University of Southern Queensland

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Design Analysis of the Bearing Component of the Hip joint Prosthesis to Improve Distribution of Forces and Frictional Wear.

A dissertation submitted by

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Abstract

This is a design analysis project aimed at reducing wear of the hip joint components by improvement of distribution of forces. Though there have been celebrated achievements in the total hip arthroplasty (THA) procedure that have brought much relief, challenges associated with wear, hip joint stresses and adverse biological response have greatly affected the longevity of the implants.

Prosthetic wear is a problem that has overshadowed the tremendous gains in the THA and has resulted in implants loosening so much that corrective revision surgeries were necessary. Previously THA has been known to be confined to the older patients but has recently crept downwards to include those in the twenties. This has increased demand and quality of the implants. The project analyses the forces that are active at the hip joint articular surfaces and by use of computer simulation, finite element analysis (FEA) was performed on the models where upon material and proposed design of the bearing were recommended.

The finite element analysis was also compared to the Herztian contact method where it can be concluded that low stresses are achievable by maximising the contact area. This was followed by the model design optimization that gave the final specifications of the proposed design. The proposed design managed to lower contact stresses from a peak of 22 MPa which was equatorial contact to 3MPa over a considerable wide area due alterations in the geometry, diameters sizes and clearances. However the model still needs to be tested in vitro to ascertain the wear characteristics.

Key words: *Stress Distribution, Prosthetic Hip Joint wear, Hip Joint Implant Tribology, Prosthetic Materials.*

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

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Chapter 1

Introduction

1.1 Introduction

When people are born, they usually grow up to develop normal and perfect joints, only to be worn out with age or abused through some reckless activities and sports. This is the tragedy that befalls one of the huge joints in the human anatomy, the hip joint. The main function of the hip joint is to link the upper human torso and the lower part and to transmit forces from the ground upwards. It also carries forces from the trunk, head, neck and upper extremities thus playing a crucial role of supporting the body weight during daily activites (Varshney 2016).

With the continuous medical advancement that humans have witnessed up to this time, it follows that life expectancy has been on the rise. Long life means there is need for a human body to support itself for a long time. This fact calls for the replacement of worn out body components and that include hip joints. This is the reason for the increase in prosthetic hip joints demand as (Nine, Choudhury, Hee, Mootanah & Osman 2014) predicted that by 2030, the number of patients requiring total hip arthroplasty in the United States of America (USA) only, will increase by about 63 % while (Derar & Shahinpoor 2015) estimated that currently one million total hip arthroplasties (THAs) are performed every year worldwide.

This rise in the number of total hip replacements is also associated with the increase in revision surgeries due many problems that affect the longevity of the hip implants. Based on data from the Australian Orthopaedic Association National Joint Replacement Registry (AOA), between 2003 and 2014 revision hip replacements in the private hospitals alone increased by 19.2 % while those in the public sector increased by 33.8 % which is a clear indication of the rising problems associated with wear of prosthetic hip implants as it is estimated that on average Australia spends around seven billion dollars annually on medical implants (AOA. 2015). Though total hip arthroplasty has evolved over the decades bringing much relief and satisfaction to many patients and surgeons respectively, however this is short lived as hip implant patients still face problems of wear of the hip joint bearing surfaces. Resultantly the mechanical wear generates wear debris that has adverse effects on the bone material and surrounding soft tissue of the hip.

1.2 Problem Statement.

The survival of hip implants depends on many varying and complex factors such that it just difficult to get a right mix of the attributes that guarantee the longevity of their life service. In general the average survival period of the hip implants is around 20 years (Hughes 2012). This is not long enough given the fact that hip replacement is now done to the young patients (those under the age of 50 years).

Mechanical factors are in the fore front of the whole host reasons why hip implants life span is not long as desired and these, coupled with the lack of suitable materials that make artificial components which exactly match the bone that is being replaced.

Patient factors that include body weight and patient daily activities also contribute to the nature of hip joint forces which in turn influence the wear rate of hip joint bearing surfaces. Once wear starts to occur the net result is a change of articular surfaces smoothness as they become more rough. This mechanical action in which bearing surfaces in contact slide relative to each other leads to higher friction rate, leading to further surface damage and high volumes of wear debris (Dattani 2007). In some sever cases depending on the materials used to make the components, the wear debris has been proved to cause esteolysis, joint tissue inflammation and ultimate implant loosening (Kumar, Arora & Datta 2014). The end result would be a shorter implant life which means many revision surgeries which are costly and complicated become necessary.

1.3 Objectives

As mentioned above in the problem statement section that implant longevity is negatively impacted by wear debris that leads to osteolysis and eventual loosening of the implant, it appears like a common feature of all joint replacements as (Bitar & Parvizi 2015) noted that about 75 % of hip replacements end up with loosening although with varying time frames. Osteolysis is a gradual process such that it is not easily detected in the period soon after implantation but may be causing extensive bone loss that may require bone reconstruction upon revision surgery (Bitar & Parvizi 2015). In view of this fact, it would be ideal to have one primary surgery that would last the remainder of the patients' lives thereby bringing down costs associated with hip replacements to both patients and governments. Such a bearing would alleviate trauma associated with revision surgery and avoid other medical complexities that linked to metal debris poisoning.

The project aim is to have better outcome for the patients as expectation and demand for better performing hip prosthetic implants rises. Hip implant patients are getting younger and younger with time and therefore, generally the demand is including the more active patients. The young patients who may engage in risky or impact sports have the potential to have long lives ahead of them thereby automatically presenting a situation that calls for the research and development of new bearing designs simultaneously with bearing materials that have low to zero coefficient of friction. Such materials are envisaged to have low volumetric wear debris over their life span, however more importantly the materials must be biocompatible with the human body at the same time, that is the materials must not cause inflammation and other adverse biological responses to the surrounding bone and soft tissue, (Derar & Shahinpoor 2015).

Additionally the research also aims to curb contact peak forces over the contact bearing surfaces by coming up with hip joint implant geometries that enhance better distribution of forces. Therefore in the pursuit of an appropriate solution, it becomes imperative to design an implant that outlives the average remaining lives of the patients thus consequently minimizing the rate of revision surgeries which is also in alignment of the recommendations of National Institute for Health and Care Excellence(NICE. According to (Derar & Shahinpoor 2015), NICE has recently adopted recommendations that stipulate the installation of implants with under 5 % failure rate or a survivorship of more than 10 years. Revision surgeries besides being costly to both patients and national budgets, they are complex and are less likely to succeed than the primary, therefore are not ideal especially for young patients as the patients stand a greater chance of having many in their lives.

It is expected that the project outcome will help in increasing prosthetic implants longevity thus improvement of patients quality of life by having a pain free range of motion.

As shown later in the research project, that since friction is the driver of wear and is dependent on the loads and the operating conditions prevailing at the hip joint, it then becomes crucial to also focus on the material selection for the determination of the best candidates with low coefficient of friction.

Wear between articulating surfaces is caused by friction and nature and magnitude of the active forces at the hip joint. Hence having bearing material combinations that are wear resistant is of paramount importance as they are less likely to generate wear debris.
The research project is also aimed at achieving all this by having good and accurate 3D models for the accurate evaluation of the hip joint stresses. As a learning process the research project has provided the author with invaluable experience dealing with Creo simulate in handling contact stress analysis which is vital in the pursuit of an appropriate solution.

1.4 Project Outline

The structure of this dissertation takes the outline stated below which is in line with the project specification, however there are some small variations or adjustments in the timelines due to new advice and knowledge became available during the course of the project. There are nine chapters are as follows:

- **Chapter 1** introduces readers into the research. This is an overview of the whole project and at the same time it defines the problem and spells out the objectives.
- **Chapter 2** is the literature review which starts by focusing on the background information to the types of hip joint replacement bearings. It also touches on anatomical construction of the hip excluding the muscles and then explores the biomechanics of the hip joint.

- **Chapter 3** is the methodology and techniques employed to achieve the specified objectives.

- **Chapter 4** is about material evaluation and selection process so that the most suitable material candidate for the hip joint is recommended. This is done through the evaluation of the published data sheets and experimental results by other researchers.

- **Chapter 5** addresses the tribology of the hip joint surfaces to augment the reduction of friction and subsequently wear on the bearing surfaces. The chapter also looks at the mechanism of wear (wear modes), action of friction and hip joint surfaces failure modes.

- **Chapter 6** presents the FEA that is performed on the hip joint models. Four bearing heads sizes of the common models that are in the market are going to be evaluated to see the location of high stress areas and how these can be reduced.

- **Chapter 7** presents discussion of the results and findings

- **Chapter 8** constitutes possible recommendations on the proposed design and further work that needs to carried on.

- **Chapter 9** is concluding remarks which includes the summary of the research.

- **The bibliography** comes after the conclusion and is a list of all the material sources used in the project research.

- Then lastly there is an appendix where other referral material for the research project will be found.

Chapter 2

Literature Review

2.1 Chapter Overview

The objective of this chapter is to explore the background information about the total hip replacement, the successes and challenges that have been faced before so that there is clear understanding of the nature of the problem of wear.

In this view the chapter presents the hip joint bearing materials combinations from which the bearing names are derived from. The materials are found in both total hip arthroplasty and hip joint resurfacing. The literature review examines the performance of these bearings in vivo highlighting the effects of the wear debris to the surrounding bone and soft tissue. The chapter concludes with the analysis of the hip joint forces that contribute to a greater extent to the nature and the rate of wear.

2.2 Types of Bearings.

The great success of the total hip arthroplasty (THA) has come but not without problems, some of which still affect patients in the long run. Some of the problems associated with this procedure are dislocations, impingement, fracture, wear which leads to metal ion poisoning (metallosis), osteolysis and soft tissue inflammation resulting from the adverse reaction to wear particles from the hip joint surfaces. Wear debris is generated by frictional action and is compounded by high contact stresses endured by the articulating surfaces during daily activities.

As noted by (Singh & Harsha 2015), THA is carried out as a last resort to patients that have advanced arthritis and are under severe pain or to those who would have had hip fractures due to accidents. Such joints are usually stiff and make daily physical activities almost impossible. Without the problem of wear generally it is expected that after THA surgery, patients regain their lost joint mobility and comfort and thereby improving their quality of life. In most cases though not all, but most the daily activities are restored.

Frictional wear has to be fully understood and adequately addressed to avoid failure due to osteolysis, joint inflammation and metallosis. Metallosis is defined as the medical condition where there is accumulation of metallic wear debris in the surrounding soft tissue while osteolysis is regarded as loss of bone material (Bitar & Parvizi 2015). The effects of frictional wear are difficult to detect immediately after implantation because it takes sometime before the symptoms manifest.

There are several bearing combinations that have been trialed with varying successes recorded and these materials have been grouped into two main categories namely hard on hard bearing couples and the hard on soft. Under the hard on hard bearings, the types include metal-on-metal (MoM), ceramic-on-ceramic (CoC), ceramic-on-metal (CoM) while the metal-on-polyethylene (MoP) and ceramic-on-polyethylene (CoP) are found under the hard on soft bearings (Fisher, Williams, Thompson & Isaac 2006).

2.2.1 Hard on Hard.

MoM bearing couples.

Metal on metal bearings consist of a metal femoral head articulating against metal cup liner in the acetabula of the same size made of similar material (Fisher et al. 2006). Another type found under the MoM bearings category is the metal resurfaced femoral head that articulates in the metallic acetabula cup. The femoral head ball has got a metal cap on it (Drummond, Tran & Fary 2015), and the procedure has its own advantages which include preservation of the femoral head bone unlike the complete removal of the femoral head as in total hip arthroplasty. Additionally metal resurfacing gives the metal resurfaced femoral head better results because there is greater stability due to minimum material removal and less disturbance of the ligament and muscle structures. These structures form around the joint and are crucial for stability. MoM bearing couples are mostly suitable for the young and more active patients because of low chances of dislocation (Drummond et al. 2015).

(Drummond et al. 2015) also states that MoM bearing combinations can be manufactured to a high degree of accuracy as they can be engineered to be very hard and yet still achieve a high degree of surface finish. These two properties are crucial for wear rate reduction as MoM bearings have been proven to have 60 times less wear rate as compared to MoP. Metal-on-metal bearing combination also has the advantage of having low inflammation owing to the absence of polyethylene component in the acetabula, however (Drummond et al. 2015) emphasizes that there is a trade-off with MoM because there is an increased risk of release of chromium and cobalt ions into the surrounding tissue and into the blood which can potentially cause metallosis. (Bitar & Parvizi 2015) also concurs and concludes that sometimes it is not the volume of the wear debris that matters but also the biologic response of the body to the metal elements which is linked to the shape of wear debris. MoM bearing combination wear debris is usually fine and needle shaped but at times is so minute that it dissolves in the blood serum as ions and can cause other medical complications.

Constituents of the implant

As illustrated in the figure 2.1, the bearing implant constitutes the femoral head ball out of metallic alloy and the metallic acetabulum. The femoral stem and the external backing of the acetabula are commonly made of porous Titanium alloy. The porous Titanium is used in the metal and bone interface because of its qualities that facilitate osteointegration. The porous nature of titanium allows bone to grow into implant thus creating a strong bond. The articular inter-surfaces are made of very hard alloys of aluminium, chrome, cobalt, iron, nickel, molybedenum, iron, silicon, magnesium and vanadium with the most commonly used being cobalt and chrome for weight bearing applications (De Martino, Triantafyllopoulos, Sculco & Sculco 2014).
The MoM bearings commonly used in orthopaedics are Cobalt-Chromium alloys, stainless steel, and Titanium alloys.

The figure 2.1 below illustrates the MoM bearing couple.

Figure 2.1: Metal on metal: (DePuy Orthopaedics, 2015)

A remarkable step in the developments of MoM bearings was seen in the 1953 in Europe with the introduction of the McKee 32 mm metal head bearing of Cobalt, Chromium alloy (Wagner, Olsson, Ranstam, Robertsson, Zheng & Lidgren 2012), (Fisher et al. 2006). Initial results of MoM cemented THA were quite promising however failures due to loosening and acetabular cup migration put the bearing combination into further review (Benson et al) cited in (Wagner et al. 2012). The failures were largely due to high friction and impact forces that released wear debris. Evidence of inflammation of the tissue around the implant was revealed during surgery inform of soft tissue that had been discolored supposedly by cobalt metal wear particles in particular (Hosseinzadeh, Eajazi

& Shahi. 2012).

Though there were some improvements on the Mckee design, the new design made the problems worse due locking and jamming. Noted as well was a significant increase in metal ion levels in the experiments conducted where there was about 15 times increase in chromium in urine tests and 11 times the level of cobalt in blood tests (Coleman et al 1973) cited in (Wagner et al. 2012). As a result, the interest in the MoM bearing combination nose dived due to high early failure rates (Fisher et al. 2006). However, the few lone surviving MoM implants that had lasted approximately 20 years renewed the interest in the MOM bearing couple around the 80s. During that period the MoM bearing couple showed a minimum wear rate of approximately 8μm.

A common feature in MoM bearings is the soft tissue inflammation reactions to metal debris from both articulating surfaces of the femoral head and acetabula and the head and neck trunnion interfaces. The condition is termed adverse reactions to metal debris (ARMD) (Drummond et al. 2015) and encompasses pseudotumours, aseptic lymphatic vasculitis associated lesions (ALVAL), and metallosis. Pseudo-tumors are said to develop as the tissue reacts with metal ions released from metallic articulating surfaces.
All these bad conditions caused by high wear rate take place as a result of edge loading which is brought about by shallow acetabula cups, and is made worse when they are mal-positioned (Drummond et al. 2015).
ALVAL is a condition in which the surrounding tissue cells react adversely, particularly to chromium and cobalt ions where reaction is attributed to the amount of wear though it is not the case in some hip implant patients.

On the contrary (Wagner et al. 2012) disputes the claims that generated renewed interest in the MoM bearings stating that in fact there has been an increase in jamming of the prosthetics and the risk of revision still remains at a rate of 3 %, however many researchers seems to agree that metal wear and particle release is a major problem that negatively impacts on the longevity of hip implants as stated by (Drummond et al. 2015).
Although it is out of the scope of this research, the other source of wear debris is the modular taper junction between the ball head and the stem, which is not the case in mono block hip implants. Mono block hip implants are in one piece with the femoral ball head and the stem joined by the neck.

With MoM bearings, it has been revealed that there is high rate of metal debris release in the short term after implantation as the mating surfaces work themselves into congruence in the first year of implant service. This is the running in period which becomes steady after about three year. In such cases it then advisable to conduct serum test periodically to monitor the levels of metal ion concentration before revision surgery is conducted. (Maurer-Ertl, Friesenbichler, Sadoghi, Pechmann, Trennheuser & Leithner 2012) conversely attributes this high wear rate in large diameter MoM to large articulating surfaces and the trunnion which tends to release a large volume of wear particles in to the surrounding soft tissue.

It also should be noted that there is low wear rate in MoM but that small amount contains toxic ions that lead to implant failure in manner stated above.

Even though there are problems associated with the MoM bearing couple there are some advantages which include the following:

- Increased toughness and decreased wear rates.
- Allows large femoral heads to be used which wear better than smaller ones.
- Reduced chances of dislocation and improved mobility (has a large range of motion) due to to large heads.
- Reduced risk of fracture and is flexible with hip resurfacing which allows preservation of the bone stock on the femur side.
- There is no inflammation in a pure MoM bearing combination as there is no polyethylene liner.
- MoM can withstand high impact without shattering as ceramics heads do. The larger head sizes are more than 10 times stable to dislocation than traditional small femoral heads on polyethylene or ceramic on polyethylene hips.

The disadvantages include:

- The continuous motion at the articulating surfaces of MoM implants inevitably causes wear and the eventual release of of microparticles of metal debris into the surrounding tissue leading to metallosis.

As a means of ascertaining the amount of wear in this type of bearing couple to establish the performance of the MoM materials (De Martino et al. 2014) suggests measuring amount of wear on the MoM bearing surfaces by evaluation of the ion concentration of cobalt and chromium in the serum. The ion concentration is dependent on the duration of the implant in service. In a communique he authored, he concurs with findings from other authors about the presence of edge loading where the ball of the implant binds into the edge of the cup causing it to flack off. This is how some of the debris is generated and more common in implants of small diameter cups. This is further discussed in the finite element analysis section on this thesis.

The situation is worse if they are placed at more than 55 degrees of abduction. When determining the extent of wear of the implant the serum test that gives chromium and cobalt concentration levels as high as more than 10 times compared to those unexposed usually are regarded as indicative of significant wear of the implant. (Maurer-Ertl et al. 2012) stipulates particularly that the values as high as 15ng/mL of Chromium and 10ng/mL of Cobalt are taken as the threshhold.

Ceramic on Ceramic

Ceramic-on-ceramic bearing is another type classified under hard on hard type of hip implants (Bal 2015). Both the femoral head and the acetabula socket are made of ceramic material which constitutes mainly aluminium oxides (alumina Al_2O_3) and zirconium oxide (zirconia ZrO_2) (Bal 2015). Ceramics have been proven to possess extremely low wear properties. Although by 2005 according to (Bal 2015), more than 5 million femoral heads and 500 000 of acetabula all made of aluminium have been implanted, there is still limited acceptance of this type of bearing because of the cost involved, complexities and high chances of sudden catastrophic ruptures. Hence of all the THA performed in USA, those of ceramic constitute less than 10 %. The figure 2.2 below illustrates the construction of the CoC bearing couple. It looks the same as the the MoM bearing in construction, only the materials differ.

Characteristics of ceramics.

For the application of ceramics in the THA a material has to have high strength, high elasticity modulus, high fracture toughness and high fatigue resistance. This is crucial to

Figure 2.2: ceramic on ceramic: (DePuy Orthopaedics, 2015)

provide mechanical reliability and to resist deformation. Although ceramics are extremely hard (hard wearing by scratching or abrasion), corrosion resistant, and biocompatible they are deficient in fracture toughness.this quality has been improved by fine tuning the manufacturing process uses fine grained raw material.

Ceramics have a crystalline structure of alumina and zirconia in which atoms are held together by strong ionic and covalent bonds. These atoms give it high compressive strength, hardness and chemical inertness. These oxides are chemically inert, resistant to corrosion and stable in bilogic environment for long periods of time. The oxides also have polar hydroxyl (OH) group that promotes interaction with aqueous body fluids to provide a lubricant layer. The crystalline nature gives it the brittleness i.e. low resistance to propagation of cracks this is a low toughness value lower than CoCr and Titanium alloys (Bal 2015).
The microstructure of the bearing is determined by the nature, quality, and distribution of the material grains, the porosity within these grains and manufacturing variables. Mechanical properties depend on grain homogeneity and purity and size consistency. High material density (low porosity) and smaller grain size gives ceramics some superior mechanical properties and strength in the bearing which make withstand the joint loads. Since the performance of an implant is dependent on the design and fracture toughness, modern manufacturing methods can achieve near zero porosity with fine sized grains uniformly distributed homogeneously throughout the material. So due to improved raw material and manufacturing process better implant deign can be produced (Bal 2015).

Brittleness and limitations:

Due to the brittleness nature of ceramics there have been unexpected and catastrophic failures of femoral the heads in vivo. Microscopic flaws from manufacturing methods, pores, notches, inconsistences and scratches have been cited as the major causes of these failures. The above flaws can also be introduced into the component during component surface matching of the finished product and during implantation surgery. So with repeated loading, stress concentration and material imperfections are conditions conducive to start cracks that subsequently grow leading to abrupt failure (Bal 2015). In contrast metals are elastic and under the same conditions they absorb the applied stress without catastrophic failure.

Failure of ceramics.

Ceramics can fail mostly in the absence of any indicative risk factors, though patient obesity, strenuous activity, trauma and cylclic loads have been listed as possible risk factors for failure of ceramic heads (Hosseinzadeh et al. 2012). These cyclic loads are known to be well below the fatigue limit of ceramics. On the other hand ceramics can withstand high compressive loads however they are very weak on tensile loads that develop inside the femoral heads. These results in catastrophic failure because of the inherently low cracking toughness (Gheorghe & Badita 2012). It is also possible that these tensile loads can be stored as hoop stresses inside the femoral heads leading to delay failure. This happens because material stress will have exceeded its fracture strength. The performance of ceramic also depend on the skills of the surgeon. For example a 5 degrees malalignment can have adverse effect resulting in cracking or chipping. The combination of a high patient body weight, extensive range of motion and subluxation of the femoral head can lead to high friction at the articulation surfaces between femoral head and rim of the liner which initiates displacement of the ceramic liner. Subsequent arbnormal strenuous activities lead to further displacement of the liner and eventually cause ceramic liner to fracture. In view of these facts it can be then concluded that most common form of failure associated with CoC is fracture as there is negligent wear between articular surfaces.

Ceramic on Metal (CoM)

This is a bearing combination that is comprised of a ceramic femoral head like in the CoC but the head articulates in a chromium cobalt metallic alloy acetabula or the Ti-6Al-4V alloy liner. It was reported that CoM bearing couple has significant low wear rates as compared to MoM bearing owing to its low coefficient of friction (Isaac, Brockett, Breckon, Van der Jagt, Williams, Hardaker, Fisher & Schepers 2009). The fact that working with ceramics, a high degree of surface finish (smoothness) and hardness which can be achieved, it means automatically the bearing couple has low wear rates, low corrosive wear, and there is improved lubrication qualities. All these contribute also towards its reduced adhesion wear (Isaac et al. 2009). In some experiments conducted pitting CoM and MoM revealed that wear rates at times were related to implant inclination rather than the design (Isaac et al. 2009)

2.2.2 Hard on Soft Bearing Couples.

Metal on Polyethylene (MoP)

This is a bearing combination that has hard part on the femoral head and a soft material usually the ultra high molecular weight polyethylene (UHMWPE) attached to socket of the acetabulum as liner. It was introduced in 1962 by Charnely according to (Fisher et al. 2006), as a low friction metal on polymeric acetabula. The metal head can be made of the metal alloys (Co, Cr, Mo, Ti, and Al) or ceramic. The bearing type Charnely introduced was a 22 mm stainless steel head which was later refined to incorporate large diameter heads of various material combinations including alloys of Cobalt-Chromium and gamma irradiated UHMWPE (Fisher et al. 2006). The figure below illustrates the MoP bearing couple.

Figure 2.3: Metal on Polyethylene: (DePuy Orthopaedics, 2015)

The MoP bearing was developed as a result of the failure s of the MoM bearings due inflammation and osteolysis. During the initial stages there was some promise of better performance but still the problem of wear remained a big challenge to surrounding soft tissue inflammation. The wearing resistance of the bearing material UHMWPE has been improved over the years by modifications to its molecular structure. In the seventies it was carbon fiber-reinforced (Hosseinzadeh et al. 2012). This was followed by high pressurized crystalized UHMWPE in the 80s which had high creep resistance and lately in the 90s saw the introduction of the cross-linked UHMWPE which made significant difference in the wear resistance (Hosseinzadeh et al. 2012). Conversely (Gheorghe & Badita 2012) argue that metal on polyethylene, developed in the 60s by Charnley in the UK has been hit with problems that include loosening, wear, osteolysis and dislocation. To curb these hiccups the heads sizes have been increased and the polyethylene been cross linked, however when the cross linking to achieved the hardness, it imparted the brittleness into it.

Following on this promising success a radiation cross linked UHMWPE was introduced about the same period. (Hosseinzadeh et al. 2012) also estimates that about 700 000 UHMWPE were implanted in 1998 worldwide which shows that UHMWPE is becoming a popular choice for the THA as compared to 200 000 hard on hard from 1988 to 2000. This constitutes less than 10 percent of all hip replacements over the same period. Despite the wide acceptance of the hard on soft bearing couple there are still many challenges associated with wear rate of UHMWPE part which is a serious drawback to the longevity of the component.
The evidence of worn debris from the articulating surfaces of the hard on soft bearing is an indication of the snowball effect of the tissue response which leads to osteolysis and eventual loosening of the femoral stem or the acetabulum component. Hence the focus of this thesis is seek to improve the wear behavior of the articulating surfaces thereby extending the longevity of the THA. MoP remains the most popular hence the basic standard which every other is measured (Isaac et al. 2009).

Ceramic on Polyethylene (CoP)

Similar to MoP, the bearing has cross- linked polyethylene acetabula that is coupled with ceramic femoral head as the hard component in this type of a bearing combination. It is most commonly used in the United States of America (USA). (Gheorghe & Badita 2012) state that polyethylene wear increases with activity and load, and often generates an aggressive response from the body where loosening and bone loss occurs (osteolysis).

This fact reinforces the need to address the joint contact stresses in order to curb the frictional wear.

2.3 Biomechanics of the Hip Joint.

Over the years there has been a lot of literature developed from experiments conducted and published about the forces that act on the hip joint and wear resistant materials of the artificial hip joint as these influence wear mechanics of the hip joint. In order to appropriately address wear at the articulating surfaces it is important to look at the forces that act on the hip joint and how to improve stress distribution or eliminate stress raisers that may give rise to frictional wear.

Anatomy of the Hip Joint.

The joint forms the crucial connection between the bones of the lower limb and the axial skeleton of the trunk and the pelvis (Gheorghe & Badita 2012). The surfaces of the femoral ball head and the acetabula socket are covered by a strong lubricated layer called the hyaline cartilage. In a normal human joint the hyaline cartilage is thick in places where the joint bears most of the body weight. The hyaline cartilage provides frictionless smooth surfaces for the moving bones to slide relative to each other. It also acts as a shock absorber thus preventing the collision of the bones of the hip joint during physical activities. The space between the cartilage layers is filled with synovial fluid that lubricates the joint capsule. The synovial fluid is secreted by the synovial membrane (Morlock, Nick & Gerd. 2011) . The head of the femur is not a perfect sphere but basically the joint looks like a ball and socket (Iglic 2008). Also found on the joint are the ligaments and muscles that stabilize the joint and prevent dislocations as shown in figure 2.4 showing a cross section of the joint below.

Mechanics of the Hip Joint.

This section addresses two ways of analysing forces acting on the hip which include a mathematical approach and the second one is by analysing results from conducted ex-

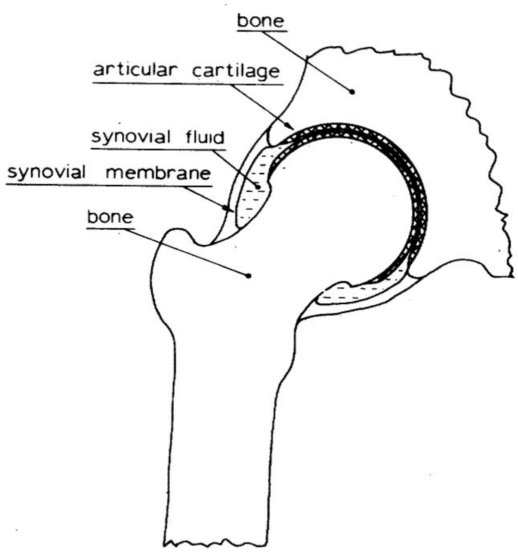

Figure 2.4: Structure of the hip: (Iglic, 2008)

periments. The mathematical way takes into considerations a number of assumptions in order to simplify the situation and as a result it gives an estimated result. In a simplified free body diagram in figure 2.5 (Mirza, Dunlop, Panesar, Naqvi, Gangoo & Salih 2010) presents the hip joint as a simplified system which consist of the lever arm with the joint as the fulcrum in which the forces on the femoral ball head is equal and opposite those in the acetabula.

Analyzing the forces at the hip joint in 2 dimensional way along the frontal plane when both legs are on the ground, the body weight (minus the weight of two legs) is shared equally between the two hip joints. However this changes when the body is in a one leg stance as shown in figure 2.5 where the weight of the swing leg is added to the body weight and all create a moment **K** (a downward turning moment around the femoral head) (Byrne, Mulhall & Bake. 2010). **K** has its moment arm **a**, that is the distance from the center of the femoral head to the line of the center of gravity. This motion is counterbalanced by the forces in the abductor muscles **M** which in turn generates a moment with its moment arm **b**.

Looking at the diagram it can be seen that moment arm **b** is shorter than moment arm **a** and hence it has to be a multiple of **a**. The magnitudes of the forces **M** and **R** depend on the ratio between the ratio of **b** and **a**. **R** is the joint reaction force and is estimated to be more than three times the body weight on a single leg stance. Therefore, any procedure that increases the body weight moment arm **a** or reduces the abductor muscle moment arm **b** increases the force on the femoral head. Therefore it can be deduced that people

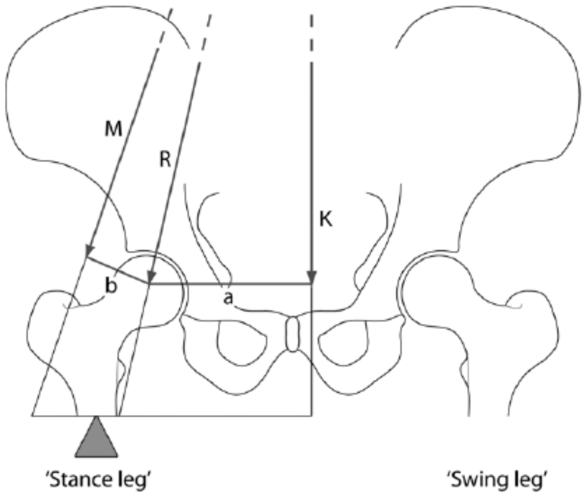

Figure 2.5: Fee body diagram of the hip joint

with short femoral necks have high hip joint forces and so are those with wide pelvis (Byrne et al. 2010).

The second way is the experimental analysis in which instrumented implants are used. Contact pressure measuring devices are embedded in the implant during primary surgery from which data is collected over a period of time for analysis. The down side of this method is that only the diseased and operated joints are analysed not the healthy and normal ones. According to the findings from (Iglic 2008), an experiment conducted on a 68 year old patient, hip stress in vivo, it was found out that very high local and non-uniform pressures up to 18 MPa were recorded during adduction and extension of the hip joint. It was also found that the maximum recorded pressure was at the superior acetabula dome. This shows that the pressure distribution has its peak at the pole region whose size is dependent on the weight applied the leg. This occurs when the patient performs actions like rising from the chair at a chair height of 45 cm. At a height less than 45 cm should expect a higher pressure reading than 18 MPa (Iglic 2008). The test also revealed that the pressures recorded during jogging and normal walking was far lower than rising especially from a squatting position. The table shows the various peak loads during motions endured by the hip.

Table 2.1: Hip contact forces measured in vivo in patients with instruments imbedded implants.

ACTVITY	TYPICAL PEAK FORCE BW
Walking, slow	1.6 4.1
Walking, normal	2.1 3.0
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	1.8-2.2
Sitting down	1.5- 2.0
Knee bending	1.2-1.8
Stumbling	7.2-8.7

Source (Byrne et al. 2010)

2.4 Chapter Summary

It has been clear that the development of the hip replacement procedure to what it is today, though has been with problems some of which are still under further research, has been evolutionary landmark. The efforts has resulted in the plurality and diversity of the researches that seek to improve the performance wear behaviour of the hip joint replacement implants.

Chapter 3

Methodology.

3.1 Chapter Overview.

The techniques employed in this research project in pursuit of a solution to the problem of wear of the hip joint implants include the literature review on the background of the problem to establish the gaps that the research is going to focus on. Evaluation of the contribution of friction in the wear mechanics of the hip joint and material selection for the best candidates follow on from the literature review. Since wear caused by mechanical means lead to biological consequences, the development of solution is hinged on the minimisation of the peak forces at the hip by increasing contact area This is achieved by varying the diameter heads and clearances since the body weight is held constant. Bearing models were run through FEA using Creo 3.0 simulate to see the magnitude of the contact stresses.

The evaluation of the design models was done through the finite element analysis (FEA) which is a powerful computer based tool that predicts high stress areas that need attention.

The effect of varying contact clearances with bearing sizes on contact stress is compared with the Hertzian contact method as a validation method. Design optimisation was finally used to come up with a proposed design that is evaluated after incorporating some design changes.

3.2 Methodology.

The work into this project is based on secondary information that is data gathered and synthesized from online search data bases as well as journals. These include the University of Southern Queensland (USQ) library, Medline, Google Scholar, PubMed, ScienceDirect, Elsevier, PMC, Springer, Scopus, The American Society of Mechanical Engineers and many more that have verifiable information on the topic. The process involved searching through these data bases by using a few search terms or key words and then going through the abstracts to determine the documents' relevance to the research. The decision to select which documents to use was based on how current the publications are and how often they have been cited by other authors. Journal articles were also checked for information consistency before they were saved in the created library for further reference. As a way of maintaining consistency and relevance, multiple data sources were used in verifying whether similar results on the experiments have been obtained elsewhere. Though there was no strict rule on the publication date range, the majority of the reference material used in the literature review starts from 2010 to the current date with a few exceptions picked from the past decades since nowadays information changes rapidly. At times it was necessary to analyse the references lists of the selected documents to gather more information and use it though not necessarily in the same manner as in the original documents. In situations where the full text documents were not available, the USQ library was contacted for assistance to access the material. The option of contacting authors of published materials was left open in case it was necessary to get more information on unpublished trials and tests.

Since it was important to analyse the hip joint forces in an attempt to solve the wear problem, joint mechanics and geometry was done in elaborate computer models in FEA where the articular stresses and pressure distribution is analysed. Previously, though still a handy tool, joint mechanics was done through numerical methods in which the representation was in simplified point loads and therefore not a better estimate of the pressures and stresses as compared to FEA. In this analysis the FEA is exclusive of the muscles and only the contact surfaces of the hip joint are in consideration. (Muscles are considered as point loads). The FEA takes into consideration the current designs in use using Creo 3.0, and then show how the improved design has less stress concentrations. The current bearing designs by many designers regard the femoral head as a perfect sphere which is not the case in reality. The proposed design takes an oval shape in accordance with the idea of increasing the contact area.

FEA is the best route in the past analyses were primarily experimental or analytical which is difficult and time consuming. this has a tendency of compromising the accuracy of the results.

FEA was performed on bearing head diameters (28, 32, 42 and 50 mm) that were generated using PTC Creo 3.0 parametric. This computational method is also used by many designers world wide because it saves time by eliminating the need to build several prototypes and time spent in the testing laboratories (Bunn, Colwell & D'Lima 2011). FEA also becomes handy in such cases and if properly implemented can give results not very different from those obtained through the experimental route. From the literature review the materials are analysed both their physical and chemical properties to ascertain their behaviour in vivo so that the best material is selected for the hip joint application. This is complemented by the use of the Ashby charts, material data sheets and the decision matrix method that is implemented. As different material deform differently under the loads, they give varying stress values due to their different stiffness values. PTC Creo 3.0 simulate is again used in the finite element analysis to understand the behaviour of the selected material under the mimicked real conditions of the hip joint. From the biomechanics section and as it shall be seen in the FEA section, greater contact area corresponds to less stress because the forces are distributed over a large area. This is also achieved by the easy with which the material can deform under the loads thus giving the assembly bearing components greater conformity to each other. Greater conformity too helps in increasing the contact area.

As means of validating what the software produces, the Hertzian contact stress calculations are conducted and compared to the those obtained through FEA method. Though there was a small difference in the values obtained due to some approximations, assumptions and material conditions, the process gave some confidence about the FEA method. By calculation, the Hertzian method showed that by increasing the femoral head diameters there was an increase in the contact area and a reduction in the normal stress, however there need to optimise the design to avoid over or under designing.

Given the nature of the project and the time constrains it was not feasible to conduct experiments on the hip joint design model in vitro, however as a justification for the new elliptic design the, proposed design was evaluated for stress comparison with the spherical shaped design with good results. Additionally all this work was done through careful resource consideration and risk assessments which have been attached in the appendix D of this research project.

Chapter 4

Material Selection.

4.1 Chapter Overview

Chapter four presents an analysis of the biomaterials found in the hip orthopaedic industry including the challenges in the application of such materials. This is followed by the comparison of the materials for the selection of most suitable candidate(s) since it is very important to use a materials that are wear resistant as well as biocompatible. These materials are then used in the computational finite element analysis to ascertain their behaviour under hip joint loads. Most of the materials discussed here have been introduced in the literature review section.

The chapter concludes by exploring the decision matrix technique that is used in the material selection for the femoral head, the stem and acetabula cup.

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4.2 Prosthetic Material Requirements.

In the biologic environment not every material that is used is without bad effects and therefore there should be every effort to optimize for the best results. The materials selected should present less adverse effects on the human body and yet still fulfil intended design functions. In the process of evaluation of biomaterials of the hip joint, it is crucial to use materials whose characteristics are close to that of a bone so that the conditions that are conducive for stress shielding are minimized. These conditions exist when the artificial implant alters to a greater extend the distribution of forces in and around the bone. The new set up leads to a decrease in the density of the bone material thus weakening the bone and making it susceptible to fracture failure. This happens when a material whose modulus of elasticity is higher than that of the bone shields the bone from the normal loads it is intended to carry. In response to this new condition the bone is known to adjust by remodelling itself. The process involves reducing the excess stiffness (bone material loss) that was existent prior to implantation leaving the bone weak. The opposite is true where the bone bears heavy loads leading to the increase of bone density as a response. In order to encourage bone growth soon after implantation and improve implant fixation, the surrounding bone should still be exposed to some forces enough to increase bone density. although the failure due to stress shielding is not directly related to wear, it is equally important avoid other potential causes of the failure that may overshadow the effectiveness of the proposed solution. Below is table 4.1 showing physical and mechanical properties of cortical bone. It becomes very important to have the prosthetic materials that closely compare with the qualities of the bone they are replacing (Cramer & Covino 2005).

Table 4.1: Mechanical and physical properties of cortical bone.

Compressive strength	190 MPa
Tensile strength	130 MPa
shear strength	70 MPa
Modulus of Elastcity	20 GPa
Poisson's Ratio	0.6
Density	1800-1900 Kg/m^3

Source (Huston 2009) and (Gilbert 2011).

Figure 4.1 illustrates the comparison of materials in fracture toughness.

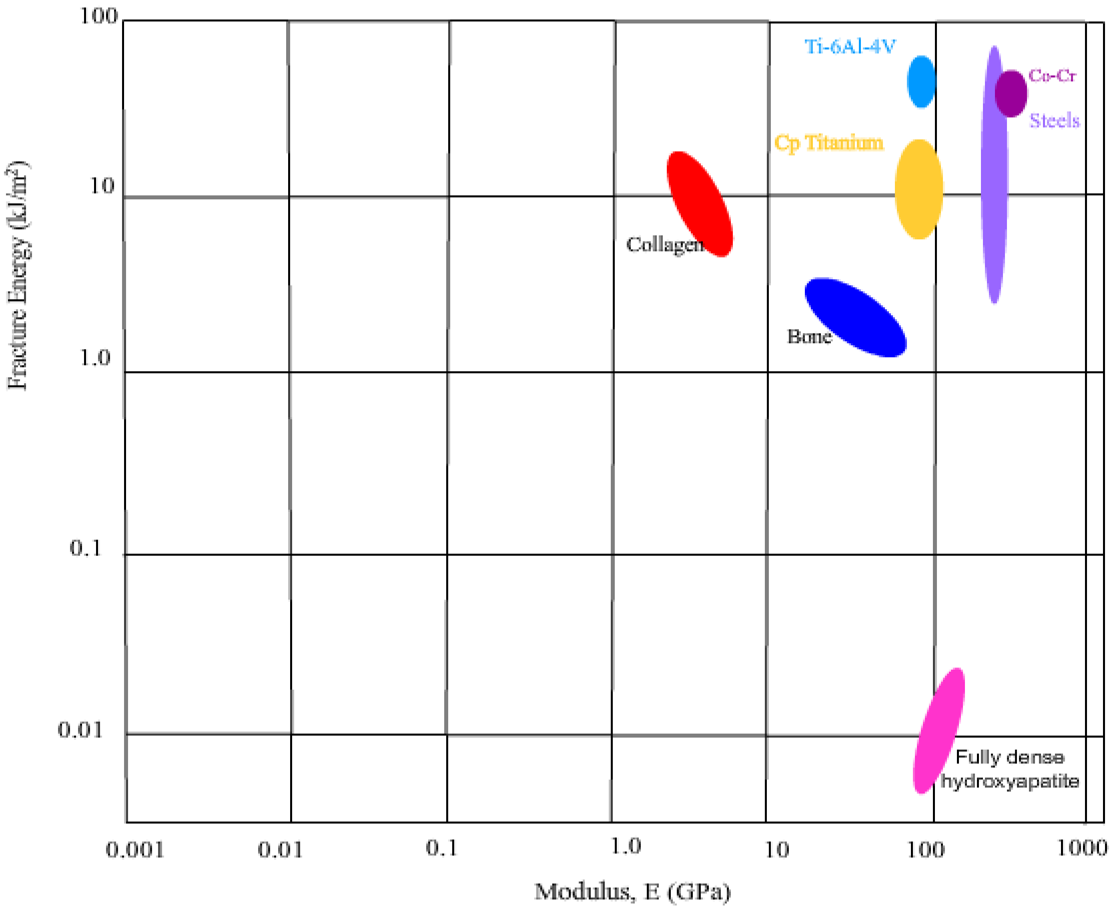

Figure 4.1: Comparison of fracture toughness. Source: Capes and McCloskey (2006)

Bones are also known to be stronger in compression than in tension and weakest in shear strength. Bone material is neither homogeneous nor isotropic and physical properties vary both in direction and location (Huston 2009). Therefore the values used in this study are generalized. Bones also get affected by age and these properties do not remain constant. For example, the longitudinal modulus of elasticity and tensile yield of the cortical bone decreases by about 2 % per decade after the age of 20. The ability to absorb energy during impact reduces by about 7 % per decade. This also means the reduction ultimate strain of the cortical bone because they become less strong, less stiff and more brittle. However something special about bone material is its ability to self repair and that is why bones can manage to remodel in the presence or lack of loads (Gilbert 2011). In view of the above, it can be seen why the the new in-coming prosthetic materials should not deviate much from the bone material properties.

Figure 4.2 shows a comparison of the prosthetic materials with those of the bone.

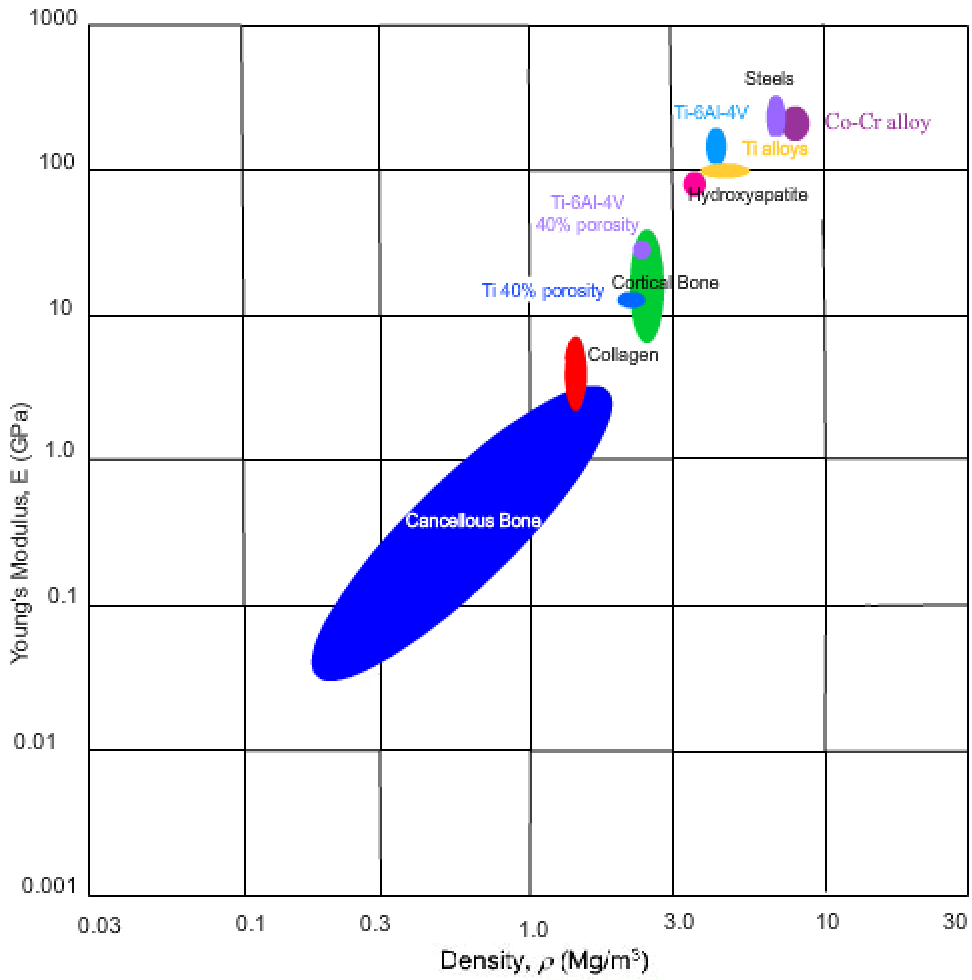

Figure 4.2: Comparison of biomaterial material young:s modulus. Source: Capes and Mc-Closkey (2006)

4.2.1 Tensile Strength.

From the wide range of engineering materials, there are mechanical properties that must be considered as important when selecting materials for hip implants to achieve a better implant service life. These include tensile strength, compressive strength, fatigue strength, ductility, biocompatibility, fracture toughness and high wear resistance (hardness).

Tensile strength is important because the implant must be able to carry the loads and maintain stability for a long implant life span without failure. During daily activities the joint components go under tensile loads as well. For example, the superior section of the femoral neck usually experiences the tensile loads and should be made of a material that can withstand these loads during motion.

4.2.2 Compressive Strength.

Most of the loads sustained by the body joints and bones in general are compressive due to gravity because the majority of the heavy and physical human activities are performed when the body is vertically orientated. This quality becomes important for the joint surfaces to withstand the cyclic loads and creep failure that is associated with it. Usually a material that is hard wearing has also high compressive strength.

4.2.3 Yield Strength.

This is crucial since the loading regime of the hip joint is cyclic therefore a material that has a low yield strength could be susceptible to early fatigue failure.

4.2.4 Fatigue Strength.

This is crucial to prevent the failure of an implant from brittleness under cyclic loads and usually this is found within a material with good yield strength.

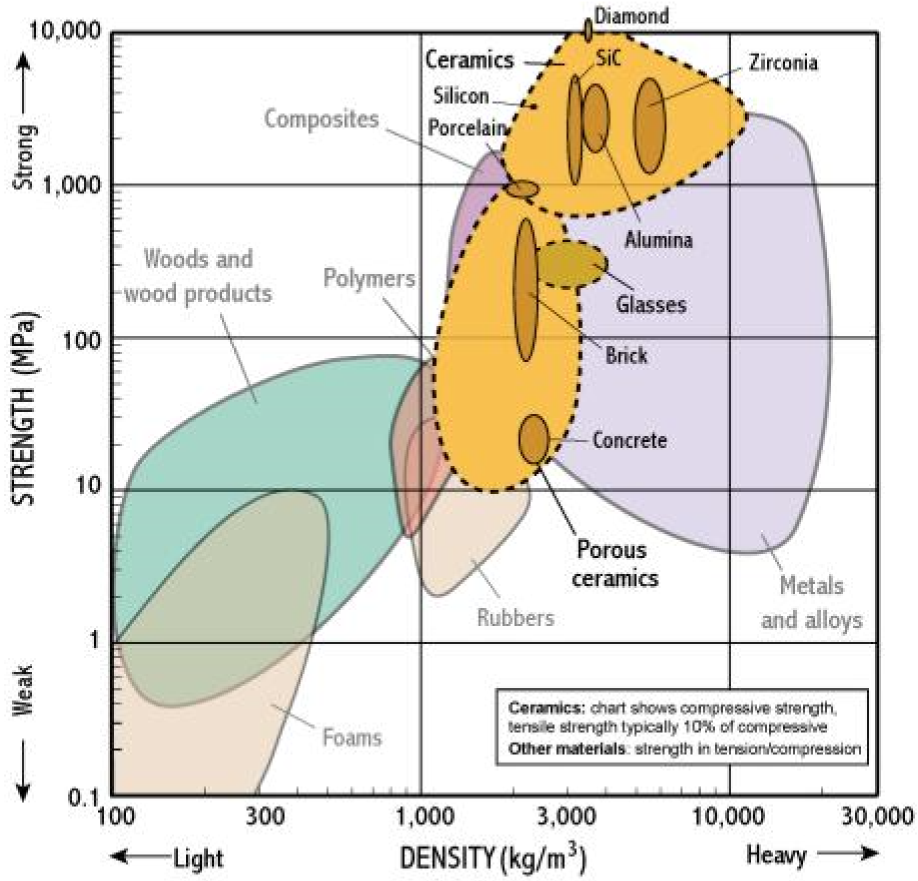

Figure 4.3: Strenth vs Density. Source: Google (2016).

4.2.5 Ductility.

This aspect is crucial during the manufacturing phase as the implant needs to be formed into the required shapes (Hermawan, Ramdan & Djuansjah 2011).

4.2.6 Hardness and Wear Resistance

Hardness is linked to wear resistance of the implant. It is crucial for the hip implant applications to have a material that hardly wears so as to have low incidences of osteolysis.

4.2.7 Biocompatibility.

It is also worth noting that the biocompatibility of the biomaterials is very important as it is a safety issue and must treated with uttermost seriousness. In the USA the

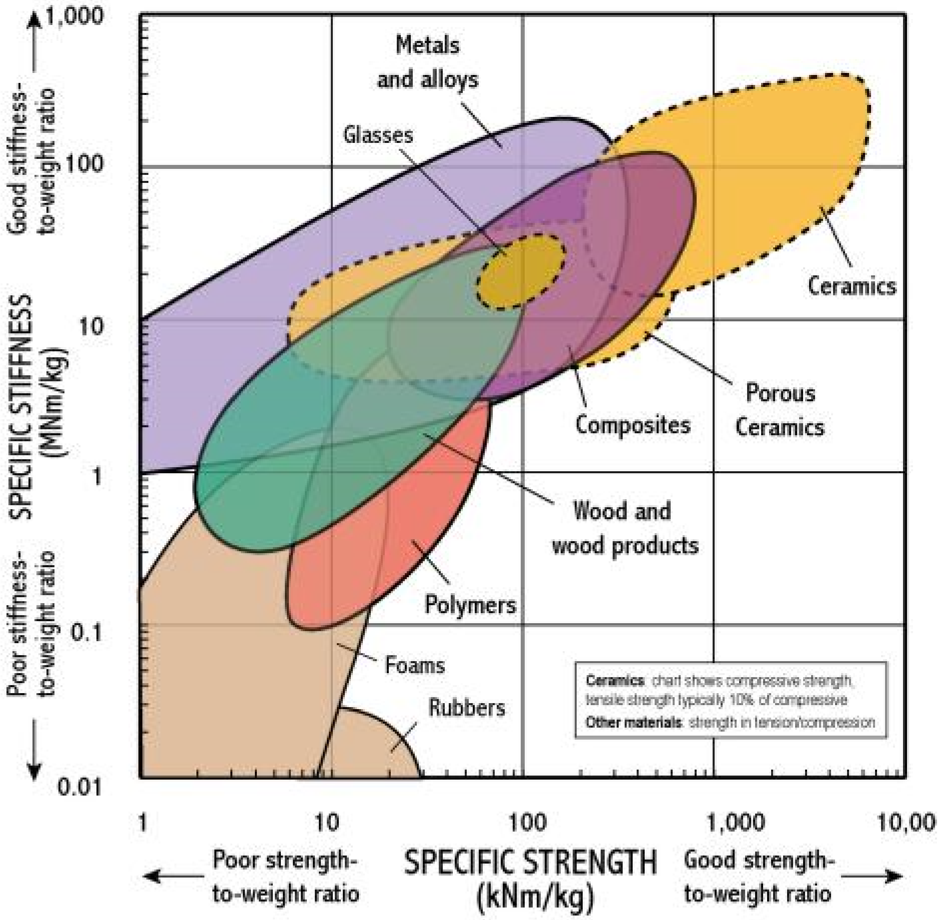

Figure 4.4: Stiffness vs Strength.Source: Google (2016).

FDA controls orthopaedic implants development and use while internationally the ISO standards must be adhered to minimise the risk of improper implants finding their way into patients. Of particular importance is the ISO 10993 that has been updated as includes requirements specifically about the chemical stability of prosthetics in the biologic host environment.

Moreover, biocompatibiliy is one of the most crucial qualities demanded of the hip implants for the longevity of the hip joint bearing. In simple terms biocompatibility means the acceptance of the artificial implant and/or its associated debris by the surrounding biological tissue or by the body as a whole without negative reactions. That is, the implant does not irritate the surrounding tissue, incite inflammation, and cause allergic immunologic response and cancers (Hermawan et al. 2011). In view of this fact the ability of a metal to resist corrosion becomes a very important consideration when selecting a material for the hip as it greatly affects the longevity of such a device. In some cases it is not possible to find all the necessary qualities in one material, hence the need to combine the material elements until a better product is achieved. This is why Titanium alloy (Ti6Al4V) is coated with hydroxyapatite (HAP) or carbonated apatite (CAP) which are biologically friendly materials that induce bone growth to achieve good implant fixation. Additionally when coated with HA it achieves rapid osseointegration such that in four weeks only there is 90 percent of implant-bone contact (Hermawan et al. 2011). HAP and CAP are ceramics used on Titanium which is not fully biocompatible and the same time ceramics on their own lack fracture toughness.

Furthermore to surface coating biomaterials can have their surfaces treated with other elements to enhance wear and corrosion resistance. For example, Titanium and Cobalt-chromium alloys can be treated with Titanium nitrides at the surfaces to be biocompatible in addition to improvement of corrosion resistance.

4.2.8 Corrosion Resistance

. Corrosion is a form of wear that is closely associated with bio-incompatibility because of the materials used which tend to trigger negative biological response. Having a material that is corrosion resistant is crucial because it reduces the chance of biological immune response and inflammation. A material that is not resistant to corrosion usually accelerates rate of wear as surfaces become rougher from miniature pits. This is common in most metals when subjected to the biologic environment where in addition to pitting, fretting also takes place due to surface stresses from cyclic loads (Aparicioa, 2003) cited in (Hermawan et al. 2011).

4.3 Non Metals

The prosthetic materials can be classified into two main classes which are metals and non-metals. Several materials have been trialled since the beginning of hip replacement. In the early days of hip replacement, materials like ivory, and glass have been tried but without success. Nowadays there have been great improvements in the materials used mainly due to continuing researches being conducted worldwide. One such material that has become the flagship of hip replacement material upon which every prosthetic material is measured against is the polyethylene, which has evolved to be known as UHMWPE since the sixties when it was introduced as the low friction arthroplasty (LFA). In the construction of the hip joint bearing components , the polyethylene element forms the liner that is sandwiched between the hard components, the femoral head and the acetabula cup metallic backing (or shell). The polyethylene liner can also be used in combination with other materials like ceramics.

4.3.1 Ultra High Molecular Weight Polyethylene (UHMWPE)

This is a type of a thermoplastic whose structure consists of long chains that help it carry the loads of the hip joint. It is manufactured by polymerization process where powders of UHMWPE are moulded directly into a desired product.

Historical development.
It was first used in the 60s by Sir John charnley in the hip and gained momentum throughout the 70s. There have been unsuccessful attempts to modify it by blending the polymer powders with carbon fibres until the late 90s where it was successfully crosslinked.

The production method involves synthesizing monomers of the polyethylene to the order of 250000 per unit molecule. This is done through compression molding under a catalyst and ram extrusion, gel spinning and sintering (Croop & Lobo 2010). Gel spinning is aimed at strengthening the UHMWPE, extruding a heated UHMWPE gel through the air and then cooled in water. This process eliminates entanglements and increases orientation which is associated with strength (Saini, Singh, Arora, Arora & Jain 2016).

The polyethylene chains which are very long are all aligned in one direction and the longer the chain is, the stronger it becomes. The intermolecular (Van de Waals) bonds between these chains are weak but due to large number of overlaps from the longer chains improves it shear strength as well as its tensile strength. Owing to the above, the polymer can achieve parallel orientation of greater than 95% and crystallinity level range from 39% to 75%. Due to the Van de Waals bonds, the polymer has poor heat resistance qualities giving it a low melting point of 136 °C however this is good enough for the hip replacement applications. The long chains are the inter-molecular bonds that give it the toughness quality and high impact strength compared to the thermoplastics. The treatment of UHMWPE in the annealing process involves heating it to about 138 °C and then cool it slowly at a rate of 5 °C per hour to a temperature of about 65. It is then wrapped in an insulating blanked and brought to for 24 hours until it is at room temperature, (Saini et al. 2016). This is a treatment for improving creep resistance qualities.

In addition to other characteristics that make the UHMWPE attractive to the orthopaedic applications include its non toxicity and fair resistance to corrosion (except oxidizing acids) because of the absence of the chemical groups like hydroxyls, esters, or amides. That is another reason why it is resistant to water, moisture, ultra-violet radiation or micro-organisms attack.

UHMWPE is also known to have low coefficient friction because of its self lubricating attributes and has highly resistant to abrasion. The material is easily workable and therefore can be easily manipulated during production.

UHMWPE however suffers from a number drawbacks that include lack of superior mechanical properties comparable to metals and it triggers adverse response from the immunity system of the body that manifests as inflammation of the surrounding joint soft tissue.

After the initial success in the conventional UHMWPE the problem of wear was troubling. As a solution to wear problem, the material was highly cross linked thus improving its hardness qualities but there were reports of surface cracking and mechanical failures that followed. The reason was the altered crystalline structure of the UHMWPE due irradiation which affected the mechanical properties (Mattei, Puccio, Piccigallo & Ciulli 2011).

Another attempt at improving the performance of the UHMWPE was re-crystallization under high pressure and gamma irradiated in air. This attempt gave a product that was inferior to the original UHMWPE. Nowadays the UHMWPE is highly cross linked with gamma electron beam radiation (50- k105 kGy) and then heat treated to give it better oxidation resistance. Furthermore there have been efforts to add antioxidants particularly vitamin E to further improve oxidation resistance without further heat treatment.

4.3.2 Peek.

According to (Green & Schlegel 2001) the application of peek in orthopaedics as a biomaterial started in 1998 when it was sold as PEEK-OPTIMA. This was after peek was tested for conformance to ISO 10993.

Polyetheretherketone, or Peek is an organic thermoplastic which posses the following qualities that makes it unique in the orthopaedic applications. It became possible to eliminate the imaging obscurities where it was used because of the ability to view tissue and bone changes whereas metallic implants are usually obscured and have shadows on x-ray, CT scans or MRI images that overlap to important areas being examined (Green & Schlegel 2001). Therefore the transparency of peek to CT scans and x-ray makes the job easier for surgeons to make accurate assessments.
Peek is also biocompatible and its application is free of metallic poisoning since it eliminates metals altogether. Like UHMWPE, peek is easily manipulated and can be modified easily into any desired finished shape during manufacturing stages. Peek has also outstanding low coefficient of friction, high strength to ratio, wear and abrasion resistance and high resistance to hydrolysis effects of ionizing radiation (Kurtz & Devine 2007). In addition it can be repeatedly ionised by ionization steam, gamma and ethylene oxide with thus minimizing the chances of infections.

The mechanical properties of peek are greatly enhanced by addition of other materials making it into a composite. It can be mixed with filler material namely glass fibers, or carbon fibers that give it improved strength. The resultant composite material has the stiffness and other qualities close to that of a natural human bone, therefore additionally it helps prevent stress shielding of the surrounding bone as mentioned before (Green & Schlegel 2001).

According to the table 4.2 above peek material can be treated with carbon fibres making it a composite material with superior qualities for the application as hip joint material. The figure 4.5 compares prosthetic material stiffness. It can be seen that carbon fibre reinforced peek has the stiffness values close to those of the femur.

Table 4.2: Variation of mechanical properties with varying fibre concentration by weight percentage.

Property	20%	25%	30%
Tensile strength	200	209	228
Flexural Strength	288	290	324
Flexural Modulus	15	17	19
Notched Impact	11	9	9.5

Source (Green & Schlegel 2001).

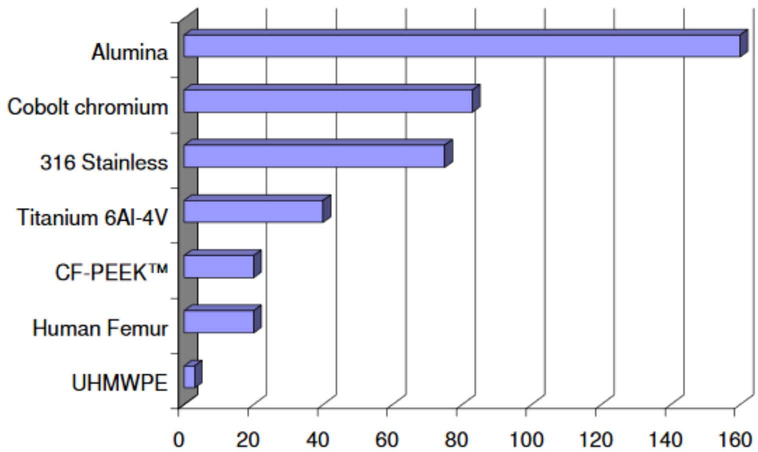

Figure 4.5: Biomaterials stiffness comparison

4.3.3 Ceramics

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Ceramics are polycrystalline materials which most of them are made out of metallic compounds. The most common ceramics used as biomaterials are aluminium oxide Al_2O_3 known as Alumina, zirconium oxide ZrO_2 also known as Zirconia, and silicon nitride Si_3N_4. According to (Kurtz & Devine 2007), zirconia has been abandoned as a biomaterial following a series of catastrophic failures and has left alumina and silicon nitride being used for acetabula and femoral components. These ceramics are further treated with Hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$ to improve the oseointegration of the implant to the bone aggregate.

Ceramics have very good compression strength but poor resistance to tensile forces Ceramics are bioinert materials and have considerable strength, however they have low ductility and are highly brittle. They are also considered the most expensive bearing components (Mattei et al. 2011).

Ceramics are extremely hard, biocompatible and have better wettability properties but have low fracture toughness which makes them fail suddenly without warning. Their structure makes it possible to achieve high manufacturing accuracy and smoothness and have very low wear debris in operation because of the high resistance to scratching or abrasion. Ceramics become less attractive because their sudden catastrophic failures and squeaking noise in vivo. However another type of ceramic material that is used to make silicone nitride tends to have better performance particularly in fracture toughness and resistant to micro-crack propagation than Al_2O_3.
Silicon nitride has a crystalline structure with the alpha and beta phases being the most common ones. The beta phase has longer has longer grains, are tougher but are softer than the alpha phases. Silicon nitride has very low coefficient of friction in water base lubricants, therefore has low wear rate. It has been reported that the only wear that takes place is by tribochemical dissolution of the material into the lubrication itself without mechanical action (Olofsson, Grehk, Berlind, Persson, Jacobson & Engqvist 2012). This is the wear that releases solid particles into the environment. Another claim is that the silicon nitride head articulating against silicon nitride acetabulum in water based lubricant produces silica (SiO_2) which is amorphous (or unstructured). Silicon nitride is also

said to be bioinert and biocompatible. Furthermore (Olofsson et al. 2012) makes clear the benefits of Si_3N_4 and silicon ions when considering the its chemical properties and its stability in the biological tissues. It degrades in phosphate buffered saline solution silicon ions can be incorporated into the bone tissue or stimulate bone formation. Silicon nitride is also known to dissolve in blood serum, gastric juice, and synthetic biochemical media at ph 7.4 without known adverse effects. All this supports its bioinertness and biocompatibility. If all of these qualities can lead to reduced wear and less adverse biological response, definitely it achieves the goal of having long implant longevity i.e. the revision surgeries are significantly reduced.

4.4 Metals.

Although metals were initially applied extensively in building machines that are non human, recently a handful have found their into orthopaedics. Generally metals are favourable candidates in the biomedical industry because of their superior mechanical properties which include good yield strength and modulus of elasticity which make the ideal for weight bearing purposes. The other advantage of using metals is that good surface finish is achievable and sterilization using the common methods is also possible. Unfortunately for the hip joint applications these qualities are superseded by need to have materials that are biocompatible as most of these metals susceptible to wear. The attached diagram compares the weight to strength ratio of the biomaterials as well as stiffness to weight ratio. This a crucial consideration in the selection of the biomaterials that are suitable to replace the removed femoral head and the acetabula shell. Table 4.3 compares the biometals properties that are crucial in hip joint applications.

The most common metals that are used in the hip joint arthroplasty are alloys of Cobalt and Chromium, austenitic stainless steel 316L, and Titanium Ti_6Al_4 (**?**).

4.4.1 Cobalt-Chromium Alloy

.

Table 4.3: Mechanical properties of metals used in medicine.

Characteristics	Stainless Steel	CoCr alloys	Titanium alloys
Stiffness	High	Medium	Low
Strength	Medium	Medium	High
Corrosion resistance	Low	Medium	High
Biocompatibility	Low	Medium	High

Source (Bombac, Brojan, Fajfar, Kosel & Turk 2007).

The other material that attracted interest because of the theoretical advantages is the metallic alloys of Chromium, Cobalt, Molybdenum, and Vanadium which hard wearing and provides superior weight bearing qualities as well a good fracture toughness. This makes them quite suitable to be used in young and active patients.

This alloy can be made by casting method. Cobalt provides the hardness and wear resistance while Chrome is responsible for corrosion resistance through the formation of a protective and passive oxide surface, the chromium oxide (Hermawan et al. 2011). Additionally, the cobalt element also tends to induce brittleness in the alloy which makes it susceptible to fracture especially of the femoral necks. This is circumvented by addition of other alloying elements like Molybdenum that contributes to the strength and corrosion resistance of the alloy (Saini et al. 2016). Even though there has been achievements in the reduction of wear of the this alloy, it is the high wear rate in the initial period that leads to the release of fine and small amount of debris that reacts with the surrounding tissue causing metallosis and other joint degradation effects that demand revision surgery as a corrective measure.

4.4.2 Titanium

.

Titanium is classified into two grades. There is commercially pure Titanium (Ti CP) that is further grouped into 4 grades according to the oxygen content present. Grade 1 has the least oxygen content of 0.18% (the least content) and grade 4 having 0.4% (the most) (Saini et al. 2016). The other constituent elements are iron, aluminium, and vanadium. These elements added in very small quantities which are varied in their concentrations that determine the different grades in the end. The iron element is responsible for corrosion resistance, aluminium is induces light weight (because of its low density) and increased strength while the vanadium acts an aluminium scavenger to prevent corrosion. The crystal lattice of titanium is close packed (alpha- phase a-Ti) and it is known that at temperatures above 880°C the alpha phase changes to bet- phase which is body centred cubic lattice. This means Ti is a dimorphic metal i.e. the material exists in two phases.

Similarly to chromium qualities, its surface also quickly forms a protective oxide layer TiO_2 thus capable of repairing itself when damaged. That is why titanium is highly resistant to chemical attack, pitting and corrosion (Hermawan et al. 2011). This layer becomes coated with proteins such that the body begins to see it not as a foreign material but part of the body. The protein is called osteopontin (OPN) and it binds to (HA) and encourages osteoclast and osteoblast adhesion. Furthermore the oxide layer offers protection against bacterial infection and maintains overall tissue integrity and bio-mechanical strength during bone remodelling (Hermawan et al. 2011).

Other titanium attributes that make it a favourite in the biomedical application of the hip joint are its modulus of elasticity close that of a bone, easy availability, strength weight ratio and catalytic capabilities for bone growth. Titanium can be easily worked on without loss of mechanical properties.

On the contrary titanium alloys come short as they have high wear rate and low sheer strength in comparison to other biometals. Therefore they are mainly used to make prosthetic stems and acetabula cup shells (metallic backing). These are areas of bone interface where there is need for bone growth into the implant.

4.4.3 Stainless Steel.

Stailess steel has got (12-15 %) nickel, (18 %) chrome and (2 %) manganese as a major elements and of these nickel is known to cause allergic reactions to some patients (Bombac et al. 2007). According to (Saini et al. 2016) stainless steels have high galvanic potentials as well as high corrosion resistance which leads to galvanic coupling and biocorrosion if stainless steel is used together with Titanium alloys. In short this is a scenario where two metals that are active (reactive) in the presence of an electrolyte but one is more reactive than the other. The more reactive one becomes the anode and loses material (ions) to the cathode one (less reactive one). The stainless steel 316L grade contains 18%, chromium by weight, 8% nickel but has also molybdenum and carbon for improvement of corrosion resistance (Hermawan et al. 2011) This alloy is corrosion resistant because of the chromium oxide layer that protects the rest of the metal underneath it from further attack.

4.5 Decision Matrix.

As it was revealed through the evaluation process of the biomedical materials that there are a mix of competing materials that can potentially do the job, it is important to come with strategy for material selection. According the nature of the solution to the problem of hip joints wear, there have been design considerations that have been drawn up based on the preceding sections and are listed in order of importance below. These criteria form the basis for the material comparison in the decision matrix to come with the best materials.

- Biocompatibility.
- Wear resistant (hard to scratching and abrasion).
- Fracture toughness - not brittle.
- Fatigue and creep resistant.
- Good yield strength to sustain the loads of everyday activities.
- Light density (good weight to strength ratio).
- Non corrosive (the ions released from the articular surfaces are nontoxic reactive with the surrounding biological material like bone and muscle)

The technique that has opted for the purpose of material selection is the decision matrix which will incorporate the design criteria mentioned above. This is a tool to use for comparison of materials so as to make decisions about which material to select. The process is based on logic and is free from bias which means the comparison criteria have been drawn up in accordance with hip joint functional requirements and the problem objectives.

These design criteria are then weighted and scored according to how crucial they are to the solution requirements. The materials with highest tally is then selected as the favourite candidate for building the proposed design.

The main goal of material selection is to use a material that satisfies the design specification and guarantee product functionality. In this case the materials are supposed to be primarily biocompatible as it may be impossible to eliminate wear all together. The materials should also be wear resistant in order to avoid the creation of wear debris that has been shown to have adverse biological reactions around the hip implant. The first step will be to investigate the qualities of the bone materials to be replaced so that there is no mismatch which can lead to stress shielding, another adverse medical condition that lead bone resorption and eventual implant loosening. With reference to material data sheets and Ashby plots attached in figures from 4.1 to 4.4, it can be observed that the two kinds of bone material found around the, cortical bone (femoral bone) and the cancellous bone (pelvic bone) have slightly different mechanical properties but are all positioned closely with Titanium alloys. Table 4.1 shows the mechanical properties of the bone in support of the above. In this research it is important to note that the bone interfaces with metallic implant in the pelvis where the metallic backing is used and in the femoral cortical bone where the stem is inserted. This then becomes important to have a material that is not very different from the bone matrix which has the properties shown in the table 4.1.

By application of the decision matrix, the materials are ranked from 1 (poor) to 5 (very good). The following materials have selected mainly due to their biocompatibility, wear and corrosion resistance which have been considered the most critical requirements in pursuit of a solution to prosthetic wear.
Below is table 4.4 that shows the weights assigned to the design criteria and the final scores for each material. It can be observed from the scores that carbon fibre reinforced peek has the highest score, followed by silicon nitride and thirdly is Titanium alloys. From this analysis peek has been selected to make the acetabula liner with the metal backing out of Ti-6Al-4V alloy. This alloy is also selected to make femoral stems owing to its mechanical and biocompatibility qualities. Silicone nitride has been selected to manufacture the femoral head due its biocompatibility and improved fracture toughness

Table 4.4: The Decision Matrix.

	Materials						
Properties	Si_3N_4	Al_2O_3	Peek	UHMWPE	S/Steel	Ti-6Al-4V	CoCr
Density	4	4	5	5	3	4	3
Elasticity modulus	4	3	4	2	4	4	4
wear resistance	4	4	4	3	3	2	4
strength/weight	4	2	5	2	3	5	3
corrosion	4	4	5	5	4	4	3
compression	4	4	4	3	4	4	4
Biocompatibility	5	4	5	3	1	5	1
Total	**29**	**25**	**32**	**23**	**22**	**28**	**22**

qualities.

4.6 Chapter Summary.

It is very important to combine the following material attributes to achieve a low wear rate bearing couple. These are biocompatibility, corrosion resistance, fracture toughness, low friction, wear resistance, strength to weight ratio and ductility. It is also very crucial to have materials whose properties are close to tat of the bone. From decision matrix silicon nitride has come up as the favourite material for the femoral head while Titanium alloy has been selected for the stem. Carbon fibre reinforced peek has been selected as the material candidate for acetabula cup.

Chapter 5

Tribology.

5.1 Chapter Overview.

It is important to explore how friction contributes to wear of the hip joint bearing surfaces in order to minimize or eliminate its effects by analysing the tribology of the articulating surfaces. This section of the project aims to solve the problem of wear by exploring the mechanism of friction friction and factors associated with it. These include the effect of coefficient of friction and the importance of lubrication in the efforts to reduce wear due to friction. The chapter concludes by comparison of predictable wear of different materials of different coefficient of friction.

5.2 Modes and Wear Mechanisms of the Hip Joint.

Tribology is defined as the study of friction, wear and lubrication as two surfaces slide past each other (Hosseinzadeh et al. 2012), (Varshney 2016). Wear of the hip joint prosthesis is primarily as a result of mechanical and/or chemical action. This research project is going to focus on the former because that is where friction is most prevalently active. When two body surfaces are in dynamic contact, there is resistance to the sliding motion due to the dynamic frictional force, which is less than static frictional force because it requires greater forces to start the sliding action than to maintain it. Frictional force is dependent on the coefficient of friction of material, which is a dimensionless number and also a ratio of tangential force F_t to normal force F_n.

This is shown by the following equation.

$$\mu = \frac{F_t}{F_n} \tag{5.1}$$

Therefore

$$F_t = \mu F_n \tag{5.2}$$

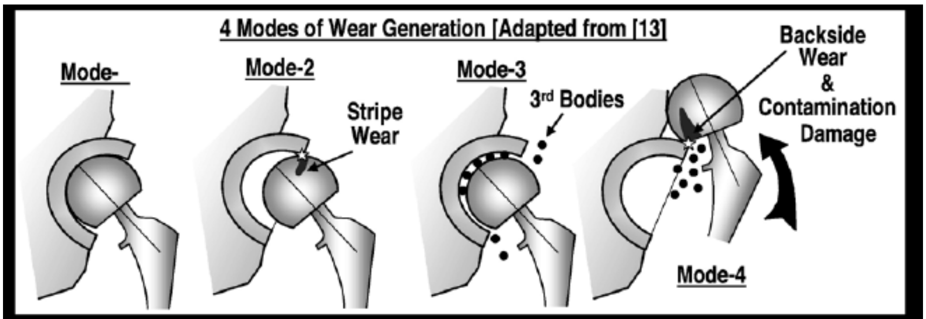
The magnitude of the applied force or the normal force and in this case the joint reaction force influences to a greater extent the nature of frictional force. However, it can also be deduced from the formula 5.2 above that the smaller the value of the coefficient of friction means the smaller the frictional force that tends to influence friction hence a material with low or negligible coefficient of friction is most ideal for hip joint bearings application. Although the tangential force contributes to frictional wear according to ASM handbook, its application is dependent on the material type and the conditions prevailing at the hip joint surfaces. Primarily its application is not influenced by the sliding velocity and the apparent area of contact.

The coefficient of friction is also influenced by the nature of the contact surfaces. There is apparent contact area which is the theoretical area of contact. This is different to true area of contact. All surfaces no matter how smooth they may appear to the naked eye, have irregularities (asperities or peaks and valleys) when viewed at microscopic level and these peaks from each of the contact surfaces form the real or true contact surface area (the contact surface topography). This is inherently a direct result of the manufacturing techniques used to make the implant. Rough surfaces usually result in high frictional rates as the loads are acting on the true contact area that is less than theoretically envisaged. The net result is the increase in contact stresses which leads to these surface peaks breaking off thereby aggravating the situation as wear evolves to include other modes and kinds of wear. Conversely any means that can improve the surface finish of the bearing material goes a long way in reducing frictional wear.

The other factor that is key to minimising coefficient of friction and wear of the hip joint besides the the surface roughness of material is the type of materials that are in contact. Some materials tend to from miniature bonds as the come into contact or tend to stick to each other. As sliding motion starts to to take place, these bonds that tend to keep the surfaces locked together have to give in in cyclic and plastic deformation of the contacting spots on the real contact area. This mechanical action of deformation leads to progressive loss of particulate debris from the bearing surfaces. The adhesion of the surface molecules or atoms to other counter-body also adds to friction force as the atoms or molecules tend to react chemically (forming bonds) and thereby raising the contact stresses.

5.2.1 Types of Wear of the Hip Joint

Figure 5.1 below illustrates the modes of wear of the hip joint prosthesis.



	Description of Wear Process for Metal-on-Metal
Mode-1	Normal polar wear of primary bearing surfaces as intended by the designer
Mode-2	One bearing surface rubbing against a non-bearing surface, e.g. joint micro-separation wear, where the head rubs against the cup rim
Mode-3	Third-body abrasive wear of the head and cup, e.g. bone particles and porous coating particles
Mode-4	Two non-bearing surfaces rubbing together, e.g. neck impingement and dislocation

Figure 5.1: https://www.researchgate.net/figure/5322077

Adhesive Wear.

Coincidentally there are four modes of wear of the hip as well as four types of wear as shown by the figures 5.1 and 5.2.

Adhesive wear takes place when articulating surfaces come into contact under pressure forming miniature bonds in between them. As stated above, when sliding motion begins, if these bonds are stronger than any of the articular surfaces, the surface breaks off and lines the stronger material, thus changing the structure of the interface. This action produces micro-particles and if they are larger than the bearing clearance become entrapped in the interface and become abrasive, thus causing more damage to the bearing surfaces (Hosseinzadeh et al. 2012).

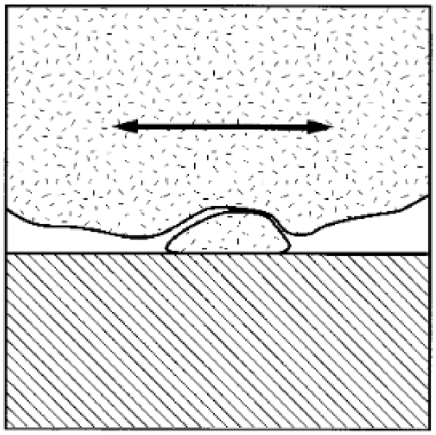


Figure 5.2: (Hughes, 2012)

As it can be seen from figure 5.1, adhesive wear comes under mode 1 in that it takes place between the articulating (intended) surfaces of the hip joint. However it should remain an important point to reduce the frictional wear at these articulating surfaces. Mode 3 begins to exist once there is generated wear debris in-between articular bearing surfaces.

Abrasive Wear.

Abrasive wear also found in mode 1 occurs when the removed material from the articulating surfaces become entrapped in the bearing interfaces wearing the surfaces even further. With time abrasive wear degenerates into third body wear and mode 3 as well. This is illustrated by figure 5.3.

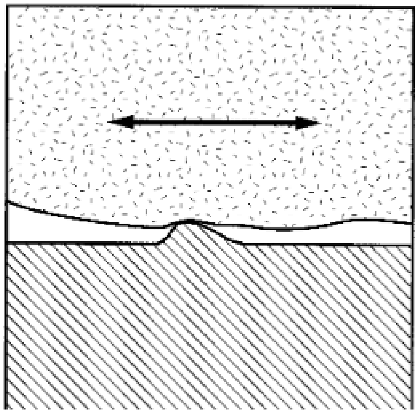


Figure 5.3: (Hughes, 2012.)

Fatigue Wear.

Fatigue wear is a result of cyclic sliding and rolling by loaded bodies. The repeated mechanical action leads to propagation of micro-cracks that run parallel and perpendicular to the articular surfaces. Eventually these cracks form shallow pits as a result of delaminations and flaking off thereby generating wear debris in the process. The action also leads to increased bearing surface roughness and ultimate fracture from crack progression. This is shown in figure 5.4.

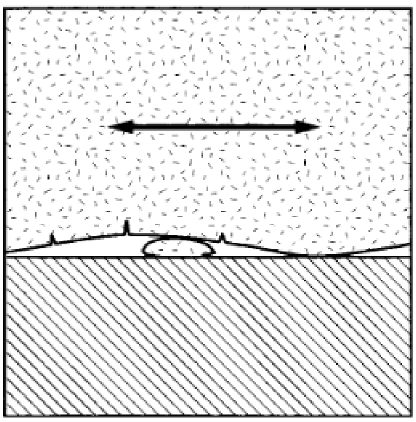


Figure 5.4: (Hughes, 2012).

Third Body Wear.

Third body wear occurs when the hard body particles become embedded in the soft material, for example when the metallic particles become embedded in the polyethylene material surface and begin to act like hard asperities against the metallic femoral head. Third body wear is also found under modes 1 and 3 as illustrated by figure 5.5.

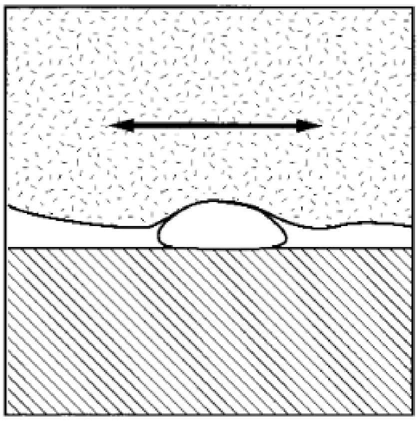


Figure 5.5: (Hughes, 2012).

Corrosive Wear.

Corrosive wear takes place as a result of chemical attack and mechanical action. It can also be seen from figure 5.1 that modes 2 and 4 are direct result implant loosening and dislocation as a result of impingement.

Figure 5.6: (Hughes, 2012).

Mode 2 This takes place between the intended surface and another non-intended surface i.e. between the femoral head and the UHMWPE metal backing. This could be due to wear of the UHMWPE liner exposing the metal backing to the femoral head.

Mode 4 This is articulation of non-bearing surfaces i.e. non-intended secondary surfaces when the femoral head locks and jams into acetabula such that it articulation takes place between the surface outside it and the metal backing.

5.2.2 Lubrication

Lubrication of the hip joint is very crucial for the reduction of the frictional wear. Therefore having the synovial fluid as the lubricant that fulfils this purpose in vivo, it becomes important to evaluate the behaviour implant materials in vitro so as to predict their performance in vivo. The implants are usually rigorously tested experimentally in various lubricating media that are similar to synovial joint fluid. Through such processes, ceramics have been established as the biomaterials that posses excellent lubricating characteristics because of their wettability qualities. It is during these vitro experiments that implant materials are assessed on how effectively they can form and maintain effective lubricating film thickness. This aspect is dependent on the Somerfled number which is basically a measure of the wettability of the material. The higher the number the thicker the film the material can form (Hosseinzadeh et al. 2012).

The range values of 1 to 3 show the that there is mixed film lubrication, with anything less than 1 means there is boundary lubrication while anything greater than 3 implies the fluid film is greater than the height of the asperities on the articulate surfaces (Hosseinzadeh et al. 2012) and this is shown in the Stribeck curve in figure 5.6 below. The Steribeck curve depicts 3 phases of lubrication i.e.

- . When the thickness of the fluid film is less or equal to the average surface roughness-there exists boundary lubrication. Asperities under this regime are in constant contact all the time, therefore this is not ideal for the bearings. Unfortunately this is that case in most rough surface bearings. The way around it is to increase bearing tolerances and/or surface finishes.
- There is transition phase where there is mixed lubrication (ML). This is a combination of fluid film and boundary lubrication and the fluid film thickness is increased. The coefficient of friction is reduced until the third phase where it is full film established (FFL).

- Full film lubrication. This is where the articulating surfaces are completely separated by the fluid film also known as the hydrodynamic lubrication and is further categorized as the (a) hydrodynamic lubrication, (b) elasto-hydrodynamic lubrication, (EHD).

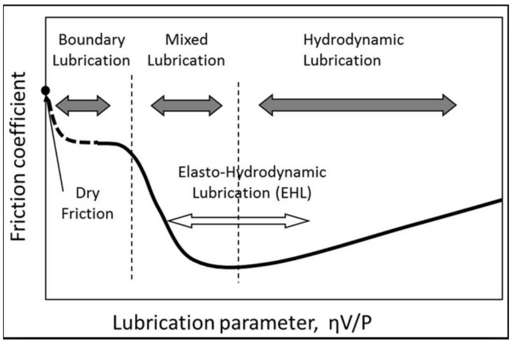


Figure 5.7: (Source: Wikipedia, 2016).

Hydrodynamic lubrication is when the joints surfaces conforming whereas the elasto-hydrodynamic, the surfaces are non-conforming like in the artificial hip joints implant. The former are the natural joints. EHD exist when the pressure in the fluid film is high enough to cause deformation of the asperities of the articulating surfaces, this means even if the film thickness is less than the asperities height a total separation of the articulating surfaces may still be achievable. In vivo circumstances where synovial fluid is in use, metal on polyethylene hip joint surfaces articulate in the mixed lubrication regime. Hard on hard bearings work in the EHD and mixed lubrication. It is observed on the contrary that there is a change to full film lubrication.

5.3 Chapter Summary.

Low coefficient of friction is is an important factor in curbing wear due to friction because, besides generating low volumes of wear debris there is low risk of implant loosening. low friction coefficient in addition is associated with low surface stresses according to (Hosseinzadeh et al. 2012).

Although many researches and trials of many bearing materials combination over the decades have established the hard on soft combination (particularly the MoP) as the favourite with surgeons and patients, there has been some shortcomings as shown in the literature review. Nevertheless, the efforts and results act as a yardstick by which other future work is referenced.

Chapter 6

Finite Element Analysis.

6.1 Chapter Overview

This chapter presents the finite element analysis method and its application in the stress analysis of the assembled models of the hip joint. There is going to be frequent reference to the biomechanics section and furthermore the chapter explores the hertzian contact method as a validation technique to the implementation of the finite element analysis. This in order to reveal the link between the variation of femoral heads diameters to the to contact stresses. Following this evaluation is the design optimization so as to avoid over or under designing with the preferred choice being recommended for further testing in vitro.

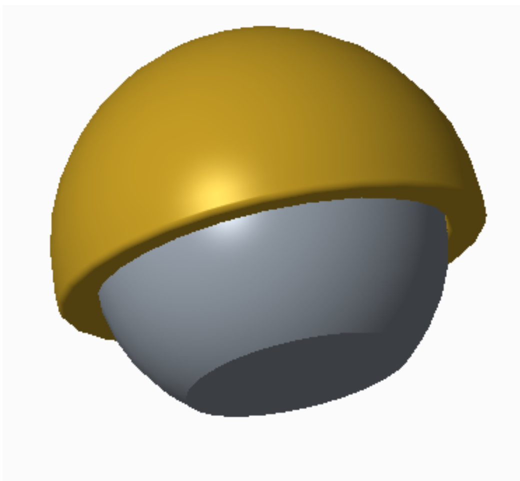
6.2 Finite Element Analysis

Finite element analysis also known as finite element method is a powerful computational tool that uses numeric techniques to solve complicated engineering problems. As the name suggest the process involves subdividing the model in to finite elements upon which the governing equations are applied to, with the results of the whole model continuum being combined to give outputs. The out puts include maximum stress, displacements, deformations and vibration frequencies (that is in case of modal or dynamic analyses). The software used in the finite element analysis is Creo 3.0 simulate and has three stages through which the model is analysed, which are pre- processing, processing and post processing.

All the analysis work is carried out in SI units to maintain consistency and minimize errors. In this study, stress distribution and displacements (deformation) are of interest as they contribute to fatigue. As a general rule for consideration when performing FEA it is important to consider the simplest type of FEA that will achieve the desired objectives and avoid complicated meshes and in this case autogem has often been used. It is recommended to use the coarsest mesh that can capture the required physical entities and reduce processing time. The other point that was considered was the aspect ratio, which is the ratio of the largest element dimension to the smallest. A value of less than 3 is regarded as ideal while a value close to 10 should sound an alarm. This means that the elongated elements should be avoided if possible. In this research, though the aspect ratio value used was around 5 the results were satisfactory.

It should be noted that the analysis was restricted to the contact surfaces of the femoral head and the acetabula cup only because that is the focus of frictional wear, hence the generated model showed the assemblies of the ball and the cup liner. The analysis was performed on the following MoM bearing diameter heads from 28 mm, 36 mm, 42 mm, and 50 mm to find out the variation of contact stresses with increasing bearing diameters as well changing clearance values. The clearance values used are zero, 24 μm and 30 μm for each bearing size. The general bearing parameters were derived from the metafix model which is similar to many designs in the industry that are spherical in shape (Coringroup 2016). This illustrated in figure 6.1.

Figure 6.1: General structure of the bearing created in Creo parametric.



In the pre-processing stage, the model is created with specified dimensions, assembled

Table 6.1: material properties and material specifications.

	Peek	Silicone Nitride
Compressive strength	20 MPa	2760 MPa
Tensile strength	21 MPa	434 MPa
shear strength	33.1 MPa	-
Modulus of Elastcity	0.69 GPa	317GPa
Poisson's Ratio	0.46	0.23
Density	940 Kg/m^3	310 Kg/m^3

Source: (Huston 2009) and (Gilbert 2011)

and material properties are assigned as seen in the table 6.1 above. The materials that were assigned to the model were taken from the decision matrix section which are ceramic (silicon nitride) for the femoral head and the carbon fibre reinforced peek for the liner.

In most cases it is very difficult to represent the real physical environment and therefore some assumptions are specified while mindful of the need to maintain accuracy of results. The following assumptions were adopted for the boundary conditions during the analysis of the model:

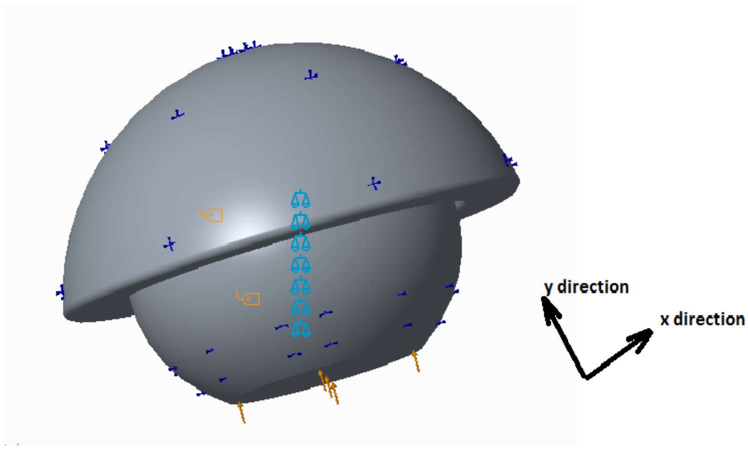
- The materials are assumed homogeneous and surface treatments (coatings) are not considered.
- Static loading is considered.
- No penetration between parts surfaces.
- Contact between femoral head and the inner acetabular line surface is non adhesive.

In Creo Simulate with the boundary conditions are assigned under the determined assumptions the model would be ready for analysis.

As can be seen from the figure 6.2 below, the model is loaded symmetrically in the Y-plane where the load is 3500 N that has been derived from the biomechanics section.

The peek liner is solidly fixed in the acetabula metallic shell hence for the finite element analysis the displacement constrains are fixed in all directions while the the femoral head is constrained in the Z and X directions but is left free in the Y direction. The contact

Figure 6.2: showing constrains and loads



between the peek liner and the femoral head surfaces has got finite friction set at 0.15 of which the value is derived from online material data sheets attached in the appendix B.

Initially the autogem meshing is used where number of elements used is 257. PTC Creo simulate uses a P meshing method i.e. the polynomial in the calculations of the displacements and stress and then updates for each element. In the second run where the mesh pattern was updated to higher number of elements for accuracy, the computational time increased tremendously depending on the capabilities of the computer in use. In the second run the number of elements used is 532.

Next is the processing phase which involves the analysis of the model where the static option is selected. The convergence is set to singlepass adaptive with no penetration between parts.

The post processing is crucial because the interpretation of results need to be accurate as decisions in the problem solving depends on it. The output are in form graphs, plots or diagrams showing the variation of stress, displacements and deformations. Also from the results the decision can be taken to alter the material type, thickness or the safety factor.

Above and below are the two extreme outcomes from the first analysis where there was polar and equatorial contact of the hip joint assembly as shown in figures 6.3 and 6.4 respectively. Equatorial contact was a result of zero contact clearance and was common with edge loading on the femoral head and rim loading on the acetabula cup. Polar contact occurs as contact takes place at the pole area of the femoral head as the mating parts begin to have clearance or the difference in diameters. However it should also be

Figure 6.3: Equatorial contact.

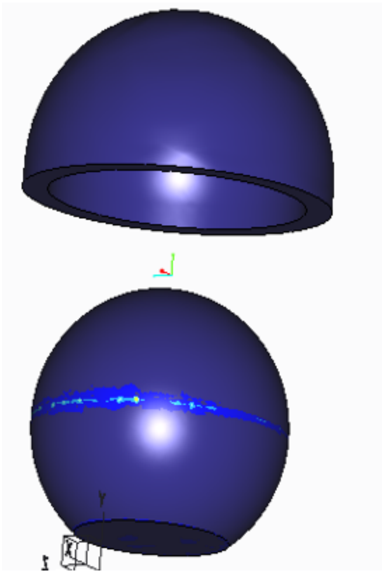
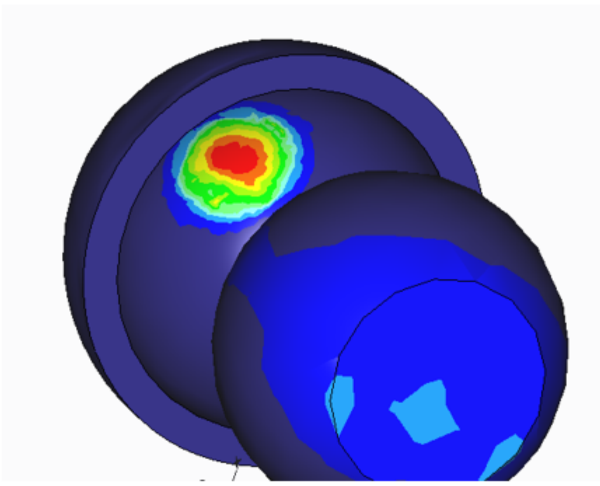


Figure 6.4: Polar contact.



noted that the size of the contact area decreases as the diameter differences increase. This is discussed further in chapter 7, The figures 6.5 to 6.7 are an illustration of the variation of the contact stresses with clearances for a 42 mm diameter head only. For the bearing sizes 28 mm, 36 mm,42 mm, and 50 mm each had three analyses for the zero, 24 μm, and 30 μm diametrical clearances.

The general pattern was maintained when the analysis was performed on the 28 mm, 36 mm, and 50 mm heads whose information has been attached in the appendix B. The results have been plotted as show by figures 7.1 and 7.2 in chapter 7.

Figure 6.5 shows full contact between femoral head and the acetabula cup however the maximum contact stresses shown is 6 MPa which is nor relevant as it is shown on the base or point of application of force. the area of interest is the inside of the acetabula liner and outside the femoral head. This is better displayed when the output in in form of contact pressures.

Figure 6.5: Full contact.

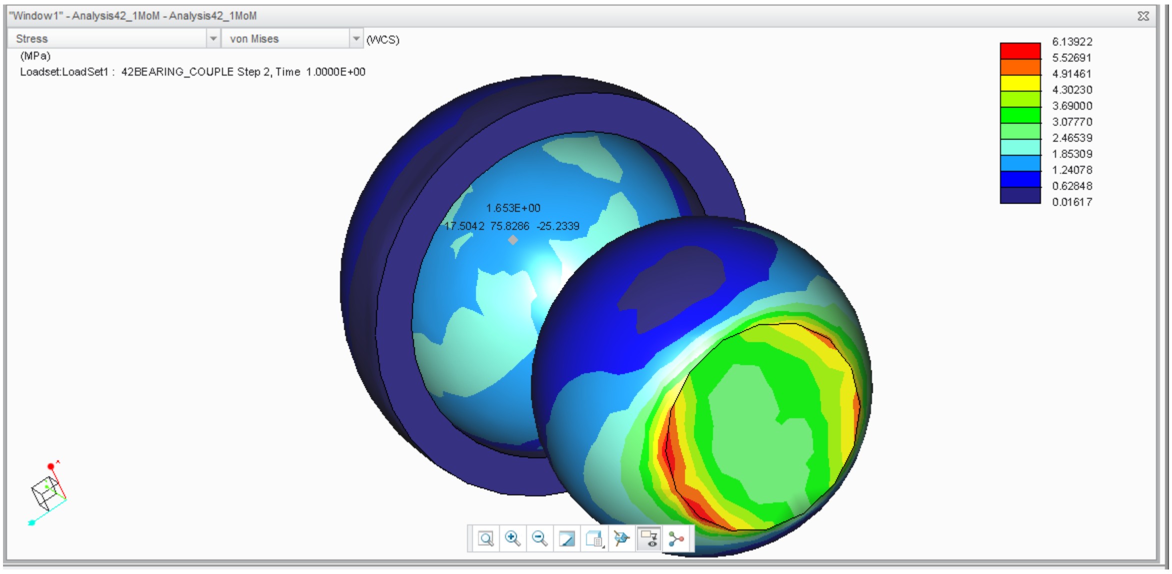


Figure 6.6: contact with 24 μm clearance.

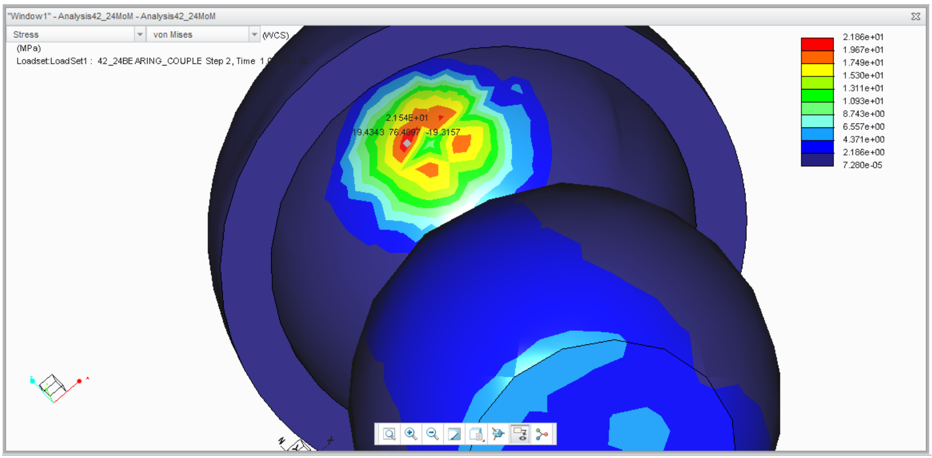
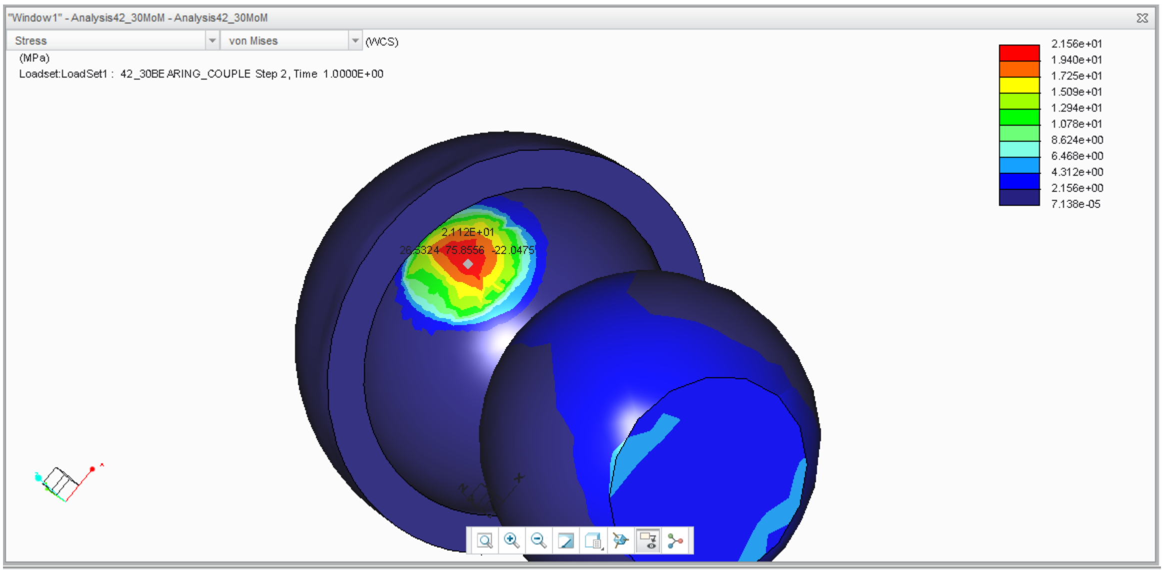


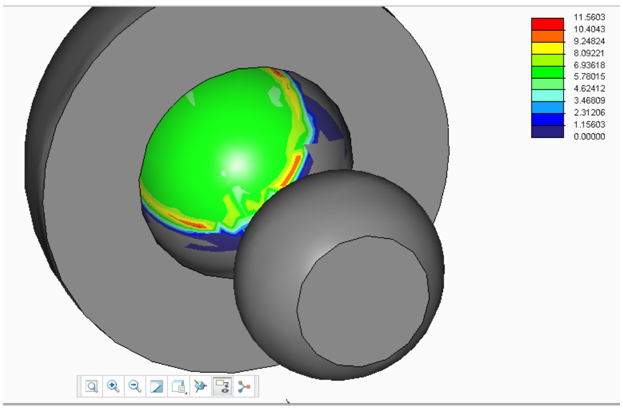
Figure 6.7: Contact with 30μm clearance.


"Window1" - Analysis42_30MoM - Analysis42_30MoM
Stress
von Mises
(WCS)
(MPa)
Loadset:LoadSet1 : 42_30BEARING_COUPLE Step 2, Time 1.0000E+00
2.156e+01
1.940e+01
1.725e+01
1.509e+01
1.294e+01
1.078e+01
8.624e+00
6.468e+00
4.312e+00
2.156e+00
7.138e-05
2.112E+01

Development of the Proposed Bearing.

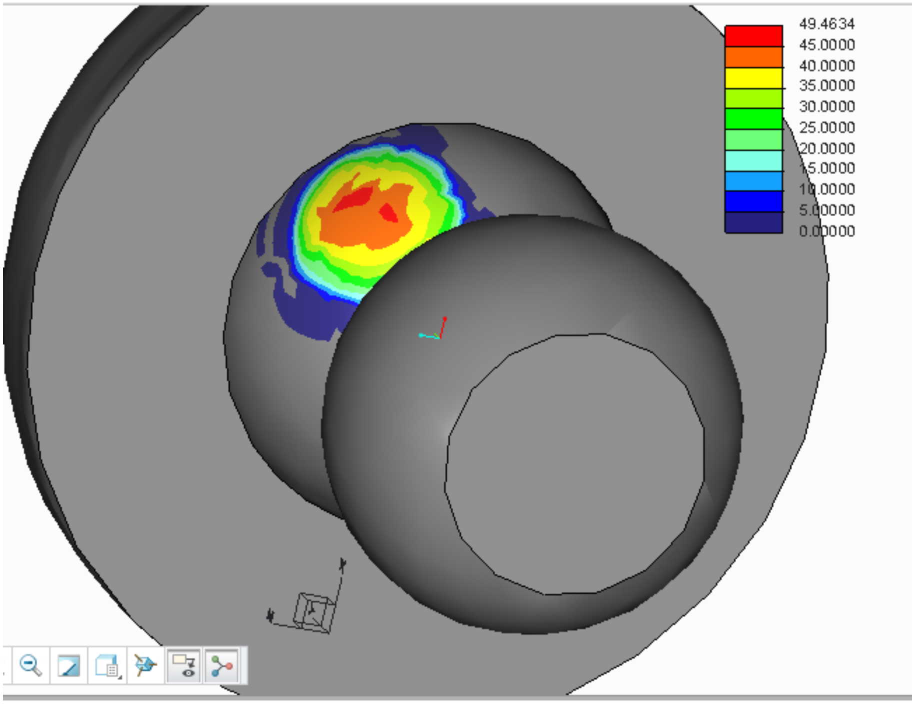
Armed with this knowledge the next step was design a bearing that would use these findings in order to solve the problem of high contact stresses, thereby reducing frictional wear. In line with keeping the maximum contact area, an elliptic model was considered especially after studying the geometry of the natural femoral head and the fact that normal forces can easily be spread uniformly if the area they are acting on is flat. The idea was developed by combining the flat and spherical (circular) geometries to arrive at the an elliptical shape. During the development phase the elliptic (oval) model had to be evaluated through finite analysis as well to find the contact stresses and contact pressures distribution pattern in comparison to the conventional spherical shaped models. The proposed model (elliptic) was generated in two sizes 28 mm and 50 mm which has been the extremities of this research spectrum. These were analysed for the contact pressure and contact stresses distribution. The elliptic model showed low stress values in both bearing diameter sizes shown by figure 7.3. More is discussed in the results section, however figures 6.8 and 6.9 illustrates how the values varied.

Figure 6.8: Contact Pressure of the elliptic model



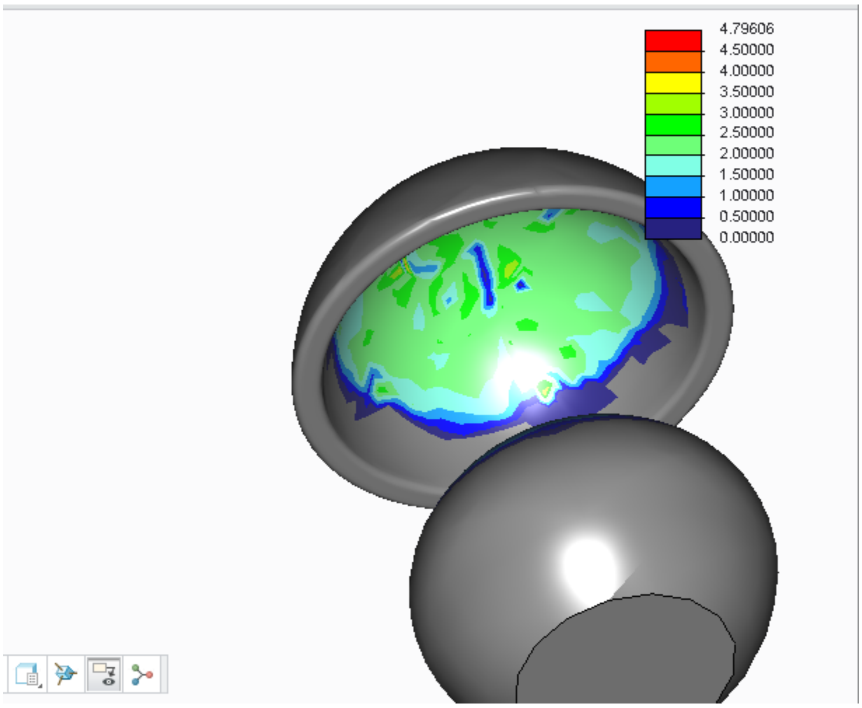
Looking at figures 6.8 and 6.9 it can quickly be seen that the elliptic model had lower contact pressures than the spherical model. The referred figures are for the 28 mm diameter head only but the full comparison is delt with in chapter 7.

Figure 6.9: Contact Pressure of the spherical model.



Although from the decision matrix, carbon fibre reinforced peek came out as the favourite material, the analysis was also performed to compare the effect of different coefficient of materials on the magnitude and distribution of stresses. The materials considered were carbon reinforced peek and UHMWPE all articulating against the silicon nitride femoral head. The figures 6.10 and 6.11 illustrate that peek has better distributed contact pressures than UHMWPE. UHMWPE had places of stress concentrations to the value of 22 MPa.

Figure 6.10: Distribution of contact pressure on silicon peek couple.

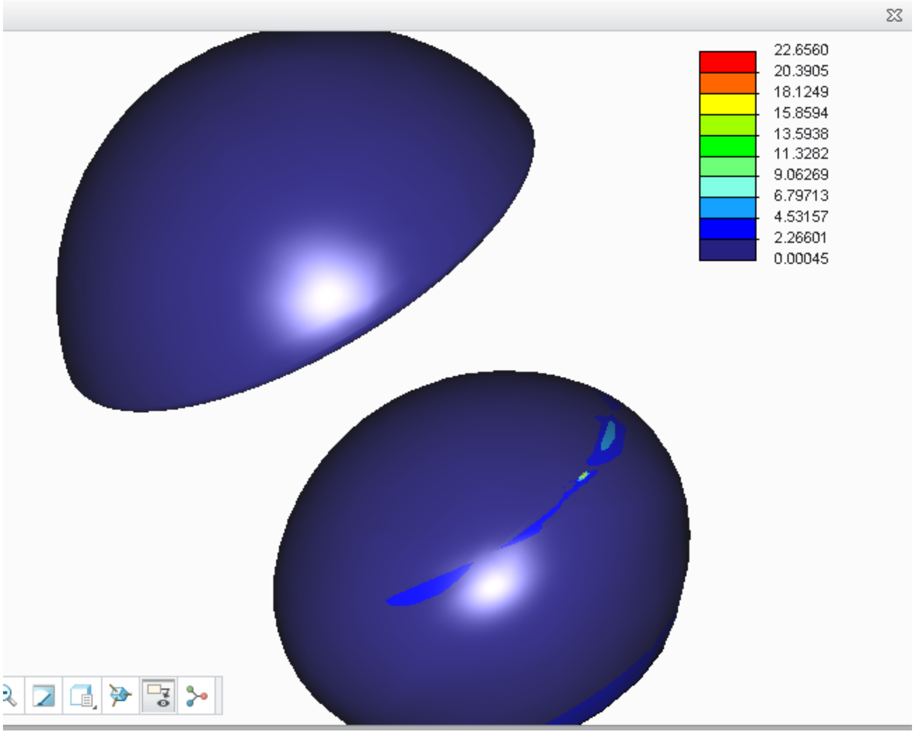


Design optimisation process.

Although this is discussed in the next chapter, the above work shows and confirms that the as the bearing diameter sizes increases, the maximum contact stresses reduce however there are some limits to the geometry of the bearing. It presents two extremities which are very low or zero clearance and the largest bearing size that can be accommodated by the pelvis socket hence a balance has to be maintained for the optimum function of the implant. A design optimisation was considered order to come up with a proposed design.

The most common bearing sizes range from 22 mm to 55 mm however the design that is considered in this analysis heads diameters range from 28 mm to 50 mm because of the pelvis socket which has been limited to 61mm. This size affects all other dimensions

Figure 6.11: Distribution of contact stress on silicon UHMWPE couple



which include the thickness of the liner. The maximum allowable stress in the design has been determined by the safety factor which has been derived using the following formula by David Ullman because of lack of information in the data sheets.

$$FS = FS(materialproperties).FS(geometry).FS(stress).FS(failureanalysis).FS(reliability)$$

(Ullman 2010).

From the parameters that Ullman defined, the safety factor scores have allocated as follows:

Reliability = 1.6 (The reliability must be high and greater than 99 %)

Failure analysis = 1.5 (The analysis is not fully developed).

Geometry = 1 (The tolerances are tight and must be maintained).

Stress = 1.3 (The loads have defined in any average manner).

Material = 1.1 (The material properties are taken from handbooks and manufacturers publications).

$$FS = (1.6)(1.5)(1)(1.3)(1.1) = 3.4$$

So for the Peek whose yield strength is 20.7 MPa the maximum value of stress that is used in the design optimisation is

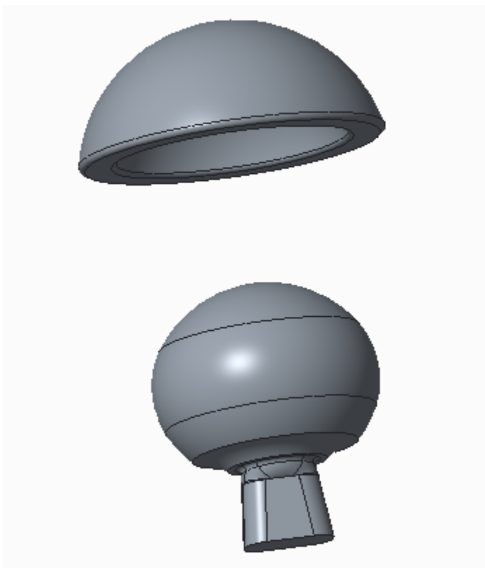
$$20.7/3.4 = 6 \text{ MPa} \tag{6.1}$$

It is important to note that the above procedure was guided by the design specifications which put the safety and reliability of the implants in the first place and therefore were scored highly.

The model was rerun in Creo simulate through the design optimisation with the following design limits:
maximum contact pressure limit set at 6 MPa and maximum clearance 24μm.

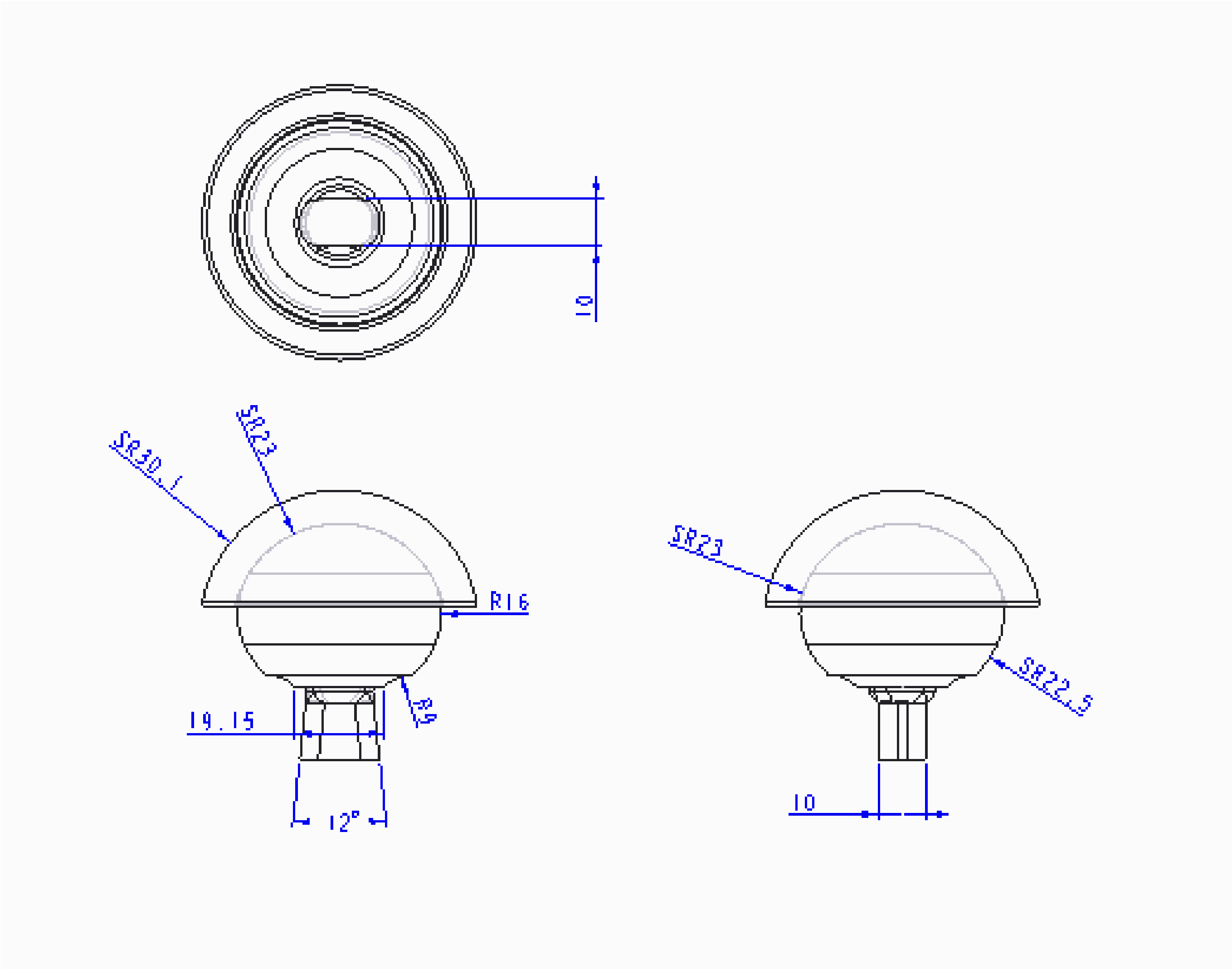
The following model parameters were obtained and were adopted for the model changes and specifications. The head major diameter obtained was 46 mm and the radial clearance was 0.005 mm. The peek cup inner diameter 46.01 mm.

Figure 6.12: Illustration of the proposed design.



The proposed design has been analysed for stress and contact pressure distribution. The results are discussed in chapter 7.

Figure 6.13: Illustration of the proposed design drawing.



Hertzian contact stress.

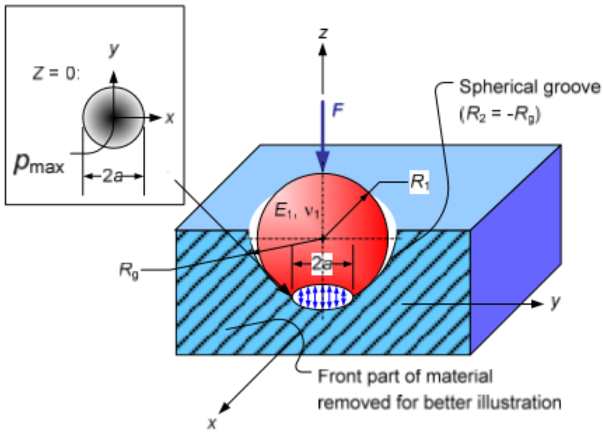
The solution design principle of the maximum contact area was derived from the Herztian contact stress method where it can be deduced that as two bodies in contact deform they generate a contact area. The bigger the contact area, the lower the stresses that are associated with the frictional wear. It is hoped that with this principle it can be shown theoretically that by varying contact clearances and diameters, contact pressure and contact area is also varied.

When two bodies come into contact under static or dynamic loads they tend to deform and the deformation corresponds to the material properties (modulus of elasticity). For spherical bodies like in the case of the femoral and the acetabula cup there is point contact if the diameters are not the same (Nisbert 2006). Theoretically full contact should be possible as the ratio of the diameters approach unity, therefore there must be variation of distribution of stress from point contact to full contact. In reality under loads the case of a point contact is less likely to occur as the bodies deform thus generating a contact area. The larger the contact area the less the contact stress and the contact area between the femoral head and the acetabula depends on the size of the clearances between the mating surfaces. In this regard it becomes important to establish the best clearance size that allows effective lubrication regime and the largest possible contact area. by using the Hertzian contact stress analysis method, the following assumptions were taken into consideration.

- The surfaces in contact are non-adhesive.
- The system is static.
- The bodies do not slide past each other during contact that is the contact is frictionless.
- The contact surfaces are continuous.
- The strains are small and within the elastic region.
- The contact area is small compared to the size of the bodies.
- Each body is considered elastic (Wikipedia 2016).

The contact stresses also depends on the normal contact force, radii of curvature and the moduli of elasticity of femoral head and the acetabula cup peek. As mentioned in the tribology section the true contact area is different to the apparent contact area but all depends on the surface texture. The figure below shows the spherical contact that can illustrate the type of contact between the femoral head and the acetabula cup.

Figure 6.14: Illustration of spherical contact.



Since the femoral head is made of the hard material it indents the Peek there by deforming it more that itself creating contact area of radius a. Given that F is the normal applied force,

$$F = \frac{4}{3} E R^{\frac{1}{2}} d^{\frac{3}{2}} \tag{6.2}$$

$$\frac{1}{E} = \frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2} \tag{6.3}$$

$$\frac{1}{R} = \frac{1}{R_1} + \frac{1}{R_2}. \tag{6.4}$$

$$a = \left(\frac{3FR}{4E}\right)^{\frac{1}{3}} \tag{6.5}$$

$$P_o = \frac{3F}{2a^2\pi} \tag{6.6}$$

Where:

- E = effective moduli of elasticity.
- v_1 = poisson' s ratio of the femoral head material.
- v_2 = poisson' s ratio of acetabula material.
- R = effective radii.
- d = the depth of indentation.

The maximum contact pressure between two (spheres) acetabula and the femoral head depends on the following factors:

- Radius of curvature.
- Magnitude of force.
- Elastic modulus of the materials involved.
- Poissons ratio of the materials involved.

The Herztian method was performed on the same size bearings that were analysed by finite element method. The results are plotted and are discussed in chapter 7.

6.3 Chapter Summary.

The design procedure was aimed at reducing contact stress by increasing hip joint bearing diameters and thereby increasing contact area. This phenomenon helped in spreading the effects of the joint reaction force over a wide area thus lowering the contact stresses. Additionally reducing the clearances between the bearing mating parts also increased the contact area thereby also reducing contact stresses. This was confirmed by the Hertzian contact stress method.

Chapter 7

Results and Discussion

7.1 Chapter Overview.

Chapter 7 presents the results of this research mainly from the finite element analysis of the spherical shaped models in comparison to the proposed elliptic design model. This chapter also discusses the project findings especially on the methodology and techniques used and compares with the Herztian method as a validation technique.

7.2 Discussion.

Varying diameters and clearances.

The FEA performed on spherical bearing models produced different contact stresses. These were easily read from the exploded views and were explicitly shown in figures 6.5 to 6.7 in chapter 6. The rest of the analysed spherical bearing models are in appendix B. It was necessary to consider contact pressures as well instead of Von Mises because in some cases the models revealed high stresses in non relevant areas like the base of the femoral head (instead of the contact areas) as shown in figure 6.5. Although an attempt was made to use the dynamic query option in getting the readings, the values were generally an estimation. The analysis was performed on CoCr (MoM) bearing couples with material properties and the boundary conditions kept constant.

The most common feature of the results (and perhaps the most important point) revealed that the contact area is increased by increasing bearing heads diameters. Figure 7.1 shows that the smallest diameter of 28 mm has the highest contact pressure for the clearances applied. While the joint reaction force is held constant, there is noticeable decline in the contact pressure and contact stresses. The same can be said when the bearing clearances are reduced. The model assemblies approach full contact as the clearances approach zero which might seem ideal when the main focus is to reduce contact stress. On the contrary this arrangement comes with no gap for lubricant ingress and furthermore it may result in equatorial contact as shown in figure 6.2. As it has been mentioned in the preceding chapters, equatorial contact is associated with edge loading of the cup and stripe wear on the femoral head (Affatato, Traina & Toni 2011), (Harris 2012) and (Hua, Li, Wang, Jin, Wilcox & Fisher 2014).
It can also bee seen from figure 6.2 that the edge loaded area is a place of high stress concentration which automatically leads to premature fatigue failure under cyclic loads.

Figure 7.1 also illustrates the increase of contact pressure between articulating surfaces as bearing clearances increase. The figure also shows the increase in stresses as the bearing size reduce which points to same underlying fact that the contact area is less for small size heads as compared to large diameter heads. This is confirmed by the graph of results obtained through Herztian contact method as shown in figure 7.2.

Although there is a degree of variation between the two plots, the important fact observed is the increase of contact pressure with decreasing bearing diameters and therefore decreasing the contact area. This instils some confidence in the FEA methods used in the analysis. The reason for the small differences in the two graphs can be attributed to the assumptions that have been used in both methods. For example the Hertzian method does not include friction which is not the case when FEA was performed on the models.

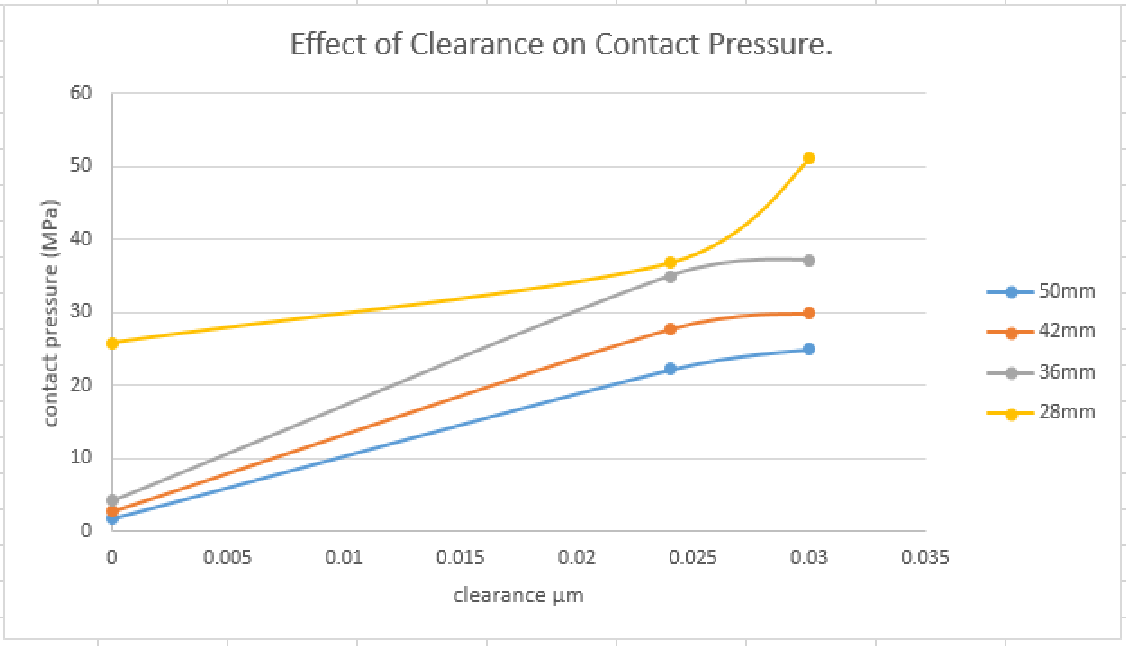


Figure 7.1: Contact stress by FEA method.

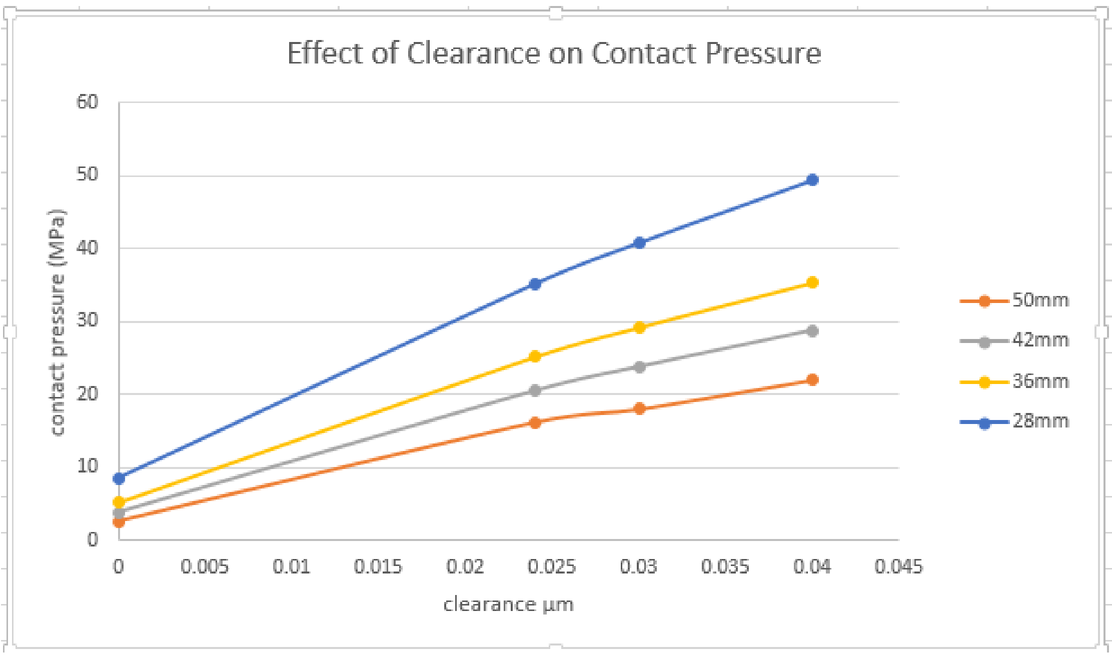


Figure 7.2: Stress variation by Hertztian method.

Evaluation of the proposed model.

As mentioned in chapter 6, when the elliptic model was analysed to ascertain the distribution of contact stresses and contact pressures in comparison to the conventional spherical model, two size diameter heads were used namely the 28 mm and the 50 mm. The out comes were plotted in to a bar graph shown in figure 7.3. Surprisingly there were lower stresses recorded on the elliptical model than the spherical model. Additionally the elliptical model showed that the stresses decreased with increase in diameter sizes. This is consistent with the results obtained by Hertzian method on the spherical model in figure 7.3. Figure 7.3 illustrates the comparison between the elliptical and spherical models.

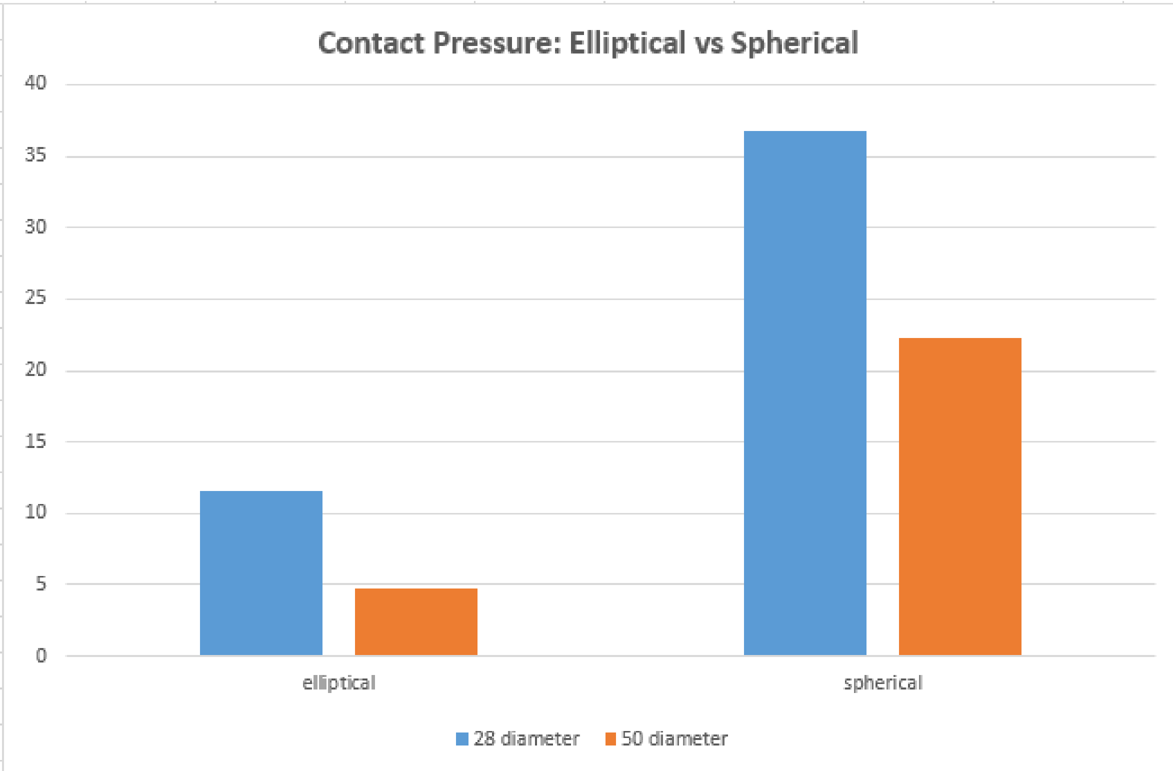


Figure 7.3: Contact Elliptical vs Spherical

The last analysis performed on the proposed design was to ascertain the suitability of the selected material from the decision matrix though finite element method. Since contact mechanics is greatly influenced by the materials used, the elliptic design was analysed to see the stress distribution patterns using carbon fibre reinforced peek in comparison to the UHMWPE as acetabula materials. They were all articulating against silicon nitride femoral head. The material with low stiffness and modulus of elasticity results in low contact stresses and pressures as the softer material wraps around the hard one. This is geometry conformity and helps further increase the contact area and it was revealed that

peek achieved lower stresses than UHMWPE as shown in figures 6.10 and 6.11 in chapter 6.
In fact UHMWPE produced a line contact which is consistent with edge loading in some CoP and MoP bearing couples (Affatato et al. 2011), (Harris 2012) and (Hua et al. 2014).

Therefore following on from the above, it was established from the biomechanics section that the magnitude of the patient weight influences to a greater extent the hip joint loads and hence there is need to uniformly spread the forces over the articulating surfaces as much as possible to avoid point and line contact as seen in polar and equatorial loading respectively.

In summary of the the above, the research has achieved some positive outcomes however there are some limitations in the application of the FEA method which could have affected the accuracy of the results obtained. First there were a number of assumptions taken into considerations in simplifying the analysis though due care was taken to replicate the actual physical system of joint mechanics. In addition, no dynamic loading was considered in the analysis of the models because the relative speed between the articular surfaces was deemed too slow to be regarded as dynamic. It was therefore considered as static system. Consequently, to a less extent the results may not represent the dynamics of the hips especially during sporting activities.

For reasons stated above it was necessary run the design optimization of which the result had significant reduction of contact stresses as seen in figures 7.4 and 7.5.

The materials used in the proposed model stem from the decision matrix. For the reason spelt out in the material selection part the most promising candidates are silicon nitride for the femoral head and the peek for the acetabula liner. The choice for the stem is the Titanium all alloys for the biocompatibility. The figures below reveal the low stresses of the new design after finite element analysis.

New Design

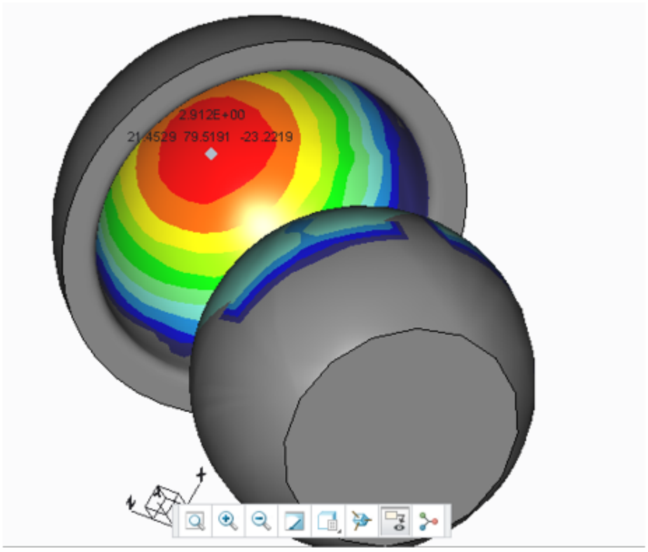


Figure 7.4: Contact stress distribution of the new design.

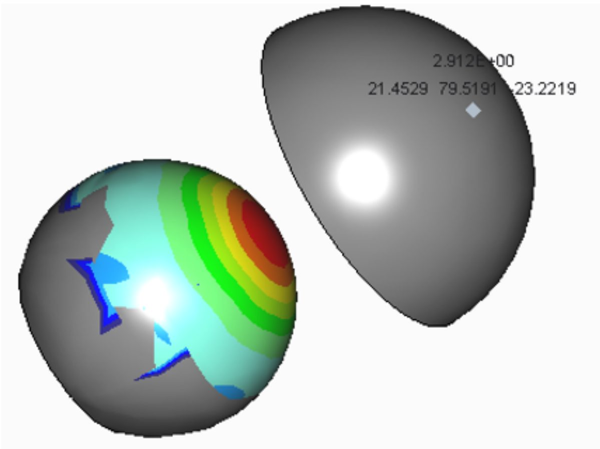


Figure 7.5: Contact stress distribution of the new design.

Chapter 8

Recommendation and Further Work.

Given the two situations of high cost of ceramic implants and the readily available material for other implants at a cheaper cost, it is important to choose a material that works. It also preserves the reputation of manufactures from lawsuits. This does not mean taking the less expensive models off the market but they can be made available and can only be used at the patients' own risks. On the contrary considering the trauma, cost and the complexity of revision surgeries it is sensible to do something that works well the first time because by cost benefits analysis in the long run it works out cheaper. In this view it is strongly recommended to trial this proposed design as it has the potential to lower the rate of wear of the hip implants. At present there is no information about the side effects of using ceramics in orthopaedics.

For further work it is recommended that the proposed model goes through a thorough testing regime and wear simulation to ascertain its wear performance both computationally and in vitro. Additionally there is also need to investigate the side biological effects of ceramics to ascertain the safety of the proposed design.

Chapter 9

Conclusion.

The longevity of hip implants are greatly affected by wear debris that ultimately leads to loosening and revision surgeries. From the study in this research it can be deduced that low contact pressures and stresses are achievable by increasing bearing diameter heads and reducing contact clearances. It has also been clearly demonstrated that the wear of the hip joint is largely due to mechanical means that have biological consequences and therefore it becomes a key factor to consider having materials that are biocompartible and wear resistant so as to avoid creation of wear debris. Using materials of modulus of elasticity close to that of the bone not only serves to evade stress shielding but also help in stress reduction for they have greater conformity.

It is evident that more people and more younger patients are getting hip replacements as a treatment hip disorders. With rising life expectancy and the average hip implants life span at 20 years it means there is going be greater chances of a revision surgeries which have been known to be less successful therefore it has been necessary to find materials and bearing design that last longer (Hughes 2012). It is hoped that with this bearing design that managed to eliminate peak and concentrated hip contact stresses, the implant longevity is increased.

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Appendix A

Project Specification

ENG 4111/2 Research Project

Project Specification

For:	**Kizito Saika**
Topic:	Design analysis of the bearing component of the hip joint prosthesis to improve distribution of forces and frictional wear.
Major:	Mechanical Engineering.
Supervisor:	Dr. Steven Goh.
Sponsorship:	Faculty of Health, Engineering & Sciences.
Enrollment:	ENG4111-Ext S1,2016. ENG4112-Ext S2, 2016.
Project Aim:	To reduce the accelerated rate of wear of the hip joint bearing surfaces by improvement of the distribution of loads (thus reducing the loads concentration on the bearing surfaces)

Programme: Issue B 13 March 2016

1. Review of the hip joint bearings in use and background information.
2. Literature review of the hip joint replacement and failure modes.
3. Design a bearing model with better distribution of forces using PTC Creo 3.0.
4. Perform FEA on the model to ascertain forces distribution using Creo 3.0.
5. Bearing materials comparison and selection.
6. Investigate hip joint lubrication and recommendations.
7. Evaluation of the model.

As time and resources permit:

1. Build a prototype bearing.
2. Test it in a simulator that mimics human hip joint.

Agreed:

Student Name: Kizito Saikal (U1009236)
Date: 13/03/2016

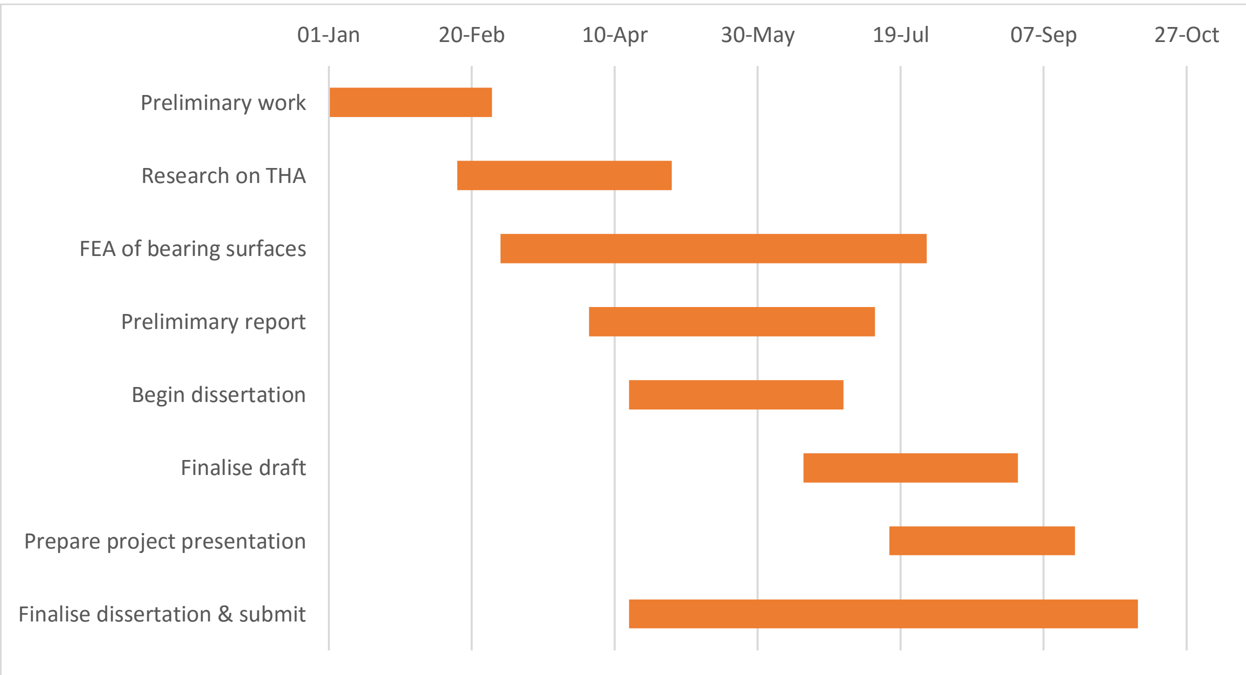
Signature:

Supervisor Name: Dr. Steven Goh
Date:

Signature:

Project Timelines

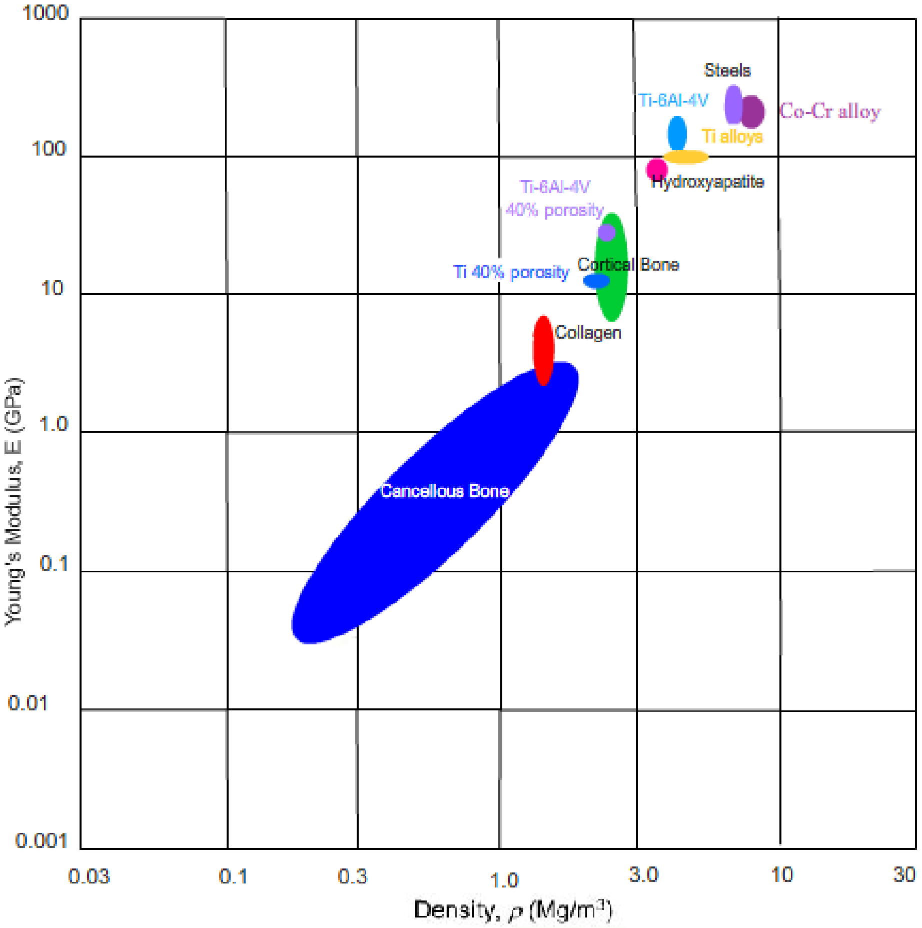
Start date	End date	Description	Duration
01-Jan	28-Feb	Preliminary work	57
15-Feb	30-Apr	Research on THA	75
01-Mar	30-Jul	FEA of bearing surfaces	149
01-Apr	11-Jul	Preliminary report	100
15-Apr	30-Jun	Begin dissertation	75
15-Jun	30-Aug	Finalise draft	75
15-Jul	20-Sep	Prepare project presentation	65
15-Apr	13-Oct	Finalise dissertation & submit	178



Appendix B

Some Supporting Information

http://core.materials.ac.uk/repository/doitpoms/tlp/bones/modulus-density.swf



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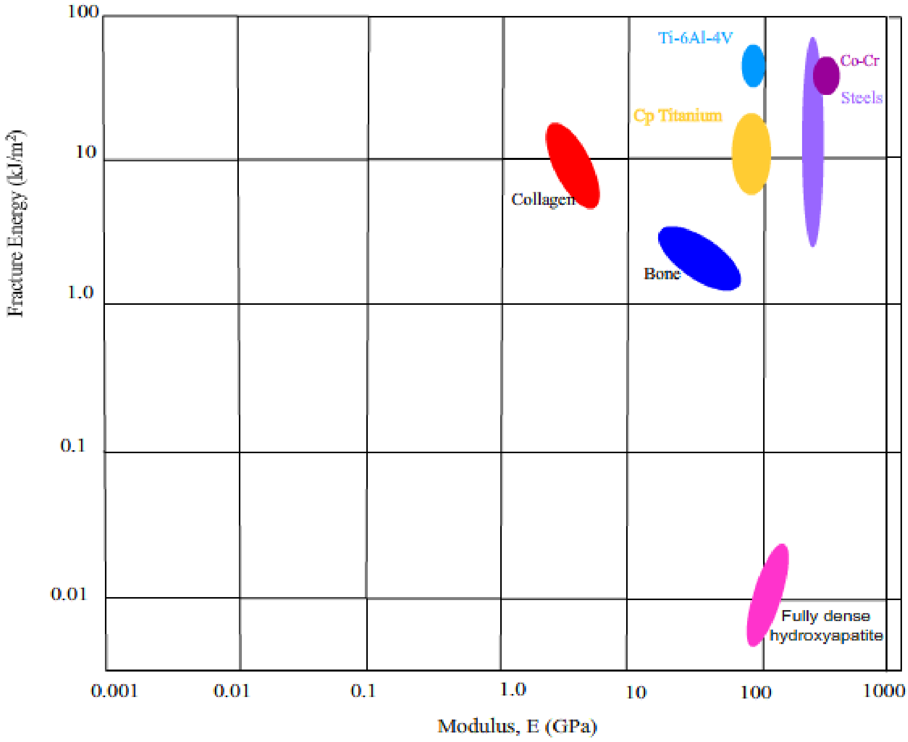

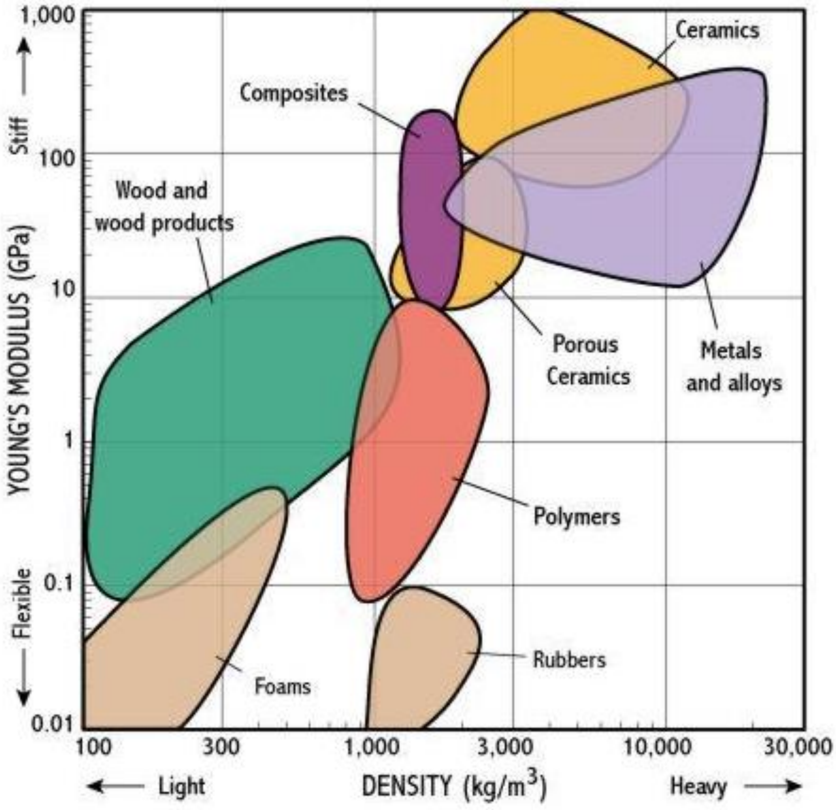

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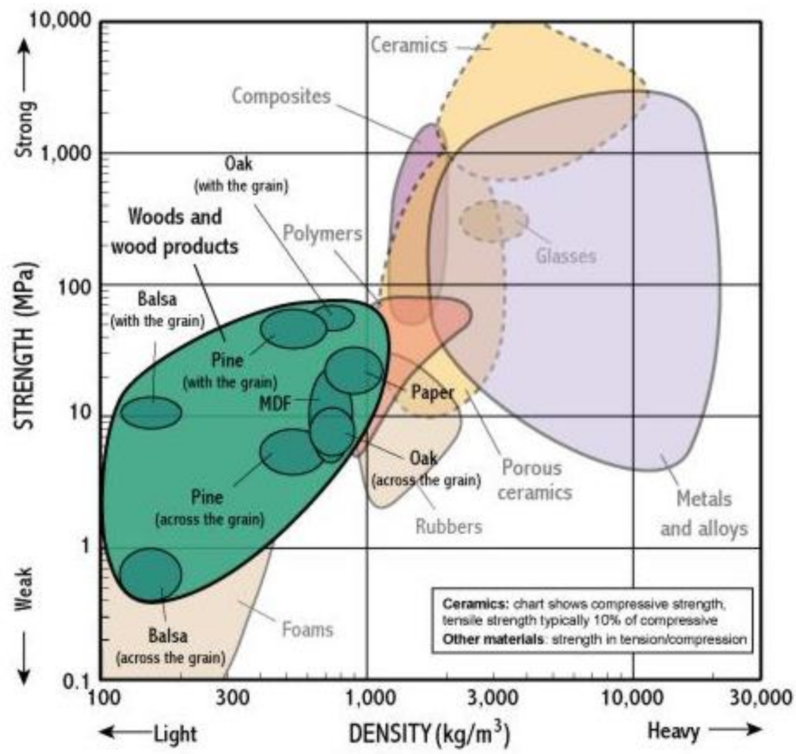

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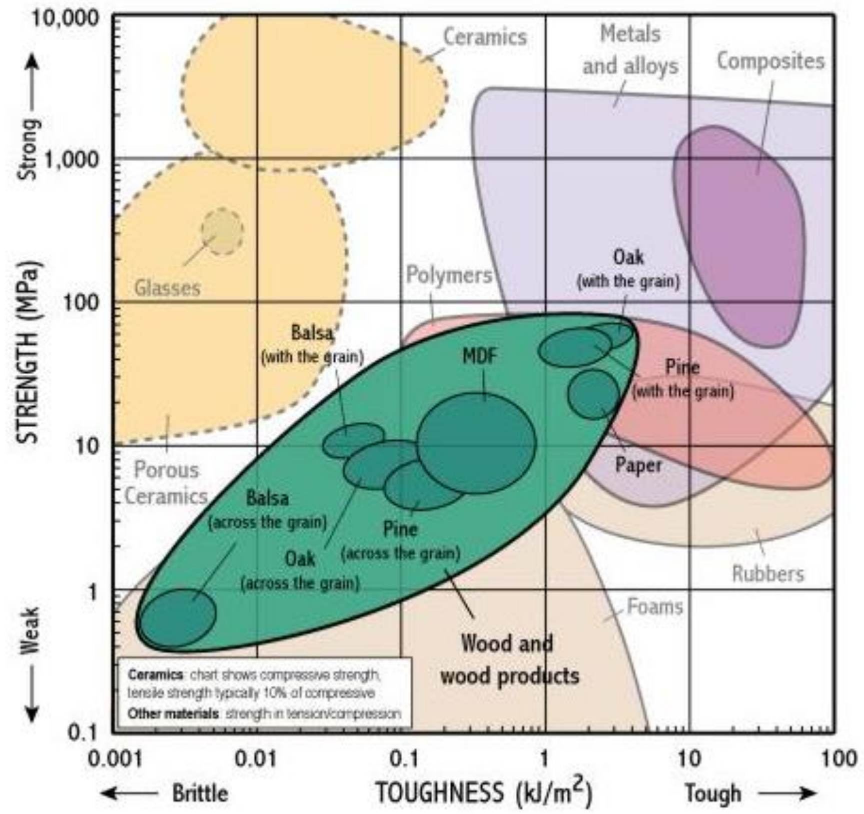

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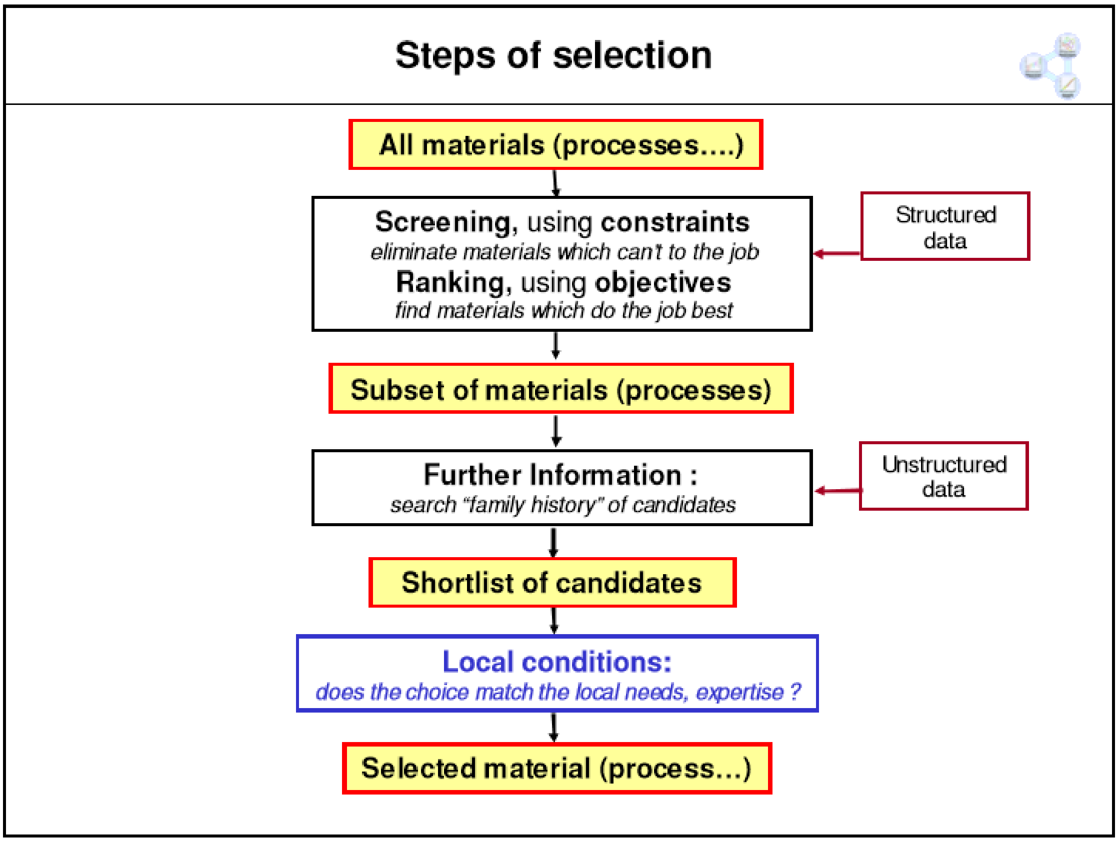

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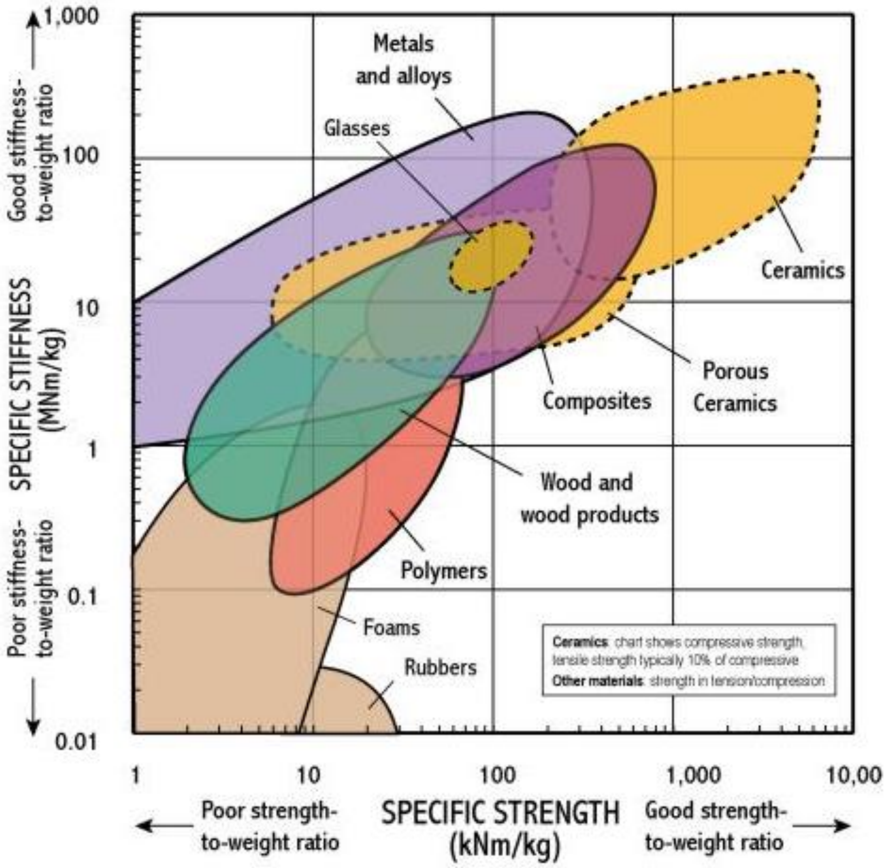

http://www.diim.unict.it/users/fgiudice/pdfs/SM_2.1.pdf

The decision matrix

Materials	**Properties**							
	Density	Modulus of elasticity	Wear resistance	Strength weight ratio	Corrosion resistance	Compressive strength	Bio-compatibility	total
Si3N4	4	4	4	4	4	4	5	29
Al2O3	4	3	4	2	4	4	4	25
PEEK	5	4	4	5	5	4	5	32
UHMWPE	5	2	3	2	5	3	3	23
Stainless steel	3	4	3	3	4	4	1	22
Titanium Alloy	4	4	2	5	4	4	5	28
CoCr Alloy	3	4	4	3	3	4	1	22

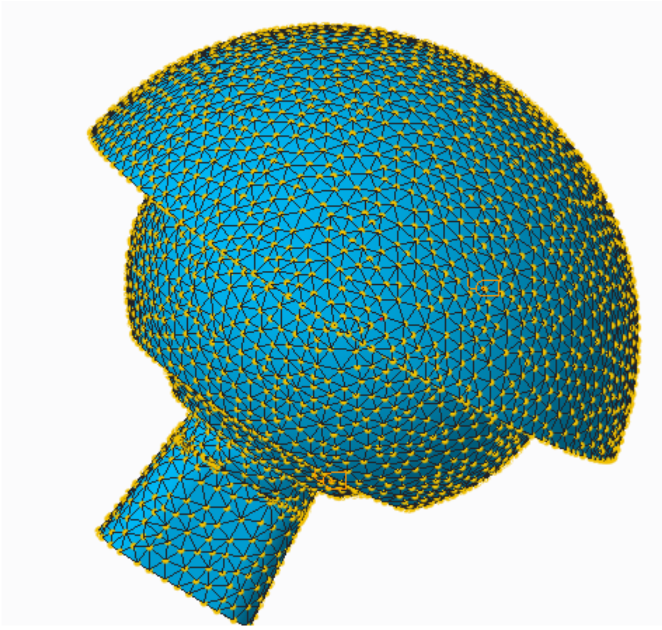

Figure B.1: mesh of the design model

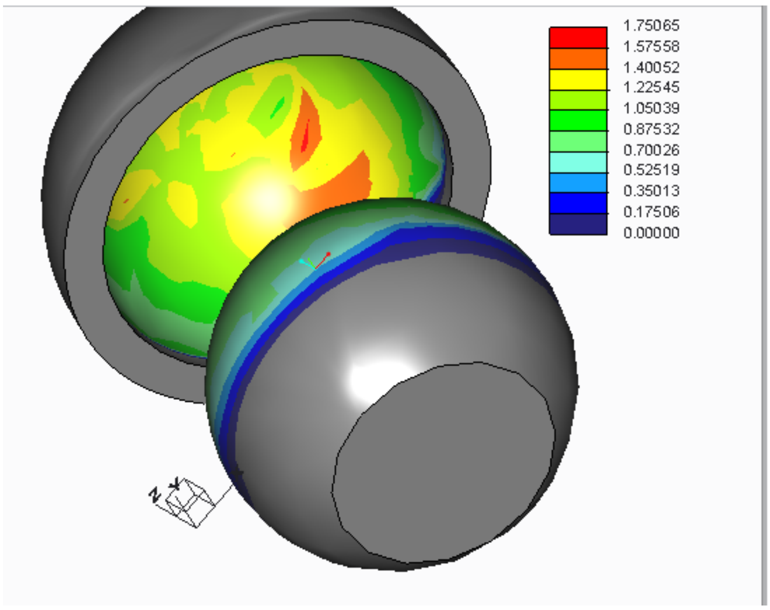

Figure B.2: contact pressure of diameter 50 mm at zero clearance.

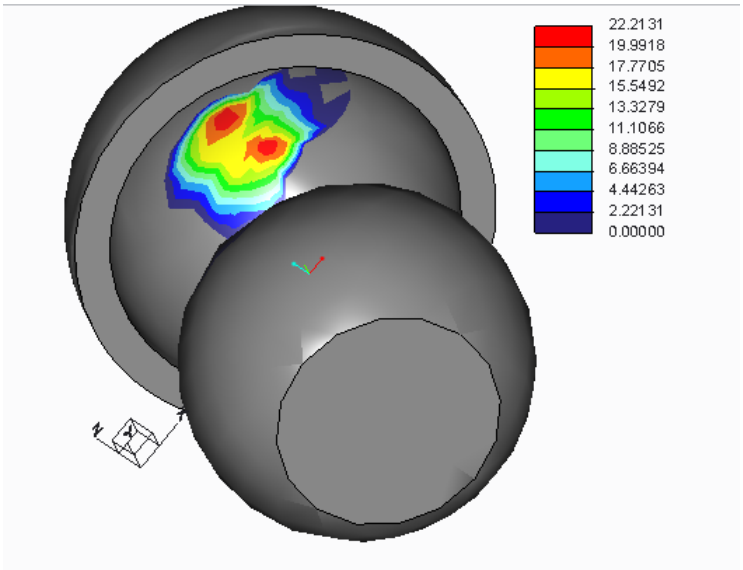

Figure B.3: contact pressure of diameter 50 mm at 24 μ clearance.

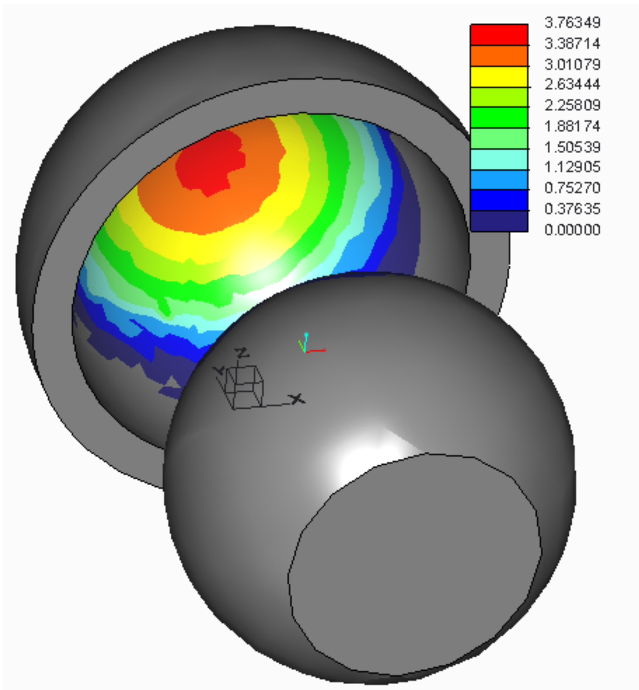

Figure B.4: contact pressure of diameter 50 mm at 30 μ clearance.

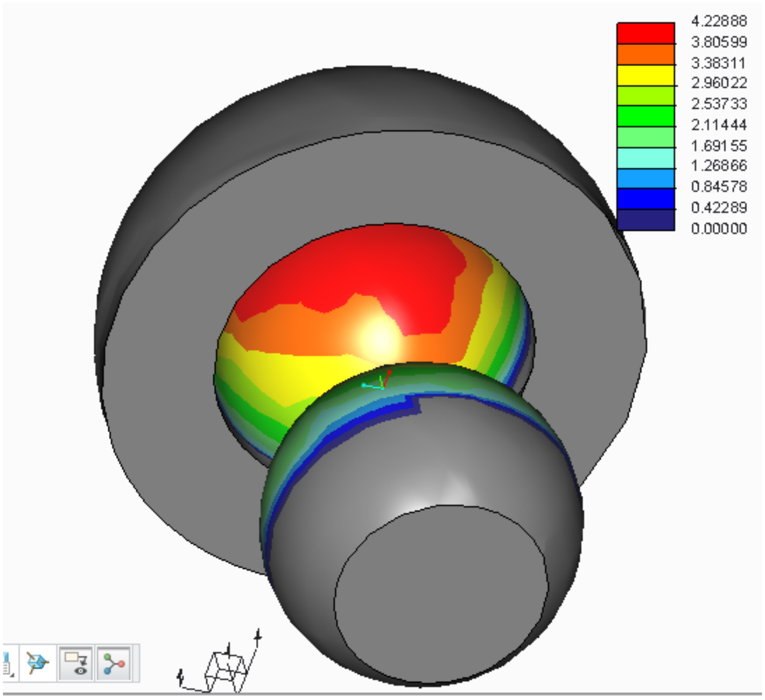

Figure B.5: contact pressure of diameter 36 mm at zero clearance.

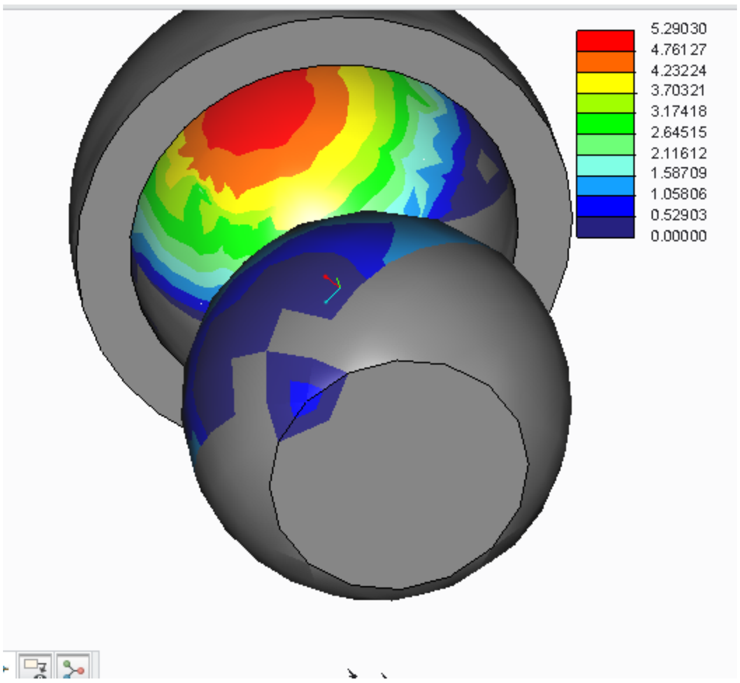

Figure B.6: contact pressure of diameter 36 mm at 24 μ clearance.

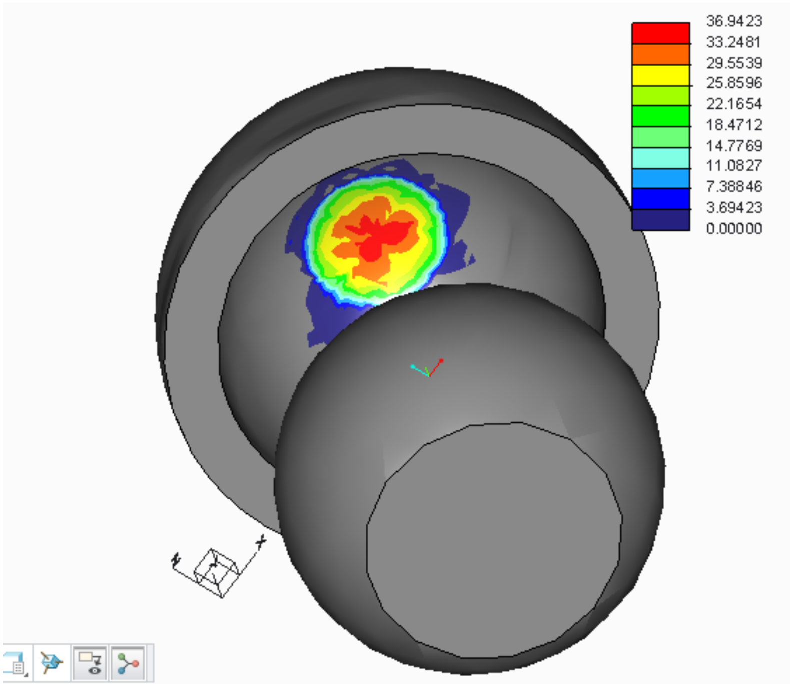

Figure B.7: contact pressure of diameter 36 mm at 30 μ clearance.

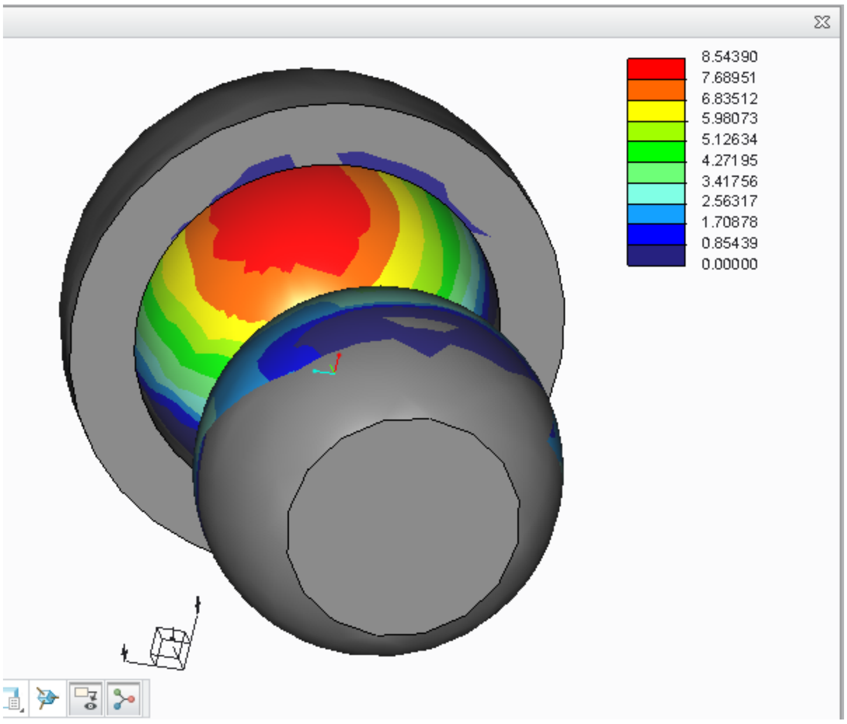

Figure B.8: contact pressure of diameter 28 mm at zero clearance.

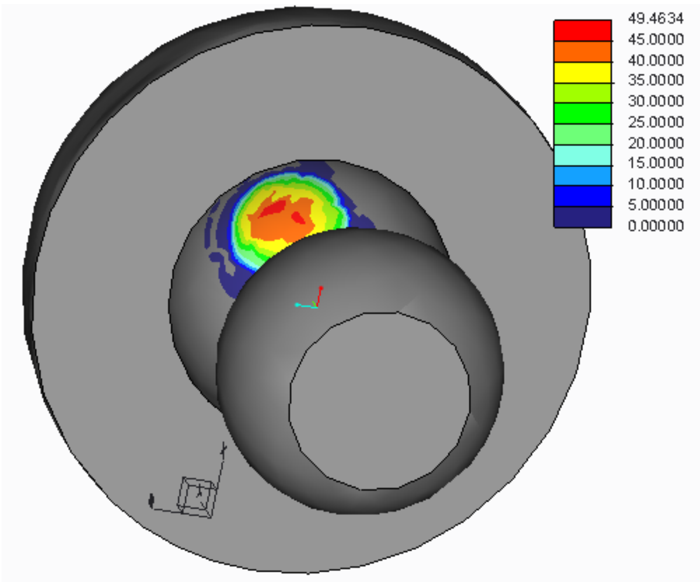

Figure B.9: contact pressure of diameter 28 mm at 30 μ clearance.

Appendix C

Data Sheets

Profile Series 3, Number 1 August 2003

THE EFFECT OF FEMORAL HEAD AND NECK CROSS SECTION ON RANGE OF MOTION

The AcuMatch® Integrated Hip System, which includes the C, P and M-Series family of stems, was designed to maximize range of motion through its innovative neck design (Figure 1). The precisely designed and machined neck flats feature a cross section of 8mm, one of the smallest cross sections in the industry. The result of the design effort includes impressive head-neck ratios for both 28mm and 32mm femoral heads (see table below) which may ultimately lead to a reduction in post-operative dislocation.[1, 2, 3]

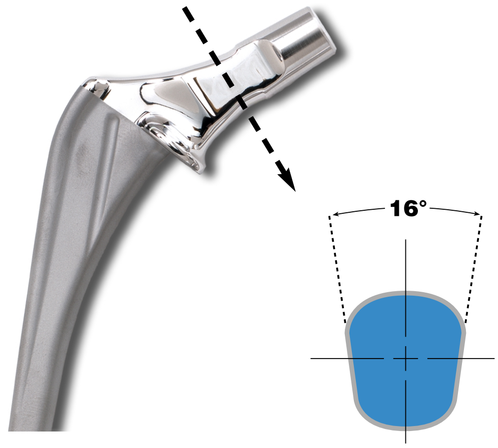

Figure 1. The AcuMatch neck is machined to minimize the medial dimension and overall cross section while also maintaining overall strength.

Important Facts About Head-Neck Ratio

Head-neck ratio is the result of dividing the femoral head diameter by the cross sectional dimension of the femoral neck. Here are two examples using the 8mm cross section of the AcuMatch femoral stems coupled with 28mm and 32mm femoral heads:

28mm/8mm = head-neck ratio of 3.5

32mm/8mm = head-neck ratio of 4

Why is head-neck ratio important?

Higher head-neck ratios increase range of motion (Figure 2). Increased range of motion may reduce the occurrence of post-operative dislocation, one of the leading post-operative complications associated with both primary and revision total hip arthroplasty.[4]

Increasing the head-neck ratio is why many manufacturers are incorporating larger diameter heads into their product lines. By increasing the femoral head diameter, the head-neck ratio will be greater and the chance of post-operative dislocation may be decreased.

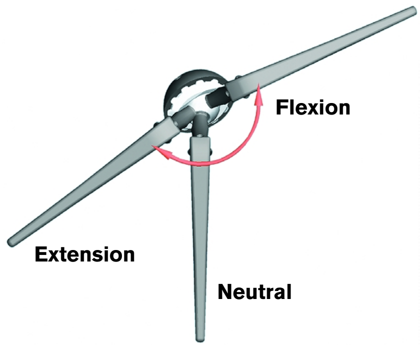

Figure 2. Range of motion is measured by the amount of flexion and extension that can be achieved following a total hip replacement. Greater range of motion may decrease the chance of post-operative dislocation.

Competitive Head-Neck Ratio Comparison:

	28mm	32mm	36mm
AcuMatch	3.5	4.0	4.5
Summit	3.0	3.4	3.85

The higher the head-neck ratio, the greater range of motion achievable.

What About the Issue of Strength?

The AcuMatch neck was designed to maximize its strength. The neck flats are angled at 16°, resulting in more material on the lateral aspect of the stem (where applied forces produce greater tensile stress) and less material on the medial aspect of the stem (where the first point of impingement occurs).[5] The result is excellent range of motion without sacrificing stem strength.[6]

Potential issues when using larger diameter heads:

- Limited to acetabula that can accept a large shell
- Minimizes polyethylene thickness

References:

1. Amstutz HC, Lodwig, RM Schurman, DJ Hodgson AG. Range of motion studies for total hip replacements. *Clin Orthop*. 1975;111:124-130.
2. Krushell RJ, Burke DW, Harris WH: Range of motion in contemporary total hip arthroplasty. *J Arthroplasty*. 1991;(6): 97-101.
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4. Vaughn BK. Management of dislocation in total hip arthroplasty. Oper Techniques. 1995; (5) 4:341-348.
5. Yamaguchi M, Bauer TW, Hashimoto Y, The spatial location of impingement in total hip arthroplasty. Sixty-fourth annual meeting, AAOS, San Francisco, CA, 1997.
6. Exactech data on file.

Technical Data sheet sponsored by:

Exactech, Inc.
Gainesville, Florida 32653
1-800-EXACTECH

0803
711-01-80

Appendix D

Risk Assessment

D.1 Risk assessment

The risks assessment for this project was carried out with implementation of the risk matrix chart. The chart shows scores associated with frequency and severity of the identified hazards with some control measures taken to minimize the impact if the risks are not eliminated altogether. Risks involved no only to the author during the course of the project but also the after effects to those who shall rely on the findings presented. Therefore it should be noted that the findings are primarily theoretical and limited for there is still need for testing the model.

Table D.1: Risk Assessment Matrix.

Probability	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequency (A)	High	High	Serious	Medium
Probable (B)	High	High	Serious	Medium
Occasional (C)	High	Serious	Medium	Low
Remote (D)	Serious	Medium	Medium	Low
Improbable (E)	Medium	Medium	Medium	Low
Eliminated				

Red means extremely high risk therefore the project task must not go ahead

Brown means high risk and special attention is required to manage the risk and its effects.

Yellow means moderate risk and and still needs attention risk management plan to minimize or eliminate it.

Green means the risk is low and does not urgently need attention but can not be ignored.

Cyan means the risk has been eliminated.

Risk Management

Risk Factor	Effects	Risk Category	Control	Result
Digressing	Waste time and then struggle to stick to schedules		Sticking to relevant material and the timelines	
Time keeping	Fall behind schedule		Make time available from work commitments and make use of local library away from family interruptions.	
Fatigue from computing for long hours	Stress and lack of concentration		Take the necessary breaks and enough sleep	
Loss of contact with the supervisor	Lose direction and could be doing something completely off topic		Regular contact is established at fortnightly.	
Loss of data and internet.	Delays in the project delivery and missing targets		Data is regularly backed up and two internet service providers have been secured	
Ill-defined objectives.	Project loses relevance and side tracks		Has been cleared at the initial stages of the project	
Limited experience with software	This affects the quality of the solution.		Have been practising software application and interpretation of results. I have consulting with those proficient in creo simulate risk has been reduced but still remains a challenge.	
Insufficient resource planning.	The risk is very real and can jeopardize the completion of the project successfully		All resources identified fort the project have been made available but the management is an ongoing process in the life of the project.	