University of Southern Queensland

Faculty of Health, Engineering & Sciences

Failure Analysis of Total Hip Replacement and the feasibility of Fibre composites as an alternative material

Research Project submitted by Swapan Sadanala

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Abstract

As biomedical engineering continues to advance in the modern age, basic engineering materials have become more useful despite their other engineering applications. Total Hip Replacement (THR) has remained as one of the biggest achievements in the history of biomedicine. As the demand for hip implants continue to increase, the necessity to improve the quality of these implants continues to increase every day. The following project provides a detailed understanding of the highlighted materials and techniques that have contribute to the development and failure of hip implants. The purpose of this project to provide a failure analysis of the hip implants currently being used in the industry and perhaps provide an alternative material as a feasible option to increase the quality of the implants.

The use of carbon fibre reinforced composite materials for biomedical hip implants is primarily focused in the following project to propose a theoretically justified preliminary design. The design is validated through a detailed Finite Element Analysis and Abrasive testing using standard methods. The results obtained through FEA suggested the addition of CFR-PEEK layer for femoral head surface offers the desirable strength and durability. To further validate the model, the abrasive test results demonstrated relatively low wear rates compared to most of the material specimens used.

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Furthermore, I would also like to sincerely thank Mr. Chris Snook, lecturer (Mechanical Engineering) for his constant support throughout the duration of my project.

Certification

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.

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Chapter -1 Introduction

1.1 – Chapter overview

The following project was undertaken based on the research projects provided by the University of Southern Queensland. This chapter provides an overall understanding of the project through analysis of the background, project aim and the objectives. An outline of the project format is detailed in section 1.5, Project Overview.

1.2 - Background

As biomedical engineering continues to advance in the modern age, basic engineering materials have become more useful despite their other engineering applications. It is evident that the use of these materials is tremendously increasing as the number medical operations continue to increase every day. First performed in 1960, total hip replacement or arthroplasty is one of the most successful operations in medicine history. The improvements in joint replacement surgical techniques and technology have tremendously increased the effectiveness of total hip replacement (AAOS 2013a). According to the Australian Orthopaedic Association, over 35,000 hip replacements are performed annually in Australia.

A hip replacement involves a surgical procedure to replace the damaged hip of a patient suffering with arthritis, a fracture or other hip diseases. The primary goal is to essentially provide the patient with a functional hip replacement joint in order to help restore their mobility and relieve any pain associated. Over the past few decades, several advances have been made in the design, construction and implantation of the artificial hip joints.

1.3 - Project Purpose

This project seeks to investigate the failure of orthopaedic hip prosthesis and the possibility of using fibre reinforced polymer composites as an alternate material based on the performance requirements. As a result, the main objective of this thesis was to develop a preliminary design with the use of CFR-PEEK as an alternative material for the femoral components in hip implants to potentially provide higher stability, reduce the risk of dislocation and resistant to abrasive wear from the component surface.

1.4 - Project objectives

- Provide an analysis of the potential causes of failure based on an extensive review of literature.
- Research into the materials used for designing the hip implant and provide and provide an alternate material based on appropriate materials selection method.
- Perform an investigation to study the mechanical performance of carbon fibre reinforced composite hip prosthesis.
- Propose a theoretically justified preliminary implant design using carbon fibre reinforced polymers.
- Validate the preliminary design based on detailed Finite Element Analysis and abrasive wear testing.
- Obtain the potential long-term results of using fibre-composite hip prosthesis.

1.5 - Project Overview

The following project is presented in a professional manner in order to provide the reader a structure to follow. The basic outline of used throughout the project is detailed below:

Chapter 1 – This chapter will provide the basic background of the project and the main purpose and objectives for conducting the research.

Chapter 2 – This chapter is essentially performed to conduct a detailed review of Total Hip Replacement from a theoretical point of view.

Chapter 3 – This chapter includes the material section process for the hip implant based on the relevant criteria.

Chapter 4 – Propose a theoretically justified preliminary design based on the conducted literature review and material selection process.

Chapter 5 - This chapter assesses the methodology used for the following project including the design considerations, risk assessment and the project timeline.

Chapter 6 – Perform FEA of the preliminary design using relevant engineering considerations such as loading, constraints, material properties and properly defined assumptions.

Chapter 7– This chapter describes the abrasive wear mechanism and the possible effects on the material, it will also include the testing and results of multiple materials to compare with the proposed CFR-Peek.

Chapter 8 – This chapter outlines the models limits and the validation of the FEA modelling which has been conduct, as well as the validation of the abrasive wear testing.

Chapter 9 – The final chapter will conclude the overall results of the testing conducted and the FEA modelling. This will also include future work and recommendations of the material.

Chapter -2 Literature Review

2.1 Chapter Overview

Hip replacement is essentially performed on patients suffering with arthritis, a fracture or other hip diseases. The primary goal of an implant is to essentially provide the patient with a functional hip replacement joint in order to help restore their mobility and relieve any pain associated. In order to analyse and compare the performance of hip prosthesis used in the modern society, it is important to develop an understanding of the basic theory behind the human hip joint.

This chapter of literature review covers the anatomy of the human hip joint and understanding the basic function of a hip implant by reviewing existing journals, books and other research material.

2.2 Anatomy of Human Hip Joint

The hip is one of the largest joints and an essential part of the body. The primary function is to make the legs mobile without reducing the ability to support the weight of human body during both static and dynamic positions. It is fundamentally a ball-and-socket joint where ball acts as the femoral head, which is the upper end of the thighbone and the socket is formed by the acetabulum, which is part of the large pelvis bone. The bone surfaces of the ball and socket are covered with articular cartilage, a smooth tissue that cushions the ends of the bones and enables them to move easily (AAOS 2013a).

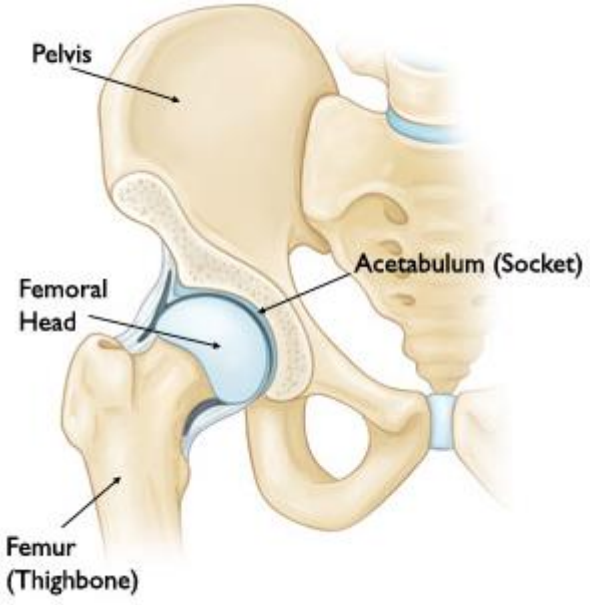


Figure 2-1: Normal Hip Anatomy (Source: AAOS 2013)

The image above provides an illustration of the arrangement of hip joint in the human body. The hip joint is formed between head of femur and acetabulum of hip bone. The femoral head is spherical while the acetabulum is cup shaped. Thus the articular surfaces are reciprocally curved (Iqbal 2011). Functionally, the hip joint provides a very high range of motion. The ball-and-socket structure of the joint allows the femur to rotate freely through a 360-degree circle. The femur may also rotate around its axis about 90 degrees at the hip joint (Taylor 2015).

2.3 Biomechanics of the hip joint

It is essential to develop an understanding of the biomechanical principals of the hip in order to gain a perspective to our understanding of the mechanism of injury. The hip is subjected to substantial amount of stress over a lifetime from movement, weight bearing and repetitive impact. Any instability in the smooth gliding of the joint surfaces can cause deterioration of the cartilage and, consequently, of the joint (Wang, Bhandari & Richard J. Lachowsk 2001). In order to understand the function of total hip, it is crucial to determine the directions of the resultant force on the joint.

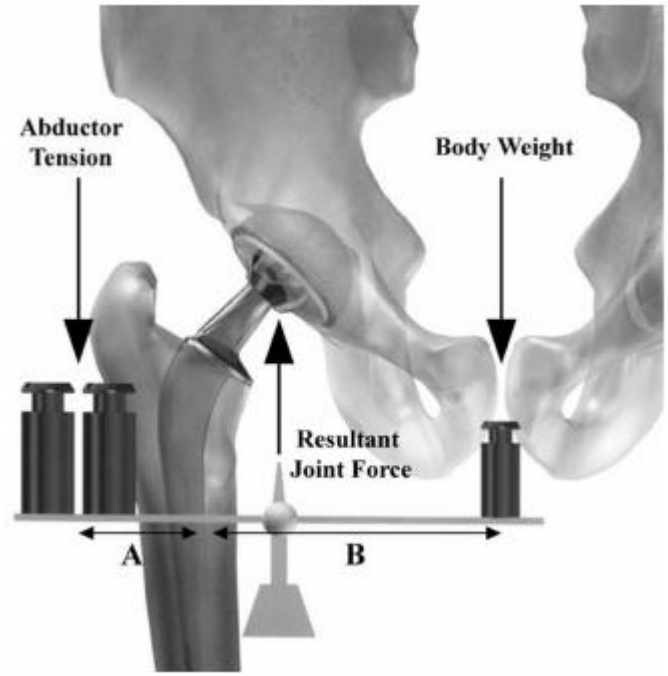


Figure 2-2: Forces acting on the hip

In principle, the hip joint performs as a fulcrum, resulting in a state of equilibrium between body weight and the opposing hip abductors (Charles et al. 2004). It moves in a combination of three basic planes: flexion and extension, abduction and adduction (side-to-side), and external and internal rotation. As a result, the muscles

that hold the body erect and allow performing actions such as walking and climbing stairs exert substantial forces across the hip in the range of three to six times the body weight (Wang, Bhandari & Richard J. Lachowsk 2001). The body weight can be represented as load applied to a lever arm extending from the body's centre of gravity to the centre of the femoral head (Albanese & Faletti 2013).

Based on the image illustrated above (Fig. 2-2), it can be seen that the length of the lever arm acting between the femoral head and the insertion of the hip abductors (distance A) is considerably smaller than that between the femoral head and body weight (distance B). As a result, the abductors must generate a force that is larger than body weight to hold the pelvis level during a one-legged stance and a greater moment to tilt the pelvis to the same side when walking (Albanese & Faletti 2013).

A recent study on imaging of prosthetic joints conducted by (Albanese & Faletti 2013) suggests the ratio the length of the lever arm of the body weight to that of the abductor musculature is approximately 2.5 : 1. In order to maintain the pelvis level, the force needed by abductor muscles must approximate 2.5 times the body weight. As a result, increasing the lever arm ratio also increases the abductor muscle force required for gait and consequently the force on the head of the femur as well (Byrne et al. 2010).

In general, a larger body weight could have a higher effect on the total compressive force on to the joint. It is important to determine the maximum forces applied on the hip joint before designing and manufacturing hip prosthesis. Studies in the past have suggested that the forces applied on the joint vary depending the type of activity performed. Walking transmits significant body weight to the hip joint, while jogging, running and contact sports generate forces significantly greater (Byrne et al. 2010). The typical peak forces acting on the hip joint based on the performed activity are represented below:

Activity	Typical Peak Force (BW)
Walking, slow	1.6-4.1
Walking, normal	2.1-3.3
Walking, fast	1.8-4.3
Jogging, running	4.3-5.0
Ascending stairs	1.5-5.5
Descending stairs	1.6-5.1
Standing up	1.8-2.2
Sitting down	1.5-2.0
Knee bend	1.2-1.8
Stumbling	7.2-8.7

Figure 2-3: Hip Contact Forces Measured In Vivo in Patients with Instrumented Implants (Callaghan et al. 1998)

2.4 Total Hip Replacement (THR)

Total hip replacement is one of the most successful and cost effective interventions in medicine. It offers reliable relief of pain and considerable improvement in function in patients suffering with osteoarthritis or inflammatory arthritis of the hip (R W Crawford 1997).

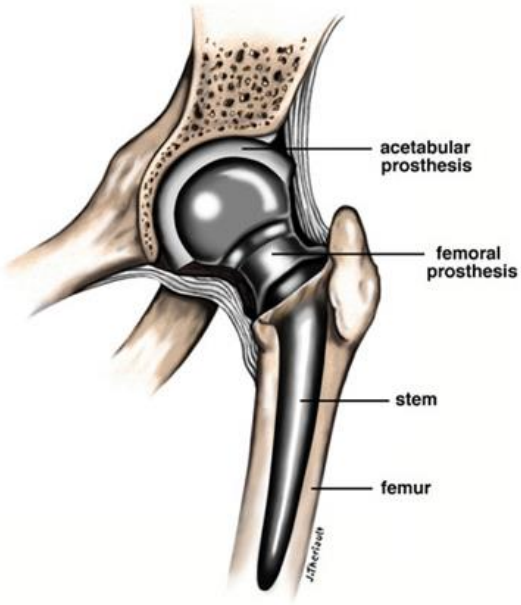


Figure 2-4: Total Hip Replacement (www.oahct.com)

The primary goal of the operation is to essentially provide the patient with a functional hip replacement joint in order to help restore their mobility and relieve any pain associated. The hip replacement requires performing the following basic steps:

- The damaged femoral head (ball) is removed and replaced with a metal stem that is placed into the hollow centre of the femur. The size of the femoral head will be chosen based on factors such as patient age, sex, other diseases and surgery.
- A metal or ceramic ball is then positioned on the upper part of the stem in order to replace the damaged femoral head.
- The bearing surface (where the ball and socket meet) is then inserted replacing the damaged cartilage surface of the socket (acetabulum). The main types of options are metal on polyethylene (plastic), metal on metal, ceramic on polyethylene, and ceramic on ceramic
- To allow a smooth gliding between the ball and socket, a spacer made up of either plastic, ceramic or metal is inserted.

2.5 Surface bearing combinations

Although total hip replacement is established as one of the most successful operations in modern medicine, the type of implant and material used when compared to another has remained one of the most important preoperative decisions made by both patient and surgeon. The materials used for the implant depend on several factors, including the age of the patient, the activity level of the patient, and the surgeon's preference (Cluett 2014). Although the design standards vary between each manufacturer, the types of implants used can generally classified into four main categories as listed below:

- Metal-on-Plastic (polyethylene or UHMWPE)
- Ceramic-on-Plastic (UHMWPE)
- Ceramic –on-Ceramic (CoC)
- Metal-on-Metal (MoM)

The categories mentioned above refer to the most widely materials used for the implant bearings. The stem and ball are inserted against the cup or acetabulum and each component can be made of one of several materials. As a result, it is important

develop an understanding of the advantages and disadvantages associated with the different bearing combinations.

2.5.1 **Metal-on-Polyethylene (Plastic)**

The metal-on-polyethylene implants are the most commonly used hip implants for total hip replacement. In this type of implant, both the ball and the socket of the hip joint are replaced with a metal prosthesis, and a plastic spacer is placed in between (Cluett 2014). The common metals used for the implant include titanium, stainless steel, and cobalt chrome. The current plastic used in hip replacement implants is referred to as Ultra Highly Cross-Linked PolyEthylene (UHXLPE) or Ultra High Molecular Weight PolyEthylene (UHMWPE), a very stable and reliable plastic material with greatly reduced risk for wear (Bonesmart 2015a). The implant is attached to the bone by either press-fitting or cementation.

2.5.2 **Ceramic-on-Ceramic**

Ceramic-on-ceramic implants are a good combination which offer longevity and reliability and are designed to be the most resistant to wear compared to the other type of implants. In this type of implants, the femoral head and acetabulum (socket) are replaced by a high-strength ceramic bearing which is capable of low wear performance. Ceramic is the hardest implant material used in the body and is generally more scratch resistant and smoother than any other implant materials being used today. As a result, there is usually no inflammation or bone loss, nor systemic distribution of wear products in the body. New ceramics offer improved strength and more versatile sizing options (Bonesmart 2015a). Although ceramic-on-ceramic implants provide several advantages, there have been various issues associated with using these type of implants. In the past, there have been concerns that these ceramic implants can break inside the body. This issue has been resolved to a great extent due to new and improved products from technology. However, (Bonesmart 2015a) suggests that squeaking still remains as a problem for a few patients. Often the noises abate over time but sometimes they don’t. Generally a revision may be necessary if the squeaking is intolerable.

2.5.2.1 **Ceramic-on-Polyethylene**

Ceramic-on-plastic implants offer a good combination due to their reliable materials. In this type of implant, the acetabular cup is made up of plastic while the femoral

head is generally made up of stainless steel or cobalt alloys. As mentioned previously, ceramic heads are harder than metal and are the most scratch-resistant implant material. The hard, ultra-smooth surface can greatly reduce the wear rate on the polyethylene bearing. These type of implants have a potential wear at a rate of approximately 0.05mm each year which is half the amount compared to metal-on-plastic. The newer, highly crosslinked polyethylene liners have shown potential wear rates as little as 0.01mm each year (Bonesmart 2015a).

2.5.3 **Metal-on-Metal**

Metal-on-Metal implants are one of the most widely used implants around the world. In these implants, both the ball and socket components are essentially made out of metals such as cobalt chromium alloy, titanium alloy or sometimes stainless steel. Metal bearings are generally available in many sizes ranging from 28 mm to 60 mm and also available in various neck lengths. The metal-on-metal implants allow the largest heads compared to the rest of implant sizes. Due to their high durability, metal-on-metal devices were expected to last longer than other hip implants. In addition, the ball in a metal-on-metal device is larger, making the hip joint more stable and less likely to dislocate which is a crucial factor in the long term success of an implant (AAOS 2013b). However, there have been many concerns due to wear debris generated from the metal-on-metal implants. After implantation, metal debris released from the hip prostheses can enter the bloodstream increasing the cobalt and chromium concentration in the blood. This could lead to reaction in some patients, such as pain or swelling around the hip, osteolysis, other parts of the body in rare cases.

2.6 Types of THR fixation methods

The optimal method of fixation for primary total hip replacements (THR), particularly fixation with or without the use of cement has been a source of debate (Abdulkarim et al. 2013). The best mode of fixation should be guided by patient based outcomes, in particular the implant survivorship as measured by revision for aseptic loosening. In the present day, the three main types of fixation methods being used for performing Total Hip Replacement include:

- Cemented fixation
- Uncemented fixation

- Hybrid fixation

There has been controversy about the best method for fixation of implants which requires an in-depth analysis for each method.

2.6.1 – Cemented fixation

In cemented implants, the implants are fixed to the bone with bone cement commonly referred as polymethylmethacrylate (PMMA). Once the polymethylmethacrylate has cured, the cemented implants achieve stability from cement-bone mechanical interlock (Wyatt et al. 2014). During the fixation, it is important to ensure both the bone and cement lock together in order to make the fixation effective. Once the fixation is done, the cement simply acts as a filler between the bone and the implant. The bone cement interface is highly dynamic with degradation of the polymer in the cement and bone ingrowth. The nature of this interface is specific to the materials used in implants (Katti 2004). One of the major advantages of using cementless implants is their long-term reported survivorship. Studies in the past have suggested that Cemented replacements are more frequently used for older, less active people and people with weak bones, such as those who have osteoporosis (NIH 2013). Patients who receive cemented implant fixation can often walk with full weight immediately after the operation. However, the fixation can lead to fatigue fractures if too much stress is applied.

2.6.2 Cementless fixation

The cementless method is based on the use of special design features and surface technologies enabling bone interdigitating ingrowth to the porous surface of the implant (GalloKonttinen, et al. 2012). As opposed to cemented implants, this type of implants relies on primary press fit stability with long term stability occurring secondary to endosteal micro fractures at the time of preparation and subsequent bone ongrowth or ingrowth (Wyatt et al. 2014). The development of cementless implants have allowed the surgeons to attach the implant to the bone without cement and these types of implants are typically larger and durable compared to cemented implants.

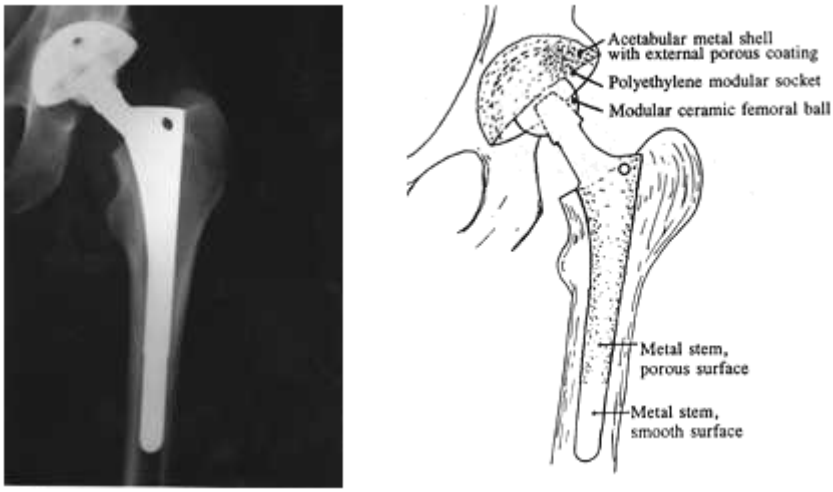


Figure 2-5: Stem type without cementless fixation (Source: www.jri-docs.com)

A typical cementless hip implant is textured or contains a porous surface coating around most of the implant allowing new bone to grow into the surface of the implant (Bonesmart 2015b). A recent study based on the physiological fixation of uncemented implants conducted by (GalloKonttinen, et al. 2012) suggests that the initial fixation of the porous-coated implants to bone depends on the shape of the implant (e.g. wedge fit, threaded design), and/or the tight micromechanical locking (press fit, friction fit, scratch fit, interference fit) of an implant to the bone bed. In addition, cementless implants offer a wider range of options particularly for the acetabulum where liner exchange may be required for postoperative instability which is usually one of the common cause for early re-operation in all primary THR (Wyatt et al. 2014).

2.7 Identifying potential modes of failure in THR

Total hip replacement is a major operation which is considered to be the one of the most successful operative interventions in modern medicine. It is recognised as one of the most performed orthopaedic operations in the modern day due to the advances made in prosthesis design, materials used and the surgical techniques to implant them. With increasing demand, a clear understanding of how THRs fail is critical in order for us to minimise future complications and optimise our interventions (Green, Khan & Haddad 2014). The main factors involved in the failure of total hip replacement are listed below:

- Patient factors

- Surgical factors
- Design factors

In order to understand the reasons for the failure, it is important to examine and identify the main factors leading to the failure. The purpose of this chapter is to investigate and provide detailed research in to the main factors listed above while examining the most common failure modes.

2.7.1 **Patient Factors**

Age, gender and aetiology of arthritis have been recognized as the most important patient factors with a bearing on implant failure caused by aseptic loosening. Total hip replacement is generally performed on older patients suffering with end-stage arthritis or femoral neck fractures sustained in accidents. According to (Green, Khan & Haddad 2014), approximately 65% of patients who undergo THR are usually aged above 65 years and are more likely to suffer with comorbidities which increase the risk of perioperative mortality and morbidity from anaesthesia and surgery.

A recent study conducted by the Swedish hip registry based on the outcomes of total hip replacements suggests that the failure rate in men are significantly higher when compared to women. Male patients under 50 years of age, primarily suffering with osteoarthritis, secondary to trauma or avascular necrosis of the femoral head have a higher chance of aseptic loosening after total hip replacement (R W Crawford 1997). Female patients suffering with rheumatoid arthritis are usually at a higher risk for possible THR failure. In general, female patients less than 55 years of age suffering from rheumatoid arthritis are involved in a higher risk group for aseptic loosening with 25% failure rates within the first 15 years.

One of the possible causes for failure of total hip replacements is the presence of disease or infection. Infection remains as one of the most complex challenges due to the interaction of patient comorbidity, microbiology, local tissue deficiency and surgeon experience making the management a specialised, multidisciplinary problem (Senthi, Munro & Pitto 2011). In the most extreme cases, where the infection cannot be controlled, the entire hip and leg may have to be removed. Infection is most likely to occur with inflammatory arthritis, psoriatic arthritis, patients taking corticosteroid treatment, chronic renal failure, diabetes mellitus, high risk surgical patients, malnutrition, and older age (R W Crawford 1997). In the presence of a prosthetic

infection, the surgeon will make an attempt at identifying the organism (bacteria) that is causing the infection (Valle 2010). Deep infection is an extremely complex situation which occurs in around 0.5–2% of total hip replacements and is the cause for revision surgery in at least 7.5% of failures (R W Crawford 1997). In some cases, the removal of THR is necessary in order to control the infection. However, this procedure and problem can result in substantial loss of bone.

2.7.2 **Surgical factors**

The survival of a total hip replacement may also depend on the surgical technique and the prosthesis positioning in order to achieve stability and equalise leg length discrepancy. Although patient-related risk factors must always be identified and corrected, surgical technique is heavily dependent upon the skill level of the operating surgeon (Green, Khan & Haddad 2014). As a result, the proper placement of the implant during surgery is critical to it remaining in place for the long term.

2.7.2.1 **Instability/Dislocation**

Instability following total hip arthroplasty is common and serious problem which generally leads to the failure of total hip replacements. Dislocation of total hip replacement is defined by the loss of contact between the femoral head and acetabular component that requires intervention to relocate the joint (Padgett & Warashina 2004). The risk of dislocation is influenced by various factors including surgical approach, implant design, failure to restore proper hip mechanics, choice of implant, and patient variables, soft tissue integrity, and neurologic disorders such as poor proprioception (Werner & Brown 2012).

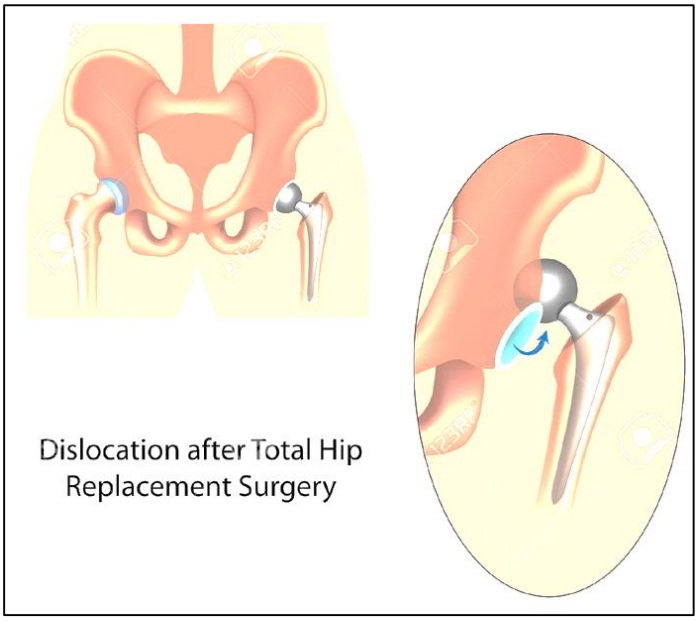


Figure 2-6: Dislocation of a hip joint after THR, Source: *www.123rf.com*

Figure 2-6 above represents the dislocation of the hip joint after total hip replacement. It can be seen that the femoral head component is dislocated from the acetabular component which could cause extreme pain and dysfunction to the patient.

While researching the information for dislocation rates among patients who received total hip replacement, different statistics were found from various resources. (Werner & Brown 2012) suggest that the dislocation occurs at a rate of 0.3% to 10% for primary THR and up to 28% for revision THR. According to (Padgett & Warashina 2004), the dislocation rates after primary THR has traditionally ranged between 1% to 3% and an increased rate of 5% to 20% after revision THR. Based on a detailed research on the types of dislocation in THR, it is accurate to state the dislocation occurs in two main categories:

2.7.2.2 *Early Dislocation*

In general, the early dislocation after total hip replacement is considered to be a controllable problem. It is usually occurred due to possible malposition of the socket and/or the shaft of the prosthesis, disproportion of the head and the socket or inadequate postoperative positioning. If an early dislocation is adequately treated it has no effect on the long-term result. Early dislocations usually occur within the first

3-6 months post operation. The following graph indicates the usual time taken for the first dislocation to occur.

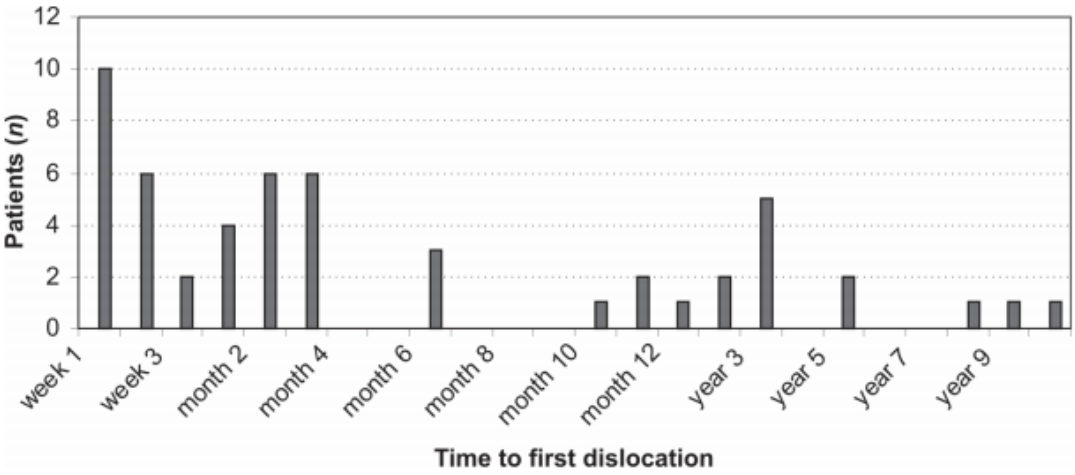


Figure 2-7: Time to first dislocation in those patients who had undergone primary hip replacement.

2.7.2.3 *Late dislocation*

Usually occurs after five or more years and may account up to 32% of all the dislocation (Charissoux, Asloum & Marcheix 2014). Late dislocation in total hip replacements have been often linked to the aspect of polythene wear. (Pulido, Restrepo & Parvizi 2007) suggest that polyethylene wear debris eliciting an inflammatory response may result in capsular distension and subsequent instability. Physicians could possibly use radiographic valuation and detection of liner wear in order to find an early solution.

As the implant designs and surgical techniques continue to advance, there is an increase in demand to identify and manage the risk factors associated with dislocation for patients undergoing total hip replacement. (Blom et al. 2008) suggests that the main factors implicated in affecting rates of dislocation include:

2.7.3 **Patient factors**

Although they are out of surgeon's direct control, patient factors must be considered and evaluated to identify the effect of unique individual factors on dislocation. (Ekellund, Rydell & Nillson 1992) showed that THR in patients older than 80 years had a twofold to threefold increase in the rate of dislocation compared with a younger group of patients. Studies in the past suggest that the gender of the patients is a significant risk factor associated with dislocation with females being at a much

greater risk than males. This gender disparity is suggested to be due to the possible muscle mass and strength differences, as well as differences in the compliance and elasticity of the soft tissues as a result of genetic and hormonal differences between the sexes (Werner & Brown 2012). Patients suffering with hip dysplasia have shown a higher rate of dislocation due to the abnormal bone anatomy and altered muscle function.

2.7.4 **Surgical factors and implant factors**

Surgical factors associated with hip dislocation are the factors directly under control of the surgeon which may contribute to instability, including surgical approach, implant factors, soft tissue repair and tensioning and surgeon experience. Surgical approach has been long implicated in the hip dislocation after total hip replacement. Studies in the past suggest that possibility of instability after THR is associated with the posterolateral approach compared with the anterolateral approach. According to (Werner & Brown 2012), higher dislocations rates have been reported for the posterior approach (5.8%) vs the anterolateral approach (2.3%). Further studies into the surgical approach indicate that around 75-90% of the dislocations generally occur in the posterior direction. As a result, the posterior approach has been less favoured although the capsular resection is required in case of anterior approach. Ultimately, the most important aspect of surgical factor is component orientation irrespective of the approach as it is primarily based on the surgeon's experience and comfort level. The positioning of implant is critical to determine the effectiveness of the implant and avoiding the possibility of dislocation and limiting other potential factors such as wear and tear.

It is essential to identify and evaluate the potential implant related risk factors associated with instability as malpositioning of components is one of the most common cause of dislocation after total replacement. Implant specific variables include restoration of length, reconstitution of femoral offset, size of femoral head, shape and socket specific variables including socket depth and possibly even socket diameter (Padgett & Warashina 2004). When selecting an implant for any patient, it is important to consider the following factors which play a significant role in hip dislocation. (Werner & Brown 2012) suggest that the larger the femoral head, the further it must sublux before it can dislocate, a distance referred to as the jump distance.

Table 1: The relationship of causes of dislocation (adapted from: http://www.dorrarthritisinstitute.org/)

Cause	Category				Total
	I	*II*	*III*	*IV*	
Positional	5	4	1	1	11
Component malposition	4	3	2	5	14
Soft tissue imbalance	5	9	4	11	29
Malposition and soft tissue imbalance	3	7	1	7	18
Total	17	23	8	24	72

2.8 Implant Factors

2.8.1 **Aseptic Loosening**

Despite the success of modern prosthetic designs, aseptic loosening of the components has remained one of the most common long-term complications. Aseptic loosening can be the result of inadequate initial fixation, mechanical loss of fixation over time, or biologic loss of fixation caused by particle-induced osteolysis around the implant (Abu-Amer, Darwech & Clohisy 2007). It generally describes the mechanical failure of the prosthesis-host interface, which primarily occurs as the end result of focal peri-prosthetic inflammatory bone loss occurring at this interface (MacInnes, Gordon & Wilkinson 2012). It is a combination of mechanical and biological processes resulting in osteolysis which is essentially the pathological destruction or disappearance of bone tissue. According to (Green, Khan & Haddad 2014), osteolysis or bone resorption is theorised to occur due to the following mechanisms:

1. The generation of microscopic wear particles released from polyethylene, metal and bone cement.
2. Access of these particles to the peri-prosthetic bone.
3. Inflammatory cellular response to the particulate debris.

Although osteolysis plays a major role in causing aseptic loosening, there are several mechanisms by which bone loss after a joint replacement may occur.

2.8.2 **Mechanical factors**

The change in position of implant generally indicates the implant failure and component loosening. Once dislocation occurs, the implant loses its stability and

peri-prosthetic particles may moderate latter stages of loosening. Although the exact mechanism by which component loosening cannot be fully understood, (Green, Khan & Haddad 2014) suggest that the mechanical factors that determine aseptic loosening are implant design, implant mal-alignment, stress shielding, and inadequate cement mantle. Another possible explanation for loosening could be due to the fatigue failure of the bone surrounding prosthesis, causing the loss of osteo-integration of a stable prosthesis.

2.9 Periprosthetic Femoral Fractures

A periprosthetic fracture is a result of a broken bone which occurs around the components or implants of a total hip replacement (AAOS 2013c). It has remained as one of the major complications which requires surgery. In order to prevent or minimize the effects, the mechanism of periprosthetic fracture has been constantly investigated in the past. The principle underlying the surgical management of periprosthetic fractures is that consideration needs to be given to the fracture location, the stability of the components and the quality of the underlying bone stock (Tsiridis, Krikler & Giannoudis 2007).

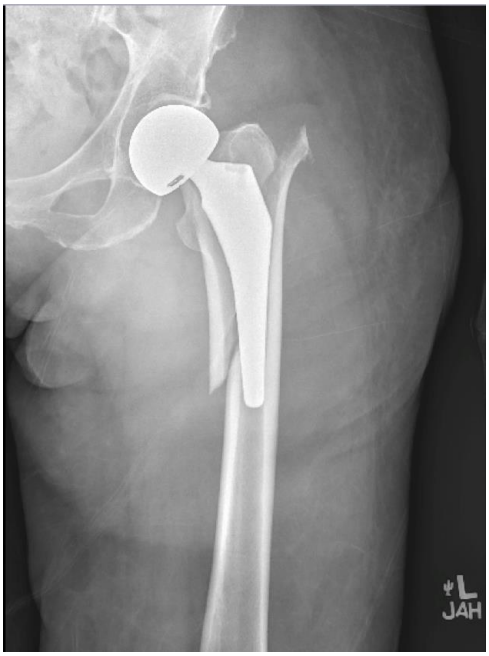


Figure 2-8: Periprosthetic Hip Fracture (Source: www.orthopaedicsone.com)

Periprosthetic fractures can essentially be divided as intraoperative and postoperative fractures. Intraoperative fractures usually occur during specific stages of the surgery while the postoperative fractures can occur between few days to several years

depending on the age, bone quality of the patient. The postoperative femoral fractures generally fluctuate from 0.1% to 4%. According to (Schwarzkopf, Oni & Marwin 2013), a reflective study of THR performed in a Mayo Clinic suggest that the postoperative femoral fracture prevalence after 19,657 primary THRs was 0.6%. In order to understand the aetiology of late periprosthetic fracture, it is important to identify the various risk factors associated. The risk factors are usually classified into patient factors or the implant factors.

The patient factors generally include aspects such as the patient's age, osteoporosis and osteolysis. The age of the patient is one of the most important risk factors related to the late fracture. Recent studies investigating the age of patients sustaining fractures suggest that the mean ages generally range between 60 to 77 years (Franklin & Malchau 2007). Osteoporosis is a condition where the bone loses its strength and density becoming weak and brittle and is a generally accepted risk factor for late periprosthetic femoral fracture. The fragility of the bone from osteoporosis can also correspond to the high percentage of fractures caused by low-energy falls points. One of the most common cause of late periprosthetic fracture is osteolysis and the resultant aseptic loosening. The localised femoral bone loss in association with a loose cemented stem was thought to be mediated by the failed cement. As a result, osteolysis is still an enormous problem in both cemented as well as cementless hip arthroplasty (Franklin & Malchau 2007).

In the past, different implants have displayed various levels of late periprosthetic fracture risk depending on their design characteristics and fixation methods. The loosening of the stem has been associated with periprosthetic fracture as it leads to increased motion at the bone interface, resulting in further bone resorption. It is also important to consider the possibility of the patient's chance to sustain periprosthetic fracture based on the circumstances. According to (Schwarzkopf, Oni & Marwin 2013), the most frequent mechanism for sustaining these fractures is a low energy fall from sitting or standing, accounting for 75% of primary THA and 56% of revision THA periprosthetic fractures.

2.9.1 **Vancouver Classification of Periprosethtic Femoral Fractures**

Over the years, there has been a wide range of systems developed to classify periprosthetic fractures. Proposed by Duncan and Masri, the Vancouver

classification system is most widely used classification for periprosthetic femoral fractures. The Vancouver classification takes into account the three most important factors in management of these injuries: the location of the fracture, the stability of the femoral component and the quality of the surrounding femoral bone stock (Schwarzkopf, Oni & Marwin 2013). One of the most important aspects of this system is its ability to help differentiate between a stable and unstable fracture as it generally requires the consideration of osteosynthesis and other factors such as age and surgeon experience.

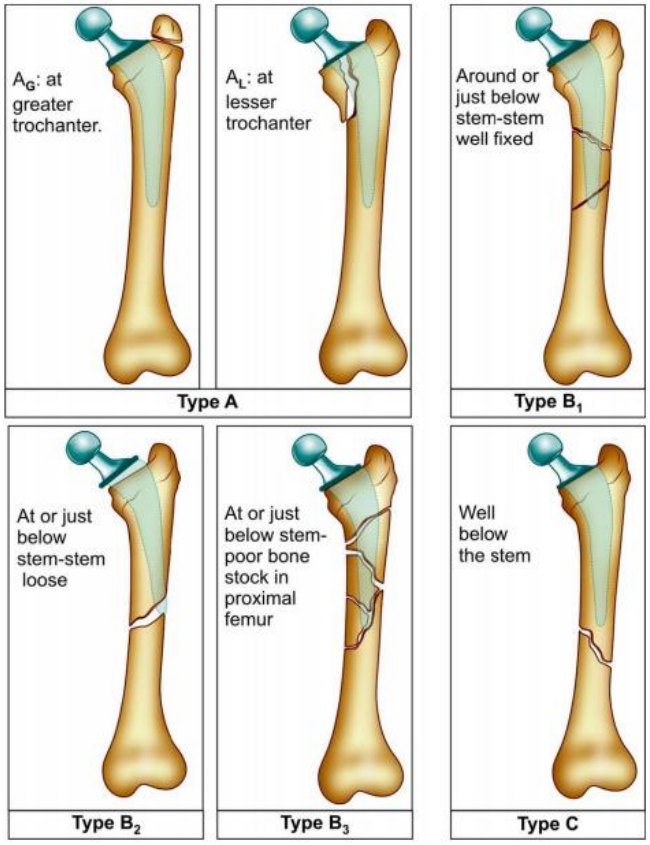


Figure 2-9: The Vancouver classification (Source: http://www.orthopaedicsurgery.uci.edu)

The image above represents the Vancouver classification of periprosthetic femur fractures around total hip arthroplasty. (Tsiridis, Haddad & Gie 2002) explain the types of fractures involved in Vancouver classification:

- Type A – These type of fractures are most commonly associated with osteopenia of the proximal femur. They are sub classified into AG fractures that involve the greater trochanter, and AL fractures that involve the lesser trochanter.

- Type B – These fractures occur around or just distal to the femoral stem. Type B fractures are sub classified based on the stability of the implant and the quality of bone stock.
- Type C – These type of fractures are far distal to the femoral stem such that the fracture can be treated using conventional methods.

The Vancouver classification system is a useful tool in diagnosis and management of periprosthetic femur. It is essential to verify the stability of the femoral component intraoperatively to properly guide treatment rationale (Gaski & Scully 2011).

2.10 Surface wear

Wear always occurs in the articulation of artificial joints as a result of the mixed lubrication regime. The movement of an artificial hip joint potentially creates billions of microscopic particles (debris) due to cutting motions (Viteri & Fuentes 2013). Generally, the type of relative motion is often referred to define the wear that is generated. The three main types of wear include:

Abrasive wear: Wear created due to harder material forced against and moving along another solid but softer surface therefore, causing grooves on the softer surface.

Adhesive wear: Wear created from restricted bonding between solid surfaces where the softer material usually releases fragments that adhere to the harder material.

Fatigue wear: Wear of a solid surface caused by fracture arising from material fatigue.

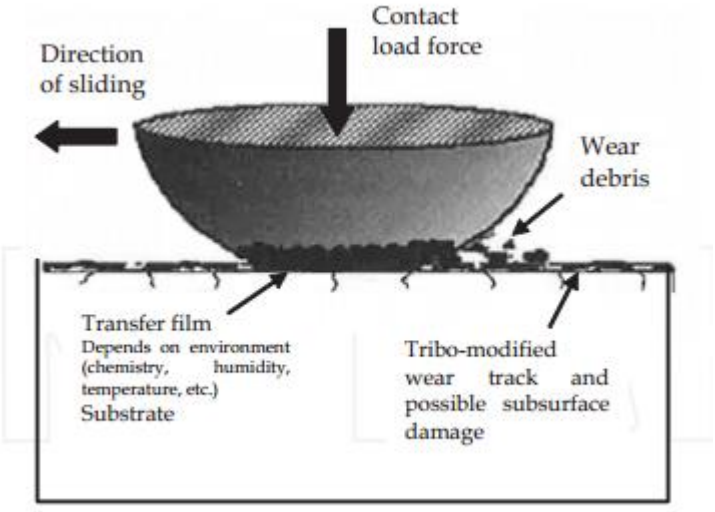


Figure 2-10: Representation of wear caused in the bearing from sliding (adapted from http://cdn.intechopen.com/)

In order to understand the effects the cobalt poisoning from the metal-on-metal hip implant, it is crucial to study and examine the process of metal erosion corrosion of the metal. (Meneghini 2012) states: 'When two metal surfaces are in contact and there is the potential for relative motion, metal debris may be generated or corrosion can take place'. In principle, a metal-on-metal hip component is designed from a cobalt-chromium alloy. After implantation, metal debris released from the hip prostheses can enter the bloodstream increasing the cobalt and chromium concentration in the blood. Recent studies on the biological consequences of metal debris from hip prosthesis suggest that the overall effects can be divided as local and systematic effects (Campbell & Estey 2013). Local effects of the metal debris are generally associated with tissue necrosis and ozonolysis caused due to the local inflammatory reaction of the soft tissue and fluid collections. These effects are normally described as 'adverse reaction to metal debris' (ARMD).The systemic effects of hip prostheses are caused when severe neurological symptoms are associated with a patient. These symptoms generally include visual impairment, diomyopathy, hypothyroidism, carcinogenicity and poor concentration.

The design used for the MoM hip implants has been one of the major areas of concern over the past few years. (Carl Heneghan 2012) provides valuable research on the two main design flaws leading to a hip implant failure. In general, the shallow joint of the prosthetic head tends to rub against the edges of the cup accelerating wear. The metal debris generated as a result of the wear accumulates in the hip joint

filling the blood with high levels of cobalt and chromium. A common problem associated with metal-on-metal implant is usage of large diameter heads. The larger heads generally tend to create higher levels of stress in the taper junction (where the head meets the stem) resulting in release of debris.

Similar to metal-on-metal implants, polyethylene wear is one of the major disadvantages of using metal-on-plastic or ceramic-on-plastic implants. Within hip implants consisting acetabular cups made of polyethylene, debris created by wear of polyethylene articulating surfaces is attacked by the body's immune system. This leads to bone loss, also known as osteolysis (Katti 2004). The factors determining the internal wear at the metal-polyethylene interface include the coefficient of friction, lubrication, load applied, diameter of the head, number of cycles and hardness of the materials (Schwartsmann et al. 2012).

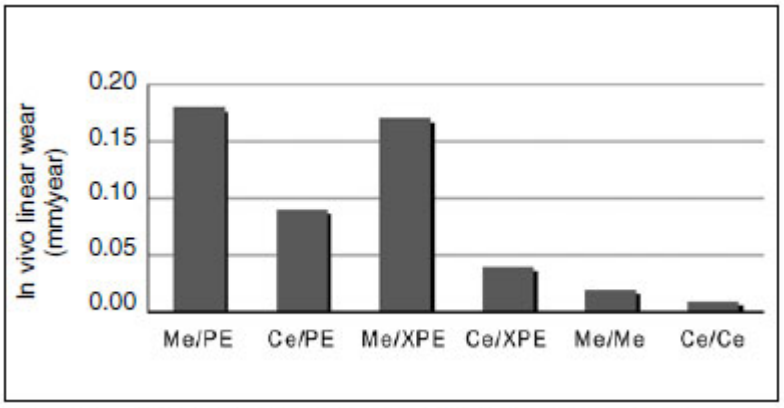


Figure 2-11: Mean rates of in vivo linear wear rates (adapted from http://www.scielo.br/)

Fig.2-11 represents the mean rates of in vivo linear wear rates per year for the head-acetabulum configurations found in orthopaedic practice. It is evident that metal-on-polyethylene produce the highest content of wear annually compared to the rest of the implants.

Chapter -3 Material Selection

3.1 Overview

The selection of materials for hip replacement components is a critical process as the implant is subjected to an environment consisting a variety of biological and mechanical conditions. The following section of the project gives a detailed insight the various types of materials currently used in hip implants to understand the material's physical properties and its biocompatibility within the body tissue. The material selection process includes the current research in material science and the challenges associated in using these materials that require further research before application in orthopaedic implants.

The initial section of the material selection process involves researching into the various types of materials currently used in order to compare and analyse the physical and biomedical characteristics of each material compared to fibre reinforced composites (FRC). The primary goal of this section is to determine the feasibility of using fibre reinforced composites (FRC) as an alternative material for hip implants. The feasibility of using the new alternative materials are then to be justified using a decision matrix system for the second section of the material selection process. Upon the completion of the material selection process, the primary objective is to perform Finite Element Analysis (FEA) and volumetric wear testing to justify the use of the new alternative materials.

3.2 Bearing surface combinations

3.2.1 **Metal alloys**

Metals have been the primary materials in Total Hip Replacement due to their high mechanical properties. One of the main advantages of using metal-on-metal bearing is the reduced wear rates compared with other implants. In general, the femoral components of total hip replacement are made of either stainless steel, Cobalt–Chromium alloys, or Titanium alloys while the components of the acetabular cup are made up of alumina or zirconia ceramic, polytertrafluoroethylene (PTFE) or Co–Cr alloy (Katti 2004).

3.2.1.1 **Titanium alloys**

The use of titanium alloy as biomaterials for hip implants continues to increase due to their lower modulus, superior biocompatibility and enhanced corrosion resistance when compared to more conventional stainless steels and cobalt-based alloys (Long & Rack 1998). Among all titanium and its alloys, the mainly used materials in biomedical field are the commercially pure titanium (cp Ti, grade 2) and Ti-6Al-4V (grade 5) alloy. As a hard tissue replacement, the low elastic modulus of titanium and its alloys is generally viewed as a biomechanical advantage because the smaller elastic modulus can result in smaller stress shielding (Viteri & Fuentes 2013). Table number 1 represents the mechanical properties of some of the common Titanium alloys used in biomedical applications.

Table 2: Mechanical properties of common Titaniun alloys (adapted from http://www.sciencedirect.com/)

Alloy	Tensile strength (UTS) (Mpa)	Yield strength (σ_y)	Elongation (%)	RA (%)	Modulus (GPa)	Type of alloy
1. Pure Ti grade 1	240	170	24	30	102.7	α
2. Pure Ti grade2	345	275	20	30	102.7	α
3. Pure Ti grade 3	450	380	18	30	103.4	α
4. Pure Ti grade 4	550	485	15	25	104.1	α
5. Ti–6Al–4V ELI (mill Annealed)	860–965	795–875	10–15	25–47	101–110	$\alpha+\beta$
6. Ti–6Al–4V (annealed)	895–930	825–869	6–10	20–25	110–114	$\alpha+\beta$
7. Ti–6Al–7Nb	900–1050	880–950	8.1–15	25–45	114	$\alpha+\beta$
8. Ti–5Al–2.5Fe	1020	895	15	35	112	$\alpha+\beta$
9. Ti–5Al–1.5B	925–1080	820–930	15–17.0	36–45	110	$\alpha+\beta$

Most commonly, the high strength Ti-6AI-4V alloy is mainly used during the designing of hip implants where the metallic cup and hip stem components are made of titanium with wear-resistant Cobalt-Chromium metal or Al2O3 ceramic ball heads. As a hard tissue replacement, the low elastic modulus of titanium and its alloys provides a biomechanical advantage due to their smaller elastic modulus which can result in smaller stress shielding (Viteri & Fuentes 2013). One of the major disadvantages of using titanium alloys are their poor shear strength and wear resistance which have limited their use in biomedical applications. Essentially,

titanium alloys are prone to fretting fatigue due to their low hardness. Studies in the past have suggested that titanium hip implants are subjected to mechanical instability due to the undesirable moving or sliding parts after insertion. This would potentially result in cause of high friction and lead to release of wear debris from the implant into the patient's bloodstream causing severe health problems. However, due to their high qualities such like high strength-to-weight ratio, melting temperature and corrosion resistance, interest in the application of titanium alloys is continually growing especially in biomedical field (Viteri & Fuentes 2013).

3.2.1.2 **Cobalt and Chromium (Co-Cr) Alloy**

Cobalt and Chromium (Co-Cr) alloys are commonly used in biomedical applications, especially in hip implants due to their multiphase structure, age hardening, and precipitation of carbides which substantially increase their hardness. The most common alloys used for hip implants are the Cobalt-Chromium-Molybdenum (CoCrMo) alloys due to their high wear and corrosion resistance, high fatigue resistance and Young's modulus. The CoCrMo alloys are composed of 58.9–69.5% Co, 27.0–30% Cr, 5.0–7.0% Mo. Based on their carbon contents, CoCrMo alloys are grouped into two categories, i.e. high-carbon alloy with 0.05–0.35 wt.% carbon, and low-carbon alloys with carbon concentration < 0.05 wt.% (Liao et al. 2013). The mechanical properties of Co-Cr alloys were obtained from the American Society Testing and Materials (ASTM F75) which are listed below:

- Ultimate tensile strength: 655MPa
- Yield strength: 450MPa
- Fatigue strength: 310Mpa
- Modulus: 210GPa

3.2.2 **Ceramics**

In general, ceramics are very hard materials and often cause reduced osteolysis and are regarded as favourable materials for joints or joint surface materials. Studies in the past have suggested that ceramic bearings produce considerably lesser debris compared to the other type of materials used. In principle, ceramic components are stable oxides, they are chemically inert and do not undergo the oxidative wear processes that can produce surface roughness on metal heads (Schwartsmann et al. 2012). One of the main advantages of ceramics are their extreme rigidity while presenting a surface of low roughness. Conventional ceramics such as Alumina

(Al_2O_3) were initially evaluated due to their excellent properties of high strength, good biocompatibility and stability in physiological environments (Katti 2004). The primary advantage of Alumina was its ability to be polished to a high surface finish and suitable for implementation in hip implants due to their high wear resistance. Alumina is usually used to fabricate the femoral head of a hip prosthesis. As the advancements in ceramic bearings continued to grow, Zirconia (ZrO_2) was initially proposed as a possible material for the femoral components due to its higher strength and resistance compared to Alumina.

Table 3: Mechanical properties of ceramics used in THR, adapted from (GalloGoodman, et al. 2012)

Type of ceramic	Grain size (µm)	Density (g/m^3)	Bending strength (MPa)	Fracture toughness ($MPa.m^{1/2}$)	Vickers hardness	Young's modulus (GPa)
Alumina *(BIOLOX FORTE)*	< 2	3.98	580	4	20	380
Zirconia	< 0.5	n.a.	> 900	8	12.5	210
ZTAMC *(BIOLOX DELTA)*	< 2	4.37	> 1380	6.5	19	> 350

Table 3 presents the mechanical properties of most commonly used ceramics used in Total Hip Replacement. The table presents the properties for a wide range of biomaterials that could possibly be used for the implants. However, their poor mechanical properties such as low strength and limited fatigue resistance restrict their applications.

3.2.3 **Polymers**

Polymers are generally used in a wide range of medical applications due to their broad range of mechanical and structural properties that depend on backbone structure, molecular weight and degree of crosslinking. For orthopaedic applications such as Total Hip Replacement, certain polymers are used due to their desirable physical and mechanical properties. The higher modulus of elasticity and density are closer to the cartilage bone composite which could potentially provide damping for the transmission of shock forces during loadings. In general, polymers do not have the compression and tensile strength of metals, but the high strength-to-weight ratio of some polymers makes them especially attractive as a material for the socket half of the joint (Amstutz 2004). The most common used polymers for hip implants include: acrylic, nylon, silicone, polyurethane, ultra-high molecular weight

polyethylene (UHMWPE), and polypropylene. The ultra-high molecular weight polyethylene is essentially formed due to polymerization of ethylene which offers a low-friction surface and high wear resistance. (S.Ramakrishna et al. 2000) provides the mechanical properties of the most commonly used polymers use in hip implants:

Table 4: Mechanical Properties of typical polymeric biomaterial (adapted from http://ac.els-cdn.com/)

Material	**Modulus (GPa)**	**UTS (MPa)**
UHMWPE	1	21
Polyacetal (PA)	2.1	67
Polymethylmethacrylate (PMMA)	4.5	59
Polyetheretherketone (PEEK)	8.3	139
Polysulfone (PS)	0.88	75
Polytetrafluoroethylene (PTFE)	0.4	28
Polyethylene terephthalate (PET)	2.85	61
Polyurethane (PU)	0.02	35

The table above (table 3) represents the mechanical properties of polymers commonly used in hip implants adapted from (S.Ramakrishna et al. 2000). It is interesting to note that the material properties of polyether ether ketone (PEEK) are relatively higher than the other polymers providing it a major advantage. Although PEEK offers potential for a good tribological material, the performance abilities of this materials have not been studied thoroughly as the material may fail under due to scuffing and/or abrasion within a medical device.

3.2.4 **Fibre Reinforced Polymer (FRP) composites**

Composites are engineered materials made from two or more materials constituting of different physical properties, which can be combined synergistically (Scholz et al. 2011). Composite materials, which can be very strong while having a low modulus of elasticity, are being studied because such materials have potential to be made into hip prostheses (SKINNER 1988). Fundamentally, a lower modulus implant material will provide a more biomechanically compatible prosthesis. As a result, composite materials are gaining importance because they offer the potential for implants with tailor-made stiffness in contrast to metals (Sridhar, Adie & Ghista 2010). A polymer

is essentially the liking of small molecules (monomers) to from larger molecules. Polymerization requires that each small molecule have at least two reaction points or functional groups (Masuelli 2013). The main objective in understanding the use of fibre reinforced polymer composites as an alternate material was to incorporate material design variables into the optimization of the femoral component of hip prostheses.

The main focus of this project is to research on the feasibility of composite materials with engineered interfaces which results in a combination of biocompatibility, mechanical strength and toughness. In modern orthopaedics, fibre reinforced polymer composites are one of the most widely used materials due to their ability to achieve both low elastic modulus and high strength. Fundamentally, polymer composites are created by combining two or more materials in separate phases where one of the materials used is a polymer. The combination of polymer with other material such a glass, carbon or other polymer is to achieve distinctive levels of properties. The fibre polymer composites can essentially be divided into three main categories:

- Fibreglass composites
- Carbon fibre composites
- Aramid fibre composites

Typically, the goal is to improve strength, stiffness, or toughness, or dimensional stability by embedding particles or fibres in a matrix or binding phase (Masuelli 2013). The matrix is the initial plastic material without fibre reinforcement. In order to achieve desirable mechanical properties for the FRP, it is important to ensure that the matrix is properly saturated and bonded with the fibres. A high quality matrix can increase the toughness and compressional strength of the composite. To prevent the possibility of failure, the fibres must also be kept separate from each other so that if failure occurs it is localized as much as possible. (Masuelli 2013).

The fibre glass composites are achieved through the combination of individual glass fibres consisting of different forms. Based on their geometry, fibre glass composites are classified into two major categories: continuous and discontinuous fibres. The common materials used for fibreglass products include silica sand, limestone, calcined alumina, borax, feldspar abd nepheline syenite (Masuelli 2013). Aramid

fibre composites are generally achieved by combining an amine group and a carboxylic acid halide group (aramid). These type of composites are high performance fibres as the molecules are characterized based on their relatively rigid polymer chains. Although fibre glass composites and aramid fibre composites provide a wide range of material advantages, they are considered to be impractical for the purpose of this project.

3.2.5 **Carbon Fibre Reinforced Polymer composites**

Carbon-fibre-reinforced polymer or carbon-fibre-reinforced plastic (CFRP) is a highly strong and light fibre-reinforced polymer comprised of carbon fibres (Masuelli 2013). At present, fibre reinforced polymers composites are one of the most widely used materials in orthopaedics. One of the main advantages in using of fibre reinforced polymer composites is to greatly improve the implant's resistance to fatigue and corrosion which have remained one of the main reasons to failure in hip implants.

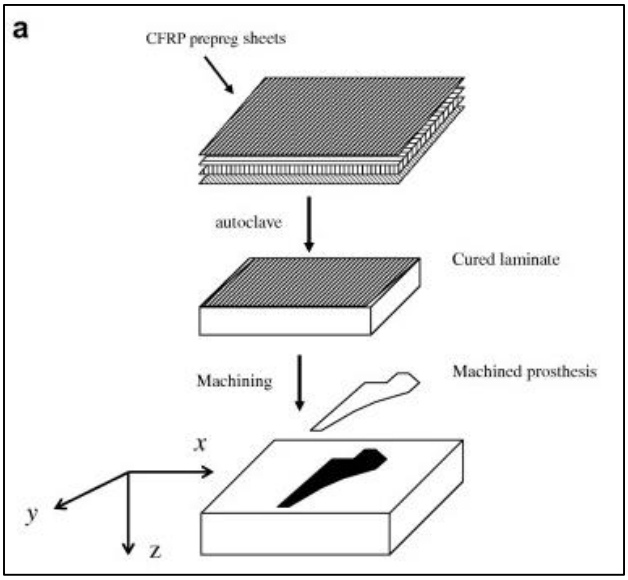


Figure 3-1: Illustrations of the steps involved in the machining of a hip prosthesis from long fibre-reinforced composites

Source: http://www.sciencedirect.com/

Fig.3-1 provides an illustrations of the steps involved in the machining of a hip prosthesis from long fibre-reinforced composites using the plate-cut technology.

It was identified earlier in the project that the use of polyetheretherketone (PEEK) in medical applications has caused a great deal of interest in the biomedical industry due to its potential for high performance and good biocompatibility. Essentially,

PEEK is a semi crystalline polymer whose properties can be varied by the use of different processing methods (Williams 2008). It is generally described by its biocompatibility and biostability due to its ability to maintain physical and chemical integrity after implantation in living tissue. The combination of strength, stiffness, and toughness, along with the ability to be repeatedly sterilized without the degradation of its mechanical properties, makes it suitable for implantable medical device applications (Williams 2008). One of the major advantages of PEEK is its ability to resist corrosion when implanted in medical devices under body conditions. Although PEEK offers potential for a good tribological material, the performance abilities of this materials have not been studied thoroughly as the material may fail under due to scuffing and/or abrasion within a medical device.

In order to identify the material performance of polyetheetherketone, a recent study conducted by (Schroeder et al. 2013) included different tests such as linear scuffing test, constant load, reciprocating sliding and free ball micro-abrasion test. The aim of the tests were to essentially identify the wear rate of PEEK based materials during scuffing or abrasive mechanisms. The illustration below represents the schematic diagram of the tests performed:

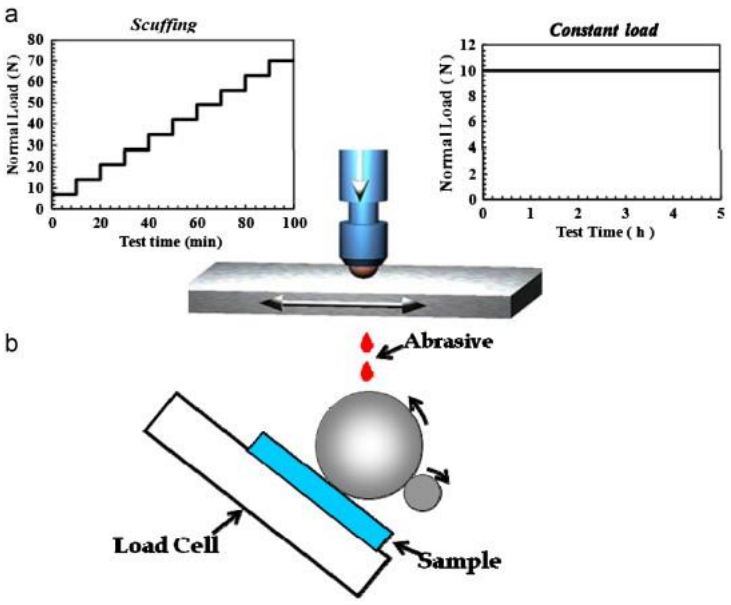


Figure 3-2: Schematic drawing of the wear tests. (a) Reciprocating linear sliding (left scuffing tests—right constant load tests. (b) Free-ball micro abrasion. (Source: Schroeder et al. 2013)

In order to reinforce the materials properties of PEEK, fibres are generally added for strengthening and to act as filler particles for lubrication. As a result, the tests

performed by (Schroeder et al. 2013) were carried out using three different specimens:

- Unfilled polyetheretherketone (PEEK)
- Carbon fibre reinforced PEEK (Composite A)
- Grade 10%PTFE + 10%Graphite + 10%CF filled PEEK (Composite B)

The unfilled polyetheretherketone (PEEK) was to be used a reference material to compare and analyse the results obtained from the tests. The following table provided a summary of the different tests performed on each material (Schroeder et al. 2013).

Table 5: Summary of the test results

Sample	Friction coefficient	Wear rate ($mm^3\ N^{-1}\ m^{-1}$)×10^{-7}	Scuffing resistance (N m)	Abrasive wear coefficient k($m^3\ N^{-1}\ m^{-1}$)×10^{-15}
PEEK	0.34±0.01	1370.0±90	15±11	40.0±5.0
Composite A	0.29±0.01	22.1±2.2	1105±759	8.5±0.5
Composite B	0.09±0.01	2.1±0.4	16834±52	1.2±0.1

Based on the results achieved from the different tests performed, it was observed that the unfilled PEEK demonstrated a relatively high friction co-efficient. Although, polyetheretherketone (PEEK) usually exhibits a higher abrasive wear resistance compared to brittle material such as Polyethersulfone (PES), it can be modified by the addition of reinforcing fibres and lubricant particles. Further research conducted by (Voss & Freidrich 1987) on the wear behaviour of fibre reinforced PEEK composites suggest that carbon fibre reinforced PEEK composites exhibit a higher wear resistance during sliding and abrasive wear conditions when compared to unfilled polyetheretherketone (PEEK). One of the most common modes of failure in hip implants is occurred from adhesive and abrasive wear leading to toxication of blood due to the generated wear debris. It is critical to study and examine the wear resistance of a material to ensure the safety of the hip implant. As a result, the possibility of using carbon fibre reinforced PEEK composite (CF-PEEK) as an alternative material for hip implants is further investigated in the project as a part of the material selection process.

Recent studies on alternative materials for femoral components of hip implants suggest that carbon fibre reinforced polyether ether ketone (CFR-PEEK) is an ideal material for orthopaedic implants due to their relatively high material properties. The use of optimal carbon fibre reinforced polyether ether ketone (CFR-PEEK) for prosthesis components is an optimal solution as the bending stiffness of composite hip implants is matched with that of bone in both the longitudinal and radial directions. (Sridhar, Adie & Ghista 2010). The use of these composites is continually increasing due to their comparatively lower rates of wear and their ability to provide high stiffness compared to metals. Furthermore, the use of CFR-PEEK could potentially avoid issues such as stress shielding and bone resorption, which are common problems experienced when stainless steel or titanium implants are used in total hip replacements (Li et al. 2015). A recent study conducted by (Wang et al. 1998) investigates into the tribological performance of a carbon fibre reinforced PEEK composite as a bearing surface for total hip replacement. The study provided a detailed insight into the behaviour of high strength polyether ether ketone (PEEK) thermoplastic as the matrix and a high strength carbon fibre as the reinforcement. The physical properties of carbon fibres and PEEK matrix are presented in the following table:

Table 6: Physical properties of the carbon fibres and the PEEK matrix

Material	Density (g/cm^3)	Tensile modulus (GPa)	Tensile strength (MPa)
UHMWPE	0.935	0.80	61
PEEK	1.30	3.80	240
PAN-based carbon fibre	1.76	231	3450
Pitch-based carbon fibre	2.00	170	1400

In the table presented above (table 6), the physical properties of carbon fibres and PEEK matrix are compared to each material. The two type of carbon fibres used included the high modulus PAN-based carbon fibre and the graphitic pitch based carbon fibre. Based on the physical properties, it can be understood that carbon fibre reinforced polymers could theoretically act as a better alternative materials when compared to original polymers. Furthermore, due to the low density of carbon fibre reinforced plastic, an improvement in agility, gait and walking speed can be noticed

(Scholz et al. 2011). As a result, the use of CFR-PEEK as an alternative material is to be researched further based on volumetric wear testing and Finite Element Analysis.

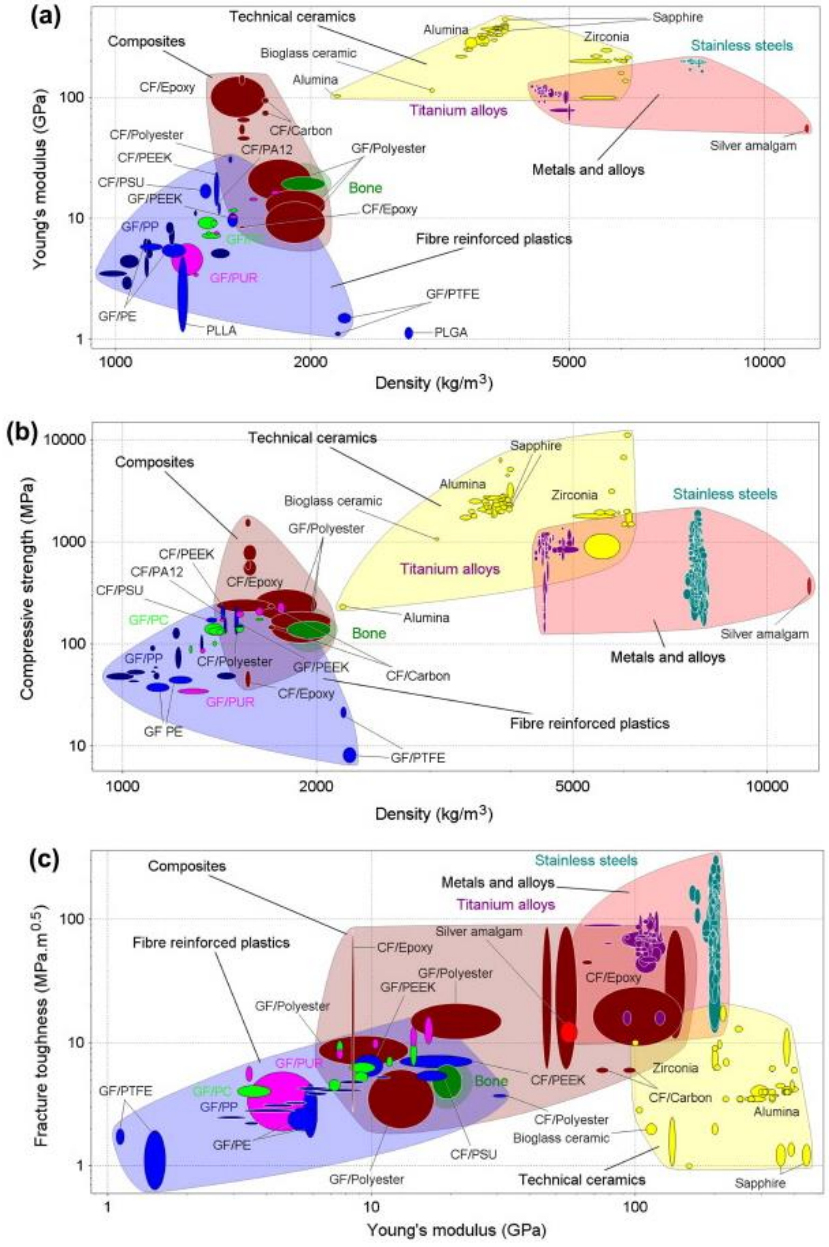


Figure 3-3: Comparison of mechanical properties pf metals, technical ceramics, composites and fibre reinforced plastics with respect to those of bone

Fig.3-3 provides the comparison of mechanical properties pf metals, technical ceramics, composites and fibre reinforced plastics with respect to those of bone. It can be seen from Fig.3-3 that the fibre reinforced polymer composites are able to

accomplish both low elastic modulus as well as high strength, in an efficient manner. In addition, corrosion and fatigue resistance characteristics are greatly improved due to the application of composite materials (Scholz et al. 2011).

3.3 Materials consideration for implants

The following section provides an overview of the various material properties used in total hip replacement. Currently, there are a wide range of engineering materials used to manufacture hip implant devices. Based on the literature review, it is evident the components of hip replacement implants are fundamentally designed using metals, polymers, ceramics and composites. The qualities and drawbacks of these material are to be evaluated in the context of mechanical properties in order to determine the most appropriate material for hip implants. The use of biomaterials in medical devices in intended to provide a better interaction with the biological systems. A recent study on the effects of biomaterials used in hip implants conducted by (Katti 2004) provides the general criteria for materials selection for hip implants:

- The material is biocompatible and provides excellent resistance to degradation in the human body environment.
- Adequate strength of the component in order to sustain the cyclic loading applied on the hip implant.
- It has suitable mechanical properties with high wear and corrosion resistance to minimize the formation of metal debris.
- Manufacturing and processing methods are economically viable.

Furthermore, while evaluating the mechanical properties of a material, it is essential to contemplate the properties of materials such as the density, ultimate strength, fatigue life, young's modulus, cost and resistance to corrosion and wear. However, before the selection of any biomaterials for a design, it is important not only to understand how the implant design works but to recognize the critical components of the design which require wisely selected materials. As a result, choosing the right materials for hip implants has posed a greater challenge to manufacturers which requires a technical analysis of selecting suitable biomaterials in order to meet the functional requirements of the implant and how it will interact with the patient's body.

3.4 Engineering requirements of the materials

3.4.1 **Strength**

The strength of a material measures the ability of the material to resist failure. According to (Ryan 2012), the toughness of a material can be defined as 'the ability of a material to absorb sudden shock without breaking or shattering'. Generally, the higher strength doesn't necessarily mean that the material possesses a high toughness. The increase in strength usually decreases the toughness of the material. For example, tempered steel is generally tough but has a relatively lesser strength than after quenching. (EngineersHandbook.com 2006) states that, 'for metals the most common measure of strength is the yield strength. For most polymers it is more convenient to measure the failure strength, the stress at the point where the stress strain curve becomes obviously non-linear'. The following diagram illustrates the Ashby chart for the material strength relative to its toughness. This chart can be used to select a material that is ideal for high strength to a low weight ratio.

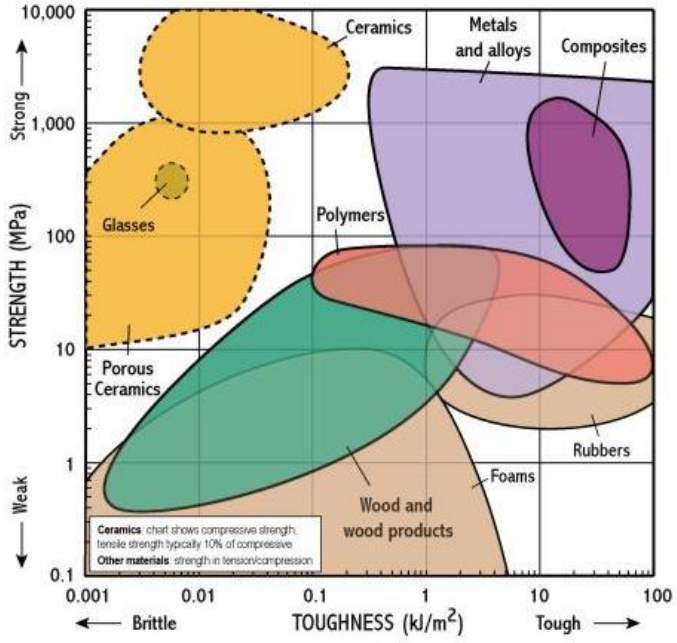


Figure 3-4: Toughness vs strength (Source: http://www-materials.eng.cam.ac.uk/)

The following chart demonstrates the yield strength in tension for all materials excluding ceramics for which compressive strength is displayed due to their considerably lower tensile compared to other materials. It is evident that the strength and toughness of a material is one of the most important requirements in this material selection process.

3.4.2 **Density**

One of the most fundamental physical aspects of a material is its density. It was stated earlier that the high strength to low weight ratio (also referred to as the specific weight) is an important material requirement. Density of a material can be used to obtain the specific gravity which can be defined as strength/density. Although a lower density can be chosen to increase the strength of the material, it is important to make sure that the lower density value would not affect the toughness of the material. Fig.3-4 can be used to identify materials for components which require high strength to low weight ratio as this would be ideal for hip implants.

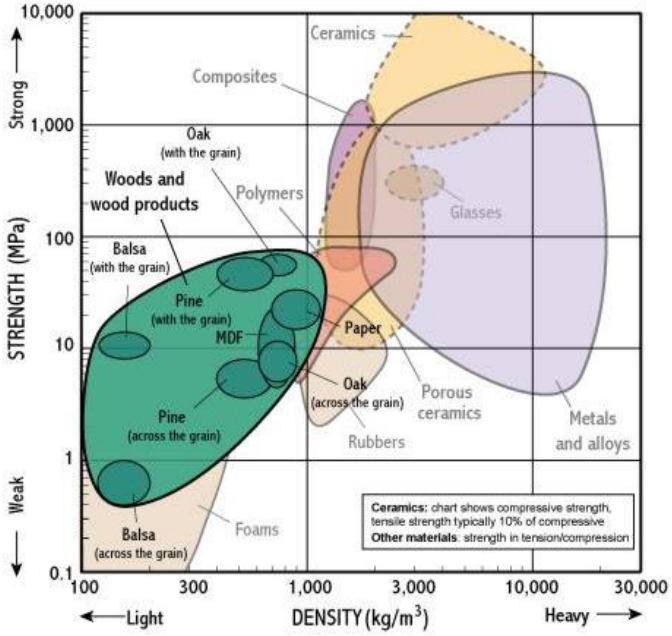


Figure 3-5: Density chart

(Source: http://www-materials.eng.cam.ac.uk/)

3.4.3 **Young's modulus**

The Young's modulus or Tensile Modulus is a material constant which is a measure of the stiffness. It can be used to estimate the elongation or compression of a hip implant when the stress applied is less than the yield strength of the material.

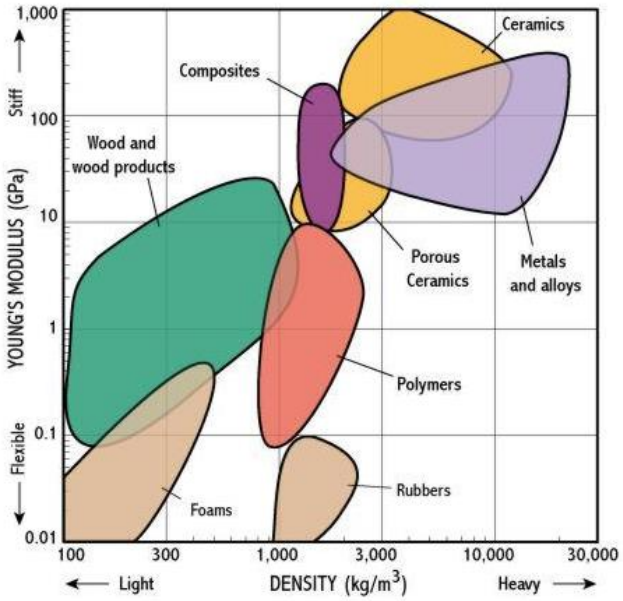


Figure 3-6: Young's modulus vs Density

(Source: http://www-materials.eng.cam.ac.uk/)

3.4.4 **Biocompatibility of implant materials**

Understanding the biocompatibility of a material has remained once of the most focused topics for long-term implant device. The insertion of a hip implant device into the human bone would alter the biomechanical environment and leads to variation in the loads applied to the bone. Due to these biocompatibility concerns, it is necessary to ensure that the material selected produces a minimum degree of rejection within the human body and include the required mechanical properties such as strength, stiffness, density and fatigue properties. Materials selection made within the context of functional requirements will improve the safety and effectiveness of the device (Helmus, Gibbons & Cebon 2008). Based on the research conducted, a wide range of materials were identified which demonstrated the required mechanical properties. These materials include metals, ceramics, polymers and carbon fibre reinforces polymer composites. However, it important to understand the biocompatibility of these materials to ensure the safety of the implant devices.

3.4.4.1 **Biocompatibility of metals**

The use of metals for hip implant materials has led to several concerns for due to their long term effects on the human body. Metallic biomaterials are generally considered are suitable materials due to their relatively high mechanical properties compared to polymers and ceramics. However, they fail to possess bio

functionalities like blood compatibility, bone conductivity and bioactivity. The three most common metals use for hip implant include stainless steel, cobalt-chromium (CoCr) alloy and Titanium (Ti) alloys. The biomedical disadvantages of using each type of material are summarised below:

- Possible increase in acetabular bone stock loss.
- Femoral neck fractures.
- Corrosion of metallic implants effecting the surrounding tissues.
- Wear debris from generated due to the surface abrasion.

One of major concerns of using metallic components is the wear generated from the components. Modular metal interfaces and abrasion, as a result of differential micro movement, generate a large amount of metallic debris into the human body (Learmonth 2003). Although the volumetric wear of a metal-on-metal implants is much lower than that of metal-on-plastic, it produces a higher number of particles possibly causing mutagenic damage.

3.4.4.2 **Biocompatibility of ceramics**

Although ceramics possess relatively low physical properties compared to metal alloys, their resistance to wear and biocompatibility allow them to be an in ideal material for hip implants. Alumina is the most commonly used type of ceramic in modern hip implants. The importance of using alumina ceramic as a bearing surface in hip implants is associated to its hardness, wettability, fluid film lubrication, inertness, high level of oxidation of alumina ceramic which provide resistance to scratches, and high biocompatibility (Jung & Kim 2010). Furthermore, the possibility of osteolysis can be decreased with the use of alumina as it is a bioinert material. One of the most desirable properties of using alumina as a material is their wear performance under loading conditions.

Table 7: Summary for a review on ceramic on ceramic hip implants (Gallo et.all 2012)

Parameter	Ceramic on Ceramic	Ceramic/Metal on Polyethylene	Metal on Metal
Wear rate	30.5±7 µm/y[64]	218.2±13.7 µm/y[64]	20–25µm/y[65]
Particle size	0.13–78 µm[66]	30 nm–10 µm[67]	30–100 nm[68]
Cellular response to wear particles	Low	High	High
Hypersensitivity induced by wear debris	No	No	Yes
Tissue necrosis, ALVAL	No or weak	Weak	High grade
Dislocation#	0.78%	0.80%	0.74%
Infection#	0.32%	0.49%	0.53%
Mechanical loosening#	0.39%	0.22%	0.20%
Revision#	1.02%	1.16%	1.12%

A recent study conducted by (GalloGoodman, et al. 2012) on the wear performance of ceramics as biomaterials provided the results of wear from ceramic on ceramic (CoC) hip implants in order to compare and analyse the wear rates from different type of implants. Based on the results provided in Table 7, the study validates that the ceramic on ceramic implants demonstrate a considerably lower wear rate compared to other combinations. Although ceramic implants demonstrate high biocompatibility, there a few concerns in using these type of implants due to potential health risks. These risks mainly include the occurring of ‘squeaking’ of ceramic bearings, potentially effecting the patient’s quality of life. Direct contact between the neck of the stem and the rim of the ceramic liner during range of motion can result in rim damage possibly resulting in accelerated wear (GalloGoodman, et al. 2012).

3.4.4.3 **Biocompatibility of Polymers**

The material properties such as high strength and stiffness make polymers one of the most applicable materials for hip implants. However, the use of polymeric materials has been researched extensively due to their biocompatibility concerns. The common polymers used include acrylic, nylon, silicone, polyurethane, ultra-high molecular weight polyethylene (UHMWPE) and Polymethyl methacrylate (PMMA). In Total Hip Replacement (THR), the implant is generally designed with an ultra-high-molecular-weight polyethylene (UHMWPE) or Polyethylene (PE) insert that articulates against a cobalt-chromium alloy or ceramic femoral head. However, the use of UHMWPE for acetabular cups has led to interfacial adhesion between tissue and implant demonstrating poor biocompatibility. One of the main biomedical concerns in total hip replacements is wear-mediated osteolysis, in which inert microscopic wear debris from the bearing cause an acute immune response that results in bone lesions that can compromise the implant (Pruitt & Furmanski 2009). Although the use of Polymethyl methacrylate (PMMA) as polymer bone cement demonstrates good material properties, it is prone to osseointegrate and possibly disturbing bone healing. Furthermore, in combination with primary (micro-) mechanical instability these properties may lead to the formation of an interface membrane and subsequent aseptic loosening (Nuss & von Rechenberg 2008).

3.4.4.4 **Biocompatibility of Carbon Fibre Reinforced Polymers (CFRP)**

Based on the literature review performed, the use of carbon fibre reinforced polyetheretherketone (CFR-PEEK) has been the primary focus for the purpose of this project. Recent studies conducted on the use of CFR-PEEK suggest that the material is readily accepted by the body and does not break over time. It has a modulus very similar to bone and an ability to withstand prolonged fatigue strain. Furthermore, the material can be manufactured to match the modulus of both cortical and cancellous bone densities (Li et al. 2015). One of the very few disadvantages in using CFR-PEEK for implant components is the possibility of the carbon fibre micro particles to be absorbed by either macrophages or foreign body giant cells. Nevertheless, the use of CFR-PEEK for hip implants has been widely recommended as it is resilient to sterilization and demonstrates negligible cytotoxic effects.

3.4.5 **Manufacturability of implant components**

Hip implants are designed to vary for different demands based on the individual requirements. As a result, it is important to carry out research to understand the manufacturing process of the implant components for more accurate means of characterisation. The main focus of this project still remains on an alternative material for the femoral head and acetabular cup of the hip implant which requires understanding manufacturing process such as fabrication process and polishing. These processes are to be studied and examined for each material to understand the ease of manufacturability of the implant components.

- **Fabrication process**

The fabrication process for implant components generally varies depending upon the materials required to be used. Fabrication of metals such as cobalt chrome, titanium and stainless steel are usually shaped by forging or investment casting, followed by rough machining, polishing and coating (Zhang, Kiat & Pramanik 2009). However, manufacturing components made of ultra-high molecular weight polyethylene (UHMWPE) requires moulding and machining involving additional time and cost. The manufacturing of femoral head or acetabular cup using ceramics such as alumina or zirconia is performed by sintering followed by grinding and polishing. Carbon fibre reinforced polyetheretherketone (CFR-PEEK) composites can be processed using conventional high-temperature techniques such as autoclave molding, compression molding, filament winding and putrusion to obtain simple or complex geometries with specific fibre orientation for the design. Further research will be performed to obtain the component manufacturing and fixation method using CFR-PEEK as the component material.

- **Polishing**

Polishing the bearing surfaces of hip implants is a critical aspect which determines the shape accuracy, surface roughness and the surface integrity of the implant components. In order to maintain a high engagement stability of bearing during different cases of dynamics loadings, it is important to achieve a high grade of surface finish for the femoral ball and acetabular socket (Zhang, Kiat & Pramanik 2009). Due to their relatively high hardness, ceramics can be polished to a very smooth finish and offer scratch resistance as a bearing surface. However, polishing

metals such as stainless steel and titanium require the use of hard abrasive compound materials to achieve the required surface finish and precision.

3.5 Material selection decision matrix

The aim of the following section is to develop a decision matrix system in order to select an appropriate material based on various factors. In order to obtain a decision matrix, the initial process requires to compare the mechanical properties of the common material types used for hip implants recognised in the literature review. The information used for the comparing mechanical properties of each material was obtained from (http://www.makeitfrom.com/ 2015). The type of material and their standards used for the information are based on the literature review performed in the project. Based on the performed literature review, the following materials are to be compared for the decision matrix system:

- *Material A – Unfilled Polyetheretherketone (PEEK)*
- *Material B – Alumina (Al_2O_3)*
- *Material C – Ultra High Molecular Weight Polyethylene (UHMW-PE)*
- *Material D – Stainless steel (316L)*
- *Material E – Titanium (Ti-6A1-4V)*
- *Material F – Co-Cr alloy (ASTM F138)*
- *Material G - Carbon-fibre-reinforced polyetheretherketone (CFR-PEEK)*

Based on the engineering requirements of materials for hip implants, the individual mechanical properties of the materials listed above are compared in the table below (Table8).

Table 8: Mechanical properties of materials used in THR

	Mechanical property				
Material	***Ultimate Tensile strength (Mpa)***	***Young's modulus (Gpa)***	***Compressive strength (Mpa)***	***Density (g/cm^3)***	***Strength-to-weight ratio***
A	95	4	120	1.32	76
B	480	290	2300	3.42	10
C	49	0.8	20.7	0.94	52
D	950	210	310	8	144
E	960	110	795	4.43	170
F	655	230	450	8.3	97
G	230	24	300	1.51	161

Material Selection

In order to achieve a decision matrix system for the material selection process, it is important to select the relevant criteria in order to distinguish the relevance of the material properties. The following table (table 7) represents the applicable criteria used to obtain the factors to be used for the decision matrix system.

Criteria	Definition
Ultimate Tensile Strength (UTS)	The Ultimate tensile strength of a material is determined based on the maximum stress that the material can withstand while being stretched or pulled before failing or breaking.
Density	Density of a material can be used to obtain the specific gravity which can be defined as strength/density.
Young's modulus	The Young's modulus or Tensile Modulus is a material constant which is a measure of the stiffness.
Compressive strength	The maximum compressive stress represents the material's ability to withstand stress before any deformation takes place.
Strength-to-weight ratio	Strength-to-weight ratio i.e specific strength is the ratio of the material's strength to its density
Biocompatibility	The material's biocompatibility with the existing tissue.
Manufacturability	The extent to which a design can be manufactured with relative ease and maximum reliability.

Based on the relevant criteria identified for each material, the following steps were undertaken to develop the material selection decision matrix:

- Select an appropriate weighing factor for each criteria.
- Select a scale within a range of ±5 as the score for each material.
- Designate an appropriate score for each material based on the relative properties.
- Determine the overall individual score for each material.
- Rank the materials based on their individual weighted score.

Table 9: Material selection decision matrix

Decision Factors		**Material Type**						
Criteria	***Wt.***	**A**	**B**	**C**	**D**	**E**	**F**	**G**
Ultimate Tensile Strength (UTS)	**2**	-2	2	-2	4	4	3	2
Density	**2**	2	3	-2	3	2	4	2
Young's modulus	**1**	-3	3	0	3	2	3	1
Compressive strength	**1**	1	4	-1	2	3	3	1
Strength-to-weight ratio	**1**	2	-4	2	3	4	1	4
Biocompatibility	**2**	1	3	-2	-4	-3	-3	3
Manufacturability	**1**	2	2	3	-1	-3	-1	-1
Weighted Scores		**4**	**21**	**-8**	**13**	**12**	**14**	**19**

The table above (Table 9) represents the material selection decision matrix constructed based on appropriate ratings for each criteria. The materials are ranked based on their individual weighted score in the table below (Table 10):

Table 10: Ranking materials based on their weighted scores

Material Type	**Material name**	**Ranking**
A	Polyetheretherketone (PEEK)	6
B	Alumina (Al2O3)	1
C	Ultra High Molecular Weight Polyethylene (UHMW-PE)	7
D	Stainless steel (316L)	4
E	Titanium (Ti-6A1-4V)	5
F	Co-Cr alloy (ASTM F138)	3
G	CFR-PEEK	2

Based on the weighted scores for each material, the respective ranking were accomplished by performing the decision matrix system. Therefore, the results obtained from the material selection process are to be analysed and discussed in the following chapter to develop a preliminary model for the project.

Chapter -4 Preliminary design proposal

This thesis was carried out to essentially identify possible alternative materials to potentially improve the performance of femoral components of the hip implants. Based on the literature review performed, it was understood that one of the major concerns with hip implants is the associated wear between the femoral head and acetabular components. Although the femoral stem component of the implant causes biomedical concerns, these issues are primarily associated with the stem fixation due to the differential movement between implant and bone. In comparison, the biomedical issues related to the femoral head and acetabular component include potential wear, instability and peri prosthetic fracture. Therefore, the objective of this section of the project is to develop a preliminary design for the bearing and acetabular components using alternative materials identified from the material selection process.

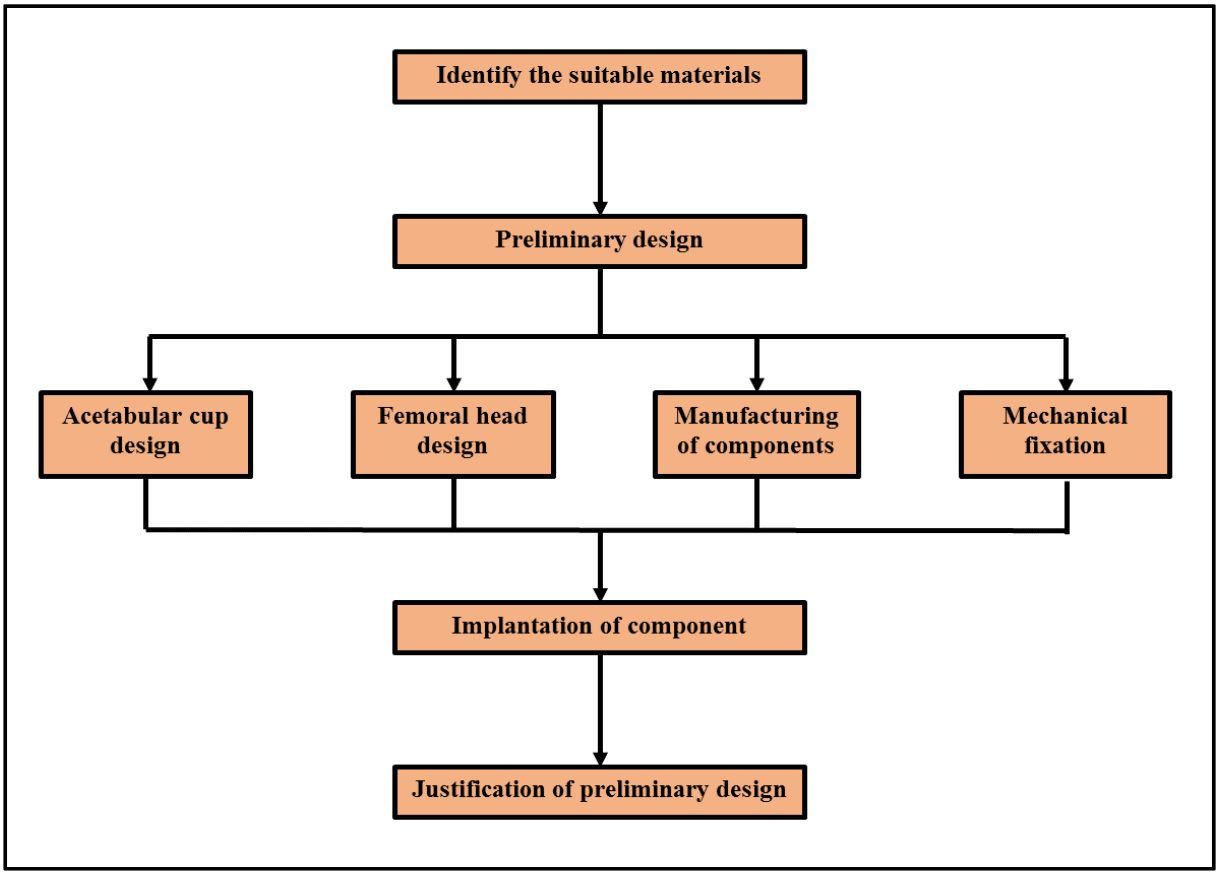


Figure 4-1: Preliminary design process flow chart

Figure 4-1, above provides a visual representation of the various steps involved for the process of developing the preliminary design.

4.1 Identifying the suitable materials

The following section provides a detailed analysis of the results obtained from the material selection process in order to identify the most suitable materials for hip implants. Based on the results achieved from the material selection decision matrix, it is evident that the use of ceramics and carbon fibre reinforced polyetheretherketone (CFR-PEEK) are theoretically the most viable option relative to the other materials. Although the metal alloys (Co-Cr) and Titanium offer a considerably high amount of strength, both the materials possess the likelihood of intoxication of blood affecting the patient's health.

One of the most important properties to consider while selecting the material for an implant is the material's biocompatibility with the existing tissue. As a result, the ideal hip implant should be designed in such a way that it provides an accurate representation to the applied loading on a real bone and it's biocompatibility with the existing tissue. Hip prosthetics that are to be in direct skeletal contact require a low elastic modulus to be structurally compatible, but a high level of strength to ensure practicability and durability. Additionally, surface compatibility must also be achieved. For instance, designing a prosthetic device from purely polymeric materials may seem appropriate (due to their low elastic modulus), however, their low strength impairs their usability.

4.1.1 Selection of material for acetabular cup

It is important to identify a suitable material for the acetabular cup based on its performance requirements upon the insertion of the implant components. Based on the material selection process, ceramics were identified as the most suitable material due to their high mechanical properties and high biocompatibility. A recent study performed by (Navarro et al. 2008) suggested the use of alumina ceramic cups due to their low wear rates, high corrosion resistance and excellent mechanical properties. Therefore, based on the research evidence and the results obtained from material selection, the use of Alumina (Al_2O_3) is recommended as the most feasible material for the acetabular cup.

4.1.2 Selection of material for femoral head

Selecting the suitable material for the femoral head is perhaps one of the most difficult decisions as it requires to consider a wide range of engineering requirements

and the potential biomedical concerns. Based on the literature review, the femoral head of a hip implant is fundamentally developed using metals such as stainless steel, cobalt chromium (Co-Cr) alloy, titanium and ceramics such as alumina and zirconia. Several studies performed on the performance of these materials provide the various advantages and disadvantages for each material based on their individual properties. Based on the performed literature review and results obtained from the material selection process (Table 10), the use of CFR-PEEK as an alternative material for the acetabular surface was identified as a suitable choice as the material provides the recommended requirements for mechanical properties while offering high compatibility. However, very limited research has been conducted in the possibility of using CFR-PEEK as an alternative material for the femoral head for the hip implants. This can be explained based on the general design and material selection of femoral head and acetabular cup components. Since hip implants are traditionally designed as Hard-on-Hard implants or Hard-on-Soft implants, the femoral head is usually designed from metals or ceramics.

The use of carbon fibre reinforced polymers (CFR-PEEK) sheet with a combination of a suitable material is to be proposed as one of the main design recommendation for the following project. The engineering requirements to select an appropriate material for the inner bearing surface of the femoral head are:

- Provide high mechanical properties such as toughness and hardenability.
- High density and strength-to-weight ratio
- Ease of manufacture

Based on the results obtained from the material selection process (Table 10), it was identified that stainless steel demonstrated relatively high mechanical properties compared to other metals and ceramics. Although the use of stainless steel as a bearing surface offers poor biocompatibility and has the potential for wear debris, these factors would be neglected due to the addition of carbon fibre reinforced polyetheretherketone (CFR-PEEK) sheet. Therefore, the stainless steel bearing surface would provide high stability due to its excellent mechanical properties, the additional CFR-PEEK sheet would interact with ceramic acetabular cup to potentially reduce the associated wear and offer good biocompatibility. The

manufacturing process of CFR-PEEK sheet and the fabrication methods are to be discussed further in the report to validate the possibility of the design.

4.2 Preliminary design

In the previous section, the suitable materials for the proposed design were identified based on their engineering requirements. The following section provides a detailed analysis of the various design factors which need to be considered to develop the desired preliminary design.

4.2.1 Acetabular cup design

The selection of acetabular cup design requires accurate preoperative planning due to the variation in design based on individual patient's requirements. The main factors which need to be considered for preoperative planning include:

- Optimal position of the cup
- Centre of rotation
- Size of the implant
- Final component position
- Abduction angle

The cup position and size and size can be determined through using template overlays on the A/P radiograph of the hip. Once these factors are determined, the intended centre of rotation of the bearing surface can be marked on the A/P radiograph (Iconacy 2012).

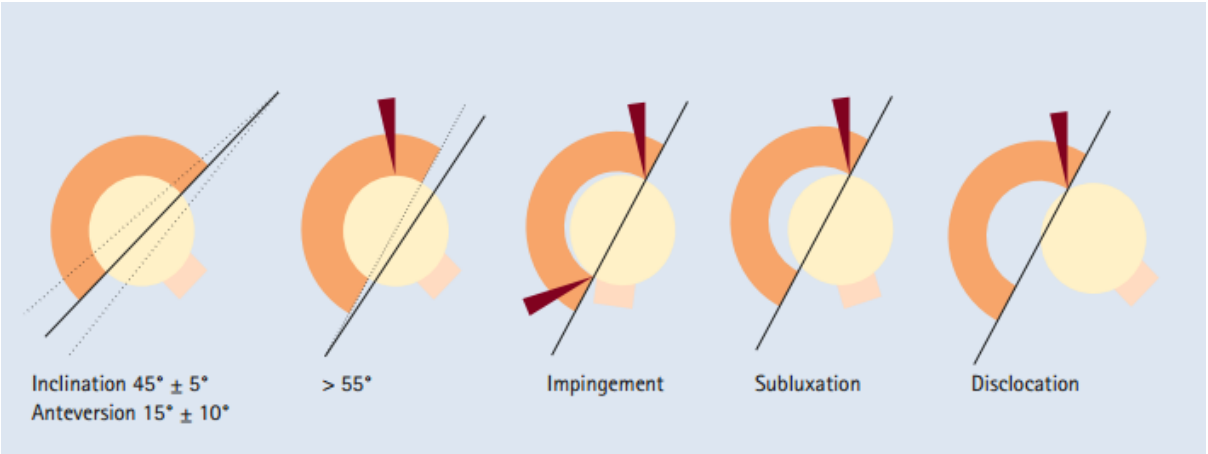


Figure 4-2: Ceramic on Ceramic implant cases (Source: (Aesculap 2015))

In general, it is recommended to achieve an abduction angle to a maximum of 45 degrees, and 10 – 15 degrees of anteversion angle.

For ceramic-on-ceramic bearing surfaces, (Aesculap 2015) suggests using 32 – 36 mm heads. The placement of cup will vary depend on the patient's anatomy and intraoperative judgement. Therefore, based on the design requirements suggested above, the most applicable acetabular cup design for this project was the 'Allofit Acetabular Cup System' designed by (Zimmer 2011). The Allofit cup replicates the original shape of the acetabulum acting as a bone-conserving implant. As a result, it is possible to preserve and use the subchondral bone as support for the implant (Zimmer 2011). The geometry of the cup model is presented below:

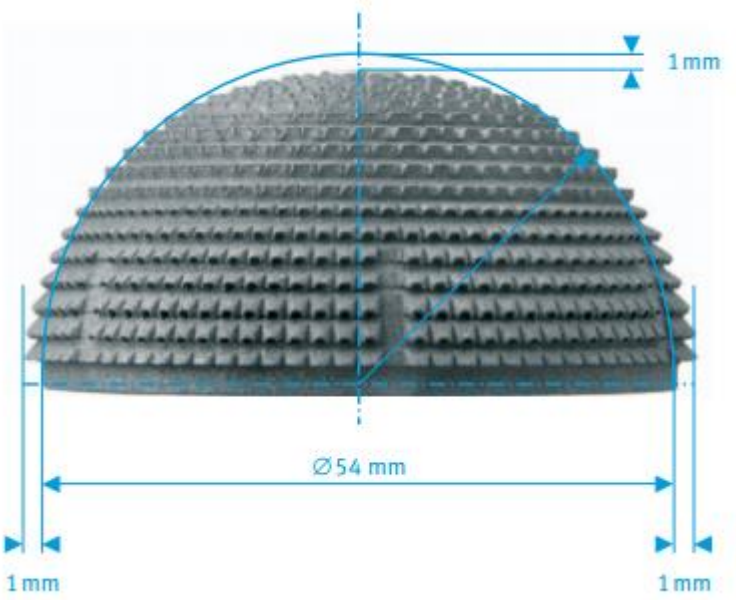


Figure 4-3: Allofit acetabular cup geometry (Zimmer 2011)

The additional teeth on the outer surface of the cup presented in (Figure 4-3) will be neglected in the preliminary design for the purpose of simplicity. The Allofit cup can de designed in different sizes ranging from 36 – 64 mm. (Zimmer 2011) also suggests that the cup design is applicable for Ceramic-on-Ceramic which is desirable for the purpose of this project. Therefore, the *Allofit* acetabular cup design will be used for the preliminary design based on the appropriate engineering factors such as thickness, abduction angle and material properties.

4.2.2 **Femoral Head design**

The following section aims to identify the ideal size for the femoral head based on the current industrial standards and performance requirements. During the initial process of the preliminary design, the design proposal was to develop a stainless steel metal femoral head with an additional layer of carbon fibre reinforced polyetheretherketone (CFR-PEEK) sheet to overcome the potential effects of wear and offer higher stability. Therefore, the primary objective is to select the ideal head size for the stainless steel femoral head to avoid the risks of impingement in the hip implant.

During the past decade, the head sizes for femoral head range were generally ranged from 22 to 28 mm. However recent studies performed on the ideal femoral size for hip implants aim to understand the feasibility of using larger femoral heads to potentially increase the range of motion and reduce the risk of impingement and dislocation. (Cross, Nam & Mayman 2012) suggests that larger femoral heads increase the head-neck ratio and range of motion and reduce the risk or postoperative dislocation.

Table 11: Range of motion with reference cup orientation (Cinotti et al. 2011)

Hip motion	**Femoral head diameter**			
	28 mm	**32 mm**	**36 mm**	**38 mm**
Flexion	115° (c-c)	125° (b-b)	125° (b-b)	125° (b-b)
Extension	55° (c-c)	66° (c-c)	66° (c-b)	66° (c-b)
Abduction	63° (c-c)	68° (b-b)	68° (b-b)	68° (b-b)
Adduction	24° (b-b)	24° (b-b)	24° (b-b)	24° (b-b)
External rotation	53° (c-c)	53° (c-c)	53° (c-c)	53° (c-c)
Internal rotation	78° (c-c)	86° (b-b)	86° (b-b)	86° (b-b)

The table above (Table 11) provides a comparison the range of motion with respect to different femoral head sizes. The data suggests that the overall range of motion was increased at an average of 5.3° moving from the 28-mm to the 38-mm femoral head (Cinotti et al. 2011). The most important benefit in using the 38-mm femoral head, compared to the 28-mm, was found during extension (11°) and during flexion (10°).

Furthermore, research has been conducted to understand the wear analysis in larger diameter femoral heads to potentially reduce the volumetric wear from the bearing surface. A recent study conducted by (Cross, Nam & Mayman 2012) investigated into the volumetric wear rates for metal-on-metal implants with larger femoral heads.

Table 12: Adjusted mean total volumetric wear (mm^3)

Head size (mm)	Mean total volumetric wear (mm^3)
26	88.431±36.341
28	95.519±21.719
32	34.290±23.945
36/40	159.64±33.430
	$p \leq 0.0134$

Based on the data provided in (Table 12), it can be understood that the use of larger femoral head sizes is a feasible option due to the reduction in volumetric wear and their ability to reduce the risk of osteolysis. As a result, the femoral head size for the stainless steel will be designed using an outer diameter of 32 mm to provide a higher range of motion.

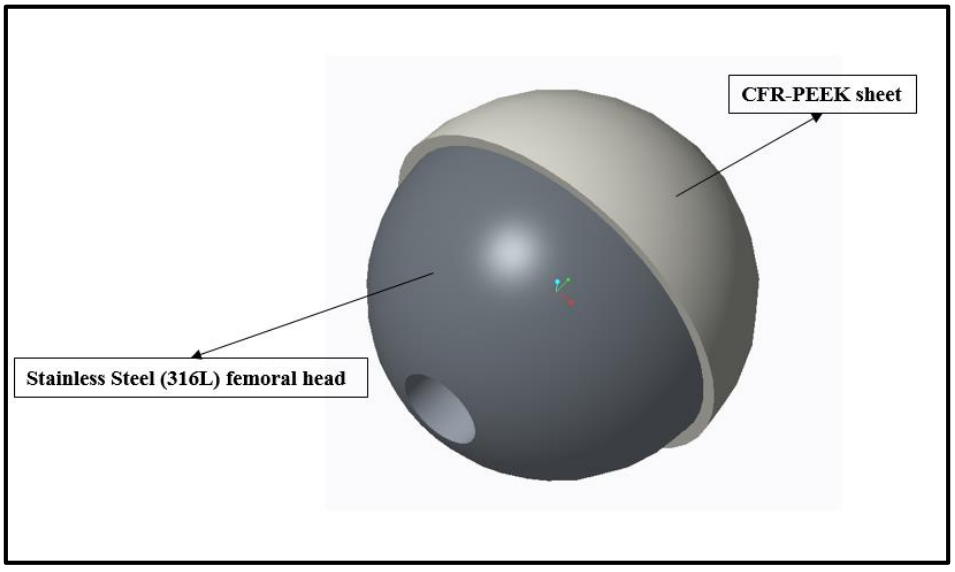


Figure 4-4: 3D model of the proposed femoral head design

The illustration above (Figure 4-4) represents the 3D model of the proposed femoral head develop using Creo Paramteric 3.0. The manufacturing process and thickness of the CFR-PEEK sheet is to be determine later in this project based on further research and design standards.

4.3 Justification of preliminary design

The following section aims to justify the proposed preliminary design and identify the potential benefits from the possibly improved design. The primary goal of this project is to investigate the failure of orthopaedic hip prosthesis and the possibility of using fibre reinforced polymer composites as an alternate material to potentially improve the long term use if of hip implants. As a result, the main objective of this thesis was to develop a preliminary design with the use of CFR-PEEK as an alternative material for the femoral components in hip implants.

The initial process of the preliminary design was to essentially identify the most suitable materials for the femoral head and acetabular cup components. Based on an in depth literature review and material selection process, the most suitable materials were selected based on their performance requirements. The proposed design was to develop a femoral head consisting of two components where the inner bearing surface was made up of stainless steel and an additional layer of carbon fibre reinforced polyetheretherketone (CFR-PEEK) sheet with a suitable thickness. Furthermore, the femoral head was to be used with a combination of a ceramic acetabular cup which offers high mechanical properties and good biocompatibility.

The preliminary design offers a potentially improved design. However, the main question “What is the purpose of this project” is still is yet to be answered. Therefore, the main goals of developing the preliminary design for this project are outlined below:

- Investigate into the potential for an alternative bearing material for THR.
- Potentially reduce the wear between the femoral head and acetabular component.
- Provide a higher stability within implant components.
- Potentially improve the long term use of total hip replacements.

Although the proposed preliminary design was theoretically justified, it is essential to validate the proposed design by performing and Finite Element Analysis. Therefore, the following objective of this thesis is to perform FEA on the preliminary model based on relevant design parameters such as the loadings, constraints and materials properties. Furthermore, real volumetric wear testing is to

be performed with the use of suitable apparatus and equipment to justify the design's potential to reduce the wear between femoral head and acetabular component.

Chapter -5 Methodology

5.1 Project outline

The general methodology used for the research project is outlined below:

- Provide an analysis of the potential causes of failure in Total Hip Replacement (THR) based on an extensive review of literature.
- Research into the materials used for designing the hip implant and provide and provide an alternate material based on appropriate materials selection method.
- Perform an investigation to study the mechanical performance of fibre-reinforced composite hip prosthesis.
- Propose a preliminary design to improve the performance and safety of hip implants.
- Select an appropriate hip implant prototype which is currently used in biomedical filed.
- Identify all the relevant parameters to be involved for simulating the model.
- Develop and verify three-dimensional finite element analysis to analyse the behaviour of composite implant in the femur.
- Analyse and discuss the obtained results from the simulation for different materials.
- Perform an abrasive wear testing for the selected materials.
- Analyse the results obtained from the wear testing to obtain the wear characteristics of the selected materials under loading conditions.
- Provide conclusion and recommendations for future work.

5.2 Design considerations for FEA model

In order to perform simulation of a hip implant with different material considerations, it was important to attain a prototype of an actual hip prosthesis which is currently being used in the biomedical industry. For the purpose of this project, the ‘Himmer M/L Taper Hip Prosthesis’ prosthesis was decided to be used to perform the simulation. The Himmer M/L Taper Hip Prosthesis is a typical hip prosthesis designed to offer comparatively lower rates of acetabular erosion and dislocation. The major dimensional parameters that would be identified from the

Himmer's model include the femoral head diameters, taper geometry, prosthetic neck diameter, stem length and also the material used for the components.

5.3 Identification of Parameters for FEA

While performing a Finite Element Analysis of a hip prosthesis, the parameters required to be considered are:

- Appropriate dimensions of the model. The essential components in this case would include the femoral head diameter, neck diameter and head inset of the acetabular component.
- Material properties of the bone and femoral components. These properties primarily include the Poisson's ratio and the Young's modulus.
- Forces and maximum stress acting on the prosthesis based on appropriate assumptions.
- Properties of blood and lubrication fluid.

5.4 Method of simulation for FEA

The simulation process will involve the use of the Zimmer prostheses subjected to loadings based on appropriate assumptions. The simulation will be done for the selected materials in order to compare and analyse the results obtained. The simulation will involve performing a static analysis of the hip implant as an accurate dynamic analysis is out the scope for this project due to the limited time. The software packages used to perform Finite Element Analysis include Creo Parametric 3.0 and Creo Simulate 3.0. Creo Parametric will initially be used to create the initial design of the hip prosthesis based on relevant parameters. Once this is performed, Creo Simulate will be used to perform the simulation to apply the suitable loads, appropriate mesh and constraints on the model.

5.5 Methodology for abrasive wear testing

As a part of justification for the theoretically proposed preliminary design, it is necessary to perform abrasive wear testing using the suggested implant materials. The testing is to be performed at a personal workplace due to the limited time available. Although it is not possible to provide an official risk assessment, the testing will be performed with all the required safety equipment and standard procedures to avoid any potential hazards within the personal workplace. The three

main materials used for the preliminary design are ceramics (Alumina), stainless steel and carbon fibre reinforced polyetheretherketone (CFR-PEEK). The following section outlines the apparatus and methodology used to perform the abrasive wear testing.

5.5.1 **Testing apparatus**

The testing apparatus chosen for performing the abrasive wear testing include:

- 150 mm × 150 mm × 3mm Alumina (Al_2O_3) sheet
- 150 mm × 150 mm × 3mm Stainless steel (316L) sheet
- 150 mm × 150 mm × 2mm 30% CFR-PEEK sheet
- Sandpaper (120 grit size)
- Random orbital sander

For the purpose of this project, the ‘480W Black and Decker’ random orbital sander was chosen to be used to perform the abrasive testing. The specifications of the sander model include:

Table 13: 'Black and Decker' random orbital sander specifications (Source: http://www.supercheapauto.com.au/)

Power	480 Watt
No load speed	4000-12000/min
Paper size	125mm
Speed settings	Variable

- Digital scale

A digital electronic scale is to be used to measure the mass of the material sheet after performing the abrasive testing.

5.5.2 **Abrasive testing procedure**

The procedure used to perform the abrasive testing using orbital sander involves the following steps:

Step 1 - Establish a stationary workplace.

Step 2 – Ensure the material specimen is fixed above the wooden block using bolts.

Step 3 – Attach an unused sand paper to the orbital sander.

Step 4 - Initiate the orbital sander.

Step 5 - Stop the orbital sander after a period of 20 minutes.

Step 6 – Replace the material specimen with a different material.

Step 7 – Repeat steps 2 to 5 for each material specimen.

Step 8 – Measure the difference in mass for each material specimen.

Step 9 – Repeat the testing for each material specimen for four days.

5.6 **Risk Assessment

A risk assessment for the project is necessary to identify all the potential risks and hazards associated with the project. The aim of the following section of the project is to develop an adequate risk assessment by using a standard method and quality control. One of the most important aspects of developing a standard risk assessment is to ensure the identification of all the risks and hazards during the execution of the project and beyond the completion of the project. Henceforward, the following risk assessment is to be developed with the consideration of the potential risks, hazards and the consequential effects due to the project.

5.7 Project timeline

In order to develop a suitable timeline, it is important to assess the required milestones or shot term goals to be achieved within the desirable competition time. The following section of the methodology aims to provide a visual framework for the structure of the project and the desired completion dates for the respective milestone.

Table 14: Project milestones

Milestones	Description	Desired completion date
Project proposal	Submit the project proposal for the desired research topic.	10th March 2015
Project specification	Provide the specification of the project including the aims, objectives and the programme.	14th March 2015
Literature review	Provide an analysis of the potential causes of failure in Total Hip Replacement (THR) based on an extensive review of literature.	30th May 2015
Material selection	Develop a material selection process based on relevant criteria, decision matrix and justification.	1st June 2015
Methodology	Provide the methodology to be used within the project including the project outline, design considerations, method of simulation, risk assessment and the resource requirements.	1rd June 2015
Preliminary report	Develop a preliminary report for the project to assess the progress of the research.	3rd June 2015
Finite Element Analysis	Perform Finite Element Analysis based on the design considerations, relevant materials and the identified parameters.	31st August
Evaluation of results	Perform a detailed review of the results obtained by comparing the theoretical and experimental data and	1st September

	providing justifications.	
Draft dissertation	Complete the draft dissertation involving substantial portion of the project.	15th September
Conclusion and recommendations	Perform a detailed review of the obtained results upon the completion of the project by providing an in-depth summary, conclusions and recommendations.	20th October
Dissertation submission	Produce a final standard dissertation for submission.	28th October

	Completion Dates							
Milestones	March	April	May	June	July	August	September	October
Project proposal								
Project specification								
Literature review								
Material selection								
Methodology								
Preliminary report								
Finite Element Analysis								
Evaluatoin of results								
Draft dissertation								
Conlucison and recommendations								
Dissertation submission								

Figure 5-1: Project timeline visual framework

5.8 *Assessment of consequential effects

5.8.1 **Consequential effects**

The primary goal of this project is to investigate the failure of orthopaedic hip prosthesis and the possibility of using fibre reinforced polymer composites as an alternate material based on the performance requirements. The project initially seeks out to determine the primary causes of failure in the modern hip implants. After performing an in depth literature of the different types of materials used in hip implants, it was established that the materials being used for modern hip implants raise concern over a wider range of health issues due to the performance failure of the implants. After performing a detailed material selection process based on a wide range of selection criteria and material selection decision matrix, it came to knowledge that the use of Carbon Fibre Reinforced Polyetheretherketone (CFR-PEEK) as an alternative material for the femoral components of the hip implants could provide a feasible option for the implant materials in the future. In order to justify the use of the new alternate material, the use of Finite Element Analysis in the

relevant software is to be performed based on the relevant parameters. The tests performed for the FEA would ideally include the comparison of stress, strain and displacement for each material based on fatigue and impact loading. Upon the completion of the Finite Element Analysis, it is to be determined if the new material would be a feasible option for the purpose of hip implants. As a result, it is important to assess all the consequential effects that are involved with the duration and upon the completion of this project.

In the case of a successful outcome for the project, the use of new material as an alternative option would be justified based on the achieved results. The potential of using an alternative material for hip implants could have a global impact on the designing of hip implants. As the demand for better and safer hip implants continue to increase throughout the globe, the use of new material as a better alternative could impact the lives of several thousands of people. However, it is important to note that a large number of resources involving further background research, testing and waste production would be required to validate the use of an alternate material in order to ensure the practicability and safety of the new implants. This is due to the possibility of the failure of the hip implants designed with the new alternative material which could impose serious health risks on patients throughout the world. As a result, it is an ethical responsibility as a professional engineer to ensure that the project is undertaken with the consideration of all the standard measures, accurate information and precautionary approach.

The code of ethics developed by (EngineersAustralia 2015) states that engineers are required to demonstrate the following responsibilities:

- Demonstrate integrity by acting on the basis of a well-informed conscience.
- Practise competently by acting on the basis of adequate knowledge. Hence, it important to ensure that the project is undertaken with high knowledge and skills in order to ensure the quality of the project.
- Exercise leadership by communicating honestly and effectively, taking into account the reliance of others on engineering expertise. As a result, it is important to maintain an effective communication with an engineering expertise throughout the duration of the project by receiving continuous

feedback and maintain the quality of the project. It is also important that the research is presented in a well-structured and organised manner for reference purposes in the future.

- Promote sustainability by balancing the needs of the present with the needs of future generations, practise engineering to foster the health, safety and wellbeing of the community and the environment. The primary goal of the project is to research on the feasibility of alternate material for hip implant to improve the safety and well-being of all the patients requiring total hip replacement.

Chapter -6 Finite Element Analysis (FEA)

6.1 Overview

The aim of the following section of the project is to perform a methodical Finite Element Analysis (FEA) in order to validate the use of carbon fibre reinforced polymers as an alternative material for hip implants. It is a standard technique used to obtain solution to wide range of engineering problems by subdividing the component into finite elements. The application of Finite Element Analysis (FEA) in this project to obtain engineering information such as stress/strain distribution, deformation and natural frequency of a component as it allows to accurately model the actual shape, loads and constraints, as well as material property combinations in hip implants.

Based on the extensive literature review performed, the feasibility of using carbon fibre reinforced polymers for hip implants was theoretically justified using a decision criteria matrix. The proposed design was to principally add CFR-PEEK sheet on metal femoral head with a combination of ceramic acetabular cub to potentially minimize the wear and improve the long term durability of hip implants. In order to validate the theoretical proposal using Finite Element Analysis, it was important to attain a prototype of an actual hip prosthesis which is currently being used in the biomedical industry. For the purpose of this project, the 'Himmer M/L Taper Hip Prosthesis' was used to perform the required simulation. The hip implant was designed based on the provided dimensions and appropriate assumptions due to availability of limited information.

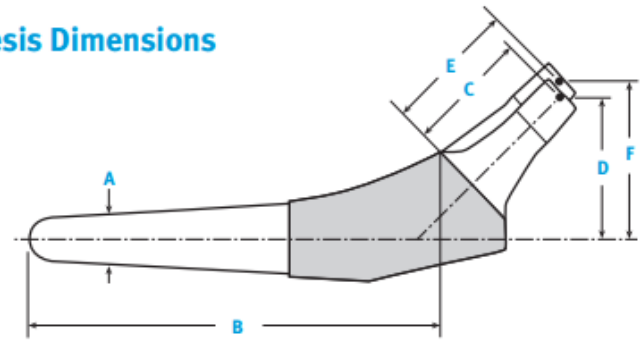
The software packages used to perform Finite Element Analysis include Creo Parametric 3.0 and Creo Simulate 3.0. Creo Parametric will initially be used to create the initial design of the hip prosthesis based on relevant parameters. Once this is performed, Creo Simulate will be used to perform the simulation to apply the suitable loads, appropriate mesh and constraints on the model.

6.2 Identifying the parameters involved

6.2.1 Dimensions of the model

The primary goal in performing Finite Element Analysis of a hip implant to develop and accurate design of the implant model based on standard dimensions and appropriate assumptions. The standard dimensions of Zimmer taper hip prosthesis are presented in a 2D drawing in the illustration below (Figure 6-1). The data provided included some of the key dimensions required to model the hip implant such as the stem size, stem length, neck length and neck offset. However, the provided data was not sufficient to design the implant to the exact accuracy of the actual model. Therefore, appropriate assumptions were considered based on data from different sources in order to successfully complete the model. The design considerations and assumptions are to be discussed further in the project.

Zimmer M/L Taper Hip Prosthesis Dimensions

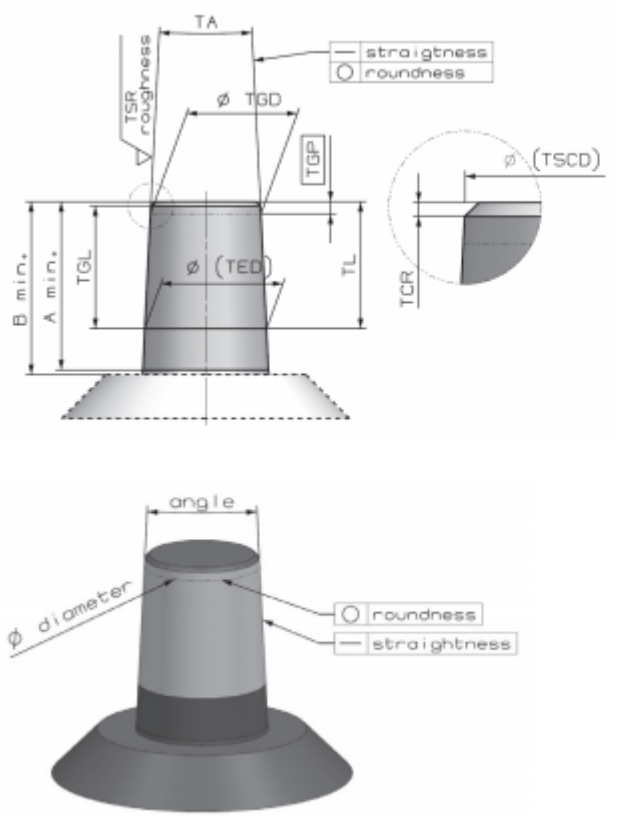


Standard Offset

Item No.	HA/TCP Item No.	A Stem Size (mm)	B Stem Length (mm)	C Neck Length (mm) When Head/Neck Component Selected is: -3.5	+0	+3.5	+7	+10.5	D Stem Offset (mm) When Head/Neck Component Selected is: -3.5	+0	+3.5	+7	+10.5
00-7711-005-00	65-7711-005-00	5	109	33	37	40	44	47	37	40	42	45	48
00-7711-006-00	65-7711-006-00	6	111	33	37	40	44	47	38	40	43	46	48
00-7711-007-00	65-7711-007-00	7.5	114	35	38	42	45	49	40	43	45	48	50
00-7711-009-00	65-7711-009-00	9	117	35	38	42	45	49	41	43	46	49	51
00-7711-010-00	65-7711-010-00	10	119	35	38	42	45	49	41	44	46	49	52
00-7711-011-00	65-7711-011-00	11	121	35	38	42	45	49	42	44	47	50	52
00-7711-012-00	65-7711-012-00	12.5	124	35	38	42	45	49	42	45	48	50	53
00-7711-013-00	65-7711-013-00	13.5	126	35	38	42	45	49	43	46	48	51	53
00-7711-015-00	65-7711-015-00	15	129	35	38	42	45	49	44	46	49	52	54
00-7711-016-00	65-7711-016-00	16.25	132	35	39	42	46	49	44	47	49	52	54
00-7711-017-00	65-7711-017-00	17.5	134	35	38	42	45	49	45	48	50	53	55
00-7711-020-00	65-7711-020-00	20	139	35	38	42	45	49	46	49	51	54	57
00-7711-022-00	65-7711-022-00	22.5	144	35	38	42	46	49	47	50	53	55	58

Figure 6-1: Zimmer M/L Taper Hip Prosthesis Dimensions (Zimmer 2014)

The Zimmer M/L Taper Hip Prosthesis essentially equips the tapered wedge design which offers a wedge fit for mediolateral safety. The fundamental design of an implant taper consists of a stem taper and a taper in the femoral ball head through a drill hole. The tapers possess characteristics such a taper angle, diameter, straightness and surface properties which are critical to obtain a precise matching of the components (Scheuber, Usbeck & Petkow 2014). Due to the limited information provided on the standard dimensions of the tapers for Zimmer taper hip prosthesis, further research was required to obtain the required dimensions to develop the implant model.



Abbreviation	Description
TGP	Taper gage plane
TGD	Taper gage diameter
TA	Taper angle
TL	Taper length
TCR	Taper chamfer/radius
TSR	Taper surface roughness
TS	Taper straightness
TR	Taper roundness
TGL	Taper gage length
TED	Taper end diameter
TSCD	Taper sharp corner dia.

Figure 6-2: Taper implant characteristics, source: (Scheuber, Usbeck & Petkow 2014)

The tapers used for hip implants generally have variable geometry due the lack of an industry standard or consensus in taper dimensions. Therefore, designing an effective implant taper requires the use of appropriate characteristics (figure 6-2) to avoid any potential collision of the taper and femoral ball head.

The design requirements for Zimmer taper hip prosthesis suggest that the use of 12/14 neck taper is compatible with the taper stem to allow an optimised range of

motion (Zimmer 2014). A recent study performed by (Scheuber, Usbeck & Petkow 2014) investigated into the compatibility of the taper and femoral ball based on different taper dimensions.

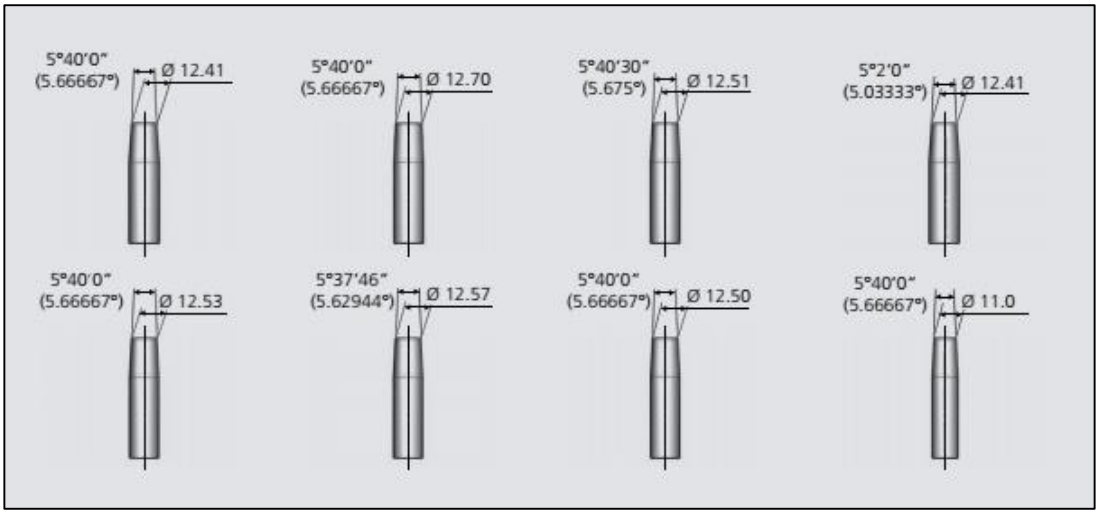


Figure 6-3: Comparison of different tapers designated to size "12/14" Source: (Scheuber, Usbeck & Petkow 2014)

The illustration above (figure 6-3) provides some of the key dimensions for different tapers all of which are designated "12/14". Based on the design requirements suggested by (Zimmer 2014), the dimensions presented in figure 6-3 could be used to develop a taper model compatible with the taper stem of the Zimmer taper hip prosthesis. Based on the obtained data, the metal stem and taper of the hip implant model was developed using Creo Parametric in order to perform Finite Element Analysis. However, the model was developed based on appropriate assumptions due to insufficient information provided by Zimmer taper hip prosthesis. Since the implant design was developed based on the assumptions, it is important to outline all the assumptions considered and the accuracy of the model was expected to be different.

6.2.2 **Engineering drawings of the hip implant model**

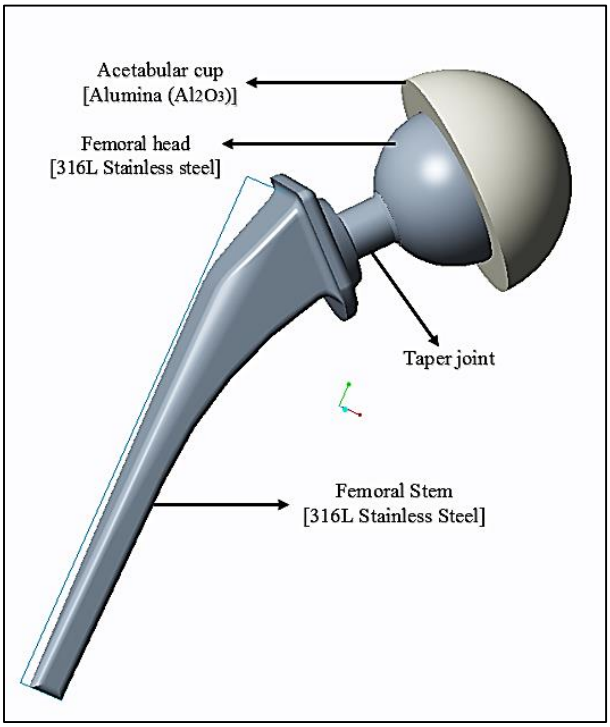


Figure 6-4: 3D model of the hip implant:

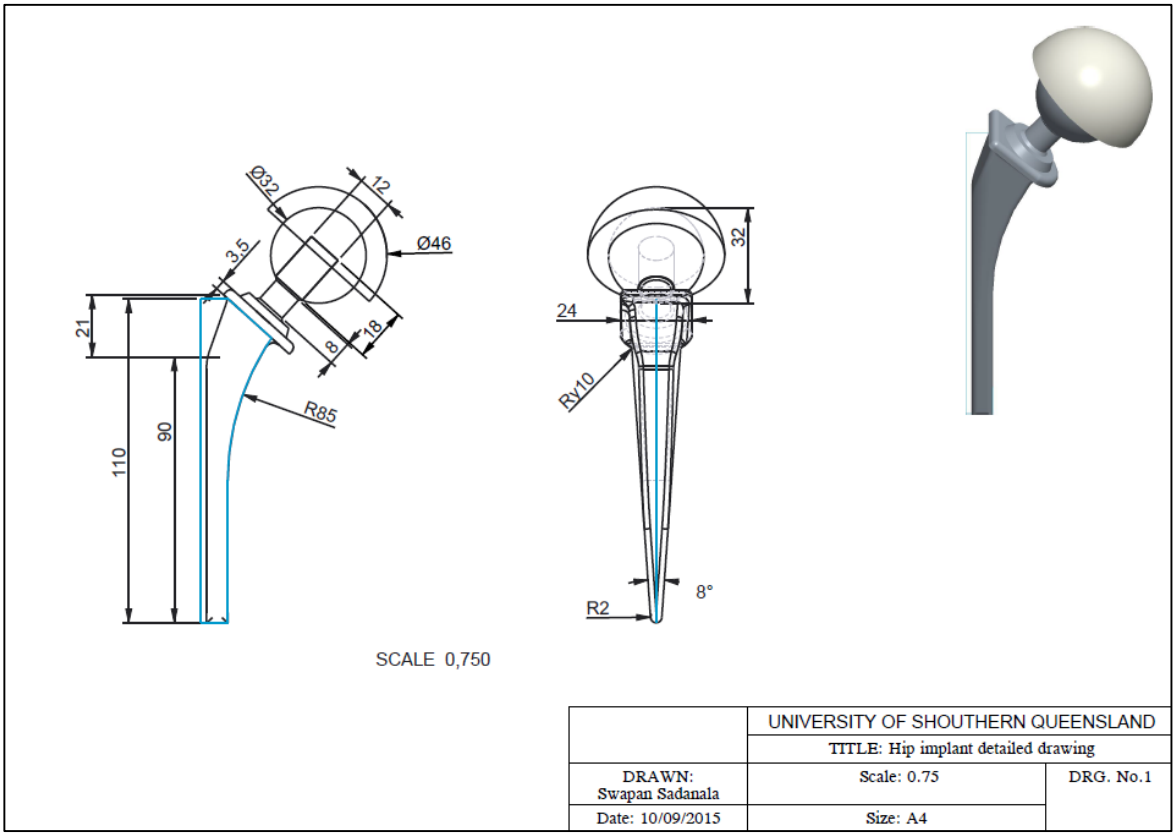


Figure 6-5: Detailed drawing of the 3D implant model

6.3 Loading conditions of the hip prosthesis

Once the geometry of the hip implant has been established, the next objective is to identify the different types of loadings and boundary conditions to perform Finite Element Analysis. There has been a wide range of research implemented in the past to recognize the different loading conditions on the hip joint prosthesis. Extensive musculoskeletal studies were established to primarily measure the forces on a hip joint during daily human activities such as slow walking, normal walking, fast walking, upstairs, down stairs, standing up, sitting down, and standing on 2-1-2 legs and knee bending (Rabbani & Saidpour 2015).

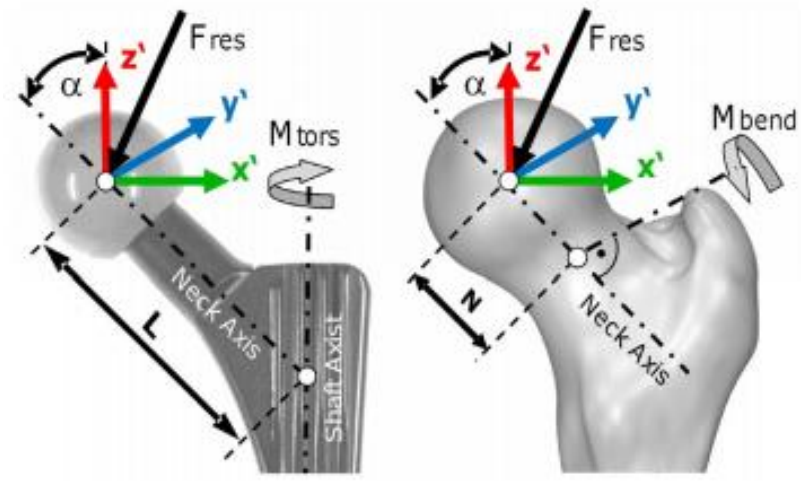


Figure 6-6: Loading conditions of a hip implant (Source: Schwachmeyer 2013)

The figure above (figure 6-6) demonstrates the co-ordinate system that was established in order to measure the forces and moments centred in the middle of the head. The hip contact force F_{res} and the components $F_{x'}$, $F_{y'}$, $-F_{z'}$ acts from the pelvis to the implant head and with respect to the coordinate system. The force component $F_{x'}$ acts laterally, $F_{y'}$ anteriorly, and $-F_{z'}$ distally along the femur axis (Schwachmeyer et al. 2013). The resultant force causes an implant moment M with components $M_{x'}$, $M_{y'}$, $M_{z'}$ around the intersection point of the shaft and neck axis. It is important to consider that a positive torsional moment $M_{tors} = -M_z$ acts in the transverse plane which rotates the implant inwards around the shaft axis (Bergmann et al. 2001).

Based on the different loads identified in the previous section, the resultant forces and moments can be determined using the equations suggested by (Schwachmeyer et al. 2013). The three main types of loads are evaluated below:

Load 1 - The resultant contact force F_{res} can be determined using the following equation:

$$F_{res} = \sqrt{(F_{x'}^2 + F_{y'}^2 + F_{z'}^2)}$$

Load 2 - The torsional moment M_{tors} can be calculated using the following equation:

$$M_{tors} = M_{z'} - F_{y'} \cdot L \cdot \sin \alpha$$

In the equation above, the anteversion angle is denoted by 'α' while 'L' represents the length on the implant neck in reference to the distance between the centre of the implant head and the point of intersection of the neck axis and the implant shaft axis.

Load 3 - The bending moment M_{bend} can be calculate using the following equation:

$$M_{bend} = \sqrt{M_{bend1}^2 + M_{bend2}^2}$$

In the equation above, $M_{bend1} = M_{x'} \cos \alpha + M_{z'} \sin \alpha - F_{y'} N$

A recent study conducted by (Bergmann et al. 2010) provided the realistic load conditions for hip implants based on *in vivo* contact force measurements. The table below (table 18) provided the peak contact forces and moments identified in different uman activities.

Table 15: Hip peak loads (Source: Bergmann 2010)

Activity	Peak contact force F (N)				Direction of F (degrees)			Peak Moment (Nm)
	F	F_x	F_y	F_z	A_x	A_y	A_z	$M_{z'}$
Walking	3900	873	540	3761	81.8	13.1	31.8	-25
Going up stairs	4200	985	1025	3951	75.5	14	46.1	37.3
Going down stairs	4200	776	613	4082	81.5	10.8	38.3	-28.8
Standing up	2900	813	203	2776	85.8	16.3	14	-15.1
Sitting down	2400	647	-9	2311	90.2	15.6	-0.8	-7.8
One leg stance	3600	405	217	3750	86.5	6.5	28.1	18.1

In order to accurately model the static loading conditions of a hip implant, it is crucial to include the femoral bone within the Finite Element Analysis. This is due to the presence of external forces such as the Ilio-tibial force and the abductor muscle force. These forces would certainly impact the resultant stress caused on the hip implant. As a result, the implanted portion of the stem was designed to be fully fixed inside the bone, simulating a perfect press-fit. The femur was fully fixed at the distal end and partially at the proximal end near the greater trochanter.

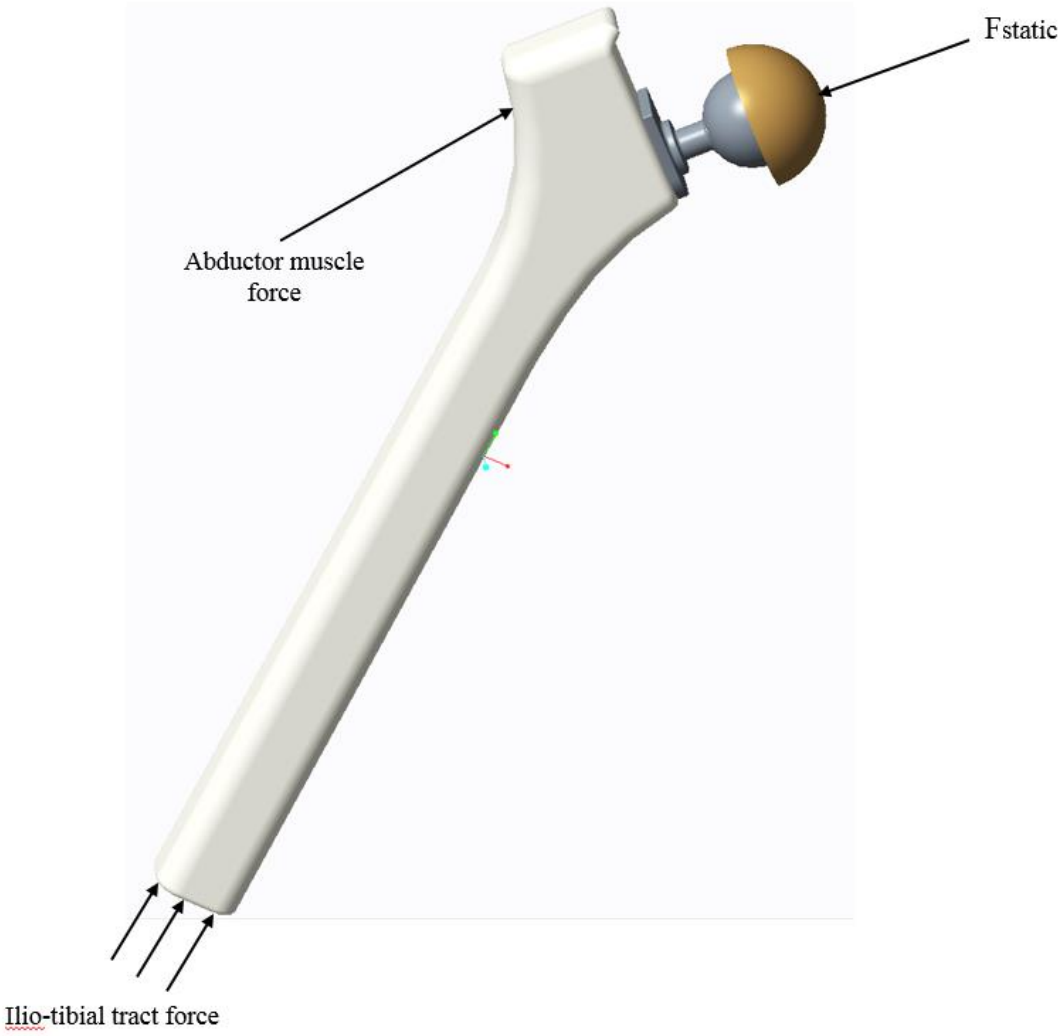


Figure 6-7: Representation of the applied loads for static loading conditions

6.4 Material properties for the components

The different materials used for femoral head remains the critical factor in validating the conceptual design proposed earlier in the project. As a result, the objective of the Finite Element Analysis is to compare and analyse the simulation results obtained using the different types of materials identified in the material selection.

Table 16: Material properties considered for FEA

Material	***Ultimate Tensile strength (Mpa)***	***Young's modulus (Gpa)***	***Density (g/cm^3)***	***Poisson's ratio***
Material A – Unfilled Polyetheretherketone (PEEK)	95	4.0	1.32	0.4
Alumina (Al_2O_3)	480	290	3.42	0.22
Ultra High Molecular Weight Polyethylene (UHMW-PE)	49	0.8	0.94	0.46
Stainless steel (316L)	950	210	8	0.30
Titanium (Ti-6A1-4V)	960	110	4.43	0.32
Co-Cr alloy (ASTM F138)	655	230	8.3	0.30
Carbon-fibre-reinforced polyetheretherketone (CFR-PEEK)	230	24	1.51	0.39
Cortical Bone	150.3	10.3	2.0	0.2

6.5 Mesh generation for hip implant model

The selection of appropriate mesh type for the implant model remained one of the most complex sections of the Finite Element Analysis. In order to mesh the implant model, a constant mesh density was used over the entire model using an automated meshing algorithm. For the purpose of this analysis, tetrahedral elements were used to mesh the solid volumes of the implant model. To ensure the accuracy of results, tetrahedral meshing is highly recommended for the use of complex 3D objects as they allow easy imposition of boundary and interface conditions and have low aspect ratios for the smallest and largest angles.

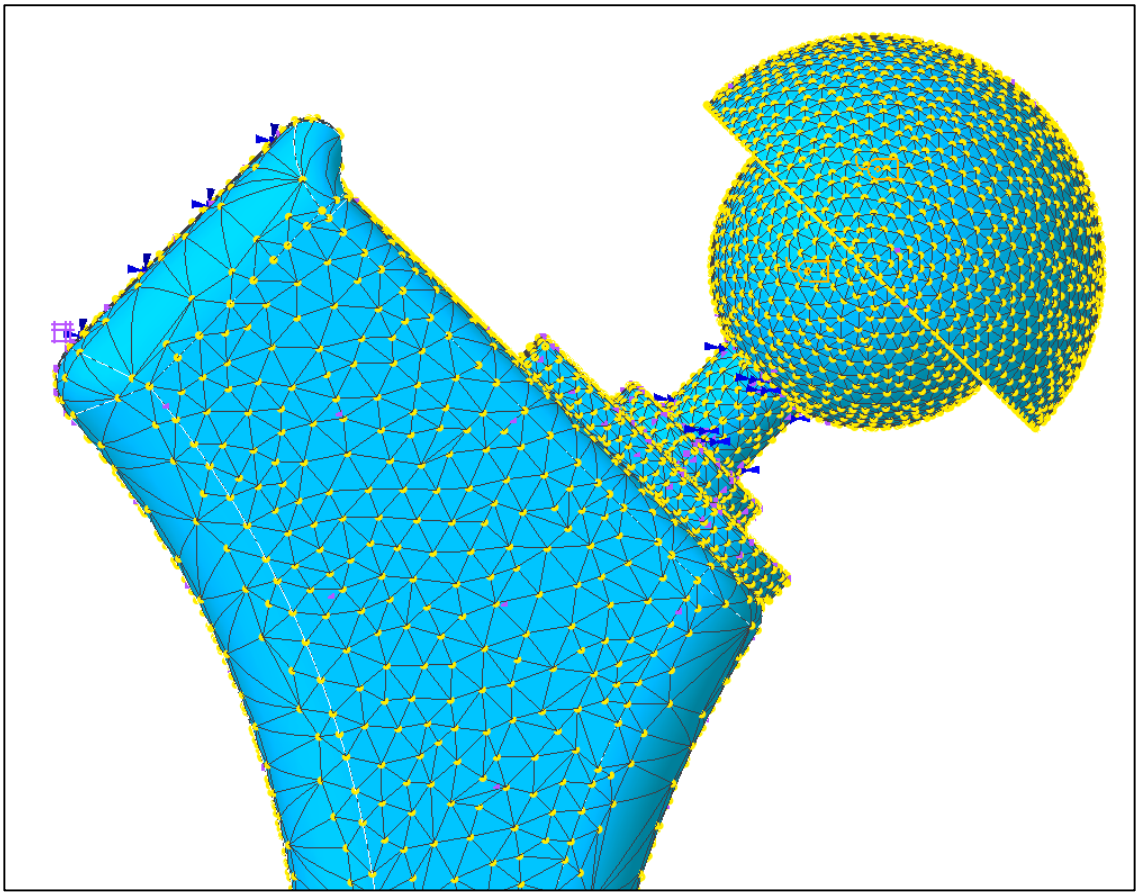


Figure 6-8: Mesh generation for implant model

The stress and strain distribution along the femoral head and acetabular remains the main focus of this analysis. In this analysis, a mesh size of 3mm was used along the bone and femoral stem whereas a 1.5mm size was used to mesh the femoral head and acetabular cup. A total of 56639 elements and 13046 nodes were created. One of the disadvantages in using the tetrahedral mesh was the possibility of creating too many tetrahedra resulting in excessive computational load. As a result, the model was designed with simple geometry to ensure the accuracy of the results.

6.6 Model Analysis

After identifying the boundary conditions and applying the suitable loading conditions, the following process is to determine the required measurements from the Finite Element Analysis. Since the analysis will be conducted based on static loading, it is necessary to obtain the stress distribution, strain distribution and the maximum displacement of the model. In order to understand the distribution of stress and strain along the femoral head, a standard number of nodes were placed on the upper surface femoral head.

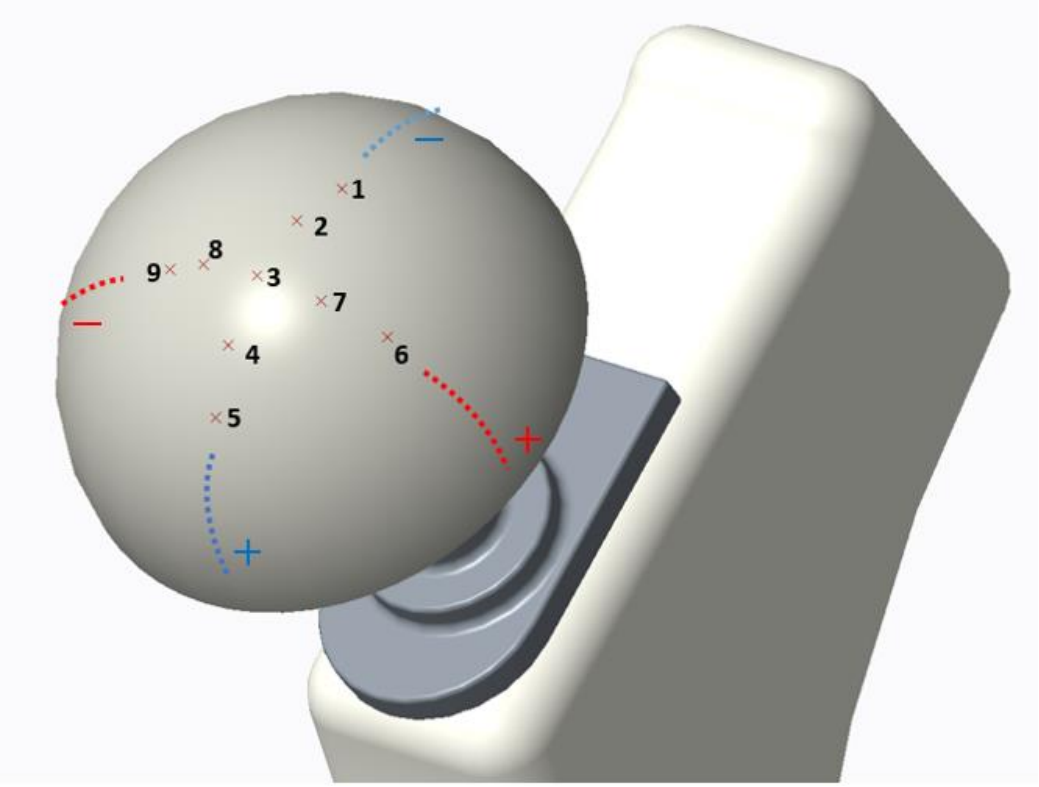


Figure 6-9: Location of nodes on the femoral head surface

The figure above demonstrates the location of nodes across the femoral head surface. These nodes are used to obtain the value of maximum principal stress and strain each individual node. The red dotted line represents the anteversion axis in the positive and negative direction. Correspondingly, the blue dotted line represents the inclination axis in the positive and negative direction. After performing FEA, the values obtained for stress and strain in the different axis will be compared to each type of material to validate the use of CFR-PEEK as an alternative material for the femoral head surface.

6.7 Finite Element Analysis Results

The following section includes the results obtained from Finite Element Analysis conducted to analyse the behaviour different femoral surface materials under static loading conditions. The maximum von mises stress, maximum principal strain and displacement for each type of material are tabulated below:

Table 17: Finite Element Analysis results

Femoral head material	Maximum Von Mises Stress (MPa)	Maximum Principal Strain	Displacement (mm)
Polyetheretherketone (PEEK)	98.9	$2.135e^{-03}$	0.0231
Alumina (Al2O3)	119.8	$1.088e^{-03}$	0.01314
Ultra High Molecular Weight Polyethylene (UHMW-PE)	217.9	$8.55e^{-03}$	0.054
Stainless steel (316L)	118.03	$1.088e^{-03}$	0.0133
Titanium (Ti-6A1-4V)	116.4	$1.114e^{-03}$	0.0143
Co-Cr alloy (ASTM F138)	113.1	$8.58e^{-04}$	0.0132
Stainless steel (316L) + CFR-PEEK	125.1	$8.45e^{-03}$	0.0133

One of the most debated topics in using Finite Element Analysis is to determine the validity of the design using Von Mises stress or the Maximum Principal Stress. The maximum principal stress fundamentally takes into account the stresses which are normal to the planes where there is no shear stress acting in the plane. These stresses are combined to produce a maximum or minimum stress to evaluate the material behaviour under fatigue or fracture based loading. The Von Mises stress essentially uses the principal stresses to calculate an equivalent tensile stress which can be compared to the allowable tension for the material. However, the maximum Von Mises stresses presented for each material in Table 20 would not give an accurate indication of the stress distribution along the femoral head surface. Therefore, maximum principal stress will be used to obtain the stress distribution plot by measuring the required values at individual nodes represented in figure 6-9.

In order to understand the behaviour of each material under static loading conditions, an effective solution is to plot the stress and strain distribution along the femoral head surface of the implant model. To achieve this, nodes were used to obtain the value of maximum principal stress and strain each individual node.

Table 18: Maximum principal stress at each node (Pa)

	PEEK	Alumina	UHMWPE	SS(316L)	Titanium	Co-Cr	CFR-PEEK + SS
Node 1	3568.6	2363.52	5168.58	847.9	1450.9	797.2	1580.6
Node 2	4639.52	2685.55	5907.9	1069.66	1890.6	973.63	2080.8
Node 3	4957.2	2769.95	6132.7	1128.8	1991.83	1023.61	2193.84
Node 4	4635.74	2692.135	5890.75	1069.87	1880.47	974.54	2080.7
Node 5	3570.93	2368.485	5163.39	846.69	1457.58	798.59	1589.8
Node 6	3587.86	2360.38	5200.63	862.981	1454.02	791.521	1584.22
Node 7	4623.4	2676.05	5882.66	1084.14	1893.33	984.5	2082.8
Node 8	4630.2	2679.48	5874.49	1083.74	1893.33	984.3	2082.6
Node 9	3572.36	2363.27	5149.33	862.15	1456.32	791.3	1589.7

Table 19: Maximum principal strain at each node

	PEEK	Alumina	UHMWPE	SS(316L)	Titanium	Co-Cr	CFR-PEEK + SS
Node 1	4.22E-04	1.38E-05	1.69E-03	1.60E-05	2.67E-05	1.48E-05	1.45E-05
Node 2	4.88E-04	1.30E-05	1.53E-03	1.54E-05	2.70E-05	1.42E-05	9.60E-06
Node 3	5.01E-04	1.27E-05	1.49E-03	1.51E-05	2.71E-05	1.40E-05	7.84E-06
Node 4	4.92E-04	1.30E-05	1.60E-03	1.54E-05	2.71E-05	4.24E-05	9.50E-06
Node 5	4.23E-04	1.39E-05	1.60E-03	1.60E-05	2.67E-05	4.89E-05	1.46E-05
Node 6	4.19E-04	3.97E-05	1.72E-03	1.60E-05	2.67E-05	1.50E-05	1.47E-05
Node 7	4.87E-04	1.30E-05	1.55E-03	1.54E-05	2.71E-05	1.42E-05	6.00E-06
Node 8	4.85E-04	1.30E-05	1.50E-03	1.54E-05	2.71E-05	1.43E-05	9.50E-06
Node 9	4.25E-04	1.40E-05	1.68E-03	1.60E-05	2.67E-05	1.50E-05	1.45E-05

The data obtained for the maximum principal stress at each node can be further used to obtain a comparison of the stress distribution along the femoral head surface within the ante version and inclination axis. As a result, the following graphs were created to visualise and compare the different stress distributions for each material.

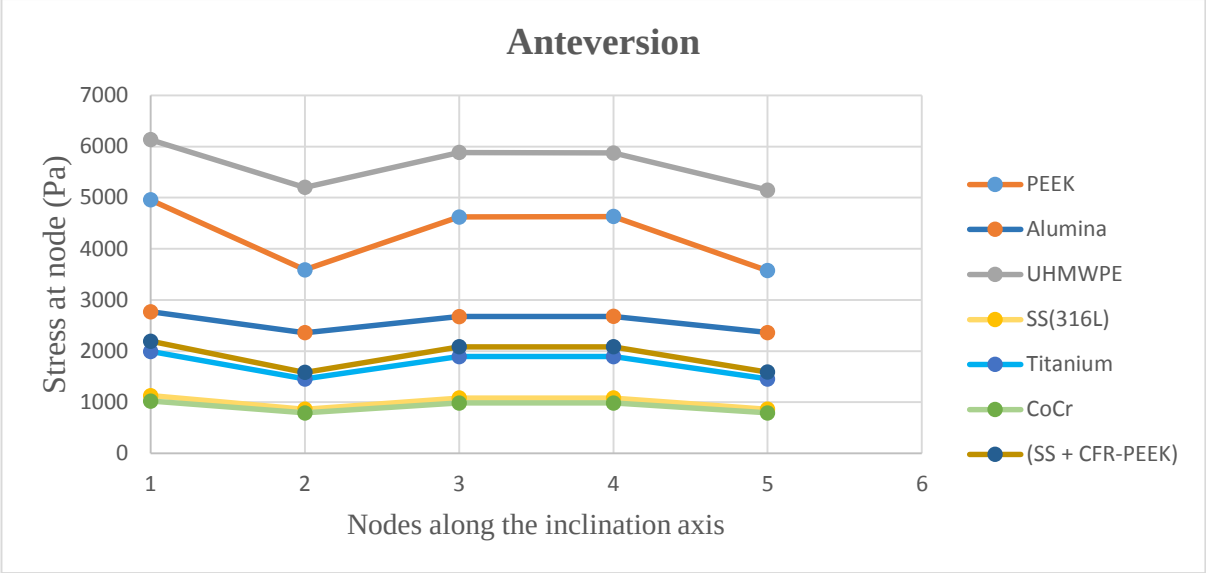


Figure 6-10: Maximum principal stress along the Anteversion axis

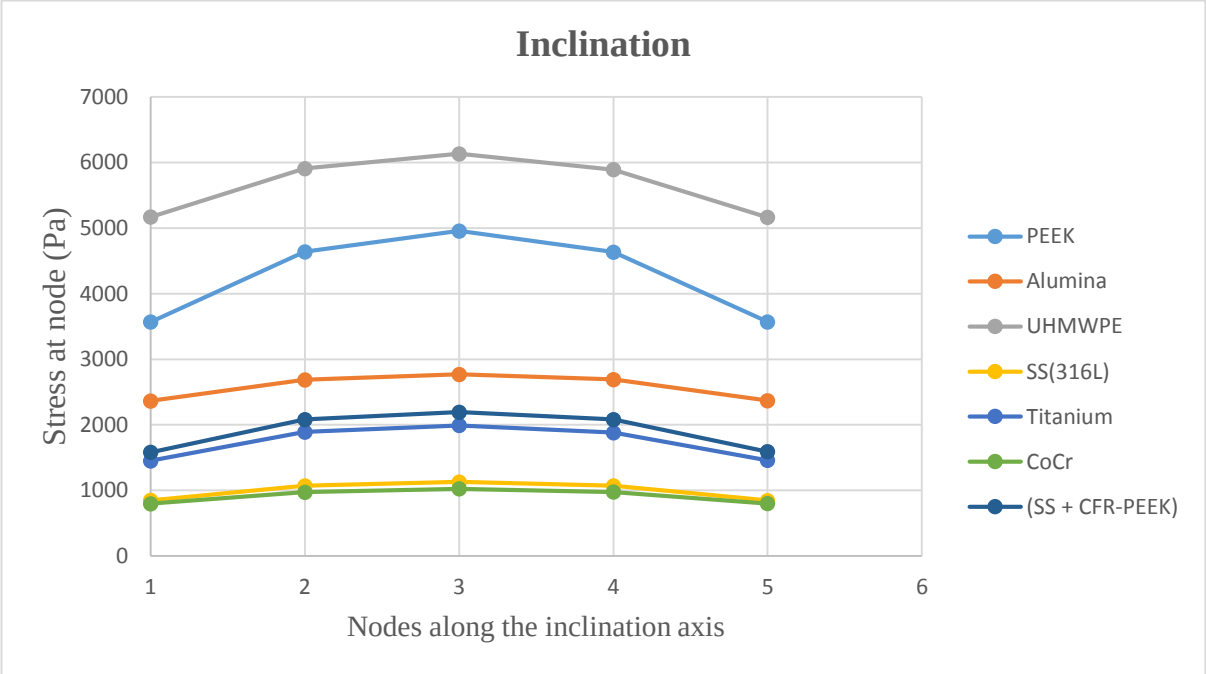


Figure 6-11: Maximum principal stress along the inclination axis

The nodes created on the femoral head surface were also used to determine the maximum principal strain at each individual node along the anteversion and inclination in order to obtain a strain distribution plot for each material.

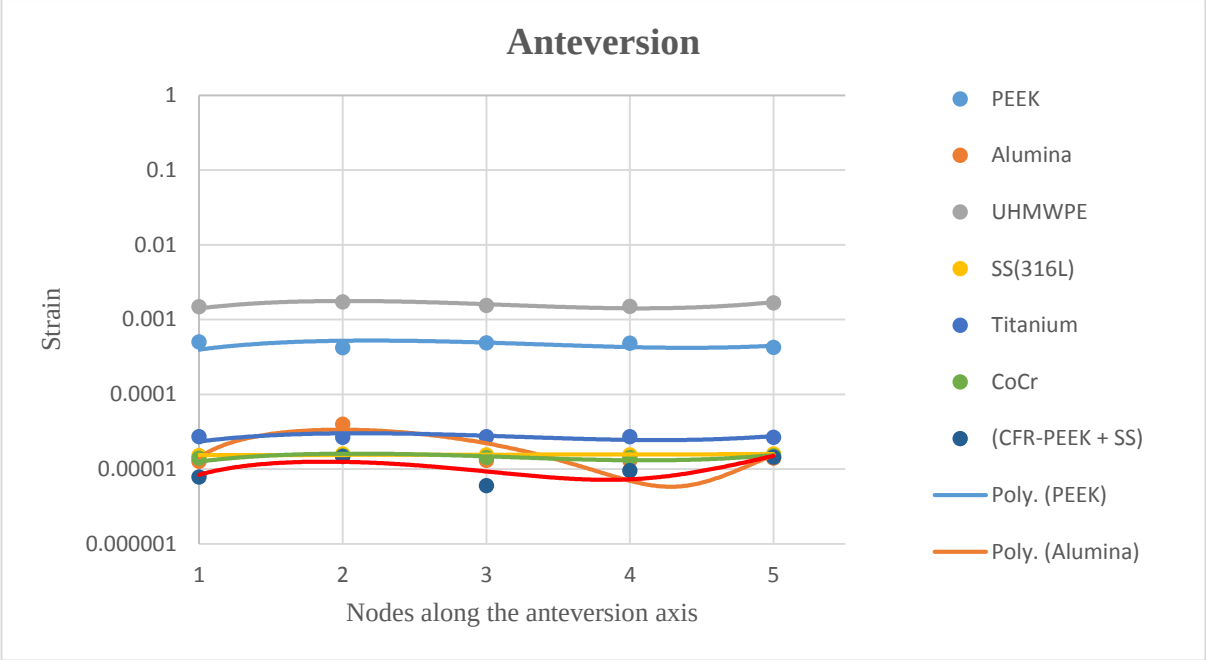


Figure 6-12: Strain distribution along the Anteversion axis

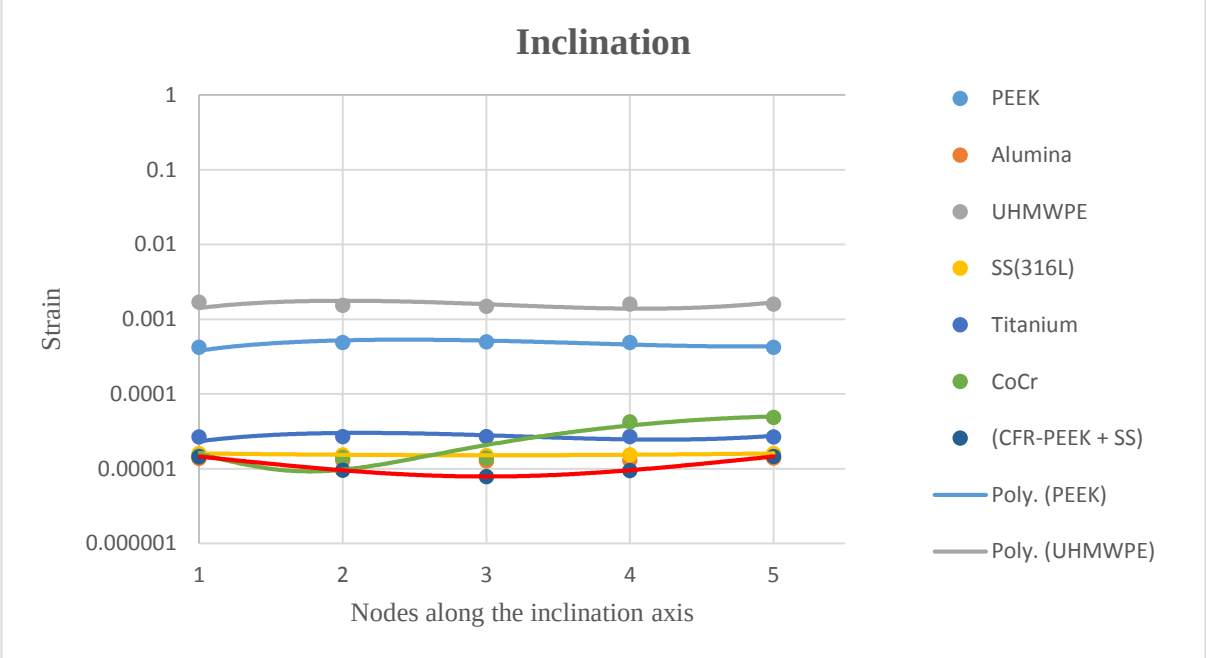


Figure 6-13: Strain distribution along the Inclination axis

6.8 Discussion

The maximum stress, strain and displacement plots obtained for each material through Finite Element Analysis are presented in Appendix C. The results obtained for the conceptual design are presented below to provide an indication of the stress and strain distribution along the hip implant model.

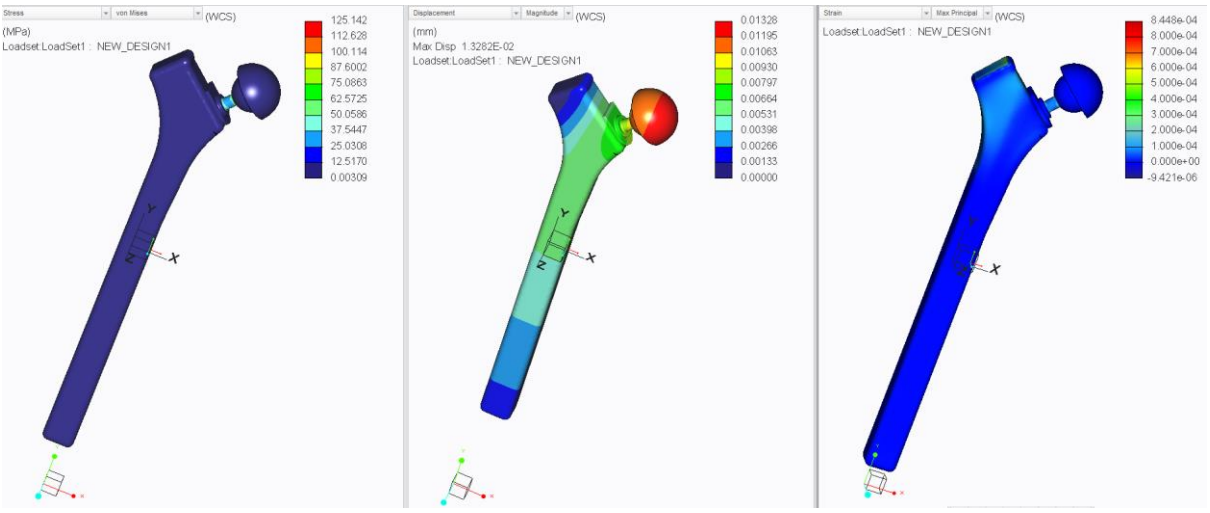


Figure 6-14: FEA results for conceptual design (CFR-PEEK + Stainless steel)

It can be seen from the image above that the maximum stress and strain distributions for the implant model occur around the taper joint of the implant. This is due to the concentration of stress around the taper joint during the static loading and the constraints applied on the implant model. The results presented in Table 20 indicate that the use of CFR-PEEK reinforced femoral head provides relatively similar stress and strain distribution compared to the other material combinations. However, these results would not provide accurate evidence to validate the design methods and materials used. As a result, the stress and strain distribution plots developed using the individual nodes would be more suitable to identify and analyse the behaviour of different materials under the applied loading conditions.

The results obtained through Finite Element Analysis, model limitations will be further discussed in Chapter 8 to validate the use of CFR-PEEK as an additional material for the femoral head of the hip implant.

Chapter -7 Abrasive wear testing

7.1 Overview

The following chapter includes the methodology, testing procedure and results obtained from the abrasive wear testing. The previous section of this project involved performing Finite Element Analysis to compare and analyse the behaviour of CFR-PEEK as an alternative material for the femoral head of a hip implant. Although the results obtained through FEA provide a comparative analysis for the different materials under static loading conditions, the analysis did not include the material wear rate due to time constraints and complexity. As a result, abrasive wear testing on different material specimens will be performed through standard testing methods to obtain a comparative analysis of the wear rate among different types of materials.

7.2 Abrasive wear mechanism

Abrasive wear is a result of a harder material being rubbed against a softer material. This type of wear is relatively difficult to control or prevent due to the different types of wear mechanisms involved. The literature suggests that there two basic modes of wear:

- **Two-body wear** – Occurs when a relatively harder surface cuts away the material from the softer surface.
- **Three-body wear** – Occurs when the wear debris from two body wear act as abrasive particles between the two surfaces.

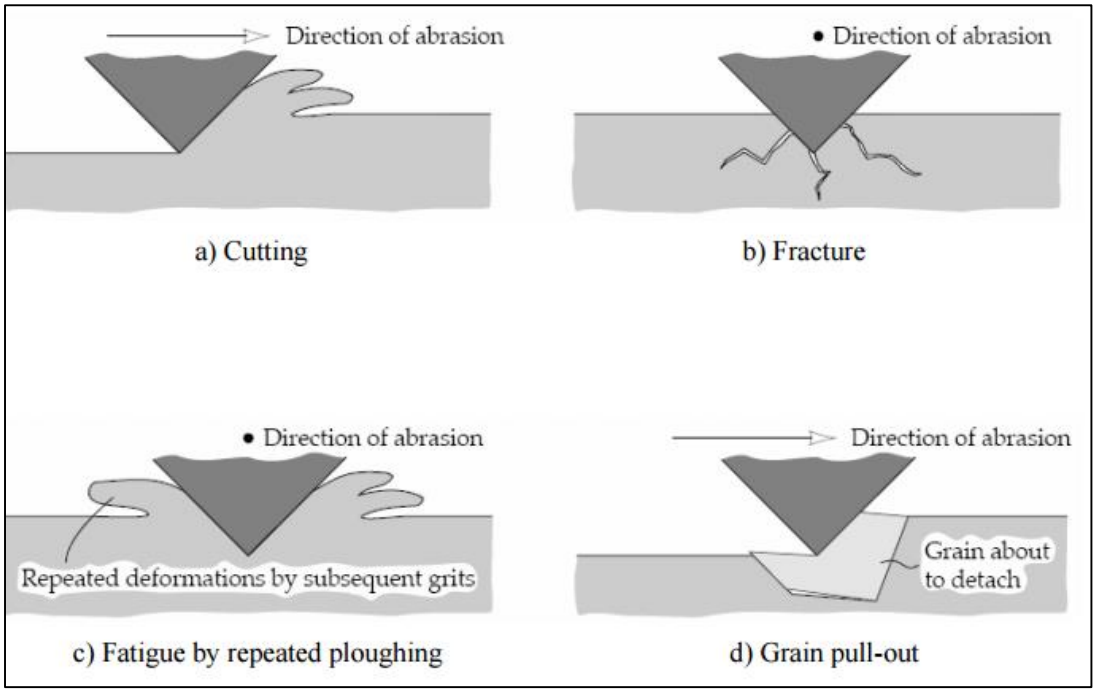


Figure 7-1: Mechanisms of abrasive wear: micro-cutting, fracture, fatigue and grain pull-out (AAOS 2001)

The figure above demonstrates the most common mechanisms of abrasive wear which involve wear due to ploughing, cutting, fracture and the grain detachment. During the process of abrasion, the micro roughened regions on the harder surface to locally plough through the softer surface. As a result, abrasive wear is occurred when material is removed from the softer surface due to the track traced by the asperity during the motion of the harder surface (AAOS 2001).

7.3 Abrasive wear in orthopaedic implants

Upon the insertion of hip implant into the patient's body, wear can occur in different modes depending on the joint articulation, function of prosthesis materials, design and implantation parameters. As a result, it is important to identify and understand the relevant parameters which contribute to the wear occurring in the hip implant.

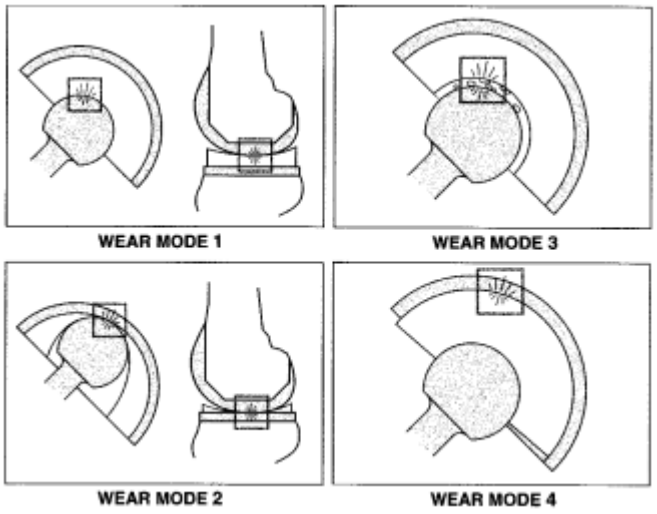


Figure 7-2: Modes of wear in orthopaedic joints (AAOS 2001)

The figure above illustrates the various types of modes abrasive wear which could occur between the implant components. Mode 1 represents the abrasive wear caused between the indented bearing surfaces such as the femoral head and the acetabular cup. Mode 2 demonstrates the wear between the femoral head surface and an unintentional surface such a worn polyethylene acetabular liner. The wear generated through mode 3 is a resultant of abrasion between bearing surfaces in the presence of third body components such as cement debris, metallic debris and bone particles (AAOS 2001). Mode 4 demonstrates the wear generated due to articulation between two unintentional surfaces. The main focus for this section is to understand the abrasive wear caused between the femoral head and the acetabular cup components. As a result, it is important to perform a suitable testing using standard methods and procedures.

7.4 Testing approach

The testing method to be used for this project is the conventional abrasive sanding. This method is generally performed using a variety of sanding devices such as random orbital, belt, planar and disc sanders. The random orbital sander is commonly used in the industry due its multidirectional abrasion pattern which can be related to many applications. In principle, a random orbital sander is a hand-held sander which vibrates in small circles or orbits. It is generally used for surface smoothing by using abrasive sand papers of various grit sizes and composition depending on the testing requirements.

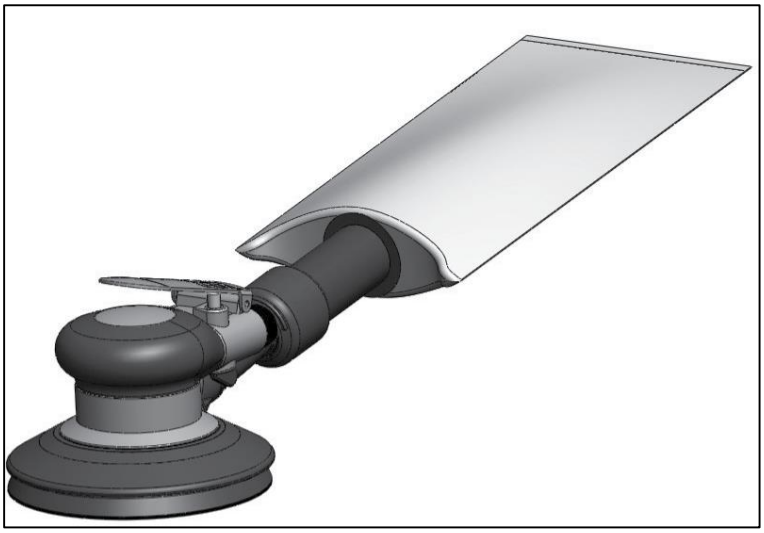


Figure 7-3: Random orbital sander (Liverseed 2012)

The image above represents a conventional random orbital sander. A self-generated vacuum is usually included to collect the abraded particles emitted into the air in concern of health and safety. One of the main advantages of using this type of sanders is their high abrasion capacity due to the overlapping of the rotation and grinding, resulting in high quality track free surfaces. Therefore, a standard random orbital sander will be used for the purpose of this testing in order to obtain the wear rates of different types of materials used for designing hip implant. The main objective of conducting this testing is to obtain the wear rates of various materials suitable for hip implants. Based on the desirability of data, the results obtained will be further used to validate the use of CFR-PEEK as an alternative material for the femoral head surface.

7.5 Testing Apparatus

7.5.1 **Materials used**

Due to the time constraints and limited budget of the project, only certain materials were used to conduct the abrasive wear testing. The material grade and dimensions of the purchased components are detailed below:

Table 20: Material properties and dimensions

Material	Grade	Dimensions (mm)
UHMWPE	Polystone 7000 UHMWPE	115 × 115 × 10
Stainless Steel	316L	115 × 115 × 10
Alumina	96% purity Aluminum Oxide	137 × 137 × 3

	(Al2O3)	
CFR-PEEK	30% pitch carbon fibre	178 × 178 × 12

7.5.2 **Random orbital sander model**

For the purpose of this project, the '480W Black and Decker' random orbital sander was chosen to be used to perform the abrasive testing. The specifications of the sander model include:

Table 21: Black and Decker random orbital sander model specifications

Power	480 Watt
No load speed	4000-12000/min
Orbit diameter	5mm
Paper size	125mm
Speed settings	Variable

7.5.3 **Additional testing equipment**

The additional equipment required to perform the testing include:

- Digital electronic scale to measure the mass of specimens at regular intervals.
- Wooden block to provide a base for the material specimen.
- M10 bols to hold the material specimen in fixed position.
- Size 80 grit sand papers.
- Protective eye wear, noise-cancelling headphones, disposable respirators.

Please refer to appendix D for testing equipment, material specimens and sand grit.

7.6 Testing Procedure

The procedure used to perform the abrasive testing using orbital sander involves the following steps:

Step 1 - Establish a stationary workplace.

Step 2 – Ensure the material specimen is fixed above the wooden block using bolts.

Step 3 – Attach an unused sand paper to the orbital sander.

Step 4 - Initiate the orbital sander.

Step 5 - Stop the orbital sander after a period of 20 minutes.

Step 6 – Replace the material specimen with a different material.

Step 7 – Repeat steps 2 to 5 for each material specimen.

Step 8 – Measure the difference in mass for each material specimen.

Step 9 – Repeat the testing for each material specimen for four days.

The following testing was conducted at personal workplace due to time constraints within the project. However, the testing was performed with the required health and safety procedures by using the required safety equipment.

7.7 Abrasive wear test results

The following table represents the results obtained from the abrasive wear testing. The testing was conducted at constant time period of 20 minutes for a total of 80 minutes to measure the difference in the mass for each material specimen.

Table 22: Abrasive Testing Results

Mass (grams)	Stainless steel	UHMWPE	Alumina	CFR-PEEK
Initial mass	687.4	77.93	48.47	563.43
After 20 mins	685.7	74.19	48.47	561.72
After 40 mins	681.3	72.74	48.46	560.24
After 60 mins	677.1	71.9	48.45	559.83
After 80 mins	671.7	71.3	48.44	559.31

In order to compare the results obtained for each material specimen, it is important to develop a cumulative difference in mass for each specimen over the time period of testing. The results obtained will be further discussed in Chapter 8 to validate the testing method.

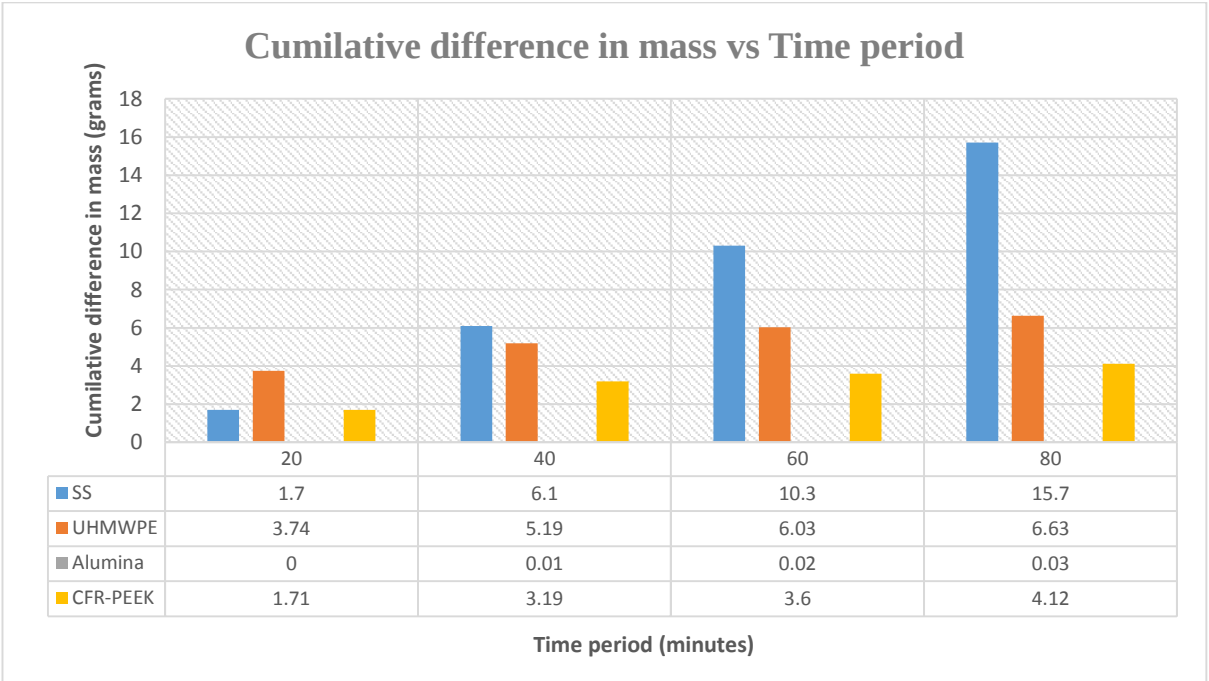


Figure 7-4: Cumulative distribution of mass for each material specimen

Chapter -8 Validation of FEA and Testing results

8.1 Validation of Finite Element Analysis Results

The first method of testing for this project was performed through Finite Element Analysis of a standard hip implant model. The conceptual design for the project suggested the use of stainless steel with an additional layer of CFR-PEEK to potentially improve the quality of life and longevity of hip implants. As a result, Finite Element Analysis was used to validate the practicability of the conceptual design.

The results obtained through FEA are presented in Section 6.5, which include the stress, strain and distribution of the implant model under static loading conditions with different materials for the femoral head surface. The results presented in Table 20 indicate that the maximum Von Mises stress, strain and displacement for the conceptual design are relatively similar to the results obtained for other material combinations such as Titanium, Stainless Steel and Cobalt-Chromium. Although unfilled PEEK, Alumina and UHMWPE femoral heads demonstrated considerably higher stress and strain, this can be expected to their relatively low mechanical properties compared to metals. However, it is important to note the similarity between the results for the conceptual design and metal femoral heads provides a positive indication of the strength and durability of the new design.

Furthermore, the stress and strain distribution graphs presented in Section 6.5 were developed to compare the results between the identified materials. The stress distribution graph presented in figure 6-10 suggests that the conceptual design demonstrated comparatively reasonable data along with metal femoral heads. Although the stress distribution along the femoral head for the conceptual design exhibit slightly higher values when compared to metals, it can still be expected to a positive results due to its considerably lower stress distribution when compared to Alumina and unfilled PEEK. In addition, the strain distribution graph presented in figure 6-12 can also be used to validate the conceptual design. Similar to the stress distribution, the conceptual design demonstrated a relatively reasonable strain values along the femoral surface. This indicates the ability of CFR-PEEK to provide high mechanical properties due to the additional support provided from the Stainless Steel.

The overall results obtained from the Finite Element Analysis suggest that the conceptual design demonstrates the potential to be provide an effective solution for designing hip implants. The main objective of conducting a static analysis of the implant model was to validate the use of the CFR-PEEK as an additional material and ensure the strength and durability of the implant design. It is important to note that performing dynamic simulation or actual prototype testing would have perhaps provided more accurate results. As a result, the next section will provide a detailed insight into the underlying effects of the model limitations and assumptions considered to develop the Finite Element Analysis.

8.2 FEA model limitations

There are a number of significant limitations in conducting Finite Element Analysis on hip implant models. The following section provides a brief analysis of the limitations considered as part of the analysis and their underlying effects on the accuracy of the simulation results.

Initially, one of the most important aspects that can questionable in performing a Finite Element Analysis on hip implant is the ability to accurately simulate real physiological loading conditions. The dynamic loads applied on the implant vary depending on the patient's motion, muscle activity, host bone quality and the implant size. In addition, the forces applied on the acetabular component of the implant would not transmit uniformly through the femoral head due to the movement of the head within the socket. Therefore, applying dynamic loading would generally provide accurate results for the stress acting on the implant. However, due to the limited available resources and time constraints, the Finite Element Analysis for this project was conducted based on static loading conditions. The loading conditions were obtained through determining the forces applied on the human hip in the case of standing assuming the body to be a rigid structure.

Secondly, all the materials used to develop the model for Finite Element Analysis were assumed to contain linear isotropic mechanical properties. Although this assumption significantly simplified the model analysis, it is important to consider the behaviour of bone under loading conditions due to nonlinearity, anisotropy and viscoelasticity. However, a recent study conducted on the comparison of Finite Element Analysis and synthetic femurs suggested that linear behaviour is a good

approximation of the femurs in axial compression and torsion (Bougherara et al. 2010).

Thirdly, the results for stress and strain distribution along the femoral head were obtained through applying static loadings on the implant model. This restricted the model from providing any indication of the volumetric wear between the acetabular cup and the femoral head surface. As a result, abrasive wear testing was performed on different materials using conventional methods in order to further validate the use of Finite Element Analysis. The validity of the testing and limitations will be discussed in the following section.

8.3 Validation of Abrasive wear testing results

The main goal in performing the abrasive wear testing was to validate the use of an additional layer of CFR-PEEK for the femoral head surface to potentially minimize the wear between the femoral head and acetabular cup. The results presented in Table 25 demonstrate a significant difference between the wear rates for each material. By developing a cumulative difference in the material specimen's mass, presented in Figure 7-4, it was observed that the Stainless Steel demonstrated the highest wear rates among all the materials. Based on the literature review performed earlier in the project, the high wear rate of the stainless steel can be expected due to its poor resistance to abrasion due to the contact between softer materials such as polyethylene or ceramics. The Alumina oxide revealed the lowest wear rate among all the materials demonstrating its ability to resist wear. The CFR-PEEK sheet provided marginally lower wear rates compared to UHMWPE and demonstrated a decrease in wear range with the progress of testing time.

8.4 Limitation of Abrasive wear testing

Although the abrasive wear testing provided optimistic results, there a number of limitations that effect the accuracy and reliability of the testing methods. The main objective of the abrasive wear testing was to obtain a comparative analysis of the wear rate for CFR-PEEK relative to other orthopaedic materials. Due to the time constraints and the lack of resources to develop a real prototype, the testing was conducted with the use of solid sheets. This would affect the accuracy of the results as it would not demonstrate a similar wear conditions which occur between the femoral head and acetabular surface One of the key limitations of this testing was the

difference in the material grade and surface finish of the material specimens. The materials used for medical devices such as hip implants generally exhibit a very high material grade and surface finish. Abrasive wear characteristics are a result of the material properties such as wettability, surface finish and the operating conditions such as lubrication. It is safe to assume that abrasive wear from the random orbital sander would not accurately simulate the wear analysis within a hip implant due to the presence of other wear mechanisms, blood and difference in contact stresses.

Chapter -9 Conclusion and Further Work

The long term durability and quality of life remain still remains one of the main challenges associated with artificial hip implants. The ultimate goal for the project was to propose a validated implant design for hip implants to potentially improve the quality of life. The results obtained from Finite Element Analysis suggested that the additional layer of carbon fibre reinforced polyetherketone (CFR-PEEK) on stainless steel femoral head offers desirable strength and durability in comparison with metal femoral head surfaces. In addition, abrasive wear testing was conducted to validate the use of the CFR-PEEK as a potential femoral layer. While the wear rate for Alumina demonstrated the most desirable results, carbon fibre reinforced polyetherketone (CFR-PEEK) is still applicable due to its relatively low wear rates compared to polyethylene or metal alloys. The low wear rates of CFR-PEEK and Alumina create the ideal combination for the acetabular cup and femoral head surface.

The process of improving a hip implant design should be aimed at optimising the use of most suitable material to increase the quality of life upon the insertion of the implant. The main advantage of improving the implant lifespan is to potentially decrease the number of revisions surgeries performed annually and offer customer satisfaction through safer and durable design.

Having performed this biomechanical study, it safe to assume that further research needs to be conducted to increase the accuracy and reliability of the model. Although the results obtained from testing provided desirable results, the methods used for Finite Element Analysis and abrasive methods were fairly rigorous and inaccurate compared to real life analysis. To further validate this model, a dynamic loading simulation or real prototype testing is highly recommended.

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Appendices

Appendix A

ENG4111/4112 Research Project

PROJECT SPECIFICATION

FOR: Swapan Sadanala

TOPIC: A Case Study in Failure Analysis and Materials Selection

SUPERVISORS: Steven Goh

ENROLMENT: ENG 4111 – S1, ONC, 2015

ENG 4112 – S2, ONC, 2015

SPONSORSHIP: Own project

PROJECT AIM: This project seeks to investigate the failure of orthopaedic hip prosthesis and the possibility of using fibre reinforced polymer composites as an alternate material based on the performance requirements.

PROGRAMME:

1. Provide an analysis of the potential causes of failure based on an extensive review of literature.
2. Research into the materials used for designing the hip implant and provide and provide an alternate material based on appropriate materials selection method.
3. Perform an investigation to study the mechanical performance of fibre-reinforced composite hip prosthesis.
4. Develop and verify three-dimensional finite element analysis to analyse the behaviour of composite implant in the femur.

Obtain the potential long-term results of using fibre-composite hip prosthesis.

Appendix B

A risk assessment for the project is necessary to identify all the potential risks and hazards associated with the project. The aim of the following section of the project is to develop an adequate risk assessment by using a standard method and quality control. One of the most important aspects of developing a standard risk assessment is to ensure the identification of all the risks and hazards during the execution of the project and beyond the completion of the project. Henceforward, the following risk assessment is to be developed with the consideration of the potential risks, hazards and the consequential effects due to the project.

Step 1 – Identify the hazards

Table 23: Identification of existing/possible hazards

No.	Identify the hazard	What could cause harm?
1	Physical effects	• Physical fatigue and tiredness caused from sitting for long periods of time. • Possible stiffness and back pain due to sitting for extended period of time with less blood circulation to muscles, bones and ligaments. • Visual impairment resulting in possible asthenopia, simple eye strain and red eyes. • Minor injury to muscles and tendons to constant repetitive movements and awkward postures.
2	Physiological effect	• Continuous mental stress due to project deadlines, imbalance between resources and demands. • Possible hypertension causing high blood pressure levels due to high stress.
3	Energy systems	• Potential threat of electric shock as result of overloading electrical circuits. • Possible physical harm such as tripping, falling due to the extension cords required in using computers.
4	Ergonomics	• Physical harm such as back pain caused due to the restricted workspace and an inadequate workstation.
5	Biological	• Upon the completion of project, the possibility of blood/bodily fluid toxicity in the patient's body upon the insertion of the hip implant in the event of a failed implant.

Step 2 – Identifying the risk

Once all the potential hazards within the project have been identified, it is important to identify the risks involved with the mentioned hazards and the likelihood of the harm occurring. In order to achieve this, a risk assessment matrix is required to be developed to assess the different levels of risk associated with the individual hazards.

Table 24: The likelihood of risk vs level consequences

LIKELIHOOD	CONSEQUENCES				
	Insignificant	**Minor**	**Moderate**	**Major**	**Critical**
Almost certain	Extreme	Extreme	Medium	Medium	Low
Likely	Extreme	Medium	Medium	Low	Low
Possible	Medium	Medium	Low	Low	High
Unlikely	Medium	Low	Low	High	High
Rare	Low	Low	High	High	High

Consequence	**Description of Consequence**
Insignificant	*No treatment required*
Minor	*Requires first aid treatment (minor cuts, burns or scratches)*
Moderate	*Requires medical treatment or possible lost time*
Major	*Extensive injuries requiring hospitalisation*
Critical	*Loss of life or permanent damage*

Likelihood	**Description of likelihood**
Almost certain	*High probability of occurring in most circumstances*
Likely	*Likely to occur within the duration of the project*
Possible	*Could possibly occur at some point*
Unlikely	*Not likely to occur within the project lifecycle*
Rare	*Occur in exceptional circumstances*

Assessed Risk Level	**Description of Risk Level**	**Control measures/ actions**
Low	In the event of an incident, highly unlikely that an injury would result.	Manage through routine procedures.
Medium	In the event of an incident, possible chances of injury to occur.	Specific monitoring or procedures required, management responsibility must be specified.
High	In the event of an incident, high probability that an injury would result.	Action plan required, ensure control measures are assessed before the activity

		is performed.
Extreme	In the event of an incident, almost certain of a permanent, debilitating injuring or death.	Requires immediate action, significant control measure to ensure health and safety.

Step 3 – Designate the risk level for identified hazards

After developing the risk assessment matrix, the following step is to rate the level of risk for the hazards identified in step 1 in order to achieve a standard risk assessment.

Table 25: Rate of risk level associated for identified hazards

No.	Assessed hazard	Risk level
1	Physical effects	Low – Medium
2	Physiological effect	Medium
3	Energy systems	Low
4	Ergonomics	Medium
5	Biological	Medium

It can be seen from the table above that the risks associated with the hazards involved are relatively low, ensuring a standard level of safety for the =duration of this project. However, it is important to ensure that the risk assessment is followed throughout the project along with the standard control measures and procedures.

9.1 Resource Requirements

The resources that will be required to complete this project include:

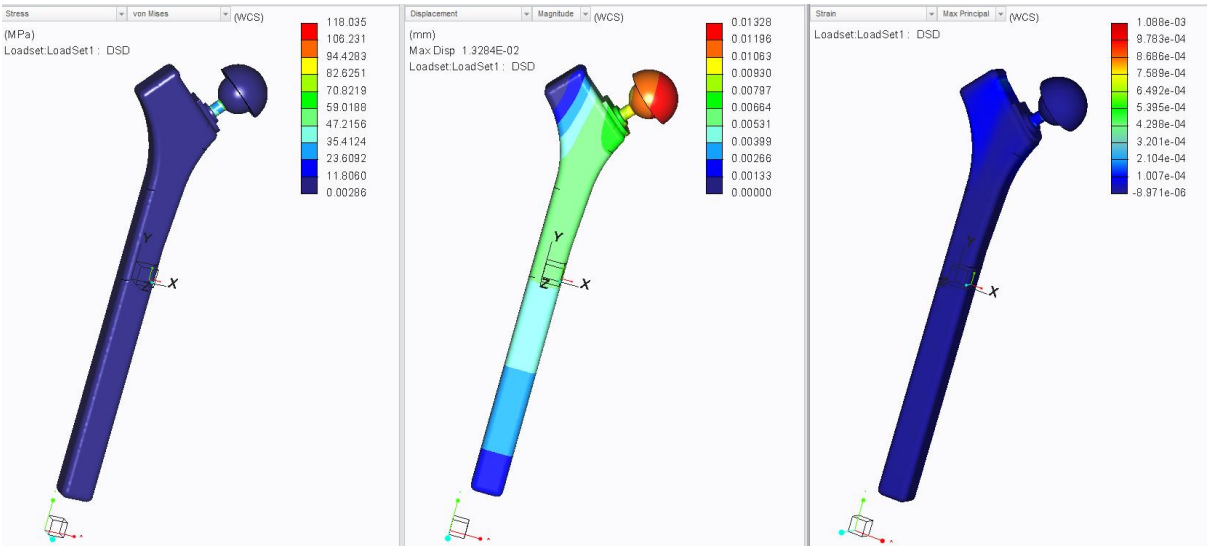
- Access to the internet, journals, articles, websites and newspaper to collect theoretical information and perform literature review.
- A standard computer capable of performing simulations and providing data.
- License and software implements.
- Access to Z-block computer laboratories during the day to perform the simulations.

The most important facility required to successfully complete the following project would be the use of computers for performing the Finite Element Analysis in order to validate the results achieved for the project. In event of computer malfunction or unavailability, it would present a critical situation due to the lack of access to the required software. However, the availability of the computers is assured through the

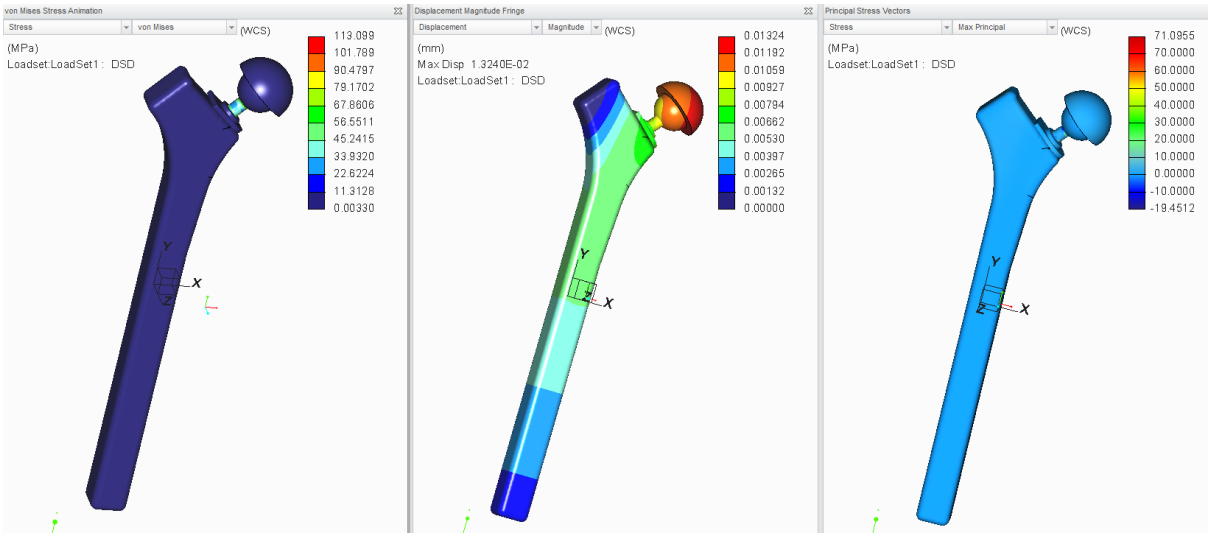
access for Z-block laboratory and after hour permission to ensure that the resources are available for the maximum amount of time. Furthermore, there are no direct budgets involved in the project as the requirement for manual testing is considered to be not required for the purpose of the project. However, it would be appropriate to consider the manufacturing costs that are potentially involved in designing the hip implants with carbon fibre reinforced polymer composites.

Appendix – C

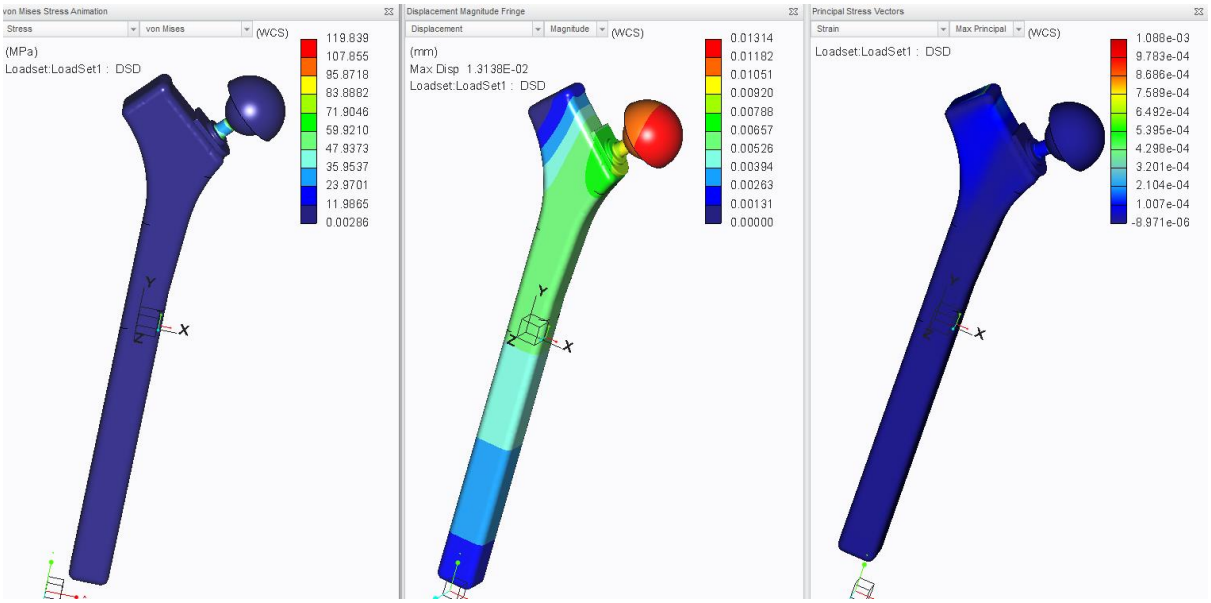
FEA results for Stainless steel (316L) femoral head



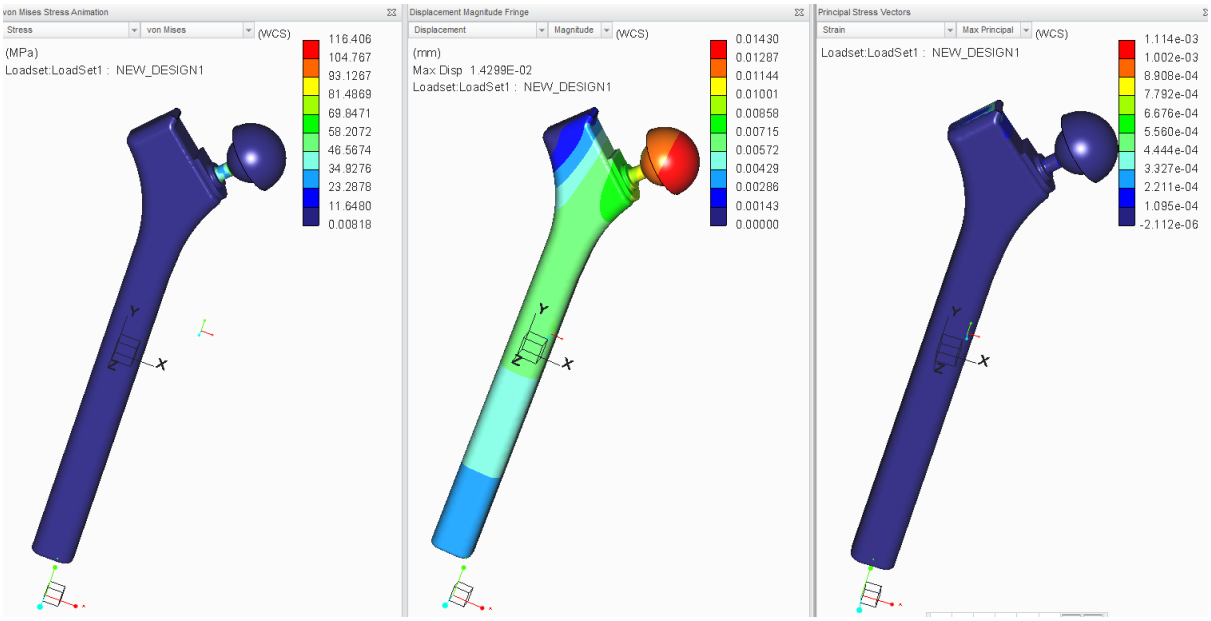
FEA results for Cobalt-Chromium (Co-Cr) femoral head



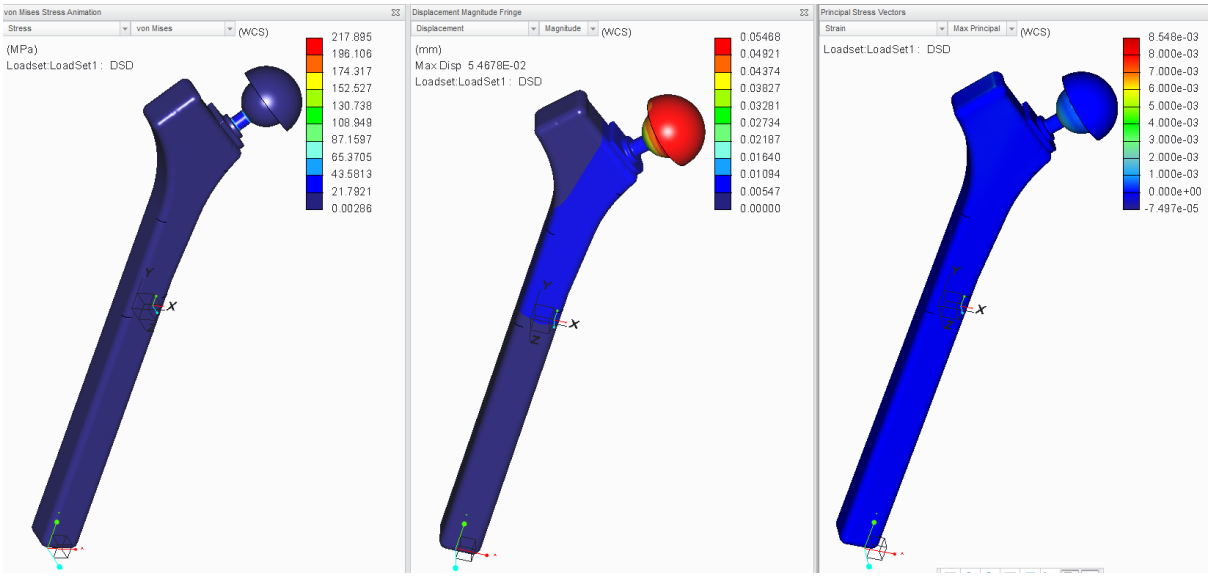
FEA results for Alumina (Al_2O_3) femoral head



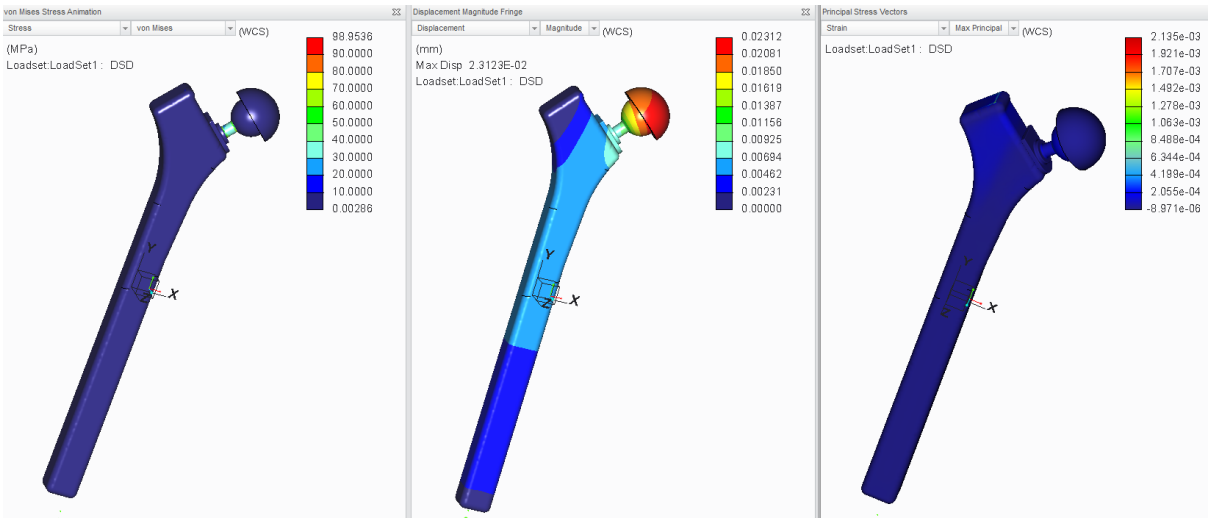
FEA results for Titanium femoral head



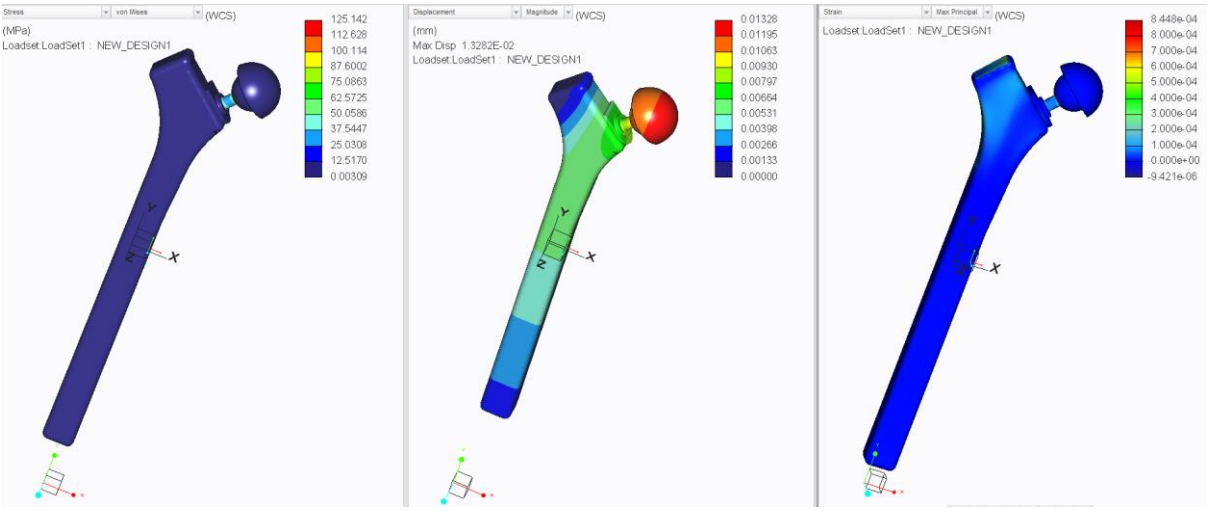
FEA results for UHMWPE femoral head



FEA results for unfilled PEEK femoral head



FEA results for combination of Stainless steel (316L) and CFR-PEEK femoral head

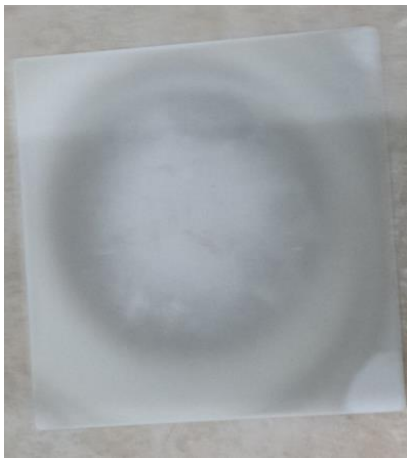


Appendix D

CFR-PEEK sheet

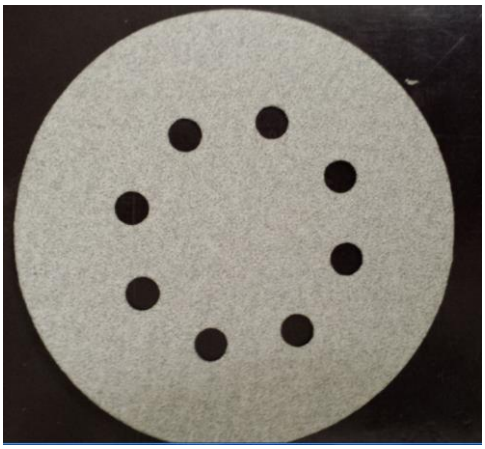
UHMPWE sheet

Alumina sheet



Stainless sheet (316L)

Sand grit paper



Setting up the testing apparatus