mobility potential was found at C1/2 in the first -20° ($p < 0.05$). As the average pain score decreased by three points post-operatively and the mobility potential generally decreased at three months post-fusion, these results suggests that the cervical spine may be successfully stabilised with bone grafts which relieves the patients' symptoms. Importantly, assessment of the mobility potential maps may be a new objective method to monitor the progress of patients after anterior cervical spine fusion.

RADIOGRAPHIC VALIDATION OF VARUS/VALGUS ANGLE MEASUREMENT OF THE KNEE BY THE VICON VX 3-D GAIT ANALYSIS SYSTEM

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The varus/valgus angle of the knee joint is a very important biomechanical measure. Denham has described the radiographic technique for taking accurate long leg weight bearing radiographs (Denham RA 1984). Morland et al (1987) have given a precise method for the measurement of radiographic analyses of the actual alignment of the lower extremity. This defines the method for measurement of the hip/knee/ankle angle. This angle should correspond to the varus/valgus alignment measured by the Vicon VX 3-dimensional gait analysis system using Vicon Clinical Manager software (Oxford Metrics, Oxford UK).

The measurement of the varus/valgus alignment of the knee has previously been compared using a 2-dimensional gait analysis technique and this confirmed the accuracy of the system in comparison with radiography (Gray et al 1995).

The measurement of the varus/valgus alignment by the gait analysis system is only reliable if a defined and accurately employed technique is used for the application and alignment of the reflective markers. The Dundee Gait Lab uses the protocol described in CAMARC (Del. No. 17 1995) to align the marker set such that knee rotation should equal zero. The correlation between the results of the Vicon VX system and long leg radiographic measurements was tested. 10 subjects had bilateral long leg films and a gait analysis assessment, thus there were 20 knees for comparison.

The mean value of the varus/valgus alignment of limbs as measured on the long leg radiographs was 0.48 + 4.1° (range -8 to +10). The mean value for varus/valgus alignment using the Vicon VX system was 0.77 + 5.12° (range -6 to 12). This was averaged in stance phase and the static rotation angle was less than 5°. The large standard deviations result from the fact that varus alignments were considered positive and valgus alignments were considered negative. These results were highly correlated with a correlation coefficient of 0.87 (p value < 0.001). This correlation was only valid when the static knee rotation value was less than 5°. The mean values were very close, with the arithmetic differences between each pair was 0.3°. These differences compare favourably with the reproducibility reported for roentgenographic assessment of the hip knee ankle axis, which has been shown to have a variability of up to 2°. (Odenbring et al, 1993).

This shows that the Vicon VX 3-dimensional system measures the varus/valgus alignment of the knee comparably with standard radiographic techniques. In any study using gait analysis systems, similar studies should be carried out to confirm the accuracy of the marker system employed in that laboratory.

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VALIDATION OF A HIP JOINT WEAR SIMULATOR

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Introduction: Osteolysis, induced by wear debris, has generated interest in the wear rates of prostheses and in particular in the comparative performance of one design against the others. To achieve this in the laboratory, various hip joint simulators have been developed. These incorporate motions and loads which replicate, to some extent, the *in vivo* conditions of hip joints. The Durham hip joint simulator is based on the "a-b automation" design where the joints are mounted anatomically and subjected to a dynamic loading cycle (Paul, 1967) with motion applied in such a way as to produce the three dimensional locus of the load vector over the head of the prosthesis and in the acetabular component. In order to evaluate the performance of the simulator, wear tests were carried out on PTFE and UHMWPE acetabular cups articulating against CoCr heads and the results were compared with other simulator wear results as well as data from explanted prostheses.

Materials and Methods: The hip joint simulator uses one DC servo motor and gearbox to drive the flexion-extension mechanism which is common to five articulating stations, and another motor and gearbox to drive a pelvic rotation mechanism also common to all five stations. The resultant joint force is applied using a pneumatic actuator and proportional valve for each station. The magnitude of the force is thus controlled by the actuator and it's orientation by the two servo motors. The control signals were chosen to give the correct resultant force vector. The test was conducted in recirculating, distilled water at 37°C for 4.8 million cycles, with 22 mm diameter CoCr femoral heads articulating against PTFE acetabular cups in two stations, and UHMWPE in three stations. In order to measure wear, a shadowgraph technique similar to that used by Hall *et al.* (1995) was used, and a linear wear rate assumed from 1 million cycles onwards so that the creep component could be found from the intercept with the y axis for a graph of penetration rate against number of cycles.

Results: The two PTFE acetabular cups showed 0.42 mm and 0.52 mm of creep in the first million cycles. The penetration rates for these cups were 0.15 mm/10^6 cycles, and 0.49 mm/10^6 cycles respectively. Creep in the

UHMWPE acetabular cups was found to be 0.118 mm, 0.122 mm, and 0.022 mm and the penetration rates were 0.04 mm/10^6 cycles, 0.03 mm/10^6 cycles, and 0.05 mm/10^6 cycles respectively.

Discussion: Previous simulator studies have found simulator wear to be generally lower than that determined *ex vivo* (Clarke, 1981). There is also some variation between rates reported by different authors in both simulator and *ex vivo* studies. Bearing these two factors in mind, the UHMWPE results compare favourably with simulator studies conducted by Dowson *et al.* (1988) and Derbyshire *et al.* (1994), but not with those of Saikko (1992). Although the penetration rates for the PTFE cups were an order of magnitude lower than the clinical results of Charnley *et al.* (1969), they were an order of magnitude greater than the UHMWPE simulator data. In addition, examination of the replicas showed that the head was tunnelling into the cup as observed *ex vivo*. In general terms, a comparison of either *ex vivo* or simulator data showed an order of magnitude difference between UHMWPE and PTFE cups, but all simulator results were generally an order of magnitude lower than *ex vivo* data for both types of cup. These findings, provide confidence that the simulator can be used to evaluate new designs of prostheses.

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FRETTING WEAR OF CHARNLEY LFA STEMS: PATTERNS OF WEAR AND CLINICAL SIGNIFICANCE

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Introduction: Orthopaedic surgeons are familiar with the appearance of damage or burnishing marks on the stems of explanted total hip arthroplasties, yet little has been written about this occurrence (1). This study describes and quantifies stem damage in a homogeneous group of explanted hip stems and relates the findings to previous investigations of the head damage and linear cup wear rate in this series of prostheses.

All seventeen stems had been inserted with radio-opaque cement containing barium sulphate, had failed by aseptic loosening between ten and twenty years of survival, and had been retrieved at first revision at Wrightington Hospital.

Materials & Methods: Seventeen explanted Charnley LFA prostheses, implanted using radio-opaque cement containing barium sulphate, were retrieved at revision operation for aseptic loosening, along with full patient and implant histories. The range of in vivo survival was 10 to 20 years, mean 13 years. The femoral stems were examined macroscopically for evidence of damage, which on the textured Vacusheen stems was visible as areas of polishing of the matte surface. The pattern and extent of damaged areas were recorded, and the naked eye appearance was confirmed by 2D contacting profilometry and 3D non-contacting profilometry. The prostheses were classified into two groups simply on the presence or absence of visible stem damage; this was carried out "blind" to the results of previous measurements performed on the heads and acetabular components of the same series (2).

Results: A characteristic pattern of wear affecting the anterolateral and posteromedial edges of the stem was identified: this is believed to be due to the retroversion torque which is increasingly recognised as one of the factors contributing to failure of total hip arthroplasty.

The previous study has shown increased linear cup wear with high head damage. When the worn and unworn stem groups were compared to the head damage groups from the previous investigation there was a strong association between stem wear and high head damage ($p = 0.012$, Fisher Exact Test).

Discussion: Although it is difficult to identify cause and effect, the triad of visible stem wear, high head damage and higher rate of linear cup wear appear strongly associated in hip arthroplasties that have failed by aseptic loosening at 10 to 20 years. We are investigating the process of fretting at the stem-cement interface further.

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AN AUTONOMOUS MONITORING SYSTEM FOR EXTERNALLY FIXED FRACTURES

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Introduction: Unstable tibial fractures are commonly treated with external fixators. Many fixator designs incorporate a "dynamisation" mechanism that allows axial movement to occur between the fracture ends to promote callus response. The effects of dynamisation on fracture healing have been extensively investigated. Monitoring of patient activity levels is usually limited to the clinical environment. The clinical data has then to be assumed for the remaining unobserved time, relying on patient compliance. Fixator performance is rarely checked in the reported clinical studies. It has been reported and is our observation that patient compliance and fixator function may not be as expected. Therefore possible large unknown variances in the occurrence of fracture fragment movement may exist in previous studies.

Methods: We present a system, comprising of a switch and data logger, which can monitor dynamised external fixators continuously. The switch is mounted across the dynamising element of the fixator and is set to throw at a predetermined level of movement, this is termed an event. The data logger board records how many events occur in each half hour. It is small and also attaches directly to the fixator. Each logger can operate for a minimum of four weeks, at which time it can be exchanged and the recorded information is uploaded to a PC. The system has been fitted to 14 patients and three types of external fixator in clinical trials. Patients have attended regular fracture clinics were fixator movement and system performance have been measured. Fracture stiffness has been used as a measure of healing.

Results: For each patient an histogram of the sum of events detected per day, post fracture, reveals compliance profiles. In general few events are observed for the first two to three weeks, probably caused by lack of weight bearing due to discomfort. Following this is a period were a high number of events are recorded. Finally a decrease in the event count is observed coinciding with increasing fracture stiffness. For a number of patients the compliance profile was very low and unpredictable. Measurements taken in the research clinics recorded jamming of the fixator in these cases. Variations in individual activity levels has been recorded.

Discussion: A greater understanding of the effects of dynamisation on fracture healing could be achieved if the variance, caused by the unknown occurrence of fixator movement, could be reduced. The system presented can monitor patient compliance and fixator function throughout the healing period of fractures. Therefore these previously unknown factors can be incorporated into the analysis to achieve more qualitative results. It is anticipated that definite trends in compliance profiles will emerge. From these trends a future "intelligent" system could estimate and inform the surgeon of a predicted healing time. Earlier detection of problems may also be possible if they adhere to a unique profile. For instance it may be expected that an hypertrophic non-union will not present a "normal" decline in the event count.

LOADING & STRESS ANALYSIS OF THE FOURTH & FIFTH LUMBAR VERTEBRAE

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To understand the cause of problems in the human spine, and ultimately how to prevent disorders, it is first necessary to understand the mechanical loads and stresses that are present. Any design of prosthetic or orthotic devices must take into account the characteristics of these mechanical forces.

The main objective of this study has to produce a three dimensional model of the fourth and fifth lumbar vertebrae. This model is then used to carry out mechanical finite element analyse of the vertebrae. Each individual vertebral geometry has produced using digitised information from a Co-ordinate Measuring Machine.

The models were then reconstructed in the form of surfaces followed by finite element meshing. Compressive loading has applied to the model through the vertebral body to determine the stresses that are present on the vertebral segment during standing.

Surgical intervention was simulated on the model by the drilling of the L4 vertebrae with a 4 mm drill similar to transpedicular screw fixation. The stresses were then compared with those of the earlier L4 model.

The analysis showed high concentrations of stress around the articular facet joints and the spinous processes. This coincides with fractures caused in the vertebrae due mainly to the overloading of the facets joints. The drilling of the hole for the transpedicular screw showed an increase in stress around these same regions away from the drill hole.

MECHANISMS FOR CONTROLLING CALLUS VOLUME DURING DISTRACTION OSTEOGENESIS

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Introduction: Distraction osteogenesis is a powerful method for treatment of bone defects and limb deformities. In this process, new bone is formed rapidly and undergoes remodelling simultaneously. The newly formed bone mainly consisted of mineralised woven and lamellar bone and was highly oriented toward the distraction forces. Bone remodelling was active and resulted in frequent newly formed haversian canals. Corticomedullary differentiation was observed, yet little is known of the regulatory mechanisms which govern the removal of the redundant callus in this process. We have known that apoptosis is a process allowing unwanted cells to be eliminated. The hypothesis in this study is that some newly formed bone tissue cells are programmed for cell death and are removed by remodelling during the rapid tissue turnover seen in distraction osteogenesis.

Materials & Methods: Mid-tibial osteotomies were performed in 16 adult New Zealand white rabbits and the tibiae were stabilised with external fixators (Orthofix M-100, Italy). 7 days later, twice daily distraction was initiated at rates of 0.3 mm. 0.7 mm, 1.3 mm and 2.7 mm/day, until 20% lengthening of the tibia was achieved. Bromodeoxyuridine (BrdUrd) (40 mg / kg) was injected intravenously to the rabbit 1 hour before killing. The distraction regenerate was processed histologically and embedded in paraffin. BrdUrd immunohistochemistry and terminal deoxynucleotidyl transferase (TdT)-mediated dUTP-digoxygenin nick end labelling (TUNEL) were performed to detect cell proliferation and DNA fragments during apoptosis. In addition, a method of dual labelling of cell proliferation by immunochemistry following the TUNEL method was developed.

Results: At a low distraction rate (0.3 mm/day) of distraction osteogenesis, DNA fragmentation was detected mainly in the central region of the newly formed bone in the distraction gap. Apoptotic cells were mainly osteocytes, with a few bone-surface cells. Proliferating cells were seen adjacent to new bone surfaces. As the rate of distraction increased (from 0.7 to 2.7 mm/day), the size of central fibrous region increased and the amount of newly formed

COLLAGEN EXPRESSION IN OSTEOPHYTES. EXAMINATION OF DECALCIFIED MATERIAL

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Osteophytes are osteochondral outgrowths found at the margins of degenerating joints. Their formation seems to be preceded by a fibrocartilaginous proliferation which then undergoes endochondral ossification. Immunohistochemical techniques have been employed to investigate this transition.

Osteophytes obtained from the margins of the femur in ten patients undergoing a T.K.R. The specimens were formalin fixed, decalcified, processed and wax embedded. 7μm cuts were taken, and every fourth sample stained with hematoxylin and eosin. The remaining samples were dewaxed with xyline and washed with alcohol and water. The sections were brought to room temperature, hydrated in TBS. After treatment with hyaluronidase (Testicular, Sigma) in acetate buffer (1 mg/ml) for 1 hour, the sections were rinsed in TBS and flooded with normal rabbit serum (Serotec) at a 1:5 dilution with TBS for 10 minutes. Serum was then removed but not rinsed, before addition of primary goat anti-type I collagen, goat anti-type II, and goat anti-type X antibody. All dilution's were made in TBS. Slides were incubated for one hour at room temperature, then rinsed in TBS before addition of rabbit anti-goat FITC conjugated secondary antibody in TBS for one hour at room temperature. FITC labelled sections were then rinsed finally and mounted in Aquamount (Fisons) before visualisation under ultraviolet light. The biotin labelled sections for type X collagen were rinsed before addition of ABComplex (Dako) for 20 - 30 minutes, rinsed again then incubated with DAB (tablet form, Sigma) for 10 minutes. Slides were counterstained with haematoxylin then dehydrated before mounting in DPX mountant (BDH) and visualised under light microscopy.

Type I collagen was expressed on the superficial (surface) layers of osteophytes. None of the specimens expressed types II and X collagen. It would appear from these findings, that osteophytes do not express type II and X collagens. However, the likelihood is that this is due to the method of processing.

THE BIOLOGY OF THE PERI-ARTICULAR OSTEOPHYTES; POTENTIAL GRAFTS FOR ARTICULAR SURFACE DEFECTS

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Osteophytes are bony outgrowths observed at the margins of degenerating or degenerate joints. Their biology is not completely understood and their manner of formation is not known with certainty. This has been investigated by a battery of tinctorial stains.

Osteophytes obtained from the margins of the femoral condyles of 25 osteoarthritic knees undergoing replacement were formalin fixed, decalcified , routinely processed and embedded. Comparative sections were stained using respectively, Toluidine blue, haematoxylin-eosin and tinctorial stains which highlight different aspects of osteogenesis.

In HE stained sections, two distinct layers were identified, viz: hyaline cartilage and trabecular bone with a well developed marrow. At the joint surface, the chondrocytes were small in size and flattened. There was hyperplasia of surface cells at the junction with a vascularised fibrous tissue. At the cartilage-bone interface, the cell were larger appeared to be isogenic, arranged in parallel columns separated from one another by matrix. In Toluidine blue stained sections, only the matrix between chondrocyte columns was intensely stained. The cytosol of the columnar chondrocytes which were often vacuolated were also intensely stained. Hypertrophic chondrocytes were observed in the newly formed bone trabeculae. In the sections stained using Ralis and Ralis method, new bone formation was confined to the base of the osteophytes. Some chondrocytes exhibited identical staining characteristics as bone cells. In the sections stained using the Tripp and Mackay technique, new bone formation was also shown to be confined to the base of the osteophyted. Following Van Gieson staining, collagen fibrils were observed arranged in longitudinal bundles separating columns of chondrocytes one from another. The arrangement was transverse in the superficial layers but haphazard in the ossifying layer.

This study reveals that the micro-architecture of the osteophyte is identical to that of the articular cartilage/epiphysis of growing bones. This therefore raises the possibility that osteophytes could be used as grafts to repair articular surface defects.

FRICTION AND WEAR TESTING OF COMPLIANT LAYER HIP JOINTS ON HIP SIMULATORS

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Introduction: Conventional UHMWPE artificial joints operate with a mixed lubrication regime which produces polyethylene wear debris, inducing osteolysis and subsequent joint failure. A new generation of artificial hip joints[1] featuring a compliant, soft bearing surface mounted to a hard backing are being developed to operate in a fluid film lubrication regime thereby reducing the amount of wear debris produced. These new joint designs have been friction and wear tested in the laboratory on simulators, to develop their performance and reduce the potential for failure in subsequent clinical trials.

Materials and Methods: Three designs of compliant layer joints were evaluated, all articulating against 32 mm diameter CoCr femoral heads. Two of the designs featured a metal backing with a sintered interface to the soft layer elastomer. The first used a 2.5 mm thick layer of Tecothane 1085A elastomer, and the second a 3.5 mm of Tecothane 1095A, but used a metal backing microball interface for the elastomer to adhere with. The designs were initially friction tested on the Durham Hip Function Simulator, as described previously[2], then wear tested using the Durham Hip Joint Wear Simulator[3] in distilled water at 37°C. During the course of the wear test the cups were periodically examined on a 3° annulus about the pole of the cup using a Zygo 'New View 100' non-contacting optical profilometer.

Results:

Compliant Layer Joint Design	Friction Factor	Duration of Wear Test / cycles	Ra. Surface Start / μm	Roughness End / μm
Sintered interface, 2.5 mm thk. layer	< 0.023	54,136	0.574	Failure
Sintered interface, 2.5 mm thk. layer	< 0.023	54,136	0.235	1.086
Sintered interface, 3.5 mm thk. layer	< 0.011	637,214	0.166	1.759
Sintered interface, 3.5 mm thk. layer	< 0.011	637,214	0.166	1.124
Microball interface, 3.5 mm thk. layer	<0.017	583,078	0.488	1.315
Microball interface, 2.5 mm thk. layer	<0.017	583,078	0.841	1.895

Discussion: The friction factors and Stribeck curves found from the friction test showed that although these compliant layer designs were operating with lower friction than conventional joints, they were still in a mixed lubrication regime. This suggests that the rate of wear debris produced would be lower than conventional joints, but not as low as may be possible. Furthermore, the thicker, harder layer of Tecothane 1095A seems to be superior to the thinner softer layer designs.

However, even after only a few articulating cycles during friction testing, visual inspection of the sintered interface designs showed delamination of the soft layer from the metal backing. This delamination continued during the wear testing, leading to complete detachment and total failure in one of the cups. The microball interface design did not show delamination even after completion of the wear test, indicating a good mechanical bond between the soft layer and metal backing. Unfortunately, the increased surface roughness seem with all the designs during wear testing, indicates that none of these designs would be suitable for clinical use.

Soft layer design cups pose problems in the measurement of wear rate as conventional techniques such as gravimetric measurement and shadowgraphing are unsuitable due to the extremely hydrophilic nature of the material and its considerable tendency to creep. The Zygo non-contacting profilometer has proved a useful tool in attempting to quantify how these soft layer cup designs may be wearing.

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MECHANISMS OF INFLAMMATORY BONE LOSS: IL-1 SUPPRESSES MARROW FIBROBLAST COLONY FORMATION BY A NITRIC OXIDE INDEPENDENT MECHANISM

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Background: The effects of cytokines on attempted bone repair during inflammatory bone loss is poorly understood. In a previous study, we found that interleukin-1 (IL-1) has an inhibitory effect on marrow fibroblast colony formation which is the in vitro expression of the mesenchymal stem and progenitor cell populations from which preosteoblasts are derived. Since IL-1 can be a potent stimulator of NO production via up-regulation of the inducible nitric oxide synthase isoform (iNOS), there is a possibility that the effect of IL-1 on colony formation is via a NO mediated pathway.

Aims: To confirm the inhibitory effect of IL-1 on colony formation and to investigate the effects of inhibitors of nitric oxide synthase isoforms.

Materials and Methods: Bone marrow cells were obtained from femorae of male New Zealand White rabbits. Marrow cells were cultured in six-well, flat-bottomed plates (~10^{-6} cells/wells in MEM with 10% FCS). Human recombinant Il-1ß (10^{-11} - 10^{-9} M) with or without inhibitors of inducible NO synthase (iNOS) (L-NIL, L-NIO; 10^{-4} M) was added just before the commencement of cell culture. After 7 days aliquots of medium were taken from each well for the measurement of NO (as nitrite) by the Greiss reaction and cells were fixed with methanol. After staining with toluidine blue, the numbers of fibroblast colonies (>50 cells) per well were counted. The significance of differences in means was assessed by Student's *t*-test.

Results: The number of colonies in control cultures (no additional reagents) was 38.5 ± 7.8 (mean ± S.D; n = 11). Inhibitors of iNOS caused small but significant decreases in colony numbers (L-NIL: 27 ± 8.2, L-NIO: 28.7 ± 6.0; $p < 0.05$). rhIL-1ß reduced the colony number dose dependently (10^{-11} M: 29 ± 5.7; $p < 0.05$, 10^{-10} M: 12.3 ± 3.5, 10^{-9} M: 2.2 ± 1.9; both $p < 0.001$). Colony numbers in the presence of rhIL-1ß and iNOS inhibitors were not significantly different to those in rhIL-1ß alone (10^{-11} M + L-NIL: 20.8 ± 12.7, + L-NIO: 29.4 ± 15.5, 10^{-10} M + L-NIL: 16.5 ± 10.6, + L-NIO: 12.8 ± 2.8, 10^{-9} M + L-NIL: 4.2 ± 1.5, + L-NIO: 2.7 ± 2.3; all $p > 0.05$).

Conclusion: Recombinant human IL-1ß was shown to suppress marrow fibroblast colony formation in a dose dependent manner. Addition of iNOS inhibitors had no significant effect on the suppression caused by IL-1, which suggests IL-1 worked via an iNOS independent pathway.

fitting tightly in the defects. The left knee of each animal was kept intact for normal control. Ten, nine and six rabbits were killed at 8, 16 and 32 weeks post implantation respectively. The repair tissue and the grafts were examined using radiology, histology, scanning electron microscopy (SEM) and mechanical testing (surface contact pressure, indentation deformation and thickness). The data of the mechanical testing were assessed using unpaired *t-test* for the significance of differences between groups.

Results: At 8 weeks, grossly, the surface repair consisted of a thin translucent membrane-like fibrous tissue which covered the graft. Radiography revealed no sign of restoration of subchondral bone in the defects. Histologically, repair tissue was predominantly fibrous and showed no safranin-O staining. SEM showed the carbon fibre rods remained intact in place. There was no subchondral bone replacement of the graft. Fibrous tissue grew into the outer braided sheath of the graft, but the core of the rod remained impervious to new tissue growth all round. A separation gap was seen between the graft and the new surface as well as between the graft and bone in the base. Mechanically, the repair surface tissue were softer than those of the normal controls ($p<0.01$), but they were not significantly different from those of non-grafted controls ($p>0.01$). The quality and quantity of repair obtained by Gateshead grafting did not improve after 16 and 32 weeks and 2 repair surfaces were worn exposing the rod after 32 weeks.

Conclusion: No ingrowth of organised repair tissue was found in Gateshead carbon rod graft up to 32 weeks post implantation. The graft was poorly supported all around. The quality of repair surface tissue, morphologically and mechanically, was similar to that of non-grafted control.

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THE BIOLOGICAL EVALUATION OF HYDROXYAPATITE AND BIOGLASS® - REINFORCED POLYETHYLENE COMPOSITES

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Introduction: There is an increase in the design of new generation biomaterials able to promote and enhance bone formation. Hydroxyapatite (HA) - and Bioglass® - particle reinforced polyethylene composites (Hapex™, Bioglass/ HDPE respectively) are being developed as second generation biomaterials (1) . It has been well documented that when Bioglass® reacts with physiological fluids surface changes occur and a biologically active hydroxy-carbonate (HCA) layer is formed. The formation of this active layer is able to affect cellular behaviour; the mechanism of action, however, still remains to be elucidated. *In vivo* studies have shown that Bioglass® is able to upregulate osteoprogenitor cells and stimulate the formation of bone. Hapex™, has also been shown to encourage bone formation *in vivo* , however, little is known about the *in vitro* cellular response to these materials (2) . In this study, we have investigated the cell-biomaterial interaction of Hapex™ and Bioglass® /HDPE using human osteoblast-like cells, representative of the cell type that the material surface will contact *in vivo*.

Materials and Methods: Human osteoblast-like cells were seeded for morphological and biochemical studies at a cell density of 1x105 and 1x 106 cells/ml respectively, and cultured in Dulbecco's modified Eagles medium (supplemented with 10% foetal calf serum). The incorporation of 3H-thymidine and total DNA (Hoechst method) was used as a measure of cell proliferation, alkaline phosphatase activity (ALP) was used as an indicator of osteoblast phenotype expression.

Results: Quantitatively, the materials tested were all able to support cell growth and differentiation. Rapid cell proliferation was observed on all materials during the first 24 hours. Hapex™, in particular, caused a significant upregulation in cell proliferation and early production of ALP activity. Interestingly, a delayed response in cellular proliferation and differentiation was observed on the Bioglass® /HDPE in the presence of culture medium. The HCA layer is known to form rapidly on Bioglass® 45S5 in non-protein containing solutions; however, the delayed response observed in this study may be due to a slower formation of the HCA layer in serum containing medium. Qualitatively, both Hapex™ and Bioglass®/HDPE composites showed good cell attachment and spreading. The cells were able to attach to all the materials tested and maintained their morphology. On Hapex™ cell filopodia were frequently seen embedded within the HA particles on the surface of the composite. These particles may provide preferential sites for cell attachment, and act as microanchors for developing direct bone bonding.

Conclusion: The results indicate that all the bioactive composites provide a good biological surface for the attachment, proliferation and differentiation of cells. A higher cell number and generally a better osteoblast expression was observed on Hapex™. The information obtained from this study will further aid in the design of second generation implant materials to promote bone bonding. It can be concluded that these composites are promising implant materials with a wide clinical application.

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SURFACE TOPOGRAPHY AND WEAR RATES OF ZIRCONIA AND CoCrMo FEMORAL HEADS COMPARED *IN VITRO*

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Introduction: It has been suggested that the surface roughness of the femoral head of a prosthesis[1] has an effect on the wear rate and hence the life of the prosthesis. Furthermore, ceramic femoral heads have been used in preference to metallic heads as it has been thought that they extend the life of prostheses due to their improved surface finish and scratch resistance.[2] However, little has been published to qualify these assumptions in the laboratory using full prostheses in hip joint wear simulators, and the latest generation of 3D, non-contacting, optical interference profilometers to examine the surface topography.

Materials and Method: - Two zirconia ceramic and three CoCrMo femoral heads were wear tested for 5 million cycles in 25% bovine serum using the Durham Hip Joint Wear Simulator[3] against 28mm diameter UHMWPE acetabular cups. Gravimetric measurement was used to measure wear, with one loaded and one unloaded control cup maintained in bovine serum to account for water absorption. The temperature of the bovine serum was monitored for all seven cups. A Zygo 'New View 100' non-contacting optical profilometer was used to measure a number of surface parameters before and after the wear test. One ceramic and one CoCrMo femoral head were examined. Up to 29 points mapped each femoral head, with the points located on the pole of the head and on 5°, 10°, 15°, 20°, and 25° annuli around the pole.

Results: - The wear rates were biphasal for all prostheses. The initial wear phase, up to 2 million cycles, gave a linear acetabular cup wear rate average of 56.05 $mm^3/10^6$ cycles against the zirconia heads, and 52.57 $mm^3/10^6$ cycles against the CoCrMo heads. Thereafter, a lower, linear cup wear phase was evident, measuring 32.60 $mm^3/10^6$ cycles and 31.13 $mm^3/10^6$ cycles against zirconia and CoCrMo femoral heads respectively.

Table I: Surface topgraphy measurements. (Mean ± SD)

	Femoral head			
	Zirconia		CoCrMo	
No. of cycles:	Zero	5 million	Zero	5 million
Ra/nm	3.67±0.51	4.30±0.25	12.85±4.33	14.74±4.30
Rrms/nm	4.70±0.63	5.47±0.33	25.66±7.63	26.82±8.85
Rmax/nm	50.71±8.60	65.84±27.6	486.7±167	540.4±297
Rpk/nm	3.48±0.22	4.43±0.27	6.75±4.46	12.53±12.1
Skew,Rsk	-0.43±0.08	-0.32±0.22	-5.57±1.18	-4.08±1.12

Discussion: The biphasal wear rates observed in this wear test have been noted by other workers,[4] compare favourably with other simulator[5] and *ex-vivo*[6] studies. The wear rates were similar for both bearing materials, despite the zirconia being smoother than the CoCrMo femoral heads throughout the wear test. However, even at the end of the wear test, the CoCrMo heads were still as smooth as some new production heads.[7] Furthermore, the low, negative skew values measured for both heads, before and after wear testing, are indicative of good bearing surfaces. The surface topgraphy had generally roughened as a result of the wear test and extending the wear test may reveal if a critical level of roughness exists beyond which wear rate begins to rise. Hypothetically, if beyond a critical level of roughness wear rate increases, then the measurements for the zirconia heads indicate that they would remain within tolerable levels of roughness longer than CoCrMo heads, thereby extending prosthetic life.

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EVALUATION OF STRAIN IN THE PROXIMAL FEMUR FOLLOWING IMPLANTATION OF A TRI-MODULAR FEMORAL STEM: A PHOTO-ELASTIC COATING STUDY

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Introduction: Osteopenia of the proximal femur and calcar resorption following implantation of cemented and uncemented femoral stems is believed to result from the phenomenon of stress shielding. It is not known whether osteopenia leads to femoral stem loosening but it is undesirable as it may pose serious problems during revision hip replacement. Investigators have examined various modifications in stem design and materials in order to overcome the problem of stress shielding. Recent innovations include the Oxford universal prosthesis, a tri-modular stem which consists of a proximal wedge designed to slide around a polished, cylindrical stem with a distal taper. It is hypothesised that the Oxford stem improves proximal femoral stress transfer, thereby minimising the problems of osteopenia and stress shielding. This *in vitro* study evaluates this stress transfer as reflected by the strain pattern in the proximal femur following implantation of the modular Oxford femoral stem using a photo-elastic coating technique.

Material and methods: Five paired cadaveric femora were stripped of all soft tissue and coated with photoelastic material. Using a test set-up, which included simulation of the hip-abductor muscles, a load of 600N was applied to each femur. Strain patterns were evaluated using a reflec-

Inverse dynamics analysis coupled with the Dynamically Determinate One-Sided Constrained (DDOSC) method was used to calculate forces transmitted by the muscles, ligaments and bones. For each data frame, the DDOSC method involves calculating all possible dynamically determinate solutions, rejecting those with compressive muscle or ligament forces and tensile contact forces, and selecting those consistent with EMG. The femoral axial forces at the level of the prosthesis transducers were then calculated for each EMO consistent solution.

The calculated and telemetered femoral axial forces during standing postures agree very well, with an average difference of 16ON during SLS and 63N during DLS. A similar agreement was also obtained for all the isometric tests. It was noted that a unique EMG-consistent DDOSC solution existed in the above tests. Durin. walking, the number of the predicted DDOSC solutions ranged from 1 to 8. For those data frames with more than one DDOSC solutions, the average values together with the upper and lower bounds were calculated. Calculated axial forces agree well with the telemetered forces.

In general, the model predicted results were all within 10% of the telemetered forces and the time varying patterns of the measured forces were followed well. Although there were 150,000 possible dynamically determinate solutions, a unique EMG-consistent solution could be found in most of the tests. The locomotor system is not redundant in a sense that all the force-bearing structures have to be used simultaneously in activity but is redundant in terms of the number of possible recruitment strategies available to achieve movement while transmitting load. It may be that a minimum of one solution is not guaranteed after surgical dissection of muscles and that a patient could be left without a single strategy with which to achieve near-normal gait. Although the model was built upon a number of simplifications of the real system. the comparison with the telemetered forces provides a validation of not only the geometry but also the solution procedures employed. It is then useful in the application to normal subjects in similar activities.

THE WEAR RATES OF UHMPWE ACETABULAR CUPS AGAINST ZIRCONIA AND CoCrMo FEMORAL HEADS COMPARED IN VITRO WITH PHYSIOLOGICAL AND SIMPLIFIED LOADING PROFILES

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An accurate replication of in vivo motion and loading can be achieved in the laboratory using a hip simulator incorporating 3 axes of motion and loading.[1] However, the capital and running costs of this type of machine restricts the number of test stations and hence the significance of the test results. Therefore, there is a need to develop more cost effective, multiple station hip simulators with a balance between complexity and accuracy of simulation.

To apply physiological loading, hip simulators require complex and expensive control systems. A square wave loading profile can be applied to simple, robust controls. Thus, a comparison has been amde between wear of prostheses using a simple swuare wave load and a physiological load cycle with the Durham simulator.

Three zirconia and two CoCrMo femoral heads were wear tested against 28mm diameter UHMWPE acetabular cups for 7.1 million cycles in 25% bovine serum lubrican uting the Durham Hip Joint Wear Simulator.[2] The joints were anatomically mounted and subjected to physiological motion. Gravimetric measurement was used to measure wear, with a soak control maintained in bovine serum to account for water absorption. The temperature of the bovine serum was monitored for all seven cups.

For the first 5 million cycles of the war test physiological loading approximating to that defined by Paul[3] was applied across the prostheses. A simplified loading profile approximating to a square wave was applied across the prostheses for the last 2.1 million cycles of the wear test.

Figure 2 presents the UHMWPE acetabular cup wear rates agains CoCrMo and zirconia femoral head for both physiological and square wave loading.

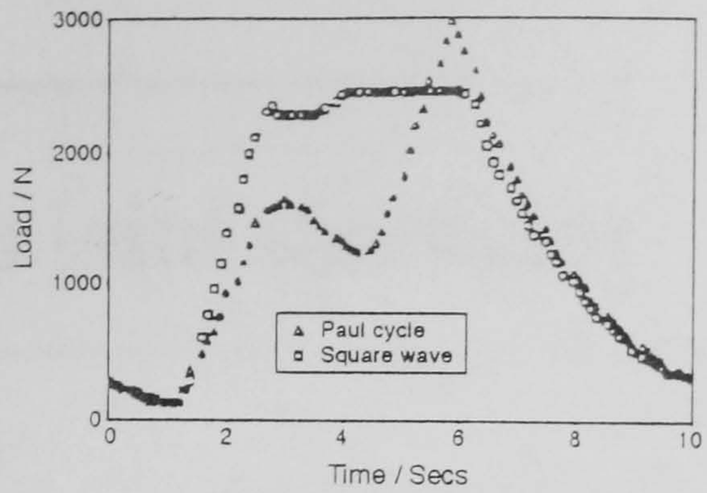

Figure 1

Loading profiles

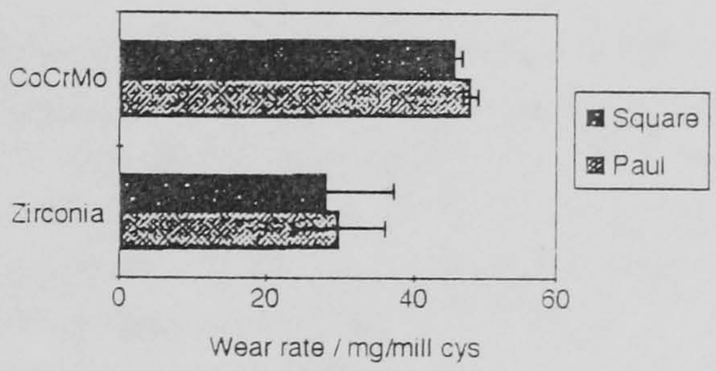

Figure 2

Wear rate results

The UHMWPE mean wear rates against CorCrMo femoral heads were greater than against zirconia and this was statistically significant at p=0.03. The wear rates with both loading profiles compare favourably with other simulator[4,5,6] studies. There was no statistically significant difference between the wear rates for the two loading profiles. This suggests that a square wave loading profile can successfully replace a physiological loading profile when wear testing.

Acknowledgments: The DTI for funding part of this the project under the CAM 1 programm. The prostheses were generously provided by Howmedica Inc.

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THE AXIS OF ROTATION FOR THR FEMORAL COMPONENTS.

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The migration of cemented femoral components after total hip replacement (THR) is a complex combination of translation and rotation in three dimensions which can only be assessed by RSA. Rotation is accepted to be an important mode of failure after THR. The Charnley Elite and the Exeter, two of the most successful femoral stems, have fundamentally different patterns of migration and rotation. The aim of this study was to determine the axis of rotation for both stems. It is likely that these differences will affect their long term function. Method. Our RSA system has been described previously. It is based on the early system descibed by Kiss et al.

We have studied with RSA 51 patients who.had 51 THR. Thirty-two had a cemented Exeter femoral component, which has a polished, tapered, collarless stem. All the patients had the operation for OA. An anterolateral approach was used in all cases. Nineteen patients had a Charnley Elite which has a vaquasheened, flanged, non-tapered stem. 0.8 mm tantalum marker balls were inserted at the time of operation in the greater trochanter, lesser trochanter and distal to the tip of the prosthesis. The patients had stereo x-rays taken postoperatively and at 3, 6 months, 1 year and 2 years.

The follow up was divided into two periods: the migration rate in the first year and after the first year. For each period the migration and rotation rate for the tip, head and shoulder of the prostheses in the x, y and z directions was determined. From the relative posterior migration of the landmarks, an estimate can be made of the orientation of the axis about which internal rotation occurs.

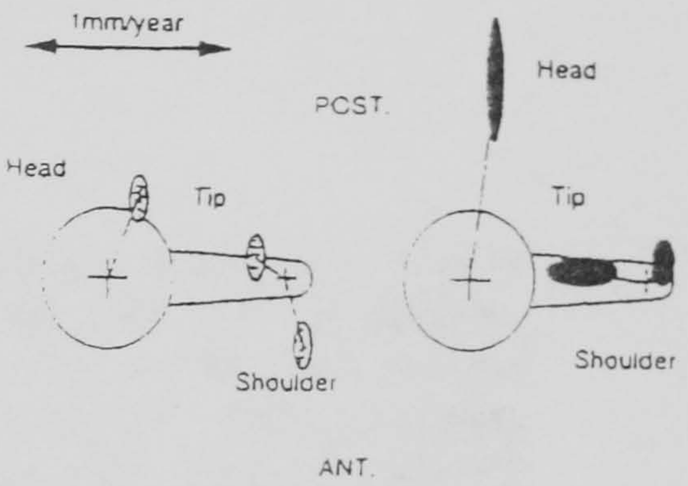

Fig. 1

Migration rate in the transverse plane for the Exeter (left) and Charnley (right). The length of the arrow represents the migration rate at the scale shown. The shaded areas represent the SE.

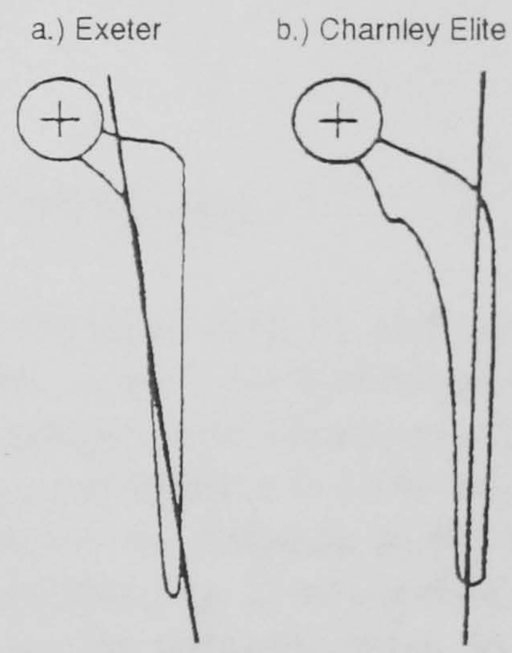

Fig. 2.

Diagram of the implants showing the axis around which the internal rotation occurs

During the first year, the most marked change in orientation of the Exeter was internal rotation (0.91 degrees/year, SE 0.18, p<0.0001). This was associated with posterior migration of the head (0.33mm/Vear, SE 0.08, p=0.0003) and anterior migration - of the shoulder (0.35mm/year, SE 0.03, p=0.01). The Charnley Elite also had rapid internal rotation (1.04 degrees/year, SE 0.42, p=0.02). This was associated with rapid posterior migration of the head (0.8Omm/year, SE 0.26, p=0.008) and no significant osterior shoulder migration (-0.09mm/year, SE 0.16, p=0.59). The Charnley posterior. head migration was 2.4 times (p=0.046) faster than the Exeter. The Exeter shoulder migrated anteriorly faster than the Charnley (p=0.048). were no significant differences between the internal rotations of the implants. For both implants the rotation continued at a much slower rate during the second year.

The rate of internal rotation of both implants was similar at about 1 Oper year. However, because of the differences in head and shoulder migration the axes of rotation are different (Fig.2). The Exeter tends to rotate around the calcar whereas the rotation of the Charnley Elite tends to occur around the stem. This is: presumably because the Exeter tends to jam in the calcar as it migrates distally within the cement mantle and therefore rotates around this point.

Evaluation of a hip joint simulator

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Abstract: To evaluate the functioning of the Durham hip joint wear simulator, the wear rates of ultra high molecular weight polyethylene (UHMWPE) and polytetrafluoroethylene (PTFE) acetabular cups articulating against 22 mm diameter cobalt–chromium–molybdenum (CoCrMo) femoral heads were studied. A wear test was conducted in a lubricant of distilled water at 37 °C for a duration of 4.8 million cycles. The average penetration rate for the CoCrMo femoral heads against UHMWPE acetabular cups was 0.03 mm/10^6 cycles, while penetration rate for PTFE cups was some twenty times greater. These results are of a similar order of magnitude to other simulator studies in distilled water and are in a similar ratio to clinical data.

Keywords: wear, hip simulators, PTFE, UHMWPE

1 INTRODUCTION

Osteolysis, induced by wear debris, has generated much interest in the prediction of wear rates of prostheses and in particular in the comparative performance of one design against others. To achieve this in the laboratory, hip joint simulators have been developed which incorporate motions and loads that replicate, to some extent, the *in vivo* conditions of hip joints. The Durham hip joint simulator is based on the A–B Automation Limited design where the joints are mounted anatomically and subjected to a dynamic loading cycle with independent, multi-axial motion. The motion and loading was applied in such a way as to produce the three-dimensional locus of the load vector over the acetabular component as seen *in vivo* [**1**]. In order to evaluate the performance of the simulator, wear tests were carried out on polytetrafluoroethylene (PTFE) and ultra high molecular weight polyethylene (UHMWPE) acetabular cups articulating against cobalt–chromium–molybdenum (CoCrMo) heads and the results were compared with other simulator wear results as well as data from explanted prostheses. Although water has been shown to give wear rates which are different from joints tested in serum, there are many results published in the literature for these conditions and this is the justification for using water in this evaluation.

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2 MATERIALS AND METHODS

The Durham hip joint simulator (Fig. 1) used one d.c. servo motor and gearbox to drive the flexion–extension mechanism which was common to all five articulating stations, and another motor and gearbox to drive the pelvic rotation mechanism. This too was common to all five stations. The resultant joint force (Fig. 2) was applied using a pneumatic actuator and proportional valve for each station. The signals used to control the force actuators were chosen to give the resultant force vector [**1**] and the input to the motors produced a cyclic frequency of 1 Hz.

The wear test was conducted in recirculating, distilled water at 37 °C for 4.8 million cycles, using three UHMWPE (annealed GUR415, non-irradiated) and two PTFE (Grade FP307985, non-irradiated) acetabular cups articulating against 22 mm diameter CoCrMo femoral heads. Both UHMWPE and PTFE soak control cups were maintained in the lubricant bath and measurements were taken every half a million cycles.

To take wear measurements, the simulator was stopped and the acetabular cups removed from each station. A cleaning protocol (see the Appendix) was then undertaken before leaving the cups to equilibrate overnight in a clean environment. The following morning gravimetric measurements were taken, using clean, dry compressed air to remove any possible contamination prior to measurement. Having completed the gravimetric measurements the wear rate was calculated by finding the true mass loss by subtracting the mass gain of the soak control sample due to moisture absorption, from the measured mass of the wear sample. The result was the true mass loss, to which a linear regression line was fitted to give the rate of mass loss.

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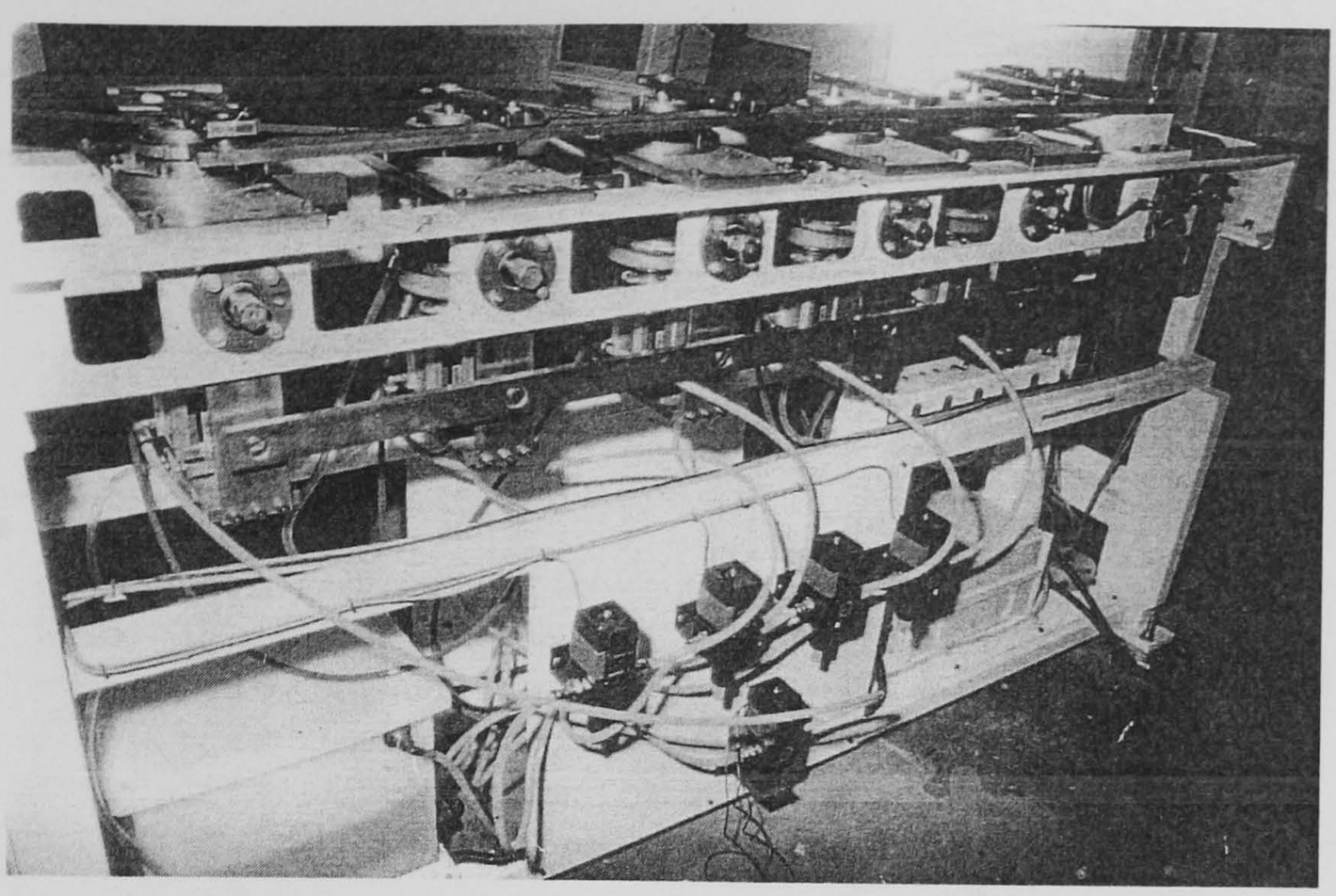

Fig. 1 The Durham hip joint wear simulator

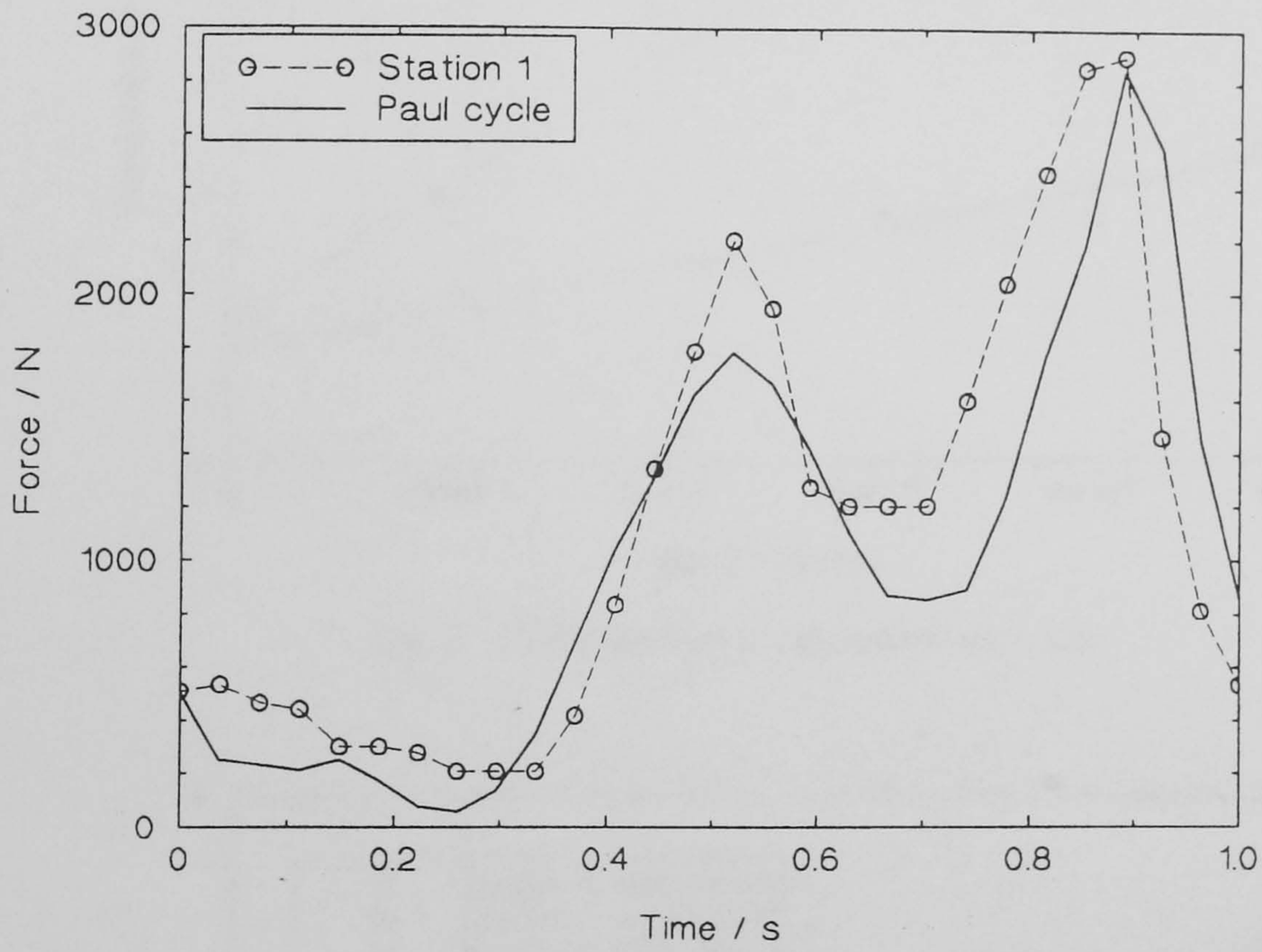

Fig. 2 The applied loading cycle

Replicas of the bearing surface were also taken using Provil MCD silicone rubber. The cup's orientation was marked on the cast prior to removal from the cup, so that penetration depth and angle could be assessed using the shadowgraphic technique [**2**].

3 RESULTS

Table 1 shows the creep component, penetration rate and mass loss due to wear for the PTFE and UHMWPE acetabular cups. The creep components and penetration rates were determined from the shadowgraph wear results, as shown in Figs 3 and 4 for PTFE and UHMWPE respectively, using a technique [**2**] to calculate wear rate and penetration from the gradient and intercept of the line respectively. The mass wear rates for the PTFE and UHMWPE acetabular cups were also determined by the gravimetric method. By assuming that the femoral head bores a cylinder into the acetabular cup, and knowing the femoral head size and acetabular cup material density, a penetration rate was calculated from the weight loss results.

4 DISCUSSION

Wear in simulators is generally lower than that observed *in vivo* [**3**] and the data in Tables 2 and 3 for simulator studies conducted in water compared with the *in vivo*

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Table 1 Results from the Durham hip wear simulator validation exercise

		PTFE 1	PTFE 2	UHMWPE 1	UHMWPE 2	UHMWPE 3
Creep component (mm)	Shadowgraph	0.421	0.540	0.113	0.124	0.027
Penetration rate (mm/10^6 cycles)	Shadowgraph	0.148	0.490	0.045	0.026	0.051
Mass wear rate (mg/10^6 cycles)	Gravimetric	104	368	9.72	5.35	19.5
Penetration rate (mm/10^6 cycles)	Gravimetric	0.29	1.02	0.03	0.01	0.05

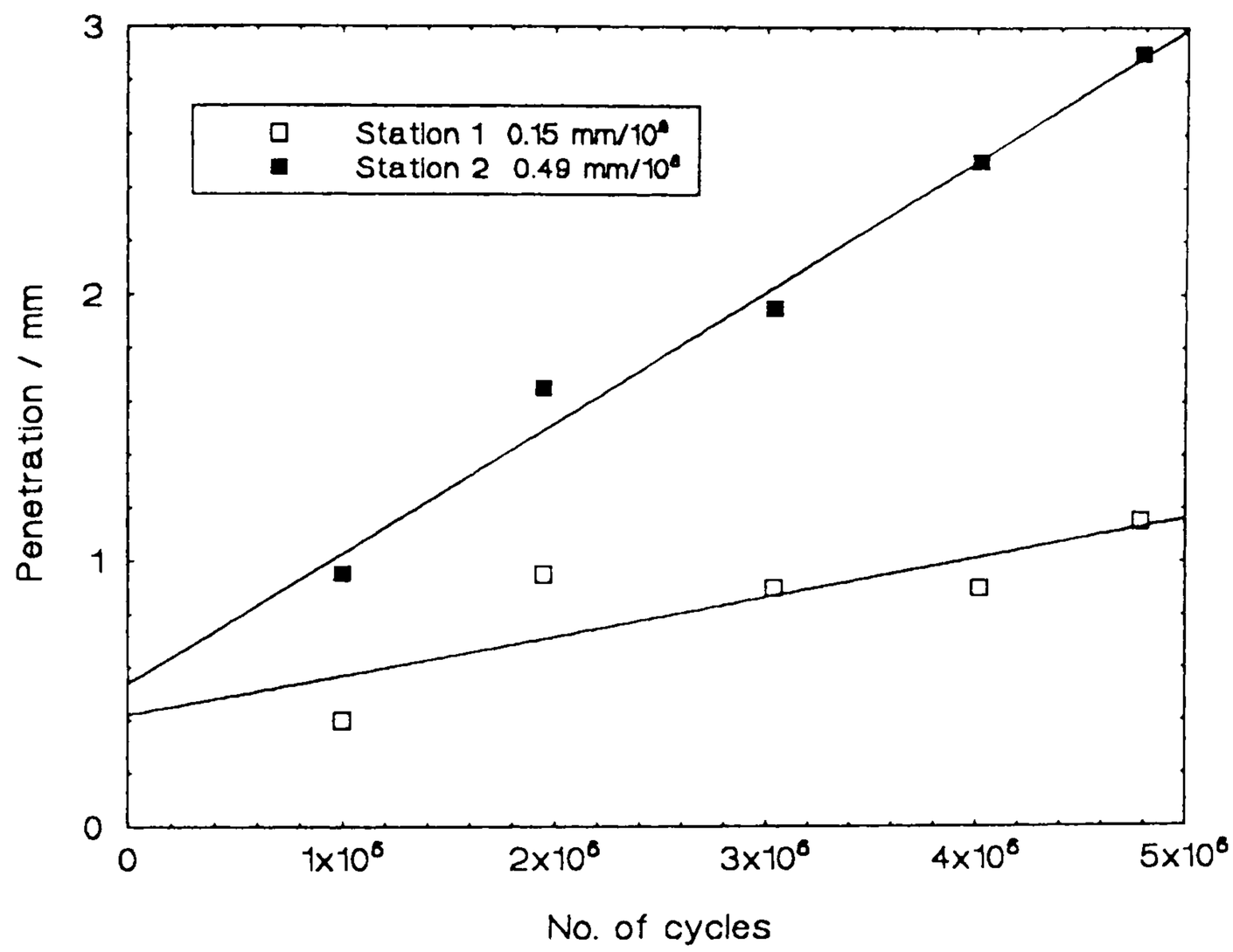

Fig. 3 PTFE acetabular cups penetration rate

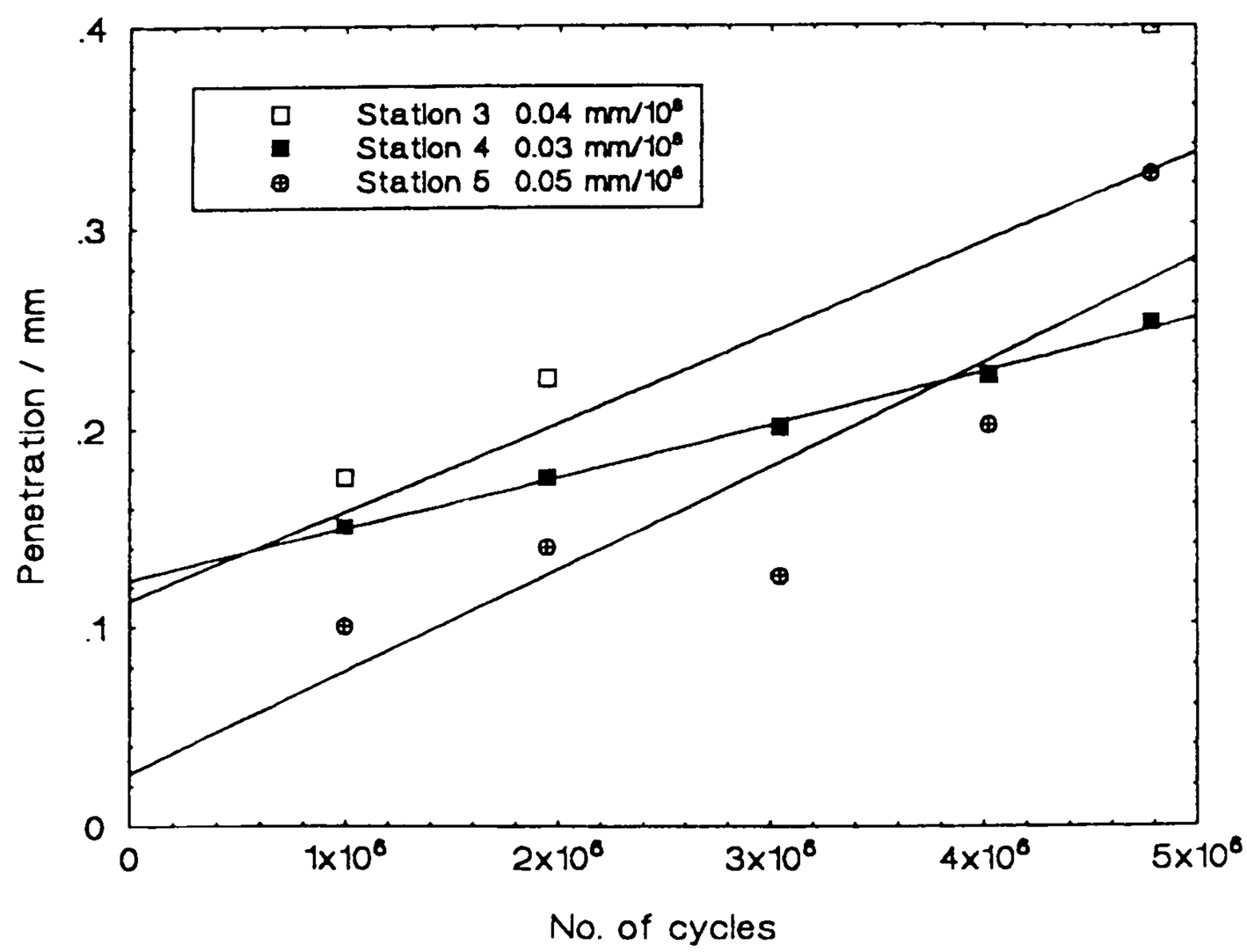

Fig. 4 UHMWPE acetabular cups penetration rate

Table 2 PTFE acetabular cup wear rates

Author/result	Duration of test /10^6 cycles or number of *ex-vivo* acetabular cups	22.25 mm PTFE cup against head type	Wear rate (mg/10^6 cycles)	Penetration rate (mm/10^6 cycles) or [*mm/yr (range)*]
Gravimetric results	4.8	CoCrMo	Cup 1: 104 Cup 2: 368	0.29* 1.02*
Shadowgraphic results	4.8	CoCrMo		0.148 0.490
Clarke [3]	0.06	Stainless steel		3.4
Good *et al.* [4]	0.52	CoCrMo	660	1.83*
Charnley *et al.* [5]	*39*	Stainless steel		*2.26* *(0.91 to 6.04)*

* By assuming that the femoral head bores a cylinder into the acetabular cup and knowing the femoral head size and acetabular cup material density, a penetration rate can be calculated from the weight loss results.

Table 3 UHMWPE acetabular cup wear rates

Author/result	Duration of test /10^6 cycles or number of *ex-vivo* acetabular cups	22.2 mm UHMWPE cup (unless otherwise stated) against head type	Wear rate (mg/10^6 cycles)	Penetration rate (mm/10^6 cycles) or [*mm/yr (range)*]
Gravimetric results	4.8	CoCrMo	Cup 1: 9.72 Cup 2: 5.35 Cup 3: 19.5	0.03* 0.01* 0.05*
Shadowgraph results	4.8	CoCrMo		0.045 0.026 0.051
Dowson and Jobbins [6]	3.1	Stainless steel		0.054
Saikko *et al.* [7]	3.0	Stainless steel	46, 51, 62	0.15*
Derbyshire *et al.* [8]	1.97	Stainless steel		0.04
Charnley and Halley [9]	*63*	Stainless steel		*0.15*
Atkinson *et al.* [10]	*25*	Stainless steel		*0.18* *(0.005 to 0.6)*
Wroblewski [11]	*22*	HDP cup/stainless steel		*0.19* *(0.017 to 0.52)*
Isaac *et al.* [12]	*87*	Stainless steel		*0.21* *(0.005 to 0.6)*
Kabo *et al.* [13]	*5*	Stainless steel		*0.127*
Hall *et al.* [14]	*28*	Stainless steel		*0.23* *(0 to 0.6)*

* By assuming that the femoral head bores a cylinder into the acetabular cup and knowing the femoral head size and acetabular cup material density, a penetration rate can be calculated from the weight loss results.

results confirms this observation. The gravimetric results for the PTFE cups compare favourably with the clinical results of Charnley *et al.* [5], both having similar high wear rates. Furthermore, the shadowgraphic results are also comparable with the clinical data. Although there is a discrepancy between the wear rates for the two PTFE cups, other researchers have found similar inconsistencies. Good *et al.* [4] found that when wear testing PTFE in water the resulting wear rate precision varied between ± 26 per cent and ± 70 per cent, with wear rates between two and seven times less than that reported by Charnley *et al.* [5]. Saikko *et al.* [7] reported up to a 29 times difference between similar cups, with a mean difference of 6.3.

The results for the UHMWPE cups were more than an order of magnitude lower than the PTFE cups for both measurement techniques. This is similar to other simulator studies reported in the literature and lower than the reported *ex vivo* data, as expected. Examination of the acetabular cup replicas used in the shadowgraphic technique showed that the femoral component was tunnelling into the cup as observed *in vivo*.

ACKNOWLEDGEMENTS

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APPENDIX

1. Rinse the acetabular cups with tap water to remove bulk contaminents.
2. Immerse the cups in a 1 per cent solution of Neutracon in an ultrasonic bath for 15 min at 40 °C; after 5 min degas to remove other contaminants.
3. Rinse the cups in a stream of distilled water.
4. Ultrasonically clean the cups in distilled water for 5 min.
5. Rinse the cups again in a stream of distilled water.

Do not touch the specimen directly from this point on to avoid contamination.

6. Dry with lint-free tissue.
7. Immerse the cups in methyl alcohol for 3 min.
8. Dry with lint-free tissue.
9. Air dry the cups in a dust-free environment at room temperature overnight.
10. Blast clean with clean, dry compressed air.
11. Weigh each acetabular cup in turn.
12. Repeat weighing until the readings are consistent within a narrow range.

Technical Note

A comparison between gravimetric and volumetric techniques of wear measurement of UHMWPE acetabular cups against zirconia and cobalt–chromium–molybdenum femoral heads in a hip simulator

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Abstract: Five cobalt–chromium–molybdenum (CoCrMo) and five zirconia femoral head components have been wear tested against 28 mm diameter ultra high molecular weight polyethylene (UHMWPE) acetabular cups for 5 million cycles in the Durham hip joint wear simulator using bovine serum as a lubricant. Wear measurements used gravimetric and volumetric techniques and no statistically significant difference was found between the measurement methods. The wear rates of the acetabular cups against both femoral heads are presented for both measurement methods. The UHMWPE acetabular cups showed a statistically significant higher linear wear rate for the first 2 million cycles than the lower linear wear rate from 2 million cycles to the end of the test, against both femoral head materials. Over the full duration of the wear test, the wear rates of acetabular cups articulating against zirconia femoral heads were lower than against CoCrMo femoral heads. The wear rates up to 2 million cycles and from 2 to 5 million cycles for both femoral head materials were consistent with other studies.

Keywords: gravimetric technique, volumetric technique, wear, UHMWPE, acetabular cups, hip simulator, zirconia and CoCrMo femoral heads

1 INTRODUCTION

The most common cause of failure in artificial hip joints is loosening [**1**] and this is generally thought to be caused by osteolysis induced by particulate debris [**2**]. While originally it was thought that the polymethylmethacrylate bone cement was responsible, more recently it has become clear that the ultra high molecular weight polyethylene (UHMWPE) wear particles are more likely to be the cause of the biological responses which cause bone lysis [**3**]. There is also growing clinical evidence that the total volume of wear debris is important to loosening [**4, 5**] and if this is true then the wear rate of polyethylene determines how long the joint replacement procedure will last. In order to determine the wear rates of different combinations of materials and designs of artificial joints prior to clinical implantation, machines have been developed which generate similar levels of wear debris to those observed clinically.

The principal aim of this study was to compare two of the most popular methods of measuring wear rates in simulator experiments. A gravimetric technique was used where the acetabular cups were weighed on a micro balance after a careful and rigorous preparation method. Fluid absorption due to the hydrophilic nature of UHMWPE was also measured with unloaded and loaded soak controls and the mass gain due to fluid absorption was taken into account. Volumetric measurement was investigated using a coordinate measuring machine (CMM) to measure dimensional changes. Dimensional changes due to creep and wear were investigated.

The second aim of the study was to determine whether there were any differences in the wear rates of

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UHMWPE acetabular cups when articulating against cobalt–chromium–molybdenum (CoCrMo) alloy femoral heads and zirconia ceramic heads.

2 MATERIALS AND METHOD

The Durham hip joint simulator [6] was originally based on the 'A–B Automation Limited' design but has subsequently been modified to allow the use of bovine serum as a lubricant. Six joints were mounted anatomically and subjected to a dynamic loading cycle [7] as shown in Fig. 1. One station applied a dynamic load across the prosthesis without any motion, thus providing a creep station. The five articulating stations combined flexion/extension of the femur, with internal/external rotation of the acetabular cup. The load vector was not simply in the vertical direction, but oscillated with the angle of swing of the femur. The combination of motion and loading cycles resulted in a three-dimensional locus of the load vector over the acetabular component, as seen *in vivo* and as used by Brummitt and Hardaker [8].

The simulator used one d.c. servo motor and gearbox to drive the flexion/extension mechanism which was common to all five articulating stations. Another motor and gearbox drove the pelvic rotation mechanism. This too was common to all five stations. The resultant joint force was applied using a Norgren proportional pneumatic valve, amplified by an SMC booster valve. This pressure was then applied to each station through a manifold to ensure that each station was loaded similarly. A Hoerbiger pneumatic actuator on each station applied the load across each prosthesis. A EuroSystem/EuroStep Servo/Stepper positioning system manufactured by Harmonic Drive Limited and programmed in Motion Interpreter (MINT) language was used to control the motors and pneumatic valves.

Two wear tests were conducted, both of which had a duration of 5 million cycles. The first test had two articulating zirconia femoral heads, three articulating cobalt–chromium–molybdenum (CoCrMo) femoral heads, and a zirconia femoral head was used in the creep station. The second test had three articulating zirconia femoral heads, two articulating CoCrMo femoral heads, and a CoCrMo femoral head was used in the creep station. This allowed data to be gathered on five zirconia and five articulating CoCrMo femoral heads spread over two wear tests. All of the prostheses were 28 mm diameter Howmedica products (Zirconia femoral heads Ref 4653-40, CoCrMo femoral heads Ref 4653-01), and the acetabular cups used in both the wear tests came from the same batch at manufacture (UHMWPE Ref 4840-2856 Lot T241633, sterilized May 1995 Lot 55301).

The tests were conducted in a lubricant of 25 per cent v/v newborn calf serum with 0.1 per cent m/v sodium azide to retard bacterial growth. (The bovine serum used in both wear tests was from the same supplier and batch; Harlan Sera-Lab Limited, Batch 6030207.) Wear rates of the acetabular cups were measured using both gravimetric and volumetric techniques using a Mettler balance and Kemco coordinate measuring machine (CMM) by directly measuring the same acetabular cups using both methods. This allowed a comparison between gravimetric and volumetric measurement. The results of the two measurement methods were then analysed using the Stata 4.0 statistical analysis package [9]. Normality was tested by applying Shapiro–Wilk and Shapiro–Francia tests, and equality of means was tested using t tests when the distribution was normal. For non-normal distributions Wilcoxon rank-sum tests were used to

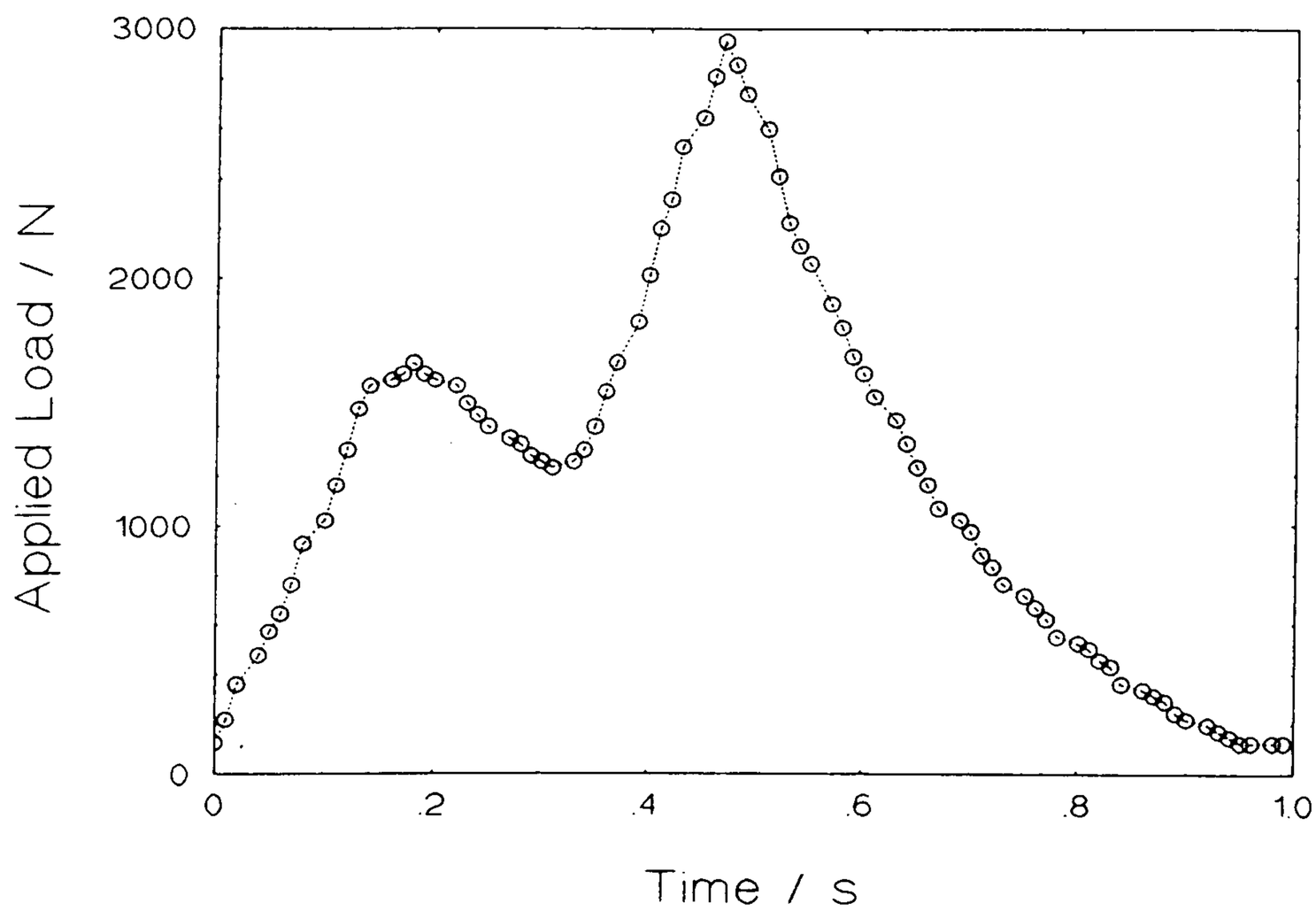

Fig. 1 Applied dynamic loading cycle

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examine the equality of medians, and Spearman's rank correlation tests applied to assess the significance of independence.

2.1 Gravimetric technique

A soak control acetabular cup was maintained to allow for water absorption in the cups due to the hydrophilic nature of UHMWPE. The creep specimen also allowed investigation into possible differences in water absorption between loaded and unloaded control specimens as suggested by Saikko *et al.* [**10**]. Gravimetric measurements were taken before each wear test then at intervals of every 0.5 million cycles during the wear tests. All the cups were removed from the simulator, cleaned, dried and weighed using the protocol given in the Appendix. The true mass loss of a worn cup was obtained by subtracting the mass gain of the loaded creep control due to moisture gain, from the measured mass of the worn cup. The result was the true mass loss which was plotted against the number of cycles of the wear test. A straight line was then fitted to different regions of the curve using the method of least squares, to give the rate of mass loss over that region. The gravimetric wear rate in mg/10^6 cycles was then converted to $mm^3/10^6$ cycles by dividing by the density of UHMWPE (983 kg/m^3) to allow comparison with the volumetric results.

2.2 Volumetric technique

Volumetric measurements were taken using a Kemco 400 coordinate measuring machine at the University of Leeds. The cups were allowed to relax and equilibrate for at least 48 hours in the temperature controlled environment of a metrology laboratory where the CMM was sited, before taking measurements using a method developed by Derbyshire *et al.* [**11**]. Measurements were taken at 0.5, 1.5, 4.0 and 5.0 million cycles for the first wear test. An initial measurement was taken before the second wear test began, followed by measurements at 0.5, 1.0, 2.0 and 5.0 million cycles during the second wear test. The creep station enabled measurement of the creep of the UHMWPE due to loading. The volumetric wear rates were calculated using the data from 0.5 million cycles onwards where creep deformation was considered to have stabilized [**12**].

3 RESULTS

3.1 Gravimetric results

The mass gain due to water absorption was greater for the dynamically loaded acetabular cups in the creep cell than for the unloaded soak controls in both wear tests. The mass gain for the creep and soak controls from the first wear test are shown in Fig. 2. Mass gain due to water absorption was therefore compensated for using the creep control sample for each wear test.

Figure 3 plots the true mass loss of an acetabular cup from test 1, station 3, which has been articulating against a zirconia femoral head for 5 million cycles. From visual analysis of a plot for a single acetabular cup over the duration of a full wear test, it is difficult to identify any particular trends in the wear rate. However, when a second acetabular cup is added to the graph it is now possible to identify a wear trend up to 2 million cycles,

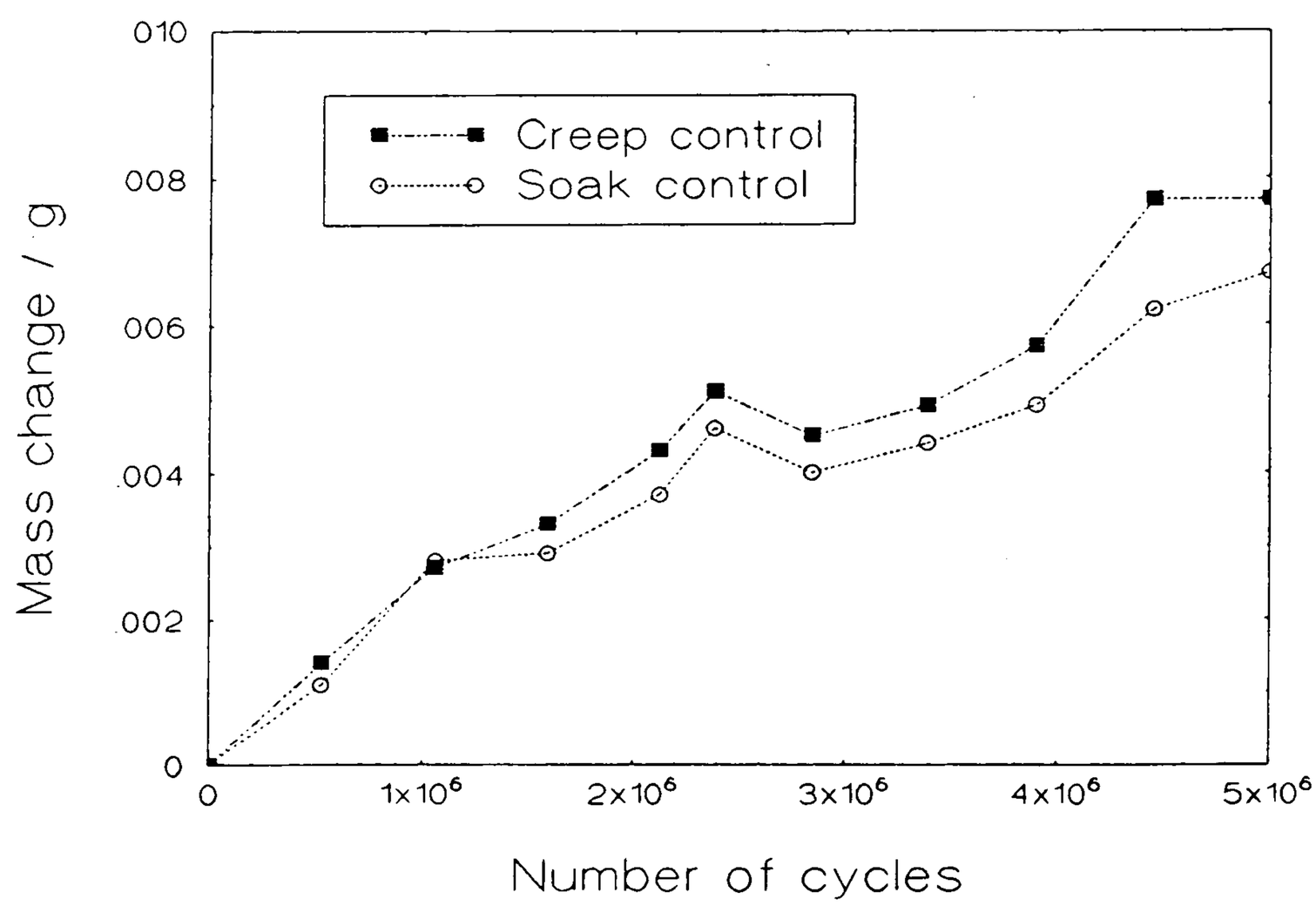

Fig. 2 Mass gain due to water absorption for the soak and creep controls in the first wear test

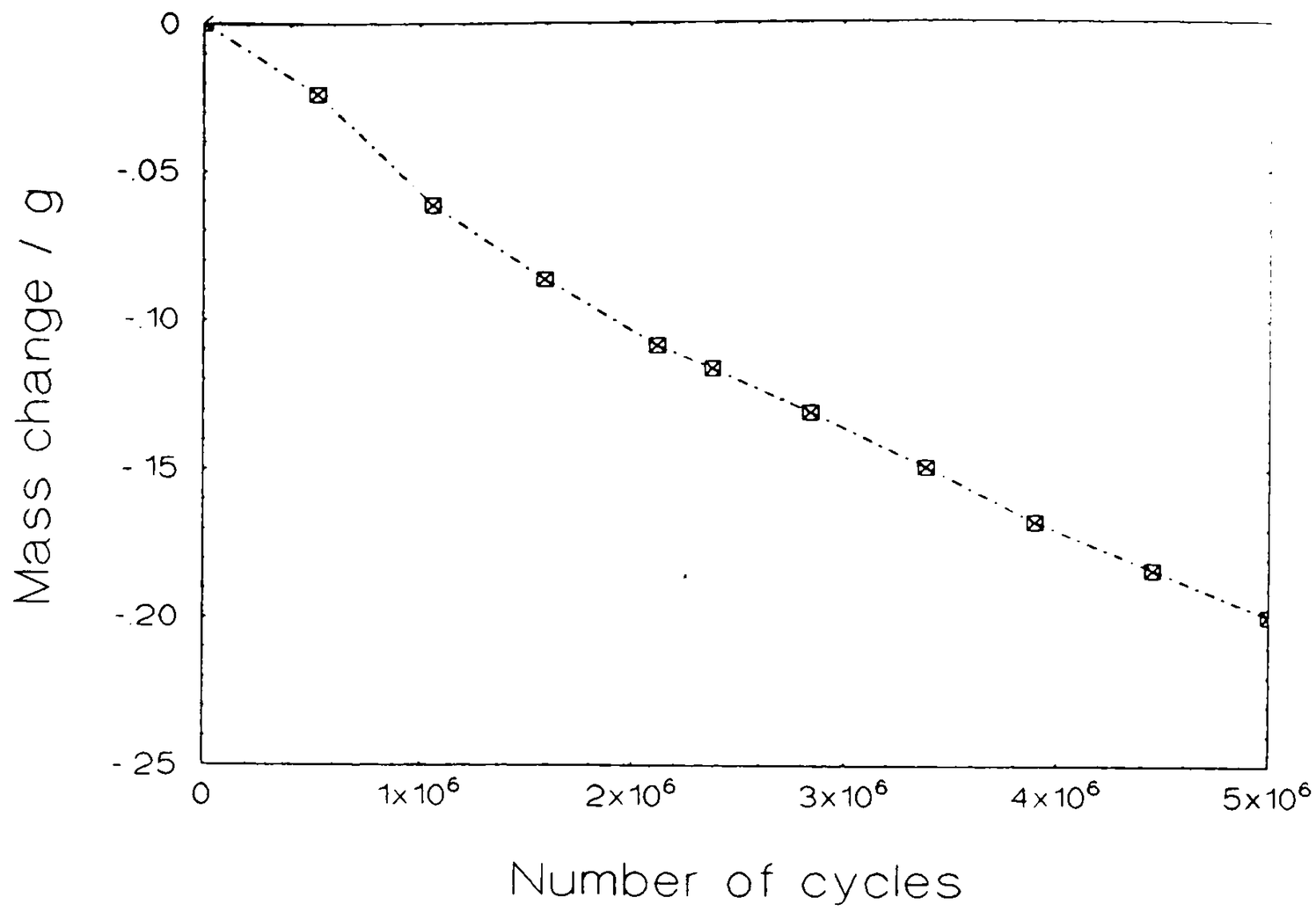

Fig. 3 Corrected mass change of an acetabular cup against number of cycles

and a second wear trend thereafter. Figure 4 plots the mass change of the previous acetabular cup as well as a second acetabular cup from test 1, station 5, which has had a CoCrMo femoral head in articulation against it. Straight lines fitted using the method of least squares to the points over these two periods, zero to 2 million cycles, and 2 to 5 million cycles, show the wear rates in each interval to be linear. Figure 5 shows an analysis from zero to 2 million cycles for the two acetabular cups previously shown in Fig. 4. Figure 6 shows an analysis from 2 to 5 million cycles for the same two acetabular cups. An excellent correlation is seen between the points and the best fit lines (using the method of least squares) for both sets of acetabular cup data. The gravimetric results showed two linear wear phases for all the wear samples. The wear rates for the two phases were significantly different at $p = 0.0012$ for all the samples.

The UHMWPE acetabular cup mean wear rates and standard errors over the full test duration found from gravimetric measurements are shown in Table 1. Figure 7 presents the mean wear rates and standard errors for cups articulating against zirconia and CoCrMo femoral heads for the initial wear phase up to 2 million cycles, the second phase from 2 to 5 million cycles, and an overall average wear rate covering the full duration of the test. The wear rates for cups articulating

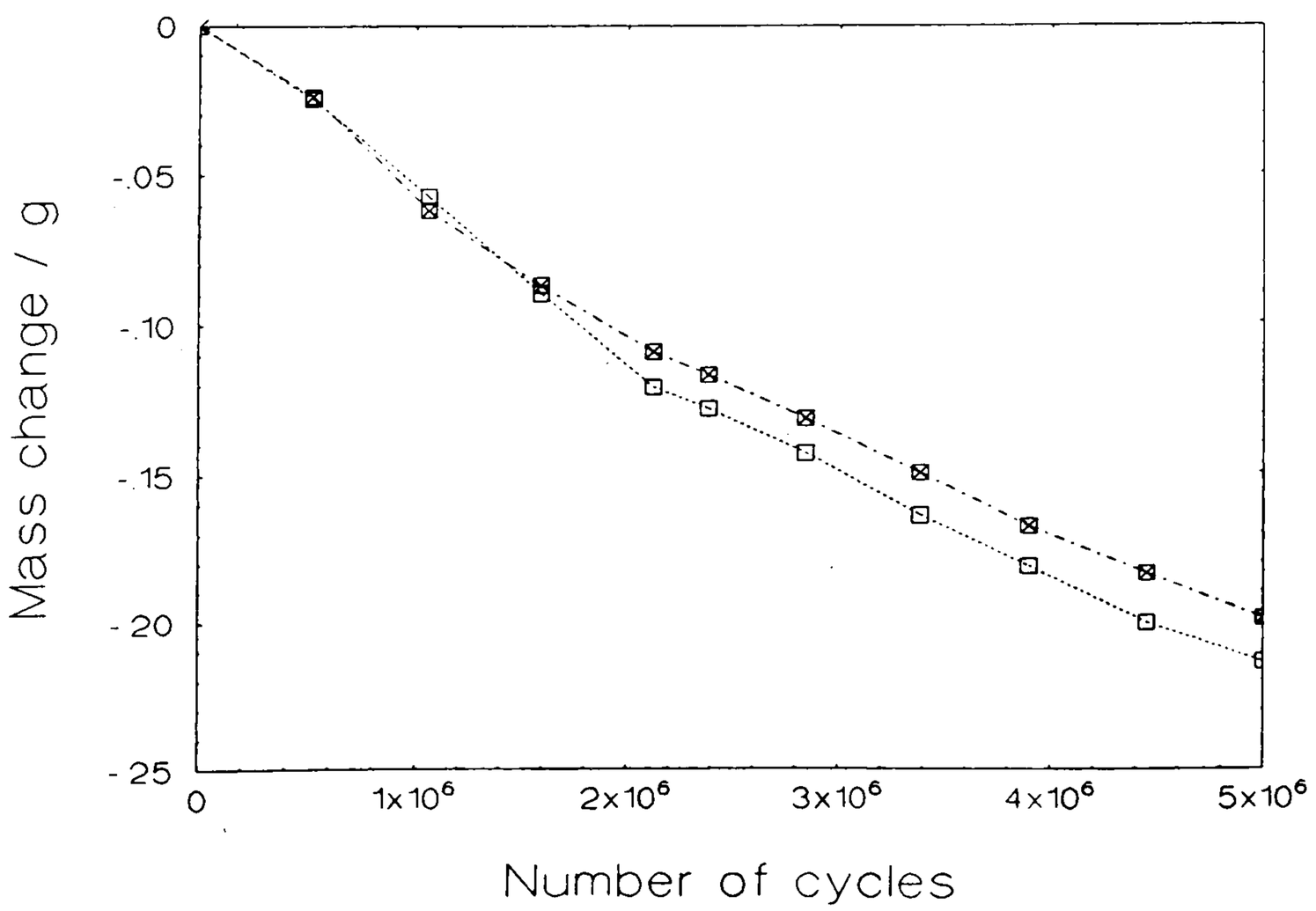

Fig. 4 Corrected mass change of two acetabular cups against number of cycles

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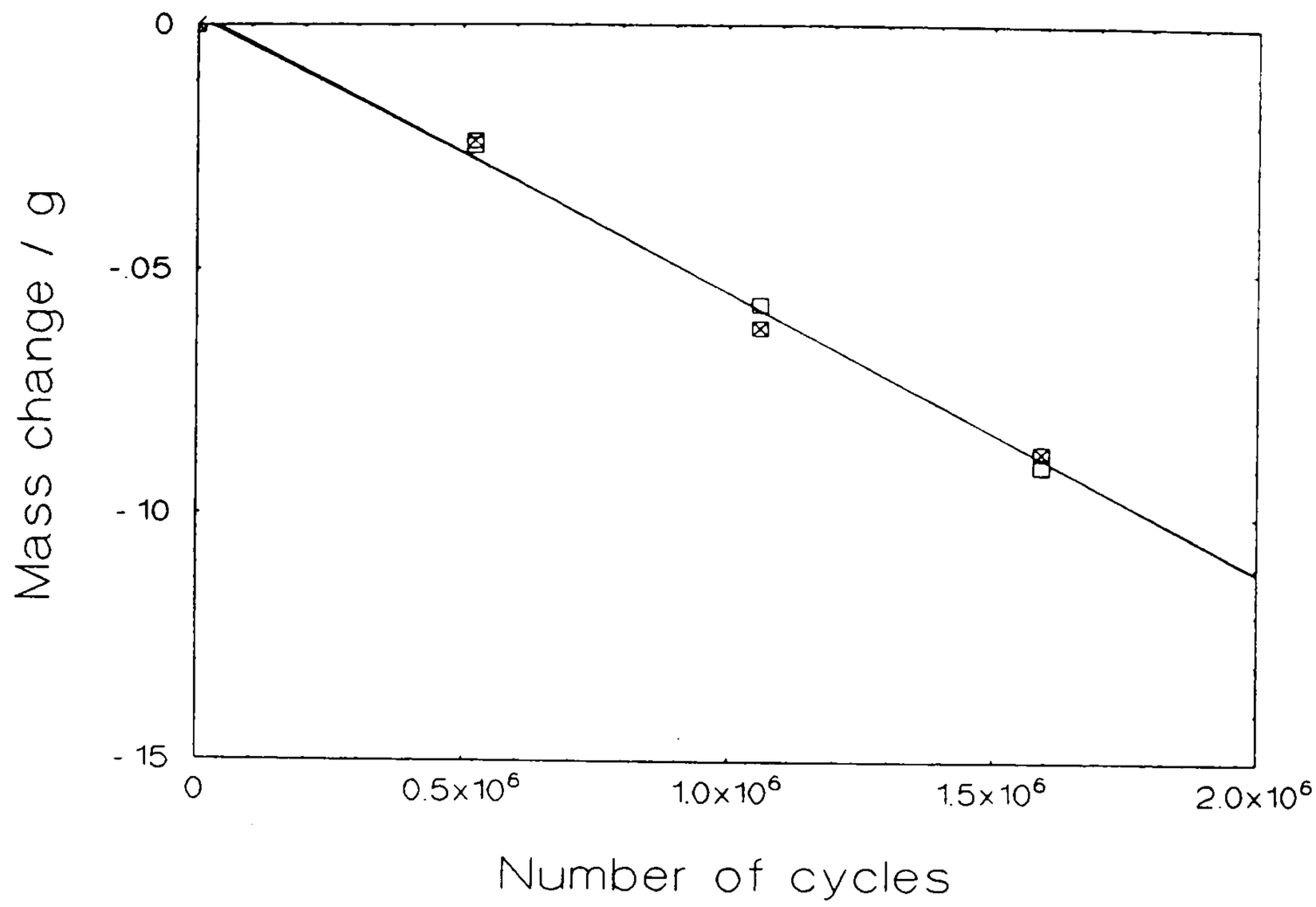

Fig. 5 Analysis from zero to 2 million cycles for the two acetabular cups shown previously in Fig. 4

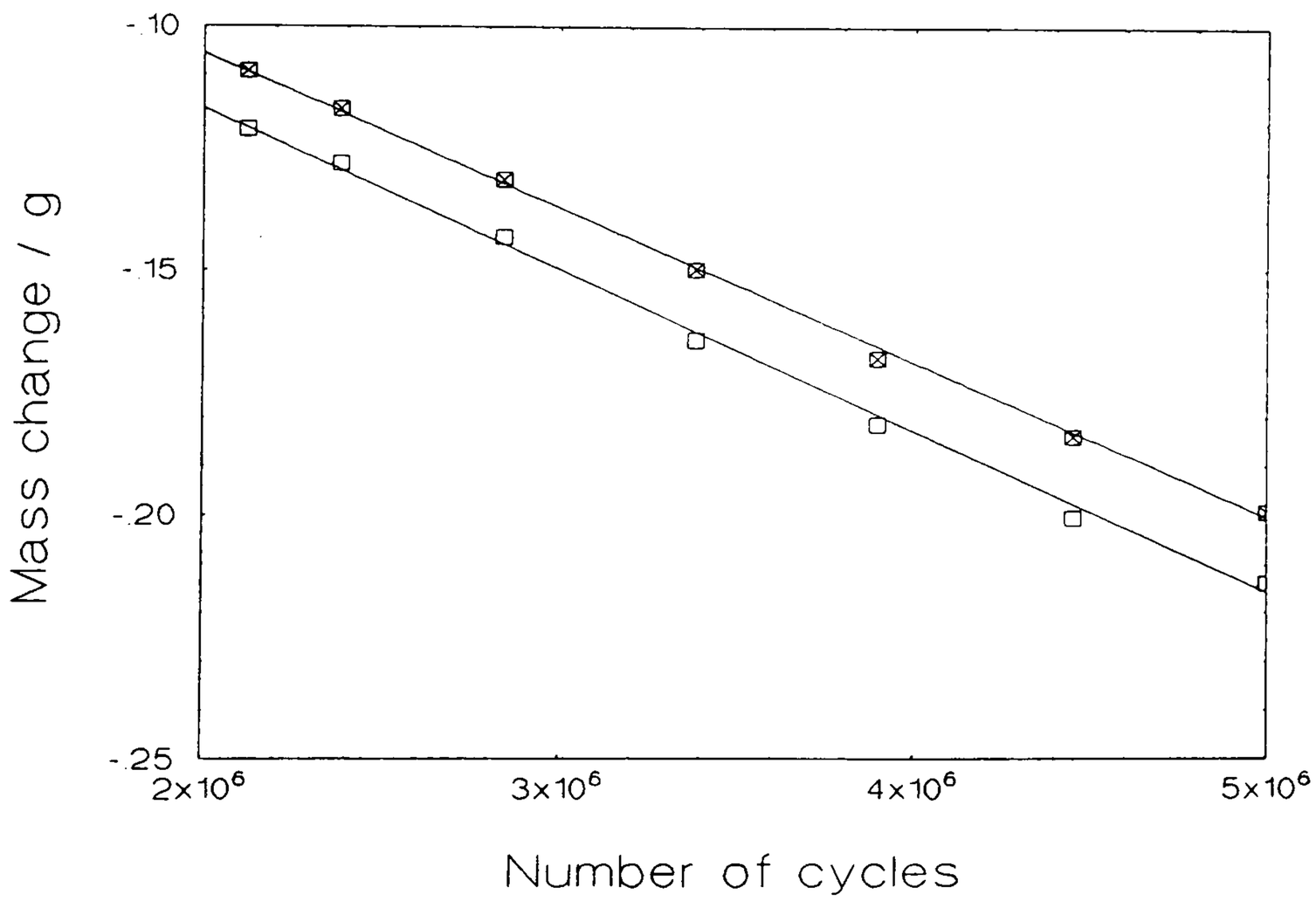

Fig. 6 Analysis from 2 to 5 million cycles for the two acetabular cups shown previously in Fig. 4

Table 1 Results of this study compared with wear rates from hip joint simulator tests of 28 mm diameter prostheses

Simulator/Author	Lubricant	Head type	Test duration (10^6 cycles)	Volumetric wear rate ($mm^3/10^6$ cycles)	Gravimetric wear rate ($mm^3/10^6$ cycles)
This study	Bovine serum	Zirconia	5.0	41.0 ± 2.6	—
This study	Bovine serum	CoCrMo	5.0	51.4 ± 3.0	—
This study	Bovine serum	Zirconia	5.0	—	38.6 ± 3.6
This study	Bovine serum	CoCrMo	5.0	—	48.2 ± 3.7
Barbour *et al.* [13]	Bovine serum	Zirconia	4.0	30.0 ± 2.3	—
Barbour *et al.* [13]	Bovine serum	CoCrMo	4.0	41.6 ± 5.3	—
Clarke *et al.* [14]	Bovine serum	Alumina	1.6	—	35
McKellop *et al.* [15]	Bovine serum	316 stainless steel	3.0	—	55
McKellop *et al.* [15]	Bovine serum	Titanium	2.0	—	39
McKellop *et al.* [15]	Bovine serum	Ti explants	1.0	—	50
Saikko [16]	Water	Various	3.0	—	0–28
Clarke *et al.* [17]	Bovine serum	Alumina	1.6	—	32.8

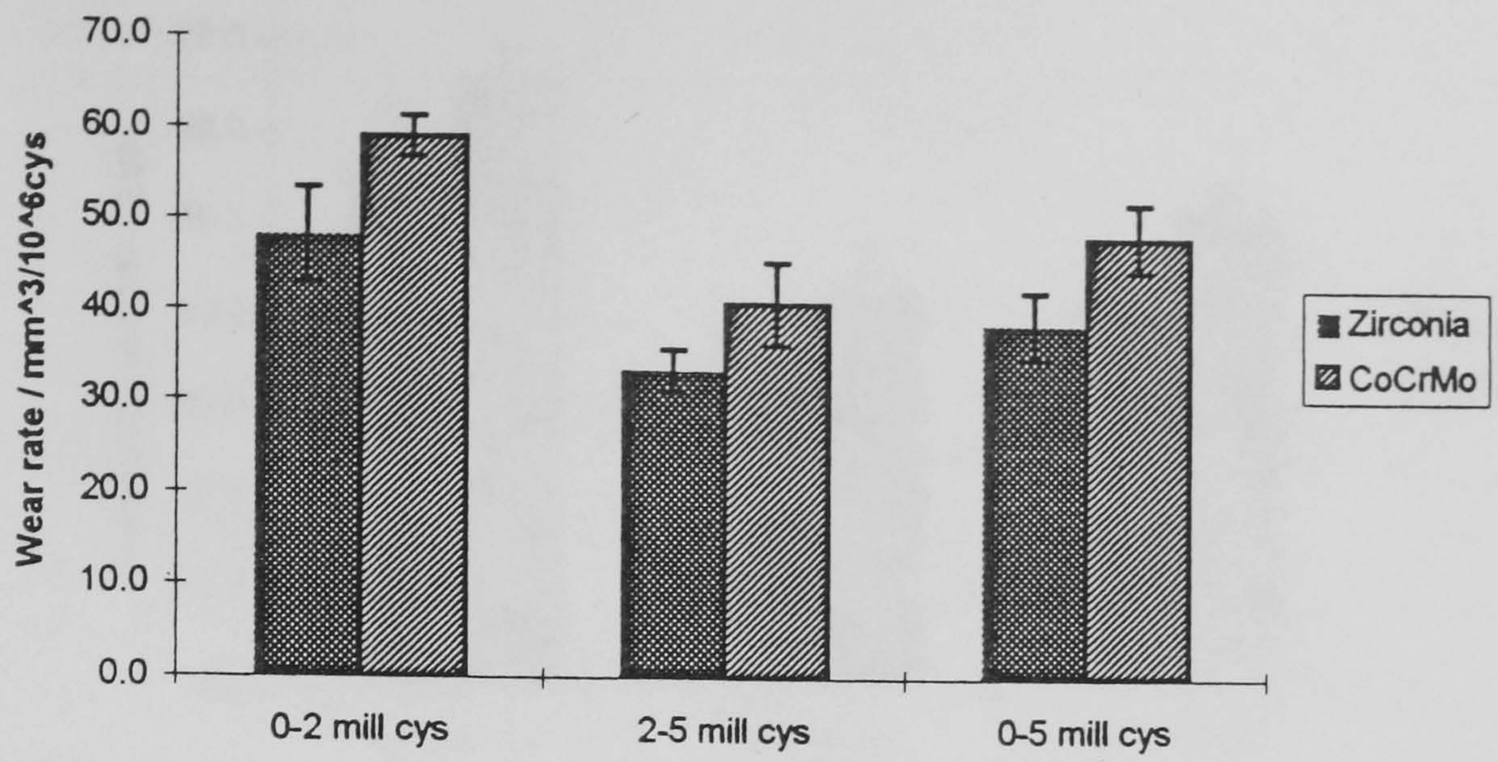

Fig. 7 The gravimetric acetabular cup wear rates against zirconia and CoCrMo femoral heads for various durations of the wear tests

against zirconia heads were lower than those articulating against CoCrMo femoral heads for the full duration of the wear test ($p = 0.096$).

3.2 Volumetric results

The deformation due to creep for the creep control in the second wear test is shown in Fig. 8. Two wear phases were found from the volumetric results for all the wear samples. An initial, high wear rate up to 2 million cycles was followed by a lower linear wear rate thereafter. These two wear rates were significantly different as confirmed by Spearman's coefficient, $\rho = -0.091$.

The volumetric mean wear rates and standard errors over the full test duration are given in Table 1. Figure 9 presents the results for cups articulating against both zirconia and CoCrMo femoral heads for the initial wear phase up to 2 million cycles, the second phase from 2 to 5 million cycles, and an overall wear rate covering the full duration of the test. The wear rates for cups articulating against zirconia heads were significantly different ($p = 0.031$) from those articulating against CoCrMo femoral heads for the full duration of the wear test.

4 DISCUSSION

The observation by Saikko *et al.* [**10**] that loaded controls gained more mass due to water absorption than unloaded soak controls was seen in both wear tests. Consequently, true mass loss calculations of the wear samples took into account the mass uptake of the loaded samples. Wear testing using gravimetric measurement therefore should incorporate a creep station to account

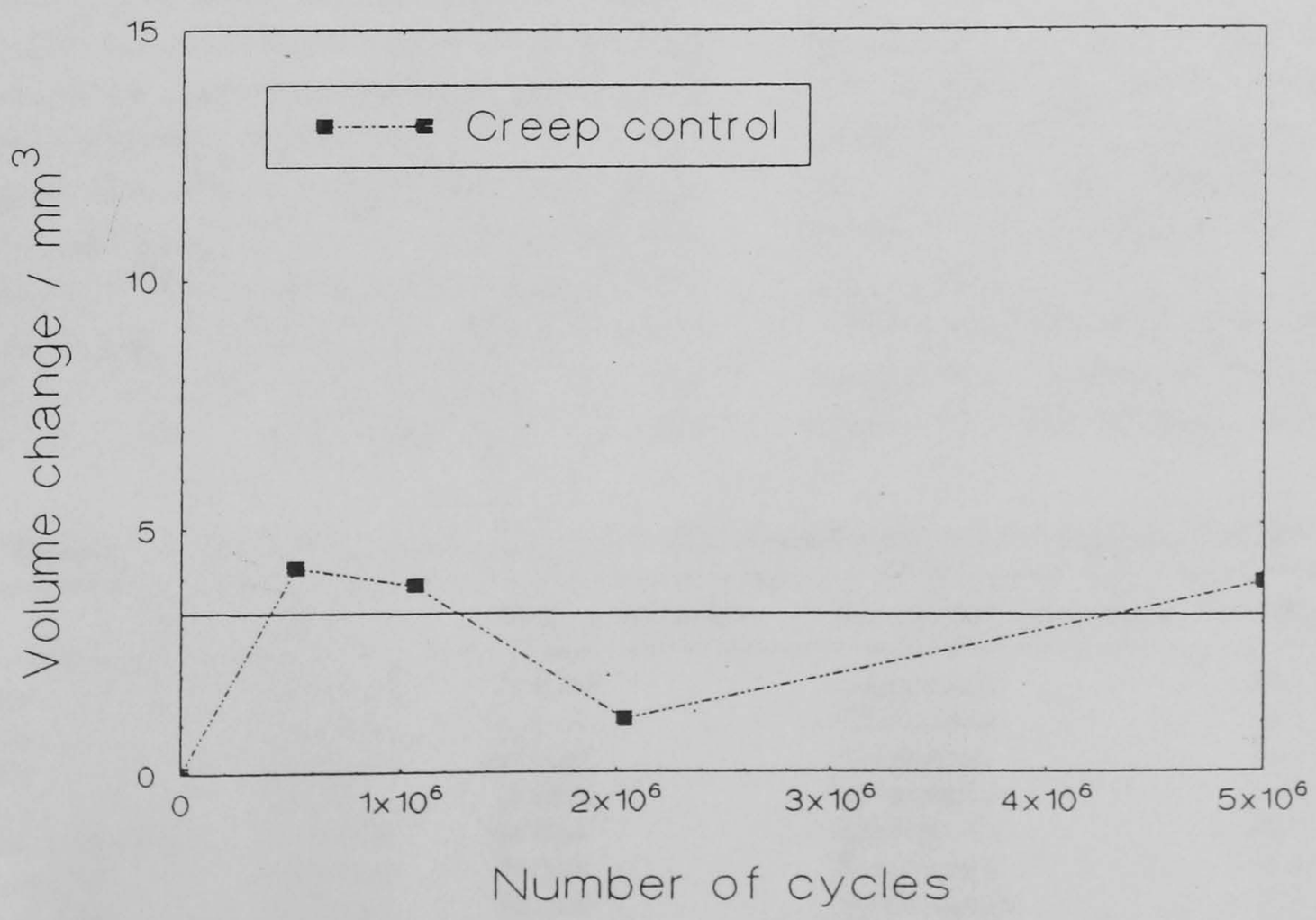

Fig. 8 Volumetric change due to creep for the 28 mm UHMWPE cup in the second wear test

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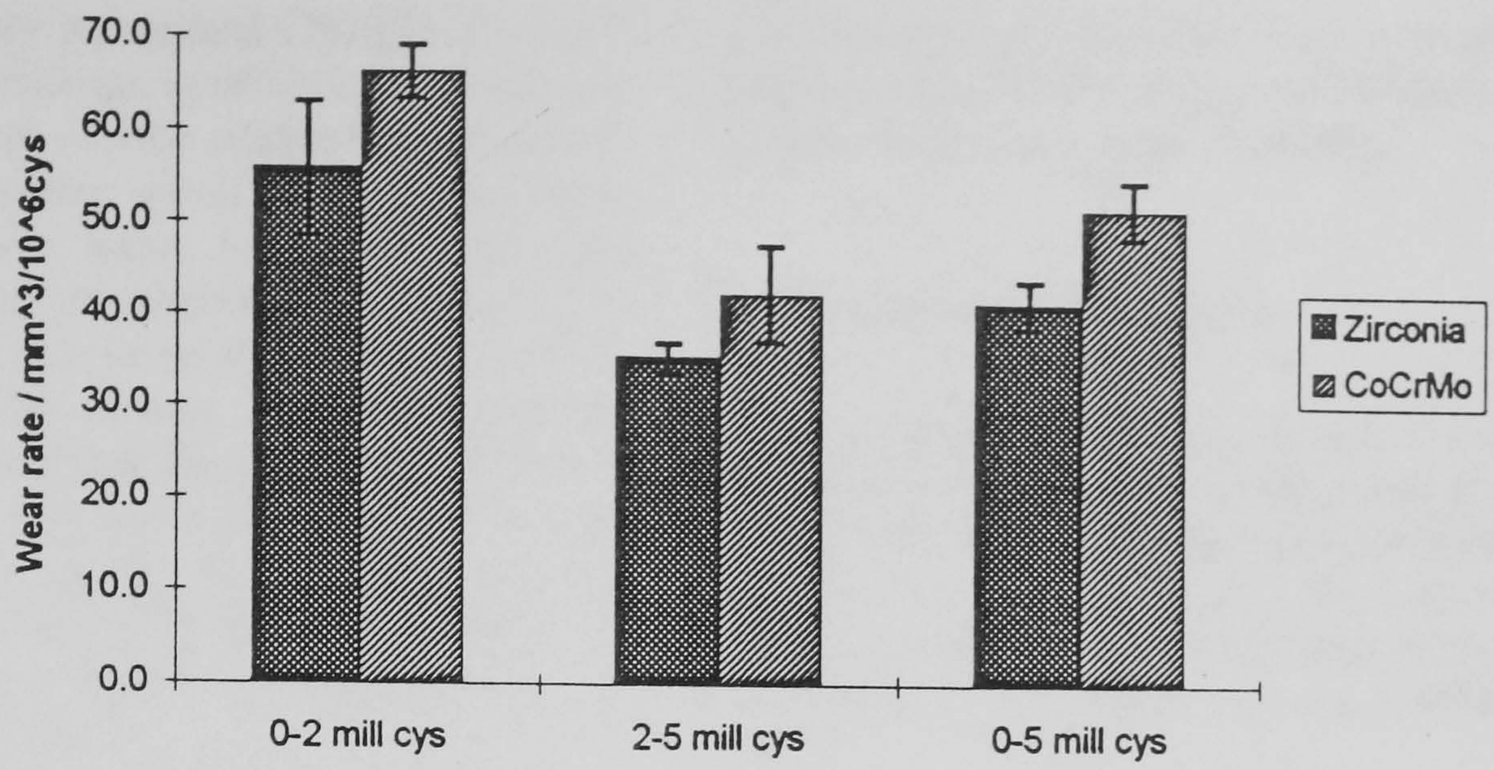

Fig. 9 The volumetric acetabular cup wear rates against zirconia and CoCrMo femoral heads for various durations of the wear tests

more accurately for the moisture absorbed by the wear samples.

The deformation due to creep with test duration shown in Fig. 8 is consistent in form with that found by Bigsby *et al.* [**12**]. Exclusion of the volumetric data from the initial part of the wear test to allow creep to stabilize, when calculating volumetric wear rates, is also consistent with other authors [**12, 13**].

The two wear phases shown by all prostheses were identified by both measurement techniques. The difference in acetabular cup wear rates against the different femoral head materials was also identified with both measurement techniques. No statistically significant difference was found between the wear rates measured using gravimetric and volumetric methods for any of the wear test intervals analysed. The biphasal wear observed in this study has been noted by Wroblewski *et al.* [**18**] and Dumbleton [**19**]. Jasty *et al.* [**20**] found a statistically significant relationship between the duration the implant had been *in situ* and the acetabular cup wear rate. Cups that had been *in situ* for short durations had significantly higher wear rates than cups *in situ* longer.

Table 1 compares the wear results of this present study with other *in vitro* studies of 28 mm diameter prostheses. The wear rates quoted for this study are the overall wear rates for the full test duration to allow comparison with the other published results which generally use this method. The results of this study showed that CoCrMo femoral heads gave higher UHMWPE acetabular cup wear rates than zirconia femoral heads did. Barbour *et al.* [**13**] also made this observation, and generally tests with ceramic femoral heads [**14, 17**] gave lower wear rates than metallic heads [**15**]. This study showed good agreement with published acetabular cup wear rate studies conducted in bovine serum.

Table 2 gives the wear results from this study and compares them with clinical results for 28 mm diameter prostheses. It can be seen that the results compare favourably when the differences between *in vitro* wear and *in vivo* wear are considered. It is generally considered that simulator wear tests produce lower wear rates than those for similar prostheses worn *in vivo* [**25**]. In a simulator, it is highly unlikely that bone or cement particles could contaminate the joint space causing possible damage to both the femoral head and acetabular cup whereas in the body this is a distinct possibility. The UHMWPE acetabular cups tested *in vitro* have frequently had shorter post irradiation ageing than cups which have been implanted. The motion and loading cycles applied by simulators are generally smooth, continuous walking patterns without the extremes seen clinically when a patient may run, climb or descend stairs, rise from a chair, or even trip and possibly fall.

Wear measurement of *in vivo* prostheses is principally restricted to radiographic measurements. The difficulties associated with making accurate measurements using

Table 2 Results of this study compared with clinical wear rates for 28 mm diameter prostheses

Author	Head type	Wear environment	Measurement technique	Wear rate ($mm^3/10^6$ cycles)
This study	Zirconia	*In vitro*	Gravimetric	38.6 ± 3.6
This study	CoCrMo	*In vitro*	Gravimetric	48.2 ± 3.7
This study	Zirconia	*In vitro*	Volumetric	41.0 ± 2.6
This study	CoCrMo	*In vitro*	Volumetric	51.4 ± 3.0
Livermore *et al.* [**21**]	CoCrMo	*In vivo*	Radiograph	48.4
Cates *et al.* [**22**]	Titanium	*In vivo*	Radiograph	48.2–61.6
Kabo *et al.* [**23**]	Various	*Ex vivo*	Shadowgraph	75.6
Devane *et al.* [**24**]	Titanium	*In vivo*	Radiograph	98.5–155.1

this technique are widely recognized [**26**, **27**]. Accurate *ex vivo* wear measurements are possible by a number of methods. However, most *ex vivo* studies use prostheses retrieved at revision surgery which are therefore more likely to show excessive wear. Sychterz *et al.* [**28**] retrieved 32 mm diameter prostheses from cadavers, and found the *ex vivo* wear rate to be 45 to 69 per cent less than that of comparable 32 mm diameter prostheses retrieved at revision. Applying the same logic and ratio to the 28 mm diameter prostheses results of Kabo *et al.* [**23**], who based their study on revision operation retrievals, would gave a wear rate of 23.4–41.6 $mm^3/10^6$ cycles. These values are clearly comparable with the *in vitro* results of this study.

This study was part of a larger collaborative research project for the Department of Trade and Industry CAM 1 project entitled, 'Accelerated test methods to predict the durability of materials and surface treatments employed for total hip replacements'. At the start of this project testing protocol was discussed and established to ensure consistency in the project between tasks and research groups. One of the protocols established was to use prostheses of the same design, from the same manufacturer, manufactured at the same time. Consequently, there has been inevitable ageing of the irradiated polyethylene components which has been shown to have an adverse effect on the wear performance of the material [**29**]. Statistical analysis of the wear rates revealed no statistical difference between the two wear tests. However, when conducting a series of wear tests over an extended period of time it may be advisable to use polyethylene components of the same age from test to test rather than from the same original batch.

5 CONCLUSIONS

The essential element of this study was to compare gravimetric and volumetric measurement techniques when measuring the wear of UHMWPE acetabular cups. The two techniques were employed to measure the wear of the same acetabular cups wear tested on the Durham hip joint simulator. No significant difference was found between the results from either technique which gives confidence that both techniques are acceptable for the wear measurement of UHMWPE acetabular cups.

As shown with this study and other research [**12**, **13**], a creep cell is not necessarily required when using volumetric measurement if the initial data during stabilization of the creep component is removed from the analysis. Interestingly, a creep cell is required for gravimetric measurement as a loaded control absorbs more moisture than a soak control over the duration of a wear test. This study also made a statistically significant observation that the zirconia femoral heads gave a lower UHMWPE acetabular cup wear rate than CoCrMo femoral heads. Furthermore, the acetabular cups had significantly higher initial linear wear rates against both femoral head materials up to 2 million cycles than the lower, linear wear rates thereafter.

ACKNOWLEDGEMENTS

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APPENDIX

Hip joint wear simulator: cleaning and drying protocol

1. Decant and freeze the lubricant in individual bottles labelling station number, prostheses and test description, test duration and date.
2. Disassemble each cup from the gaiter and mount, then wash the cups and soak control in tap water to remove bulk contaminants.
3. Immerse the cups in a 1 per cent solution of Neutracon in an ultrasonic bath for 30 min at 40 °C, to remove other contaminants.

Do not touch the specimen directly from this point on to avoid contamination

4. Rinse the cups under tap water and then under a stream of distilled water, before drying with lint-free tissue. Finally, immerse the cups in acetone for 2 min to remove water from the surface. Dry with lint-free tissue.
5. Air dry the cups for 2 h, with the articulating surface exposed to atmosphere.
6. Measure the weight loss or gain of the cups using the Mettler AE200 balance, to 0.1 mg, taking an average of at least three readings. Remove any dust on the cups with a blast of dry compressed air.