CHAPTER 1

INTRODUCTION

1.1 Development history of total hip replacement

Owing to the crippling nature of arthritis, the medical profession has been trying for well over a century to successfully treat this debilitating disease especially when it attacks the hip joints (Charnley, 1979; Schaldach & Hohmann, 1976). It was clear that many people required surgery to relieve the terrible pain and keep their joints mobile. Initial attempts to treat arthritic hips included arthrodesis (fusion), osteotomy, nerve division and joint debridements. The goal of these early debridements was to remove arthritic spurs, calcium deposits and irregular cartilage in an attempt to smooth the surface of the joint.

During this period, there was a concerted search for some material that could be used to resurface or even replace the hip. Several proposals and trials were made including the use of muscles, fat, chromatised pig bladder, gold, magnesium and zinc. All met with failure. Surgeons and scientists were unable to find a material which was biocompatible with the body, and yet strong enough to withstand the tremendous forces placed on the hip. (http://www.utahhipandknee.com/history.htm; http://www.geocities.com/ hip_ replacements/history)

In 1925, a Boston surgeon, MN Smith-Peterson (M.D.), moulded a piece of glass into the shape of a hollow hemisphere which could fit over the ball of the hip joint and provide a new smooth surface for movement. Although the glass proved to be biocompatible, it was not able to withstand the forces acting across the hip joint and resulting stresses from walking. Dr Smith-Peterson then tried other materials including plastic and stainless steel without any major success (http://www.geocities. com/hip_replacements/history).

An improvement was made in 1936 when scientists manufactured a cobalt-chromium alloy which was almost immediately applied to orthopaedics. This alloy is very strong and corrosion-resistant and is still used in orthopaedics today. Although the material proved to be successful, the technique of resurfacing the femoral head was found to be less than adequate. Pain relief was not as predictable as had been anticipated and hip movement remained limited for many patients.

The mould technique did not allow surgeons to treat the numerous and varied arthritic deformities of the hip.

In the 1950s Thompson and Moore (http://www.utahhipandknee.com/history.htm) separately developed replacements for the entire ball of the hip. These could be used to treat hip fractures and also certain arthritic cases. This type of hip replacement, called hemi-arthroplasty, only solved the problem of the arthritic femoral head (ball). The diseased acetabulum (hip socket) was not replaced. The prosthesis consisted of a metal stem which was placed into the marrow cavity of the femur, fitted with a metal ball (one-piece construction) which fitted into the hip socket (see Figure 1.1).

Although very popular in the early 1950s, results remained unpredictable and arthritic destruction of the acetabulum persisted and was not solved. A further problem was that there was no known method for properly securing the implant to the bone. After the development of good cementing techniques, this prosthesis is still used today for the treatment of fractured femurs (Robinson & Adams, 2002). Large numbers of patients, however, developed pain because of loosening of the implant with subsequent loss of mobility.

Figure 1.1: Austin-Moore prosthesis

As early as 1938, Dr Jean Judet and his brother, Dr Robert Judet of Paris, (http://www.utahhipandknee.com/history.htm), attempted to use an acrylic material to replace arthritic hip surfaces. The design of the prosthesis was very similar to the Austin-Moore model except for the material. The acrylic provided a smooth surface but unfortunately tended to work loose. This idea did lead Dr Edward J Haboush from the Hospital for Joint Diseases in New York City to utilise "fast-setting dental acrylic" to glue the prosthesis to the bone. This started a new era of implant-fixation techniques.

In England, an innovative surgeon, Sir John Charnley, was also attempting to solve these ongoing problems. Some of his ideas were so bold and creative that he was seriously questioned by many of his colleagues. Charnley aggressively pursued effective methods of replacing both the femoral head and the acetabulum of the hip. In 1958, he dealt with the problem of an eroded arthritic socket by replacing it with a Teflon implant (see Figure 1.2). He hoped that this would allow for a smooth joint surface to articulate with the metal ball of the femoral component. When Teflon did not achieve this goal he went on to try polyethylene (Charnley, 1979; Mendenhall, 2000). This worked well. In order to obtain fixation of this polyethylene socket, as well as the femoral implant to the bone, Charnley borrowed poly(methyl methacrylate) (PMMA) from dental supplies. This substance, known as bone cement, was mixed during the operation, then used as a strong grouting agent to firmly secure the artificial joint to the bone. This was the birth of low-friction arthroplasty.

Figure 1.2: The early prosthesis as designed by Sir John Charnley. Note the migration of the femoral head into the Teflon.

By 1961, Charnley was performing this type of surgery on a regular basis with good results (McCoy et al., 1988; Schulte et al., 1993; Klapach et al., 2001). He further improved the techniques and component designs. Thousands of people were successfully relieved of their hip pain and the long-term results became predictable. (Schulte et al., 1993; Klapach et al., 2001)

1.2 Current concepts

Total hip arthroplasty has been offered to younger and more active patients with increasing frequency over the last decade as the clinical success of this operation continues to be validated. The general concept of prosthesis used for total hip arthroplasty is a modular system consisting of an acetabular component, a femoral component and a femoral ball fitted between the acetabulum and femoral component to establish the articulating effect (Mallchau et al., 2000; Huo and Cook, 2001; Davidson et al., 2002).

The materials commonly used for the various components are as follows:

Acetabulum

Ultra-high molecular weight polyethylene (UHMWPE)

Metal alloy (chrome-cobalt, 316L stainless steel)

Ceramics (alumina)

Femoral head

Metal alloy (chrome-cobalt, 316L stainless steel, vitalium)

Ceramics (alumina, zirconia)

Femoral Stem

Chrome-cobalt

316L stainless steel

Orthron 90

Titanium (90-6Al-4Va)

1.3 Principal clinical diagnosis — total hip replacement

Only a small number of countries are keeping records of the state of hip surgeries performed. The leading hip replacement registers are the “Swedish National Hip Arthroplasty Register” (Mallchau et al., 2000), the “Norwegian

Arthroplasty register" (Havelin et al., 2003) and the Report by the "Australian Orthopaedic Association" (Davidson et al., 2002; Davidson et al., 2003). According to these reports, the number of primary procedures performed per year is 17 378 in Australia for the period 1/7/2001 to 30/6/2002, just over 11000 in Sweden for the year 2000, and 6 108 in Norway for the period 2002. These numbers equate to approximately 110 - 120 total hip replacements (THR) per 100 000 inhabitants per year. It is estimated that the total number of primary replacements in the United States of America amounts to approximately 200 000 per year (Huo & Cook, 2001). The average age for receiving a total hip replacement in Australia for female patients is 69.6 years and for male patients it is 66.1 years. Female patients account for 52.6% of all THR procedures and male patients for 47.4% of all procedures performed.

According to the report by the Australian Orthopaedic Association, the primary diagnosis resulting in primary total hip replacement is osteoarthritis as can be seen in Figure 1.3. Of all the reasons total hip replacements were performed in Australia, osteoarthritis is the main cause of hip joint degeneration in 87.7% of the cases.

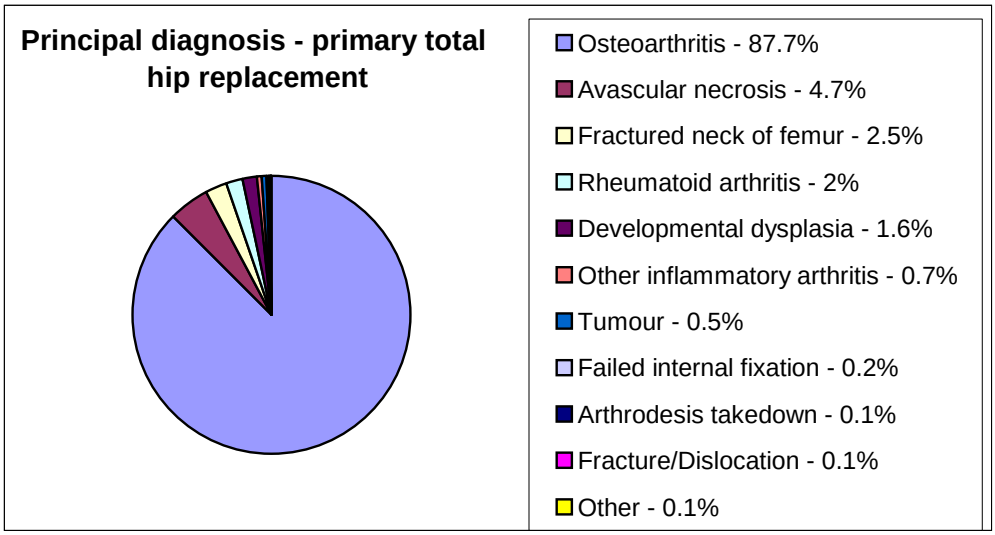

Figure 1.3: Principal diagnosis - primary total hip replacements (Davidson et al., 2002; Davidson et al., 2003)

Osteoarthritis is responsible for 75% of all the total hip replacements performed in Sweden and for 70% of replacements in Norway.

1.4 Clinical diagnosis resulting in revision hip replacement

Revision hip replacement is the exchange or removal of one or both components (Mallchau et al., 2000).

According to the Swedish, Australian and Norwegian hip registers endorced by the literature reviewed, the major cause for revision hip replacement is a phenomenon known as aseptic loosening, resulting from osteolysis. (Claus et al., 2001; Dumbleton et al., 2002; Manley et al., 2002; Foguet et al., 2003; Oakley et al., 2003; Wilkinson et al., 2003). Osteolysis occurs as a response to implant-derived particulate debris, and possibly other stimuli, resulting in increased local osteolastic bone resorption. Therefore the major cause of osteolysis is polyethylene wear debris generated during activity (Davidson et al., 2002; Davidson et al., 2003).

The clinical presentation of aseptic loosening can be explained as an attack on the bone tissue by the immune system as a result of the polyethylene wear debris present in the area. The schematic presentation of the mechanism is presented in Figure 1.4 with a clinical case shown on X-ray in Figure 1.5. The osteolastic bone resorption is shown in Figure 1.6.

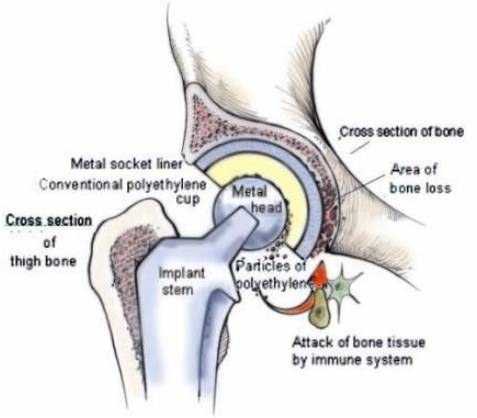

Figure 1.4: Schematic presentation of mechanism resulting in osteolysis (http://www.geocities.com/hip_replacements/history)

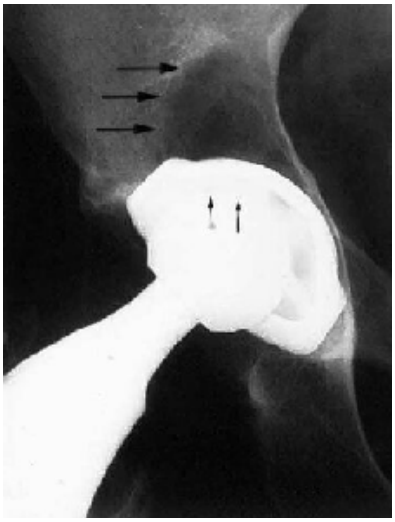

Figure 1.5: Wear debris-mediated osteolytic lesion superior (above) loose press-fit modular acetabular component. Note eccentricity of liner; mechanical failure ensued 5 years post-operatively. (Dumbleton et al., 2002)

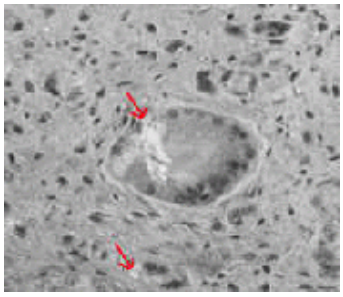

Figure 1.6: Polyethylene from an acetabular liner that has been attacked by the body, resulting in giant cells that eat away the bone resulting in component loosening (Manley et al., 2002)

Aseptic loosening resulting from osteolysis induced by excessive wear is therefore a major problem in total hip replacement (see Figure 1.7). From the Australian hip register, it is seen that during the period 1/7/2001 to 30/6/2002 a total number of 3 710 revision procedures were performed. The total number of revisions attributed to aseptic loosening resulting from osteolysis-induced wear amounts to 63%, while in the Swedish register, the total number of revisions attributed to aseptic loosening is 75%, and in Norway it amounts to 68%. Revision total hip replacements amount to approximately 22% of the primary total hip replacements done during the same period in Australia. Female patients account for 1 664 of the procedures done and the male patients account for 1 422.

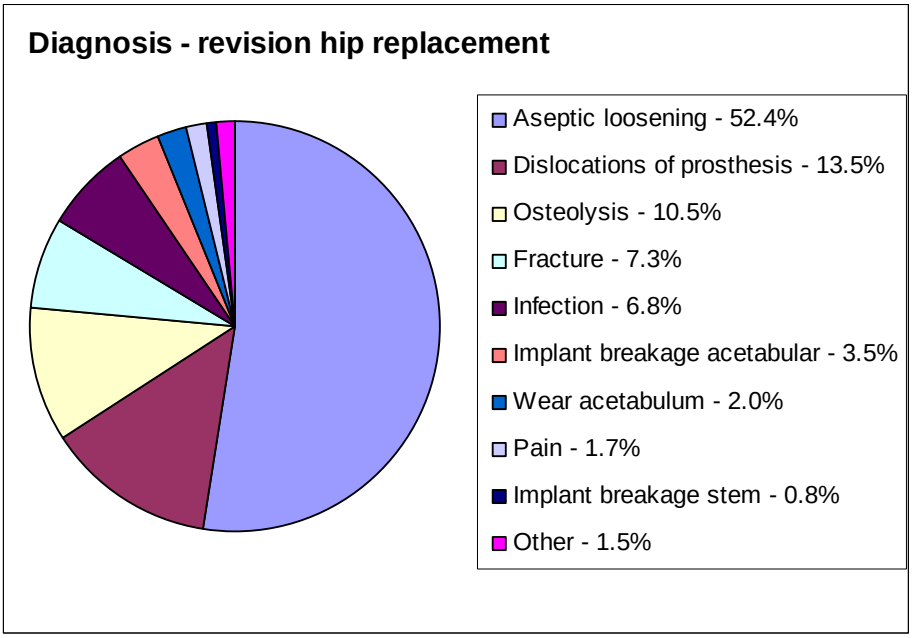

Figure 1.7: Diagnosis — revision surgery hip replacement (Davidson et al., 2002, Davidson et al., 2003)

The average survival rate for the various designs varies dramatically (Davidson et al., 2002, Davidson et al., 2003). The Charnley prosthesis still has a survival rate of approximately 85% after 15 years (McCoy et al., 1988; Schulte et al., 1993; Mallchau et al., 2000; Klapach et al., 2001; Davidson et

al., 2002; Davidson et al., 2003). If other designs are included the statistics are quite different. For the elite plus prosthesis with an acetabular component manufactured from hylamer together with a zirconia femoral head, the survival rate after six years is a catastrophic 36% (Norton et al., 2002). A summary of the survival rates for different models of cemented and uncemented prostheses can be seen in Figure 1.8. (Havelin et al., 2003) These failures are mainly attributed to osteolysis due to excessive wear. In those hips that had already failed, the acetabular component wear at 36 months was on average 2.04 mm.

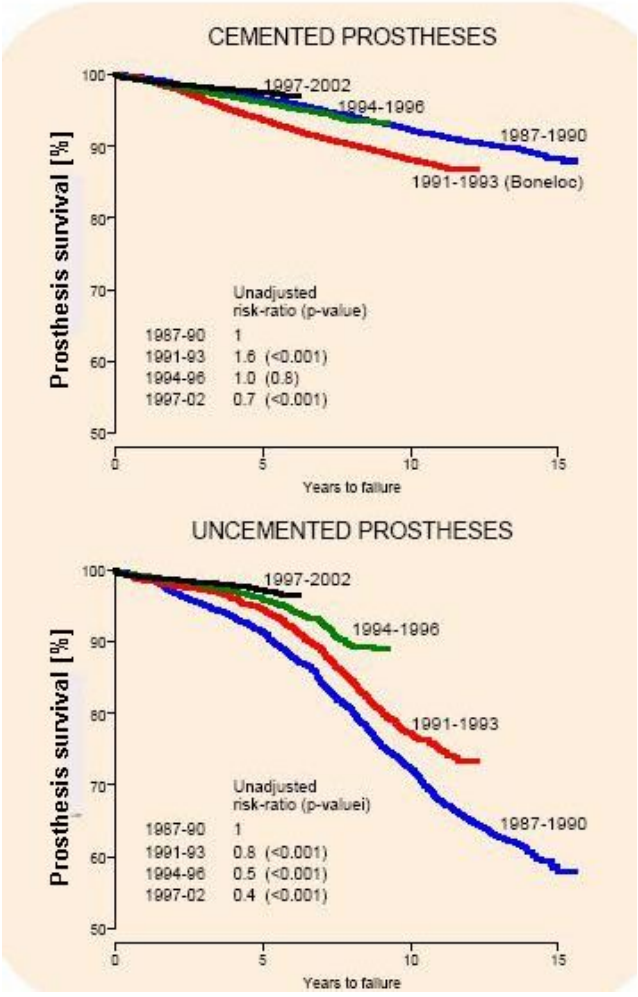

Figure 1.8: Survival rate for different models of cemented and uncemented prostheses (Havelin et al., 2003)

1.5 Aim of study

Local osteolastic bone resorption as a direct result of polyethylene wear debris generated during activity is a major factor causing component loosening, resulting in total hip replacement.

The aim of this study is to obtain a better understanding of the mechanical failure mechanism when the femoral head rotates in the UHMWPE acetabular socket.

This investigation begins with a comprehensive literature survey to establish the current state of affairs regarding the design, materials, failure analysis and life expectancy of implants used during hip replacement surgery. The literature survey is followed by a chapter in which the criteria are set to enable a detailed failure analysis of the retrieved components.

The next phase in the research is a failure analysis on retrieved components by making use of:

- Visual inspection
- Liquid dye penetrant
- Stereoscope
- Electron microscope
- Electrophoresis
- Mass-spectrometric analysis
- Analysis of the wear particles retrieved

This failure analysis was performed to gain a clear understanding of the mode of failure on the bearing surface in the retrieved components.

A study is also undertaken to obtain an indication of the creep behaviour of UHMWPE test pieces manufactured with different manufacturing techniques. This is necessary in order to arrive at a better understanding of the behaviour of the material at high contact stress values and at localised high operating temperatures. The various manufacturing techniques also include

crosslinking of the material in a hydrogen atmosphere. Making use of the data gathered during the previous phases, an experimental verification was made possible making use of a hip simulator and various other experimental techniques to verify the formation of the wear debris as well as the heat generated in the joint. This verification enables a better understanding of the failure mode in the bearing.

The last part of the study is the determination of the lubricating capabilities of retrieved synovial fluid to allow an evaluation of the lubrication available in the joint after the implantation of the various components.

CHAPTER 2
LITERATURE REVIEW

2.1 Introduction

The literature survey presented below first covers a review of the current designs for total hip replacements prostheses/implants being used throughout the world. To fully understand the function of the hip, it is necessary to obtain a good understanding of the biomechanics of the joint. It is also necessary to have an understanding of the materials that are being used for the manufacture of these implants.

The rest of the chapter is devoted to an overview of the current research in retrieval studies; wear mechanisms; the effects of different sterilisation techniques on service; the effect of crosslinking on the characteristics of the material and an overview of the current hip simulators being used for in-vitro testing. Another area that is discussed in this thesis is the lack of lubrication in the joint and the consequences of insufficient or inadequate lubrication. A literature review of research into the lubricating capabilities of synovial fluid is also presented.

In this thesis a different set of criteria from an engineering base is proposed to be used to evaluate the retrievals for the different wear mechanisms active in-vivo. To be able to make this proposal, it is important to understand the set of criteria currently in use, as well as its shortcomings.

As crosslinking of UHMWPE is seen as a short-term solution to the problem, the effect of crosslinking on the material characteristics needs to be understood. In this thesis, results are presented, indicating the influence of crosslinking on the creep behaviour of UHMWPE. As crosslinking is achieved by means of gamma irradiation, it is also necessary to look into the effect of the different sterilisation techniques on in-vivo life as well as the effect of the

different sterilisation techniques on the mechanical properties of the materials involved. Again, the influence of the different sterilisation techniques on the creep behaviour of the base material is investigated.

As the new ISO standard for the testing of hip implants came into effect in 2002 (ISO 14242-1, 2002), the standard of current simulators must be investigated. The simulator used for in-vitro testing in this investigation differs from the simulators proposed in the ISO standard. The reason for using a simulator that does not conform to the ISO standard is explained in Chapter 7.

2.2 Review of existing designs

Various companies are currently manufacturing components for total hip replacements. Although their designs differ slightly in the smaller detail or in the approach to total hip replacement, for example, cemented or uncemented implants, the basic modular design of all these designs is the same, as can be seen from the respective data sheets (http://www.aesculap.de/; http://www.centerpulse-orthopedics.com/uk/en/Home/Home; http://www.depuy. com/; http://www.ceraver.fr/anglais/sommaireang.htm). A basic modular design is shown in Figure 2.1.

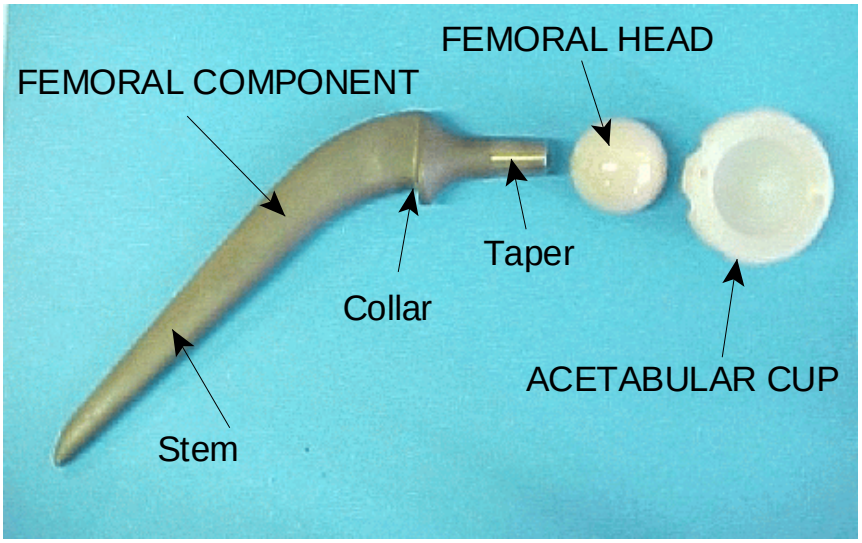

Figure 2.1: Basic modular design of total hip replacement

2.2.1 Femoral component

The design of the femoral component can be divided into three regions namely the design of the stem, the design of the collar area and the taper for the fitment of the femoral head (see Figure 2.1).

The design of the stem can vary according to the following concepts:

a. Taper or straight stem
b. Length of stem, anything between 160 mm (primary total hip arthroplasty) to 240 mm for revision total hip arthroplasty
c. Smooth or highly polished surface finish
d. Surface with or without flutes
e. Sharp or round corners
f. Cemented or uncemented, where there are a number of surface coatings available to establish bone in growth (Engh & Bobyn, 1985), namely sintered bead or a bio-active coating such as hydroxyl-apatite.

The use of a collar determines the design of the collar. The principal reason for the use of the collar is to transmit the load via the smaller trochanter area into the cortical bone of the femur. These designs tend to cause bone resorption (degeneration of the bone in the area under compression) just below the collar in the cortical bone. (See illustration of bone resorption below collar in Figure 2.2.)

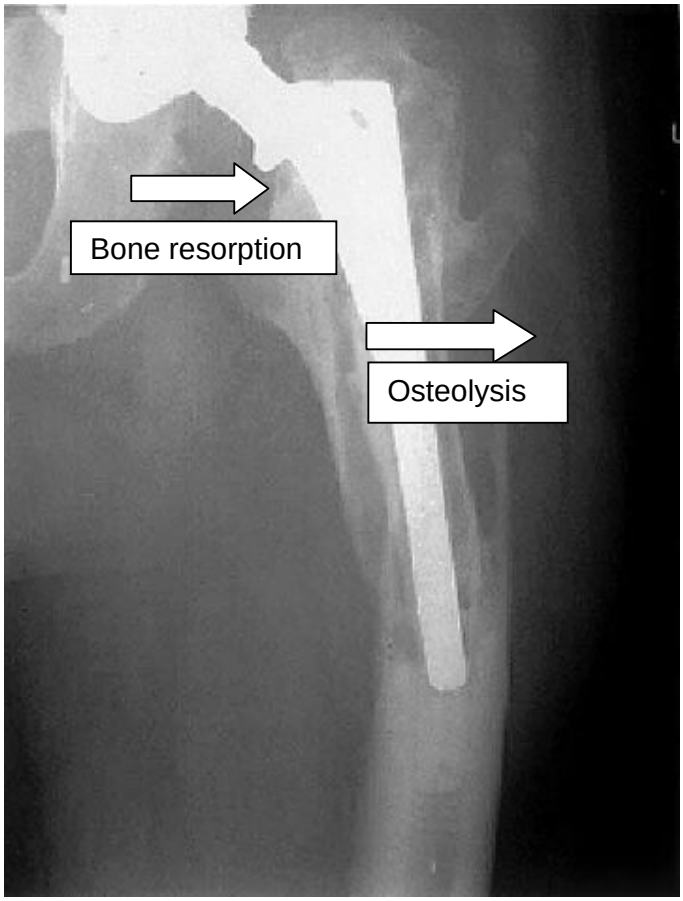

Figure 2.2: Femoral osteolysis with signs of bone resorption below collar (Dumbleton et al., 2002)

The taper on the femoral stem is used for the fitment of a modular femoral head. The whole design philosophy behind a loose femoral head is that with variation in taper depth the length of the implant can be changed to accommodate and rectify differences in leg lengths (http://www.aesculap.de/; http://www.centerpulse-orthopedics.com/uk/en/Home/Home; http://www.ceraver.fr/anglais/sommaireang.htm; http://www.depuy.com/). The standard tapers being used are 10/12 or 12/14 tapers both with a 6º included angle.

2.2.2 Femoral head

The femoral head acts as the male part of the bearing interface in the

replacement of the joint. The major design change in the design of the femoral ball, apart from the material changes, is the change in diameter. The diameters used are 22, 26, 28, and 32 mm.

The taper depth on the femoral ball also varies to enable the surgeon to compensate for changes in patient leg length. The options available are -5, 0, +5 and + 10 mm. All the tapers are 10/12 or 12/14 with a 6° included angle.

2.2.3 Acetabular cup

The acetabular cup acts as the female part of the bearing interface in total hip arthroplasty. The design of the acetabular component can vary according to the following concepts:

a. Cemented or cementless components, where the cementless components have a bearing liner mounted inside a metal backing and the metal backing is coated either with sintered beads or hydroxy-apatite to promote bone in growth into or onto the implant. (See Figure 2.3.)

b. The metal back acetabular cup can be kept in position with cortical bone screws, especially during revision total hip arthroplasty (see Figure 2.4), or with spikes, if the back of the cup is equipped with spikes to stabilise the cup.

c. The liner can either be factory-fitted or be fitted during the procedure. Where the liner is fitted during the procedure, it clips into the metal backing to keep it in position.

d. Material used — UHMWPE, ceramic or metal alloy

e. The use of a retaining ring is also becoming more popular, especially in patients where the risk of dislocation is high.

f. The back of the acetabular cup, in cemented implants, can also vary in design to establish compression of the cement mantle and to ensure an even distribution of the cement.

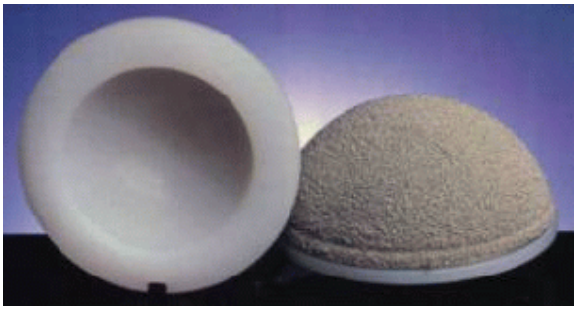

Figure 2.3: Polyethylene liner with hydroxy-apatite coated metal back (http://www.aesculap.de/)

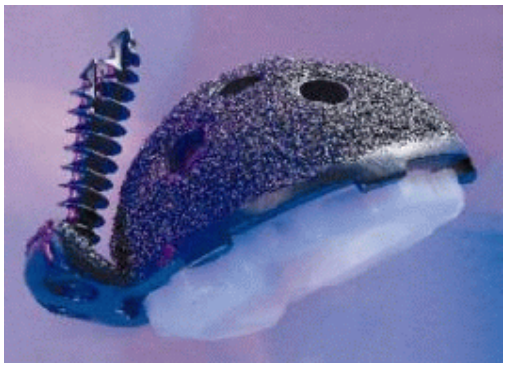

Figure 2.4: Polyethylene liner in metal back with holes for fixation (http://www.depuy.com/)

If the statistics of the existing hip registers are taken into account the most common system used for total hip arthroplasty is a cemented polyethylene acetabular component in conjunction with either Cr-Co or ceramic femoral heads (Mallchau et al., 2000; Davidson et al., 2002; Davidson et al., 2003). A comparison of the in-vivo wear rates between Cr-Co and UHMWPE; and ceramics and UHMWPE is discussed in paragraph 2.6.1.

2.3 Biomechanics of the hip joint

When the body is supported on only one leg, its centre of gravity S_6 has to be balanced vertically above the bearing area of the foot. (See Figure 2.5.) This determines the posture as a whole, including the posture of the leg and joint

position (Kummer, 1976).

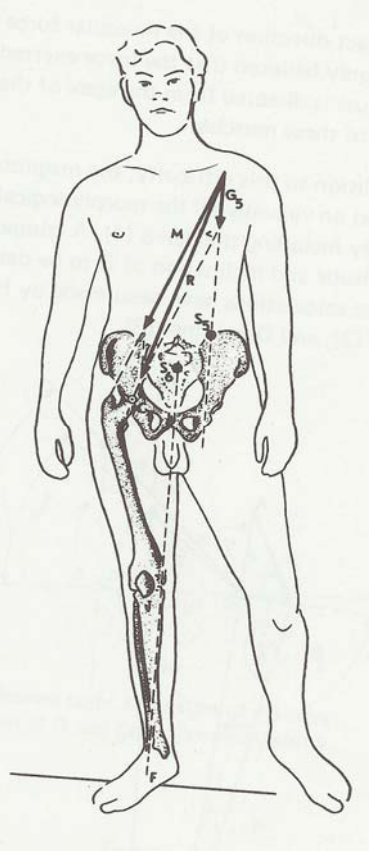

Figure 2.5: Man standing on his right leg. The gravity vertical line from S_6 falls in the supporting area of the right foot. The weight G_5 is to be balanced in the right hip joint. M - abductor muscles of the right hip, R - hip resultant, S_5 - centre of gravity of the body mass must be borne in the right hip joint (Kummer, 1976).

With regard to the hip joint of the supporting leg, the centre of gravity S_5 has to be considered; and the moment of the mass G_5 must be balanced in the joints by means of the abductor muscles. The magnitude and direction of the joint-resultant load then depend on the

- Direction and tension of the hip abductors – (see Figures 2.6, and 2.7.)
- Posture of the pelvis
- Length and posture of the leg.

The direction and tension of the abductor muscles are related to the lever arm

of the load (depending, among other things, on the width of the pelvis), to the length of the femoral neck and trochanter, and to the angle between the neck and shaft. Furthermore, it must be remembered that the posture of the leg is strictly determined by the position of S_6, on account of the equilibrium conditions.

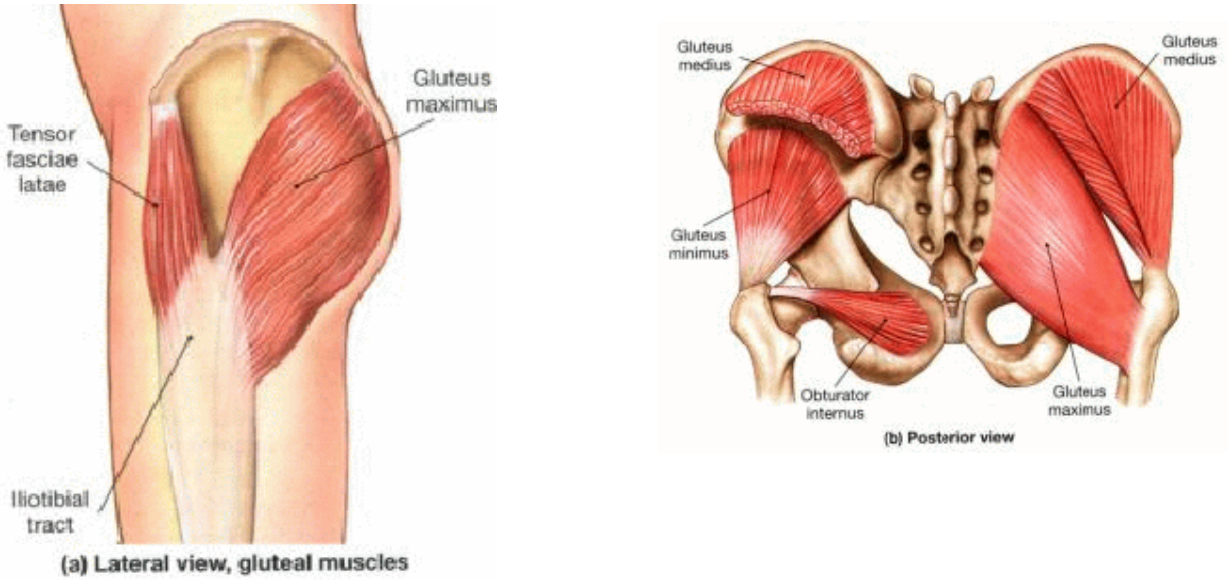

Figure 2.6: Side (lateral) and back (posterior) view of abductor muscles (http://www.geocities.com/hip_replacements/history)

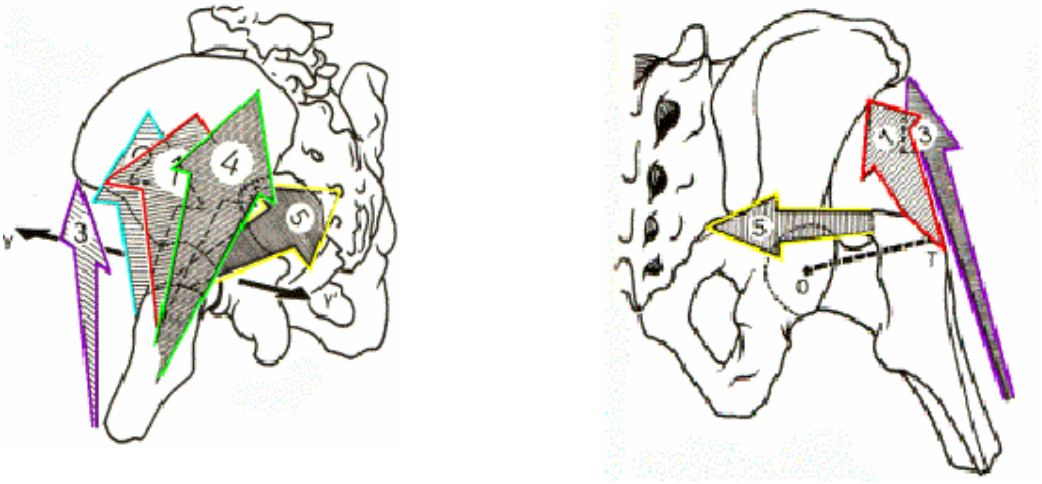

Figure 2.7: Side and back view of abductor forces acting on hip joint (http://www.geocities.com/hip_replacements/history)

The resultant force resulting from the various abductor muscles acting on the hip joint works in on an angle of 13.7° away from the most posterior point of the face towards the posterior side (Kummer, 1976). (See Figure 2.8.)

The resultant force acting on the hip, as described, generates an in-vivo resultant force on the acetabular cup. Measured from the anteroposterior view of the liner, this vector is orientated at a mean of 19.3° away from the face of the liner towards the apex as shown in Figure 2.9 (Sychterz et al., 1996).

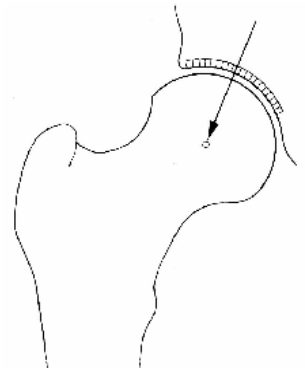

Figure 2.8: Stress distribution to the normal hip joint (Kummer, 1976)

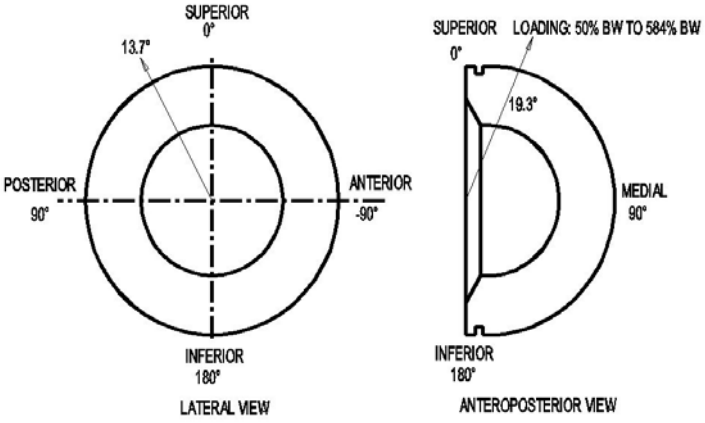

Figure 2.9: Graphical presentation of the loading on the acetabular cup (Paul, 1976; Kummer, 1976; Sychterz et al., 1996; Zupanc et al., 2001)

An exact analysis of the resultant load, acting on the hip joint, is difficult since the precise load in the relevant muscles has not yet be determined nor can the force transmitted by the ligaments at any instant be inferred from external measurements. By making reasonable assumptions for the position of the resultant force transmitted by certain groups of muscles, Paul (1976) was able to establish a basic loading pattern for the hip joint. The graphical presentation of these forces can be seen in Figure 2.10 and a summary of the results obtained in Table 2.1.

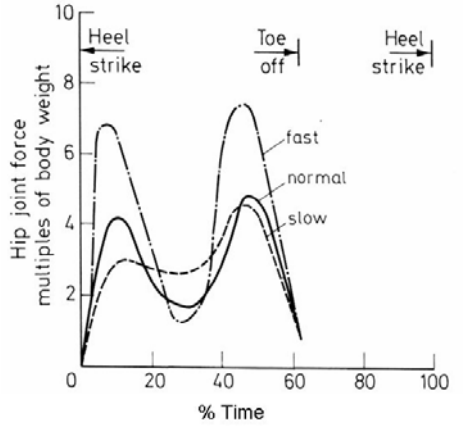

Figure 2.10: Variation with time of hip joint forces for slow, normal and fast walking (Paul, 1976). The scale of the x axis is percentage time

Table 2.1: The maximum joint forces present in the hip joint, for a range of activities (Paul 1976)

Activity	**Maximum joint force — Multiples of body weight**
Level walking	
- slow	4.9
- normal	4.9
- fast	7.6
Up stairs	7.2
Down stairs	7.1
Up ramp	5.9
Down ramp	5.1

The work done by Paul was verified by Bergmann (1985; 1993). Two femoral components were instrumented with strain gauges and transmitters. The two prostheses were then implanted into two patients. After the recovery period, strain measurements were taken while the patients were walking at different speeds on a treadmill. The data were analysed and plotted as a resultant force acting on the hip joint during the walking cycle. The plotted data can be seen in Figure 2.11.

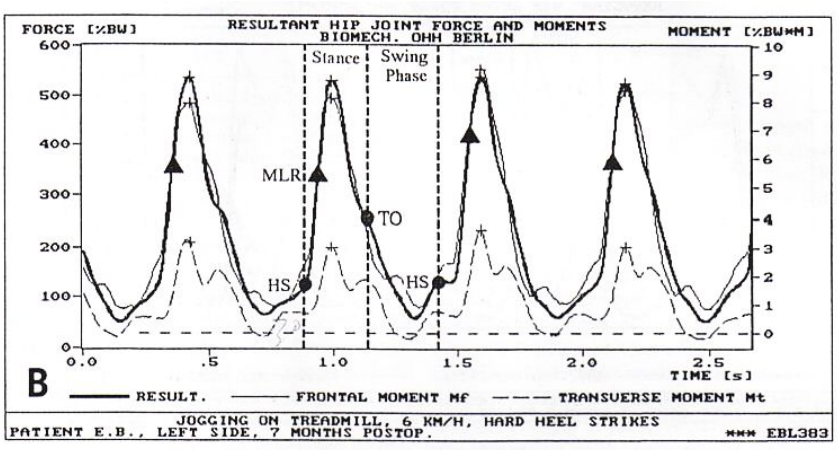

Figure 2.11: Resultant force on hip joint for patient jogging on treadmill at 6 km/h (Bergmann et al., 1993, Bergmann et al., 1995). HS: heel strike, TO: toe off; MLR: measured load profile

The maximum loading on the hip joint during fast walking, according to Bergmann et al., is 580% times the body weight of the patient, with the minimum loading, to prevent dislocation, 50% of the body weight. The increase of 530% is a result of the abductor muscles active across the joint.

As these actual measured values are deemed to be more accurate (by this researcher), than the calculated values of Paul (1976) or ISO 14242-1 (2002), this load profile is simulated in the University of Pretoria hip simulator which was designed and built for this study.

2.4 Material properties of ultra-high molecular weight polyethylene (UHMWPE)

From previous studies (Mallchau et al., 2000; Claus et al., 2001; Davidson et al., 2002; Dumbleton et al., 2002; Manley et al., 2002; Norton et al., 2002; Davidson et al., 2003; Foguet et al., 2003; Oakley et al., 2003; Wilkinson et al., 2003) it is evident that the unacceptably short, life achieved with hip implants mainly occurs from aseptic loosening of the acetabular cup. These authors also reveal that osteolysis, as a result of the UHMWPE wear debris, is the major cause of this aseptic loosening. In the work done by Dumbleton et al. (2002), it was shown that osteolysis is rarely observed if the wear rate is smaller than 0.1mm per year. Ultra-high molecular weight polyethylene has become the industry standard material for the manufacturing of acetabular components (Mallchau et al., 2000; Davidson et al., 2002; Davidson et al., 2003). The focus of this study is therefore on the wear and the wear mechanisms of UHMWPE as used in acetabular cups.

UHMWPE is a tough, durable material with a low coefficient of friction. The density (Lewis, 2001; Engineering materials handbook, 1987) of this material varies between 9 260 and 9 340 kg/m^3 and a typical value for the coefficient of friction (lubricated) is 0.05 to 0.1, depending on the type of lubrication.

A frequently used guide to the capacity of marginally lubricated or dry bearings (Hutchings, 1992) is the value of the product PV, where P is the mean bearing pressure in MPa (load divided by projected bearing area) and V is the sliding velocity in ms^{-1}. A typical dry PV value for this material is 4 N/mm^2.m/s, as shown in Figure 2.12, with a maximum compression strength of 10 MPa determined at room temperature.

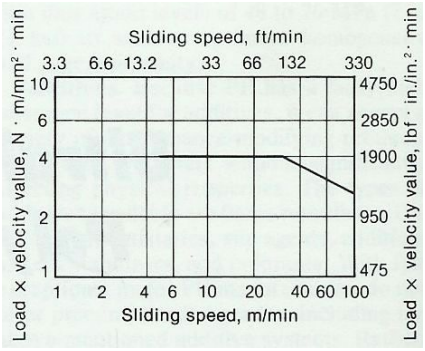

Figure 2.12: PV values for UHMWPE at 20°C (Engineering Materials Handbook, 1987)

The molecular mass of UHMWPE is almost ten times that of high-density polyethylene. UHMPWE has the highest abrasion resistance and impact strength of any plastic (Engineering Materials Handbook, 1987). Combined with a low coefficient of friction, UHMWPE yields a self-lubricating, non-stick surface. Its static and dynamic coefficients of friction are significantly lower than those of steel and most other plastic materials. The basic chemical unit of UHMWPE is $-CH_2-$. Thus, a 4×10^6 molecular weight resin contains approximately 285×10^3 carbon atoms or units in the polymer chain (Engineering Materials Handbook, 1987).

Because of its self-lubricating, non-stick, lightweight and wear-resistant characteristics, UHMWPE is widely used as bearing material in joint replacements. Although the material can maintain its properties at high temperatures only for a very short time, **"**it is recommended that in journal bearings temperatures above 40°C should be avoided at all times**"** **(**Engineering Materials Handbook, 1987). From Figure 2.13, it is clear that the izod impact value of this material decreases dramatically if the material is heated above 40°C as the material becomes more ductile, suggesting that, for a given geometry and loading condition plastic flow is more likely to occur.

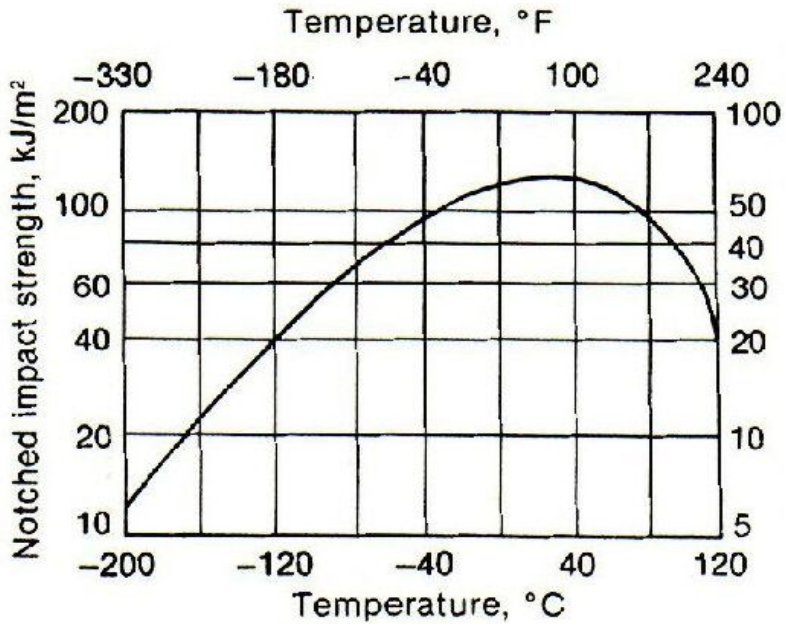

Figure 2.13: Izod impact strength against temperature with 15° double V notched (Engineering Materials Handbook, 1987)

UHMWPE is a material that is susceptible to plastic flow under constant pressure applications. From Figure 2.14, an increase in creep (% compression) of almost 12.5% at 56 days under a pressure of 12 MPa, and at a temperature of 20°C, is visible. In the designed life of a prosthesis of 20 years (Malchau et al., 2000; Davidson et al., 2002; Davidson et al., 2003), 56 days represent in the order of 0.78% of the expected lifespan of an acetabular cup. It must, however, be noted that in the cup the material is more constrained against creep than in the case of a test piece. (It will be shown that 12 MPa is the typical pressure inside an acetabular cup.) This data correlates with the data published by Sun et al. (1996); Lee and Pienkowski (1998); and Meng Deng et al. (1998). From Figure 2.13, it can be seen that the material softens at temperatures above 40 °C. The softening leads to an increase in plastic creep. From the material specifications, the maximum short time operating temperature (seconds) is 80°C with the melting point 135 - 138°C (Material data sheet, UHMWPE, Poli HiSolidur, 1999). Note, however, that the creep flattens off, especially in a confined space, and that the almost

linear graph of Figure 2.14 cannot simply be extrapolated. This aspect is discussed further in this thesis in the discussions of the experimental phase.

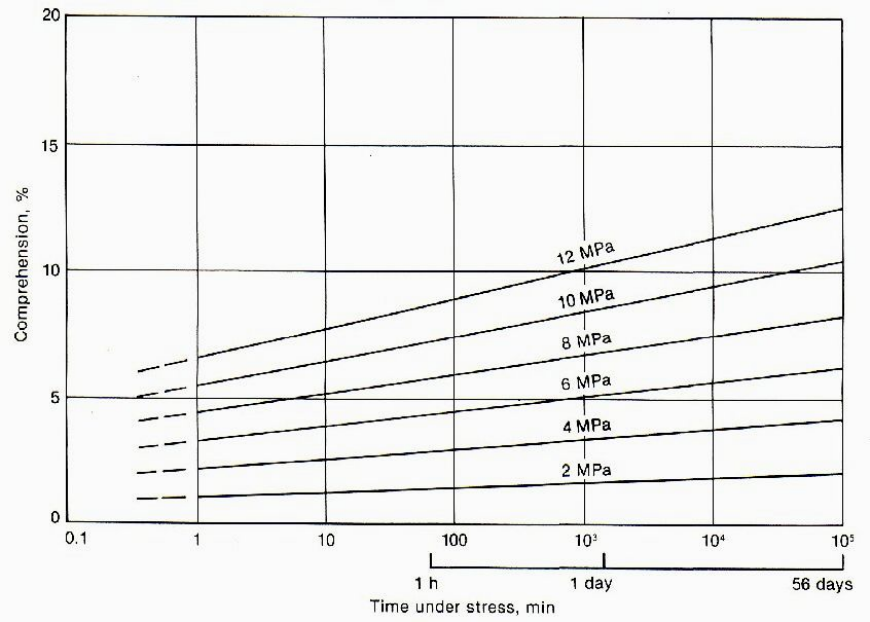

Figure 2.14: Compression creep for various loads at 20°C (Engineering Materials Handbook, 1987)

Chemical crosslinking with 0.3 to 0.5% organic peroxides (an active ingredient) has been found to improve wear resistance by as much as 30% over a non-modified resin, while reducing deformation under a load (Du Plessis et al., 1977; Sun and Wang, 1996; Oonishi and Kuno, 1997; Wang et al., 1998). Thin film transparency improves, and density is lowered by a reduction in crystallinity. Crosslinking can also be accomplished by beta or gamma irradiation.

The mechanical properties for UHMWPE can differ taking into account the various manufacturing methods (Lewis 2001), whether moulded or extruded and the amount of annealing. A summary of the average mechanical properties of UHMWPE is shown in Table 2.2.

Table 2.2: Mechanical properties of UHMWPE (Charnley, 1979; Material data sheet, Poli HiSolidur, 1999; Lewis, 2001)

Property	**Typical value**	**ASTM test method**
Density (kg/m^3)	9260 - 9340	D792
Tensile strength at yield (MPa)	21	D638
Tensile strength at break (MPa)	48	D638
Elongation at break (%)	350	D638
Young's modulus (GPa)		
At 23 °C	1.6	D638
At -269 °C	2.97	D638
Izod impact strength (kJ/m)		
At 23 °C	1.6	D256(a)
At -269 °C	1.1	D256(a)
Hardness, shore D	62-66	D2240
Water absorption (%)	0	D570
Poisson's ratio	0.28	
Dynamic coefficient of friction on polished steel		
Dry	0.1 - 0.22	
Water	0.05 - 0.1	
Oil	0.05 - 0.08	
PV values (N/mm^2.m/s)		
Dry	4	See figure 2.12
Wet	6 - 7	
Maximum load (MPa) - compression	10	
Maximum contact speed	120 m/min	

The values for yield and izod impact strength are given at room temperature and at sub-zero temperatures where this material performs excellently. However, at elevated temperatures, as can be seen from Figure 2.13 above,

there is a decrease in performance.

Various tensile creep studies have been conducted on UHMWPE by different authors (Sun and Wang, 1996; Lee and Pienkowski, 1998; Material data sheet, Poli HiSolidur, 1999). The results of these studies appear similar to the data presented in figure 2.14 given earlier. The major gap in this data and within these studies is that they either did not consider creep at elevated temperatures, or they only investigated the virgin material and did not consider the effect of sterilisation by irradiation or the effect of the crosslinking of the material. An indication of the behaviour of the material under these conditions and with different sterilisation techniques is discussed in Chapter 3 of this thesis.

It is also important to note that the PV values specified in Table 2.2 above apply to ventilated bearings with a specific geometry. If the temperature inside the bearing rises above the permissible value the PV values must decrease to compensate for the lack of heat dissipation from the bearing surface, because the heat generated cannot be dissipated. Although the Engineering Materials Handbook (1987) specifies an operating temperature below 40°C, the manufacturers of UHMWPE specify 80°C as the maximum short term service temperature while the melting point of the material is 135 - 138°C (Material Data Sheet, Poli HiSolidur, 1999). It must be noted that the allowable PV data is not available for crosslinked material.

2.5 Wear and wear modes in acetabular components

Whenever surfaces move over relative to each other, wear will occur, with damage to one or both of the surfaces, generally involving progressive loss of material. In most cases, wear is detrimental, leading to increased clearances between the moving components, unwanted freedom of movement and loss of precision with a resulting increase in mechanical loading and yet more rapid wear. This rapid wear can also result in fatigue failure (Sun & Wang, 1996).

Contact between polymers, or between a polymer and a metal, is

predominantly elastic; therefore the friction and wear behaviour of polymers differs fundamentally from that of metals. In the plasticity index (ψ) equation (Hutchings, 1992):

$$\psi = \frac{E}{H}\left(\frac{\sigma}{r}\right)^{1/2} \qquad (2.1)$$

The ratio E/H, where E is Young's modulus and H is the hardness of the material, determines the extent of plasticity in the contact region. The surface topography is also important. For metals the ratio E/H is typically 100 or more, while for many of the polymers E/H is only about 10. The plasticity index for a polymer thus has only one tenth of the value for metal, and the contact is therefore almost completely elastic, except against very rough surfaces.

A second factor that plays an important role in the friction of polymers is the strong time dependence of their mechanical properties. Most polymers are visco-elastic (Engineering Materials Handbook, 1987; Sun & Wang, 1996) and also show a marked increase of flow stress with strain rate.

The friction and, therefore, the wear of polymers, such as metals, can be attributed to two sources: a deformation term, involving the dissipation of energy in quite a large volume around the local area of contact, and an adhesion term originating from the interface between the slider and the counterface. The regions where these two sources of friction and wear originate are illustrated in Figure 2.15, for the sliding of a hard asperity over a polymer surface. As for metals, the distinction between the deformation and adhesion components of friction is somewhat artificial, and under many circumstances no clear demarcation can be made. However, in some experiments, and in some practical applications, one term dominates and can then be examined in isolation (Hutchings, 1992).

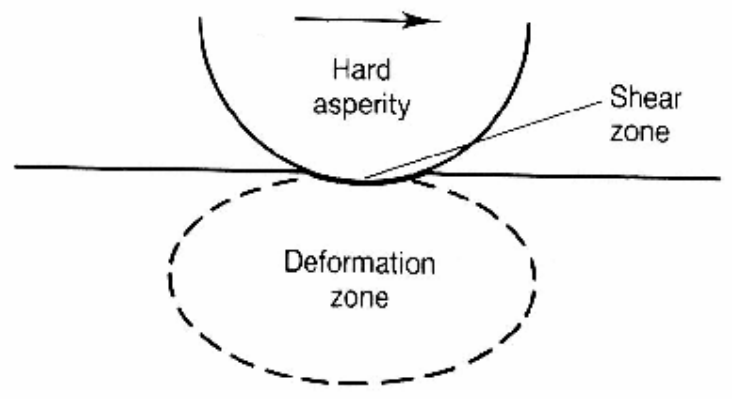

Figure 2.15: The origins of the friction associated with the sliding of a hard, smooth surface over a polymer surface (Hutchings, 1992)

Wear modes for acetabular cups have been defined in literature as an aid to orthopaedic surgeons to enable them to classify the hip joint failures of their patients. This classification is not really intended to be used in an engineering examination of the failed components.

As this classification is open to interpretation, a different classification is proposed in Chapter 4, which will help researchers in identifying the applicable wear mode. This proposed classification is based on engineering principles to aid in the determination of the root cause of mechanical failure of the components. The existing wear modes, as described in literature, for intended use by the medical profession are (Schmalzried et al., 1999):

Mode 1 wear: Results from the motion that is intended to occur between the two primary bearing surfaces, such as the motion of the prosthetic femoral head against the polyethylene acetabular bearing surface

Mode 2 wear: Refers to the condition of a primary bearing surface that moves against a secondary surface it is not intended to slide against. For example, Mode 2 wear occurs when a femoral component penetrates through a modular polyethylene bearing liner and then moves against the metallic shell of the acetabular, in the case of a metal

backing. At this point the implant has long exceeded its useful life.

Mode 3 wear: Refers to the condition of the primary surfaces as they move against each other but with the interposition of third-body particles. In Mode 3 wear, the origin of the contaminant particles is unknown. They directly abrade one or both of the primary bearing surfaces.

Mode 4 wear: Refers to two secondary (non-primary) surfaces sliding against each other. An example of this mode of failure is the neck of the femoral part sliding against the rim of the acetabular component. This wear mode is normally a direct result of misalignment and leads directly to third-body wear and early loosening of the cup.

Mode 1 wear is natural for a well-functioning transplant while Modes 2, 3 and 4 are unacceptable and will lead directly to early failure. The above classification is used by the medical profession to report on their patients. It does not attempt to qualify or quantify adhesion or abrasion or any other factor as already mentioned.

Unless the surgeon can clearly see third-body wear (any particle entering the bearing surface), for example, from bone deposits or cement particles, he/she is unable to identify the basic cause of failure stemming from third-body wear. *Failure*, as used in this context, means the point where the bearing is unable to perform its intended function without causing the patient discomfort. There are a number of variables that can affect the wear of the polyethylene bearing in-vivo, including the wear resistance of the material as well as the loads, sliding speed, motion pattern, manufacturing processes for the polyethylene component, implantation technique, use of the joint including frequency of use (Charnley & Halley, 1975), design specifics, such as conformity between the femoral head and the cup, lubrication, heat conduction, etc. (Fourie & Burger, 1999). The wear resistance of the polyethylene component is a function of the

base resin, the manufacturing process, the method of sterilisation and the extent of crosslinking (Du Plessis et al., 1977; Fisher et al., 1995; Wang et al., 1995; Sun and Wang, 1996;).

Polyethylene wear is also a function of the motion pattern (Wang et al., 1997; Charnley & Halley, 1975). In wear tests like reciprocating pin-on-disk tests, the quoted rate of polyethylene wear for a given set of parameters is 10 to 100 times lower than in wear tests that use crossing motion paths as found in a hip joint. Wear tests with a crossing motion path more closely simulate the wear occurring in-vivo. A problem that is found in most of the wear literature is based on either reciprocating pin-on-disk or circular pin-on-disk tests although a lot of work is done on simulators that will be discussed later in Chapter 7 (Wang et al., 1997).

Increased roughness of the femoral counter surface may dramatically accelerate wear of the polyethylene component. Experimental studies have indicated that a threefold increase in the roughness of the femoral counter surface can cause at least a tenfold increase in the rate of polyethylene wear (Dowson et al., 1987; Livermore et al., 1990; Li & Burstein, 1994). See Figure 2.16 for the results of the wear coefficient for steel on UHMWPE. From Figure 2.16 it is clear that there is an optimum surface finish for mating material in a bearing couple.

The explanation for the shape of the data in Figure 2.16 is given when one examines the function of the asperities on the surface of a bearing as indicated in Figure 2.17. The main functions of the irregular shape of the asperities are to transport lubricant into the bearing surface area (Hutchings, 1992) and to keep the two bearing surfaces apart. If the surface roughness (R_a value) is increased, the asperities increase in size to the extent where the asperities start functioning as a rasp. On the other hand, if the surface roughness is decreased (R_a value), the surface is too smooth to aid in the transport of the lubricant into the bearing surface area leading to lubrication starvation and subsequent seizure of the bearing. The crossover point for

surface roughness (R_a) for steel sliding on UHMWPE is 0.06 µm.

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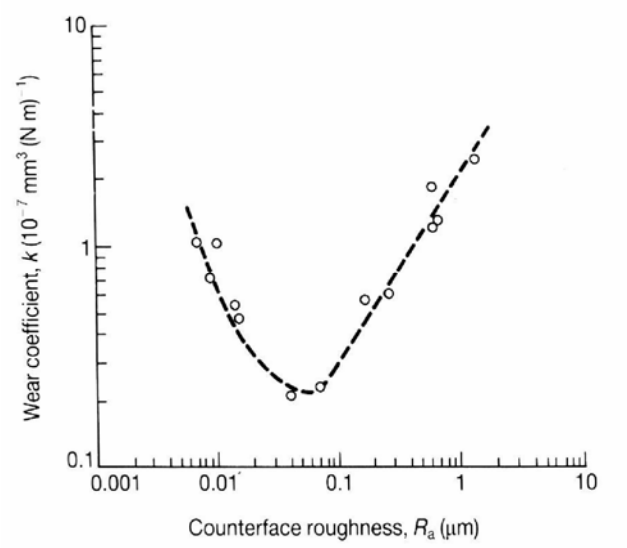


Figure 2.16: Wear rate of UHMWPE dry sliding against a steel counter face, as a function of the roughness of the steel surface (Hutchings, 1992)

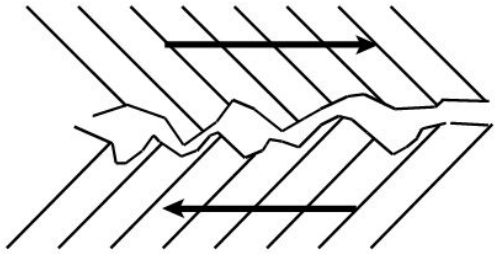


Figure 2.17: Illustration of the asperities on the surface of a component after manufacturing (Hutchings, 1992)

The polyethylene wear rate is also sensitive to the specific type of surface damage that exist in a contact pair or that occurs during service. However, in clinical comparisons in which the operating environment of the articulation is

more variable, ceramic heads are reported to have demonstrated rates of wear that are lower than those of metallic heads (Schmalzried et al., 1999). This derivation is not totally true as indicated by Buford and Goswani (2004). In this study, cases are reported where the wear rate (mm/yr) for UHMWPE against alumina (0.1 mm/yr) is larger than for UHMWPE against stainless steel (0.08 mm/yr), both for 28 mm femoral heads. There are also reported cases where the wear rate is 0.04 mm/yr for UHMWPE against cobalt-chromium, as well as cases with a wear rate of 0.03 mm/yr for UHMWPE against alumina (Buford & Goswani, 2004). If one looks at the distribution of these results statistically it is clear that the bearing couple cannot be evaluated alone, but the patient conditions, that is activity levels and quality of synovial fluid, must be taken into account. Apart from comparing the results of this study to the work done by Buford and Goswani (2004), the results of the current investigation were also compared to the work done by Jasty et al. (1997) and Sychterz et al. (1996).

As an important part of this study the variation in wear rate is explained by the theory that the lack of lubrication in the joint plays a major role in the wear mechanism active in the bearing couple.

Decreased geometric conformity between the femoral head and the acetabular component can lead to a drastic increase in the contact stresses resulting in plastic flow or creep. Apart from being dependent on the Young's modulus (E) and the Poisson's ratio (ν) of the material, the biggest single influence on the contact stress is the size of the contact on the bearing interface as illustrated in Figure 2.18 (Boresi & Sidebottom, 1985).

In total hip replacements the dominant wear mechanisms appear to be micro-adhesion and micro-abrasion with wear particles less than 1 μm in length (Barbour et al., 1995; Maloney et al., 1995; Scmalzried et al. 1997). Osteolysis is mostly attributed to these sub-micron wear particles (Clauset al., 2001; Dumbleton et al., 2002; Manley et al., 2002; Foguet et al., 2003; Oakley et al.,

2003; Wilkinson et al., 2003). Subsurface delamination, pitting and fatigue cracking with the release of much larger wear particles have also been identified as important mechanisms of wear (Maloney et al., 1995; Scmalzried et al., 1997). This study shows that wear particles as big as 0.5 mm were retrieved from patients. A detailed analysis of retrieved cups will be presented in Chapter 5.

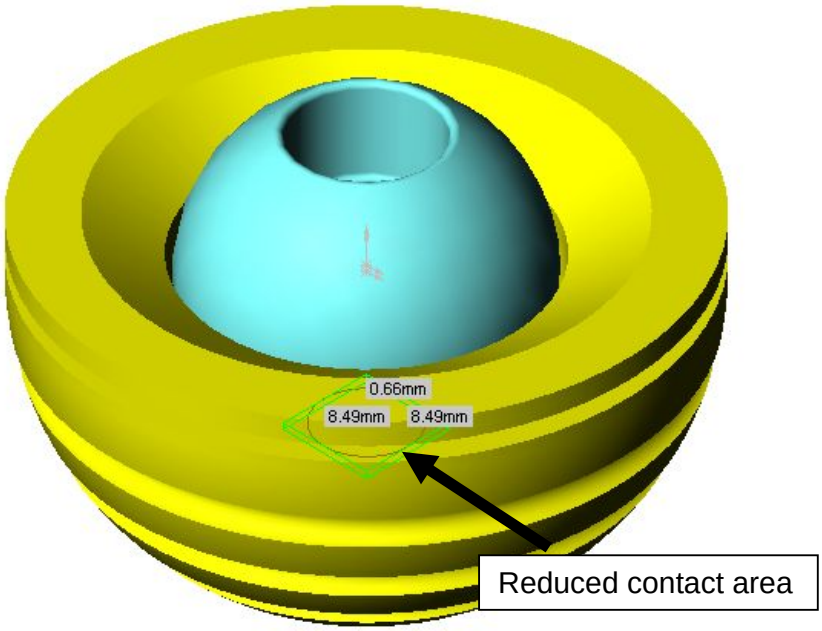


Figure 2.18: Graphical presentation of the effect of reduction in conformity on reduction in contact area – contact area becomes much smaller

2.6 Summary of previous retrieval and wear studies

2.6.1 Summary of retrieval studies — excluding crosslinked components

Various wear studies, based on X-ray analyses, have been published over the years (Charnley & Halley, 1975; Bragdon et al., 1997; Jasty et al., 1997; Wang et al., 1997; Bajaria & Bellare, 1998; Pietrabissa et al., 1998; Kesteris et al., 2003; Orishimo et al., 2003; Buford & Goswani, 2004). When this data is carefully analysed it is evident that the main aim was to try and determine the average linear wear over a period of time and not as much to determine the exact cause of mechanical failure. Doing a study by means of X-rays as detail failure analysis is problematic. Table 2.3 gives a summary of the available

results. The big scatter in the amount of linear wear per year is also not explained.

These studies were done by means of X-rays and the magnification factor of the X-rays is not consistent. It can be argued that the data as shown is of very limited value because it is not possible to measure accurately to one tenth of a millimetre on X-ray plates. X-rays are printed in shades of grey with not always a clear distinction between the edges. (See Figure 2.2 for an example.) Another effect is that some of the metals tend to create a halo effect around the material which makes measuring the component exactly very difficult. The only conclusion possible from these studies is an approximate wear rate over a period of time.

Table 2.3: Summary of in-vivo wear rates as per literature from Jasty et al. (1997)

Study	Number of samples	Average linear wear/year mm/year	Range mm/year
Charnley and Halley, 1975	72	0.15	0 - 0.6
Griffith et al., 1978	493	0.07	0 - 0.24
Wroblewski, 1985	21	0.21	0 - 0.41
Wroblewski, 1986	103	0.1	0 - 0.43
Livermore et al., 1990	227	0.13	0 - 0.39
Wroblewski et al., 1992	57	0.07	0.01 - 0.2
Cates et al., 1993	99	0.08	0 - 0.37
Cates et al., 1993	134	0.11	0 - 0.31
Hernandez et al., 1994	97	0.14	0 - 0.92
Hernandez et al., 1994	134	0.22	0 - 1.41
Woolsen and Murphy, 1995	80	0.14	0 - 0.35
Wroblewski et al., 1996	19	0.06	0.024 - 0.32
Sychterz et al., 1997	96	0.17	0.02 - 0.45

In the work done by Buford and Goswani (2004), existing data from the literature was summarised to determine the extent of the range of linear wear rates (mm/yr) taking into account the materials of the mating couples that are metal on polyethylene hip replacements and ceramic-on-polyethylene replacements (see Tables 2.4 and 2.5).

Table 2.4: Wear rates of metal -on- polyethylene total hip implants as summarised from existing literature data (Buford & Goswani, 2004)

Acetabular bearing	**Femoral bearing**	**Femoral head diameter [mm]**	**Average liner wear rate [mm/yr]**
Polyethylene	Cobalt-chromium	28	0.14
Polyethylene	Stainless steel	22	0.14
Polyethylene	Stainless steel	22	0.13
Polyethylene	Cobalt-chromium	32	0.1
Polyethylene	Stainless steel	28	0.08
Polyethylene	Stainless steel	22	0.09
Polyethylene	Cobalt-chromium	28	0.05
Polyethylene	Cobalt-chromium	32	0.04
Polyethylene	Stainless steel	28	0.04

Table 2.5: Wear rates of ceramic-on-polyethylene total hip implants as summarised fromexisting literature data (Buford & Goswani, 2004)

Acetabular bearing	**Femoral bearing**	**Femoral head diameter [mm]**	**Average liner wear rate [mm/yr]**
Polyethylene	Alumina	28	0.1
Polyethylene	Alumina	28	0.1
Polyethylene	Alumina	28	0.08
Polyethylene	Alumina	32	0.03
Polyethylene	Alumina	28	0.03
Cross-linked Polyethylene	Alumina	22	0.03

From the study by Buford and Goswani (2004), it again became clear that there is a significant spread in the amount of linear wear for the different bearing couples as well as for bearing couples from the same material. The study by Buford and Goswani (2004), however, does not try to explain this difference in linear wear rates.

In a similar study done by Kesteris et al. (2003) the data of 42 total hip replacements due to loose acetabular components was compared to the data of 41 total hip replacements due to loose femoral components all because of aseptic loosening due to osteolysis. The summary of the data can be seen in Table 2.6 and the graphical presentation of the data is provided in Figure 2.19.

Table 2.6: Mean (mm or mm^3), standard deviation and range of wear measurements from retrieved acetabular components at revision surgery (Kesteris et al., 2003)

	Linear wear [mm]	**Linear wear rate [mm/yr]**	**Volumetric wear [mm^3]**	**Volumetric wear rate [mm^3/yr]**
Cup group cup replacement	3.4 ± 1.4 (1.2-7.4)	0.3 ± 0.1 (0.1-0.6)	1086 ± 454 (397 – 2215)	84 ± 37 (26-173)
Stem group Stem replacement	1.5 ± 0.9 (0-4.3)	0.1 ± 0.1 (0-0.3)	531 ± 332 (109-1506)	40 ± 23 (6-106)

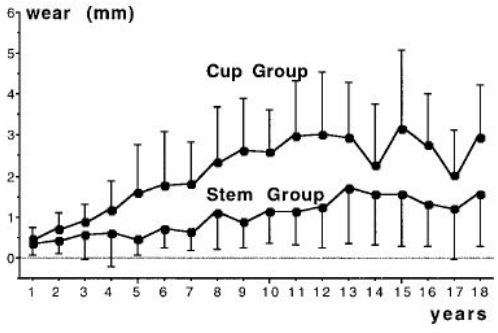


Figure 2.19: Linear wear in the cup replacement and stem replacement group (Kesteris et al., 2003)

If one brings the data as presented by Kesteris et al. (2003) and Buford and Goswani (2004) into the context of the work done by Dumbleton et al. (2002), it is clear that if the wear rate exceeds 0.1 mm/yr a loose acetabular component can be expected. The practical wear rate threshold of 0.05 mm/yr, as suggested by Dumbleton et al. (2002), to prevent osteolysis seems not to be acceptable if one looks at the data as presented by Buford and Goswani (2004) and Kesteris et al. (2003).

It must again be emphasised that in all of these studies the actual wear mechanism was not identified and the scatter in the wear data was not explained. This thesis shows that the dominant wear mechanism is localised overheating and that the scatter in the wear data is influenced by the difference in the lubricating capabilities of the synovial fluid present.

A different approach was followed by Sychterz et al. (1996) and by Jasty et al. (1997) in two separate studies. Wear of retrievals was measured volumetrically. A summary of their results is given in Table 2.7. In these studies, no attention was given to the mechanism of failure, but again only to the extent of wear. However, very useful information was gathered, regarding the location of the maximum wear in these cups (see Figure 2.20). These studies, however, do not distinguish between wear, plastic creep, plastic flow, extrusion, delamination, pitting and the like. The main aim of these studies was to establish the amount of material loss over a period of time.

Table 2.7: Results of retrieval studies where wear was determined volumetrically (Sychterz et al., 1996; Jasty et al., 1997)

	Mean Rate linear wear per year	**Range mm/year**	**Mean volumetric wear per year**	**Range mm^3/year**
Sychterz et al. (1996)	0.07	0.02 - 0.18	245 mm^3	1.0 - 131.3
Jasty et al. (1997)				8 - 284

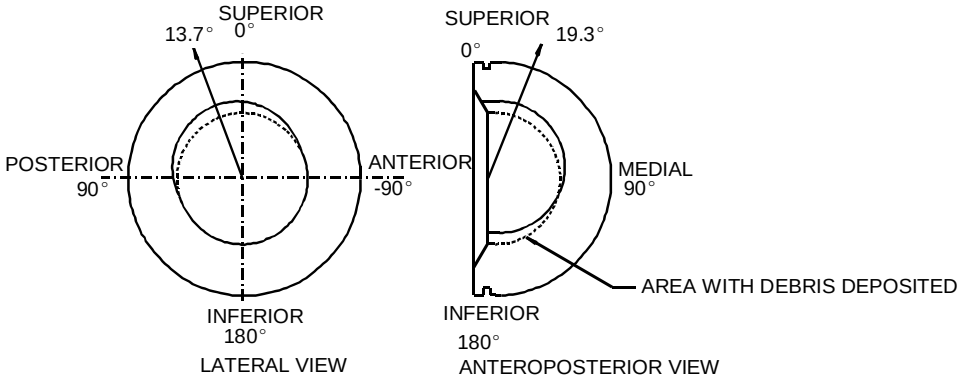


Figure 2.20: Position of maximum wear in cups according to Sychterz et al. (1996)

From Figure 2.20, it can be seen that the wear in the lateral view was orientated at 13.7 ° away from the most posterior point of the face towards the posterior side. From the anteroposterior view of the liner, this vector was orientated at a mean of 19.3° away from the face of the liner towards the apex.

According to these studies, 'burnishing' was the most common type of polyethylene wear. (Note: The use of the word *burnishing*, in this context, is a misnomer when considered in terms of the commonly understood meaning of the word *burnishing* as used in engineering terms. *Burnishing* is a process whereby a smooth hard tool (using sufficient pressure) is rubbed on the material surface. This process flattens the high spots by causing plastic flow of the material. Roller burnishing improves the finish and size of a part and is not a wear mechanism. Plastic flow or creep or perhaps polishing would have been more appropriate.) Scratching and pitting also occurred in all the liners studied by Sychterz et al. (1996), but were less severe. Permanent plastic deformation, embedded particles and abrasion were also seen. Another interesting finding by Sychterz et al. (1996) was that the wear rate was higher in the metal backed cups (average 10.9 years in-vivo) than in the all polyethylene cemented cups (average 12.4 years in-vivo), contrary to what would have been expected. No engineering explanation was given for this observation.

Jasty et al. (1997) investigated the influence of head diameter. In this study, it was found that the wear rates were higher with 32 mm diameter heads, intermediate with 28 and 26 mm heads and the lowest with 22 mm heads. These conclusions regarding femoral head size are not supported by the work done by Buford and Goswani (2004). (See Tables 2.4 and 2.5.) Once again, the study did not distinguish between wear and creep and no engineering explanation was given for these failures.

The most common types of damage reported by Jasty et al. (1997) were polishing of the running surface (see Figure 2.21), fine scratches (55 μm or less in width), see Figure 2.21, flaking (delamination of the surface), pitting, cracking, coarse abrasive wear (scratches 100 μm or more in width), embedded particles of metal or cement and dislocation. Additional findings by Jasty et al. (1997) are shown in Figures 2.21 to 2.24.

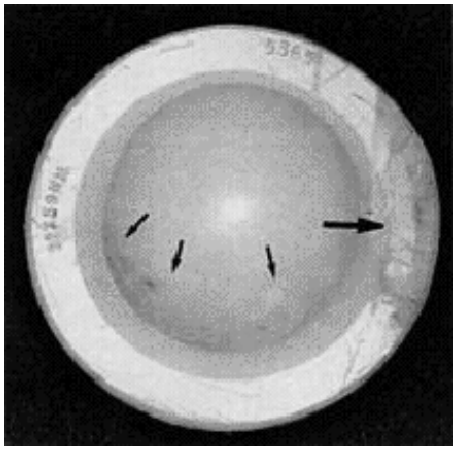


Figure 2.21: Photograph of a polyethylene acetabular component (Jasty et al., (1997) retrieved during a revision that was performed because of osteolysis six years post-operatively. There is an eccentric pattern of wear. The superior worn area is highly polished and is separated from the inferior, less worn area by a ridge (small arrows). Note the evidence of impingement anteriorly (a large arrow). Discolouration and flaking are seen in the less worn area

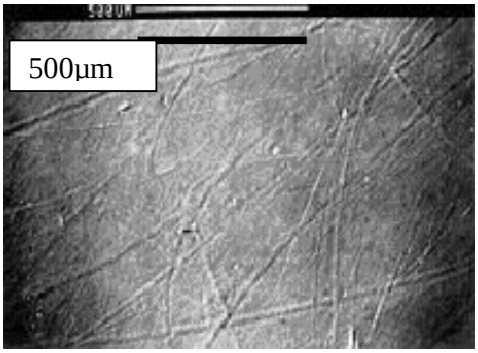


Figure 2.22: Scanning electron micrograph showing the highly worn area with numerous multidirectional fine scratches in a well-fixed acetabular component that was retrieved at autopsy ten years after implantation (original magnification, x 79.5)

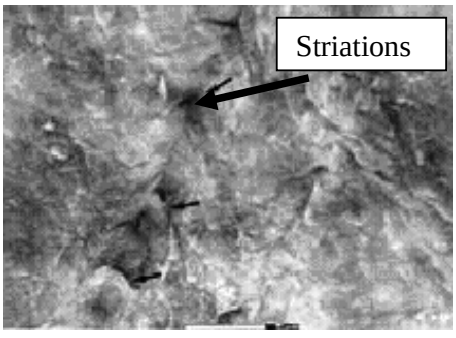


Figure 2.23: Scanning electron micrograph showing striations (arrows) perpendicular to the direction of the scratches, indicating tearing of the material during abrasive wear (original magnification, x 3900)

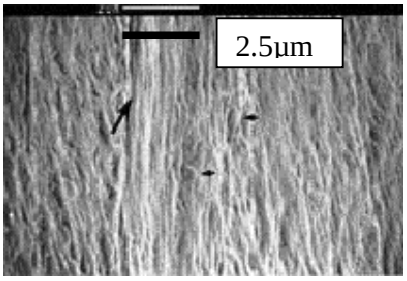


Figure 2.24: High-power scanning electron micrographs of a component retrieved six years after an arthroplasty. Reorganisation of the material has occurred during the wear process

In Figure 2.24 the scratch that formed much earlier is still visible. Within the scratch, the polyethylene is drawn into fine fibrils oriented parallel to the scratch (a large arrow). Scratches are not visible in adjacent areas, but fine fibrils, one micrometer or less in diameter, are present over the entire area. These fibrils are the major source of sub-micrometer wear particles. There are tears in the fibres in some areas and curled fibres (small arrows) (original magnification, x 10 400).

According to Jasty et al. (1997), McKellop et al. (1997) and Wang et al. (1997), the dominant mechanisms of failure are abrasion and adhesion at the surface.

If the test results between the studies of Jasty et al. (1997) and Sychterz et al. (1996) are compared, it is evident that a certain correlation between the different types of wear is observed, but no engineering explanation is given.

Various studies were undertaken by Schmalzried et al. (1997) and Maloney et al. (1995) to determine the size and distribution of wear particles found in tissue surrounding the joint at failure. A summary of the results can be seen in Table 2.8. From the results, it can be seen that the majority of wear particles (90%) is smaller than 0.7µm. (It will again be shown during the discussion in this study that particles as big as 0.5 mm were retrieved from tissue surrounding the joints of the samples retrieved during revision surgery.)

In a further study done by Young-Hoo and Kim (2001), the mean and annual linear wear and mean and annual volumetric wear between UHMWPE

acetabular cups working together with zirconia and chrome cobalt femoral heads were investigated in 70 patients with a mean of 6.4 years post-operatively. The mean linear wear in the zirconia femoral heads, of diameter 22 mm, was the highest — 1.25 mm compared to the 0.7 mm of the chrome cobalt femoral heads. The annual wear rate was 0.21 mm for the zirconia femoral heads compared to the 0.12 mm for the chrome cobalt femoral heads. The mean volumetric wear was again the highest for the zirconia femoral heads, — 730.79 mm^3 compared to the 264.67 mm^3 for the chrome cobalt femoral heads.

Table 2.8: Summary of sizes of wear particles as determined by Schmalzried et al. (1997) and Maloney et al. (1995)

Design of cup	**Shape of particles**	**Mean size of particles (μm)**	**Size of 90% of particles (μm)**	**Mean total no. of particles per gram of tissue(in millions) (Range is given in parentheses)**
Fixed	Spherical or globular	0.4	< 0.7	1 443 ± 1 496 (92 – 4 286)
Bipolar	Spherical, needle or flake-like	0.7	<1.1	2 935 ± 1 489 (725 - 4 698)

In a comparative study by Eggli et al. (2002), between chrome cobalt femoral heads of different sizes, 22 and 32 mm, the volumetric wear for the 22 femoral heads, at an average follow-up time of 71.4 months was 41.5 mm^3/year compared to the 120.3 mm^3/year for the 32 mm femoral heads.

2.6.2 Summary of follow-up study on crosslinked components (see paragraph 2.9 for the effects of crosslinking on the properties of UHMWPE.)

Crosslinked cups were implanted in almost 1 000 cases during the years 1978 to 1982 in Pretoria and Johannesburg by Grobbelaar and Weber (Grobbelaar et al., 1999). These cups were manufactured from UHMWPE and then crosslinked in an acetylene atmosphere. A follow-up study was done in 1999, where a review protocol was drawn up and all patients fitting this protocol were examined; and the hip joints were evaluated by means of X-rays. The average follow-up of the patients was 15.5 years. In all, 103 patients were examined and investigated during the course of this study. After the publication of the results of various studies by Oonishi et al. (1997) and Muratoglu et al. (2001) on techniques to improve the crosslinking quality of the UHMWPE as well as published results on various in vitro wear studies on simulators by Mckellop et al. (1997) and Mckellop et al. (2000), in conjunction with the publication of clinical results by Grobbelaar et al. (1999) and Muratoglu et al. (2004) the use of crosslinked acetabular components has become popular again.

The results of the Grobbelaar et al. (1999) study are as follows: In 86 of these patients, no wear could be measured and the rest of the wear varied between 0.7 and 1.5 mm. In Figure 2.25, an example of an X-ray is shown of the worst case in this follow-up. The total wear is given as 2.5 mm. No engineering explanation is given to explain the wear mechanism. Again the problem remains that, owing to magnification of the X-ray, it is very difficult to measure on X-rays.

The results of this study look very promising, but the practice of crosslinking was discontinued internationally in 1983 after a number of fractures, presumably caused by the reduction in izod impact strength values, occurred (Oonishi & Kuno 1997). The use of crosslinked acetabular cups has since been resumed and is on the increase (Mallchau et al., 2000; Davidson et al.,

2002; Davidson et al., 2003).

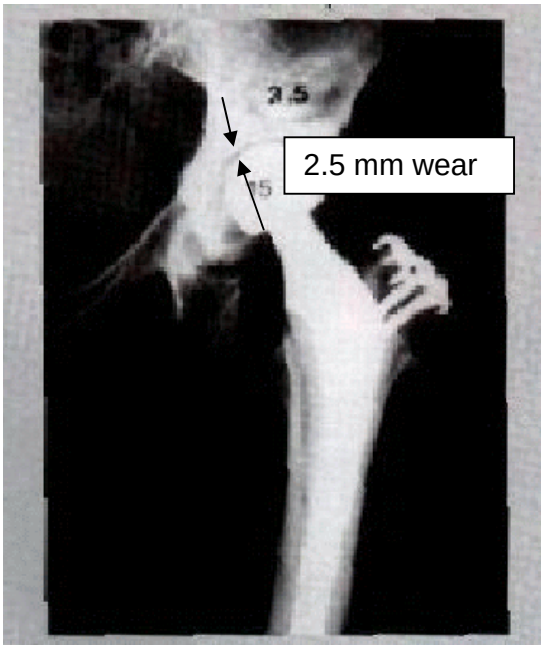


Figure 2.25: X-ray that shows 2.5 mm wear in cup as indicated by arrows as an eccentricity. No scale was shown in the reference but 30 mm femoral head serve as scale (Grobbelaar et al., 1999).

2.7 Results from simulator studies — in-vitro testing found in literature

Results of a number of simulator studies were found in the literature (Davidson et al., 1988; Kukureka et al., 1995; Wang et al., 1995; Wang et al., 1998; Clarke et al., 1996; Lu and McKellop, 1999; Wang et al., 1999; McKellop et al., 2000; Ries and Scott, 2001). Most of the simulator studies were done with bovine calf serum (BSA) as lubricant, while the average operating speed for these simulators was 1.5 to 2 Hz according to the ISO specification 14242-1 and ISO TR 9325 specification for simulator testing.

The materials tested during these in-vitro tests varied from metal alloy on metal alloy (stainless steel on stainless steel and chrome cobalt on chrome cobalt) to various femoral heads (alumina, zirconium, stainless steel and chrome cobalt) on UHMWPE, whether crosslinked or tests performed on the virgin material.

These studies reported that proteins precipitated as thin sheet-like deposits on the bearing surfaces, as well as in the simulator. In the study done by Lu and McKellop (1999), the temperatures were monitored by drilling holes in the ceramic femoral balls and mounting thermocouples 0.5 mm below the surface. The measured temperatures were extrapolated by means of a finite element analysis (FEA) to the bearing surface. The surface temperature was estimated to be between 60 and 99°C. The precipitation of proteins was regarded as an artefact of the simulators (Lu & McKellop, 1999). During the same study by Lu and McKellop (1999), the BSA (Bovine serum albumen) was heated up in a test tube and it was found that the proteins in the BSA started to precipitate at 60°C. After1 hour at 90°C, 40% of the proteins had precipitated (Lu & McKellop 1999). The studies investigated frictional heating and protein precipitation in a hip simulator as a function of the material of the femoral head, the rotation of the component (inverted or anatomically), the cycling speed and the volume of the lubricating chamber. The volume of fluid used varied between 45 and 135 ml. Although it is not stated as such, a very important conclusion can be drawn from the temperature at which precipitation of the proteins occurred. The high temperature calculated by the FEA was confirmed by the protein deposits inside the cups during the actual testing.

Friction was measured by making use of a custom-designed 3-axes strain gauge torque transducer mounted on a load axis above the test chamber. During these studies, it became evident that there was an increase in torque applied as the test progressed. This finding confirmed the work done by Wang et al. (1998), namely that solid protein is not a good lubricant.-depending the concentration of protein present During the testing phase of this thesis, it has also been shown, that the denaturated solid proteins perform even worse (apart from the fact that BSA is not a good lubricant.)

During these simulator studies, two major observations were made, namely:

a. The importance of multidirectional motion in the wear mechanism and wear testing of UHMWPE
b. Solid proteins are found not to be effective in boundary layer lubrication

applications.

A common observation of all these investigations was that all cups examined, exhibited the characteristic appearance of surface stretching in the form of fibril formation or fibrillation. McKellop et al. (1997) believe that this fibril morphology was a result of micro-adhesive wear or just third-body abrasive wear. Wang et al. (1997) proposed that fibril appearance simply reflected the occurrence of molecular orientation on a worn surface, which could be the result of either adhesion or abrasive wear.

The Wang et al. (1999), examinations of simulated tests on acetabular cups revealed the following four types of surface features:

a. Regular and irregular arrays or surface rip-off and bumps
b. Oriented and non-oriented loose fibrils
c. Oriented fibrils with no loose ends
d. Multidirectional scratches within which loose fibrils are sometimes seen.

According to Wang et al. (1999) features b, c and d are associated with high rate of wear, while feature (a) is associated with low wear rates. No reference was made to the effect of temperature and no engineering explanation was provided for these failures.

The importance of measuring temperature as accurately as possible to the bearing surface is indirectly borne out by the work of Davidson et al. (1988). A heat transfer analysis was compiled for femoral implants in simulator studies. During these studies, temperature rises of only a maximum of 10°C were recorded. What is not clear from this study is the size of thermocouples used in the simulators. It would seem that only bulk temperatures were recorded and the local hot spots were ignored.

In a study done by Ries and Scott (2001), wear particles retrieved from a simulator were measured and examined under a scanning electron

microscope at 10 000 times magnification. The wear debris was generated in a simulator with bovine serum as a lubricant, where the acetabular cup is submerged under 130 mm of lubricant, and running against a chrome cobalt femoral head at 1 Hz, according to the Bergmann et al., (Figure 2.11) and ISO 14242-1 (Figure 2.39) load profiles. The volume of lubricant is not known as the size of the reservoir was not specified. The wear particles for the non-irradiated, ethylene-oxide sterilised acetabular cup can be seen in Figure 2.26.

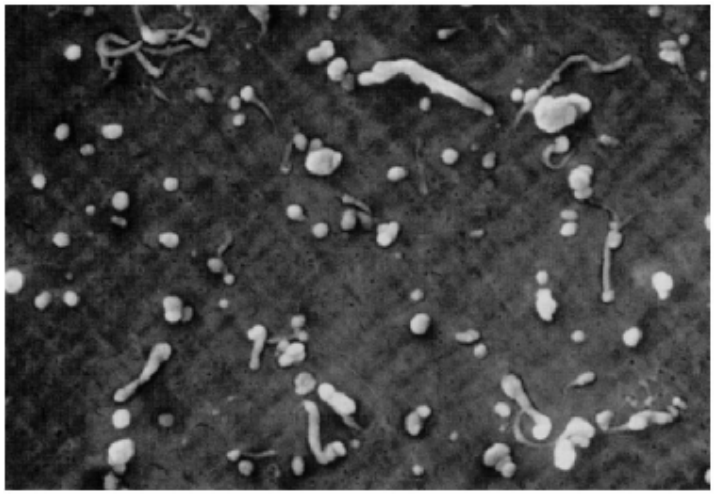


Figure 2.26: Particles of non-irradiated, ethylene oxide sterilised UHMWPE against chrome cobalt femoral head (x 10 000) (Ries & Scott, 2001)

2.8 Effects of gamma-irradiated sterilisation on wear characteristics

Sterilisation and crosslinking of polyethylene affect its wear rate (Rimnac et al., 1994; Fischer et al., 1995; Parr and Jack, 1995; McKellop et al., 1997; Wang et al., 1997; Orishimo et al., 2003). A time-dependent increase in the extent of oxidation can result from gamma sterilisation in air. The gamma irradiation breaks molecular bonds in the long polyethylene chains, giving rise to free radicals. Oxygen can combine with these free radicals. Saum (1994) and Parr and Jack (1995) reported subsurface oxidation which remains significant up to 2 mm below the surface. Oxidation as deep as 3 mm into test samples was also found by Rimnac et al. (1994). Trieu and Paxson (1995) demonstrated an oxidised surface layer as thick as 6 mm in UHMWPE components.

The common understanding of the oxidation process is as follows (Lewis, 2001; Parr & Jack, 1995): UHMWPE initially consists of extremely long molecular chains which provide excellent abrasion resistance. Sterilisation by gamma irradiation causes chain scission by breaking of chemical bonds and creating reactive free radicals. Oxygen diffuses into the material and reacts with the free radicals to cause oxidation, which leads to much shorter molecular chains. As a result, the original properties of polyethylene, including abrasion resistance, change significantly. Preliminary data indicates that long-term oxidative degradation can alter the performance of the polyethylene in total joint replacement, especially its resistance to fatigue wear, which can cause pitting and delamination.

An appreciable difference in hardness between the surface layer and the core results from gamma sterilisation. Extensive reduction in toughness was also found in the case of gamma sterilisation. Similar to elongation, the reduction in toughness of the surface layer is more severe upon ageing of the component. This indicates an increase in surface embrittlement that is caused by oxidation.

Research has shown that most of the oxidation occurs during post-radiation ageing and not during the sterilisation process, because long life free radicals exist in the UHMWPE as a result of reduced mobility within crystalline regions (Rimnac et al., 1994; Trieu & Paxson, 1995).

In simulator studies Ries and Scott (2001) had shown that the particle morphology of non-irradiated, ethylene-oxide sterilised components (Figure 2.26) is almost the same as for inert gas gamma-irradiated components (see Figure 2.27).

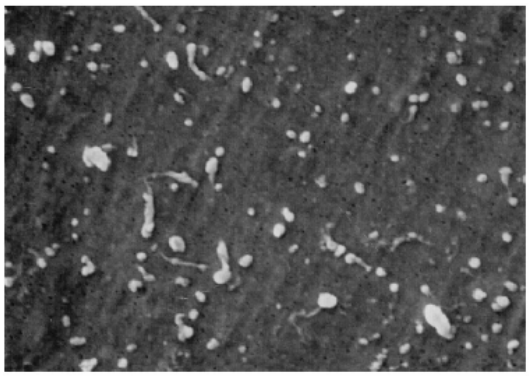


Figure 2.27: Wear particles of inert gas gamma-irradiated UHMWPE against chrome cobalt (x 10 000) (Ries & Scott, 2001)

In a study done by Orishimo et al. (2003), the long-term in-vivo wear performance of two groups of well-functioning cementless acetabular cups sterilised by two different methods, namely gamma irradiation and ethylene-oxide were compared. The first group consisted of 31 acetabular cups sterilised by means of gamma irradiation while the second group consisted of 28 acetabular cups sterilised with ethylene oxide. The linear wear rate follow-up data for the gamma-sterilised acetabular cups can be seen in Figure 2.28 while the follow-up data for the ethylene oxide acetabular cups can be seen in Figure 2.29. On average, it can be seen that the linear wear rate in mm/year for the gamma-sterilised cups is slightly better than for the ethylene oxide cups.

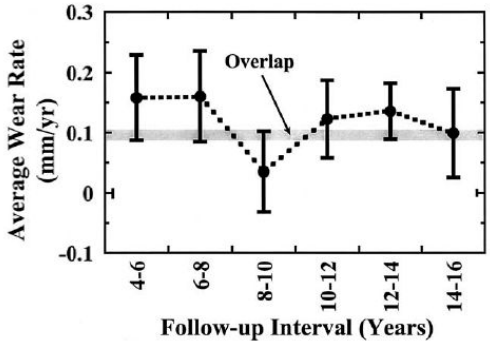


Figure 2.28: Average wear rate for acetabular components sterilised with gamma radiation (Orishimo et al., 2003)

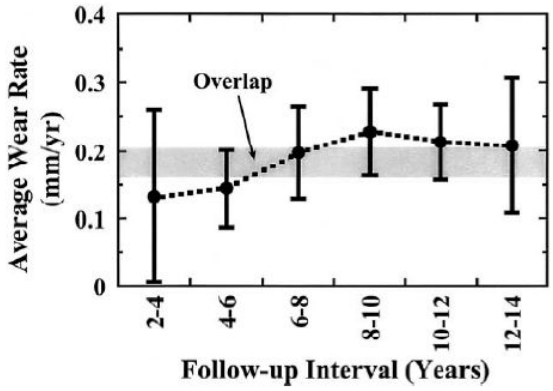
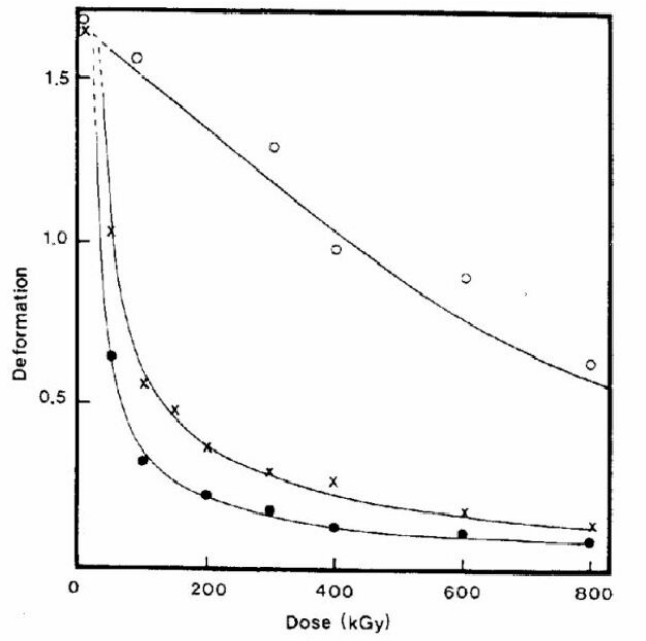


Figure 2.29: Average wear rate for acetabular components sterilised with ethylene oxide (Orishimo et al., 2003)

2.9 Effects of crosslinking on characteristics of UHMWPE

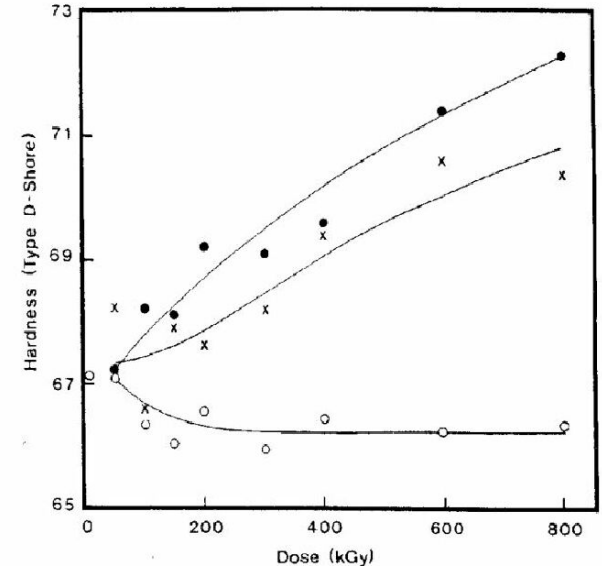
Crosslinking, as a method to improve the properties of UHMWPE, has been tried and used over the years with limited success. The success was limited despite an almost 30% improvement in abrasion resistance (Sun and Wang, 1996; Oonishi & Kuno, 1997). The major factor preventing crosslinked material from being the industry standard for acetabular cups is the reduction in the izod impact strength. According to the various hip registers, crosslinked UHMWPE is again becoming more popular (Mallchau et al., 2000; Davidson et al., 2002; Davidson et al., 2003). This material, however, also showed better wear resistance and, as such, it is important to review the research in this field. An extensive study into crosslinking of UHMWPE was done by Du Plessis et al. (1977), which yielded excellent results. UHMWPE was used and crosslinked with irradiation in the presence of acetylene and chlorotrifluoroethylene (CTFE) as well as nitrogen, which was used as an inert atmosphere. All the gases used were of an analytical grade. The material was irradiated at different dosages. Tensile and impact strength tests were carried out at temperatures of 37°C. The tensile strength (Figure 2.30) showed a decrease in strength with an increase in radiation, the surface hardness (Figure 2.31) increased markedly, while the izod impact strength (Figure 2.32) values decreased dramatically. It must be pointed out that the effect of elevated temperatures above 37°C, on the properties of crosslinked

UHMWPE is not known.



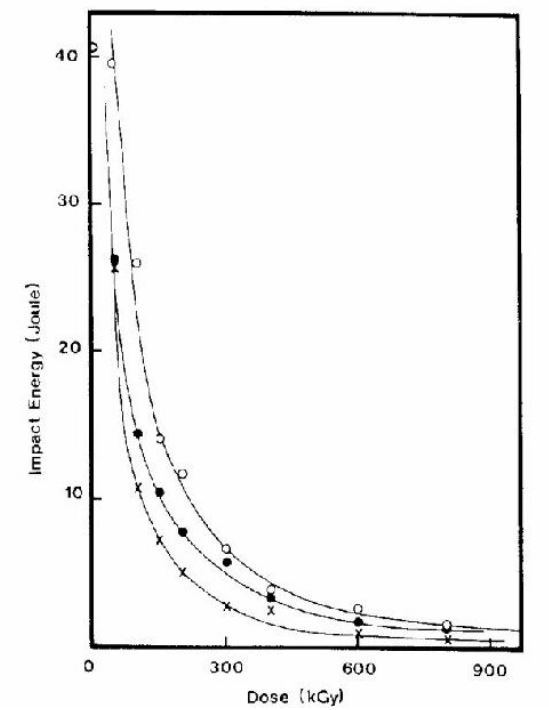
- Acetylene and CTFE, ○ Nitrogen, x Acetylene

Figure 2.30: Deformation of crosslinked UHMWPE (Du Plessis et al., 1977).



- Acetylene and CTFE, ○ Nitrogen, x Acetylene

Figure 2.31: Surface hardness of crosslinked UHMWPE (Du Plessis et al., 1977)



- Acetylene and CTFE, ○ Nitrogen, x Acetylene

Figure 2.32: Impact energy of crosslinked UHMWPE (Du Plessis et al., 1977)

In the simulator study done by Ries & Scott (2001), the wear debris formed when running crosslinked UHMWPE against a chrome-cobalt femoral head showed a significant decrease in quantity and size (Figures 2.33 and 2.34) if compared to the debris formed with non-irradiated UHMWPE running against a chrome cobalt femoral head. The tests were done with UHMWPE acetabular cups crosslinked at different levels of irradiation, namely 5 Mrad (Figure 2.33) and 10 Mrad (Figure 2.34), and then compared to the wear found in non-crosslinked components.

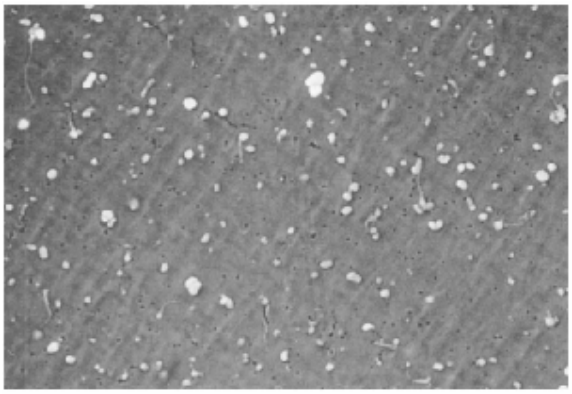


Figure 2.33: Wear particles of highly crosslinked UHMWPE subjected to 5 Mrad of gamma irradiation (x 10 000) (Ries & Scott, 2001)

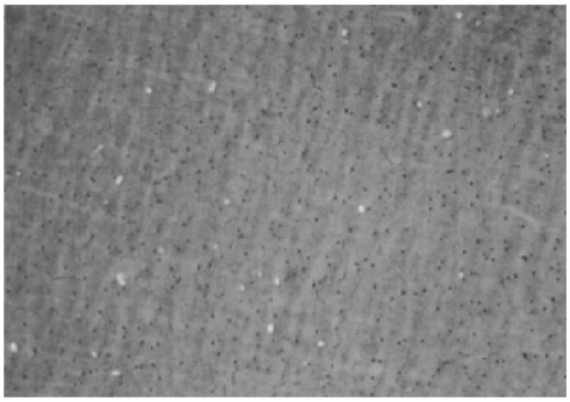


Figure 2.34: Wear particles of highly crosslinked UHMWPE subjected to 10 Mrad of gamma irradiation (x 10 000) (Ries & Scott, 2001)

2.10 Hip simulators for in-vitro testing

Various studies employing hip simulators are used to evaluate the performance of acetabular cups of various designs, materials and material combinations for longevity (Davidson et al., 1988; Kukureka et al., 1995; Wang et al., 1995; Clarke et al., 1996; Wang et al., 1998; Lu and McKellop, 1999; Wang et al., 1999; Mckellop et al., 2000; Smith and Unsworth, 2000; Ries & Scott, 2001; Saiko et al., 2001; Tipper et al., 2001; Calonius and Saiko, 2002; Masaoka et al., 2003). In all of these tests, wear is either measured as linear wear or as volumetric wear with some of the studies analysing the

retrieved wear debris.

A number of designs for simulators are used of which the Boston simulator, (see Figure 2.35) is the most common. These simulators are all described in literature and are using either/or both the Paul load profile (Paul, 1976) (Figure 2.10) or the Bergmann profile (Bergmann et al., 1993; Bergmann et al., 1995) (Figure 2.11) or a combination of the two. The biggest difference between the two profiles is that the Paul profile was calculated where the Bergmann was measured. A summary of eight contemporary hip simulators is given in Table 2.9 with a summary of the various motion waveforms shown in Figure 2.36.

Figure 2.35: Boston hip simulator
(http://www.geocities.com/hip_replacements/ history)

A major disadvantage of these simulators is the high capital cost, as well as the expensive operating cost owing to the fact that the load is applied via a computer-controlled servo hydraulic system. The result of this is that simulators were, until now, inaccessible for primary research, owing to the fact that they were mainly positioned at major manufacturing companies.

Table 2.9: Summary of contemporary hip simulators (Calonius & Saikko, 2002)

Design	Euler sequence and partition of rotations, and classification of axes	Direction of load, and component relative to which it is fixed		Assumed position or neutral position in computation		Reference
				Head axis	Cup	
BRM offset lever	$FE_{h,s} \rightarrow AA_{h,m} \rightarrow IER_{h,m}$	V	c	V	H	Present study, see Fig. 5
AMTI	$AA_{c,m} \rightarrow FE_{c,s} \rightarrow IER_{h,s}$	V	h	V	H	Bragdon et al. (1996)
Munich	$FE_{c,m} \rightarrow AA_{c,m} \rightarrow IER_{c,s}$	V	h	45°	45°	Ungethüm (1976)
Leeds Mk I	$IER_{c,s} \rightarrow FE_{h,s} \rightarrow AA_{h,m}$	Changing	Neither	45°	45°	Dowson and Jobbins (1988)
ISO/DIS 14242-1	Not specified	V	c	30°	30°	Draft ISO/DIS 14242-1 (2001)
Durham Mk II	$IER_{c,s} \rightarrow FE_{h,s}$	V[a]	h	45°	45°	Smith and Unsworth (2001)
Leeds Mk II	$IER_{c,s} \rightarrow FE_{h,s}$	V	c	45°	45°	Barbour et al. (1999)
ProSim	$IER_{c,s} \rightarrow FE_{h,s}$	V[a]	h	V	35°	Goldsmith and Dowson (1999)
HUT-3[b]	$IER_{c,s} \rightarrow AA_{h,s} \rightarrow FE_{h,m}$	12° to V	c	45°	45°	Saikko (1996)
BRM zero-offset lever[b]	$FE_{h,s} \rightarrow AA_{h,m}$	V	c	V	H	Saikko and Ahlroos (1999)

Note: h, head; c, cup; s, stationary axis; m, moving axis; V, vertical; H, horizontal.
[a] In neutral position of FE cradle.
[b] Included here for comparison; their slide tracks were computed earlier, Saikko and Calonius (2002).

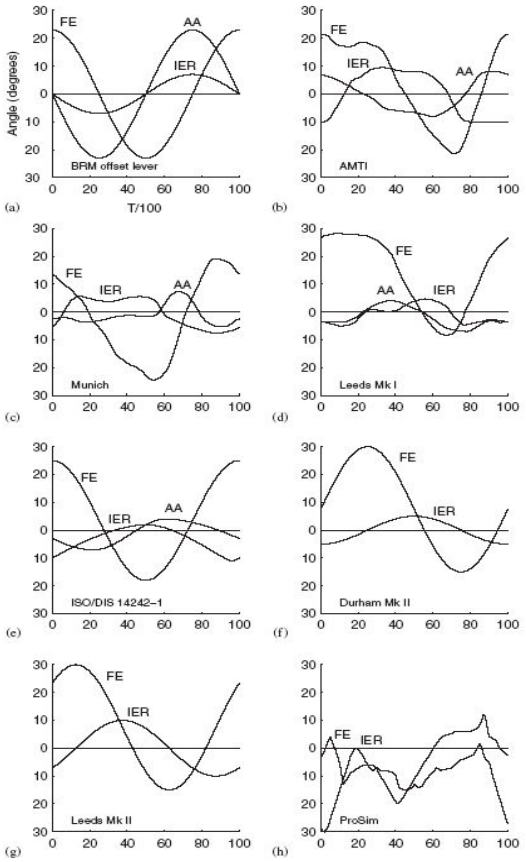


Figure 2.36: Motion waveforms used in computation of slide tracks for hip simulators

a BRM with offset lever
b AMTI
c Munich
d Leeds Mk I
e ISO 14242-1
f Durham Mk II
g Leeds MK II
h ProSim

Positive angle represents flexion, abduction and internal rotation, and negative angle represents extension, adduction, and external rotation.

The above simulators all used various concentrations of bovine serum as lubricant. The lubricant was stabilised with 0.1% sodium azide to retard bacterial growth (Davidson et al., 1988; Kukureka et al., 1995; Wang et al., 1995; Clarke et al., 1996; Wang et al., 1998; Lu and McKellop, 1999; Wang et al., 1999; Mckellop et al., 2000; Smith and Unsworth, 2000; Ries & Scott, 2001; Saiko et al., 2001; Tipper et al., 2001; Calonius and Saiko, 2002; Masaoka et al., 2003). The cups were mounted inverted with the acetabular component pointing upwards. A typical design of such a simulator is shown in Figure 2.37 with a close-up photograph of such a simulator shown in Figure 2.38. In the literature the volume of lubricant in the receptacles is not always specified but in the articles where the lubricant volume is specified the volume of lubricant varied from 100 ml/receptacle (Saikko et al., 2001) to 350 ml/receptacle (Wang et al., 1996). In all the cases, where specified, the fluid was replenished twice daily with distilled water and the total amount of fluid was changed at each wear measurement which is every 250 000 cycles (Masaoka et al., 2003).

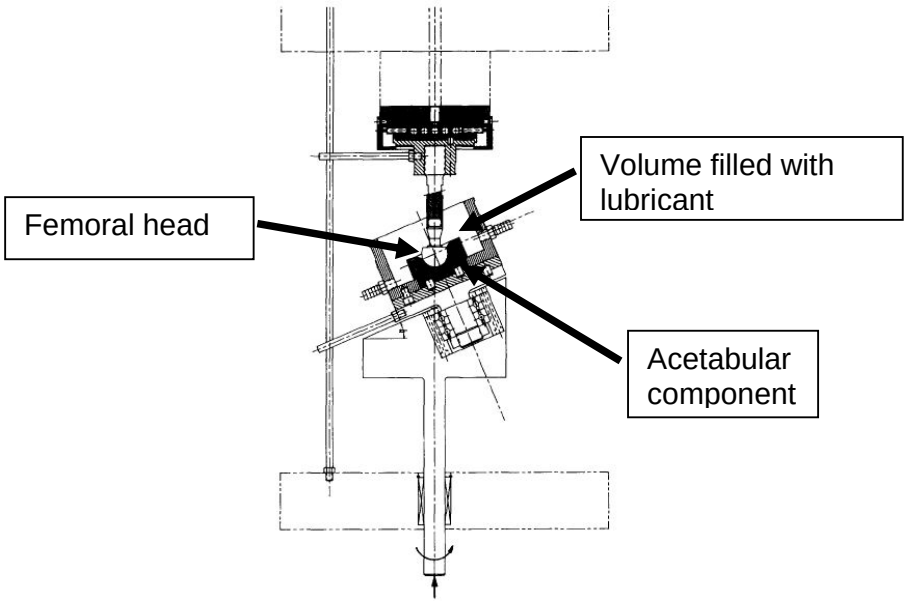


Figure 2.37: Schematic illustration of the loading/motion configuration of the Bi-axial rocking motion (BRM) hip simulator. (Wang et al., 1996)

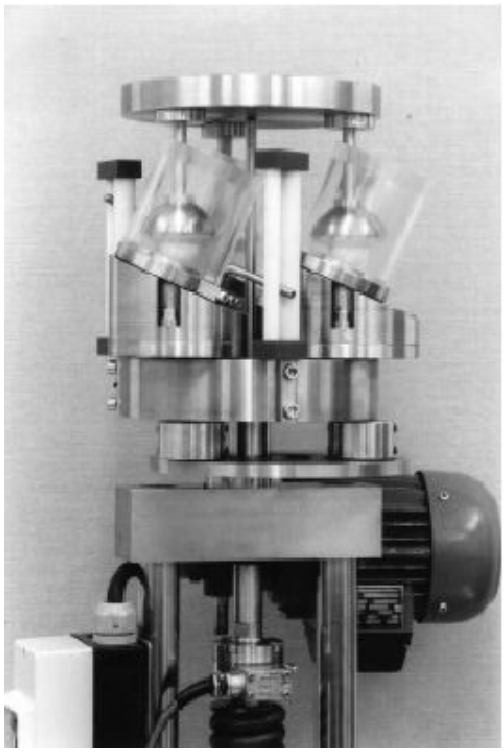


Figure 2.38: Three-station, statically loaded bi-axial rocking motion (BRM) hip wear simulator (Saikko et al., 2001)

If the design of the existing simulators, as shown in Figure 2.37, is analysed it is seen that the cup is continuously rotated in one direction resulting in an elliptical wear pattern inside the cup. Although the load is applied according to the load waveforms shown in Figure 2.36, the wear pattern is still elliptical and the asperities on the surface are continuously loaded in one direction, making it extremely unlikely that surface fatigue will occur.

A major problem common to these designs is retrieving of the wear debris and the concentration of bovine serum in the lubricant during testing. As mentioned, the wear debris is retrieved every 250 000 cycles when the simulator is stopped, the acetabular cup is removed and the retrieved lubricant

is passed through filters (0.2µm) to retrieve the wear debris (Smith & Unsworth, 2000; Saikko et al., 2001; Masaoka et al., 2003). The machines are then again assembled, the receptacles filled with the lubricant and the test started. The problems with this method are the following:

- The concentration of the lubricant is not constant throughout the test
- The accumulative effect of the wear debris of 20 million cycles is not achieved
- The removal of the test specimen from the machine destroys the wear pattern with the effect that a new test is effectively started on re-starting.

In 2002, an ISO standard (ISO 14242-1, 2002) was published specifying the hip simulators to be used in future testing. The load profile is a combination of the work done by Paul (1975), Bergmann et al. (1993) and Bergmann et al. (1995) with the following major exceptions:

- The maximum load is specified as 3 kN where Bergmann and Paul had taken the maximum load as up to 580% of body weight. (See Figure 2.39.) For the European male lying on the 50% percentile (ergonomic data) this is 4.9 kN.
- The load profile is for 40% of the loading cycle kept at a minimum of 0.3 kN.

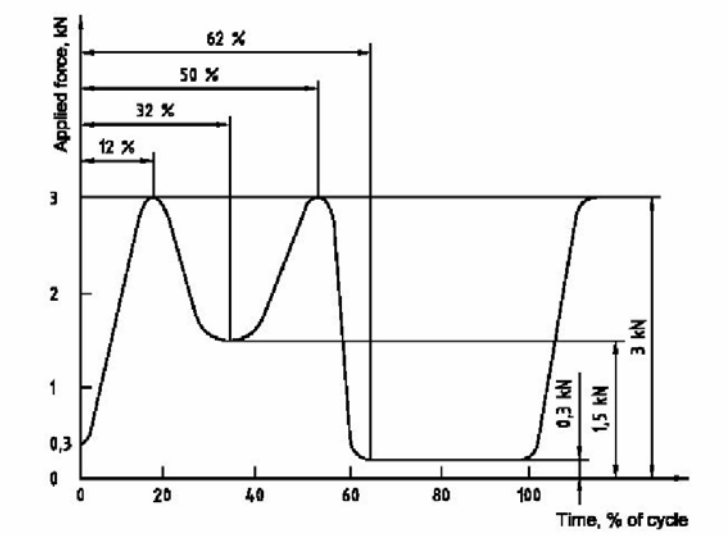


Figure 2.39: Loading profile for hip simulator according to ISO standard (ISO 14242-1, 2002)

The lubricant to be used is also specified as calf serum (25% ± 2%) diluted with de-ionized water (balance). An anti-microbial reagent such as sodium azide, may be added. The amount of lubricant per test station is not specified.

Apart from the specification regarding lubrication, extension/flexion, adduction/abduction and inward/outward rotation (see Table 2.10), the following general specifications apply:

- Operate the simulator at 1 Hz ± 0.1 Hz
- Replace the fluid lost by evaporation during the test at least daily, by adding de-ionized water. Replace the fluid test medium completely at least every 500 000 cycles.
- Stop the test for measurements atleast after 500 000 cycles, one million cycles and at least every one million cycles thereafter until the test is terminated.
- Remove the test specimen and control specimen from the testing machine and take wear measurements

Table 2.10: Variation with time of angular movement to be applied to the femoral test specimen (ISO 14242-1, 2002)

Time, % of cycle ± 1 %	0	21	50	62	100
Angle of flexion (+) or extension (–) ° ± 3 °	25		– 18		25
Angle of adduction (+) or abduction (–) ± 3 °	3	7		– 4	3
Angle of inward (+) or outward (–) rotation ± 3 °	– 10		2		– 10

The general specification has the same problem regarding the removal of the test specimen for wear measurements as discussed earlier. This is a very serious problem, because the biggest drawback of all simulators is currently the lack in correlation of in-vivo wear mechanism and in-vitro results, as stated by Harris (http://www.centerpulse-orthopedics.com/uk/en/Home/Home). The simulator wear studies predict unrealistically long life, which is not attained as can be seen by various retrieval studies, as discussed in paragraph 2.6.

2.11 Summary of literature review

After examining the vast amount of available literature on the relevant topics, the following shortcomings were identified:

- Insufficient data on the creep characteristics of UHMWPE at elevated temperatures, after gamma irradiation and after crosslinking.
- A look at a well-defined set of failure criteria that will allow the researcher to objectively analyse retrieved acetabular components.
- A complete engineering failure analysis on retrieved acetabular components to establish the reason for mechanical, not clinical, failure of acetabular components.
- The failure to develop an inexpensive hip joint simulator that is physiologically more representative and that will yield more accurate in-vitro results.
- Difficulties in obtaining an indication of the lubricating capabilities of synovial fluid and explaining the scatter in the wear results as found in the literature.