THE DESIGN OF A SEALED ARTIFICIAL HIP REPLACEMENT

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TABLE OF CONTENTS

ABSTRACT

Total hip replacement is a very successful orthopaedic procedure for patients with disabling joint diseases. However, it is common for these implants to last for only 10-15 years before revision surgery is required. The major long term complication in total hip arthroplasty is aseptic loosening which has largely been attributed to wear of prostheses. Wear particles emanating from any of the interfaces of the replacement system are known to interact with the tissues surrounding replacements causing an adverse tissue response and eventual loosening of the implant. Of particular concern is the amount of wear debris produced at the articulation of the femoral head and acetabular component.

The aim of this thesis is to produce a new design of artificial hip prosthesis that addresses the problem of wear particles and subsequent loosening.

Prior to designing a new replacement system an extensive historical review of hip replacement was undertaken. In addition the mechanisms, determinants and biological implications of wear have been examined. The anatomy and biomechanics of the hip joint were considered and current materials and their biocompatability assessed for possible use in this design. All of these subjects were analysed critically prior to design and development of a new system.

A sealed modular hip replacement system has been designed and developed in this thesis. The joint is sealed with a polymer sleeve that attaches near the periphery of the acetabular insert and a flange on the modular femoral head. These components combine to form a sealed bearing which would be delivered sterile from manufacture, ready for implantation at the time

of surgery. A sealed joint ensures that wear particles cannot escape to the surrounding tissues and also prevents debris from entering the articulation and causing third body wear.

The sealing membrane traps all wear particles produced at the articulating surface within the sealed joint and it is proposed that a wear particle collection chamber is employed to collect them. The use of a ceramic or other porous material in which particles can lodge will reduce second body wear of the joint surfaces.

As some of the designs developed in this thesis are novel concepts with commercial potential, a provisional patent has been filed. A preliminary marketing exercise has also been undertaken with a major implant manufacturer.

The author believes that this novel design of hip replacement system has the potential to increase the survival of hip replacement systems by the elimination of a major long term failure mode of aseptic loosening caused by wear particles.

DECLARATION

This thesis contains no material which has been accepted or published for the award of any other degree or diploma in any University. Furthermore to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of this thesis.

I hereby give consent for this thesis to be made available for photocopying and loan.

Signed _

Namal Sasrika Nawana,

1st June 1995

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LIST OF FIGURES

NOMENCLATURE AND ABBREVIATIONS

AJC	Artificial Joint Capsule
ASTM	American Society for Testing and Materials
CoCr	Cobalt Chromium
F	frictional force
FDA	Food and Drug Administration
μ	coefficient of friction
mm	millimetre(s)
MNGC	multinucleate giant cell(s)
N	normal force
N.m	newton metres
PMMA	polymethylmethacrylate
r	radius of femoral head
T	frictional torque
TiAlV	Titanium Aluminium Vanadium
TGA	Therapeutic Goods Authority
UHMWPE	ultra high molecular weight polyethylene
WPCC	wear particle collection chamber

CHAPTER 1

INTRODUCTION

Joint replacement surgery, or arthroplasty, is performed in patients to relieve pain and to retain or restore movement in the joint. In hip replacement the options are to replace the entire joint with an artificial joint, or to replace the bearing surfaces alone with resurfacing components. Such operations can result in restoration of joint function for periods greater than 20 years, prior to the requirement of revision surgery due to a recurrence of pain. However, joint replacements are also known to fail at any time during this period (Charnley *et al.* 1973; Smith and Turner 1973; Amstutz *et al.* 1976; Beckenbaugh *et al.* 1978; Dobbs, 1980; Sutherland *et al.* 1982; Poss *et al.* 1984; Hozack *et al.* 1990; Eiskjaer and Ostgard 1993) and many mechanisms of failure have been postulated. This thesis examines the design of an artificial hip prosthesis in relation to the problems of wear and subsequent loosening of the components.

Hip replacement systems have evolved since their first use in the early 1900s. Modern systems commonly use CoCr alloys, titanium alloys and ceramics for the head combined with these materials or polyethylene for the cup and a metal femoral stem component. Wear particles are produced in all of these systems due to the articulation of the acetabular and femoral components at relatively high loads, for a large number of cycles. Particles are also produced at the fixation interfaces (Buchert *et al.* 1986). These particles can all migrate to the fixation interface via the body fluids that are present (Murray and Rodrigo 1975; Howie *et al.* 1990; Schmalzried *et al.* 1992), subsequently causing osteolysis. The long term result is

The Design of a Sealed Artificial Hip Replacement

loosening of either the acetabular or femoral component of the hip prosthesis causing failure of the artificial joint (Howie *et al.* 1993).

Whilst wear particles are one causative factor of loosening and failure of prostheses, other mechanisms for loosening exist also. Mechanical loosening (Amstutz *et al.* 1976; Pellicci *et al.* 1979; Gruen *et al.* 1979) due to poor implant design or failure of fixation, has also been reported widely. However, many of these problems have been addressed by improved design (Lee *et al.* 1973; Harris *et al.* 1982; Paterson *et al.* 1986; Ling *et al.* 1994). Infection is also a problem but again reports have shown a decrease in the incidence of infection as a cause of loosening (Kamme and Lindberg 1981; Gristina and Kolkin 1983; Poss *et al.* 1984).

1.1 Aim

A major long term complication in hip replacement is aseptic loosening associated with the excessive production and subsequent egress of wear particles from the joint surfaces of hip replacement systems to the surrounding tissues. This causes a biological response resulting in bone resorption and loosening of the implant.

The main aim of this thesis is to design a novel hip replacement system to reduce or eliminate the problem of wear particles.

1.2 Hip Arthroplasty - A History

Over the last century total hip arthroplasty has been performed to relieve pain and restore function in deficient or damaged hips with considerable success. Throughout this period, different implant designs, as well as surgical instrumentation and techniques have evolved to improve the longevity and quality of treatment with this type of procedure.

1.21 Early work

Early attempts at interposition arthroplasty, where materials were merely inserted between the bone ends of the joint, produced relatively poor results largely due to the selection of unsuitable materials. Interposition of tissue between the bone ends was tried as early as 1860 by Verneuil (1860) in the tempromandibular joint and continued into the early 1900s with Lexer (1908) using fascia between the joint surfaces of the hip in 1908. Other authors (Murphy, 1905; Loewe, 1913; Murphy, 1913; Putti, 1921) have also investigated the use of various other tissues for this purpose, all unsuccessfully. Ivory replacements (Gluck, 1891) and gold foil insertions (Jones and Lovett 1929) both proved unsuccessful. Smith-Peterson (1948) endured early failures of glass, celluloid, pyrex and bakelite before he implanted the first cobalt-chrome mould prosthesis in 1938 (Smith-Petersen *et al.* 1947). This implant enjoyed considerable success but still results were not satisfactory (Smith-Petersen *et al.* 1947; Aufranc, 1957).

1.22 Total hip replacement

Total hip replacement replaces the acetabular component and femoral component, complete with stem, in a non-functioning joint.

In 1938, Wiles (1958) implanted a stainless steel total hip replacement and in 1939 Haboush introduced a total hip replacement with a Cobalt Chromium alloy (CoCr) femoral component and an acrylic acetabular component. This procedure resulted in failure due to wear, primarily of the acrylic but also to a lesser extent of the CoCr component. Haboush (1953) continued experimenting and in 1951 developed a total hip replacement, with both components made from CoCr, which was cemented to bone using acrylic cement. The use of acrylic cement was later popularised by Sir John Charnley (1960). In 1946 Judet and Judet (1950) used acrylic femoral head replacements with limited success and 2 years later McBride (1961) developed this prosthesis further, using a threaded stem with a locking screw.

The quest for improved materials continued, particularly for replacements of the femoral head, with polyethylene and nylon also being tried without success. Failure due to excessive wear occurred in the convex femoral head and polymer components were deemed unsuitable for this configuration. McKee and Farrar (1966) produced a range of CoCr implants and realised the importance of firm fixation to bone. The Stanmore total hip used cobalt chrome for both components, with an acetabular bearing insert, designed for replacement after a period of implantation (Alsema *et al.* 1994). Poor fixation caused failure in this system and acrylic cement was subsequently used. Charnley (1961,1972) successfully employed this technique in 1960 with a Thompson prosthesis. Charnley's work into the lubrication of animal joints lead to his philosophy of providing a low friction bearing for total hip replacement. The use of polytetrafluoroethylene (PTFE) (Charnley, 1963) initially was unsuccessful due to wear

problems but a high density component fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE) proved to be more successful. Acrylic cement became used routinely to improve fixation and UHMWPE is still the principal material used for acetabular components.

The Ring (1968) prosthesis returned to cementless fixation using cobalt chrome components. Cementless fixation continues to be a trend in modern prostheses, with long term loosening and cement failure remaining a draw back to cemented fixation.

Aluminium oxide ceramic (Semlitsch *et al.* 1977; Heimke *et al.* 1979; Zweymuller, 1979; Riska and Holmstrom 1981) was introduced as an articulating surface claiming a lower coefficient of friction than both metal bearing on metal and metal on polyethylene combinations. Early clinical results were promising (Heimke and Griss 1981; Stock *et al.* 1980; Zweymuller, 1979) but more recently, loosening of the femoral stem has been reported (O'Leary *et al.* 1988; Trepte *et al.* 1994) as well as fracture of the femoral heads (Holmer and Nielsen 1993; Burckhardt and Berberat 1993).

Much of the development of total hip arthroplasty has been reactive in recent years with empirical designs being marketed to address the problem of wear of components, the question of cement or cementless fixation (Wroblewski, 1993) and finding a design of prosthesis that closely mimics physiological loading of the femur (Weinans *et al.* 1993; Verdonschot *et al.* 1994; Huiskes *et al.* 1992).

The choices of bearing materials have included CoCr alloys, titanium alloys and ceramics for the head combined with these materials or polyethylene for the cup, all chosen to combat

The Design of a Sealed Artificial Hip Replacement

wear. Each system has encountered difficulties including ascertaining optimal clearance and tolerance for metal on metal implants (Streicher *et al.* 1990), wear of UHMWPE and its implication as a cause of bone resorption (Howie *et al.* 1987; Howie *et al.* 1994) and fracture of ceramics (Holmer and Nielsen 1993).

Fixation of the components has also been a focus of research. For cemented replacements pressurisation of the cement and new tools have resulted in fewer failures due to cement fractures (Harris and Davies 1988; Davies *et al.* 1991; Davies and Harris 1993). For uncemented components porous stems (Henry *et al.* 1993; Engh *et al.* 1994) are being used and more recently hydroxyapatite coatings have been introduced as osteoconductive materials (Ducheyne *et al.* 1980; Soballe *et al.* 1990; Soballe *et al.* 1992; Furlong, 1993). It is suggested that bony ingrowth occurs into this coating giving excellent bone to prosthesis fixation. However no long term results are available at this stage. Currently there is some evidence to suggest that coatings can be abraded from the implant (Campbell *et al.* 1993; Collier *et al.* 1993).

1.23 Resurfacing hip arthroplasty

Smith-Petersen's work (Smith-Petersen, 1948; Smith-Petersen *et al.* 1947) in moulded interposition arthroplasty initiated the concept of preserving the femoral head and this principle led to the development of resurfacing arthroplasties. Rather than implanting a femoral component with a stem in the canal, the head of the femur is simply "resurfaced" with a suitable material. In 1968 Muller used cobalt chrome alloy for both components. Paltrieneri and Trentani used cement for fixation in 1971(Trentani and Vaccarino 1978), at the same time as Furuya (Furuya *et al.* 1978) in Japan. Both cemented and cementless versions

The Design of a Sealed Artificial Hip Replacement

were tried with some success(Tanaka, 1978; Bierbaum *et al.* 1982). Poor materials selection and designs also brought many failures, (Freeman *et al.* 1978) consequently by the 80s reports of high failure rates with cemented resurfacing arthroplasties had caused the procedure to go out of favour (Head, 1984; Howie *et al.* 1986;). After this period Professor Amstutz has been the most active contributor to the design and use of resurfacing arthroplasty (Amstutz *et al.* 1986; Amstutz, 1991). His group have tried metal backed sockets, hybrid fixation (ie. cementless acetabular and cemented femoral components), alumina femoral hemisurface and porous coated cobalt chrome femoral components (Amstutz *et al.* 1987; Hedley *et al.* 1994). The use of resurfacing hip arthroplasty is now very limited but a renewed interest is apparent, with the principle of conserving bonestock for future operations.

In recent years new designs and developments in hip arthroplasty have occurred largely in response to the inability to find materials whose wear behaviour can be controlled. This thesis aims to address the problem of wear in a novel manner.

1.3 Synopsis

In designing a new hip replacement system, a number of preliminary investigations have been made. A historical review of hip replacement has already been discussed. A knowledge of previous design successes and failures is imperative, prior to the design of a new implant. A central theme of this thesis is wear, the mechanisms and determinants of wear and also the biological response to wear particles. These points have all been researched as they are primary considerations in the choice of materials and the design specifications of this new implant.

The anatomy and biomechanics of the hip joint have also been investigated. A new design should be as anatomical as possible and this is one of the design goals. A consideration of the biomechanics is necessary to ensure that the replacement system is able to sustain the normal physiological loading conditions. Current materials in hip replacement systems and their biocompatability are examined. This information also feeds into the design specification. Following the completion of these preliminary investigations, design goals were formulated and a new replacement system designed. Further consideration is also given to the proposed assembly and surgical insertion of the device. A preferred embodiment of the design is then discussed. A provisional patent was filed for a sealed modular joint replacement and preliminary marketing of the product was undertaken with a major implant manufacturer.

In this thesis the design of a hip replacement system is examined at all levels. Investigations of previous designs, wear and its deleterious effects, relevant anatomy and biomechanics, current materials and biocompatability preceded the major design work.. The novel designs were then patented and further development and preliminary marketing were undertaken.

CHAPTER 2

WEAR

An investigation of wear and its effects has been undertaken. An understanding of these topics provides background information into the design of a new replacement system. Issues such as the size of wear particles produced during articulation of the joint, provide data to be used in the design specification.

Wear of a prosthesis occurs along all fixation interfaces and also at the articulating surface of the joint. With repetitive loading, damage occurs at the contacting surfaces of the two materials causing a loss of material. The mechanisms of wear include abrasive, adhesive, corrosive, fretting and fatigue wear.

2.1 Types of Wear

Abrasive wear occurs when two surfaces come into contact with each other under load and the asperities on each surface abrade each other causing the loss of material from either component.

Adhesive wear occurs in a similar manner, with large contact pressures. The materials fuse together rather than abrading, before the relative motion of the two components cause the bond to break. Material from each component is thus embedded in the matrix of the opposing

material and some material is liberated as debris. Adhesive wear can thus contribute to the amount of abrasive wear.

These two types of wear are proportional to the coefficient of friction, applied load and distance traversed by the surfaces (Weightmann, 1977).

Corrosive wear occurs when metal implants are left in-situ in the body for any period of time. The degree of corrosive wear is dependant on the materials used. The two main forms of corrosive wear are firstly, the release of metallic ions to the environment, known as ionisation and secondly the formation of metallic oxides known as oxidation.

Fretting wear occurs when there is vibration or relative micromotion of components. This type of wear has been commonly reported in the tapers of modular femoral components (Lieberman *et al.* 1994; Dujovne *et al.* 1993).

Fatigue wear occurs when a material is repeatedly loaded over a period of time. The degree of fatigue wear is determined primarily by the contact stresses applied and the material properties of the implant including its molecular weight, crystallinity and oxidation. This type of wear is commonly seen at impingement sites on acetabular cups (Wiadrowski *et al.* 1991).

Another form of wear is third body wear, where small particles such as metal particles, bone debris or bone cement come between the contacting surfaces (McKellop *et al.* 1980). The stresses are high in this situation and even the metal heads of prostheses can be scratched.

Figure 2.1.1 is a photograph of a severely worn Wagner acetabular cup component and Figure 2.1.2 is a photograph of a carbon-polyethylene cup component. Wear marks are clearly visible on the implant's articulating surface and where impingement has occurred on the rim. Both implants were retrieved at the time of revision surgery at the Department of Orthopaedics and Trauma at the Royal Adelaide Hospital.

Figure 2.1.1 (Top) A photograph of a severely worn acetabular cup component retrieved at revision surgery. The cup has been completely worn through.

Figure 2.1.2 (Below) A photograph of wear in a carbon-polyethylene cup component. Extensive abrasive wear is seen throughout the articulating surface. The peripheral wear was probably created during the removal of the device.

2.2 Determinants of Wear

The coefficient of friction is dependant on the contacting materials and the force with which they are brought together. The type of material used determines the frictional force or shear force under load. The coefficient of friction (μ) is defined as the ratio of the frictional force (F) to the force applied normal to the direction of motion (N).

$$\mu = F/N \tag{1}$$

In the normal human hip, wear is minimal even with approximately a million loading cycles a year and this can be attributed to the extremely low coefficients of friction ranging from $\mu = 0.008$ to $\mu = 0.02$ in hyaline cartilage (Unsworth *et al.* 1991, Jasty and Smith 1992).

In artificial joints typical coefficients of friction range from 0.05 for Charnley metal - polyethylene combinations to 0.13 for CoCr articulations of McKee Farrar implants (Amstutz, 1991). It is obvious that these values are significantly higher than those normally seen in the healthy natural hip joint.

Another commonly used term, especially in relation to hip joint simulator studies, is Frictional Torque (T). This is simply the product of the radius of the femoral head (r) and frictional force (F).

$$T = r \times F \tag{2}$$

The Design of a Sealed Artificial Hip Replacement

wear and demonstrated an increase in wear resistance of oxidation resistant polyethylene (McKellop *et al.* 1992). The material properties of each component is therefore an important determinant in the volume of wear produced.

2.3 Quantifying Wear

Wear has been characterised and quantified in the laboratory with a number of different tools. Such tests have some innate drawbacks, including the length of time over which they must be undertaken. This is because a large number of cycles are required to obtain any kind of predictive accuracy. Mimicking physiological performance and allowing for different regimes of wear including the presence of third body particles such as PMMA bone cement are both important aspects of wear testing.

The testing of materials in the laboratory is conducted at a number of levels (McKellop and Clarke 1983). Firstly materials are screened to ascertain their potential as bearing surfaces and typical tests at this stage include; pin on disc , annulus on disc , rotating disc on flat and rotating ring on conforming block. Once materials have undergone this process, a more complex study is undertaken using test rigs with actual prostheses in joint simulators. These simulators aim to replicate physiological loading conditions using appropriate gait cycles and typically use a water, saline or serum lubricant.

Most implant manufacturers will undertake hip joint simulation studies to analyse the probable wear rates of their implants. A minimum of one million cycles is usual as this is a typical number of cycles for one year of implantation of a prosthesis. There have been

numerous studies comparing different articulations of components (Semlitsch *et al.* 1977; Rose *et al.* 1978; Davidson, 1993; Saikko, 1992; McKellop *et al.* 1992; McKellop *et al.* 1992). In making a comparison between studies it is important to note the head size that is used since this is a determinant of surface area of contact and hence applied pressure. The type of lubricant is also important. Water, saline and serum are all commonly used but yield different results (McKellop and Clarke 1983). Serum from bovine blood samples produces wear patterns more congruous to those observed in retrievals (McKellop *et al.* 1978) compared with saline and water. A shortcoming of a number of studies is the omission in reporting the clearance of components, as this has a significant implication on the volumetric wear.

Laboratory wear testing has become increasingly sophisticated over the last two decades. With the evolution of prostheses the ability to screen materials for their wear performance, prior to usage, has increased accordingly. The ability to compare between different studies conducted in this period is limited due to the incongruity of test methods. Attempts are being made to standardise test methods, especially by the American Society for Testing and Materials. McKellop and his group are perhaps the most prodigious investigators in this field at present (McKellop *et al.* 1992) and comparisons have been made of a number of implants from different manufacturers using a multi station joint simulation system. A recent study, from this group, has shown that CoCr alloy femoral heads with closely defined dimensional tolerances produced wear rates comparable to the alumina and zirconia ceramics, when articulated against polyethylene. For all tests 32 mm head sizes were used. The authors speculated that the higher surface roughness of the ceramic implants over the CoCr alloy caused the increased wear rates. . When a bovine serum lubricant was used, the typical wear rates per million cycles were 20 mm^3 for CoCr heads to around 30 mm^3 for alumina and

zirconia femoral heads. The study also investigated the use of other lubricants and demonstrated different outcomes with each. However, when comparing the effect of different lubricants, a similar pattern was observed between groups. Typical wear rates ranged from around 20 mm^3 / million cycles for CoCr heads with a bovine serum lubricant, to as high as 100 mm^3 / million cycles for Alumina coupled with an albumin solution as a lubricant

The large body of work carried out by researchers on wear characteristics of implants in the laboratory, whilst vital in providing an indication of the expected wear rates of implants, must be tempered with data obtained from clinical observation. The wear rates reported from radiographic studies (Clarke *et al.* 1976; Beckenbaugh *et al.* 1978) and retrieved implants (Livermore *et al.* 1990; Wroblewski, 1985) tend to be higher than those predicted from laboratory testing. This can be attributed to a number of factors including the possible presence of third body particles, the application of extraneous loading situations not simulated in the laboratory and varied lubrication regimes. A recent paper by Kabo *et al.* compared radiographic and direct measurements of wear and found that x-ray measures slightly underestimated the wear measured directly. The wear rates they reported, however, were more similar to simulator predictions than previous clinical reports.

As new designs and materials enter the marketplace, it is imperative that both laboratory and clinical studies of wear are continued to catalogue prospective and newly employed implants.

2.4 Wear Debris and the Effects on Tissue

The wear of materials articulating against each other is inevitable. The action of the wear debris emanating from these joint surfaces and their possible role in joint loosening has long been postulated.

During the evolution of hip arthroplasty, early designers when choosing materials tended to concentrate on strength, corrosion resistance and in Charnley's case low friction. The example of Charnley's use of Poly-tetra-fluoro-ethylene as an articulating material underlined the need to take wear into consideration when selecting materials.

When reporting on failed implants, pathological changes in association with corrosion products were reported (Sinibaldi, 1976). The evidence of stained tissue or wear particles around failed prostheses was seen as a consequence of loosening or a repercussion of poor material selection or poor implant design. Aseptic loosening was then largely attributed to mechanical loosening (Amstutz *et al.* 1976; Pellicci *et al.* 1979; Gruen *et al.* 1979) and long term problems due to wear particles were not envisaged for implants that were stable in the short term. Reports of the presence of wear particles around failed implants however continued to increase.

The first histopathological study to report that wear particles were stored in macrophages was by Willert and Semlitsch (1977) in 1976, reporting on failed CoCr implants. These investigators proposed that an equilibrium existed in stable implants where the production of particles is matched by their removal via the lymphatic system and macrophages. Excessive wear may cause bone resorption, due to an imbalance in this equilibrium and an overload of the macrophages which had already taken up wear particles, causing tissues at the fixation

interface to take up particles. Prosthesis loosening would be the likely outcome. Vernon-Roberts and Freeman (1994) related the large number of cement and metal particles surrounding the fixation interface of prosthesis to be associated with tissue necrosis in these regions.

Loosening of implants was often attributed to failure of the bone cement (Andersson *et al.* 1972), with early authors also bringing into question the carcinogenic (Heath *et al.* 1971; Laskin *et al.* 1954), thermal (Jefferiss *et al.* 1975) and toxic (Swensson *et al.* 1956) potential of the product. Autopsy retrieval of Charnley cemented implants revealed relatively little foreign body response to cement (Charnley, 1970), but Charnley himself noted and expressed concern relating to the presence of macrophages at the interface of implants (Charnley, 1979). At this stage no strong links between osteolysis and the effect of macrophages had been made and cement was perceived as the Achilles heel of arthroplasty (Jones and Hungerford 1987). Efforts were devoted to improving cementing technique (Davies *et al.* 1991; Harris and Davies 1988; Davies and Harris 1993) and a shift towards cementless fixation emerged. The problem of implant loosening did not resolve itself, even with the use of cementless implants, retrievals of which also showed osteolysis associated with wear particles (Chiba *et al.* 1992; Chiba *et al.* 1994; Urban *et al.* 1994; Fahmy *et al.* 1993).

Having established the presence of macrophages and the concomitant presence of wear particles, the likelihood that they played some part in the osteolytic process was more widely accepted by researchers. Eftekhar (1985) reported localised areas of macrophages in regions containing wear particles to have an increased cellular activity over adjacent regions of tissue also containing macrophages.

The finding of wear particles along solidly fixed interfaces of bone and prosthesis lead to the theory that not only particles, but macrophages containing particles could migrate via body fluids. Arthrographic studies confirmed that fluid penetrated the bone - prosthesis interface (Murray and Rodrigo 1975; Howie *et al.* 1990, Schmalzried *et al.* 1992). Figure 2.4.1 illustrates the concept of wear particles migrating along the fixation interface of the prosthesis. It should be noted that the production of wear particles is increased when the implant becomes loose. There is potential for significant damage in the period between loosening and eventual revision surgery, as patients may not have any symptoms during the early stages of loosening.

Figure 2.4.1   Migration of particles from the articulating surfaces to the fixation

interfaces of both the femoral and acetabular components.
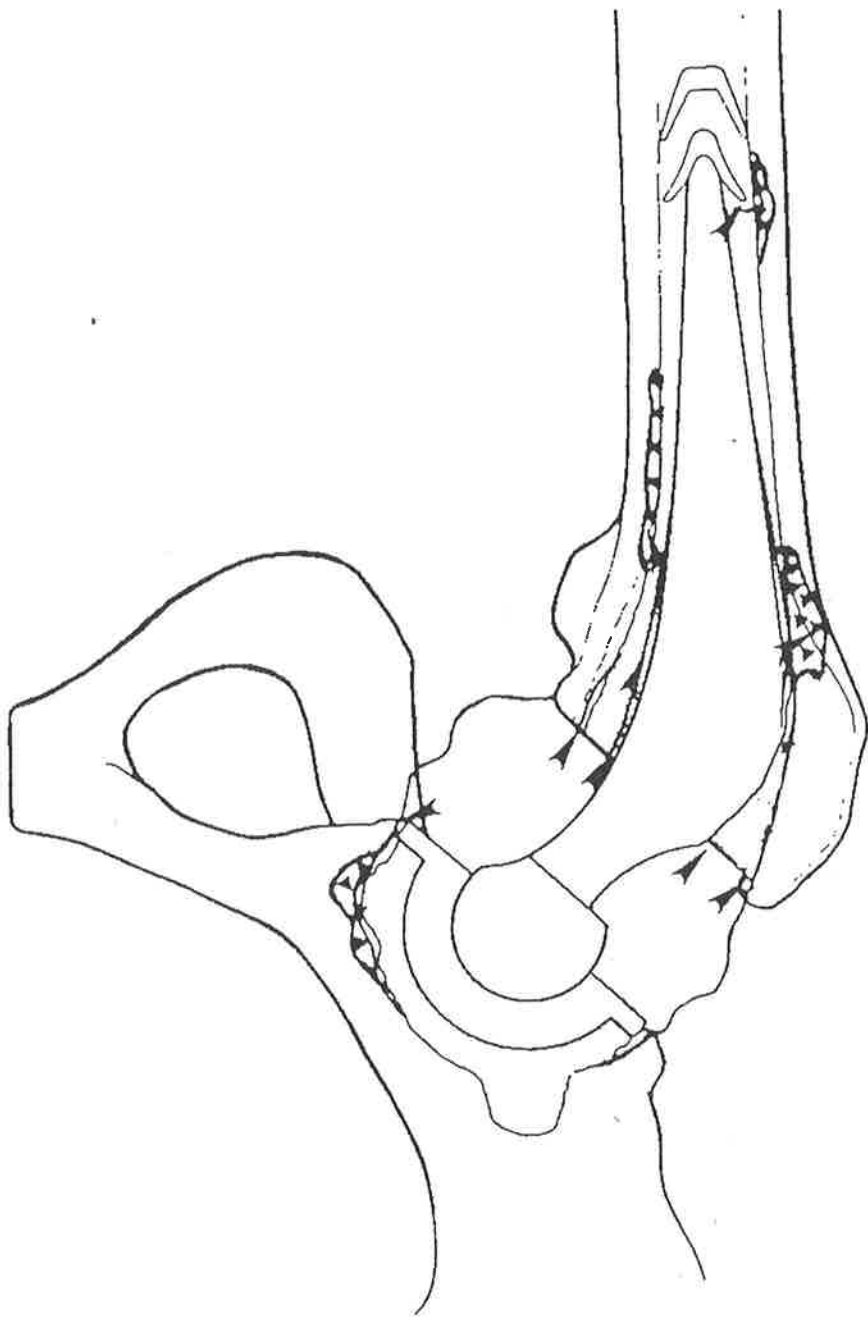
The concept that wear particles may stimulate macrophages to produce inflammatory mediators, which in turn stimulates bone resorption (Howie *et al.* 1993), followed work by Goldring (1983) and also Horowitz (1991). These authors both reported elevated levels of Prostaglandin E2 in the synovial fluid and tissue surrounding retrieved aseptically loose prostheses.

The main mediators thought to be involved in bone resorption are Interleukin-1 (Gowen *et al.* 1983), Prostaglandin E2 and Tumour Necrosis Factor (Chambers and Horton 1984; Whicher, 1985; Murphy, 1985; Durum, 1985).

Figure 2.4.2 shows a possible mechanism for bone resorption, proposing that inflammatory mediators produced by macrophages following the phagocytosis of particles stimulate osteoclasts or an interaction between osteoclasts and osteoblasts to induce bone resorption.

Other authors suggest that macrophages can induce bone resorption directly by releasing oxide radicals and hydrogen peroxide (Mundy *et al.* 1977; Kahn *et al.* 1978; Teitelbaum *et al.* 1979; Quinn *et al.* 1992; Athanasou *et al.* 1992; Campbell *et al.* 1990)

Studies in rats of intra-articular injection of particles (Howie and Vernon-Roberts 1988), aimed at looking at the long term effects of wear particles of CoCr. They demonstrated persistent necrotic areas, with the number of particles in the subsynovium remaining relatively unchanged. The implication is that the wear particles produced will tend to accumulate over the lifespan of a joint replacement.

Further studies in rats compared the response to injection of cobalt chrome versus aluminium oxide particles of similar size (Howie and Vernon-Roberts 1988). After 1 and 4 weeks and again at 3 months a higher macrophage to particle ratio was seen in cobalt chrome, as opposed to the aluminium oxide particles. The type of material has therefore an important bearing on the type and severity of tissue response.

The size of particle is also a critical determinant in the type of response. Metal particles typically range in size from 0.3 microns to 2 microns, whilst for polyethylene the size range is significantly greater, 2 to 14 microns (Lee *et al.* 1992). Large particles are engulfed by multi nucleate giant cells (MNGC) (or a group of 2 -50 macrophages), whilst smaller particles, less than 5 microns in size are phagocytosed by macrophages resulting in the release of cytokines.

Loosening can be detected radiographically by radiolucent lines surrounding the implant. A loose prosthesis is shown in Figure 2.4.3 and radiolucent lines are clearly visible around the femoral stem and to a lesser extent around the acetabular component. Figure 2.4.4 is a low power microscope view of tissue surrounding a loose prosthesis. Macrophages are clearly abundant in this region. The use of polarised light clearly discloses the presence of UHMWPE particles, which are birefringent (Figure 2.4.5).

Figure 2.4.3 An xray of a loose hip prosthesis. Lucent lines are clearly visible around both the stem and cup of the replacement system.

Figure 2.4.4   (Top) Tissue adjacent a loose prosthesis showing abundant macrophages.

Figure 2.4.5   (Below) A polarised light image of the same tissue clearly exposes the presence of UHMWPE wear particles.
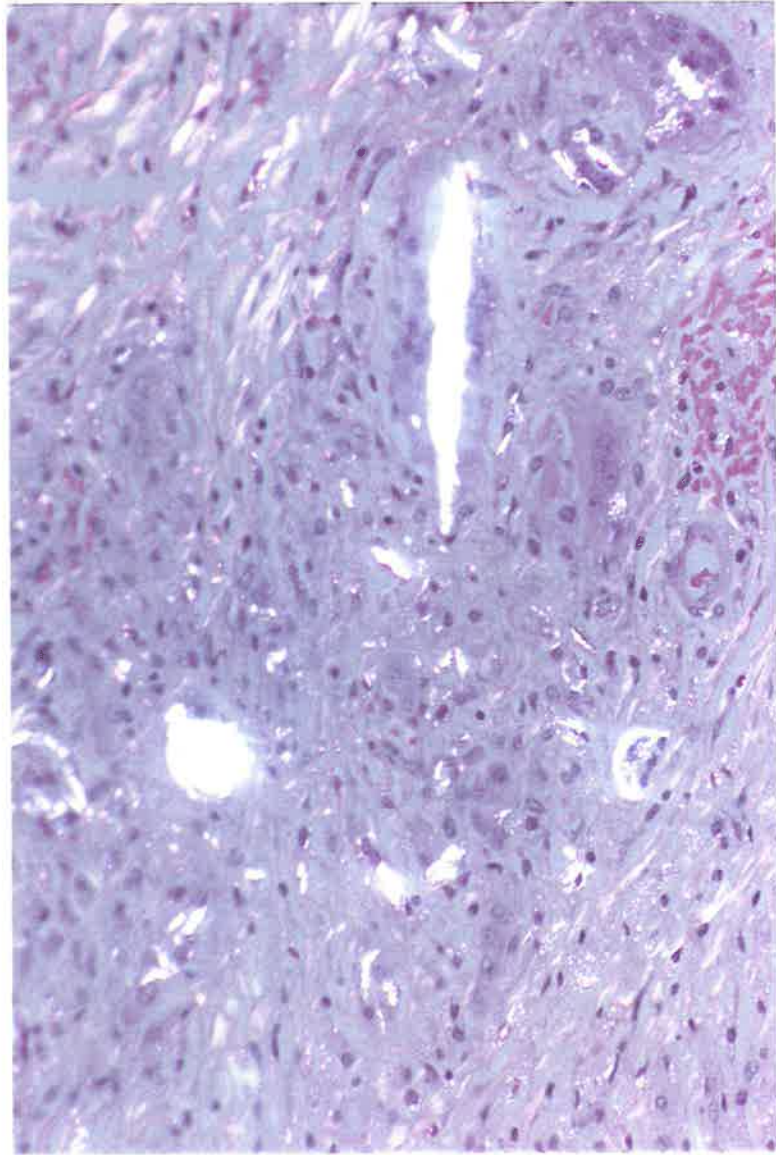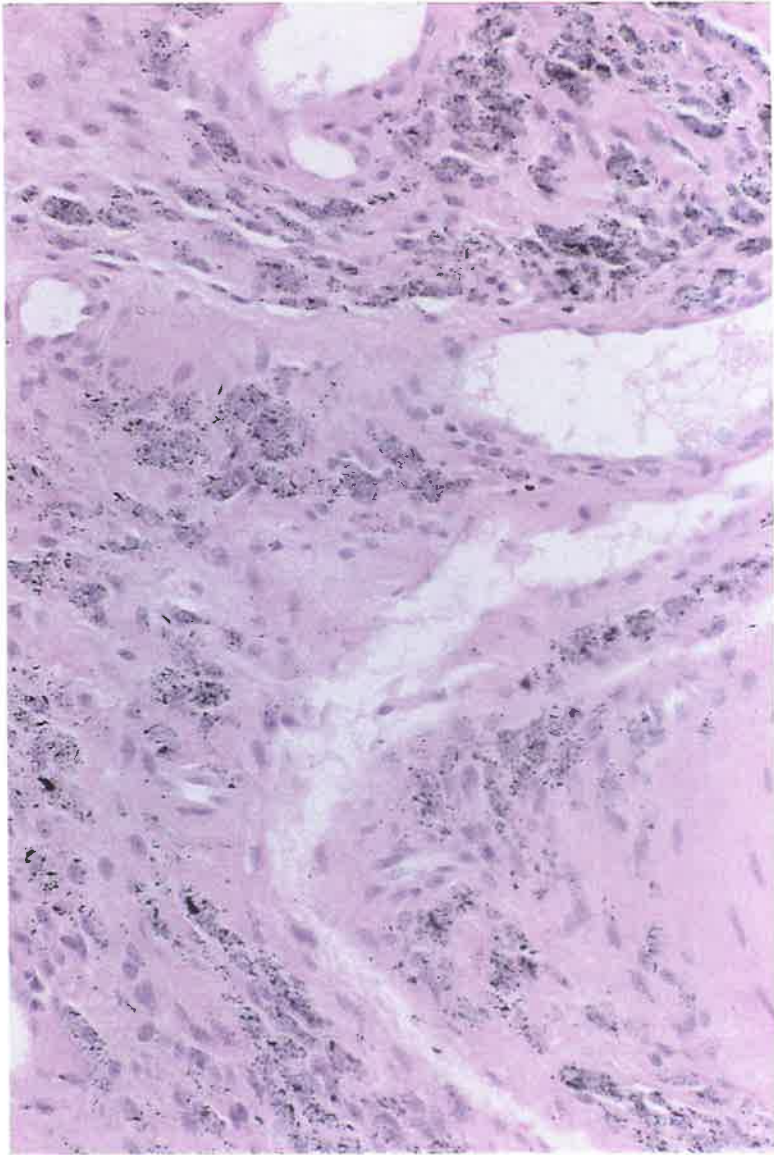
Failure of total hip replacements is predominantly due to aseptic loosening , in the long term. Wear debris produced during the operating life of the artificial joint has been implicated as a significant contributor to bone loss around implants. The mechanism by which bone resorption occurs has been investigated by many authors. Both the direct resorption of bone by macrophages and the release of mediators of resorption, by macrophages, following phagocytosis of particles have been reported. The type, size and number of particles are important determinants in the ensuing type and severity of tissue response.

Wear particle induced osteolysis is a major problem in joint replacement as it reduces the lifespan of replacement joints and makes revision surgery more difficult due to bone loss. It is therefore highly desirable to reduce or eliminate the lifespan of hip replacement systems.

CHAPTER 3

ANATOMY AND BIOMECHANICS OF THE HIP

When contemplating the design of an artificial hip prosthesis it is imperative to have a knowledge of the anatomy and mechanics of the hip joint. This new design of prosthesis aims to emulate the anatomy of the hip joint closely. Current and previous designs emphasise the need to load the bones physiologically and considering the biomechanics of the joint is essential to this. This chapter concentrates on the relevant anatomy (Hoppenfeld *et al.* 1984; Gray, 1967) and biomechanical information of the hip joint.

The hip joint comprises the articulation of the head of the femur with the acetabulum. Both the anatomy and range of motion of the hip will be described. The role of different muscle groups in providing flexion, extension, abduction, adduction, internal and external rotation of the hip are also stated. The ligamentous attachments around the joint are described and a brief description of the biomechanics of the hip joint is provided.

3.1 Bony Anatomy

The important components of the pelvis in relation to hip replacement are the acetabulum and surrounding bone. Above the acetabulum, the main bony landmarks are the anterior inferior and anterior superior iliac spines. Medially lies the superior and inferior pubic rami and below it is the ischium (Figure 3.1.1).

The Design of a Sealed Artificial Hip Replacement

Figure 3.1.1   Bony anatomy of the pelvis and proximal femur. (1) Acetabulum, (2) Anterior Superior Iliac Spine, (3) Anterior Inferior Iliac Spine, (4) Superior Pubic Rami, (5) Inferior Pubic Rami, (6) Ischium, (7) Greater Trochanter, (8) Lesser Trochanter, (9) Femoral Neck, (10) Femoral Head.
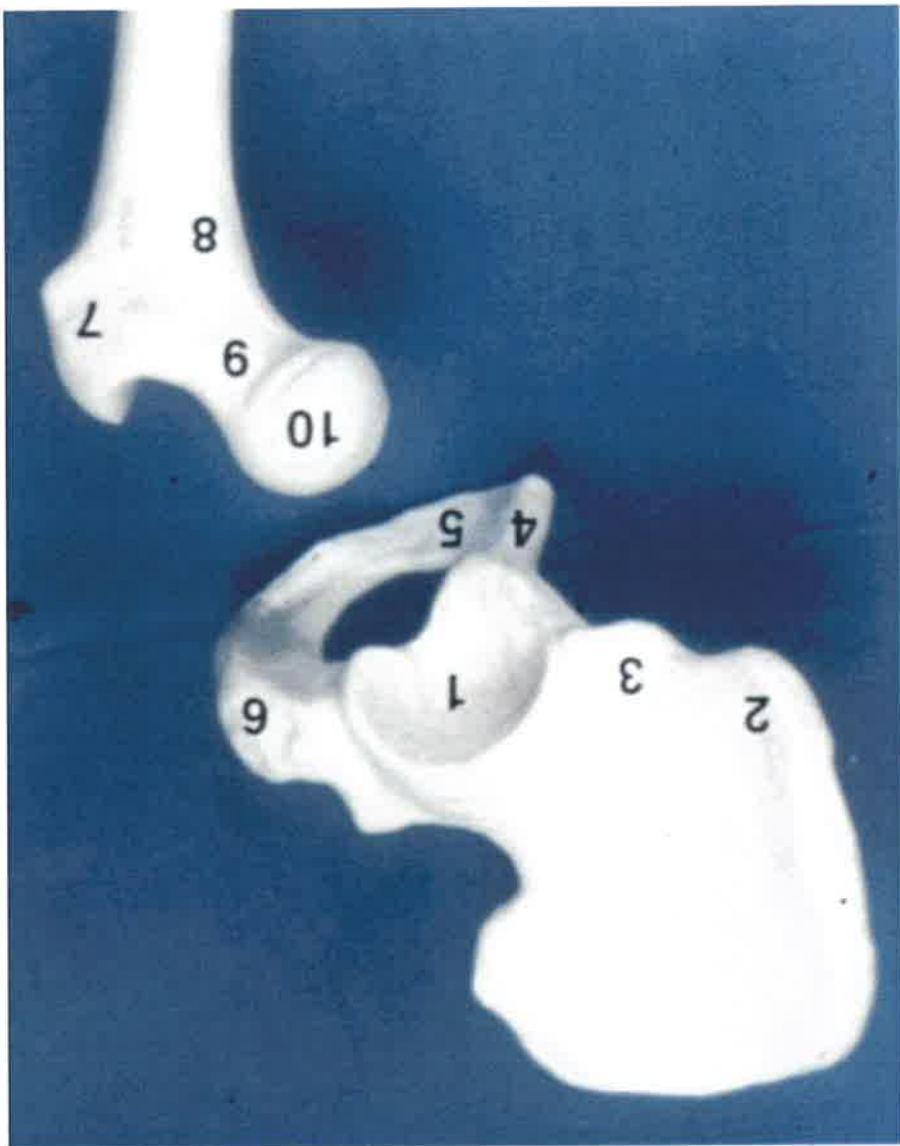
The acetabulum is essentially hemispherical in nature but often surgery must be undertaken in extremely dysplastic, or irregularly shaped, hips (Silber and Engh 1990; Schuller *et al.* 1993). The articular cartilage of the acetabulum forms an incomplete ring and is thickest superiorly, where the highest loads are transmitted. The acetabular labrum surrounds the periphery of the acetabulum. The ligaments of the acetabulum are described in Chapter 3.3.

The availability of bone stock for acetabular reaming and screw placement is an important anatomical consideration and has important implications to design specifications of acetabular components. The posterior superior and posterior inferior regions of the acetabulum contain the best available bone stock for screw fixation (Wasielewski *et al.* 1990). The anterior superior and anterior inferior regions should be avoided as implantation in these zones may endanger the external iliac artery and vein as well as the obturator nerve, artery and vein.

In terms of the anatomy of the proximal femur, the main bony landmarks are the greater and lesser trochanters, neck and head of femur (Figure 3.1.1).

3.2 Muscles Acting at the Hip Joint and their Innervation

Each of the main muscle groups involved in providing motion at the hip joint are discussed and their innervation documented. Many of these mechanisms act in combination during normal activities.

3.2.1 Flexion and extension

The main flexor of the hip joint is the Iliopsoas muscle with most other muscles attaching at the front of the thigh contributing to flexion also. These include Rectus femoris, Pectineus and Sartorius. The adductors also aid in this movement, particularly in the early stages of flexion. Table 3.2.1.1 lists the flexors of the hip joint and their innervation.

The gluteus maximus and the hamstring part of the adductor magnus are the main extensors of the hip and are equally effective regardless of knee position. Hyperextension of the hip is prevented by the action of the iliofemoral ligament as well as through some muscle action. Table 3.2.1.2 lists the extensors of the hip joint and their innervation.

Muscle	Nerve
Chief Flexors	
Iliopsoas	Nn. to Iliopsoas
Pectineus	Femoral / Obturator
Tensor fasciae latae	Superior Gluteal
Adductor Brevis	Obturator
Accessory Flexors	
Sartorius	Femoral
Adductor longus	Obturator
Adductor Magnus	Obturator
Gracilis	Obturator

Table 3.2.1.1 The flexors of the hip joint and their innervation.

The Design of a Sealed Artificial Hip Replacement

Muscle	Nerve
Chief Extensors	
Gluteus maximus	Inferior Gluteal
Adductor Magnus	Tibial
Accessory Extensors	
Semimembranous	Tibial
Semitendinosus	Tibial
Biceps Femoris	Tibial
Gluteus Medius	Superior Gluteal
Gluteus minimus	Superior Gluteal
Piriformis	N. to piriformis

Table 3.2.1.2 Extensors at the hip joint and their innervation

3.2.2 Adduction and abduction

The chief adductors of the hip are Adductor Brevis, Longus and Magnus and these muscles are assisted by Gracilis and Pectineus. Contact with the opposite limb limits this range of motion, however flexing the thigh allows a larger range. The motion is limited by the iliofemoral ligament and the tension of the abductors at the extremes of the range of motion. Table 3.2.2.1 lists the adductors of the hip joint and their innervation.

The gluteal muscles are the main group used during abduction but are assisted by Tensor Fascia Latae and Sartorius. The tension of the adductors and pubofemoral ligament limits the motion but it is essentially unimpeded. . Table 3.2.2.2 lists the abductors of the hip joint and their innervation.

Muscle	Nerve
Chief Adductors	
Adductor brevis	Obturator
Adductor longus	Obturator
Adductor Magnus	Obturator and Tibial
Gracilis	Obturator
Gluteus Maximus	Inferior Gluteal
Accessory Adductors	
Pectineus	Femoral or Obturator
Obturator Externus	Obturator
"Hamstrings"	Tibial

Table 3.2.2.1 Adductors at the hip joint and their innervation

Muscle	Nerve
Chief Abductors	
Gluteus Medius	Superior Gluteal
Gluteus Minimus	Superior Gluteal
Tensor fasciae latae	Superior Gluteal
Accessory Abductors	
Piriformis	N. to Piriformis
Sartorius	Femoral

Table 3.2.2.2 The abductors of the hip joint and their innervation.

3.2.3 Rotator muscles at the hip joint

The main internal rotators of the hip joint are tensor fascia latae and Gluteus minimus. The movement is strongly resisted by the external rotators and the ischiofemoral ligament. The Obturators, Gemelli and Quadratis Femoris are the main external rotators of the hip joint. Piriformis and Gluteus Medius are the main supporting muscles. The movement is much more powerful than internal rotation and is only resisted by the medial iliofemoral ligament and the tension of the internal rotators. Table 3.2.4.2 lists the main internal and external rotators of the hip joint.

A knowledge of the anatomy is particularly important in choosing the surgical approach (Amstutz *et al.* 1976; Albrektsson *et al.* 1981) as soft tissue management contributes to the outcome of the joint replacement.

Muscle	Nerve
Chief Internal Rotators	
Gluteus minimus	Superior gluteal
Tensor fasciae latae	Superior gluteal
Accessory Internal Rotators	
Adductor brevis	Obturator
Adductor longus	Obturator
Adductor Magnus	Obturator and Tibial
Pectineus	Femoral or Obturator
Semitendinosus	Tibial
Chief External Rotators	
Gluteus maximus	Inferior gluteal
Piriformis	To piriformis
Obturatur externus	Obturator
Obturator internus	N. to obturator internus
Superior gemellus	N. to superior gemellus
Inferior gemellus	N. to inferior gemellus
Quadratus femoris	N. to quadratus femoris
Accessory External Rotators	
Gluteus medius	Superior gluteal
Sartorius	Femoral
Iliopsoas	Nn. to iliopsoas

Table 3.2.4.2 Internal and external rotator muscles at the hip joint and their innervation.

The Design of a Sealed Artificial Hip Replacement

3.3 Ligaments at the Hip Joint

There are three major ligaments at the hip joint. Each are described according to their attachments, iliofemoral, ischiofemoral and pubofemoral. Other ligaments include the ligament of the head of the femur and the transverse ligament.

The iliofemoral ligament attaches at the anterior inferior iliac spine and to the body of the ilium between this spine and the acetabulum. Its base attaches along the intertrochanteric line making it somewhat triangular in shape. It strongly resists hyperextension of the hip joint.

The ischiofemoral ligament is the thinnest of the three ligaments and as its name suggests it arises from the ischium, posterior to the acetabulum and below it. The fibres attach on the neck of the femur at the junction with the greater trochanter.

The pubofemoral ligament arises from the pubis, close to the acetabulum and attaches to the lower surface of the femoral neck, blending with the iliofemoral ligament. It is predominantly stressed during abduction of the thigh, assisting the adductor muscles in constraining excessive abduction.

These three ligaments in combination comprise the capsule of the hip joint.

3.4 Range of Motion

The range of motion of the hip joint is age and sex dependant. Table 3.4.1 (Boone and Azen 1979) shows the average range of motion for males younger than 19, older than 19 and an average of both.

Position	Average (Age ≤ 19)	Average (Age >19)	Average motion (°)
Beginning position flexion	3.5 (4.3)	0.7 (2.1)	2.1 (3.6)
Flexion	123.4 (5.6)	121.3 (6.4)	122.3 (6.1)
Extension	7.4 (7.3)	12.1 (5.3)	9.8 (6.8)
Abduction	51.7 (8.8)	40.5 (6.0)	45.7 (9.3)
Adduction	28.3 (4.1)	25.5 (3.6)	26.9 (4.1)
Inward rotation	50.3 (6.1)	44.4 (4.3)	47.3 (6.0)
Outward rotation	50.5 (6.1)	44.2 (4.8)	47.2 (6.3)

Table 3.4.1 - Typical range of motion in normal male subjects. Mean and (Standard Deviation) shown.

It is desirable that an artificial hip joint can allow the range of motion that a natural hip joint exhibits. Enclosed acetabular components, designed to minimise dislocation, significantly reduce the possible range of motion due to impingement of components. Impingement is undesirable as it is a contributory factor to implant loosening and fatigue wear at the periphery of acetabular cups (Howie *et al.* 1994).

3.5 Biomechanics of the Hip

The calculation of forces in the hip joint has been done both mathematically and directly using instrumented prostheses (Hodge *et al.* 1989). Rydell (1966) was the first to use an instrumented prosthesis to measure hip force, using an Austin-Moore hemiarthroplasty with a subcutaneous cable to transmit data. He reported forces ranging between 1.6 and 3.3 times bodyweight for level walking. More recent authors have used telemeterized devices (Davy *et al.* 1988; Kotzar *et al.* 1991). Bergmann *et al.* (1993) reported on two patients with telemetric prostheses inserted. Forces of around 2.8 times bodyweight were recorded for level walking at a rate of 1 kilometre per hour. For more strenuous activities, much higher loads were recorded. Walking at around 3 kilometres per hour produced around 4.1 times bodyweight and jogging and very fast walking raised this figure further to 5.5 times bodyweight. Interestingly, stumbling caused 7.2 and 8.7 times bodyweight forces to be registered for each patient respectively. Torsional loads are also prevalent in the hip joint and moments around the femoral stem were 40.3 N.m and 24 N.m in the two patients measured. Loads in the hip joint can be many times bodyweight, even during light exercise. Strenuous activities or shock loads, such as experienced in stumbling, can increase the reaction force even further.

Although mathematical models tend to give a lower estimation of the contact forces experienced in the hip (Brand *et al.* 1993), in comparison with direct measurements from instrumented implants, they provide another source of valuable information in the estimation of hip joint force. The discrepancy between data may be due to the many assumptions that must be made in mathematical modelling.

An understanding of the biomechanics of the hip joint is essential in designing a replacement joint. A knowledge of the reaction forces during all loading conditions allows the safe design of the articulating surface. The designs currently available on the market have incorporated these design requirements. For this reason the design of the bearing components has not been undertaken as part of this thesis.

CHAPTER 4

MATERIALS AND BIOCOMPATABILITY

When realisation that an essential requirement in prosthesis design was to limit wear and minimise loosening, significant efforts were made to design implants with these goals in mind. The main thrust of this work is now to do with the selection of materials, especially for the articulating surfaces. This chapter examines the most common modern materials and also looks at the biocompatability of implanted materials. By analysing the relative success and failure of previous and current materials, a valued judgement can be made on the type of materials to incorporate in a new design of replacement system.

4.1 Biocompatability

The biocompatability of a material relates to how it interacts with the biological environment in which it is placed. Not only is the host response important, but also the response of the material to the host. When choosing materials for implantation, consideration should be given to each of these aspects. Each material used has different chemical, surface, material and mechanical properties and must be assessed accordingly. Material properties such as corrosion resistance must be closely investigated. Mechanical properties such as implant stiffness affects the manner in which the bone and fixation interfaces are loaded. Wear particles of titanium alloys, cobalt chrome alloys and polyethylene all produce a host response. Surface properties of materials influence wear and biological fixation and must also

The Design of a Sealed Artificial Hip Replacement

be assessed for biocompatability. The ASTM has established guidelines for biocompatability of materials and these should be consulted. In particular standards F361, F469, F748 and F981 address biocompatability.

The materials used in artificial joints are described in this chapter and their relative biocompatability discussed appropriately.

4.2 Choice of Materials

The history of total hip replacement design is plagued with examples of poor materials selection. It is well recognised that the choice of appropriate materials for the bearing surface and fixation interfaces is critical to the survival of hip replacement systems and until now has been the principle mechanism through which the problems of wear debris have been limited. Each of the most commonly used modern materials will be examined in this chapter.

4.2.1 Ultra High Molecular Weight Polyethylene

The combination of metal and UHMWPE as the bearing surface for total hip replacement systems still remains the benchmark to which other systems must be compared.

Despite polyethylene wear debris being implicated in bone resorption (Howie *et al.* 1987; Howie *et al.* 1990), excellent long term results have been gained with implants using this bearing combination (Kavanagh *et al.* 1989). Recent designs however have continued to improve on UHMWPE. The method of production and manufacture (Trainor and Haward

1994) is said to play an important role in the determination of the wear characteristics of polyethylene. The normal production methods are to machine either ram extruded or compression moulded inserts. Compression moulded products are said to have better crystallinity and integrity (Sun *et al.* 1994) and therefore improved wear characteristics.

Other recent concerns include the effects of gamma irradiation carried out for sterilisation purposes and the effects of oxidation from this and other processes. The use of gamma irradiation, in polyethylene tibial inserts, has been shown to break down the long polymer chains, reducing crystallinity and molecular weight; causing less resistance to wear (Saum, 1994). Oxidation continues to occur after packaging and implantation in the body and the material properties are reduced following this process. An increase in wear resistance is seen in oxidation resistant polyethylene (Saum, 1994).

4.2.2 Metals

Alloys of CoCr are the mainstay of metals used in hip replacement. They have excellent hardness, compression strength and corrosion resistance. Particles of these alloys, like polyethylene, have been linked with osteolysis (Howie *et al.* 1992) but, like polyethylene, some excellent long term results have been achieved in implants using this bearing material. Both components of the McKee Farrar replacement system were made from a cobalt chrome molybdenum alloy and August *et al.* report an 84% survivorship at 14 years (August *et al.* 1986) in a review of 230 arthroplasties. Concern was also raised about toxicity of both chrome and cobalt which have been associated with organ disease (Dobbs and Minski 1980). Due to the mechanical properties of CoCr alloys they are very difficult to machine and forge.

In addition these alloys have a high modulus of elasticity and it is generally thought that close matching of the elastic modulus of an implant to that of bone, may improve the mechanism of load transfer in replacement systems.

For the reasons of easier machinability and lower modulus, Titanium-Aluminium-Vanadium alloys, typically TiALV or Ti_6Al_4V, became an attractive proposition for use in total hip replacement systems. In addition these alloys also have excellent corrosion resistance due to a a passivation layer predominantly of Titanium Dioxide. Titanium alloy wear particles have been implicated in bone resorption (Witt and Swan 1991; Howie *et al.* 1992; Rae, 1986) and the biological activity of Vanadium and Aluminium have caused concern (Faulfner-Hudson, 1964). As Titanium alloys have a lower hardness than cobalt chrome based alloys the volume of wear exhibited by the bearing surfaces is higher than those for CoCr (Zimmer, 1994; Agins *et al.* 1988). Adverse tissue response and relatively large volumetric wear has brought the introduction of niobium alloys of titanium which are claimed to have improved wear properties and no toxic effects on tissue . Efforts to harden the surface of titanium femoral heads have been made using nitriding and ion implantation (Rostlund *et al.* 1989). The use of these hard coatings certainly improves the immediate wear characteristics of implants, however thinning of the layers of coating has brought the concern of accelerated wear in the long term due to hard third body particles, of the coating, wearing against the soft substrate of titanium.

In comparing the biological activity of CoCr and titanium alloy particles, Haynes *et al.* (1993) reported that although, at high particle concentrations, toxicity of CoCr particles to macrophages was found, titanium alloy particles induced the release of mediators to bone resorption through a much broader range of concentrations (Haynes *et al.* 1993). They imply

that although titanium particles are only minimally toxic the stimulation of mediators of bone resorption is of major concern to the long term stability of implants made from these alloys.

Regarding the manufacture of metal articulations, the components may either be forged or cast. Despite the technical difficulties in forging CoCr components, the resulting material properties are extremely desirable. Strength and hardness values are superior in forged components than cast and hence wear characteristics are also superior (Streicher *et al.* 1990). Hot forging is a further advantage (Semlitsch *et al.* 1991), creating a more uniform grain structure. Components are often annealed, or heat treated, following casting to relieve residual stresses and improve mechanical properties.

Both CoCr and titanium alloys have had limited success as bearing surfaces for hip replacement systems. Although some excellent long term results have been achieved using either of the two materials, significant problems are still associated with their wear products. Particles of both titanium and cobalt chrome alloys have been implicated in bone resorption. Attempts to produce harder wearing alloys are in progress but for the time being, wear seems to be an unremitting factor especially in articulations of metals and polyethylene.

4.2.3 Ceramics

Ceramic - ceramic hip replacements were introduced in 1970 by Boutin (1972) with the dual rationale of low friction and low wear in comparison to metal - polymer combinations. Both ceramic - ceramic (Griss *et al.* 1975; Sedel *et al.* 1990) and ceramic - UHMWPE devices have been manufactured in increasing number since this time. The problem of wear particle

osteolysis is less widely reported in ceramic implants and in the available reports contention remains as to the biodegradative nature of Alumina. Whilst Griss *et al.* (1974) concluded macrophage response to intra articular injection of alumina was minimal, Uchida proposed the exact opposite (Uchida, 1985). Both studies were carried out by injection of particles into rat knees. A further study of intra articular injection of Alumina into rat knees by Howie *et al.* (1988) reported that in comparison to CoCrMo alloy particles, significantly lower levels of macrophages were seen after 1 week however a similar macrophage response to alumina and cobalt chrome was seen after periods of 4 weeks and 3 months. Wear is still a problem with this bearing surface and additionally catastrophic wear has been reported in some implants (Plitz and Hoss 1982). Alumina components have also been reported to break (Griss and Heimke1981; Holmer and Nielsen 1993).

There are relatively few long term survivorship studies on ceramic prostheses however Sedel *et al.* have shown a 98% survivorship of implants at 10 years following the implantation of a "Ceraver Osteal" implant in 75 patients. Only 71 patients were reviewed. Their report did indicate, however, that they had a number of impending failures and these they attributed to poor surgical technique to do with poor coverage and fixation of the acetabular component. In their discussion they propose that regardless of reports of wear and fracture of Alumina, properly toleranced and quality controlled implants, should produce excellent results, with minimal wear if they are inserted correctly.

4.2.4 Polyurethane - Soft Layers

Perhaps the latest innovation in bearing surface technology is that of "soft layer" prostheses (Unsworth *et al.* 1990; Jin *et al.* 1991; Dowson *et al.* 1991; O'Carroll *et al.* 1990). An improvement in the wear rates of hip replacement systems is being sought through the use of polyurethane materials (Blamey *et al.* 1991) which mimic the lubrication mechanism evident in the normal acetabulum, that of fluid film lubrication. These bearings comprise a thin layer of material with a low elastic modulus, which can deform to help produce a fluid film between articulating surfaces in the presence of a lubricant (synovial fluid).

Blamey *et al.* (1991) measured a friction factor in the range of 0.003 to 0.009 compared to a polyethylene insert used as a control of 0.017 to 0.042 (Auger *et al.* 1993). The friction factor for the compliant layer bearing is consistent with fluid film lubrication. If these conditions can be generated and maintained in vivo, extremely low wear rates can be expected. It can be surmised that if the joint were to run without lubrication, extremely high coefficients of friction and wear rates may result. Should the joint seize up, even intermittently, increased load transfer to the fixation interfaces may produce premature loosening. As yet only simulator studies have been reported and in vivo animal trials are awaited to enable a better understanding of the true potential of this system.

4.3 Conclusions

Currently the problem of wear particles is largely being addressed with efforts to improve the wear resistance of bearing surfaces. The preceding discussion underlines the fact that, to date,

no bearing surface has been able to limit wear enough to preclude osteolysis and consequently implant loosening in the long term.

The evidence from this review is that the current benchmark for articulating surfaces is CoCr - UHMWPE. Ceramic - UHMWPE implants with carefully designed and toleranced components and meticulous surgical insertion show potential, although longer term results are needed to ascertain definitively whether they offer an advantage over forged CoCrMo - UHMWPE combinations. Metal - metal articulations are also returning to the marketplace. No evidence is available to suggest an improved performance over metal - UHMWPE combinations. Instead speculative design changes and data from wear simulator studies, have provided the basis for their re-introduction.

At present wear in the articulating surfaces of implants is inevitable and hence this project explores the novel concept of sealing the articulating bearing of the joint replacement in order to eliminate the effect of wear particles. The design of this new implant is discussed in Chapter 5.

the surgical insertion method and there are many drawbacks to this particular design. During the course of this Master's degree similar designs to these were developed independently, and further conceptualisation and development has produced additional novel concepts. A sealed modular hip replacement system has been designed which aims to fulfil further design criteria including ease and safety of surgical insertion. The designs aim to provide a practical prosthesis for use in artificial joint replacement. A provisional patent has been filed on these designs following consultation with A.P.T. Patent Attorney's and Luminis Pty. Ltd. who established that the claim remained outside the existing patents. Luminis Pty. Ltd. is the University of Adelaide's commercialisation company. All commercial developments arising from the University are managed through this company. The patent is discussed in detail in Chapter 7 and this chapter concentrates on all designs developed during the Master's program.

5.1 Design Goals

The main design goal was to produce a device that eliminates the problem of wear particles. The device should be safe and reliable for the entire period of implantation. For safety, all materials must be biocompatible. They must be designed and produced according to the appropriate biocompatability standards. No added risk to the patient should be incurred through the implementation of this device rather than conventional systems. The device must be able to stay in service for a period of 25-30 years as, ideally, implants will survive for an increased length of time without the complication of loosening associated with wear particles. This design specification may be difficult to achieve, however, careful materials selection is the key to its success.

The new implant must be able to operate in the physical environment of the hip joint. The device must withstand the normal loading conditions and permit a full range of motion.

The system must be easy to insert surgically. Cumbersome or prolonged surgical insertion is undesirable for a number of reasons. Surgeons are unlikely to use a device which is significantly more difficult to insert than other systems that are also available. Increased time in operation amounts to increased costs and resource allocation. Hip replacement is conducted extensively in the elderly and if patients must remain under general anaesthesia for longer periods, an increase in the risk of mortality may result.

The device must be relatively easy to manufacture. The primary reason for this design goal is quite simply cost. To remain competitive, the cost of manufacturing an implant must be kept to a minimum. Hospitals are necessarily looking closely at implant cost and cheaper systems may be favoured over more complex designs, regardless of the implications on survivorship.

The implant should be anatomical and physiological. Every effort should be made to produce a device which mimics closely both the anatomy and physiological mechanics of the original healthy joint.

The implant should be marketable and be attractive to both the surgeon and the patient. Surgeons should feel comfortable in using such a device and must be persuaded to move from the use of conventional replacement systems to this new design. This is a secondary goal as it is oriented towards the commercial success of the implant, rather than the long term success of the design itself. Marketing plays a significant role in the commercial success of an implant and should be considered accordingly.

The Design of a Sealed Artificial Hip Replacement

These design goals provide a starting point for design and by no means are exhaustive of the proposed functional requirements. Further specifications are enumerated in the ensuing sections and the implementation of all these various design goals are described accordingly.

5.2 Artificial Joint Capsule

The primary design goal is simply to negate the problem of wear debris. After some deliberation the concept of confining the particles to the replacement system itself was established. The initial problem was how to achieve this whilst maintaining the normal range of motion of the device. The motions of the joint include flexion - extension, adduction - abduction and internal and external rotation. None of these should be inhibited.

By sealing the joint with a compliant sleeve, these motions could be permitted without obstruction. Furthermore such a configuration would fulfil a number of other design goals immediately. Cost should not increase dramatically as the polymer should be relatively inexpensive. Sealing the articulation restores the anatomy of the hip joint. When a total hip replacement is undertaken, it is common practice to resect the three ligaments that form the natural joint capsule when excising the head and neck of femur. The space that is created by this resection will be filled by the prosthesis including the compliant polymer which forms the "Artificial Joint Capsule" (AJC). This AJC seals the articulation of the femoral head in the acetabular component, preventing the egress of wear particles to the surrounding tissues. By confining particles to the replacement system, biological problems associated with wear

debris are eliminated. A sealed device would also halt any particulates entering the joint, thus protecting the bearing surfaces by eliminating third body wear.

5.2.1 Material selection

The use of a compliant polymer to seal the joint surfaces brings with it the problem of selecting an appropriate material. A polymer must be able to fulfil a number of criteria before it can be deemed acceptable for use in this application. Not only must it permit the normal range of motion but it should possess sufficient compliance not to require large forces for its own deformation.

During normal operation it is estimated that the polymer would only be required to sustain 100% elastic strain. However to avoid fatigue failure a material must be chosen that deforms elastically many times more than this. The fatigue life of the device must be in the order of 30 million cycles. It is suggested that a material that has an elastic strain range of 200% to 400% would be suitable however fatigue life testing must be carried out to confirm this.

An analysis of wear in Chapter 2 revealed that particles are often in the sub micron range (Lee *et al.* 1992). Many polymers may allow some amount of sub micron level particles or fluid through such a membrane and it is suggested that this is probably unacceptable. The material must also be waterproof, even at high elastic elongations of the sleeve.

Consideration must be given to the biocompatability of the polymer and as such the material must be able to operate unimpeded in the physiological environment of the hip joint. A

medical grade polymer must be used or developed according to the existing standards. The material itself must be thermally stable at body temperature and slightly above. It is recommended that a thermal stability of at least 50° C be adhered to in selecting the material. It must not only be thermally stable, but must not interact chemically with the surrounding tissues or fluids. It is impossible to find a truly bio-inert material but silicones and polyurethanes are both classes of materials which have long been used in biomedical applications and it is envisaged that possible materials for the AJC may come from these two families of polymers.

During the course of this thesis the author made contact with a number of implant and polymer manufacturing companies to research suitable biomaterials for use in the sealed artificial hip joint. In general an unwillingness to yield information regarding biomaterials, especially of medical grade, was found from companies without some disclosure of design concepts. Due to the priority nature of designs, disclosure of designs or concepts could only be carried out under confidentiality agreement. The issue of obtaining suitable materials was discussed during preliminary marketing of this device however no specific material was selected. Investigations with these companies revealed that waterproof polymers with elastic strain ranges of 450% were available. These polymers were also said to have excellent tensile strength and good abrasion resistance. It is likely that polymers either exist or can be developed to fulfil the design specifications of the AJC. However, further contacts must be made with industry to gain access to them. A collaborative venture may be required with an appropriate company before these materials can be secured. This type of activity is not within the scope of this thesis.

The rudimentary requirements of the polymer have been described, however, further designs require different material characteristics. To allow lubrication of the joint, water and fluids from around the joint could be allowed into the AJC but particles must still be precluded from leaving the joint space. Whilst this may be a difficult design criteria to fulfil, the potential benefits warrant further investigation of materials. Again, it is unknown whether companies have the capability to produce this type of material and closer links with industry must be made to secure this information.

5.2.2 Design of the Artificial Joint Capsule

The main design goals have been fulfilled by the use of a compliant polymer to form an artificial joint capsule. The design of the AJC is discussed in terms of the simplest concepts, that fulfil these goals, then additional ideas and design manifestations are proposed also.

The ligaments around the hip joint can be up to 5 mm thick in parts. The artificial membrane will have a cross sectional thickness of 2 mm which leaves considerable room on the inside of the AJC to avoid impingement and still provide the required fatigue life and strength properties. In the simplest form of the device, the AJC will be made from sheets of flat polymer. The manufacture of this design is discussed in Chapter 6.1.

Impingement of the polymer sleeve in the articulation of the replacement system is undesirable as it may damage the material. This becomes another design specification. To address this possible problem, the polymer sheath can be made with ridges as shown in Figure 5.2.2.1, allowing it to concertina in and out. The internal volume of the sealed bearing is

maintained during motion. As the ridges curve outwards, the polymer will spring out, keeping the joint space clear and minimising the likelihood of trapping the polymer between the acetabular and femoral components. The design could ensure impingement of the neck of the femoral component occurs at the rim of the articulating surface of the acetabular component. If this is the case, it is only possible for the polymer to be interposed between components in the event of dislocation or secondary impingement. Secondary impingement occurs when the femoral neck strikes the external rim of the acetabular component. Impingement however is a source of wear and may also be a contributory factor to loosening as forces are transmitted to the fixation interfaces of the implant.

The use of ridges also reduces the amount of pre-stress required to tension the AJC. If a flat cross section is used, the polymer must be quite taut to begin with, such that when flexed, the unloaded side will not sag into the articulation.

In the simplest conceptualisation, the AJC should not allow any substance to enter or leave the bearing surface. However, another possibly advantageous design, would allow fluid in to lubricate the joint, but prevent particles from leaving the joint capsule. In order to allow fluid in to lubricate the joint, the AJC would require tiny pores. Wear particles are often sub micron in size and as such may escape to the tissues. In order for this type of design to be practical, further features may have to be incorporated. The use of a wear particle collection chamber as described in Chapter 5.4.1 may enable such a system. However if a porous material is utilised, its strength and fatigue life will be reduced and it would be more susceptible to degradation. The increase in surface area increases the likelihood of a significant chemical reaction and may allow adhesion of tissues or deposition of minerals and other sediment carried in bodily fluids. These are both undesirable outcomes.

The concept of allowing lubricating fluid into the joint may not preclude the possibility of some particles leaving the replacement joint. However, the overall sentiment should be that the AJC will significantly reduce the number of wear particles leaving the artificial joint to interact with the tissues. The probability of aseptic loosening due to the effect of wear particles should thus be decreased significantly. This embodiment is in concordance with the design aim to reduce the egress of wear particles to the surrounding tissue.

Further design concepts include the incorporation of a single stiffening ring or multiple rings which can be employed to maintain the internal volume of the sealed prosthesis, to ensure no impingement against the articulating components. The rings divide the AJC into smaller sections of membrane which can flex and move relative to each other. This enables less compliant materials to be used as the polymer itself is subjected to lower loads. The overall stress on the AJC is also reduced, although stress concentrations at the stiffening rings may be introduced. The rings themselves may be made from thin stainless steel or titanium which can be embedded in the polymer moulding, or in a more preferable version, they may be made from the same polymer. This concept is an extension of the ridged principle already discussed. The moulding should have a cross section as shown in Figure 5.2.2.2, whereby the majority of the polymer cross section would be 2 mm thick whilst intermittent rings maybe upto 4 or 5 mm thick. The thinner cross sections will deform more, allowing the required range of movement. The rings will allow the maintenance of the internal volume, and enable the AJC to concertina in and out. This, like the ridge design, should minimise the likelihood of impingement. The sections of the AJC, created by the rings, are allowed to flex relative to each other. The provision of stiffening rings made from the same polymer section is in concordance with the design goal to enable ease of manufacture. By using as few material combinations as possible, material and production costs should be reduced.

The Design of a Sealed Artificial Hip Replacement

Figure 5.2.2.1 (Top) A cross section of the AJC showing the use of ridges. The ridges allow the internal volume of the AJC to be maintained and lends shape to the device.

Figure 5.2.2.2 (Below) The cross section required for a polymer with stiffening rings. The majority of the polymer cross section is 2 mm thick, whilst intermittent stiffening rings are 4 mm thick.

2 mm

4 mm
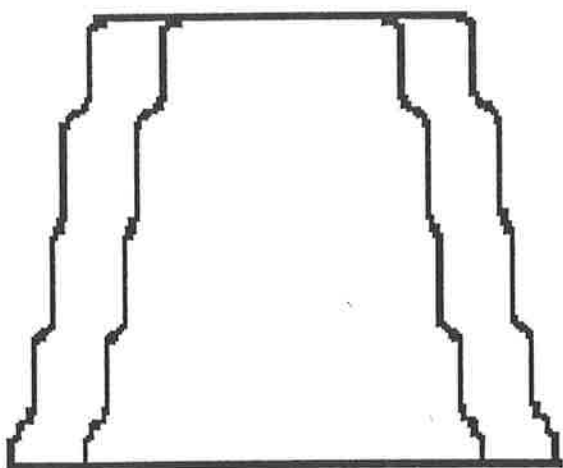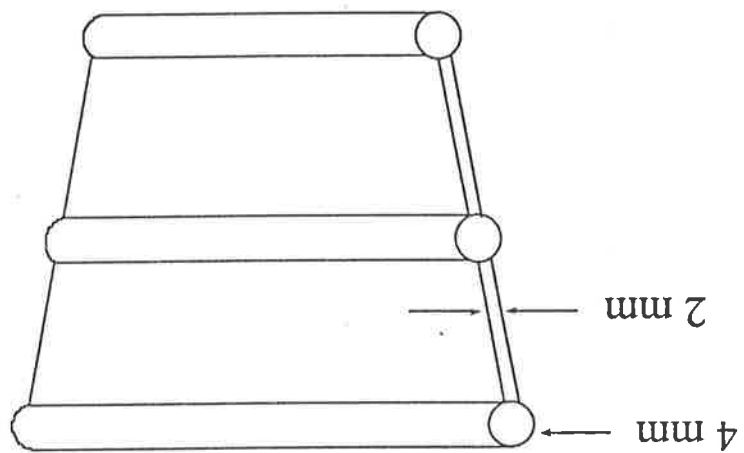
The articulation of the replacement joint is sealed at the time of manufacture and assembly rather than intraoperatively. Sealing the joint at the time of surgery has been patented previously by Collier, along with the accompanying surgical technique. The design goal of providing ease of surgical insertion is fulfilled by the use of a sealed modular bearing unit. Such a unit is delivered sterile from manufacture. Its assembly and surgical insertion are discussed in Chapter 6. This design alleviates the problems of blood and other materials prevalent intraoperatively, which may interfere with the sealing of the device. Such materials may in fact be sealed into the joint at the time of surgery causing obstructions to the articulation and possibly causing accelerated wear, as the interposed materials would increase the surface stresses. Furthermore during a complex surgical procedure, the risk of damaging the polymer itself are considerable when attempts to seal the joint are made. Additionally the joint may not be sealed properly and testing the integrity of the seal is difficult once insertion is complete. The design goals of ease of surgical insertion, safety, reliability and providing an attractive product to the surgeon are all unfulfilled.

For these reasons the use of a sealed modular bearing unit is highly desirable. Whilst it is possible to have a subassembly using the entire femoral stem, rather than simply a modular femoral head, it is not desirable as this would lead to a cumbersome insertion at the time of surgery. Therefore it is preferable to adapt a system in which the modular head, acetabular cup liner and the compliant polymer are assembled at the factory. This type of system is suitable for total hip modular systems as well as resurfacing arthroplasties and can be sterilised in the factory, ready for surgery. A groove on the acetabular component, 2 mm from its periphery and a small flange on the femoral component allow the use of a retainer to locate the polymer sleeve. The retaining system itself must be biocompatible and provide a constant clamping load for upto 30 million cycles. The retainer should have the properties of being

creep resistant and should not cut or abrade the polymer. The cross section of the groove in the acetabular component and the retaining flange on the femoral component are critical factors in ensuring this does not eventuate. An optimal cross section will minimise the stress on the polymer, whilst locating it securely.

5.3 Bearing Surface

Having reviewed the literature on the evolution of bearing materials for hip arthroplasty, the choice of bearing materials for this implant must also be made. As particles are trapped by the AJC, in effect this selection is not critical.

It has already been explained that a modular system is preferable and with this in mind, an UHMWPE liner in combination with a CoCr alloy head would be the first choice of articulation. However the possibility exists for the use of an alumina ceramic head or even a metal - metal articulation. From a marketing standpoint it is important to demonstrate that a sealed artificial hip joint concept is applicable to different bearing articulations, as different manufacturers may see a potential for their own product.

5.4 Additional Features

The main design features of the sealed artificial hip joint have been specified. However, some additional possibilities may be included to address possible concerns or perceived shortcomings of the main designs.

5.4.1 Wear Particle Collection Chamber

Sealing the bearing surfaces effectively retains all wear particles within the joint and this allows the possibility for second body wear to take place. Should a metal - polymer articulation be used for instance, polymeric and metallic debris may be interposed between the articulation. Metal particles in the articulation would impart extremely high stresses and the polymer in particular would be worn at an accelerated rate.

A wear particle collection chamber may be incorporated to minimise the number of particles that interfere with articulation. If a lubricant is used in the sealed bearing system, a natural mechanism for transfer of particles into the ball and socket articulation is created via the fluid. Collecting particles in a chamber reduces the probability of particles causing second and third body wear. This is especially important for wear particles of the metal femoral head, as these metal particles against polyethylene will cause accelerated wear of the acetabular cup.

There are a number of ways in which this design concept can be fulfilled. A micro-slotting system which depends largely on gravity (Figure 5.4.1.1) could be used whereby particles would collect at the bottom of a chamber after essentially being filtered through 1 or 2 very thin sheets. The sheets would be approximately 0.5 mm thick and can be metallic or polymeric.

Another possibility is the use of a ceramic annulus at the base of the sealed modular bearing. The porous nature of the ceramic material enables the particles to collect within it and will effectively act as a labyrinth for particles to be trapped in. The incorporation of a flange on the modular femoral head may be required to mount this chamber. However, any increase in

the neck width should be kept to a minimum as impingement of the femoral neck or AJC against the acetabular component is undesirable. A small flange will most likely be incorporated to attach the AJC to the femoral head component (See Chapter 5.2.2) and this would be suitable to mount the WPCC on to. The natural slope from the acetabular rim to the femoral component attachment ensures the requirement of a relatively small chamber. The annulus can be a split-ring device which uses an interference fit between components. The design is such that each component is manufactured identically for ease of manufacture and assembly. Figure 5.4.1.1. shows a thin sheet with slots to filter particles and Figure 5.4.1.2 a ceramic annulus. The use of a ceramic annulus is the preferred design of WPCC. In choosing an appropriate ceramic, or other material, selection of an appropriate porosity should be made carefully. The size of particles typically range from sub micron to 10 microns and the pores must be able to accommodate this range of sizes.

The use of a lubricant inside the sealed artificial hip joint provides a mechanism for debris to be transported in and around the AJC. The incorporation of a wear particle collection chamber would, in one possible scenario, prevent or reduce the likelihood of this occurrence. The lubricant, however, may disrupt the effectiveness of such a chamber.

Figure 5.4.1.1   (Top) A wear particle filter can be attached to the base of the femoral head, trapping wear particles and reducing second body wear. The holes are shown in the inset.

Figure 5.4.1.2   (Below) A ceramic annulus for use as a wear particle collection chamber. The split-ring arrangement allows easy assembly following manufacture.
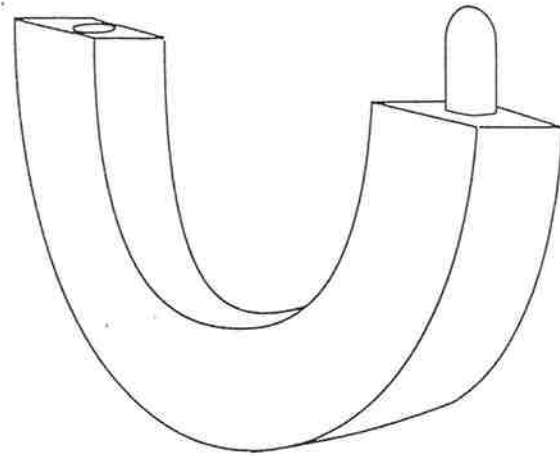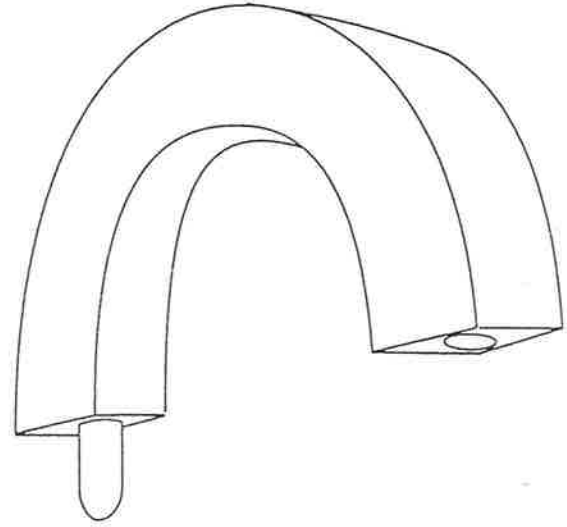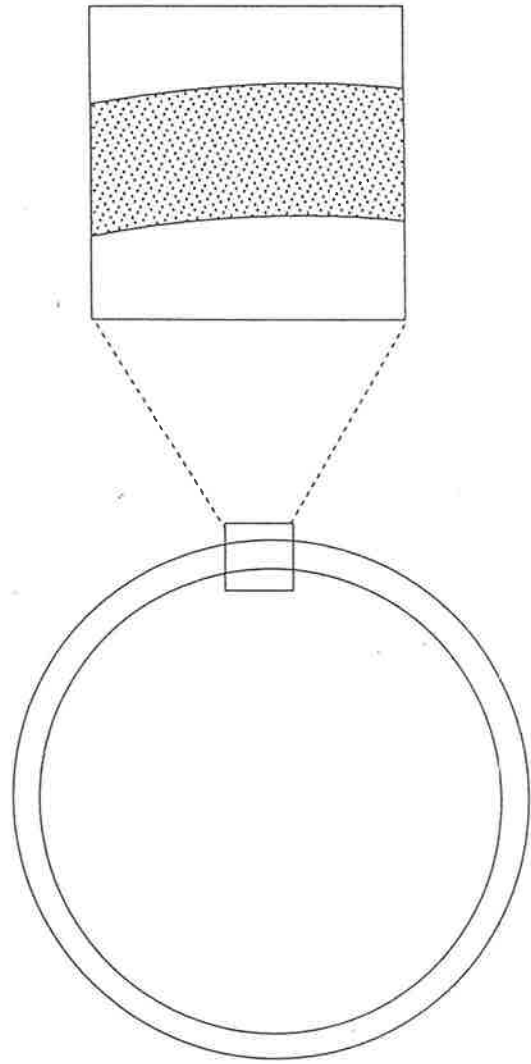
5.4.2 Dislocation Latch

It is commonly reported that hip replacement systems dislocate following joint replacement surgery. Early or post-operative dislocation has been reported as the most common (Amstutz, 1991). However high rates have also been reported for late dislocation. Some authors have suggested that with increasing experience in a surgical procedure, the dislocation rate is reduced (Charnley *et al.* 1973). In Charnley and Cupic's review a 2 percent rate was reported and this figure was reduced in a subsequent study also from the Wrightington hospital to around 0.5% (Etienne *et al.* 1978). The overall incidence of dislocation varies between 0.5% and 8% in the literature. The salient point is that hip dislocation cannot be treated as a negligible occurrence. Designs of joint prostheses must address this problem.

When dislocation occurs in a sealed hip joint the important consideration is to determine whether the AJC has been breached and the articulating surface has been exposed to the body, which would result in wear particles interacting with tissues. Two possible solutions are suggested.

By incorporating a latch mechanism, the AJC would be released in response to the application of a significant force as in dislocation of the femoral head. This would ensure no breach of the AJC. However, revision surgery may be necessitated if this system were utilised. This design would also further complicate its design and manufacture and for this reason it is most likely an undesirable inclusion. However, if the problem of dislocation cannot be resolved by other means, the use of this additional feature may be necessitated.

The second possibility is simply to make the AJC polymer membrane sufficiently robust to withstand any force applied during dislocation of the hip joint. This method would not require revision surgery, with the femoral component simply being manipulated back into position. The AJC will act in place of the natural capsule and reduce the likelihood of complete dislocation. As described in section 5.2.1 the polymer cross-section would range between 2 and 5 mm in thickness which would enable it to withstand dislocation load. Its compliant nature should allow it to elastically deform in this situation. Should the device be able to withstand such a loading condition, it would help approximate the joint following dislocation. This may allow the surgeon to simply manipulate the joint, back into place, rather than embarking on further surgery. Rather than the AJC being a potential liability during dislocation of the hip, it may in fact be a further strength of the device. It is desirable to have an opening taper on the acetabular cup liner (See Figure 5.9.2) to facilitate a more easy relocation of the femoral head should dislocation occur (Murray, 1992). This may further reduce the requirement of revision surgery following dislocation.

The AJC is connected to both the acetabular liner and the femoral component or head, resulting in a further problem. The dislocation load will be transferred to these points of fixation and so they too must be sufficiently robust to withstand such a force. The compliant nature of the AJC should keep these loads to a minimum. Furthermore, additional loads may also be transmitted to the fixation interfaces and may contribute to mechanical loosening. These potential problems should be minimised by careful selection of the material properties of the sealing polymer.

5.4.3 Radiographic mesh

The AJC membrane is made using a compliant polymer sleeve. Should dislocation occur the AJC cannot be detected radiographically and hence it is not possible to determine whether the system remained sealed. A normal hip replacement system can be monitored on x-ray and it would be convenient if this sealed design of hip replacement could also be tracked radiographically. A solution to the problem of tracking the polymer with x-ray is to incorporate a radio-opaque mesh into the membrane. This would increase the stiffness of the material. However, the stiffness of the mesh must be balanced with the compliance of the polymer to produce the desired mechanical characteristics. The convenience of monitoring the integrity of the AJC radiographically is a strong reason for incorporating the mesh into the main design. If metal stiffening rings were incorporated then the integrity of the AJC could be tracked radiographically. These additions, however, may reduce the fatigue resistance of the AJC. Another possibility is to load the polymer with a filler that can be detected radiographically. A common filler used for this application is barium. However, the use of such a filler may have implications on the mechanical properties of the AJC.

5.4.4 Additional Bearing

An additional bearing can be incorporated on either the acetabular or femoral component of the prosthesis to facilitate movement of the joint without over-extension of the polymer. The primary aim of this design concept is to reduce the applied stress on the polymer by supplying one degree of freedom, around the axis of the acetabular insert or femoral head, in which the polymer membrane can rotate freely under minimal load. This bearing would most likely be

attached to the acetabular insert. This is particularly the case if a wear particle collection chamber is incorporated in the design, since it would be mounted at the femoral component. A cross section of the device is shown in Figure 5.9.2.

The polymer membrane will be attached to the bearing and not the periphery of the acetabular insert in this design. As the bearing is mounted on the periphery of the acetabular insert, it facilitates mainly flexion and extension of the hip. The range of motion of the hip joint in this plane is approximately 130 degrees and the bearing is therefore put to good use in reducing the load on the polymer membrane.

5.5 Replacement systems

In the event of failure of the sealed modular bearing system, it is possible to simply replace this entire component, should the femoral and acetabular backing components be still adequately fixed. The component is simply removed and another sealed modular bearing system inserted. If this is not the case and either femoral or acetabular component revision is required, a normal revision procedure would have to be carried out. The possibility exists for continued use of the sealed unit or replacement if it has also been damaged.

Replacement of the sealed modular bearing unit is potentially expensive in comparison to replacement of either the acetabular insert or femoral head component only. However implant cost is only a fraction of surgical and hospital costs. Overall, a significant increase in the cost of revision surgery is not envisaged.

5.6 Fixation

The design of fixation systems for the acetabular backing cup and femoral stem component is outside the scope of this thesis. However, as an acetabular liner and backing cup are used, the possibility for micromotion and hence wear between these two components exists (Guttmann *et al.* 1994; Rosner *et al.* 1994). This should be minimised as particles emanating from this interface would not be captured by the AJC and the tissues would be exposed to this particulate debris.

Similarly, studies have shown that particulate debris can be created at the taper connecting the femoral head to the stem (Dujovne *et al.* 1993 Lieberman *et al.* 1994). Many designs use a "microthread" on the taper, which is said to prevent micromotion at this interface.

Another source of wear debris is at the femoral stem - cement interface. Care should be taken to minimise micromotion, through implant design and the use of good cementing techniques. The surface finish of the femoral stem may play an important role in the relative adhesion to the bone cement.

5.7 Lubrication

The lubrication of natural joints is via fluid film lubrication (Unsworth *et al.* 1991). In this type of lubrication a thin layer of fluid is trapped between opposing surfaces keeping them apart so that surface wear is minimised. It is believed that the fluid film is maintained due to elastic deformation of the cartilage. Coefficients of friction in a healthy natural joint, with

fluid film lubrication, range between 0.005 and 0.02 (Unsworth *et al.* 1991; Jasty and Smith 1992). Current total hip arthroplasties do not operate with this type of lubrication, although prototype polyurethane bearing prostheses have been able to develop this type of lubrication experimentally (Unsworth *et al.* 1988; Auger *et al.* 1993; Dowson *et al.* 1991).

A number of possibilities exist for lubrication of the artificial joint. Saline, water or an artificial lubricant could be used to fill the joint whilst still allowing motion of the polymer. It is also a possibility that the joint may be run dry (ie. without lubricant) and depending on the bearing surfaces used, this may not significantly increase overall wear. The use of a lubricant within the enclosed bearing would mean that all particles produced would be transported around the joint and significantly, into the articulation. This may in fact increase the wear rate of the bearing as particles become interposed between the articulating components. However the incorporation of a wear particle collection chamber as discussed in Chapter 5.4.1 may nullify this potential problem. A further possibility is that the use of a lubricant may retard the effectiveness of such a collection chamber. The solution to these problems lies in testing and joint simulator studies which must be used to comment conclusively.

The biocompatability of any lubricant used is also of paramount importance. Should a breach of the AJC occur, the lubricant should not have any deleterious effects on the body. Saline or water are thus attractive propositions as possible lubricants, as they would be readily taken up by the body and discharged.

5.8 Design Concept and Preferred Design

Having completed a broad design process, encompassing many different design features, a preferred design of the sealed modular hip replacement has been selected.

The sealing membrane would have a cross section as shown in Figure 5.2.1.2. This membrane has a nominal cross sectional thickness of 2 mm with stiffening rings, 4 mm in diameter incorporated into its design. The product is manufactured in a sub assembly comprising the acetabular insert, modular femoral head and AJC compliant polymer. The polymer is fastened to a groove in the acetabular insert and a small flange in the femoral head component. The product is delivered sealed and sterile to surgery. A wear particle collection chamber has been incorporated and is located at the base of the modular femoral head component. This additional design feature enables the collection of debris and the reduction of second body wear.

The bearing surfaces should preferably be of a polyethylene acetabular insert component and a modular CoCr alloy head component. The acetabular insert should have an opening taper to facilitate relocation of the femoral head in the event of dislocation. The membrane itself is suitably robust, owing to its thickness and compliance, to withstand the forces exerted during dislocation. The femoral head should be forged with a small flange for location of the polymer sleeve and wear particle collection chamber.

Although more complex embodiments were considered, this design is favoured for its simplicity of manufacture and surgical implantation.

5.9 Detailed Drawings - Components

An exploded view of the device is shown in Figure 5.9.1. The hip replacement system comprises an acetabular backing shell, femoral stem component and a sealed modular bearing unit. A drawing of the sealed modular bearing unit sub-assembly is shown in Figure 5.9.2. An opening taper on the acetabular insert allows easy relocation of the femoral head in the event of dislocation. Figure 5.9.3 shows this subassembly with two additional design features. An additional bearing has been incorporated on the acetabular insert to allow flexion - extension of the joint with minimal strain exerted on the polymer sleeve. A wear particle collection chamber has been incorporated on the base of the modular head.

Figure 5.9.1   A drawing of the sealed modular hip replacement (exploded view)

There are three main components which include the acetabular backing cup, sealed modular

bearing unit and femoral stem.
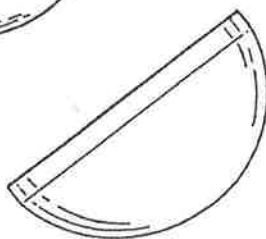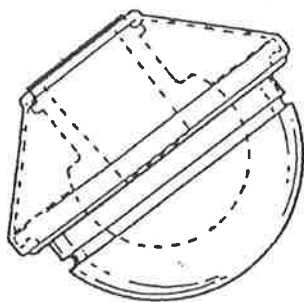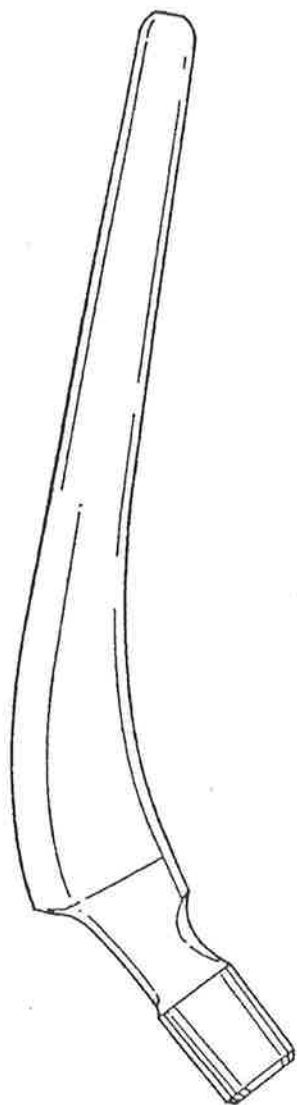
Figure 5.9.2   (Top) A drawing of the sealed modular bearing unit sub assembly. The

bearing is sealed at a groove in the acetabular insert and a small flange at the base of the

modular head. An opening taper has been incorporated on the acetabular insert.

Figure 5.9.3   (Below) The sealed bearing unit with 2 additional modifications. An

additional bearing has been included at the periphery of the acetabular insert and a wear

particle collection chamber at the base of the femoral head.
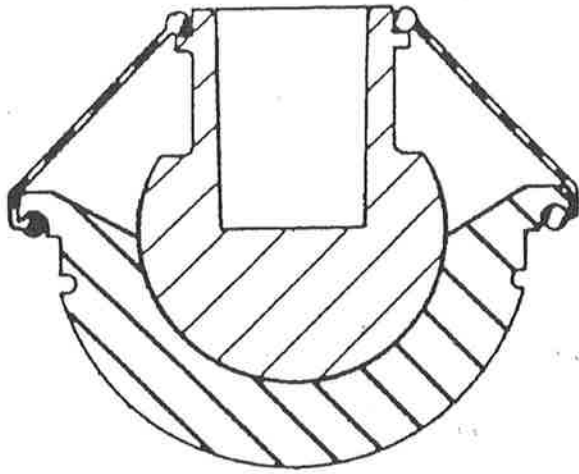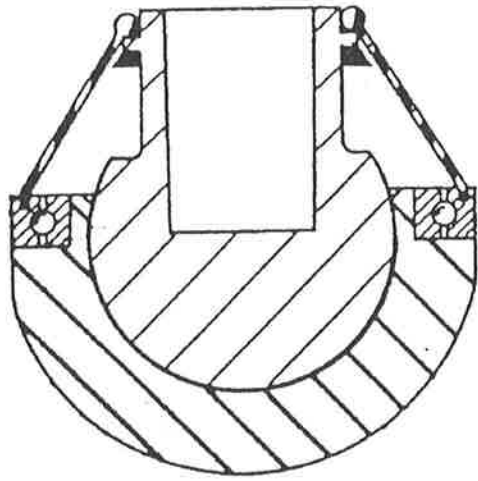
5.10 Design Model

A model was manufactured to display the design principles of the device during preliminary marketing. A full prototype has not been manufactured due to cost restrictions. The sealed modular bearing unit is shown disassembled in Figure 5.10.1. Simple "O" rings were used to seal the device and a flat compliant polymer section was used to make the AJC. The circular stamping method was used to make this sleeve. Note the flange on the femoral component which has been accentuated on this design model. Figure 5.10.2 shows these components fully assembled to make the sealed modular bearing unit. This type of unit would be sterilised and packaged at manufacture. Figure 5.10.3 is a photograph of the sealed artificial hip joint model. The device is arranged in an exploded view fashion similar to Figure 5.9.1, however, the acetabular backing cup is not shown. Figure 5.10.4 shows the femoral stem and sealed modular bearing unit once connected. The model was created using convenient and inexpensive materials rather than those proposed in the preferred design. The compliant polymer was able to provide the required range of motion. The model displays the relevant design features of modularity and sealing of the bearing surfaces.

Figure 5.10.1 (Top) Photograph of the disassembled sealed modular bearing unit. Included are the acetabular insert, compliant polymer, modular femoral head and retainers. The compliant polymer has been made using concentric circles. Gaskets were used to seal the device and the flange on the femoral head allows location of the polymer sleeve.

Figure 5.10.2 (Below) Photograph of the fully assembled sealed modular bearing unit.
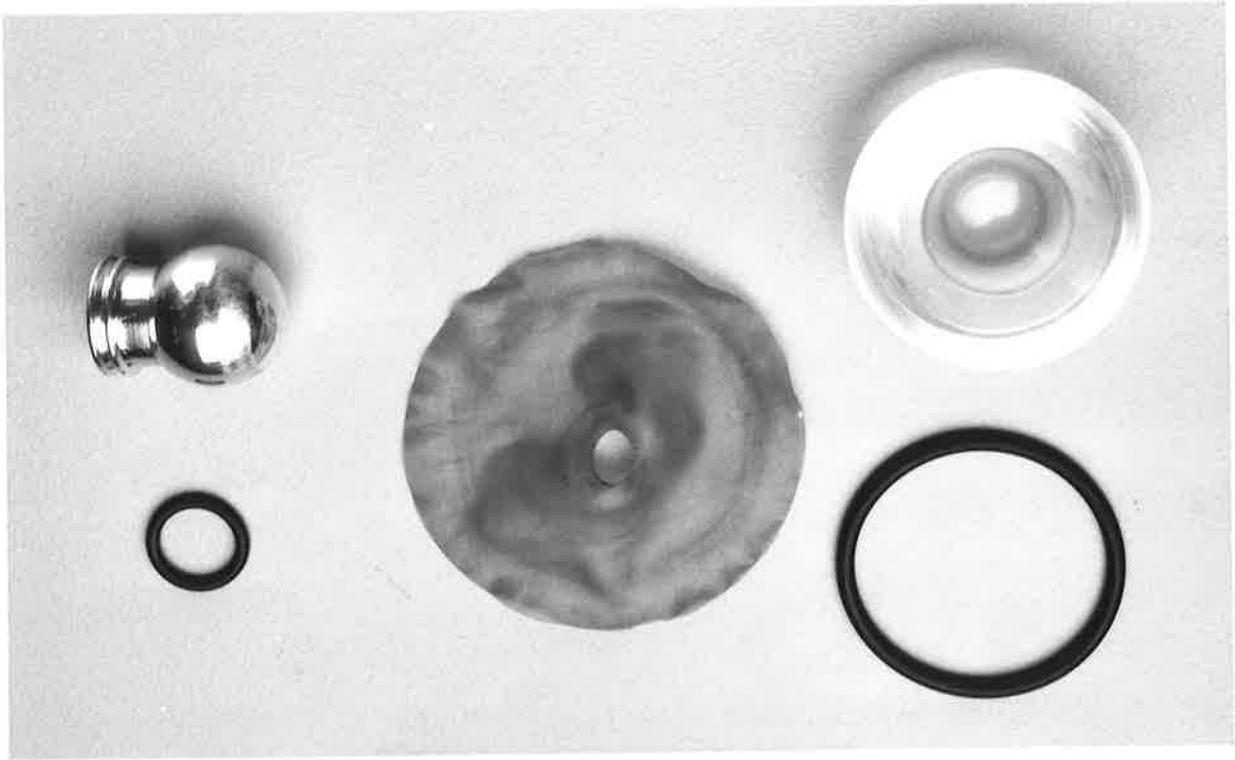
Figure 5.10.3   (Top)   Photograph of the sealed artificial hip joint model with the

sealed modular bearing unit and femoral stem components prior to connection.

Figure 5.10.4   (Below)   The assembled sealed modular hip replacement model.   The

acetabular backing cup is not shown.

CHAPTER 6

ASSEMBLY AND SURGICAL INSERTION

When designing the sealed artificial hip replacement, considerations were initially directed towards how the designs could fulfil the aims of the project. So when contemplating a method of sealing the device and still allowing a full range of motion, a compliant polymer membrane was conceptualised. Similarly the other design goals that have been enumerated were all addressed. However, having fulfilled the functional requirements of the device other design features were considered. In particular, the device was designed in terms of manufacture and surgery.

Design of the product for ease of manufacture and assembly is extremely important, as any device must be cost effective to compete in the open market. If difficult or time consuming manufacturing methods are required, costs tend to escalate quickly. Similarly, design for ease of surgery is equally important, as surgeons simply will not use a device if it is significantly more laborious to use than alternatives. Cost reduction is a vital consideration in the health sector and additional implant costs must be minimised.

The sealed artificial hip joint has been designed with consideration given to the functional aims, manufacturing methods and surgical procedure. This chapter briefly describes some possible manufacturing and assembly methods and surgical implantation.

6.1 Assembly Method

The sealed modular bearing component comprises a compliant polymer sheath, polyethylene acetabular cup insert and cobalt chrome modular head system.

The polyethylene acetabular cup insert is manufactured in the usual manner, with the addition of one process. A 3 mm radius groove is machined into the acetabular insert 2 mm away from its periphery (see Figure 6.1.1). It is most likely that the modular head would be a forged cobalt chrome component. As a result a machining process would have to be carried out after forging to create a groove in which to clamp the polymer. This is undesirable as the forged material is hard to machine. It is, therefore, preferable to create a small flange on the femoral head which can be included in the forging process of manufacture.

Figure 6.1.1   (Top) Attachment of polymer sleeve to the acetabular component is made 2 mm inside the periphery. A 3 mm groove is created. (Below) A ridge section is used directly adjacent to the connection to assist in the sealing and firm location of the device.

R 1.5 mm

2 mm

ridge

retainer
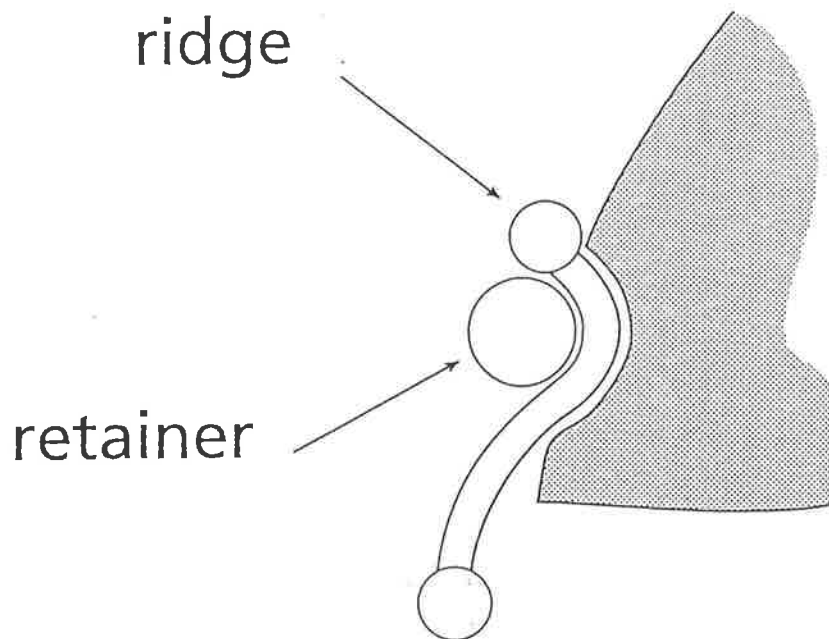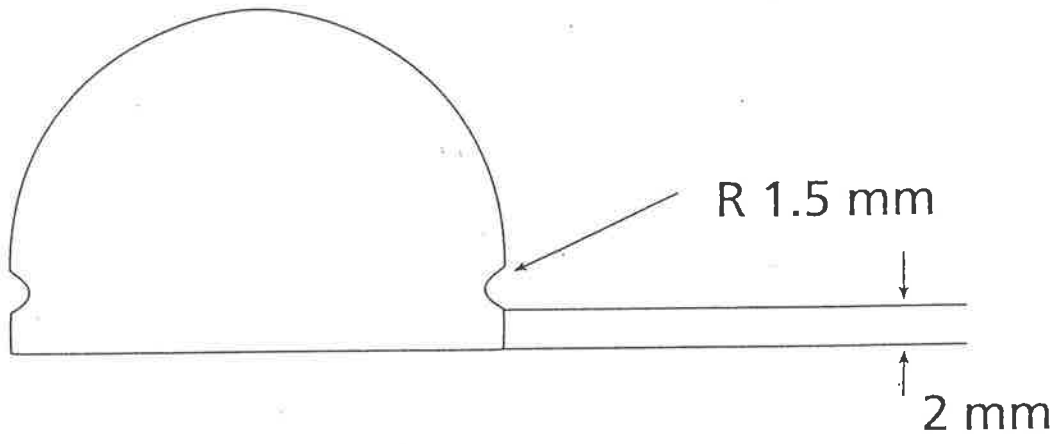
The polymer is placed over a groove 2 mm inside the rim of the acetabular cup insert and is clamped in place by a circular loop of wire. Similarly the sheath is passed over a flange on the femoral component and a circular wire clamps it in place. A ceramic annulus is assembled on the flange of the femoral component prior to being sealed. The system is sterilised and packaged, ready for implantation.

The AJC itself can be moulded with a suitable thermosetting polymer into any desired cross section. Alternatively the AJC can be stamped from sheets of polymer which in the simplest version has a 2 mm thick, flat cross section. Stamping the component using a die with concentric circles (see Figure 6.1.2) would perhaps be more economical than moulding or casting however this is related to the production numbers. Stamping has the advantage of not requiring any fusion of the membrane, which may be required by other designs.

The hole created in the membrane is less than the diameter of the neck of the femoral head. This ensures that it fits tightly beneath the flange of the femoral component. It is then simply passed over the flange of the femoral component and fastened. Then the femoral head and acetabular liner are brought together and finally the membrane is passed over the groove of the acetabular liner, where it is also fastened securely. It should be noted that the prestress applied to the AJC should be minimised as a constant tension load reduces the fatigue life of the polymer.

More complex designs of the AJC utilise different cross sections of polymer sheets. For both the ridged and stiffening ring designs of polymer sheet, a very specific cross section must be used as shown in Figure 6.1.3.

Figure 6.1.2   (Top) The cross section to be stamped if a flat polymer is used in manufacture.

Figure 6.1.3   (Middle) A new cross section to be stamped if a polymer with ridges or stiffening rings is used.

Figure 6.1.4   (Below) A polymer sheet to allow a concentric circle stamping procedure for polymers with stiffening rings.
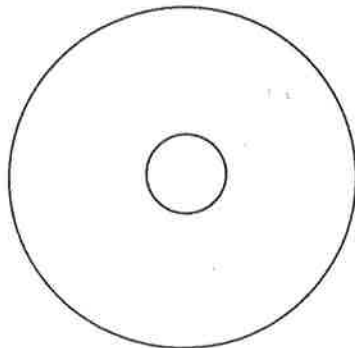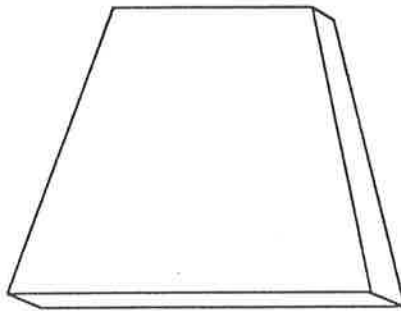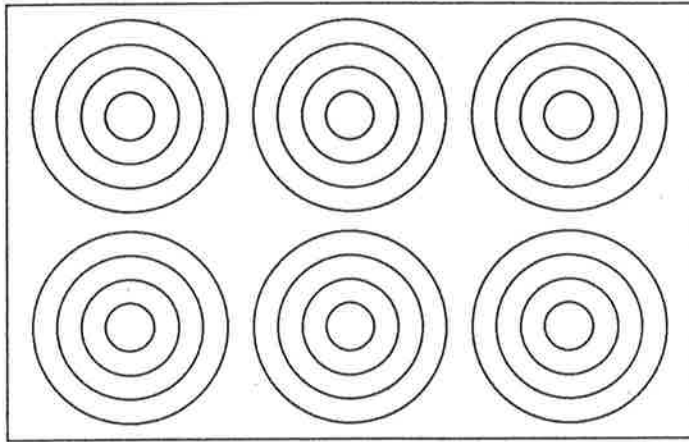
A circular cross-section is no longer suitable unless the polymer sheets can be prepared with the pattern shown in Figure 6.1.4. Although production of a polymer in this pattern may be more expensive, the considerable benefit of not requiring a bonding process must be duly considered. Care must be taken to align the sheets in the same relative position for stamping such that each sealed bearing will have an identical polymer membrane sealing it. This is important for quality assurance as well as for assembly.

The connections at the femoral and acetabular ends should be made to the smaller cross sectional width of 2 mm to enable a smaller groove at the acetabular component and a smaller flange at the femoral component. It may be desirable to have a ridged section directly adjacent to the connection system to assist in sealing the device (see Figure 6.1.1). Once the polymer sheet has been stamped to the appropriate shape, it must be joined using a bonding process.

Once assembly of the sealed bearing unit is complete, a further important step in production must be carried out. The seals in each subassembly must be tested rigorously. The test must not incur a risk of damaging the membrane and must be relatively quick and inexpensive.

6.2 Proposed Testing and Current Standards

To have any new implant accepted for use it must have undergone certain testing and standards approval. The governing body in America is the Food and Drug Administration authority (FDA) and in Australia it is the Therapeutic Goods Authority (TGA). All materials must conform to a standard and in America the American Society for Testing and Materials

(ASTM) set the quality standards for materials, including those used for medical implantation. The standard for Cobalt Chrome Alloys is ASQC - 1968 and for Titanium alloys is C1 - 1968. There are many standards for the mechanical properties and attributes required for medical implantation. The ASTM guidelines must be referred to for all of these standards. As no standards would exist for sealing bearing surfaces, adequate accredited testing of the device would have to be approved and the product design cleared by the TGA in Australia or the FDA in the USA. Testing should be carried out in close consultation with all administrative bodies.

6.3 Surgical Insertion Method

Surgeons use a variety of techniques when undertaking hip arthroplasty. Perhaps the most commonly used operative approach for total joint replacement is the antero-lateral approach. The benefits of this approach include excellent exposure of the acetabulum and safety during reaming of the femoral shaft. Reaming of the femoral shaft is made easier by release of the abductor mechanism. The Smith-Peterson incision is shown diagrammatically in Figure 6.3.1.

Another commonly used approach is the posterior approach which is used for a number of different operations of the hip, as it offers easy, safe and quick access to the joint. The patient is placed in the lateral position for surgery and the typical incision is also shown in Figure 6.3.1.

Figure 6.3.1   The Smith-Peterson (Top) and posterior (Below) approaches to the hip
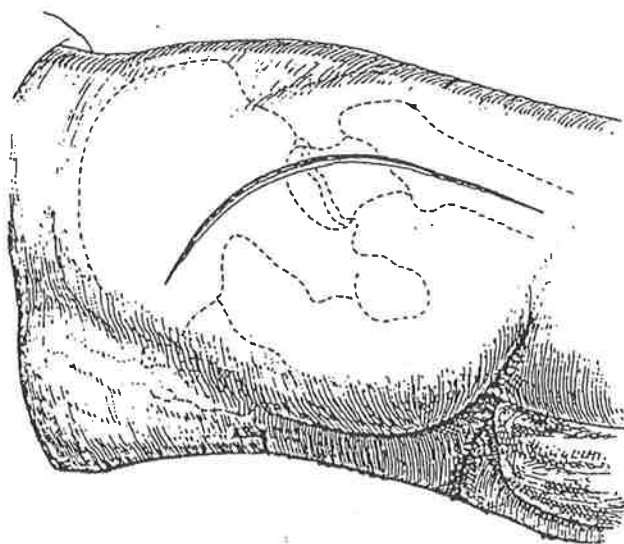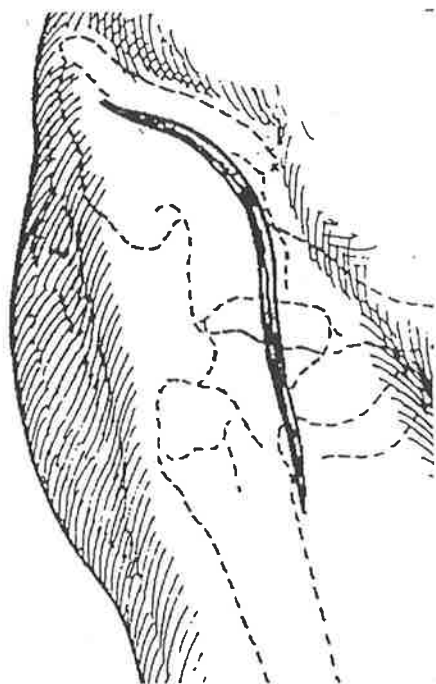
Hip arthroplasty is undertaken with the acetabulum and femoral head and neck in plain view. Once the head and neck of the femur have been resected, reaming of the acetabulum can take place. Muscles are retracted to allow easy access to the joint.

Following the completion of the incision and exposure of the joint, the acetabulum is reamed and the acetabular backing cup is inserted. The femoral stem component is inserted following appropriate preparation of the femoral canal for either a cemented or cementless design.

The sealed modular bearing component, is inserted after the femoral component and acetabular backing cup are in place. A jig is placed in the taper of the modular head and the acetabular insert located in the backing cup. A mallet can be used on the taper - jig to exert a force on the bearing unit. A snap-fit mechanism locks the two acetabular components together. A retractor may have to be used to distract the femoral stem and acetabulum during this part of the procedure. Once the acetabular insert is in place, distraction can be released and the modular head located onto the femoral stem taper. Care must be taken at all times during the surgical procedure, to ensure no damage is done to the AJC.

This offers an extremely simple surgical procedure and is preferable to sealing the joint at the time of surgery.

CHAPTER 7

PATENT AND PRELIMINARY MARKETING

During the course of this project a provisional patent was obtained for some of the design concepts and a preliminary marketing project was undertaken. This chapter addresses the patent and the marketing concepts that were developed.

7.1 Provisional Patent

A Student Project Participation Agreement was entered into at the beginning of the Masters degree program in recognition of its commercial potential. It is the University's policy that should any commercialisation of products occur, as a result of work conducted whilst undertaking a project, then commercialisation should be carried out through Luminis Pty. Ltd. A copy of this agreement is in Appendix 2. Letters from the authors employers were obtained confirming no interest in the intellectual property developed in the Masters program, whilst concurrently employed with them.

A provisional patent was granted from 19th April 1994 and has since been renewed as a provisional patent, on 23 March 1995. The first provisional patent was assigned an application number PN5154 and the subsequent patent number PN1931. Existing patents have been established for an enclosure member to seal the joint intraoperatively (U.S. Patent Number 4731088) and the accompanying surgical technique. (U.S. Patent Number

The Design of a Sealed Artificial Hip Replacement

4822368). A.P.T. Patent Attorneys and Luminis agreed that the provisional patent filed as part of this Masters thesis falls significantly outside the claims of these established patents and therefore represent novel concepts in their own right.

The main claims made in the patent are firstly to provide a sealed modular joint prosthesis that prevents the egress of wear particles to the surrounding tissues. The patent claims a simpler and safer surgical technique through the use of a prosthesis which has been delivered sealed and sterile to surgery. Further claims for a secondary bearing unit and a wear particle collection chamber are made and additional design concepts are disclosed. The patent has not been restricted to hip replacement systems and is equally applicable to other joints in which wear particles may become a problem. The knee and tempromandibular joint are both possible applications.

The latest provisional patent has been included in Appendix 1.

7.2 Marketing

The scope of this thesis includes initial discussions with manufacturers regarding the development of these patented designs and discussions will continue beyond completion. The patent on the designs has been extended and will be assessed in March 1996, by the University of Adelaide for renewal. In the meantime, efforts to secure financial support for the development of the prosthesis will be continued. Manufacturers of suitable polymeric materials will be approached directly, such that the device can be prototyped through them, prior to new marketing ventures being undertaken with implant manufacturers. Presentation

of a working model, rather than just design concepts, will be a significant step in bridging the conceptual gap between conventional hip replacement systems and this proposed new generation of sealed hip replacement systems. The University of Adelaide and Luminis Pty Ltd. will maintain its commercial interest in this project, even after final completion of the thesis.

7.2.1 Confidential Disclosure

Following the patenting process, a preliminary marketing strategy was conceived and implant manufacturers identified as suitable to evaluate the design concepts for potential development under a confidentiality agreement. A copy of an agreement with Depuy International Pty. Ltd. has been included in Appendix 2. The agreement ensures that the information discussed during preliminary marketing may not be disclosed for a minimum period of 2 years.

7.2.2 Concepts to Discuss with Manufacturers

The marketing of a new hip prosthesis is an enormous undertaking. The total hip replacement market is growing rapidly, both within Australia and throughout the world. This can be attributed to a number of factors including ageing populations, better health care standards, an increase in the indication for primary surgery and an increasing number of revision procedures. A report from the Australian Institute of Health and Welfare indicated that in 1992 approximately 9,500 primary hip replacements were conducted and a further 2,000 revision procedures were carried out in Australia.

As implant manufacturers are well aware of the potential market for an innovative hip design, issues of world and Australian market size and volume do not require discussion during preliminary marketing. Instead the philosophies involved in the conceptual development and the potential for this product to take a place in the future of hip arthroplasty are proposed.

An explanation of the history of arthroplasty is important in order to emphasise that the past two decades have been largely concerned with new materials and fixation methods. New designs have been very reactive to complications and failures. Most recently the wear of replacement systems has been scrutinised. The years prior to 1970 produced the major design evolutions, progressing from interposition arthroplasty to resurfacing and total hip replacement. The sealed modular hip replacement is proposed as the new generation of hip replacement and is marketed as a natural step in this evolutionary process.

Conventional hip replacement systems have concentrated on the replacement of the acetabulum and proximal femur. The idea of replacing the joint capsule, that is resected during arthroplasty, with an artificial joint capsule of compliant polymer delivers the concept of a sealed artificial hip prosthesis. The device can therefore be looked upon as very anatomically oriented, in that it replaces a normal anatomical structure and this is a potential marketing strength. The sealed modular bearing unit is delivered sterile from surgery and provides a simple insertion technique similar to current methods for total hip replacement.

The potential benefits are described in terms of containment of wear particles from the tissues surrounding the artificial joint and protecting the joint surfaces themselves. Surgery is very similar to conventional methods. The implementation of a sealed artificial hip replacement has the potential to increase the expected lifespan of hip replacement systems.

CHAPTER 8

CONCLUSIONS AND FUTURE DIRECTIONS

8.1 Summary

The major long term complication in total hip arthroplasty is aseptic loosening. Loosening may be a result of mechanical loading, infection or the necrotic effect of wear particles on the tissues surrounding implants. The incidence of mechanical loosening or sepsis is reducing, implicating wear particles as the main cause of loosening and hence failure of the hip replacement system. The aim of this thesis was to design a novel hip replacement system to reduce or eliminate the problem of wear particles.

The design of a new replacement system was undertaken following the investigation of many other important associated fields. Current and previous implant designs, wear and its deleterious effects, relevant anatomy and biomechanics of the hip joint, currently available materials and their relative biocompatability were amongst the topics that contributed to the design process.

The concept of a sealed modular hip replacement system was explored. A compliant polymer, attached between the acetabular insert and modular femoral head created an artificial joint capsule . The polymer must be selected to enable the complete range of motion of the prosthesis under load and have a life expectancy of some 30 million cycles itself. It must have the attributes of being waterproof and thermally and chemically stable for the

environment of the hip joint. It has been designed with a specific cross section to minimise the likelihood of impingement and to maintain the internal volume of the artificial joint capsule. Ridges in the membrane allow particular sections to flex relative to each other, reducing the amount of prestress and loading stress on the polymer. The membrane is located in a groove in the acetabular liner and over a flange on the modular femoral head. These attachments are made at the time of manufacture, at which point the integrity of the seal is also tested. This sealed modular bearing is delivered sterile to surgery.

Implantation is carried out using conventional surgical techniques whereby the acetabular backing cup and femoral stem components are inserted prior to the inclusion of the sealed modular bearing unit.

A provisional patent on the design concepts involved in this new hip replacement system was filed and a confidentiality agreement between Luminis Pty. Ltd. and Depuy International Pty. Ltd., a major implant manufacturer, was signed prior to disclosure of design concepts.

The main preliminary marketing concepts for this product, emphasise the natural step of sealing hip replacement systems to contain wear and protect bearing surfaces. Modularity allows flexibility, safety and ease of surgery. The device is promoted as the next generation of hip replacement system, surpassing total and resurfacing hip arthroplasty.

This projects has examined the design of a novel hip replacement system at all levels and has prepared the author well for continued and more advanced work in the design of artificial replacement systems. The main aim of the project, to produce a novel design of artificial hip replacement system to combat the problem of wear particles, has been achieved.

8.2 Future Directions

The University of Adelaide and Luminis Pty. Ltd. will maintain a commercial interest in this design of hip replacement system. The next step will be to approach biomedical polymer manufacturers directly, to produce a suitable polymer with which to seal the joint. Once this has been achieved a prototype can be created and tested on joint simulators to ascertain its efficacy in containing wear particles. The volumetric wear from the implant should be measured to ensure that second body wear does not significantly increase the overall bearing wear. This should be done in conjunction with testing of a wear particle collection chamber with and without lubricant. Different cross sections of polymer should be tested to ascertain the ability to provide the required range of motion and minimise stress in the polymer. Impingement and fatigue life studies should also be conducted.

After a working prototype of the device has been manufactured, a new marketing initiative should be undertaken.

8.3 Conclusion

The concept of a sealed modular hip replacement system has the potential to take its place in the evolution of hip replacement systems. Sealing the articulation of the joint, to preclude the effects that wear particles may have on the tissues surrounding hip replacement systems, is a step away from the traditional designs. The provision of a sealed modular bearing unit, allows a surgical technique that would be safe and not dissimilar to conventional methods.

Wear is an inexorable process and whilst manufacturers have managed to limit wear of joint prostheses in the laboratory, these results are not necessarily mirrored in the clinical experience. Traditional methods have been unable to control wear and other solutions must be sought. A sealed modular hip replacement offers an exciting novel possibility.

The marketing of a new design of joint prosthesis is a difficult process. Engendering a change in the thinking of manufacturers and surgeons from the traditional, to this new design concept represents the most significant obstacle to success.

With suitable further research, development and collaboration, it is the authors opinion that this is a viable concept for hip replacement.

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APPENDIX 1 - PROVISIONAL PATENT

PROVISIONAL PATENT APPLICATION

LUMINIS PTY LTD

SEALED MODULAR JOINT REPLACEMENT

ORIGINAL

PROVISIONAL SPECIFICATION FOR AN INVENTION ENTITLED

Invention Title: SEALED MODULAR JOINT REPLACEMENT

Name of Applicant: LUMINIS PTY LTD

Address for Service: A.P.T. Patent and Trade Mark Attorneys
1 King William Street,
Adelaide, S.A. 5000

The invention is described in the following statement :

This invention relates to the general field of orthopaedic surgery and more particularly to artificial joint replacement. A sealed modular joint replacement is disclosed which prevents the egress of wear particles from the bearing surfaces to the surrounding tissue and allows simpler surgical implantation techniques.

5   BACKGROUND ART

Prosthetic joints have been developed to replace many of the crucial joints in the human body. The most common joints for prosthetic implantation are the hip, shoulder, knee and elbow joints. Ball and socket type protheses have been developed for replacement of hip and shoulder joints and hinge type protheses have been developed for knee and elbow

10   replacements.

Joint replacement has been the subject of medical research and experimentation since the early 1900's. Much of the work has focussed on hip arthroplasty due to the catastrophic effect on mobility if this joint fails and the frequency of hip problems in the general population. Total hip arthroplasty has been successfully performed for many years although

15   the working life of the artificial joint is still regarded as less than satisfactory. The failure of artificial hips, indeed any artificial joint, is primarily a materials problem. Over the past several years research has been directed at developing hip protheses from materials which increase the life of the joint and therefore reduce the need for revision surgery.

Modern artificial hip joints typically comprise a metal spherical femoral component

20   articulating in a polyethylene acetabular component. In the case of total hip arthroplasty the femoral head is excised and a component is inserted into the medullary canal of the femur, whilst a resurfacing hip arthroplasty simply shapes the femoral head sufficiently to allow secure implantation of a metal surface. In both cases the acetabular component is fixed to the pelvis.

25   Despite advances in materials for artificial joints an unacceptable failure rate still occurs. Recent research has concentrated on determining the reason for early failure of the artificial joint. A primary reason given for artificial joint failure has been the effects of wear particles. Wear of the artificial joint occurs at both the articulating surfaces of the joint as well as at all fixation interfaces and is primarily abrasive rather than adhesive or corrosive. Abrasive wear

30   results in small wear particles being produced. These particles include polyethylene, metal, cement and even bone.

Should the particles become interposed between the bearing surfaces, the high stresses developed in the joint results in accelerated abrasion and production of further wear particles.

There is also strong evidence to suggest that wear particles cause a biological response to resorb bone around the implant resulting in loosening and eventual failure of the prosthesis.

The problem of wear particles has been addressed in part by an enclosure member for a prosthetic joint described in United States Patent No 4731088 in the name of J.P. Collier. This patent describes a flexible enclosure which is applied to a conventional artificial hip joint to isolate wear particles produced by interengagement between the components of the joint. The Collier solution has the problem of requiring a complicated surgical technique, described in United States Patent No 4822368, requiring 13 steps and involving the fitting of the flexible enclosure over the femoral ball and the acetabular component during the surgical implantation.

OBJECT OF THE INVENTION

One object of the present invention is to provide a sealed modular joint prothesis that prevents wear particles contacting with surrounding tissue.

It is also an object of the present invention to provide a modular joint prothesis which requires a simpler and safer surgical technique for sealed joint replacement than prior known techniques.

It is a further object of the invention to provide a modular joint prothesis in which the articulating components are sealed and delivered sterile to an operating theatre.

It is a still further object of the invention to provide a modular joint prothesis incorporating a secondary bearing to enable the use of less compliant materials for sealing the bearing surfaces.

It is a yet further object of the invention to provide a modular joint prothesis in which wear particles are trapped and restrained from causing secondary wear in the articulating components.

DISCLOSURE OF THE INVENTION

In one form of the invention although it need not be the only or indeed the broadest form there is proposed a sealed bearing module for a modular joint prothesis comprising :
a first modular component having a bearing surface;
a second modular component having a bearing surface;
wherein the bearing surface of the first modular component rotates against the bearing surface of the second modular component thereby forming an artificial joint; and
a resilient sheath enclosing the bearing surfaces of the first and second modular components, said sheath sealing against the first modular component and the second modular component

so as to form a cavity while allowing substantially unrestricted rotation of the first modular component relative to the second modular component.

In preference the modular joint prothesis comprises three components being the sealed bearing module, a first connecting component and a second connecting component wherein the first and second connecting components are adapted to connect to the skeleton adjacent the joint to be replaced and to the sealed bearing module. In preference the connection between the connection components and the sealed bearing module is an interference or snap fit to facilitate easy assembly during surgery.

In preference the sealed bearing module is pre-assembled and delivered sterile to surgery.

In preference the sheath is a resilient polymer sheath formed from non-porous material such as polysiloxane or other similar polymers. Alternatively the sheath material may be semi-permeable with pores in the range 0.1 to 100 micron and preferably less than 1.0 micron.

In preference the sheath includes stiffening rings arranged to form a concertina section. A concertina section assists the resiliency of the polymer sheath to ensure free rotation of the first modular component relative to the second modular component and helps maintain the internal volume of the device.

In preference the sheath incorporates a radio opaque mesh to facilitate x-ray inspection of the sheath for damage.

In preference the first modular component is formed from surgical grade cobalt chrome molybdenum alloy and the second modular component is formed from ultra-high molecular weight polyethylene. Alternatively, one or both components may be formed from ceramic, other metals or other polymers.

In an alternative form of the invention a rotatable bearing is incorporated between the sheath and either the first or second modular component. The bearing reduces the resiliency requirements of the sheath by providing a rotational degree of freedom between the first and second modular components. This additional bearing facilitates the use of a much wider range of materials for the sheath.

In preference the sealed bearing module includes a wear particle collection chamber adapted to collect and trap wear particles. The chamber preferably comprises a slot filled with a porous, particle retaining ceramic.

BRIEF DESCRIPTION OF THE DRAWINGS

To further assist in understanding the invention reference will be made to the following drawings in which :

FIG 1   shows an exploded view of a sealed modular hip replacement joint;

5   FIG 2   shows a cross-sectional view of a first embodiment of a sealed bearing module;

FIG 3   shows a cross-sectional view of a second embodiment of a sealed bearing module incorporating a sheath rotating bearing.

DETAILED DESCRIPTION OF THE DRAWINGS

10   Referring now to the drawings in detail there is shown in FIG 1 a prosthetic hip comprising a sealed bearing module 1, femoral component 2 and acetabular component 3. During surgical implantation the acetabular component is attached to the pelvis by screws, cement or other means. Some shaping of the pelvis may be required.

The head of the femur is excised and the stem 20 of the femoral component 2 is secured to
15   the femur by insertion into the medullary canal. The femoral component 2 also includes a neck 21 and spigot 22 which is adapted for an interference fit into a corresponding socket 10 in the sealed bearing module 1. The acetabular component 3 and the femoral component 2 are conventional components typically formed from cobalt chrome molybdenum alloy.

The sealed bearing module 1 comprises a modular head 4 with a bearing surface 5 adapted to
20   rotate with a minimum of friction against a corresponding bearing surface 6 of a modular cup 7. The modular head 4 is typically made from cobalt chrome molybdenum alloy and the modular cup 7 is typically formed from ultra-high molecular weight polyetyhlene. Other materials such as ceramic, other metals or other polymers could be used for one or both of the modular components.

25   Enclosing the bearing surfaces 5 and 6 of the modular components 4 and 7 is a resilient polymer sheath 8 which seals against the modular cup 4 and the modular head 7. In one preferred form there are lips moulded in the modular cup such as depicted by 9 in FIG 2 and in the modular head such as depicted by 11. A diameter of the sheath 8 at a larger end 12 is somewhat smaller than the diameter of the lip 9 of the modular cup 7 and the sheath is
30   therefore retained on the cup. Similarly, a diameter of a lower end 13 of the sheath 8 is smaller than the diameter of the lip 11 and the sheath is constrained upon the ball 4.

The resiliency of the sheath 8 allows it to be stretched during assembly of the sealed bearing module to facilitate positioning the larger end 12 of the sheath 8 over the lip 9 of the modular

cup 7. The resiliency of the sheath also allows freedom of movement of the ball relative to the cup while maintaining an effective seal. Stiffening rings may be incorporated into the sheath to maintain internal volume when under load from surrounding tissue. Alternatively, the sheath may be moulded to incorporate ridges equally performing this function.

5   The sheath 8 is shown as a linear structure extending between the lip 9 of the modular cup 7 and the lip 11 of the modular head 4. To aid in the pliability of the sheath the stiffening rings may be arranged to form a concertina section. Other embodiments of the sheath 8 which satisfy the requirement of enclosing the bearing surfaces will be evident to persons skilled in mechanical engineering.

10   A sheath formed from silicone rubber or other polymeric material will be invisible to x-rays and will not inhibit x-ray inspection of the joint. However, x-ray inspection will not be able to identify any damage to the sheath such as a tear. To facilitate x-ray inspection of the integrity of the sheath a radio opaque mesh may be incorporated in the sheath. The mesh could be formed from filaments of metal such as stainless steel.

15   The sheath 8 may be formed from non-porous material such as a medical grade polysiloxane although any material that is sufficiently resilient to permit free rotation of the ball 4 in the cup 7 would be suitable. If a non-porous material is used the cavity 14 formed by the sheath could be filled with a lubricating fluid such as saline or other lubricating material. Alternatively, the sheath 8 could be formed from a semi-permeable material which would
20   allow natural body fluids to permeate the joint and lubricate the bearing surfaces.

An advantage of the sealed bearing module is that it can be assembled in sterile conditions and delivered sterile to surgery. Surgical procedures are simplified because the acetabular component 3 and femoral component 2 can be implanted as per normal then the sealed bearing module simply put in place to complete the procedure. The time required to complete
25   the procedure is reduced since there is no need to assemble the module during the procedure.

A second embodiment of the sealed bearing module is shown in FIG 3. In this case the larger end 12 of the sheath 8 is connected to the modular cup 7 by a bearing 15. An inner portion 16 of the bearing 15 is attached by suitable means to the modular cup 7 and the sheath 8 is attached to an outer portion 17 of the bearing 15. In this embodiment the bearing
30   15 provides rotational freedom around the cup and the resiliency of the sheath provides bending freedom. This embodiment reduces the mechanical stress on the sheath but increases the complexity of the module. Since the module is pre-assembled the increased complexity does not translate to increased surgery time. Furthermore, as the bearing 15 is within the cavity 14 the wear particles which the bearing 15 will produce will be retained
35   within the cavity.

Wear particles formed in the sealed bearing module will fall to the lowest point of the cavity under the influence of gravity however agitation could cause particles to move around the cavity and become interposed between the bearing surfaces 5 and 6. In a further embodiment a wear particle collection chamber is incorporated in the modular joint to minimise this

5   possibility. In one form the chamber comprises an annular slot formed in the lip 11 and filled with a porous ceramic or similar material. Wear particles are trapped within the pores of the ceramic and the number of wear particles in the cavity is therefore reduced. Alternative forms of the chamber providing greater or lesser degrees of particle retention can also be used.

The modular joint prothesis has been described above in terms of its application to hip

10   replacement. The invention is not limited to hip joints and can be embodied as a shoulder, knee, elbow or other joint. In each case a sealed bearing module is provided which mitigates the effect of wear particles thereby reducing the incidence of joint failure. Surgical implantation techniques are also simplified because the sealed bearing module is pre-assembled and delivered sterile to surgery.

15   The description of the preferred embodiments is by way of illustration only and is not meant to be limiting on the scope or implementation of the invention. Other embodiments will be evident to those skilled in the relevant art without departing from the spirit of the invention.

Dated this   23rd day of March 1995

20

LUMINIS PTY LTD
By their Patent Attorneys
A.P.T.
Patent and Trade Mark Attorneys

APPENDIX 2 - CONTRACTS

STUDENT PROJECT PARTICIPATION AGREEMENT

THIS AGREEMENT made the   *Tenth*   day of *January* 19 *94* .

BETWEEN:

THE UNIVERSITY OF ADELAIDE, a body corporate established pursuant to The University of Adelaide Act 1935 (hereinafter called "the University") of the one part

AND: Mr Namal NAWANA

of   27 Moorhouse Avenue
       MYRTLE BANK   SA   5064

(hereinafter called "the Student") of the other part.

WHEREAS:

A.   The University, in its Department of   Surgery   , conducts studies, research and development in connection with a project entitled

     Design of a Sealed Artificial Hip Joint

     which project is acknowledged by the Parties to comprise work which has potential commercial value to the University (hereinafter called "the Project").

B.   The Student, being a student in the said University Department, desires to participate in the Project.

NOW THEREFORE in consideration of the covenants hereinafter set forth, the University and Student agree as follows:

1.   In this agreement, the term "Intellectual Property" includes:

     (a)   patentable and non-patentable inventions;

     (b)   designs;

     (c)   trade marks;

     (d)   works subject to copyright (including written or audio-visual material and computer software but excluding the Student's thesis);

     (e)   trade secrets relating to know-how and preliminary arrangements for commercial development;

     (f)   proprietary rights granted under the Plant Variety Rights Act and the Circuits Layouts Act subject to any special policy developed with respect to such rights;

10. In the event that the Student is an originator or inventor of intellectual property arising from the Project, the University will agree to share the benefits derived from commercial applications of the said intellectual property with the Student, in the manner described in The University of Adelaide Handbook of Administrative Procedures, Sub-section 10.13, Para. 8.

11. The obligations hereunder shall survive the termination of the Project.

SIGNED for and on behalf of)

THE UNIVERSITY OF ADELAIDE)
_____

on the *tenth* day of *January 1994*)   (Mrs E Tobin
Registrar, Graduate Studies

in the presence of:)

R M SCARCELLA
_____   _____
(Name of witness)   (Signature of witness)

SIGNED by THE STUDENT)

on the *Tenth* day)

of *January* , *1994*)

in the presence of

M. J. Pearcy
_____   _____
(Name of witness)   (Signature of witness)

Grad. St/31 October 1991

<u>DISCLOSURE AGREEMENT</u>

DISCLOSURE AGREEMENT BETWEEN DEPUY AUSTRALIA PTY LIMITED of 11-13 Palmer Court, Mt Waverley, Victoria 3149, Australia (Hereinafter referred to as "DEPUY")

AND LUMINIS PTY LIMITED of 10-20 Pulteney Street, Adelaide, South Australia 5000, Australia (Hereinafter referred to as the "UNDERSIGNED").

This Agreement is made the TWENTY SIXTH day of MAY 1994, by and between the UNDERSIGNED AND DEPUY.

WHEREAS, the UNDERSIGNED has certain technical information relating to the written subject matter described as Sealed Modular Joint Replacement (hereinafter referred to as the "INFORMATION"); and

WHEREAS, DEPUY is engaged in extensive research activities relating to medical devices which activities may already, or during the normal course of research and development, involve the INFORMATION; and

WHEREAS, the UNDERSIGNED is desirous of disclosing said INFORMATION to DEPUY for evaluation; and

WHEREAS, DEPUY is interested in examining the INFORMATION in order to determine the desirability of acquiring rights in and to the INFORMATION and under any patent or design rights obtained therefor;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

I. The UNDERSIGNED shall disclose the INFORMATION to DEPUY in writing and in sufficient detail to enable DEPUY to fully evaluate and document such disclosure. A copy of any patent application(s) which has been prepared relating to the INFORMATION any correspondence issued by any Patent Office in connection therewith shall also be supplied as part of this disclosure.

II. DEPUY agrees to accept the disclosure of the INFORMATION and treat the INFORMATION with the same degree of care to avoid disclosure as DEPUY employs with respect to its own information of like importance which it does not desire to have published or disseminated, DEPUY shall not be liable for any unauthorised disclosure unless it fails to safeguard the INFORMATION with such care.

III. The acceptance of the INFORMATION by DEPUY shall not give it the right to use the INFORMATION other than for evaluation purposes until or unless a formal written contract is entered into providing the terms and conditions of such use. The evaluation of the INFORMATION by DEPUY may include subjecting it to tests, analyses, experiments or clinical studies as are warranted and may include the disclosure of the INFORMATION to DEPUY employees, lawyers, investigators, consultants, and to affiliated companies of DEPUY.

IV. The obligation of DEPUY under Article II and III shall extend for a period of two (2) years from the date of this Agreement but shall not extend to all or any part of the INFORMATION:

(a) which is in the public domain or publicly known or available prior to the date of disclosure; or

(b) which can be demonstrated to have been in the possession of DEPUY or its affiliate(s) or available to DEPUY or its affiliate(s) from another source prior to disclosure; or

(c) which become part of the public domain or publicly known or available by publication or otherwise, not due to any unauthorised act or omission on the part of DEPUY; or

(d) which is rightfully received by DEPUY from a third party; or

(e) which DEPUY or its affiliates derive independently of such disclosure; or

(f) which is approved for release by written authorisation of the UNDERSIGNED.

V. If no further agreement with the UNDERSIGNED is reached concerning the INFORMATION and the two (2) year period in Article IV has expired, each party shall be relieved from all obligations under this Agreement and the UNDERSIGNED will rely on such patents as the UNDERSIGNED then owns for the protection of the INFORMATION.

VI. The UNDERSIGNED represents and warrants that it is the owner of and/or has the full right and authority to (i) disclose the INFORMATION to DEPUY and (ii) sell, assign, license or transfer

all rights in the INFORMATION to DEPUY. Further, the UNDERSIGNED warrants there have been no sales, assignment, license or transfer to any person, firm or corporation which would be inconsistent with the grant of exclusive rights to DEPUY nor other act which has allowed the INFORMATION to be dedicated to the public.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

SIGNED by A HALSALL

for and on behalf of

DEPUY AUSTRALIA PTY LTD

in the presence of G BOOTHMAN

SIGNED by P R HART

for and on behalf of

LUMINIS PTY LTD

in the presence of N NAWANA

Ref: AH/jbv/Agreement/2