University of Southern Queensland

Faculty of Health, Engineering and Sciences

INVESTIGATION IN FAILURE ANALYSIS AND MATERIALS SELECTION IN TOTAL HIP REPLACEMENT PROSTHESIS

A dissertation submitted by

Liem Nguyen

in fulfilment of the requirements of

Courses ENG4111 and ENG4112 Research Project

towards the degree of

Bachelor of Mechanical Engineering

Date: 30 October 2014

Abstract

In the prostheses technology, the development of hip joint materials for hip replacement in human body is probably one of the most challenging problems. Even the history of hip arthroplasty is over 100 years; we still have encountered enormous challenge, mainly deal with the quality of the prosthetic materials. Many different material experiments and surgical approaches have been taken around the world to improve the performance of the prosthesis.

The purpose of this document is to investigate the failure of the hip replacement and the total hip replacement in particular. It also provides the failure analysis and methodology as well as exploring the design specification and material selections of human hip replacement prosthesis.

Keywords: Total Hip Replacement, Total Hip Replacement Prosthesis, Hip Replacement Failure Analysis, Hip Arthroplasty, Hip Implant, Hip Implant Materials Selection, Cemented Implant, Cementless Implant.

University of Southern Queensland

Faculty of Health, Engineering and Sciences

ENG4111/ENG4112 Research Project

Limitations of Use

The Council of the University of Southern Queensland, its Faculty of Health, Engineering & Sciences, and the staff of the University of Southern Queensland, do not accept any responsibility for the truth, accuracy or completeness of material contained within or associated with this dissertation.

Persons using all or any part of this material do so at their own risk, and not at the risk of the Council of the University of Southern Queensland, its Faculty of Health, Engineering & Sciences or the staff of the University of Southern Queensland.

This dissertation reports an educational exercise and has no purpose or validity beyond this exercise. The sole purpose of the course pair entitled “Research Project” is to contribute to the overall education within the student’s chosen degree program. This document, the associated hardware, software, drawings, and other material set out in the associated appendices should not be used for any other purpose: if they are so used, it is entirely at the risk of the user.

University of Southern Queensland

Faculty of Health, Engineering and Sciences

ENG4111/ENG4112 Research Project

Certification of Dissertation

I certify that the ideas, designs and experimental work, results, analyses and conclusions set out in this dissertation are entirely my own effort, except where otherwise indicated and acknowledged.

I further certify that the work is original and has not been previously submitted for assessment in any other course or institution, except where specifically stated.

Liem Nguyen

0061017424

Signed: _____

Dated: _____

Acknowledgements

I would like to express my gratitude and appreciation to the following people:

- Dr Steven Goh, Senior Lecturer at University of Southern Queensland, also my supervisor, who has been giving me tremendous support, ideas, advices and guidance that I need to complete my project.
- My dad, Nguyen Van Thai and my mom, Tran Thi Chinh, for all the love and support that I need during my journey in Australia as an oversea student. They never stop loving and supporting me, during the tough times when I cannot figure out how to support myself and afford my education tuition in university.
- My uncle, Trieu Ho and my aunty, Hoanh Nguyen, for providing me all the basic living and care while I stay in Australia.
- All my lecturers during my four years study in University of Southern Queensland for teaching me not only professional skills which I need for my career but also life skills.
- All my friends whom I have met along the way.

Table of Contents

List of figures

List of tables

Chapter 1- Introduction

1.1 Background

Hip replacement is also known as hip arthroplasty is a surgical procedure where the human hip joint is replaced by a prosthetic implant. The purpose of replacing hip joint is to help relieve physical pain and fix the severe damage of the hip as well as increase mobility for the patients.

Hip replacement was first performed in 1960, and is considered to be one of the most successful operations in the medical industry. A large number of Total hip replacements have been performed around the world. According to the Agency for Healthcare Research and Quality, more than 285,000 total hip replacements are performed each year in the United States (AAOS, 2011)

Over the years, the surgeons and technologists make daily efforts to improve the quality as well as the efficiency of the total hip replacement outcome. The ultimate goal is to create a hip prosthesis that is reliable and can last at least a human life time. The success rate of total hip replacement is reported to be greater than 95% in many series and a longer than 10-year follow-up. (Ulrich et al. 2007) An increasing number of patients who are undergoing total hip replacement are expected to maintain a high level of activity as well as the life expectancy has increased which lead to the rising demand of these arthroplasties. With these reasons, the number of revision procedures for total hip replacement is expected to be higher in the future even the primary operation success rate is high.

1.2 The Problem

Total hip replacement (THR) surgery helps relieve the pain and improve mobility for the patients. Most people who have their hip joint replaced do not need more surgery. However, there are still some cases where patients are required revision surgery.

Total hip replacement revision can be a financial burden for patients as well as the heath care. It is also less favourable than the primary total hip replacement. There are a few reasons why the THR fail and this can be classified into three groups: patient-related factors, implant-related factors and failures related to inadequate surgical technique (Ulrich et al. 2007).

There are many complications associates with THR. The most common problem of THR is hip instability dislocation. This is because artificial-hip is smaller than normal hips. Depending on the patient's certain position, for instance, pulling the knees up to the chest can cause the ball come out of the socket (NIAMS 2010). Some other failures are component loosening, infection, wear and tear and periprosthetic fractures.

More details of failure analysis and material selection will be provided in chapter 2, 3 and 4 of this document.

1.3 Project Objectives

There are two main needs for this project:

- Failure analysis of the prosthesis
- Material selection for prosthesis parts

The failure analysis will describe the failure modes of the prosthesis. Each part of the implant component will be examine carefully to see where the part might fail and what can be modified to improve the quality of each part. This leads to the need of understanding the right material selection used for each part of the component by comprehending the main function of each part and what kind of force applied on the parts that lead to failure. Finally, a conceptual design will be introduced and backed up with some research and analysis.

1.4 Overview of the Project

This dissertation aims to provide the reader an understanding of what total hip replacement is, the failures and materials related to total hip replacement and what methodology for failure analysis and materials selection should be used.

Chapter 1 will basically provide the introduction of total hip replacement, the background, the current problem with THR in the world, the objective of this project and the overview.

Chapter 2 will provide more in details with literature reviews of the biology as well as the biomechanical of hip joint. Different types of parts and implant insertion will also be provided. The failure modes and material selection criteria will also be mentioned.

Chapter 3 will provide the methodology for failure analysis, risk assessment and some other calculation that relates to the topic.

Chapter 4 will provide the material selection. Explanation on why certain material is used for certain part will be included in this chapter.

Chapter 5 will be discussion on the content that has been covered and recommendation and further studies need to be taken.

Chapter 6 will be a concise summary of this document.

Chapter 2 – Literature Review

2.1 Overview

This chapter of literature review will establish the need to fully understand the structure of hip joint. Every part of the hip joint is studied in details about their structure and how they function. By understanding the structure and function of hip joint, the performance of the hip prosthesis will be analysed and compared to find out which part of the prosthesis perform well, which part needs to be improved and where on the prosthesis is more likely to fail.

Moreover, this literature review will help gain the understanding about the hip joint and prosthesis to decide which materials will be used to make the prosthesis based on the nature of human hip joint and the human body environment.

2.2 Theory behind Human Hip Joint

2.2.1 Human Hip Joint Structure

Hip joint is one of the human body's largest joints. It has a ball and socket structure.

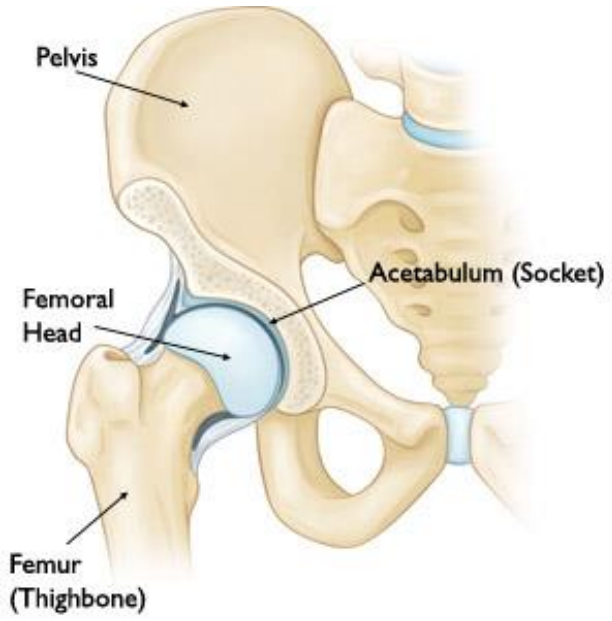


Figure 2.2.1: Human Hip Joint Anatomy (source: AAOS 2011)

Figure 2.2.1 above shows the structure of human hip joint. The socket is formed by the acetabulum which is a part of the pelvis bone on the top. The ball is the femoral head which is located on the top end of the femur (thigh bone).

To move smoothly and easily the ball and the socket are covered by a smooth tissue called the articular cartilage, which is located at the connection between the ball and the socket. Surrounding the hip joint is a thin tissue called synovial membrane. In a healthy hip, this membrane produces small amount of fluid that lubricates the cartilage and reduces almost all the friction create during the movement. The ligaments or the hip capsule is a group of tissues which connect the ball to the socket to provide stability.

2.2.2 Biomechanics of the Hip Joint

McGeough (2013) stated that the hip undergoes cyclic loading that is three to five times that of the weight of the body. It also has to withstand loads as high as 12 times the body weight.

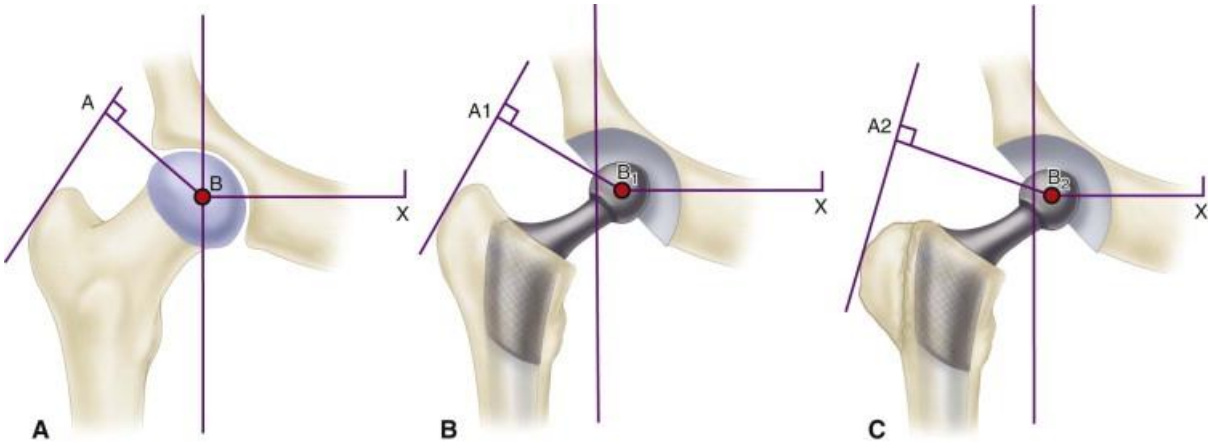


Figure 2.2.2: Forces acting on the hip (Harkess and Crockarell 2013)

In order to describe and understand the forces acting on the hip joint, the body weight can be considered as a load applied to a lever arm extending from the centre of gravity (X) of the body to the centre (B) of the femoral head. From figure 2.2.2 it can be seen that the moment created by the body weight acting on lever arm BX has to be counter-balanced by the moment caused by the abductor musculature acting on the shorter lever arm AB. The lever arm AB is extended from the centre of the femoral head to the lateral aspect of the greater trochanter. The three variations A, B and C in figure 2.2.2 above show the different lengths of lever arm AB and BX. Case A is a normal human hip joint. The lever arm AB might be shorter than normal in an arthritic hip. In case B, the acetabulum medicalization shortens the lever arm BX. The lever arm A1B1 is lengthened by the use of high offset neck. In case C, the lever arm A2B2 is lengthened further and the abductor musculature is also tightened by the lateral and distal reattachment of osteotomized greater trochanter (Harkess and Crockarell 2013).

To maintain the pelvis level when standing on one leg the force generated from the abductor muscles must be approximately 2.5 times the body weight because the ratio of the length of the lever arm BX to AB is about 2.5: 1. Harkess and Crockarell (2013) stated that the load on the femoral head in a stance phase of gait is estimated

to be three times the body weight which is about the same in straight-leg raising situation. This load is the sum of forces created by the body weight and the abductor.

In arthritis and other hip disorders where the femoral neck is shortened or part or all of the femoral head is lost, the abductor lever arm is also shortened. In an arthritic hip, the ratio of the lever arm of the body weight to that of the abductors (BX to AB) could be up to 4: 1. This ratio can be surgically changed to approach 1:1 (in figure 2.2.2 C) by reattaching the osteotomized greater trochanter laterally (Harkess and Crockarell 2013). This will reduce the moment produced by the body weight and in theory will reduce the total load on the hip by 30%.

Paul (cited in McGeough 2013) found the maximum force acting on the hip as in the table 1 below:

Table 2.2.2: Maximum force at hip (expressed as a multiple of body weight) (McGeough 2013)

Activity	Hip
• Level walking slow • Level walking normal • Level walking fast • Upstairs • Downstairs • Up ramp • Down ramp	• 5 • 5 • 8 • 7 • 7 • 6 • 5

Understanding the biomechanical forces on the hip helps the design process and increases the sustainability of the prosthesis. When knowing the maximum forces that can apply on certain part of the prosthesis, the design and manufacturing processes can be a lot easier. With this, the prosthesis quality can be increased and the failure rate will be reduced.

Depending on the type of action and the body weight condition of the patients, the force can apply differently. One of the cases where the hip is subjected to the high amount of load is the condition of jumping. In this case, the load can be about ten times that of the body weight. The torsional force acting on the hip can be increased when combining other actions such as ascending or descending stairs, moving on an incline surface or sit up from the chair, as well as when carrying heavy things.

This comes to the conclusion that the forces acting on the femoral component adjacent to the hip can be increased by the increase of physical activity and the body

weight. These increasing forces can lead to loosening, bending or even breaking of the femoral stem. More of the failure modes and analysis will be found in the next chapter of this document.

2.2.3 Common Causes of Hip Pain

The main reason why people have their hip replaced is because of the severe hip pain that they cannot carry any longer. The most common cause of chronic hip pain is arthritis. The common forms of arthritis are: osteoarthritis, rheumatoid arthritis, and traumatic arthritis (AAOS, 2011). Below is the picture of a hip with osteoarthritis.

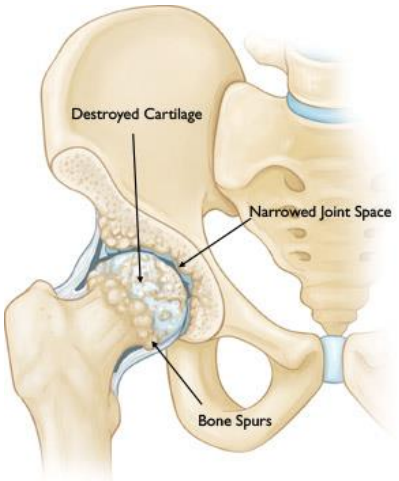


Figure 2.2.3: Hip joint with osteoarthritis (AAOS 2011)

It can be seen that with osteoarthritis, the hip joint is damaged. The cartilage is destroyed as well as the joint space is narrowed. The bone spurs as seen in figure 2.2.3 above.

AAOS 2011 reported the common types of arthritis as below:

- Osteoarthritis. It is common for people who are 50 years of age and older. This is an age-related "wear and tear" type of arthritis and often in individuals with a family history of arthritis. The cartilage wears away which causes the bones to rub against each other and lead to pain and stiffness of the hip joint.
- Rheumatoid arthritis. The symptom of this disease is that the synovial membrane becomes inflamed and thickened. This is an autoimmune disease. The cartilage is damaged by chronic inflammation and this also leads to pain and stiffness.

- Post-traumatic arthritis. This type of arthritis can follow a serious hip injury or fracture.
- Avascular necrosis. This causes destruction of the joint articular surfaces due to limiting the blood supply to the femoral head and can cause the surface of the bone to collapse.
- Childhood hip disease. Even the problem occurs when the patients are young and successfully treated during childhood; they may still cause arthritis later on in life. The reason is because the hip may not grow normally which can affect the joint surface.

It can be understood that all types of hip arthritis above cause the cartilage damaged and lead to pain and stiffness of the hip joint. To relieve the pain and increase mobility for the patients, total hip replacement is introduced.

2.3 What Is Total Hip Replacement (THR)

2.3.1 Background of Total Hip Replacement and THR Prosthesis

Total hip replacement, also known as total hip arthroplasty is a surgical procedure where the damaged bones and cartilage of the hip are removed and replaced with prosthetic components.

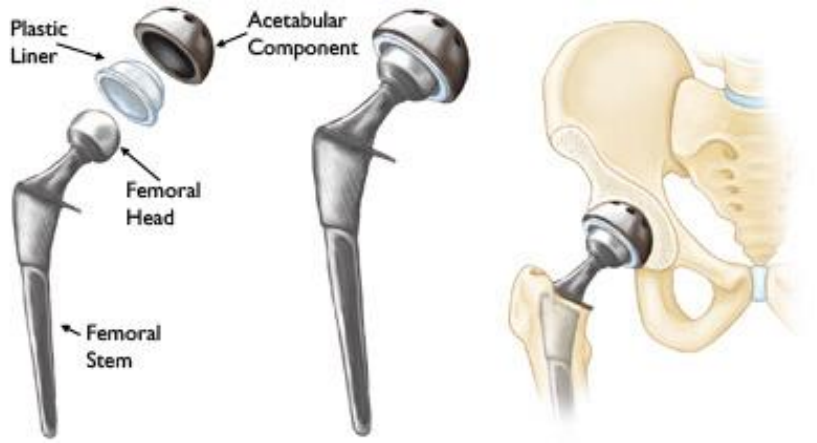


Figure 2.3.1: Total Hip Replacement. (Left) individual component; (Centre) the components merged into an implant; (Right) the implant fits into human hip. (AAOS 2011)

Figure 2.3.1 above illustrates the components of common total hip replacement prosthesis and how it fits into the hip joint. The picture of the left shows the individual component. It consists of the femoral stem, femoral head, plastic liner, and the acetabular component. The picture in the centre shows the implant when all parts merged together. The picture on the right shows how the implant fits into the human body to replace the hip joint.

The procedure of a hip replacement is very complex. First, the damaged femoral head is removed and replaced with the femoral stem that is placed into the hollow centre of the femur (thigh bone). The femoral stem is either cemented or press fit into the bone. This process needs to be deliberately done because if the femoral stem is not attached into the femur carefully, it can cause fracture along the thigh bone.

Depending on the material of the prosthesis, a metal or ceramic ball will be placed on the top of the femoral stem to replace the damaged femoral head which was removed. Next, the damaged cartilage surface of the socket (or the acetabulum of

the pelvis bone) is removed and replaced with a metal socket. The socket is held in place by screwing or cementing it into the pelvis bone.

Lastly, a plastic, ceramic or metal spacer is placed between the new femoral head (ball) and the socket to create a smooth gliding between the ball-and-socket structures. This allows the prosthesis move freely as the human hip.

2.3.2 Types of Bearing Surface Combination in Total Hip Replacement

When performing a total hip replacement, one important decision the surgeon will make is which bearing type will be used. The bearing part is an extremely important area which allows two moving part of the THR prosthesis (femoral head an acelabular cup) join together to create a movable hip joint.

The assembly between the femoral head and the acetabulum can vary according to the combination of the different pairs of biomaterials that are used in the manufacturing process. The material options for bearing is based on many variables such as patients age, life style, weight, needs, etc.. Each pair of material has different benefits and drawbacks.

There are four types of bearing surface combinations that are used as replacement for the hip acetabular femoral component. These types are classified by the materials used for the bearing components. They are Metal-on-Polyethylene, Metal-on-Metal, Ceramic-on-Polyethylene, and Ceramic-on-Ceramic (Rodríguez-González 2009). These types can also be narrowed down into two classifications: hard-on-soft bearings and hard-on-hard bearings. The soft bearing is always towards the acetabular component.

The most common pair is Metal-on-Polyethylene but recently metal-on-metal has been used frequently. To achieve high precision when fitting, it is recommended that the proximal femoral components and the acetabular heads should come from the same manufacturer to ensure the exact dimensions. The longevity of the implant is affected by the biological response to particles of wear when in all cases of pairs of assemblies between the femoral head and the acetabulum.

2.3.2.1 Metal-on-Metal (MoM) Bearings

The first widely used MoM THR bearings were cobalt-chromium alloy bearing against itself. This had a very high relative rate of failure and was then replaced by the Charnley prosthesis which consisted of a stainless steel ball and a polyethylene socket (Hosseinzadeh, Eajazi, and Shahi 2012).

Since the femoral head is relatively large, the metal bearings are made in many sizes between 28mm to 60 mm. The large head provides more stability and higher range of motion as well as reduce the risk of hip dislocation (BoneSmart n.d.). The metal-on-metal (MoM) hip bearings produce wear debris in one form or combination of the four basic wear mechanisms of adhesion, abrasion, corrosion and surface fatigue (Wimmer et al. 2003). Even wear is reduced in MoM bearings; it is still a biocompatibility problem. Various adverse local tissue reactions such as pain, solid mass formation and periarticular fluid accumulation have been reported to be related to wear debris and corrosion products of MoM bearings (Harkess and Crockarell 2013). Low-carbon alloys should not be used in MoM bearings because it has six times greater volumetric wear rate than high-carbon alloys (Brown et al. cited in Ahn et al. 2009).

2.3.2.2 Ceramic-on-Ceramic (CoC) Bearings

The CoC type of bearing is recommended for active or relatively young patients. Ceramic is harder than metal and has smoother surface due to its high density. It is more resistant to scratching from wear particles and this makes it desirable for THR bearings. BoneSmart (n.d.) reported that ceramic has the lowest wear rate of all and is 1000 times less than metal-on-polyethylene. Fisher et al. (cited in Ahn et al. 2009) reported that volumetric wear rates of CoC bearings have been as low as 0.1 mm^3/million cycles and this type of bearing outperforms other bearings.

2.3.2.3 Metal-on-Polyethylene (MoP) Bearings

This type of bearing for THR is commonly used in United States. It has a metal femoral head which is either made by stainless steel or cobalt alloys and a polyethylene (plastic) acetabular cup. The benefits of this include durable, versatile and adequate toughness for most patients. Some limits of this bearing type can be wearing over time which leads to bone loss and hip revision.

2.3.2.4 Ceramic-on-Polyethylene (CoP) Bearings

CoP bearings has ceramic as the material of the femoral head and polyethylene as the material for acetabular cup. Ceramic-on-UHMWPE (Ultra high molecular weight polyethylene) creates a good combination of reliable materials where ceramic femoral heads are the most scratch-resistant material for implant. BoneSmart (n.d.) reported CoP bearings have 50% less wear rates than MoP.

2.4 Types of THR Implant Insertion

Depending on the type of fixation used to hold the implant in place, there are three common ways to fit the implant into the body. They are: cemented, cementless or hybrid (which is a combination of both cemented and cementless components) (Earl's View 2011).

2.4.1 Cemented Total Hip Replacement

In the last 40 years, there have been many studies on the methods and the materials used to hold the femoral head and the acetabular components in place. The most common bone cement used today is polymethylmethacrylate (PMMA). PMMA is an acrylic polymer. Cemented fixation method relies on the stability of the interface between the prosthesis, the cement and the solid mechanical bond between the cement and the bone.

The benefit of using cemented method is that the patients can walk without support immediately after surgery. Even though the cemented implants have a long track record of success, they are not recommended for everyone. The bond between cement and bone is very reliable and durable generally. This cemented method is recommended for older people because they are less likely to put tresses on the cement that could lead to fatigue fractures (Earl's View 2011).

2.4.1.1 Cemented Femoral Components

For femoral components with cemented fixation, acrylic cement becomes the standard (Harkess and Crockarell 2013). The cemented stem is placed in a neutral position within the canal to reduce the chance of thin cement mantle areas. The stem design needs to have various sizes available. The reason for this is to allow the stem to take up approximately 80% of the medullary canal cross sectional area. The optimal cement mantle is 4mm proximally and 2mm distally. The method used to create more uniform cement mantle and centralize the stem within the femoral canal is applying PMMA centralizers that are affixed to proximal or distal of the stem (see figure 2.4.1.1 below).

Figure 2.4.1.1: Integral proximal PMMA spacers and additional centralizer facilitate proper stem position and uniform cement mantle. (Harkess and Crockarell 2013)

The length of the stem depends on the femoral canal geometry and size. The materials used to manufacture cemented femoral components will be discussed in great details in chapter 4.

2.4.1.2 Cemented Acetabular Components

The acetabular socket for cemented fixation method originally used thick-walled polyethylene cups. The external surface was grooved to increase stability within the cement mantle. Figure 2.4.1.2 shows a typical type of cemented acetabular component that use polymethyl methacrylate spacers and textured surface to optimize the prosthesis and cement mantle interface.

Figure 2.4.1.2: Acetabular component designed for cement fixation (Harkess and Crockarell 2013).

Harkess and Crockarell (2013) said there has not been substantial improvement on long-term survivorship of cemented acetabular components and therefore cementless fixation starts to be promoted to be used for most patients.

2.4.2 Cementless Total Hip Replacement

Fixation problems of femoral components with acrylic cement started to emerge in the mid-1970s which led to the introduction of cementless components. Biological fixation requires two important factors, which are the reliable intimate contact between the implant surface and the host bone and the immediate mechanical stability during surgery.

The concept of bone ingrowth and osseointegration are widely used in cementless implant fixation method. Osseointegration (also called osteointegration) refers to the intimate contact of the bone tissues with the surface of an implant. The term bone ingrowth refers to the formation of bone within the porous surface structure of an implant (figure 2.4.2)

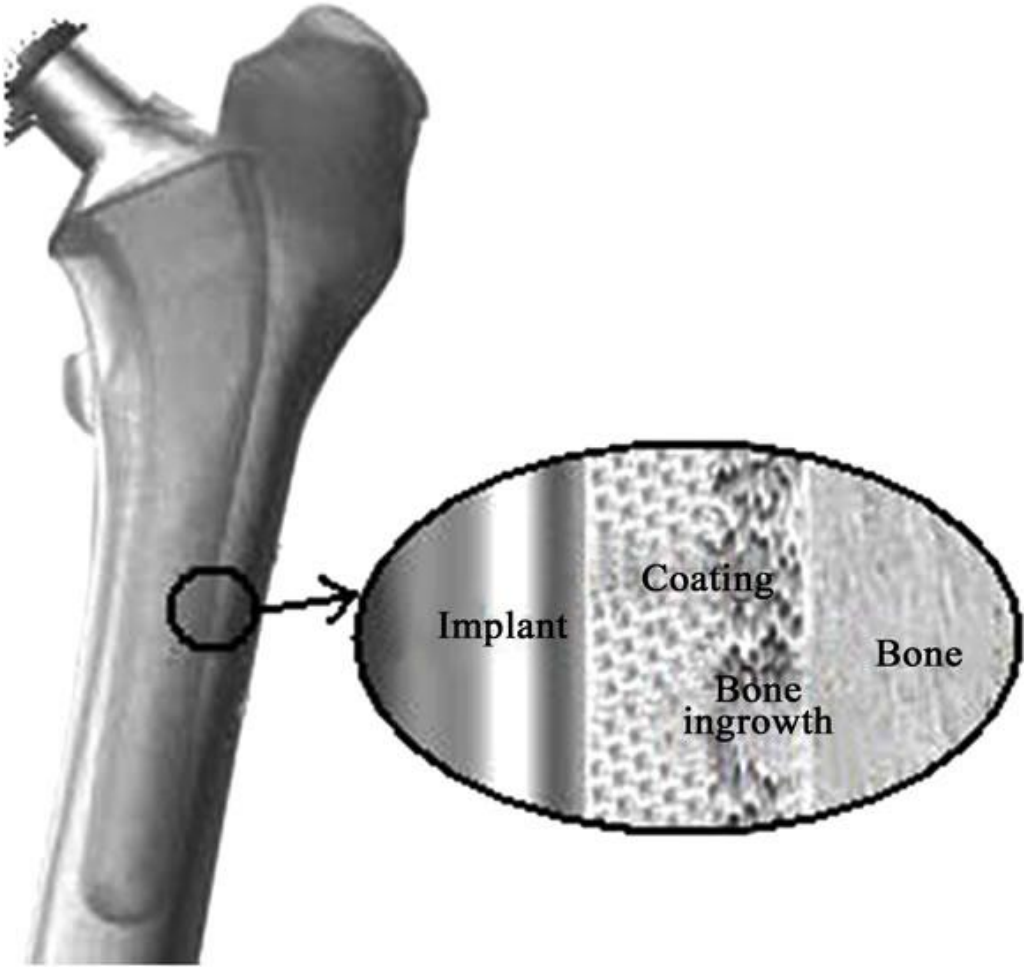


Figure 2.4.2: A bone ingrowth is observed in the coated zones of the stem increasing the stiffness of the bone/ stem interface (Andrade-Campos , Ramos and Simões 2012)

2.4.2.1 Cementless Femoral Components

The implant designs for the cementless method are larger and longer than those used with cement. The surface of these implants should be conducive to attract new bone growth. In order to allow the new bone actually grows into the surface of the implants, the surface has to be textured or have a surface coating. The durable fixation for cementless stem designs is dependent on the bone ingrowth into the porous coating.

Porous coatings have been created by either fibre mesh or beads which are implied by diffusion or sintering bonding process. The fatigue strength of the implant may be reduced because these two bonding processes require heating of the underlying substrate. The pore size of between 100 and 400 μm is considered to be the optimum for bone ingrowth into a porous surface (Harkess and Crockarell 2013). So far porous coatings have demonstrated durable fixation for many cementless stem designs. For example, femoral stem and acetabular component designs use tantalum and other high porous metals for cementless fixation because they may improve the initial stability of the implant due to their high coefficient of friction against cancellous bone. Porous tantalum implant surface has been reported to have extensive and rapid bone growth.

For cementless femoral components, the femur must be prepared to match precisely the stem that is to be inserted and the implant design must be so accurate and professional so that the implant components are able to fit as closely as possible inside the femoral endosteal cavity. To enhance implant fixation, many designs of cementless femoral component have been used combinations of various types of surface modification such as hydroxyapatite coating, porous coatings, plasma spraying and grit blasting (Harkess and Crockarell 2013). The coating type and extent is controversial but it is agreed that the proximal boundary should be circumferential. Furthermore, the circumferential porous coating of the proximal aspect of the stem limits the osteolysis development in the early stage and creates an affective barrier to the ingress of particles.

The cementless method requires a longer time to heal than the cemented method, mainly because the stability of the cementless method depends on the growth of new bone to make it firm. When performing the cementless method, a very precise

approach must be taken so that the implant channel must match the shape of the implant itself as close as possible. If the gap between the implant and the channel is larger than 1mm to 2mm, the new bone growth cannot bridge this gap. Berry and Lieberman (2012) mentioned that gaps which are greater than 2mm are not compatible with bone formation.

Figure 2.4.2.1: Troy Press-fit / HA Coated Cementless Femoral Stem (Covision Orthopaedics 2012)

Figure 2.4.2.1 shows a press-fit hydroxyapatite (HA) coated cementless femoral stem. This particular femoral stem uses cast titanium as the primary material. More analysis on materials selection for femoral stems will be provided in chapter 4.

Cementless THR is usually recommended for younger patients who are more active and have good bone quality where new bone growth can be predictably achieved. Compared with cemented implants, surgeons need to be more precise when applying the surgical techniques and instrumentation as well as choosing the suitable type and size of implant.

2.4.2.2 Cementless Acetabular Components

Most cementless acetabular components use porous coating to encourage bone ingrowth which provides stability overtime for cementless fixation method. The porous coating is applied on the entire circumference of the acetabulum. For press-fit method, the acetabular cup is allowed to have 1 to 2mm larger than the reamed acetabulum. Fixation devices such as pegs or screws are used to facilitate bone ingrowth and the most extensive ingrowth has been reported in acetabular components that are fixed with at least one screw (Harkess and Crockarell 2013).

Figure 2.4.2.2: Cementless acetabular cups with different types (Yoon, Park and Lim 2013).

There are many types of cementless acetabular components. Figure 2.4.2.2 show some of the common types: A is the threaded type, B is expansion type and C is hemispherical type. When using cementless implants, the interaction between the bone and implant, bone quality and implant materials are the main factors that determine the survival rate and how successful the long-term follow-up fixation is. In general, this type of implant has shown high success rate in primary THR and relatively good performance on long-term follow-up (Yoon, Park and Lim 2013).

2.4.3 Hybrid Total Hip Replacement

This technique was introduced in the early 1980s (Harris 1996) and the long term results are being measured. The hybrid method is a combination between the cemented and cementless method. The hybrid THR usually has the acetabular socket inserted to the pelvis bone without cement and the femoral stem inserted to the femur with cement (see figure 2.4.3). This technique takes the advantage of excellent track records of cementless hip socket and cemented stems (Earl's View 2011).

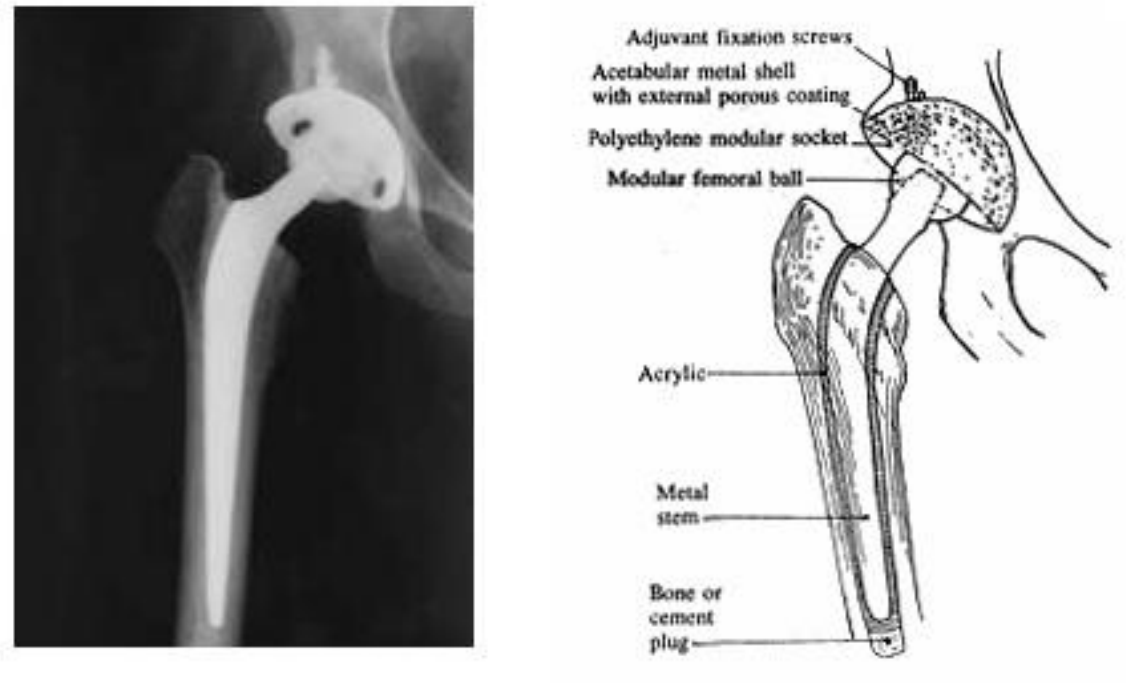


Figure 2.4.3: The structure of a hybrid THR (Joint Replacement Institute n.d)

The cementless acetabular component of hybrid THR is fixed into the pelvis bone by screws and its surface has porous coating to attract bone ingrowth. The cemented femoral stem of hybrid THR uses acrylic cement to bond the prosthesis with femur.

2.5 Total Hip Replacement Failure Modes

The rate of primary total hip replacement is increasing over the past decades and expected to rise more in the future. It is estimated that there will be nearly 100,000 revision hip procedures in United States by 2030 (Kurtz S et al 2007). The percentage of which each type of failure mode occurs varies from study to study and depends on numerous factors such as patient's age, gender, type of implants, etc… Based on the research and analysis of Bozic et al. (2009) who used The Healthcare Cost and Utilization Project Nationwide Inpatient Sample database of 51,345 revision THR procedures from October 2005 to December 2006 in the United States, the most common cause for revision surgery were instability and dislocation (accounting for 22.5%), followed by aseptic loosening (19.7%) and periprosthetic infection (18.4%). Similar studies also reported that instability contributed to 35%, aseptic loosening to 30%, osteolysis and wear to 12%, infection to 12% and periprosthetic fracture to 2% of the revisions (Springer BD et al 2009).

The purpose of this section is to describe the mechanisms of failure of the revision THR. The most common failure modes will be mentioned in details in this chapter.

2.5.1 Instability

Instability is one of the most common modes of Total Hip Replacement (THR) failure and leads to revision surgery. A sample database of revision THRs performed in a period of 15 months across the United States reported that instability and dislocation is the most common cause of THR failure which contributes to 2 to 5% in primary THR (Sanchez-Sotelo and Berry 2001) and up to 22.5% of revision THR (Bozic et al. 2009). Instability can be divided into 2 classes, they are dislocation and subluxation.

Dislocation is when there is a complete separation between the femoral head and the acetabular component and it is a major complication after THR surgery. Lee et al. (2008) described hip prosthesis dislocation is when the prosthetic femoral head escapes from the acetabulum of the prosthesis in a THR or from the natural acetabular cavity of the pelvis bone in a bipolar hemiarthroplasty. In other words, dislocation is when the ball comes out of the socket completely. Hamilton and McAuley (cited in Miki et al. 2012) reported that dislocation is believed to be related to prosthesis or bone impingement and to insufficient soft tissue tension.

Dislocation still remains a major complication of THR. Harkess and Crockarell (2013) said “The prevalence of dislocation after total hip arthroplasty is approximately 3%”. There have many published studies on the dislocation topic of THR, specifically about its causes and treatments; however the results produced from these studies have been conflicting (Charissoux, Asloum & Marcheix 2014).

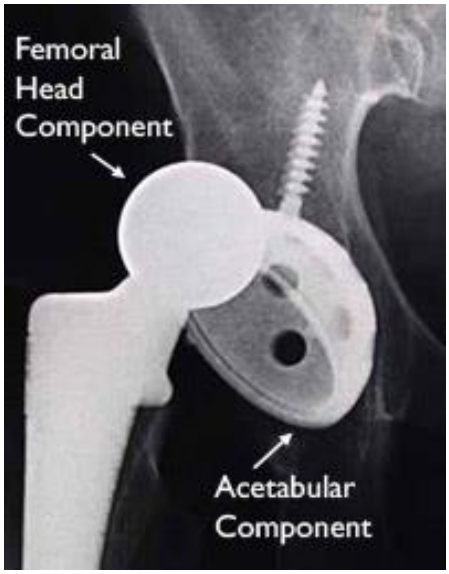


Figure 2.5.1: Hip Implant Dislocation (AAOS 2011)

Figure 2.5.1 above shows the dislocation of the hip. The femoral head component is completely outside of the acetabular component. Dislocation in THR can be divided as either early or late depending on the time after primary THR. A late dislocation can have occurred at a minimum of 5 years after the primary THR and still comprise nearly one third of all dislocations (Knoch et al. 2002)

Huten and Langlais (cited in Charissoux, Asloum & Marcheix 2014) provided the three categories of dislocations which are based on the time to occurrence. They are:

- Early dislocations: This is the most common case which occurs within the first 3-6 months after THR due to inadequate healing and accounts for 50% to 70% of all dislocations.
- Secondary dislocations: This occurs between 3-6 months and 5 years after THR and contributes from 15% to 20% of all dislocations. The common cause for this is the resumption of previous activities.
- Late dislocations occur more than 5 years after THR and account for 32% of all dislocations. The mean time to occurrence is 11.3 years. The common cause of late dislocation is often related to polyethylene wear.

Subluxation refers to a partial separation of the femoral head from the acetabular component. In this case, the ball starts to come out of the socket but it does not stay fully outside. Hip subluxation is also called partial dislocation.

Depending on the implant design and position, the THR's desired range of motion is set on implantation. Therefore if the joint motion is excessive this can lead to impingement of the femoral neck on the acetabular cup. When this occurs, the rotation centre of the hip implant will move to the rim of the cup instead of locating at the femoral head centre. At this point, if the motion continues, it will lead to subluxation of the femoral head. Kluess et al. (2007) also reported that the material failure of THR components such as brittle fracture of ceramic components and excessive wear of polyethylene liners can be caused by recurrent impingement due to high localised contact stresses at the impingement site.

There are various factors that have been associated with increased risk for instability. These are component positioning, design specifications, surgical approach, soft-tissue laxity, anatomic abnormalities and patient noncompliance. The epidemiological factors that negatively affect stability are previous hip surgery, osteonecrosis or inflammatory arthritis preoperative diagnosis, prior hip fracture, advanced age and female sex (Harkess and Crockarell 2013). However, there is no objective method for determining the cause of dislocation (Miki et al 2012).

The rate of postoperative dislocation is affected by the choice of surgical approach. For example, the dislocation rate when a posterolateral approach was used is found to be 6.9% compared with 3.1% when an anterolateral approach was used (Berry et al., cited in Harkess and Crockarell 2013). Revision THR and other previous surgery on the hip make postoperative dislocation occur more common. A 7.4% dislocation rate is reported in a group of 1548 revision total hip procedures by Alberton et al. (cited in Harkess and Crockarell 2013) with at least 2-year follow-up.

The placement of the components is the most common reason for instability. This occurs when using an improper femoral neck length or malpositioning of the acetabular component. The safe zone for appropriate version of acetabulum is described as having acetabular inclination of 40±10 degrees and anteversion of 15±10 degrees (Lewinnek et al. 1978). The surgical technique and implant design

can result in different rates of instability. Kelley et al. (1998) found that appropriately used larger femoral head sizes have been shown to result in lower dislocation rates.

Patient noncompliance is another factor that associates with dislocation. Dislocation can occur if the recommended range of motion is exceeded. In posteriorly approached hips, patients are recommended to avoid any flexion more than 90 degrees and to minimize adduction and internal rotation movements (Jacofsky & Hedley 2012)

2.5.2 Component loosening

Component loosening is the second most frequent long term complication after primary THR and contributes to 19.7% of THR revisions (Bozic et al. 2009). Component loosening may be diagnosed by clinical function. The implant failure is only indicated if these radiolucent lines are progressive and patients presents with pain (Jacofsky & Hedley 2012). Acetabular and femoral loosening commonly lead to revision and are considered to be the most serious long-term complications of THR.

The diagnosis criteria of femoral and acetabular component loosening have not been universally accepted (Harkess and Crockarell 2013).

Component loosening is a multifactorial process and can be classified into implant-specific factor, surgical factor and patient-specific factor. Patient-specific factors include the level of activity of the patient, gait mechanics, body mass index, etc… Implant-specific factors consist of material choices, bearing couple, and the implant design. Surgical factors include component composition, component fixation, reconstruction of the joint mechanics and initial stability as well as the experience of the surgeon.

When loosening happens at the early state, the cause might be related to poor initial fixation and design. Late loosening is related to the wear of the prosthetic components which is the major problem (McGee et al. 2000).

Technical factors that contribute to implant failures should always be considered to minimize the incidence of femoral or acetabular component loosening. Jacofsky & Hedley (2012) stated that for cemented components, the surgical factors include a

cement mantle that is too thin or failure to pressurize the cement adequately. In cementless components, surgical factors can be inadequate removal of soft cancellous bone in the femoral neck, missed occult fracture, component undersizing and component malpositioning.

In conclusion, aseptic loosening is a multifactorial process and it depends on patient-specific factor, surgical techniques and implant design. Advanced implant design and surgical techniques will need to be studied more in the future to improve the result and reduce the component loosening.

2.5.3 Infection

High morbidity and cost associated with periprosthetic hip infection makes it the most devastating complication after primary THR. It is estimated that infection makes up to 15% if all revision surgeries (Bonzic KJ et al 2009).

There are 3 categories of infection: acute (early), chronic (late) and acute hematogenous (Jacofsky & Hedley 2012). Acute periprosthetic infection is an early postoperative infection and attributed to an intraoperative contamination. It usually occurs within 4 to 6 weeks and can goes up to 12 weeks after surgery. After this period of time, the infection is defined as chronic infection. The infected prosthesis which may be the result of seeding from a blood borne pathogen into the joint is called acute hematogenous infection.

Trampuz A and Zimmerli W (2005) stated that the infected hip joint can present with either quite vague symptoms, such as malaise or decreased function of the affected joint or it can have the signs of infection such as pain, fever, swelling, tenderness or erythema. The most common complaints received from patients with infected hip are pain.

In conclusion, infection in prosthetic hip is one of the most devastating complications of THR and it is critical to minimize the incidence of infection through antibiotic prophylaxis. The extending operative time, hospital stay and prolonged use of urinary catheters should be avoided. Once the infection is suspected, early surgical treatment should be done to eliminate the infection more efficiently than delayed treatment.

2.5.4 Periprosthetic Fracture

Periprosthetic fracture is a problematic complication after THR. There are two parts where periprosthetic fractures occur: femur and acetabulum. As the population ages, the subsequent bone loss around the prosthesis also increases. Periprosthetic fractures can lead to the failure of the arthroplasty. The fractures can occur at different stages of the arthroplasty.

Most periprosthetic fractures occur around the femoral stem. This is the most common periprosthetic fracture and requires some form of treatment. The fractures of the hip socket (acetabulum) are less common (AAOS 2013).

2.5.4.1 Periprosthetic Acetabular Fractures

Periprosthetic fracture of the acetabulum is an uncommon complication and a very rare event compared to femoral fracture. There are very few reports about periprosthetic fracture of the acetabulum. The majority of acetabular periprosthetic fractures occur intraoperatively, and most are undisplaced cracks that have little or no influence on cup stability (Wolff and Berry 2009). Gras et al. (2010) concluded the characteristics of fracture are very similar and involves the upper part of the posterior column and the medial wall. Peterson and Lewallen (1996) mentioned about two types of periprosthetic fracture of the acetabulum, they are: type 1 with well-fixed cup component and type 2 is with loosening of the THR cup-component.

The treatment for type 1 fracture is proposed by conservative approach and it is considered to be the least risky option when loosening is excluded. For type 2 fracture, it is necessary to have operative procedure with revision and exchange of the acetabular cup and the use of cables, plates and screw to assist fracture fixation (Gras et al. 2010). This study also mentioned that for acetabular fracture, percutaneous screw fixation is good for fracture healing because this provides preservation of soft tissue and untouched fracture hematoma for later THR revisions.

Very few reports of acetabular fracture that is associated with cemented acetabular components. McElfresh and Coventry (cited in Wolff and Berry 2009) reported that there was only one periprosthetic fracture of the acetabulum out of 5400 THRs using this cemented technique. However, in the case of the cementless acetabular component, a large amount of hoop stresses may be produced with press-fit designs which increase the chance of incidence. Therefore this requires a proper surgery

technique and attention to the host bone quality when inserting the components to prevent this complication. Other factors that can lead to this intraoperative fracture are over-reaming of acetabulum which weakens the host bone and great discrepancy between reamed size and cup size which may cause excessive hoop stresses.

A very informative summary of causes and treatments for acetabular periprosthetic fracture was done by Gelalis et al. (2010). This report provides the references for acetabular periprosthetic fracture. The authors had reviewed the available studies about this type of fracture and included in a table. A reproduced version of it can be found below in table 2.5.4.1

Table 1.5.4.1: Cause and treatment for acetabular periprosthetic fractures, reproduced from Gelalis et al. (2010)

Authors	Number of cases	Cause of fracture	Treatment type	Reference
Chatoo et al.	1	Aseptic loosening, osteolysis	Revision of acetabular component, osteosynthesis	cited in Gelalis et al. (2010)
Andrews et al.	1	Stress fracture	Restriction of weight bearing	As above
Harvie P. et al	1	Trauma	Skeletal traction and delayed revision with original components in situ	As above
Woolson	1	Trauma (fracture-dislocation)	Skin traction, delayed revision arthroplasty and osteosynthesis	As above
Old et al.	1	Forward bending (fracture-dislocation)	Closed reduction, abduction orthosis	As above
Sanchez-Sotelo et al	3	Osteolysis	Revision arthroplasty	As above
Miller	9	Infection or periprosthetic osteolysis, forward bending, fall	Removal of prosthesis	As above
Peterson et al.	11	Fall or blunt trauma, unknown	Non-operative, acute or delayed revision arthroplasty	As above
Sharkey et al	13	Intraoperatively during cup insertion	Augmentation screws, autograft, restriction of weight bearing, immobilisation, cup revision, spica cast	As above

2.5.4.2 Periprosthetic Femoral Fractures

Periprosthetic fractures may occur intraoperatively (during THR procedure) or postoperatively (after THR procedure). It presents with pain, swelling, deformity, instability to use the limb, etc… To diagnose fracture, physical examination should be performed and radiographic evaluation should be conducted. The bone quality should be scanned for any fracture. Berry (cited in Difazio and Incavo 2005) reported in a review of the Mayo Clinic Joint Registry that intraoperative femur fractures occur in primary THR at 1% rate and in revision THR at 7.8% rate. The presence of thin cortices from implant migration and osteolysis increase the risk of fracture in revision surgery than primary procedures. Females and elderly patients or those with inflammatory arthritides, bony deformity or deficiency are at risk for periprostheic fractures. The mean time interval from primary THA to fracture and from revision to fracture was reported by Lindahl et al. (2005) was 7.4 years (range, 1-262 months) and 3.9 years (range, 1-229 months) respectively. A same–level fall (at the position of sitting or standing) is the most frequent cause of fracture which accounts for 75% in the primary THR and 56% in the revision THR.

Intraoperative fractures can occur during the primary THR or revision THR. Wolff and Berry (2009) stated that femoral fractures may occur during femoral bone preparation, femoral prosthesis implantation, or hip reduction in primary hip setting. During a THR procedure, femoral fracture can likely occur in one or more of several stages. Fractures can occur in the early stage when the hip is dislocated. A moderate rotational force can create fracture in the fragile bone of elderly patients, or those with arthritis and osteoporosis. Fractures can also occur during broaching and insertion of the femoral component. The chance of fracture is influenced by the bone quality. Poor bone quality is a risk factor which increases the probability of fracture.

Postoperative periprosthetic fractures may occur after a few days or even years after the primary surgery. The main risk factors associated with this type of fracture are osteolysis and implant loosening.

2.5.4.3 Classification of Femoral Fractures

A new classification system for periprosthetic femoral fractures is called the Vancouver classification. The Vancouver classification system divides periprosthetic fractures into 3 categories based of the location of fracture. This system has been confirmed to be valid and reliable in terms of fracture location, implant stability and bone stock by Brady et al. (2000).

Type A is fracture in proximal metaphysis without extending into the diaphysis. Type B is fracture around or just below the stem. These fractures involve the proximal diaphysis but can be treated with long stem fixation (Harkess and Crockarell 2013). Type C is fracture well below the tip of the stem and may include the distal femoral metaphysis. Each type is then subdivided into 3 subtypes. Subtype 1 is simple perforations, subtype 2 is nondisplaced and subtype 3 is displaced. Figure 2.5.4.3a below shows the 3 types A, B and C of intraoperative periprosthetic femoral fracture.

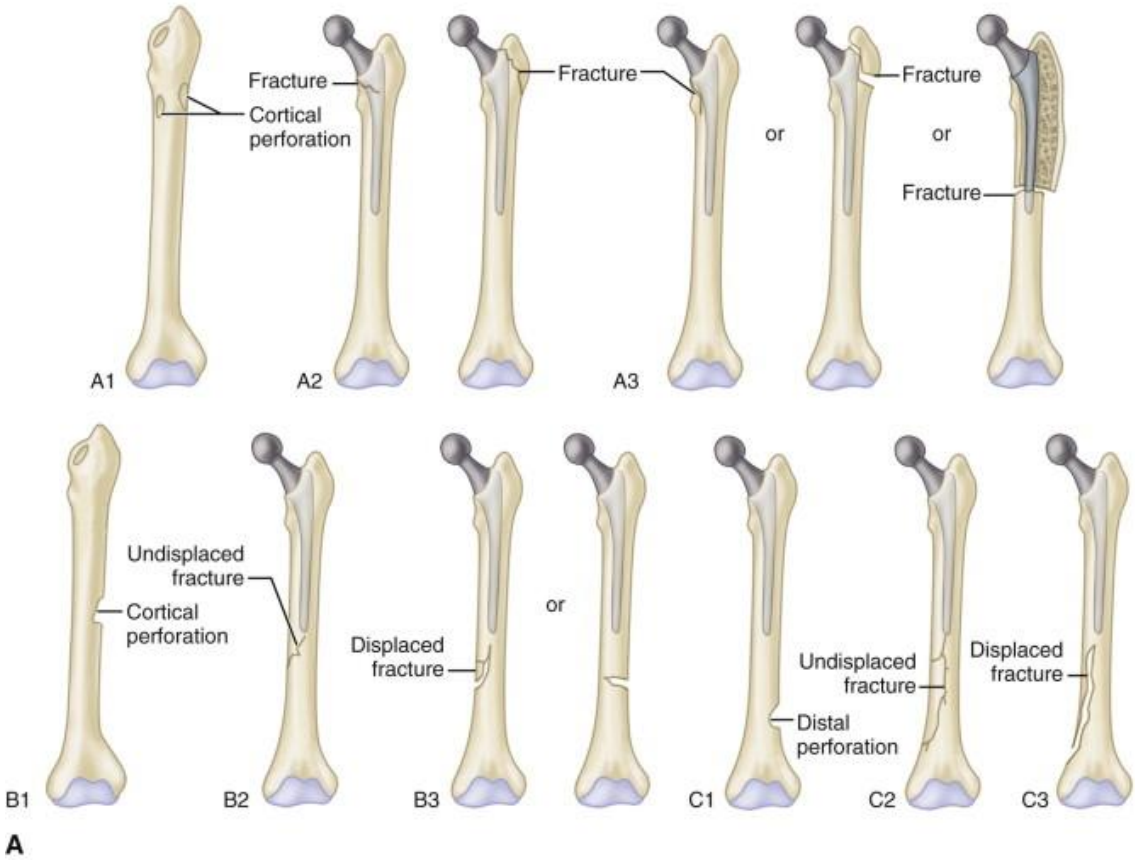


Figure 2.5.4.3a: Intraoperative periprosthetic fractures of femur (Harkess and Crockarell 2013)

The goal for periprosthetic fracture treatment is to enhance the arthroplasty function and achieve anatomic alignment, preservation and fracture union (Difazio and Incavo 2005). Reconstructive surgeons develop the treatment strategies based on the Vancouver classification system algorithm. Treatment decisions for fracture depends on the location of fracture, quality of bone stock, stability of fracture and implant, patient's age and surgeon's experience. Depending on the level and displacement of the fracture, some of the treatment options were mentioned in Harkess and Crockarell (2013) such as long stem revision, bone grafting, cerclage, or open reduction and internal fixation.

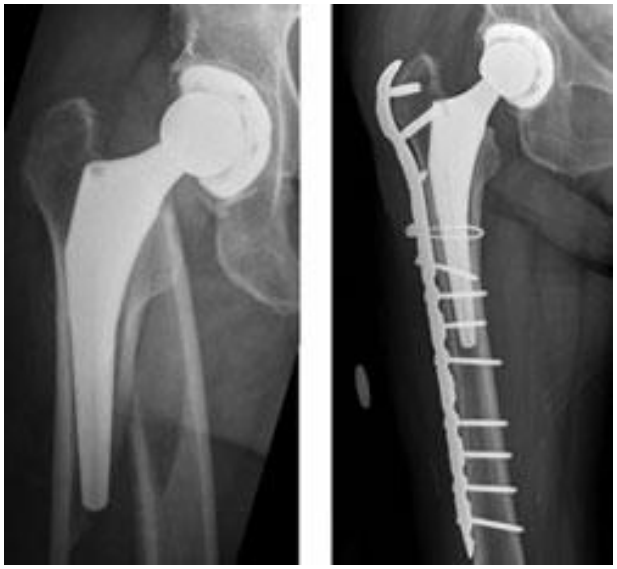


Figure 2.5.4.3b: X-ray taken shows the periprosthetic fracture (left) and the fracture has been treated with plate, screws and cable (right) (AAOS 2013)

Most cases of fractures require surgery. If the implant is still attached firmly to the femur, an internal fixation treatment is introduced. The bone fragments are first repositioned and held together with special screws, cables or by attaching metal plates to the outer surface of the bone as in figure 2.5.4.3b above (AAOS 2013). In some other cases, the stem of the implant is loose and to treat the periprosthetic fracture, the old implant has to be removed and replaced by a new implant. This is called joint revision.

Numerous risk factors for sustaining a periprosthetic fracture are female gender, increased age, history of trauma, osteoporosis, etc… Studies concluded that cementation of components increases femoral stability and reduce risk of periprosthetic fracture (Jacofsky & Hedley 2012). In cementless THR procedure

intraoperative femoral fractures occurs very common. This type of fracture was reported by Berry (cited in Harkess and Crockarell 2013) in 5.4% of cementless primary arthroplasties and in 21% of cementless revision procedures.

In conclusion, the complication of periprosthetic fracture is a common mode of failure for THR. As the patients get older, the occurrence of these fractures also increases.

2.5.5 Wear and Tear from Hip Implant

Another common complication of THR is wear and tear of the sockets. Wear is unavoidable in any material application. According to the report (Lombardi AV et al., 2004), Metal-on-metal bearings do produce significantly less volumetric wear than metal-on-polyethylene bearings in laboratory experiments and probably in real human body.

The wear particles can be absorbed by surrounding tissue and cause inflammation and swelling in and around the joint. Depending on the material used to make the implant components, there are different types of debris. Different materials can cause different long-term complications. For example, Metal-on-Metal hips where both the femoral component and the cup are made of metal will create debris that primarily made of cobalt and titanium ions. This type of debris can cause a condition known as metallosis. On the other hand, when the bearing surface combination is metal-on-plastic, it will create polyethylene particles that can lead to a condition known as osteolysis.

The wear problem can be very dramatic. If metal ions from the wear spread from the surrounding tissues into the blood, the blood ion levels will go up and can cause physical conditions such as mental cognitive problems, severe headaches and problems with the nervous system as well as emotional imbalance. Some other cases, the wear particles can react with the human system and result as the body is toxic.

2.6 Materials Criteria used for Implant Components

There have been many advances in the design and implantation of artificial hip joints over the past half-century, with the purpose of resulting in a high percentage of successful long-term outcomes. Different materials have been used and tested to produce the optimum outcome for the prosthesis that last longer in the human body without causing any bad results.

The materials used in a THR implant have four characteristics in common (AAOS 2007):

- Biocompatible. This means the materials have to be friendly with the human body without causing any local or a systemic rejection response.
- Resistant to corrosion, degradation, and wear. The human body is a moist environment therefore the material has to be resistant to corrosion. They also need to retain their strength and shape for a long time. Having the material that is resistant to wear is extremely significant in preventing the further destruction of bone and surrounding tissue caused by the wear particles when the implant components rubs against each other.
- Having mechanical properties that are similar to the hip joint properties. They need to be strong enough to withstand the body weight when performing different activities such as running, walking, and other daily activities. They also need to be flexible enough to handle stress without breaking, and smooth enough to create comfort for the patients.
- Having high standard and quality. This aims to make the prosthesis last longer in the human body without having further revision surgery.

Chapter 3 – Failure Analysis of THR

3.1 Overview

This chapter will look at the methodology undertaken to identify the failure analysis of the prosthesis. As a part of completing this work, the risk assessment and assessment of consequential effects, implications and ethics were undertaken and included in appendix D and E.

For the analysis of complicated failure modes such as dislocation, wear, periprosthetic fracture and loosening, the method is to review the available published papers and resources to assist the find.

For finding stress analysis of THR, the model used for this analysis is called “Thompson Hemiarthroplasty Prosthesis”. The goal is design a 3D model of this prosthesis on Creo Parametric software for finite element analysis (FEA). There are currently not many studies found on the topic of Thompson prosthesis finite element analysis. Therefore this report might be useful for further studies of this model. The outcome should produce stress distribution along the prosthesis for all cases such as walking, running, jumping, jogging etc… It is then to compare with literature reviews to produce the failure analysis and material selection recommendation.

Thompson hemiarthroplasty is a popular hip prosthesis which was introduced in 1950s. This prosthesis still remains popular today because of its simplicity which allows trainee surgeons to use for faster operation for the medically-unfit patients (Lloyd and Calder 2006).

The model used for this report is chosen from a common Thompson prosthesis design in the market. The dimension of this model is shown in the 2D drawing in figure 3.1 below. Some of the key dimensions of this prosthesis are femoral head diameter (43mm) and stem length (140.68mm).

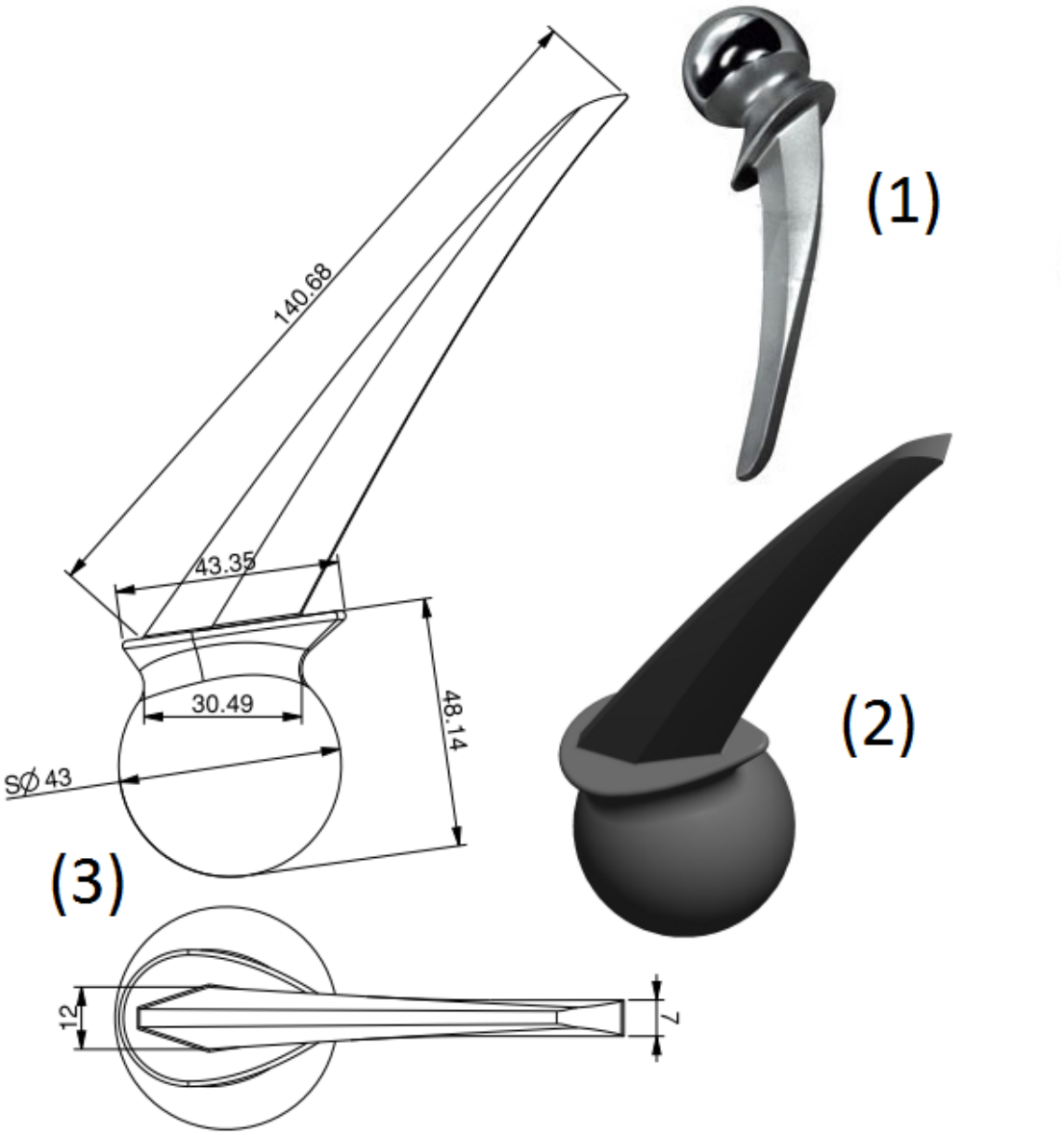


Figure 3.1: Thompson Hemiarthproplasty prosthesis dimension

3.2 Finite element analysis (FEA) of Thompson Model

The hip prosthesis must be attached securely and properly inside the femur to be able to perform at its best. As mentioned before, there are two methods used to secure the fixation of the prosthesis in the skeleton. These two methods are cementless and cemented techniques. Regardless of the fixation methods, the design of the stem should be able to eliminate the high stresses at the fixation areas to minimize the chance of short-term fracture and long-term fatigue failure.

To ensure the safety of the prosthesis design, both static and dynamic analyses should be conducted. Kayabasi and Erzincanli (2006) said prosthesis is often designed according to the results of static analysis. These analyses are conducted under body weight.

The following model is developed in Creo Parametric. This shows where the forces are acting on the prosthesis. The assembly of Thompson prosthesis model is as in figure 3.2a and 3.2b below.

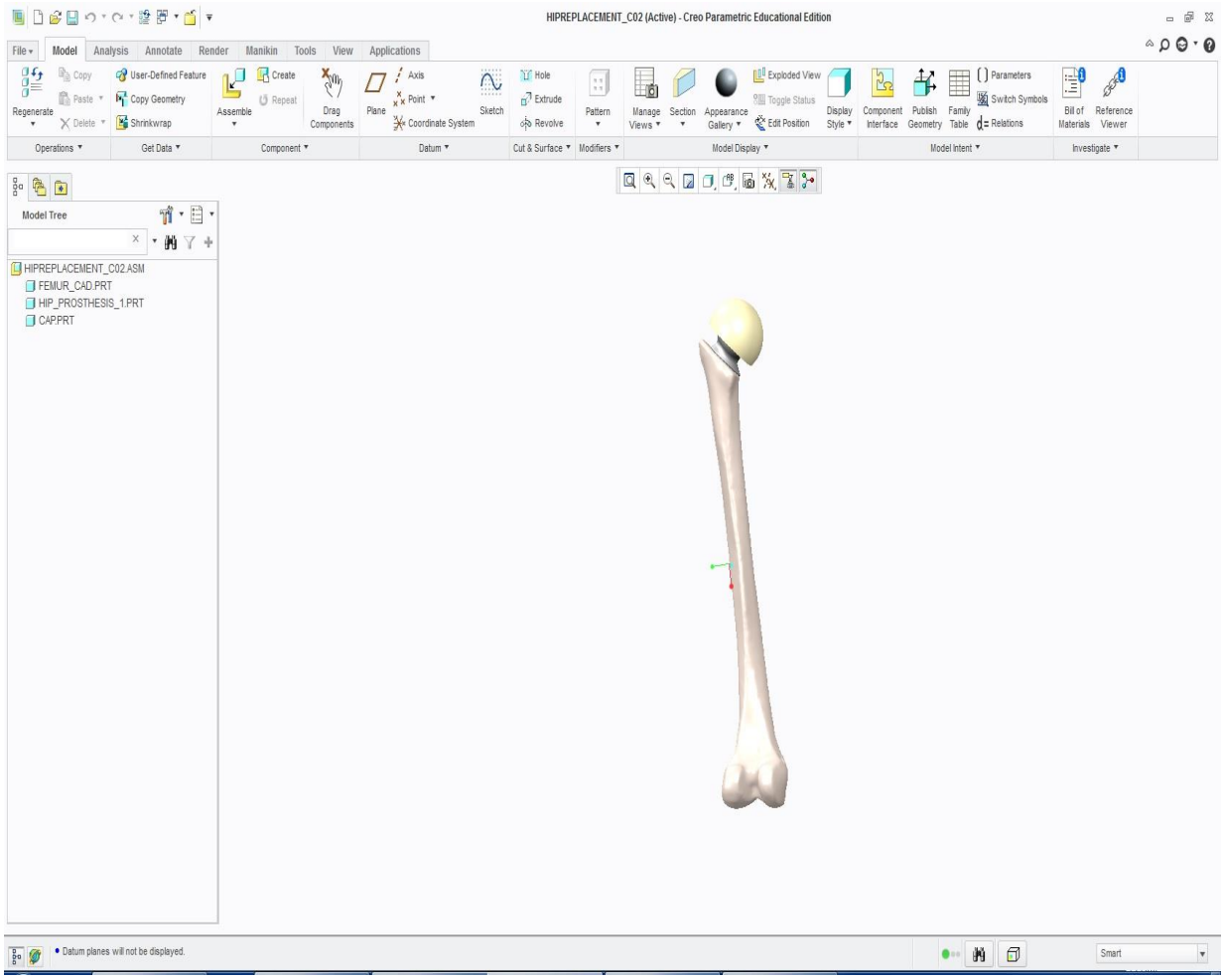


Figure 3.2a: The 3D assembly of Thompson Prosthesis in Creo Parametric

All parts of Thompson prosthesis were modelled and assembled in Creo Parametric 2.0. The assembly is them simulated for computational calculations.

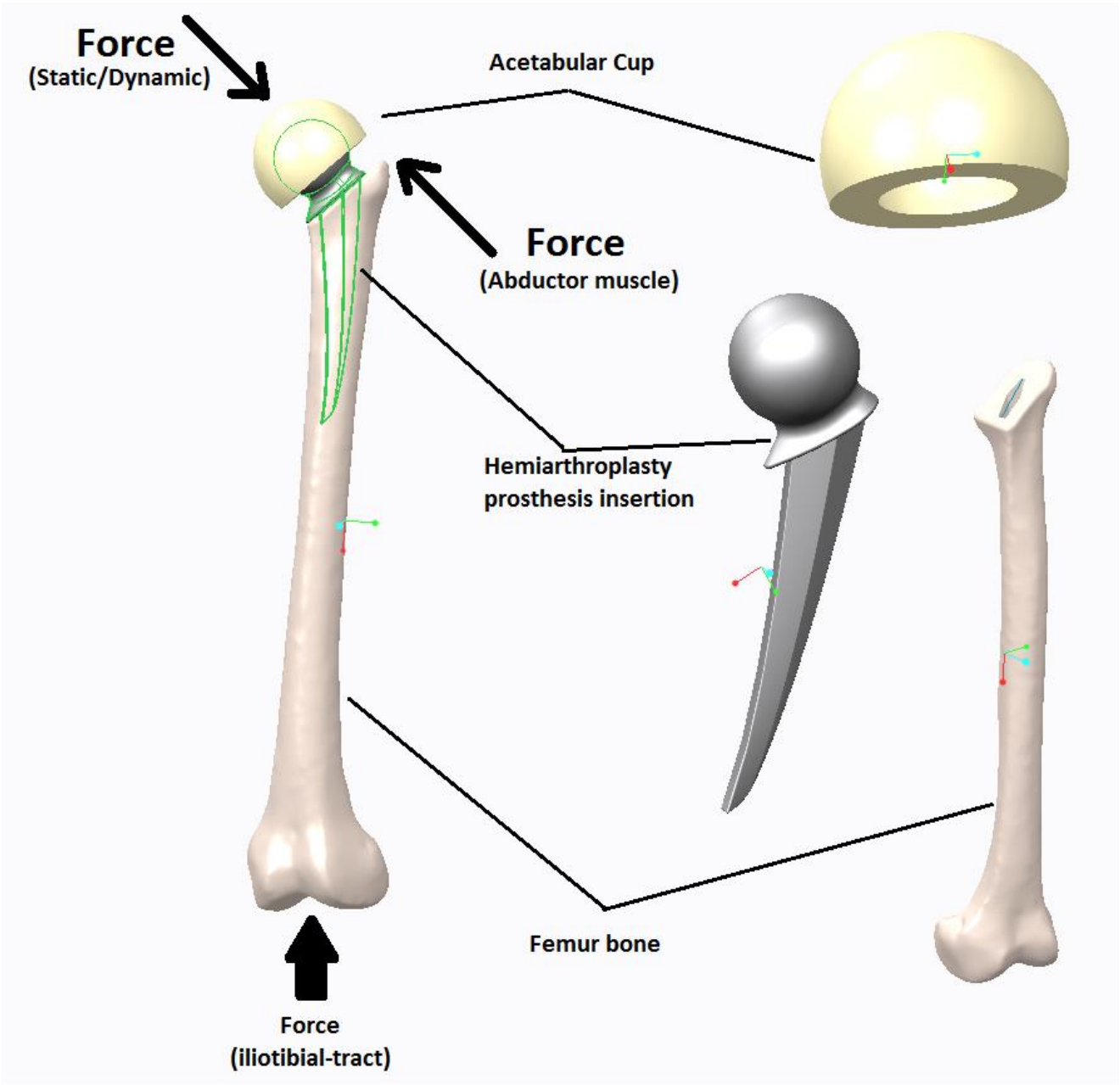


Figure 3.2b: The 3D model of Thompson prosthesis and the insertion of it in femur bone

To obtain the FEA for the model, materials used for each part must be assigned. For the purpose of this study, the materials used for prosthesis and bone are described in table 3.2 below.

Table 3.2: Material properties used in the FE models

Part	**Material**	**Young's Modulus (GPa)**	**Poisson's ratio**
Femoral stem and femoral head	Stainless steel	200	0.27
Acetabular cup	Ceramic	346	0.31
Bone	Bone	10	0.15

Experimental determination of cortical bone's Poisson's ratios has been done by a few studies but the results vary with respect to methods. Different determination methods produce different values of Poisson's ratio. For example, Ashman et al. (1984) used the ultrasonic continuous wave technique and found Poisson's ratio values ranged between 0.27 and 0.45. Reilly and Burstein (1975) used extensometers and found the Poisson's ratio value to be between 0.29 and 0.63. Another variation of Poisson's ratio values was found between 0.12 and 0.29 by using ultrasonic method (Pithioux, Lasaygues, and Chabrand 2002). For the FEA of this document, the Poisson's ratio value for bone was chosen to be at 0.15. The maximum force acting on the hip used based on the theory of table 2.2.2 in chapter 2 above.

Kayabasi and Erzincanli (2006) stated that the static load represents a person's weight. The abductor muscle load is applied at an angle of 20 degree to the proximal area of the greater trochanter. The iliotibial-tract load is applied to the bottom of the femoral bone in the vertical direction along the femur. The femur's distal end is constrained not to move in horizontal direction. For safety purpose, the maximum equivalent stress on the hip prosthesis must be lower than the endurance limit of the prosthesis materials. A maximum or an infinite fatigue life is requiring excellent design for the hip implant should satisfy.

3.3 Finite element analysis (FEA) Results of Thompson Model

Table 3.3: Stress analysis results on Thompson prosthesis for various cases

Cases	**Maximum Stress (MPa)**
Standing	1.884e+01
Walking	1.450e+02
Jogging	2.320e+02
Running	2.901e+02
Go upstairs	1.988e+03
Go downstairs	2.157e+03
Weight lifting	2.203e+03

This result will be discussed later in chapter 5. Refer to appendix B for the result images.

3.4 Femoral Head and Acetabular component analysis

A recent FEA of femoral head and acetabular component was performed by Kluess et al. (2007). This study aimed to understand the impact of the femoral head size on dislocation, impingement and stress distribution in THR. This study used four different combinations between cobalt-chromium femoral heads and ultra-high molecular weight polyethylene liners. The dimensions used in this test are recorded in the table 3.4 below.

Table 3.4: Component parameters used in Kluess et al. (2007) FEA

Name of components	**Size**
Femoral head diameters	28, 32, 36, 40 mm
Liner's wall thickness	7 mm each
Head inset of acetabular component	2 mm
Prosthetic neck diameter	14 mm
Lubrication gap between prosthetic head and liner	24 μm

The computation calculations were performed using ABAQUS V 6.4 and Patran 2004. After performing the computational calculations and testing the component in mechanical testing devices, the relationship between the femoral head size and failure modes begins to emerge.

Kluess et al. (2007) found that by increasing the femoral head size, the contact stresses at the liner during subluxation is decreased. The head diameter of 40 mm produced 1.25 MPa of contact pressure, which is less than half of what is produced by a 28 mm head diameter (3.25 MPa). This study also found that larger femoral heads produce higher maximum resisting moments and increased impingement-free range of motion. The results found by Kluess et al. (2007) also agree well with those of Peter et al. (2007), Howie et al. (2012) and Jameson et al. (2011)

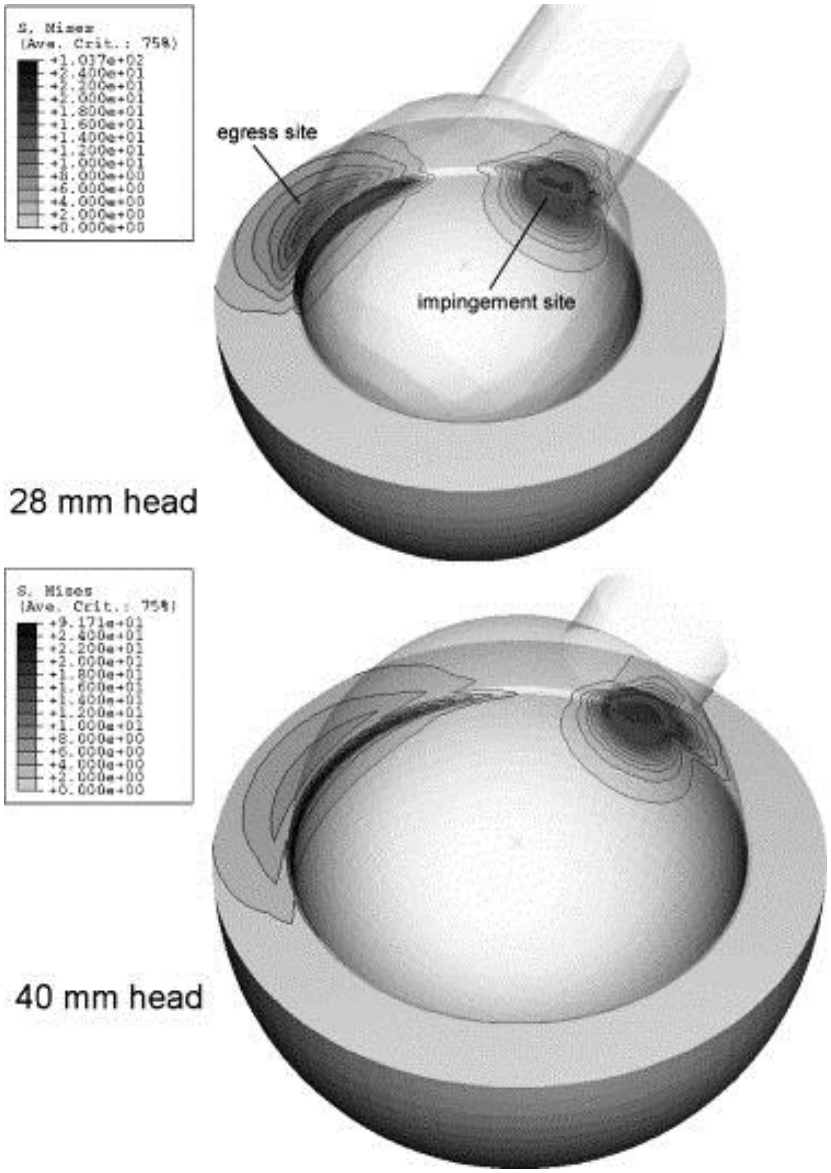


Figure 3.4: Stress plots of two implants with 28 and 40 mm head size (Kluess et al. 2007).

This figure shows stress plots comparison between a 28 mm head diameter and a 40 mm head diameter. It can be seen that an excessive contact stresses in the liner is located at the prosthetic neck with. Also, stresses decrease with higher liner diameters at the egress site. Jameson et al. (2011) reported with the use of large femoral head sizes, a significant reduction in dislocations has been noticed. Howei et al. (2012) said a larger 36-mm articulation resulted in a significantly decreased incidence of dislocation compared with a 28-mm femoral head articulation in the first year after THR. Peters et al. (2007) also discussed a 38 to 56 mm MoM bearing head size has low dislocation rates (0.4%) at short-term follow-up.

3.5 Femoral Stems analysis

For cemented femoral components, the success rate depends on many factors. Lennon, McCormack and Prendergast (2004) said loosening is the cause of majority of cemented femoral components. This study and Morgan et al. (2003) discussed that femoral prosthesis loosening is possibly caused by the fatigue failure in bone cement mantle. Understanding loosening mechanism will help improve the performance and success rate of cemented femoral stems. The common and important question around this is whether the cement damage is at the cement-bone interface, stem-cement interface or the voids. Race et al. (2003) concluded that the early cement cracks failure is concentrated at cement-bone interface with formation of micro-cracks. The results found in this study suggest that the cracks associated with cement-bone interface were 31±6.2%, which is more than stem-cement interface (11±5.2%) and voids (6.1±4.8%). However, Stolk et al. (2002) discussed that the most important interface is between stem and cement because the difference in stiffness between stem and cement produces high localized strain in the cement mantle. Berry and Lieberman (2012) stated that the cemented femoral component failure rate was high when cemented revisions were used due to cement-bone interface mechanical failure.

3.6 Dislocation Analysis

Harkess and Crockarell (2013) suggested that the prosthesis-cement interface with debonding and subsequent cement fracture is where the failure of cemented stems occurs. The stability of the stem is greatly affected by the shape of the stem. For example, stems with circular shapes tend to have less rotational stability. The rotational stability of stems can be improved by having the stem designs with irregular surface types such as grooves or a longitudinal slot. Other noncircular shapes, such as an ellipse or a rounded rectangle also increase the stability of the stem within the cement mantle. However, if debonding process occurs, the roughened or textured surface stems produce more debris with motion than smooth or polished surface stems. The design of stem is recommended to be collarless, polished and tapered in two planes (Harkess and Crockarell 2013). This is to maintain compressive stresses and allow small subsidence amount inside the cement mantle.

In the case of Thompson Prosthesis, the stem has a complicated irregular shape which includes six different surfaces (refer to figure 3.1). This design of stem therefore has higher stability compared to other stem designs with circular shapes.

3.7 Periprosthetic Fracture

Cook et al. (2008) and Harris et al. (2010) reported that periprosthetic femoral fractures occur in 0.1–6% after THR surgery. These fractures are often associated with loosening of femoral component. In some cases, the treatment for periprosthetic fractures is non-operative but typically extensive surgery is required.

The methodology for testing periprosthetic fracture is to use Vancouver classification for femoral fracture as a measurement and finite element analysis as the computational calculation. In this section, type B1 of Vancouver fracture is discussed.

As discussed earlier in chapter 2, type B fracture is the fracture that occurs around or below the stem. A FEA for Vancouver B1 periprosthetic fractures was done by Chen et al. (2012). This study used an artificial femur as the basis for solid model, U2 femoral stem for prosthesis stem and cable plate wires and screws as fixation method. The purpose here is to test the stability of different fixation methods to repair Vancouver type B1 periprosthetic fracture. The model was constructed as in figure 3.7 below

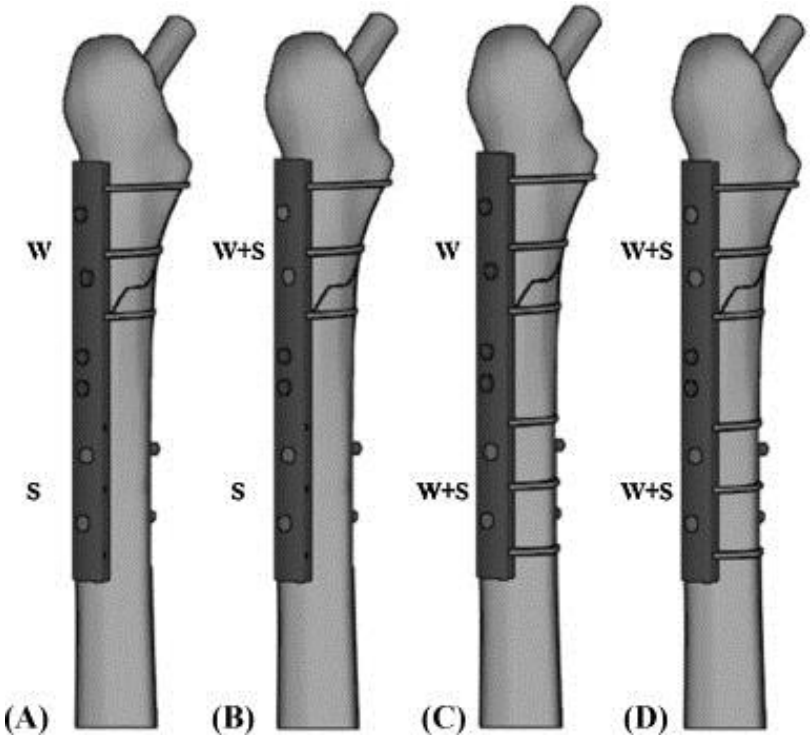


Figure 3.7: Analysis models of FEA performed by Chen et al. (2012).

Model A uses 3 wires at proximal and 2 bicortical screws at distal. Model B uses 3 wires and 2 unicortical screws at proximal and 2 bicortical screws at distal. Model C uses 3 wires at proximal, 2 bicortical screws and 3 wires at distal. Finally, model D uses 3 wires and 2 unicortical screws at proximal and 2 bicortical screws and 3 wires at distal. The results of this study is shown in table 3.7 below

Table 3.7: Results of maximum stress and bone displacement from FEA of 4 models (Chen et al. 2012)

Model	Maximum Stress (MPa)	Bone displacement (mm)
A	284.785	2.5888
B	209.364	2.1916
C	242.304	2.5755
D	191.795	2.1725

From the results in table 3.7, it is very clear that model D provides better outcome. Both maximum stress and bone displacement in model D are lower compared to the other three models. By using both proximal and distal screws, the fixation is reinforced. This method is also known as ‘The locking-plate concept’. Cronier et al. (2010) concluded that this locking-plates method has shown immeasurably beneficial to the extent where conventional fixation methods have reached their limits.

Chapter 4 – Materials Selection for THR

The challenge in materials selection for total hip replacement prosthesis is that the design requires many different essential properties which are very difficult to find in only one material. The method for finding materials selection used here is to review other analyses on materials selection and compile the results of what the most suitable materials are used right now.

Luckey and Kubli (1983) mentioned the five areas must be considered carefully to determine a good implant material, which are mechanical properties, design and functionality, corrosion resistance, tissue reaction, and surgical implications.

An ideal biomaterial is expected to have a very high biocompatibility which means there is no adverse tissue response when inserting inside the human body environment. It also must have high wear and fatigue resistance, low elastic modulus, high mechanical strength and a density as low as that of bone. This chapter will look into the materials selection for THR prosthesis parts based on literature review and analysis.

4.1 Materials Selection for Femoral Stem

Since femoral component replaces a major portion of femur bone, it needs to have a Young's modulus similar to that of cortical bone and be able to handle the stress which acts on the top of the femur and transmits through the cortical bone in a healthy hip as in figure 4.1a below.

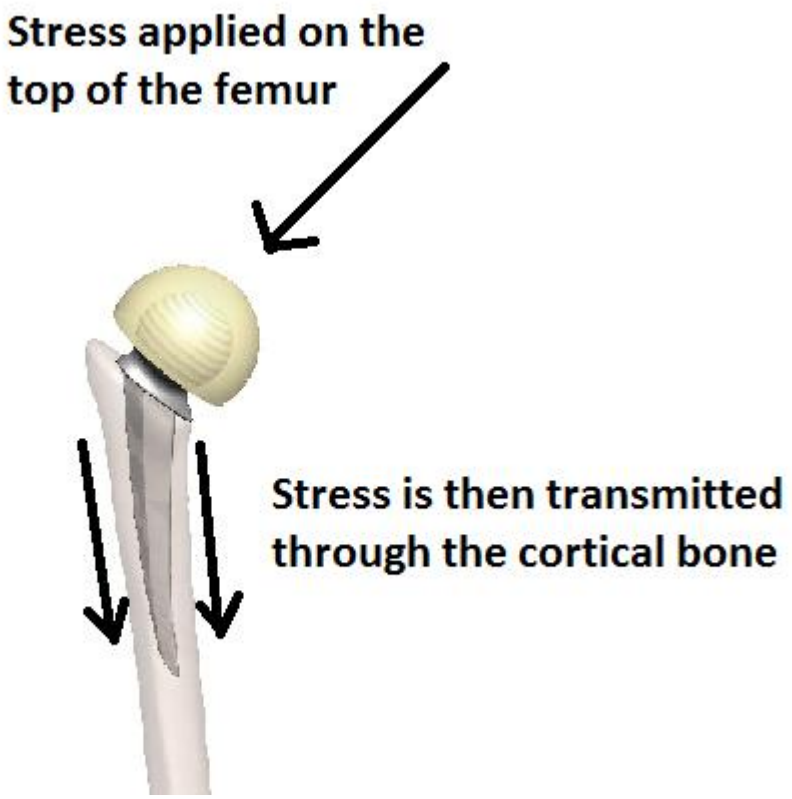


Figure 4.1a: How the stress transmits through femur bone

A dilemma that designers have to face when choosing the material for cementless femoral stem is the balance when choosing high-stiffness and low-stiffness femoral implant materials. When replacing the hip joint with prosthesis components, high-stiffness materials are used to ensure an acceptable range of implant-bone micromotions. The disadvantage of using high-stiffness materials is that they can significantly change the stress distribution of the host bone compared to before surgery. The loads that were originally transferred through bone before total hip replacement (THR) are now carried mainly by the hip implant. Huiskes, Weinans and Van (1992) and Head, Bauk and Emerson (1995) suggested that there is a mismatch in stiffness between the femoral implant and the bone. The loads that are carried by the implant will result in stress shielding and bone remodelling around the implant

subsequently. To respose to this problem, the body will increase osteoclast activity that will cause bone resorption. Bone resorption and subsequent weakening of the complete reconstruction may be caused by this stiffness mismatch. An option for solving this problem is to use implants with low bending stiffness to reduce periprosthetic stress shielding.

The challenge in optimizing cementless implants is to choose the materials that have the balance between high-stiffness characteristic to reduce micromotions and low-stiffness characteristic to reduce periprosthetic bone remodelling.

Although ceramic is responsible for 70 wt% of bone material (Capes and McCloskey 2006), however, femoral stem component cannot use ceramics because they are too brittle. Polymers are also not a good choice due to the incapability of sustaining fatigue. Metals are used in general because of high yield strength and good fatigue resistance. The drawback of using metals, however, is the stress shielding which can be produced because of high stiffness. This will be explained further more in this chapter.

Some metals have excellent biocompatibility and mechanical properties therefore they are used as biomaterials. The number one disadvantage of using metals in an in-vivo environment is its corrosion tendency. Corrosion will lead to material disintegration which will weaken the implant and produce harmful corrosion-related products to the surrounding tissues.

Vanadium-steel alloy was the very first metal alloy used for human body (Oldani and Dominguez 2012). However, this alloy has inadequate corrosion resistance and is no longer in use. Stainless steel was then used widely for implant fabrication because of its excellent corrosion resistance. Nowadays, some of the implants still use stainless steels because they are easy to produce and relatively cheap. Nevertheless, they can cause extreme adverse reactions after surgery for people who have allergies to nickel, which is an element, can be found in stainless steels. Titanium was introduced into the medical field for implant fabrication in the late 1930s (Oldani and Dominguez 2012) and early 1940s (Van Noort 1987).

.

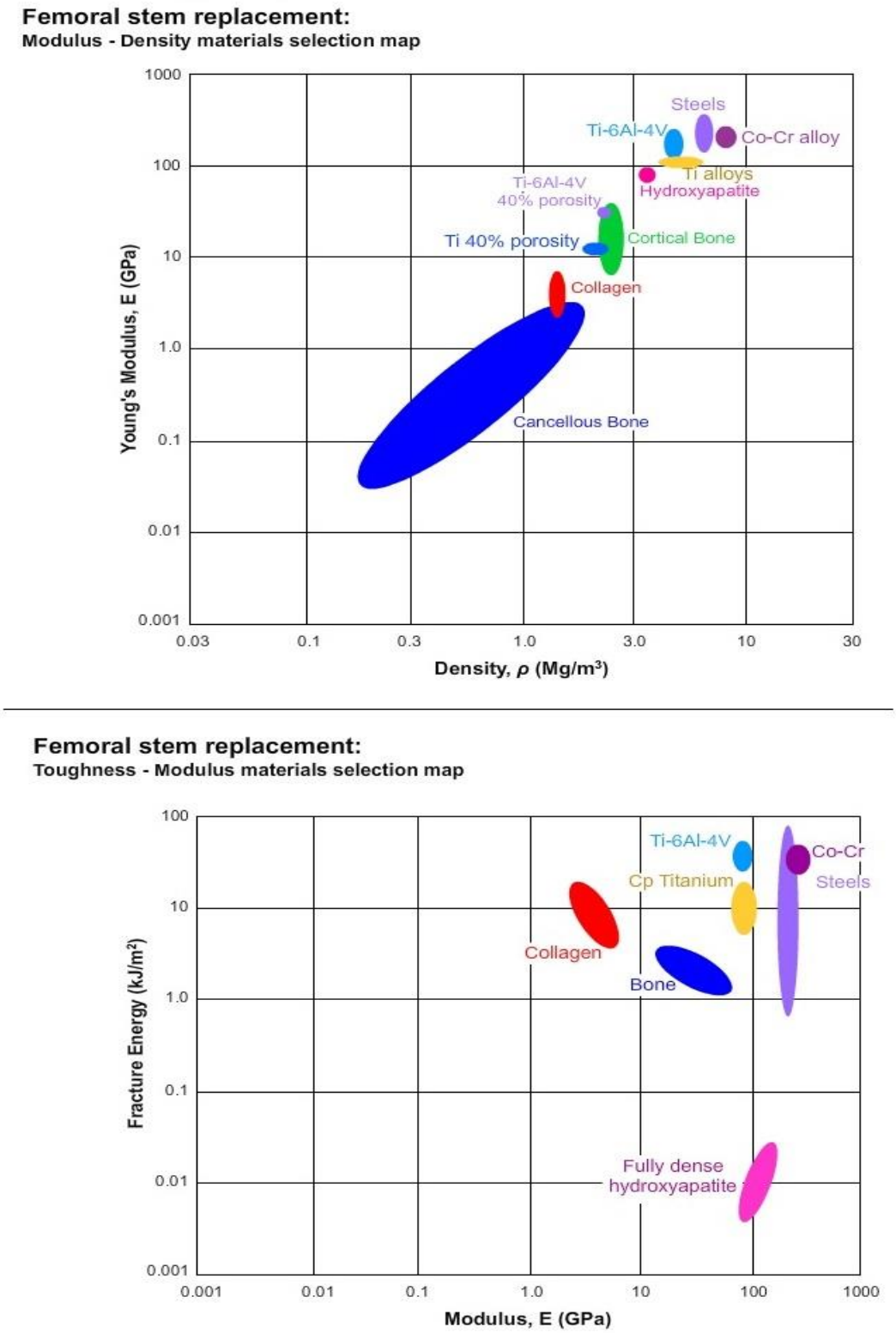


Figure 4.1b: Materials Selection Maps showing some of the most commonly considered metals for femoral stem replacements (reproduced from Capes and McCloskey 2006)

The first materials selection map on the top of figure 4.1b compares modulus and density of different types of bone and the common used materials. It can be seen clearly that steels have the highest Young's modulus and much higher than that of bone. This means that stress shielding will be a serious issue if choosing steels for designing femoral components. The American Iron and Steel Institute (AISI) type 316L is the primary stainless steel that is currently recommended for manufacturing implant devices (Newton and Nunamaker 1985). Many studies including Manivasagam, Dhinasekaran and Rajamanickam (2010), Hornberger, Virtanen, and Boccaccini (2012) and Raval and Choubey (2005) have shown a concern about the biocompatibility of 316L stainless steel and its corrosion resistance in vivo. Even though stainless steels are highly resistant to corrosion in nature, but localized corrosion can be found in these alloys when using in certain environment such as human body. These studties also mentioned that the corrosion products under corrosive attacks could be very harmful for humans. Aksakal, Yildirim and Gul (2004) reported that allergens such as cobalt, nickel, chrome and their compounds are found in stainless steel's corrosion products. Morais et al. (1998, 1999) claimed that 316L stainless steel releases toxic corrosion products to osteogenic cells. The differentiation and proliferation of these cells are also affected. Beyond a certain concentration of this may disturb the normal behavior of marrow cell culture.

Surgical implants also require the biomaterials that have an elastic modulus close to that of bone. The compatibility of Young's modulus between the implant and bone is extremely important for hip implants' long-term performance and expected life. This vital significance is now realized by many medical engineers when designing implants. Cuppone et al. (2004) found that the Young's modulus of the cortical bone in the middle of the femoral shaft has a value of 18.6±1.9 GPa. This number is close to the find of Luckey and Kubli (1983), which is approximately 16.5 GPa. The modulus of elasticity of titanium alloys is about 110 GPa. This is much lower than the Young's modulus of stainless steels (about 210 GPa) and Co-base alloys (240 GPa) (Dadvinson & Gergette, 1987). The modulus-density materials selection map in figure 4.1b clearly shows that titanium and its alloys have the closest Young's modulus value to bone. Moreover, this figure also shows that the density of titanium alloys is also closest to that of bone. Even the modulus of elasticity of titanium is considerably higher than that of bone; it is still unlikely to have any major significance

(Van Noort 1987). This means between the three materials here, titanium alloys are the ideal biomaterial for this criteria.

The mechanical strength requirement for surgical implants must be greater than that of bone. The ultimate strength of bone ranges from 83 MPa to 117 MPa, whereas titanium alloys have the yield strength from 207 and 1379 MPa (Luckey and Kubli 1983). Having high yield strength is a critical factor when choosing biomaterials for medical applications such as hip implants because the body weight is supported on this highly stressed point. Some titanium alloys are currently used in the industry can have up to 828 MPa of minimum yield strength. In the toughness- modulus materials selection map in figure 4.1b, titanium and its alloys (Ti6Al4V) has the highest fracture energy (KJ/m^2) compared to steels and Co-Cr. The excellent strength to weight ratio and high resistance to creep deformation make titanium a good material choice for fabricating femoral stems over stainless steel and cobalt alloys. Table 4.1 below shows the mechanical properties of the common titanium alloys.

Table 4.1: The comparison between different grades of titanium alloys (Luckey and Kubli 1983)

Materials	**Ultimate Tensile Strength (MPa)**	**Yield Strength (MPa)**	**Elongation (%)**	**Reduction of Area (%)**
Grade 1	241	172	24	30
Grade 2	345	276	20	30
Grade 3	448	379	18	30
Grade 4	552	483	15	25
Ti6Al4V (Grade 5)	862	793	10	25

Titanium was reported by Van Noort (1987) to be the only metal biomaterial to osseointegrate. This review also concluded, “Titanium and its alloy are well tolerated by the biological environment and rank among the best metallic materials for clinical use”. Titanium implants are well tolerated by animals (Both, Beaton and Davenport 1940) and reported by Hille 1966; Laing 1977; Williams and Meachim 1974 (cited in Luckey and Kubli 1983) that there is little or no inclination toward corrosion in vivo (within the living organism) or in vitro (outside of a living organism) tests.

The most common titanium base alloys for implant biomaterials are commercially pure titanium (Ti CP) and extra low interstitial Ti-6Al-4V (ELI). These alloys remain essentially unchanged when inserted into the human body environment and are classified as “biologically inert biomaterials” (Oldani and Dominguez 2012). Titanium alloys do not enter into the chemistry of human body as quickly as other biomaterials may. For example, nickel hypersensitivity has been induced by some stainless steels in the surrounding tissues. However, titanium alloys do not promote any adverse reactions and are tolerated well inside the body even when the body is able to recognize them as foreign and tries to isolate them. Therefore, the expected life span of the prosthetic components is substantially extended.

The titanium alloy Ti-6Al-4V has the composition of 6% aluminium and 4% vanadium by weight is often used more than commercial purity titanium alloy as it provides more fatigue resistance and increases toughness. It is also significantly stronger than CP Ti while having the same thermal properties and stiffness. Furthermore, Ti-6AI-4V alloy is easy to weld and machine than the titanium pure form.

The Ti6Al4V alloy also has some disadvantages such as its low wear resistance which can be a problem in articulations surfaces. The price of titanium is more expensive than stainless steel but a smaller mass of titanium would be used when making implants than steel.

For cemented femoral stems, high strength superalloy is recommended as the material selection (Harkess and Crockarell 2013). Cobalt-chrome alloy is preferred by the designers because of its high modulus of elasticity. This characteristic might help reduce the stresses within the proximal cement mantle.

For cementless femoral stems, Harkess and Crockarell (2013) recommended the use of cobalt-chromium alloy or titanium alloy. These two materials have been proven to have satisfactory outcome so far. Since the design is for cementless fixation method that requires a surface coating, cobalt-chromium alloy is combined with a sintered beaded surface and titanium alloy is combined with one of the surface enhancement material.

Similar to the properties of titanium alloys and their popularity in medical devices, Cobalt–chromium (Co–Cr) alloys have also been extensively used for medical

implants because of their excellent biocompatibility, high corrosion resistance and mechanical properties. However, many designers have recommended titanium as the material choice for cementless femoral component because of its lower modulus of elasticity (compared to cobalt-chromium and stainless steel), high fatigue strength and superior biocompatibility.

4.2 Bone Ingrowth Coating Materials for Cementless Implants

The survival rate of cementless implant components depends totally on the growth of host bone into and onto the implant surface; otherwise implant loosening will occur (Jasty et al. 1997). Mai et al. (2010) concluded that having surface texture for cementless femoral stems is one of the most important factors for long-term fixation. A minimization of micro-motions at the implant-bone interface must be taken into account in order to facilitate bone ingrowth. As mentioned earlier in chapter 2, high porous metals are used for the coating of cementless implant components. Tarala, Janssen and Verdonschot (2011) used finite element analysis and found that the tantalum with an inner CoCrMo core produces high performance implant design. This study also confirmed that tantalum coatings perform slightly better with respect to Epoch stem and considerably better with respect to a Ti alloy stem.

The high protective effect of using tantalum coating is also proven in recent studies. Dorn, Neumann and Frank (2014) performed a simulator test to find out the corrosion behaviour of tantalum coating for both cobolt-chromium and titanium modular necks. The tests were done in one dry assembly and two wet assemblies. One wet assembly was contaminated with calf serum and the other was with both calf serum and bone particles.

Figure 4.2 below shows the results of the corrosion behaviour test performed by Dorn, Neumann and Frank (2014) in the serum-plus-bone-fragment assembly for titanium modular neck (left) and tantalum-coated cobalt–chromium modular neck (right). Titanium modular neck shows some marked depositions on large portions of the surface and almost no visible grooves on the surface. This indicates that there are corrosive material attacks when testing titanium modular neck in wet assembly. However there are no visible depositions or corroded areas on the surface of tantalum-coated cobalt–chromium modular neck. The surface has a metallic shine,

except where the contact marks are. This study proves that corrosive attacks happen on titanium surfaces in vitro and no signs of corrosion in dry assembly. In contrast, no traces of chemicla attacks or corrosion on tantalum-coated cobalt–chromium surfaces in both wet and dry assemblies. This study again confirmed the protective effect of tantalum coating and suggested that the risk of implant failure due to corrosion may be reduced when implementing tantalum coating as surface coating.

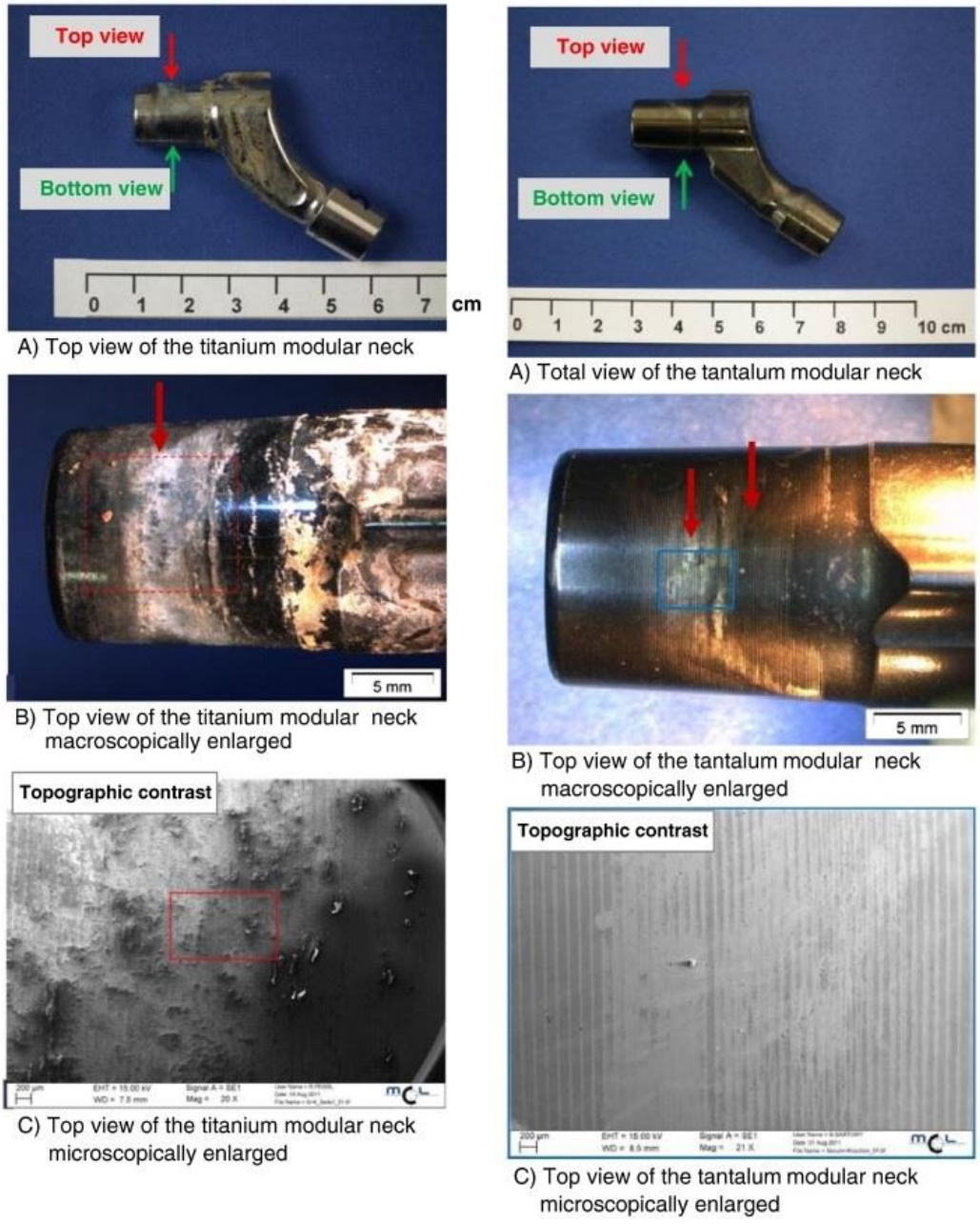


Figure 4.2: The results of corrosion behavior test between titanium modular necks (left) and tantalum-coated cobalt–chromium modular necks (right) in the serum-plus-bone-fragment assembly (Dorn, Neumann and Frank 2014).

4.3 Materials Selection for Bearing Surfaces

The conventional metal on polyethylene bearing surfaces generates particulate polyethylene debris. The main concern is the biological response to the debris that leads to aseptic loosening of the implants and osteolysis. Recent research is trying to focus on finding the alternative bearing surface materials with the expected outcome is to produce less particulate debris from these bearings. A review from Kumar, Arora and Datta (2014) said the bearing surfaces such as metal-on-metal, ceramic-on-polyethylene and ceramic-on-ceramic have shown to reduce friction rates and therefore lower wear rates compared to conventional metal-on-polyethylene bearings. This review also mentioned about the promising and encouraging results from ceramic-on-highly crosslinked polyethylene, ceramic-on-ceramic and metal-on-highly crosslinked polyethylene articulations for active and young patients. The metal-on-metal bearing surfaces have been shown significant safety concerns in clinical experience until now.

The criteria for choosing ideal bearing surfaces for hip implants (Minakawa et al 1998) are:

- Having low biological and tissue reaction to wear debris
- Having high resistance to third body wear
- Generating small volume of wear debris
- Having low coefficient of friction
- Be able to permit adequate fluid film lubrication during stance phase without increasing wear (this is achieved by having enough deformation of articular surfaces).

In the last decades, cobalt-chromium femoral head articulating with an ultra-high molecular weight polyethylene (UHMWPE) acetabular component has been the most acceptable bearing surface couple for hip prosthesis (Kumar, Arora and Datta 2014). This combination of bearing surface has proven to produce the most consistent results in THR (Black 1997).

UHMWPE was first used as a bearing surface for acetabular component in 1958. The early wear is the major issue of metallic heads combined with UHMWPE. Factors such as implant geometry, material properties, sterilization and limited shelf

life influence this early wear (Sandiford et al. 2012). Chronic inflammatory response to foreign body is the consequence of wear debris generated by metal on UHMWPE bearings. Ultimately, this response leads aseptic loosening and fixation failure because of osteolysis in periprosthetic bone (Maloney et al. 1990, Vernon-Roberts and Freeman 1977 and Willert 1977).

Over the years, polyethylene wear particles cause periprosthetic osteolysis to occur at certain level, depends on the wear rates. Green et al. (1998) and Dumbleton, Manley and Edidin (2002) found that osteolysis occurs more commonly when the wear rate is greater than 0.1mm/year and less commonly when the wear rate is less than 0.05mm/year.

A discovery in 1998 was the use of highly crosslinked polyethylene (HXPE) for the first time clinically. This significantly improved the performance of UHMWPE bearing surface and reduced the wear rate substantially. Kurtz and Dorr et al. (cited in Kumar, Arora and Datta 2014) said the crosslinking of polyethylene uses gamma radiation and thermal treatment to decrease wear rates (both adhesive and abrasive) and increase oxidation resistance. Follow-up studies and simulator studies from 10-22 years by D'Antonio et al. (2005), Atienza and Maloney (2008) and Digas et al. (2007) have shown an insignificant amount of wear during the expected life span of the highly crosslinked UHMWPE acetabular components. These clinical findings reported that wear reduction can be provided by using HXPE. Atienza and Maloney (2008) claimed that up to 42% to 100% of volumetric wear has been decreased when compared to conventional metal on polyethylene articulations in vitro hip simulator wear studies. Harkess and Crockarell (2013) said a reduction between 80% and 90% in wear with HXPE has been shown in test data from contemporary hip simulators. The early to intermediate in vivo clinical results found that the HXPE wear properties are surpassing to conventional UHMWPE properties. Alternate cross-linking and free radical quenching techniques have been developed for second-generation HXPE materials to further minimize wear and oxidation.

Chapter 5 – Discussion and Recommendation

The results in table 3.3 of finite element analysis for Thompson Prosthesis model indicate certain level of activities can affect the stress distribution along the prosthesis differently. Maximum stress acting on the hip implant found to be when running and jogging. The high stresses acting on implant when performing these activities also mean the hip joint will carry a relatively high stress at the same time. Therefore it is generally recommended that patients need to follow surgeon's advice after THR and avoid activities that cause too much stress which will lead to failure.

The risk of dislocation and the postoperative range of motion are influenced by the size of the femoral head and the diameter of the femoral neck. Larger femoral head sizes show lower dislocation rates.

For periprosthetic fractures, most of the incidences happen at the femur bone. The bone quality is one of the most important factors that affect the rate of failure. When performing the press-fit method for femoral stem, surgeons need to be very careful, especially with elderly patients or patients who have low bone density.

For cemented THR, Cement-bone interface is believed to be where the early damage of cemented THR components occurs. Using centralizers that are affixed to proximal or distal part of the cemented femoral stem will create uniform cement mantle, centralize the stem and therefore improve the fixation. For cemented acetabular component, using surface textures will improve the bond between cement and the implant.

The materials selection for cemented THR is high strength superalloy. Cobalt-chrome alloy is ideal because of its high modulus of elasticity which helps reduce the stresses within the proximal cement mantle.

For cementless THR, using high porous coatings such as Tantalum will produce extensive and rapid bone ingrowth which promotes high quality fixation. When performing cementless method for patients, surgeons need to make sure that the gap between the implant and the channel is not more than 2mm, otherwise new bone growth cannot reach this gap and loosening will occur. This means the shape

of the implant and the implant itself must be as close as possible. The acetabular cup for cementless fixation is allowed to have 1 to 2mm larger than the reamed acetabulum for press-fit approach.

The materials selection for cementless THR is titanium and its alloys because of its lower modulus of elasticity (compared to cobalt-chromium and stainless steel), high fatigue strength and superior biocompatibility. Ti-6Al-4V is preferred than commercial titanium because it is slightly stronger and has more fatigue resistance and toughness.

For surface bearing, cobalt-chromium femoral head articulating with an ultra-high molecular weight polyethylene (UHMWPE) acetabular component has been the most acceptable bearing surface couple for hip prosthesis.

Cementles fixation is considered to be an alternative for younger and active patients since the success of cemented THR and long-term follow-up is shown for elderly patients but produces higher rate of aseptic loosening and osteolysis for younger and active patients.

In comparison between the two implant types: cemented and cementless, it is no one right answer to choose which one more than another. The choice, however, is made based on the function of the joint, the patient’s expectation, patient’s health and especially their quality of the bone, the objective of the surgery, and the surgeon's experience as well. Different surgeons will prefer one method more than the other. It is vital to have agreeable discussion between surgeons and patients to produce a desirable outcome for the patient’s hip replacement.

The recommended ideal design for THR should utilize all the recommendation in this chapter in terms of materials and fixation methodology.

Chapter 6 – Conclusion

Total hip replacement is an enormous topic which there is never-ending more research and improvement. This document has provided some basic and advance information about background of THR, failure analysis and materials section. There are a number of limitations to the analysis of this document that should be taken into consideration. There several modes of failure and for each failure type, there are different ways or methodologies to analyse the situation.

In general, this THR topic has raised agreements and conflicts between researchers and their findings. The reference list below is the main source of where the majority of information and analysis in this document come from. The author has done what could be done in a limited time and resource and included a personal disclaimer in the appendix section.

Total hip replacement has been the most successful orthopaedic surgeries performed all the time. There is a promising future for this arthroplasty to perform even better for patients. The need to study this topic and testing new materials to improve the current design are always necessary.

References

Ahn, H, Graham, B, Howard, A, Kreder, HJ, Lau, JTC, Lin, SS, Mahomed, NN and Whelan, D, 2009. '*Which Bearing Surface Should Be Used: Highly Cross-Linked Polyethylene versus Metal or Metal versus Ceramic on Ceramic*?'. In: J. G. Wright, ed. *Evidence-Based Orthopaedics: The Best Answers to Clinical Questions.* 1st ed. s.l.:Elsevier Inc., pp. 565-571.

Aksakal, B, Yildirim, ÖS and Gul, H, 2004. '*Metallurgical failure analysis of various implant materials used in orthopedic applications*'. *Journal of Failure Analysis and Prevention,* 4(3), pp. 17-23.

Andrade-Campos, A , Ramos, A and Simões, J, 2012. '*A model of bone adaptation as a topology optimization process with contact*'. *Journal of Biomedical Science and Engineering,* 5(5), pp. 229-244.

Aoi, T. Toshida, A., 2009. '*Hip Replacement : Approaches, Complications and Effectiveness testing 123'.* New York, NY, USA: Nova Science Publishers, Inc..

Ashman, RB, Cowin, SC, Van Buskirk, WC and Rice, JC, 1984. *'A continuous wave technique for the measurement of the elastic properties of cortical bone*'. *Journal of Biomechanics,* 17(5), pp. 349-361.

Atienza, CJr and Maloney, WJ, 2008. *'Highly cross-linked polyethylene bearing surfaces in total hip arthroplasty*'. *Journal of surgical orthopaedic advances,* 17(1), pp. 27-33.

Berry, DJ and Lieberman, J, 2012. *Surgery of the Hip.* Har/Psc editio ed. s.l.:Elsevier Health Sciences.

Black, J., 1997. *'Prospects for alternate bearing surfaces in total replacement arthroplasty of the hip*'. In: W. Puhl, ed. *Performance of the Wear Couple BIOLOX Forte in Hip Arthroplasty: Proceedings of the 2nd Symposium on Ceramic Wear Couple.* Germany: Ferdinand Enke Verlag, Stuttgart: s.n., p. 2–10.

Bonesmart, n.d., '*Hip Replacement Implant Materials'*, viewed 12 May 2014 <http://bonesmart.org/hip/hip-replacement-implant-materials/>

Bothe, RT, Beaton LE and Davenport HA, 1940. '*Reation of bone to multiple metallic implants*'. *Surg Gynecol Obstet,* Volume 71, pp. 598-602.

Bozic, KJ, Kurtz, SM, Lau, E, Ong, K, Vail, TP, Berry, DJ, 2009. '*The epidemiology of revision total hip arthroplasty in the United States*'. *The Journal of Bone and Joint Surgery,* 91(1), pp. 128-133.

Brady, OH, Garbuz, DS, Masri, BA & Duncan, CP, 2000. *'The reliability of validity of the Vancouver classification of femoral fractures after hip replacement*'. *The Journal of Arthroplasty,* 15(1), pp. 59-62.

Capes, J and McCloskey, C 2006, *'Biomaterials and Biomedical Materials: Structure of Bone and Implant materials*', published by DoITPoMS, University of Cambridge. <http://www.doitpoms.ac.uk/tlplib/bones/stem.php>

Charissoux, JL, Asloum, Y & Marcheix, PS, 2014. '*Surgical management of recurrent dislocation after total hip arthroplasty*'. *Orthopaedics & Traumatology: Surgery & Research,* 100(1), pp. S25-S34.

Chen, DW, Lin, CL, Hu, CC, Wu, JW and Lee, MS, 2012. '*Finite element analysis of different repair methods of Vancouver B1 periprosthetic fractures after total hip arthroplasty'*. *Injury,* 43(7), pp. 1061-1065.

Cook, RE, Jenkins, PJ, Walmsley, PJ, Patton, JT and Robinson, Cm, 2008. '*Risk factors for periprosthetic fractures of the hip: a survivorship analysis*'. *Clin Orthop Relat Res,* 466(7), pp. 1652-1656.

Covision Orthopaedics 2012, '*Troy Press-fit / HA Coated Cementless Femoral Stem',* Covision Medical Technologies Limited, viewed 22 July 2014 <http://www.covision-medical.co.uk/index.php?option=com_content&task=view&id=250&Itemid=240>

Cronier, P, Pietu, G, Dujardin, C, Bigorre, N, Ducellier, F and Gerard, R, 2010. '*The concept of locking plates*'. *Orthopaedics & Traumatology: Surgery & Research,* 96(4), pp. S17-S36.

Cuppone, M, Seedhom, BB, Berry, E and Ostell, AE, 2004. '*The longitudinal Young's modulus of cortical bone in the midshaft of human femur and its correlation with CT scanning data*.'. *Calcified Tissue International,* Volume 74, pp. 302-309.

D'Antonio, JA, Manley, MT, Capello, WN, Bierbaum, BE, Ramakrishnan, R, Naughton, M and Sutton, K, 2005. '*Five year experience with crossfire highly cross-linked polyethylene*'. *Clinical Orthopaedics and Related Research,* Volume 441, pp. 143-150.

Davidson, JA and Georgette, FS, 1987. '*State of the Art Materials for Orthopedic Prosthetic Devices'.* Creative manufacturing engineering program, EM87-122. ed. s.l.:Society of Manufacturing Engineers.

Difazio, FA & Incavo, SJ, 2005. *'Periprosthetic Fracture after Total Hip Arthroplasty*'. *Seminars in Arthroplasty,* 16(2), pp. 119-126.

Digas, G, Kärrholm, J, Thanner, J and Herberts, P, 2007. *'5-year experience of highly cross-linked polyethylene in cemented and uncemented sockets. Two*

randomized studies using radiostereometric analysis'. *Acta Orthop,* 78(6), pp. 746-754.

Dorn, U, Neumann, D and Frank, M, 2014. *'Corrosion Behavior of Tantalum-Coated Cobalt–Chromium Modular Necks Compared to Titanium Modular Necks in a Simulator Test*'. *The Journal of Arthroplasty,* 29(4), pp. 831-835.

Dumbleton, JH, Manley, MT and Edidin, AA, 2002. '*A literature review of the association between wear rate and osteolysis in total hip arthroplasty*'. *The Journal of Arthroplasty,* 17(5), p. 649.

Earl's View 2011, '*Hip Implants – from American Academy of Orthopaedic Surgeons*', viewed 21 June 2014, <http://earlsview.com/2011/08/21/hip-implants-from-american-academy-of-orthopaedic-surgeons/>

Foundation, A. R., 2012. *'Autoimmunity Research Foundation'.* [Online] Available at: http://mpkb.org/home/patients/assessing_literature/in_vitro_studies [Accessed 13 July 2014].

Gelalis, I.D, Politis, A.N, Arnaoutoglou, C.M, Georgakopoulos, N, Mitsiou, D and Xenakis, T.A, 2010. *'Traumatic periprosthetic acetabular fracture treated by acute one-stage revision arthroplasty. A case report and review of the literature*'. *Injury,* 41(4), pp. 421-424.

Gras, F, Marintschev, I, Klos, K, Fujak, A, Mückley, T & Hofmann, GO, 2010. *'Navigated Percutaneous Screw Fixation of a Periprosthetic Acetabular Fracture'*. *The Journal of Arthroplasty,* 25(7), pp. 1169.e1-1169.e4.

Green, TR, Fisher, J, Stone, M, Wroblewski, BM and Ingham, E, 1998. *'Polyethylene particles of a 'critical size' are necessary for the induction of cytokines by macrophages in vitro.'*. *Biomaterials,* 19(24), pp. 2297-2302.

Harkess, JW & Crockarell, JR, 2013. *'Arthroplasty of the Hip'*. In: *Campbell's Operative Orthopaedics.* 12th ed. s.l.:Elsevier Inc, pp. 158-310.

Harris, B, Owen, JR, Wayne, JS and Jiranek, WA, 2010. *'Does femoral component loosening predispose to femoral fracture? An in vitro comparison of cemented hips'*. *Clin Orthop Relat Res,* 468(2), pp. 497-503.

Harris, W., 1996. *'Hybrid total hip replacement: rationale and intermediate clinical results*'. *Clinical Orthopaedics and Related Research,* Volume 333, pp. 155-164.

Head, WC, Bauk, DJ and Emerson Jr RH, 1995. *'Titanium as the material of choice for cementless femoral components in total hip arthroplasty*'. *Clinical Orthopaedics & Related Research,* Volume 311, pp. 85-90.

Hornberger, H, Virtanen, S and Boccaccini, AR, 2012. *'Biomedical coatings on magnesium alloys – A review*'. *Acta Biomaterialia,* 8(7), pp. 2442-2455.

Hosseinzadeh, HRS, Eajazi, A and Shahi AS 2012, *'The Bearing Surfaces in Total Hip Arthroplasty – Options, Material Characteristics and Selection*', Recent Advances in Arthroplasty, Dr. Samo Fokter (Ed.), ISBN: 978-953-307-990-5, InTech <http://www.intechopen.com/books/recent-advances-in-arthroplasty/the-bearing-surfaces-in-total-hip-arthroplasty-options-material-characteristics-and-selection>

Howie, DW, Holubowycz, OT, Middleton, R and a Large Articulation Study Group, 2012. *'Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial'*. *J Bone Joint Surg Am,* 94(12), pp. 1095-1102.

Huiskes, R, Weinans, H and Van, RB, 1992. *'The relationship between stress shielding and bone resorption around total hip stems and the effects of flexible materials'*. *Clinical Orthopaedics & Related Research,* Volume 274, pp. 124-134.

Jacofsky, DJ & Hedley, AK, 2012. *'Fundamentals of Revision Hip Arthroplasty: Diagnosis, Evaluation, and Treatment'.* 1st ed. s.l.:SLACK Coperated.

Jameson, SS, Lees, D, James, P, Serrano-Pedraza, I, Partington, PF, Muller, SD, Meek, RM and Reed MR, 2011. *'Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England'*. *J Bone Joint Surg Br,* 7(876-880), p. 93.

Jasty, M, Bragdon, C, Burke, D, O'Connor, D, Lowenstein, J and Harris, WH, 1997. *'In vivo skeletal responses to porous-surfaced implants subjected to small induced motions*'. *Journal of Bone and Joint Surgery,* 79(5), pp. 707-714.

Joint Replacement Institute n.d., '*Types of Hip Replacement and Methods of Fixation'*, viewed 12 June 2014 <http://www.jri-docs.com/hip-resurfacing-replacement/hip-replacement/resources/types-of-hip-replacement-and-methods-of-fixation/>

Kayabasi, O & Erzincanli, F, 2006. *'Finite element modelling and analysis of a new cemented hip prosthesis'*. *Advances in Engineering Software,* 37(7), pp. 477-483.

Kelley, SS, Lachiewicz, PF, Hickman, JM & Paterno, SM, 1998. *'Relationship of femoral head and acetabular size to the prevalence of dislocation'*. *Clinical Orthopaedics & Related Research,* Volume 355, pp. 163-170.

Kluess, D, Martin, H, Mittelmeier, W, Schmitz, K and Bader, R, 2007. *'Influence of femoral head size on impingement, dislocation and stress distribution in total hip replacement'*. *Medical Engineering & Physics,* 29(4), pp. 465-471.

Knoch, MV, Berry, DJ, Harmsen, WS & Morrey, BF, 2002. *'Late dislocation after total hip arthroplasty'*. *J Bone Joint Surg Am.,* 84(11), pp. 1949-1953.

Kumar, N, Arora, GNC and Datta, B, 2014. *'Bearing surfaces in hip replacement – Evolution and likely future'. Medical Journal Armed Forces India,* Volume 70.

Kurtz S, Ong K, Lau E, Mowat F, Halpern M., 2007, "*Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030.*", J Bone Joint Surg Am. 2007; 89(4): 780-785.

Lee, HH, Lo, YC, Lin LC & Wu, SS, 2008. *'Disassembly and Dislocation of a Bipolar Hip Prosthesis'. Journal of the Formosan Medical Association,* 107(1), pp. 84-88.

Lennon, AB, McCormack, BAO and Prendergast, PJ, 2004. *'The relationship between cement fatigue damage and implant surface finish in proximal femoral prostheses*'. *Medical Engineering & Physics,* 25(10), pp. 833-841.

Lewinnek, GE, Lewis, JL,Tarr, R, Compere, CL & Zimmerman, JR, 1978. *'Dislocations after total hip replacement arthroplasties'.* Journal of Bone and Joint Surgery*,* 60(2), pp. 217-220.

Lindahl, H, Malchau, H, Herberts, P & Garellick, G, 2005. *'Periprosthetic femur fractures: Classification and demographics of 1049 periprosthetic femoral fractures from the Swedish National Hip Arthroplasty Register*'. *The Journal of Arthroplasty,* 20(7), pp. 857-865.

Lloyd, J. M & Calder, J. D. F, 2006. '*The Thompson hemiarthroplasty: A new problem for an old favourite*'. *The Journal of Bone and Joint Surgery,* 88B(7), pp. 949-950.

Lombardi AV, Mallory TH, Cuckler JM, et al., 2004, "*Mid-term results of a polyethylene-free metal-on-metal articulation*", J Arthroplasty 2004; last viewed on 15th May 2013

Luckey, HA and Kubli, F, 1983. *Titanium Alloys in Surgical Implants: A Symposium,* s.l.: ASTM International.

Ludwigson, D., 1965. *Requirements for metallic surgical implants and prosthetic devices. Metals Engineering Quarterly.* s.l.:s.n.

Mai, KT, Verioti, CA, Casey, K, Slesarenko, Y, Romeo, L and Colwell, CW Jr, 2010. *'Cementless femoral fixation in total hip arthroplasty*'. *The American Journal of Orthopedics,* 39(3), pp. 126-130.

Maloney, WJ, Jasty, M, Harris, WH, Galante, JO and Callaghan, JJ, 1990. '*Endosteal erosion in association with stable uncemented femoral components*'. *Journal of Bone and Joint Surgery,* 72(7), pp. 1025-1034.

Manivasagam, G, Dhinasekaran, D and Rajamanickam, A, 2010. '*Biomedical Implants: Corrosion and its Prevention - A Review*'. *Recent Patents on Corrosion Science,* Volume 2, pp. 40-54.

McGee, MA, Howie, DW, Costi, K, Haynes, DR, Wildenauer, CI, Pearcy, MJ and McLean, JD, 2000. '*Implant retrieval studies of the wear and loosening of prosthetic joints: a review*'. *Wear,* 31 July, 241(2), p. 158–165.

McGeough, J., 2013. *The Engineering of Human Joint Replacements.* Somerset, NJ, USA: John Wiley & Sons, Ltd.

Miki, H, Sugano, N, Yonenobu, K, Tsuda, K, Hattori, M & Suzuki, N, 2013. '*Detecting cause of dislocation after total hip arthroplasty by patient-specific four-dimensional motion analysis*'. *Clinical Biomechanics,* 28(2), pp. 182-186.

Minakawa, H, Stone, MH, Wroblewski, BM, Lancaster, JG, Ingham, E and Fisher, J, 1998. '*Quantification of third-body damage and its effect on UHMWPE wear with different types of femoral head.*'. *The Bone & Joint Journal,* 80(5), pp. 894-899.

Morais, S, Dias, N, Sousa, JP, Fernandes, MH and Carvalho, GS, 1999. '*In vitro osteoblastic differentiation of human bone marrow cells in the presence of metal ions*'. *Journal of Biomedical Materials Research,* 42(2), pp. 176-190.

Morais, S, Sousa, JP, Fernandes, MH, Carvalho, GS, de Bruijn, JD and van Blitterswijk, CA, 1998. '*Decreased consumption of Ca and P during in vitro biomineralization and biologically induced deposition of Ni and Cr in presence of stainless steel corrosion products*'. *Journal of Biomedical Materials Research,* 42(2), pp. 192-220.

Morais, S, Sousa, JP, Fernandes, MH, Carvalho, GS, de Bruijn, JD and van Blitterswijk, CA, 1998. '*Effects of AISI 316L corrosion products in in vitro bone formation*'. *Biomaterials,* 19(11-12), pp. 999-1007.

Morgan, RL, Farrar, DF, Rose, J and Forster, H, 2003. '*Creep behavior of bone cement: a method for time extrapolation using time–temperature equivalence'. Journal of Materials Science: Materials in Medicine,* 14(4), pp. 321-325.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), 2010. *'What Is a Hip Replacement? Fast Facts: An Easy-to-Read Series of Publications for the Public'.* [Online] Available at: http://www.niams.nih.gov/Health_Info/Hip_Replacement/hip_replacement_ff.pdf [Accessed 26 August 2014].

Newton, CD and Nunamaker, DM, 1985. '*Textbook of Small Animal Orthopaedics'.* s.l.:J.B. Lippincott Company.

Oldani, C and Dominguez, A, 2012. '*Titanium as a Biomaterial for Implants'.* s.l.:INTECH Open Access Publisher.

Peter, R, Lübbeke, A, Stern, R and Hoffmeyer, P, 2011. '*Cup Size and Risk of Dislocation After Primary Total Hip Arthroplasty*'. *The Journal of Arthroplasty,* 26(8), pp. 1305-1309.

Peters, CL, McPherson, E, Jackson, JD and Erickson, JA, 2007. '*Reduction in early dislocation rate with large-diameter femoral heads in primary total hip arthroplasty*'. *The Journal of Arthroplasty,* 22(6), pp. 140-144.

Peterson, CA & Lewallen, DG, 1996. '*Periprosthetic fracture of the acetabulum after total hip arthroplasty*'. *The Journal of Bone and Joint Surgery,* 78(8), pp. 1206-1213.

Pithioux, M, Lasaygues, P and Chabrand, P, 2002. *'An alternative method to determine the elastic properties of cortical bone*'. *Journal of Biomechanics,* Volume 35, pp. 961-968.

Race, A, Miller, MA, Ayers, DC and Mann, KA, 2003. '*Early cement damage around a femoral stem is concentrated at the cement/bone interface*'. *Journal of Biomechanics,* 36(4), pp. 489-496.

Raval, A and Choubey, A, 2005. '*Surface conditioning of 316LVM slotted tube cardiovascular stents*'. *Journal of Biomaterials Applications,* 19(3), pp. 197-213.

Reilly, DT and Burstein, AH, 1975. '*The elastic and ultimate properties of compact bone tissue*'. *Journal of Biomechanics,* 8(6), pp. 397-405.

Rodríguez-González, FÁ 2009, "*Biomaterials in Orthopaedic Surgery*", published by The Materials Information Society, ASM International, First printing, December 2009

Sanchez-Sotelo, J & Berry, DJ, , 2001. '*Epidemiology of instability after total hip replacement*'. *Orthopedic Clinics of North America,* 32(4), pp. 543-552.

Sandiford, NA, Alao, U, Skinner, JA and Samsani, SR 2012, '*Hip arthroplasty, recent advances in hip and knee arthroplasty'*, in SK Fokter (ed.), *Recent Advances in Hip and Knee Arthroplasty,* 978-953-307-841-0, InTech,
<http://www.intechopen.com/books/recent-advances-in-hip-and-knee-arthroplasty/hip-arthroplasty>

Springer BD, Fehring TK, Griffin WL, Odum SM, Masonis JL, 2009, "*Why revision total hip arthroplasty fails*", Clin Orthop Relat Res. 2009;467(1):166-173

Stolk, J, Verdonschot, N, Cristofolini, L, Toni, A and Huiskes, R, 2002. *'Finite element and experimental models of cemented hip joint reconstructions can produce similar bone and cement strains in pre-clinical tests*'. *Journal of Biomechanics,* 35(4), pp. 499-510.

Tarala, M, Janssen, D and Verdonschot, N, 2011. '*Balancing incompatible endoprosthetic design goals: A combined ingrowth and bone remodeling simulation*'. *Medical Engineering & Physics,* 33(3), pp. 374-380.

The American Academy of Orthopaedic Surgeons, 2011. '*Total Hip Replacement'.* [Online] Available at: http://orthoinfo.aaos.org/topic.cfm?topic=a00377 [Accessed 15 April 2014].

The American Academy of Orthopaedic Surgeons, 2013, '*Fracture After Total Hip Replacement*', viewed 15 April 2014, <http://orthoinfo.aaos.org/topic.cfm?topic=A00634>

Trampuz A, Zimmerli W, 2005, "*Prosthetic Joint Infections: update in diagnosis and treatment*", Swiss Med Wkly, 2005; 135(17-18):243-251

Ulrich, SD, Seyler, TM, Bennett, D, Delanois, RE, Saleh, KJ, Thongtrangan, I, Kuskowski, M, Cheng, EY, Sharkey, PF, Parvizi, J, Stiehl, JB, and Mont, MA, 2008. '*Total hip arthroplasties: What are the reasons for revision?*'. *Int Orthop,* 32(5), p. 597–604.

Van Noort, R., 1987. '*Titanium: the implant material for today*'. *Journal of Material Science,* Volume 22, pp. 3801-3811.

Vernon-Roberts, B and Freeman, MAR 1977, '*The tissue response to total joint replacement prosthesis*', in SAV Swanson and MAR Freeman (ed.), The Scientific Basis of Joint Replacement, Pitman Medical Publishing, Tunbridge Wells, pp. 86–129

Willert, H., 1977. '*Reactions of the articular capsule to wear products of artificial joint prosthesis*'. *Journal of Biomedical Materials Research,* 11(2), pp. 157-164.

Wimmer, MA, Sprecher, C, Hauert, R, Täger, G aand Fischer, A, 2003. '*Tribochemical reaction on metal-on-metal hip joint bearings- A comparison between in-vitro and in-vivo results'. Wear,* 255(7-12), pp. 1007-1014.

Wolff, LH, Berry, DJ, 2009. '*Chapter 64 Periprosthetic Fractures of the Lower Extremity*'. In: B. Browner, et al. eds. *Skeletal Trauma , Forth Edition.* s.l.:Elsevier Inc., pp. 2843-2861.

Yoon, TR, Park, KS and Lim, HA, 2013. '*Cementless Implant in Total Hip Arthroplasty*'. *Hip Pelvis,* 25(1), pp. 14-20.

Appendix

Appendix A – Project Specification

University of Southern Queensland

Faculty of Engineering and Surveying

ENG4111/4112 Engineering Research Project

Project Specification

FOR: Liem Nguyen

TOPIC: Investigation in failure analysis and materials selection in Total Hip Replacement prosthesis.

SUPERVISOR: Steven Goh

ENROLMENT: ENG4111 - S1, 2014

ENG4112 - S2, 2014

PROJECT AIM: This project aims to improve the design of the Total Hip Replacement prosthesis parts to reduce the risks of potential failures.

SPONSORSHIP: Not applicable

PROGRAMME: Issue A, 13th March 2014

1. Literature review of failures and materials relating to total hip replacement design and manufacture of prosthesis parts. As part of the literature review, a critical analysis of the chronological progress of the hip replacement industry and the impact on patients.
2. Determine suitable and rigorous methodologies for failure analysis and materials selection.
3. Analyse the performance failures of the prosthesis parts to determine the failure modes.
4. Apply materials selection strategies for relevant parts of the prosthesis design.
5. Recommend a conceptual design to reduce the risks of potential failures.

As time and finance permit:

6. Laboratory testing of the relevant prosthesis parts or equivalent.

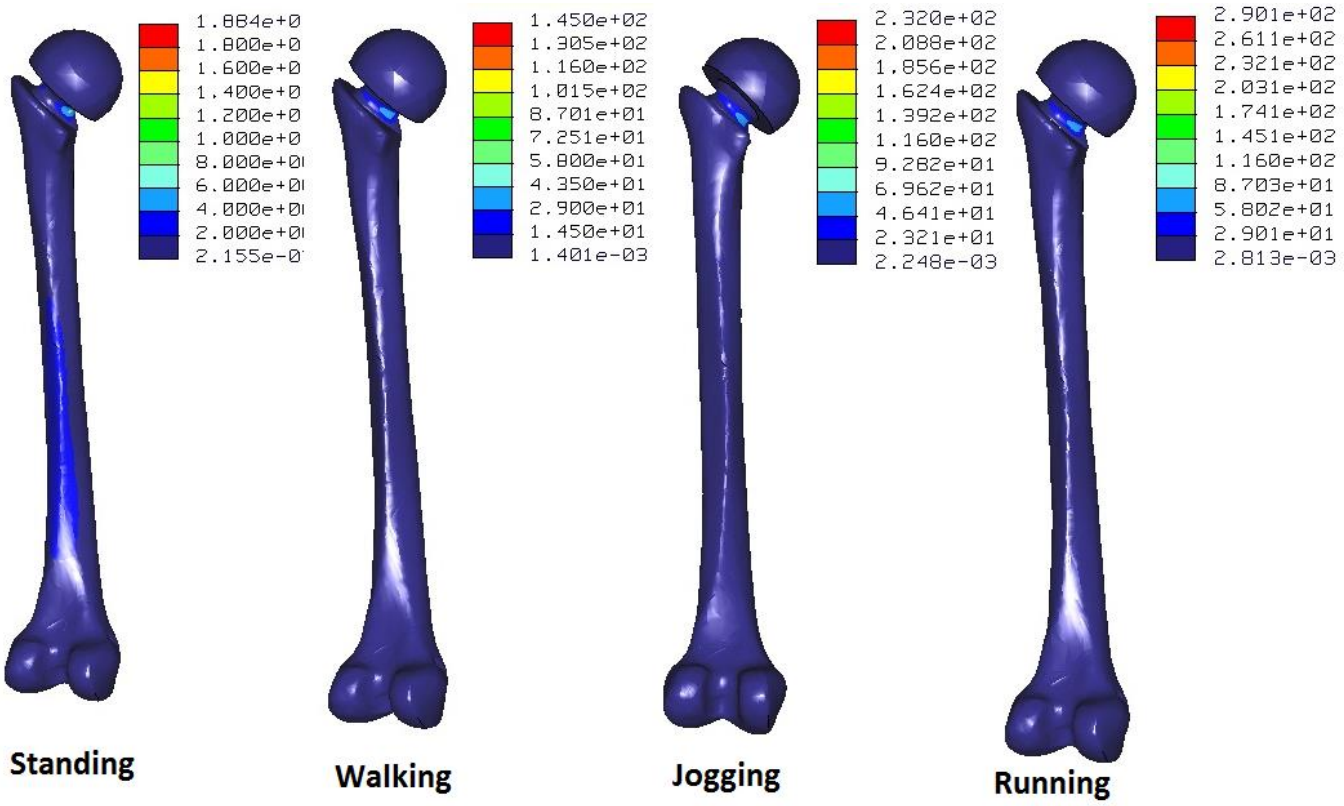
AGREED: _____ (Student) Date: 13/3/14

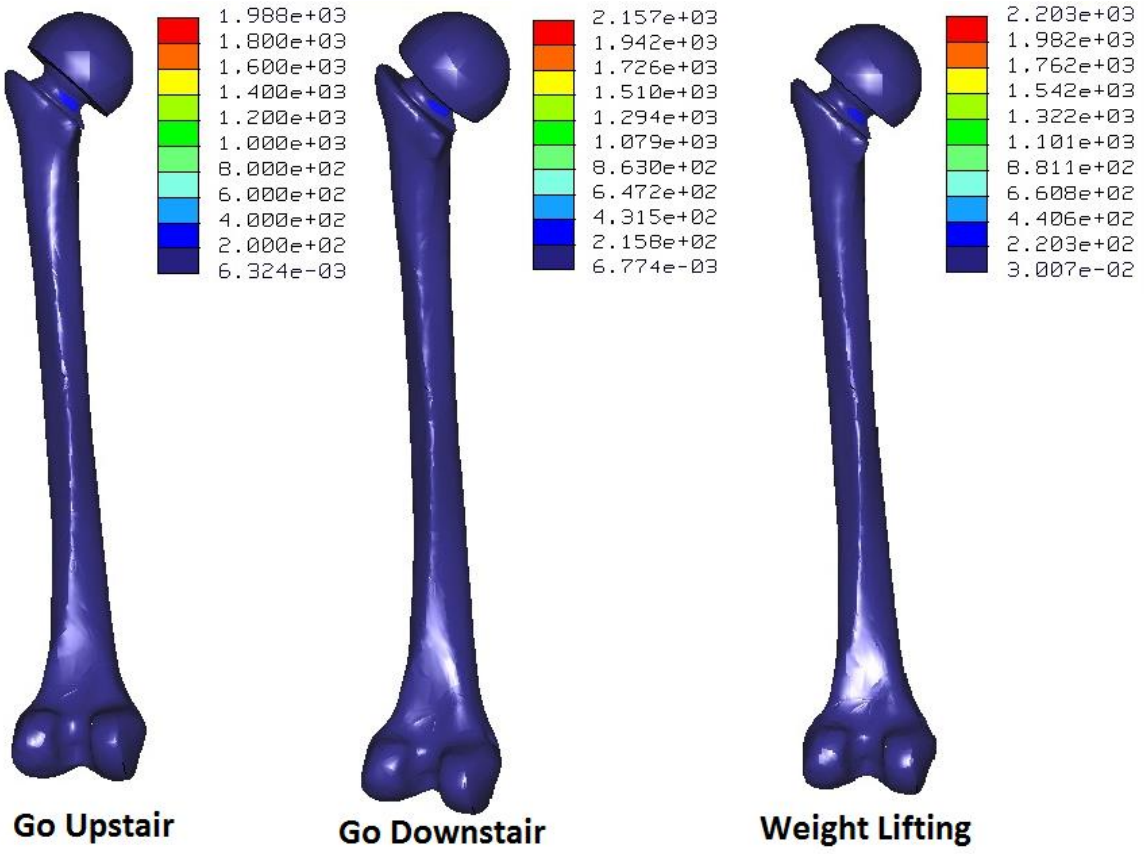
_____ (Supervisor) Date: 13/3/14

Examiner/co-examiner: _____

Appendix B – FEA results of Thompson Prosthesis

Some current results of Stress analysis of prosthesis




1.988e+03
1.800e+03
1.600e+03
1.400e+03
1.200e+03
1.000e+03
8.000e+02
6.000e+02
4.000e+02
2.000e+02
6.324e-03
2.157e+03
1.942e+03
1.726e+03
1.510e+03
1.294e+03
1.079e+03
8.630e+02
6.472e+02
4.315e+02
2.158e+02
6.774e-03
2.203e+03
1.982e+03
1.762e+03
1.542e+03
1.322e+03
1.101e+03
8.811e+02
6.608e+02
4.406e+02
2.203e+02
3.007e-02
Go Upstair
Go Downstair
Weight Lifting

Appendix C – A personal disclaimer from author

Disclaimer

This document is produced by a 4th year mechanical engineering student for the final year dissertation as a requirement to complete his Bachelor of Mechanical Engineering Degree.

All efforts have been made to ensure accuracy, but the author will not be held responsible for any remaining inaccuracies. This document can be used as a reference for further study and research about Total Hip Replacement topic. However it is not a professional medical paper that is certified, qualified or approved by any medical organisation.

Medical doctors, surgeons, researchers and other professions must not rely solely on the findings of this document for their practice. It is highly recommended to look further into other documents and resources, including the ones listed in the reference list in the end of this document to learn more about the topic.

Appendix D - Risk Assessment

Part 1 - Potential risks

Even this project mainly focuses on research and literature review, there are still some risks that can arise when researching, development the conceptual design as well as the future risks that might involve when people rely on the finding of this project.

Risk assessment helps identify the potential risks that are likely to occur and the consequence of it and it is very important in any project especially in engineering project. Developing the risk management strategy will eliminate the likelihood and the consequence of an unfortunate event to occur. A practical approach must be taken for risk assessment.

The procedure that will be used here is taken from the ENG3003 Engineering Management: Study Book 2 (2014). Risk assessment consists of 4 steps:

Step 1: Hazard Identification

Step 2: Risk Assessment

Step 3: Risk Control

Step 4: Monitor & Review

The first step in a risk assessment is to identify the different possible hazards. The following are the possible hazard that might occur during testing the prosthesis model:

- Electrical hazards from power supplies in the laboratory.
- Operation of machines that used to test the parts.
- Handling materials with sharp edge or cutting chips.
- Stripping or falling in the laboratory.
- Heavy things fall on feet.

Similarly there are also some hazards that might occur when researching literature review for the project as well as the risks involved if other people rely on the quality

of this project for use in the future. Comparing to the quality and expectation of a professional document in the total hip replacement industry, this report might have the following limits.

- Inaccurate information provided in report
- Insufficient practical testing

Part 2 -Risk assessment and management

This section will cover the last three steps of a risk assessment process which is risk assessment (step 1), risk control (step 3), monitor and review (step 4).

In order to perform a risk assessment, a risk assessment matrix will be used in table 6.1 below. For each of the hazards mentioned in the section above, the consequences involved in each hazard will be rated based on the damage it might have on human resources and finance. The risk level is based upon the consequence it might have and the likelihood of this event to occur. The result is then recorded in table 6.2 below.

Risk assessment matrix

Likelihood	Consequences				
	1 – Low	2 – Minor	3 – Moderate	4 – Major	5 - Catastrophic
5- Almost Certain	M	H	E	E	E
4 – Likely	M	H	H	E	E
3 – Moderate	L	M	H	H	H
2 – Unlikely	L	L	M	M	M
1 – Rare	L	L	L	L	L
Recommended action					
E: Extremely High Risk – Must Not Proceed The Task					
H: High Risk – Must Require Special Procedure/Supervision					
M: Moderate Risk – Risk management Plan/ Work Method Statement/Workplace Safety Required					
L: Low Risk – Follow Normal Procedure					

Risk assessment result table

Risk	Consequence	Risk level	Current control	Additional control required
Electrical hazards from power supplies in the laboratory.	When testing prosthesis and using electronic machines might represent some electronic shock hazard.	Low risk	Be careful of the electricity wiring system and power boards when using.	Low risk- no further control required
Operation of machines that used to test the parts.	Cutting, Puncturing, fingers/hands between doors,	Moderate risk	Ensure machine operators trained. Follow instruction in machine user manuals and wear safety gears when operating machine.	Moderate risk – report to site supervisor about injuries or machine damage
Handling materials with sharp edge or cutting chips.	Small Cuts in fingers/hands when handling chips or sharp edges not carefully.	Low risk	Wear appropriate safety gears.	Low risk- no further control required
Stripping or falling in the laboratory.	Laboratory floor can be slippery and causes falling,	Low risk	Be mindful of your steps when moving around and wear appropriate safety shoes	Low risk- no further control required
Heavy things fall on feet.	Prosthesis parts can drop on feet if not handled properly	Low risk	Wear appropriate safety shoes	Low risk- no further control required
Inaccurate information provided in report	Report produced by university student might have some limit in professionalism and accuracy	Low risk	Check other reliable sources and seek for more experts' advice when consider using the findings in this report	Low risk- no further control required
Insufficient practical testing	There are limiting practical resources when producing this report. It's mainly based on previous researches	Low risk	Check other reliable sources and seek for more experts' advice when consider using the findings in this report	Low risk- no further control required

Appendix E – Assessment of consequential effects, implications and ethics

Part 1 - Consequential effects and implementations

Consequential effects play an important role in any engineering and spatial science technical activity. In this project, the main consequential effects need to be concerned is the accuracy of the findings of this project and the feasibility and practicality of the conceptual design and recommendations. Since this project is about total hip replacement on human body, therefore there needs to have further intensive studies, researches and testing before implementing anything recommended in this project.

Part 2 - Ethical responsibility

As engineering practitioners, the benefits of community and the creation of engineering solution for sustainable future are our priority. We use our knowledge and skills to serve the community ahead of other sectional or personal interests.

According to the code of ethics (Engineers Australia, 2010), engineers need to demonstrate the following four regulations:

- Demonstrate of integrity
- Practise competently
- Exercise leadership
- Promote sustainability

To demonstrate integrity, it is important to do the right and appropriate things in a professional manner. Integrity is also about being honest and trustworthy, accepting responsibility and be prepared to explain the work and reasoning as well as respecting the dignity of other people.

Competent practice is about maintaining and developing knowledge and skills and act on the basic of adequate knowledge (Engineers Australia 2010).

Leadership in engineering practice needs to be exercised. Practising leadership is about support and encourages diversity, uphold trustworthiness and reputation of the practice of engineering and communicate effectively and honestly. Finally, in engineering practice, sustainability needs to be promoted to balance the needs for now and the needs for future generations. The health and well-being of the community and environment need to be engaged responsibly.

----------The End ----------