EVALUATION OF LOAD-TRANSFER PATTERN IN IMPLANTED FEMUR BY PATIENT-SPECIFIC FE ANALYSIS

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Declaration

I hereby declare that this thesis is based on my original work and that, to the best knowledge and belief, except for quotations and citations, which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted or produced by another party in fulfilment, partial or otherwise, for any other degree at another university or institute of higher learning, except where due acknowledgement is made in the text.

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Acknowledgement

Time flies. It has been around two semester since I managed to get this FYP topics and worked it out along the semesters, with the first day of working this task, full of nervousness and curiosity and many expectations of my life as final year student. Now, I am very happy to write these acknowledgement and to have opportunity to express my gratitude to all the people who supported and guided me throughout this course.

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List of abbreviations

THR	Total Hip Replacement
THA	Total Hip Arthroplasty
HU	Hounsfield Unit
FEA	Finite Element Analysis
FEM	Finite Element Method
OA	Osteoarthritis
CAD	Computer-aided Design
CT	Computed Tomography
STL	Stereo Lithography
ρ_{app}	Apparent density
NW	Normal Walking
SU	Stairs Up
BW	Body Weight
BC	Boundary Condition
MRI	Magnetic Resonance Imaging

Abstrak

Pembedahan penggantian pinggul (THR) merupakan kejayaan terunggul dalam bidang pembedahan orthopedic tetapi masalah atau kekurangan muncul akibat daripada kesan selepas pembedahan dijalankan iaitu 'hadangan tegasan'. Sifat semulajadi tulang adalah sangat kompleks disebabkan komposisi biologi tulang tersebut. Ini kerana tulang mempunyai sifat heterogen dan anisotropik. Perbezeaan dari segi kekejangan antara tulang dan implant adalah salah satu faktor utama berlakunya 'hadangan tegasan'. Tambahan pula, 'stress shielding' berlaku jika berlaku di dalam struktur yang keras dan lebih fleksibel disatukan akan menyebabkan hakisan tulang kortikal yang akan menjerumus kepada kegagalan berfungsi untuk sendi prostesis.

Tujuan kajian ini adalah untuk meneroka dan mengkaji sama ada 'hadangan tegasan' akan menjadi lebih teruk jika menggunakan bahan yang berlainan untuk ortopedik implan yang bakal digunakan dalam THR. Oleh itu, model tulang dibentuk menggunakan CT-data daripada pesakit itu sendiri khususnya dan sifat isotropik dan heterogen akan digunakan untuk model tulang peha manakala untuk sifat dan bahan ortopedik implan, bahan campuran aloi seperti Ti-6Al-4V dan Co-Cr-Mo digunakan. Semua daya dan kondisi sempadan akan dikenakan ke atas model tulang untuk aktiviti harian yang berlainan. Kaedah unsur terhingga juga digunakan untuk mengkaji prinsip anjal terikan sepanjang tulang peha menggunakan teknik 'zon Gruen'.

Hasil menunjukkan ketegangan maksimum berlaku sepanjang sisi tulan peha pada posisi 4 dan mampatan maksimum pula berlaku sebelah tengah pada posisi 3 dan 4. Perbezaan peratus terikan untuk kedua-dua aktiviti adalah sangat tinggi antara tulang peha dan implan aloi-CoCr berbanding tulang peha dan implan aloi-Ti.

Jurang perbezaan peratus yang tinggi adalah kerana implan yang mempunyai sifat yang sangat keras jika dibandingkan dengan sifat semulajadi tulang akan menghalang agihan yang tekanan sekata tekanan sepanjang tulang peha dan sekaligus menyebabkan kedudukan implan menjadi longgar dan akhirnya kegagalan prostetik akan berlaku.

Abstract

Total hip replacement (THR) is considered the most successful orthopedics surgery but eventually there is flaw rise from the effect of post-surgery itself which is stress shielding. Nature behavior of bone is considered a complex biological material due to its heterogeneous and anisotropic properties. The differences in stiffness between bone and the implant which is one of the main factor of occurring shielding stress. Stress shielding occurred in structures combining stiff with more flexible, in which results in bone loss and cortical thinning which lead to joint prosthesis failure.

This research aims to explores the shielding stress would become severe when different types of orthopedic implant materials is used in THR. Therefore, 3-D bone model was developed based on CT-data scan by patient-specific and isotropic with heterogeneous material properties was assigned to the femur, whereby Ti-6Al-4V and Co-Cr-Mo were chosen as standard orthopedic implant materials. The maximum load generated during one complete gait cycles in normal walking and climbing upstairs were chosen for FE analysis. The principle elastic strain along the femur, both in intact and implanted femur conditions, were investigated based on Gruen mapping zone.

Results show that maximum tension favors on the lateral side at region 4 and maximum compression mostly tends to occur on medial side at region 3 and 4. For both type of activities, there are percentage difference in strain value between femur and implanted femur, where differences is higher in CoCr-alloy implants rather than Ti-alloy implant.

The large percentage difference between intact and implanted femur indicates that that gap strain value is high, and this is merely due to effect of stiffness used in implants that eventually shielded the stress from distribute along the femur, which can lead to implant loosening and prosthetic failure.

1 Introduction

1.1 Research background

A hip fracture (femoral fracture) is where the upper quarter of the femur (neck) bone break in. It is among the most common injuries that require hospital admission. The extent of the break depends on the forces that are involved. No matter on what types of fractures involved, the consequences somehow may lead to substantial mortality and morbidity. There are specific types of femoral fracture involved which are intertrochanteric, femoral neck, sub trochanteric and greater trochanteric fractures. Almost 90% of the proximal femoral fractures occurs in patients older than 50 years old in United States each year. Furthermore, proximal fractures incidence is 2 to 3 times higher among females than incidence such as fractures among males. In fact, the risk of sustaining the fractures doubling every 10 years after the age of 50 years. However, such fractures basically can occur at any age. These fractures also results from low-energy injuries and can be categorized as unusual fractures pattern[1]. Basically, there are four different type of hip fracture and is often due to osteoporosis. Osteoporosis is a disease where the risk of broken bone is high due to decrease in bone strength. A hip fracture is a fragility fracture due to a fall or minor trauma in someone with weakened osteoporotic bone. The clinical presentation of a hip fracture is usually an elderly patient who sustained a low-energy fall and now has pain and in unable to bear its own weight. Hip fracture patients are typically older than age of 65, with mean age of 85. The patients usually presents after a fall with complaints of pain on the affected side and loss ability to move. MRI or CT is needed to make the diagnosis and identify the fractures in the patient that suffer consistent pain and inability to ambulate[2].

Orthopedic implants can be considered one of the important products in this era and it also widely in used. Total Hip Arthroplasty (THA) and Total Hip Replacement (THR) are the common surgical processes to threat the hip fracture patients[3]. THR basically involves surgical procedure whereby the diseased cartilage and bone of the hip joint is surgically replaced with artificial materials. There are two types of the implanted femur. The one with cemented or without cement (uncemented) located at the stem. The cement joints are attached to the existing bone with cement, which act as a glue and attaches the artificial joint to the bone. For un-cemented joints, they are attached using a porous coating that is designed to allow the bone to adhere at the artificial joint. The replacement involves surgical removal of the diseased ball and socket and replaced them with metal/ceramic ball (acetabular prosthesis) and stem (femoral prosthesis) into the cortical femur bone and an artificial plastic/ceramic which act as a socket.

However, there are certain risks of hip replacement surgery either the risk during recovery period or long term risk that may occur months to years after the surgery. The main concern of this study is the long term risk such as loosening of the artificial hip joint parts and also the `shielding stress’ that would occur at the shaft of the femur. According to the Wolff`s law of bone remodeling, the implantation of hip stem into medullary canal of proximal femur will results in change or alteration of stress-strain pattern along the femur shaft. This change may be associated with `stress shielding’. Although stress shielding raises concerns of prosthetic loosening and peri-prosthetic fracture, but the long term effect of stress shielding have not yet been correlated with side effects of implant survival[4].

1.2 Problem statement

As the total hip joint replacement (THR) has been considered to be the most successful orthopedic surgery of twentieth century, its prosthetic life however can be its fatal flaw. After replacement, the shielding stress in the proximal femur is considered to be the mechanical loss and eventually lead to joint prosthesis failure[5]. For ideal hip arthroplasty situation, the stress distribution indeed should be even at the intact femur and the remaining femur`s shaft. Strain shielding occurred in structures combining stiff with more flexible, is considered the significant factor that lead to a osteopenia which is the reduction of density in bone surrounding the implant to a level insufficient to compensate normal bone lysis[6]. Bone loss and cortical thinning eventually lead to joint prosthesis failure. According to Wolff’s law, bones adapt to the mechanical load they receive. Once the hip replacement is conducted, the load is carried mainly by the implant itself and not by the femur. This phenomenon is due to a mismatch in stiffness between the hip implant and femur (almost 10 times higher in implant), with variations related to natural physiological conditions[7]. Even though, to assume the overall density of the femur (cortical and cancellous bone) are the same, it would definitely inadequate to justify the results, unless if it is involve in the study of mesh convergence with different element sizes. In this study, the bone mechanical properties were assumed to be isotropic linear elastic with heterogeneous property that have different Young`s Modulus correspond to the Hounsfield unit (HU) values obtained from MIMICS software will be constructed to obtain better computational data analysis. In addition, homogeneous 3-D implanted femur will be also generated via Marc 2010 where the property is basically depends on the materials used. The mapping of bone heterogeneous materials property which is Young's Modulus along the femur`s shaft and contralateral femur basically will be executed in Fortran software based on data in DICOM file and HU greyscale units relation obtained. With all the properties that has been mapped to the bone, stress-strain analysis on the intact and implanted femur will be evaluated by using Marc Mentat 2010 software with actual loading condition and a boundary condition at specific daily life activity.

1.3 Objectives

1. To compare the stress-strain distributions of the 3-D profile implanted femur and the contralateral osteoarthritis femurs using finite element analysis (FEA) relative to the external loading with boundary condition by using MSC. Marc software.
2. To identify the potential problems when stress shielding effect becomes significant.
3. To provide a suggestion to threat the contralateral osteoarthritis joint for the case of second hip operation.

1.4 Structures of the thesis

This thesis is divided into five chapters. Chapter one introduces about the problem and dilemma regarding the THR. Chapter two mainly about literature review on the case study which is stress shielding. Chapter three is the methodology being conducted for this study. Chapter four explained about results and discussion obtained for the whole process of conducting this study. Lastly, chapter five is the conclusion of regarding the result obtained and several improvements to conduct this type of study in the future.

2 Literature review

2.1 General view

Total hip replacement (THR) is an orthopedic surgery where it enable a lot of people who suffers from any-related problems in joint femur to live their life back as a normal people and gaining an active and healthy lifestyle. Variety of orthopedic knowledge applied in the THR such as type of hip implant used and also orthopedic surgery in which may cure a painful and dysfunctional joint with long-lasting and highly functional prosthesis. Structural analysis are performed to predict the peak stresses occurring within the intact femur and THR femur, with respect to real condition peak loads during normal gait at particular time/motion.

2.2 External structure of femur

The femur (Figure 2.1) or thigh bone is the longest, heaviest, and strongest bone in the entire human body. A lot of activities, such as running, jumping, walking, standing and including all of the body`s weight is supported by femurs. The femur is a long bone and is also a major component of the appendicular skeleton (portion of the skeleton of vertebrates consisting of the bones or cartilage that support the appendages such as pelvic girdles). On its proximal end, the femur forms a smooth like spherical process known as the head of the femur. The head of the femur forms the ball-and-socket hip joint with the cup-shaped acetabulum of the hip bone. The rounded shape of the head allows the femur to move in almost any direction at the hip, including circumduction as well as rotation around its axis. Just distal from the head, the femur narrows considerably to form the neck of the femur. The neck of the femur extends laterally to provide extra room for the leg to move at the hip joint, but the thinness of the neck provides a region that has probability to fractures[8].

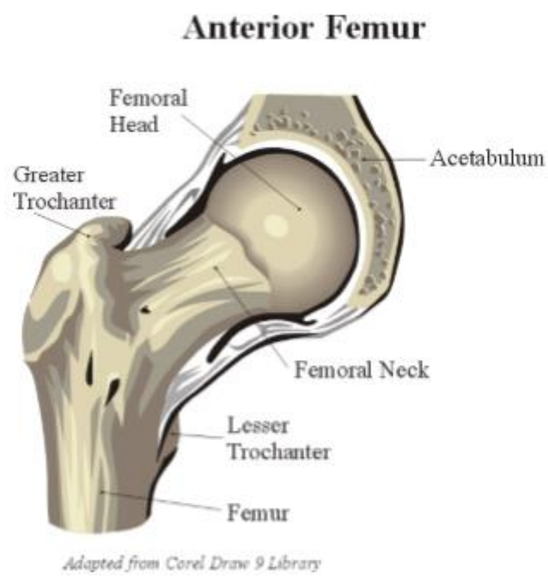


Figure 2.1 Femur or thigh bone; anterior view [7]

2.3 Internal structure of femur

A femur cross-section (Figure 2.2) basically consists of three layers; the periosteum (outside skin of the bone); the hard compact bone; and the bone marrow. First is a layer of thin, whitish skin Periosteum that is packed with nerves and blood vessels where it supplies the cells of which the hard bone below is built. For the next layer is a mass-dense bone which is called the compact bone. It is cylinder in shaped and have abundant of tiny holes and passageways where it runs the nerves and blood vessels to supply rich oxygenated blood and nutrients to the bone. The properties of dense layer compact bone supports the weight of the body and mostly it is made up of calcium and minerals. Since the Cortical bone is the hardest and densest tissue in the human body, it is used to support and protect the soft tissues of the body and give the body shape[9]. As stress is applied to specific regions of the body through weight bearing activities, the thickness of cortical bone may vary over time. When stresses are applied to the bone, the body responds by activating osteoblasts to produce mineral matrix and form additional layers of cortical bone. When stress on the bone decreases, osteoclast cells break down the mineral matrix to release mineral ions into the blood and reduce the bone’s mass. These processes help to control the strength and mass of bones where this phenomena is related to the Wolff`s Law; if loading on a particular bone increases, the bone will remodel itself over time to become stronger to resist that sort of loading[10]. The other types of bone found inside the femur cross-section is Trabecular (Spongy) bone. This spongy bone comprises the majority of interior long bone tissue, in addition to that of the hip and vertebrae. It is also called spongy or cancellous bone because of its soft, spongy texture.

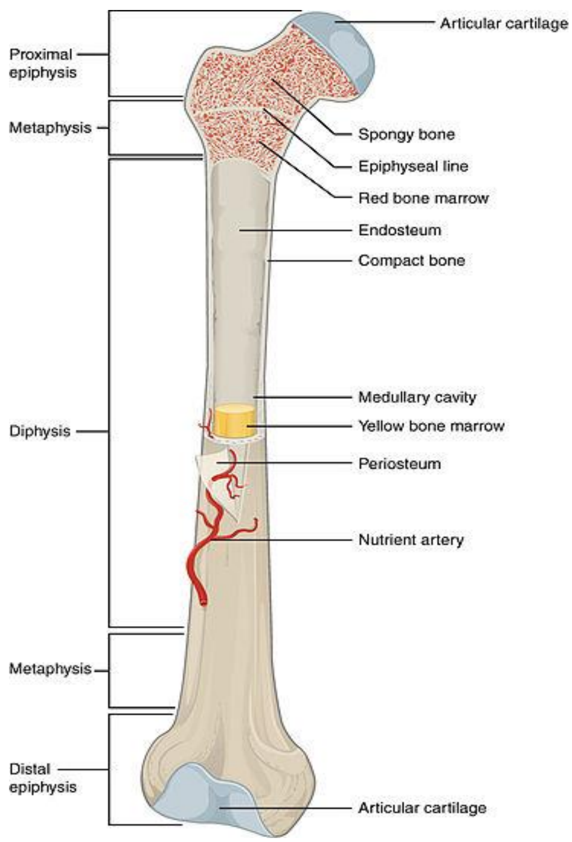


Figure 2.2: Femur`s internal structure; anterior view[11]

2.4 Bone diseases

Diseases can occur everywhere in all body parts including bone. Diseases such as osteoarthritis or arthritis can cause damage to the joints that causes difficulty to do daily activity routine such as walking, standing and many more (Figure 2.3). By an estimation of certain study, 20% of adults have reported some form of arthritis, where the percentage increases to almost 50% with adults 65 years and above. The bad effect of arthritis in the hip is where it decreased joint space[12]. Osteoarthritis is part of arthritis where it occurs when the cartilage on the end of bone begins wearing away, causing pain and stiffness. When the cartilage wears away completely, the bones rub directly against each other causing decreased mobility and chronic pain. It is characterized by progressive degeneration of articular cartilage and usually attacks in elderly population[13]. This disease is characterized by damage to hyaline articular cartilage in which involves the whole joint and also changes to subchondral surface. This will leads to subchondral sclerosis, the formation of subchondral cysts and also increased pressure within the bone. Patients may suffer a degree of synovitis that associated with the arthritis as well as a thickening of capsule around the joint. Radiographic evidence of osteoarthritis includes narrowing of the joint space, osteophytes and overloading in the form of bony sclerosis. Osteoarthritis manifests as joint pain, although the cause of pain is unknown[14].

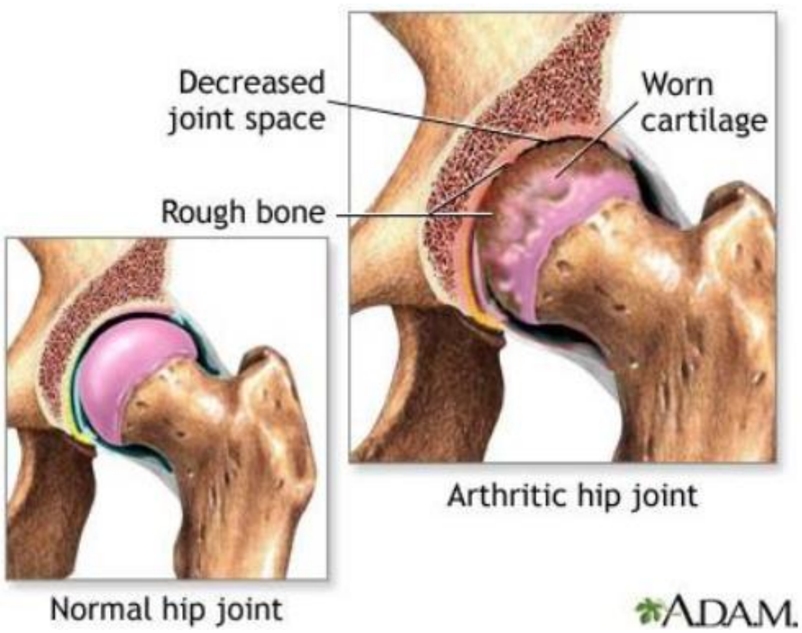


Figure 2.3 Normal and arthritic hip joint[12]

2.5 Total hip arthroplasty (THA)

Arthroplasty is an orthopedic surgical procedure where the musculoskeletal joint is replaced, remodeled, or realigned by osteotomy (a surgical operation whereby a bone is cut to shorten or lengthen it or to change the alignment). Total hip replacement (THA) basically have been successfully employed in order to threat the end stage of arthritis, rheumatoid arthritis and also bone fracture at the femurs[12]. It can be considered as a surgical procedure to restore the function of a joint. A joint can be restored by resurfacing the bones. An artificial joint (called a prosthesis) may also be used. This surgery aim to restore function and relieve pain by replacing the articulating surface of the joints. Now there are range of components, materials and with variety of surgical techniques available for THA[13]. The artificial femoral components materials and properties can be varies. The total hip arthroplasty (THA) consists of replacing both the acetabulum and the femoral head. The femoral stem can either have 2 types which are cement or cement-less.

2.6 The Effect of Implant Material Selection on Stress Shielding

It is expected that an increase in load transfer from the stem to the proximal femur is due to decreasing of stem stiffness and more likely stress shielding will be reduced. Implant materials will give a huge effect to the stem stiffness and the Young`s Modulus of the implant materials is a major factor of transferring the stress evenly to the surrounding bone[15]. Moreover, the static numerical analysis that was performed for models made of Ti-6Al-4V alloy and CoCr Mo alloy, shows that value of Von Misses stresses are smaller than the yield strength of both models but higher than yield strength of 316L stainless steel[16]. Even more, an optimized femoral component design can be obtained by optimization technique and different material models with combined 3-D stress analysis model for reducing and smoothing stresses adjacent to the interface. The safety factor and fatigue life can be calculated by static and dynamic FE analysis where Ti-6Al-4V materials is the best stem shape for fatigue under static loading.[17]. This shows that implant made of Ti-6Al-4V alloy can be considered as an implant materials since it stiffness which is not too high. Therefore, there is potential to reduce the stiffness mismatch between femur and the hip implant and reduce the stress shielding. In paper research of C. Piao, there are differences in geometry and also elastic modulus between anatomical and traditional prosthesis. As the specimens were implanted into shaft specimen, stress shielding rate in the proximal 1-10 stations in lower femoral neck dissection-type by anatomical is lower than traditional prosthesis. As the analysis suggested that titanium was used for anatomical prosthesis, and since titanium has lower elastic modulus, this type of prosthesis had a significant role in reducing the stress shielding effect when external load is applied as compare to the traditional prosthesis where cobalt-chromium- molybdenum alloy was used. [5]. The research by B. Ellison had stated that Mallory-Head femoral cementless stem with tapered titanium design and circumferential proximal plasma spray porous coating with titanium substrate eventually does not cause the classic radiographic signs of stress shielding. The titanium substrate applied to this stem is thought to have more closely match stiffness of native femur. In addition, the current study provides evidence that this type of implant does not causes stress shielding in most patients at an average of 14 years follow up. Alternatively, most of the cases shows that either increased or unchanged of cortical thickness over time in all locations surrounding the femoral stem when using tapered design with Titanium materials [4]. In a research proposed that fatigue strength is a parameter that should be consider for material selection in artificial hip structures. As many believes that the reduced stress in the bone (stress shielding) is one of the problems threatening the long-term fixation of uncemented stems. The high encouragement of using materials with low stiffness for prosthesis in order to reduce stress shielding[18]

2.7 Mechanical Properties of Bone

The major parameters that will affect the mechanical behavior of bone is by its porosity. The corticol bone tend to be more stiff and able to withstand higher stress due to its high mineral content. The next covering layer of bone which is cancellous bone where it is less dense and has lower elastic of modulus. Although it cannot withstand higher stress as compared to corticol bone, it is able to undergo higher strain before failure. The common mechanical property for both cortical and cancellous bone are anisotropic in nature. It is where the elastic modulus and strength of the bone itself depends on its orientation. For corticol bone, it has similar or transverse isotropic properties along the direction of anterior-posterior (AP) and medial-lateral (ML). For the cancellous bone, the correlation basically is not obligatory accurate because it is anisotropic based on its trabecular morphology. Moreover, corticol and cancellous regions of the bone have properties which are anatomically site dependent or mechanically heterogeneous for its whole domain. One study related to the human proximal tibia showed that the Young`s modulus of the cancellous bone with same metaphysis at different location basically can differ its value by 100 times[12].

Table 2:1 Parameter/property used by other researchers for bone study

Part	Parameter/property	Value	Reference
Proximal femur	Constant Poisson`s ratio	0.3	S. Obeidat et al.[19]

Furthermore, the human bone in nature basically possess as an anisotropic and heterogeneous where the properties mainly depends on the direction and location. The consideration of cancellous bone in the model`s property sometimes was excluded for simplification and it will only minimally effect the stiffness and failure mode of the femur[18]. On G. Treece research, the cortical thickness estimation requires a good estimation of cortical density, so it is good to assume the density is constant at all points on the proximal femur[20]. M. Cuppone et al.[21] in his study was concerned with investigating whether a relationship between the Young`s modulus of bone and the CT number (Hounsfield units) existed. As the three-point bending test was conducted, the result indicate that in femoral mid-shaft, the cortical bone has an average Young`s modulus value of 18.6 GPa where this value basically well agrees with the data obtained by other researchers by using different experimental techniques. [22]Sensitivity of model is an important criteria where it can provide certain assurance that the model is “accurate” or at least it has reasonable reflection of reality. In this case, conducting a parametric analysis, the materials properties can be varied but most of the studies just applying homogeneous property to the bone where basically this is not accurate to the actual behavior of the bone in nature. Conditions of the bone itself whether it is linear elasticity, isotropic, anisotropic, homogeneous and heterogeneous will affects the validity and sensitivity of the bone. From R. Nareliya study[23], it stated that the human bone is highly heterogeneous and nonlinearity in nature. So it is difficult to assign materials properties along each direction of the bone model. The following properties basically are applied for the analysis of femur bone:

Table 2:2 Material properties used for femur bone analysis

Material property	Value	Reference
Density Young`s Modulus Poisson`s Ratio	2000 Kg/m3 2.130 GPa 0.3	R. Naraliya [23]

Besides that, an approach of applying heterogeneous materials property to the bone model where the whole femur model was divided into ten layers longitudinally which is based in difference of bone density in that particular direction using MATLAB 2007R[19]. Some have argued where FEM cannot satisfy model with complex materials properties such as complex biological systems. Much on the early research on FEM is mainly to demonstrate and validate the methodology rather than solving specific problem regarding to bone strength. Somehow, new advancement technology have steps forward and advanced computer software and hardware allowed for arbitrarily complex models. From all of the approaches, it is important to aware that bone particularly behave anisotropic and heterogeneous in nature. The mapping of bone density and Young`s Modulus based on HU units on each of the elements are crucial in FEA because it eventually will give more accurate and reliable data compared to only applying a single material property to the bone. Thus, a linear isotropic and heterogeneous material properties will be applied in this bone model and FEA will be executed to predict the stress-strain around the femur. Although the results from FEA itself is not fully accurate and reliable, since FEM is just a tools of results predictions, perhaps the gist of this method will improve the study in orthopedic field.

2.8 Finite element modelling (FEM)

The stress distribution in a structure mainly depends only on this four aspects:

- Magnitude and configuration of loading conditions.
- Geometry of the structure (implants geometry and shape).
- Materials property (implant`s property and bone`s property in nature).
- Physical nature of connections with the environment (boundary conditions) and between different materials (interface conditions).

For this study which is structural stress analysis, these aspects must be described by means mathematically (in theoretical stress analysis), where numerical methods such as finite elements methods is employed[18].

Finite element modelling (FEM) basically has been used in engineering field for the analysis, investigating and understanding of engineering problems. Besides, FEM has been executed to study stress-strain bone in surrounding implant, simulate the response of the bone to the implant and implant design features[12]. Nevertheless, Finite Element Analysis (FEA) can provide certain estimation on stress-strain within a structure (femur) and it is a valuable tools to make a predictions on how structure will behave mechanically[22]. In work K. Colic et al. showed that the numerical (3-D) models of femoral implants using FEA that were created eventually gave results close to the one obtained from experimental values[16]. The FEM is an advanced simulation technique and has been used since 1972 in orthopedic biomechanics and can be considered as important tool in design and analysis of THR and other orthopedic device. This simulation streamlines the design condition and thus preventing permanent damage caused by wrong execution action[17]. It need to be understand that FEA is just a mathematical estimation and some of it may not experimentally verified, so FEA does not prove that something is true, but suggesting on what might happen by assuming the circumstances one has entered into the computation are correct. The boundary conditions itself is very important to the behavior of the model when doing a simulation. For example, it is crucial for the bone model is constraint during loading with respect to the activity [22]. The use of FEM software such as Marc Mentat software can be considered a reliable estimation tools for this study. The simulation must at least have some experimental validation in order to apply external loading and boundary condition for specific activities based on HIP98 (hip joint loading) collection data and by M. Heller at al. works[24].

2.9 Terminology describing the musculoskeletal system

The view and description of human body and its movement anatomical terminology was developed and used by researchers. A three-dimensional coordinate system (Figure 2.4) which is basically consisting of three anatomical planes is defined as follows, and the explanation of each plane is given in Table 2:3:

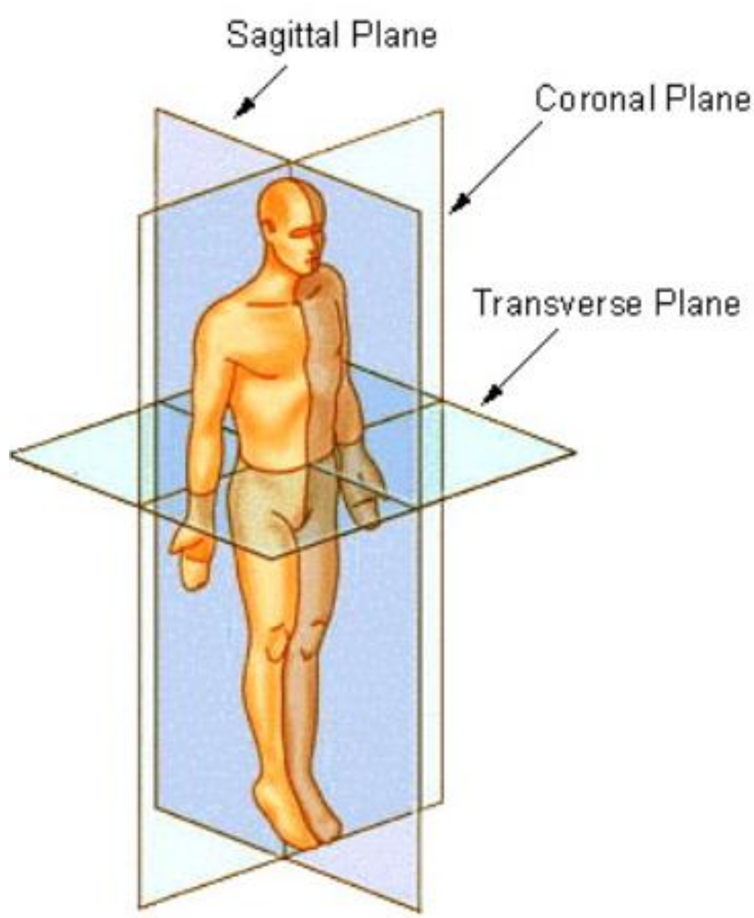


Figure 2.4 Anatomical body planes[25]

Table 2:3 Three coordinates system used in human anatomy[25]

Plane	Direction and function
Coronal plane (Frontal)	• Vertical plane running from side to side • Divides the body in anterior and posterior portions
Sagittal plane (Lateral)	• Vertical plane running from front to back • Divides the body into right and left side
Axial plane (Transversal)	• Horizontal plane • Divides the body into upper and lower parts
Median plane	• Sagittal plane through the midline of the body • Divides the body into right and left halves

3 Methodology

3.1 General view

There are many methods to model a femur bone. The simplest case is where the virtual femur is modelled as a straight shaft with a neck that extended from the shaft itself with certain angle, curvature and length. The CAD model is generated into single three dimensional model with the help of different dimension obtained from human bone femur. This is mainly due to unavailability of such data from patient itself. The bone model is assumed as natural composite and isotropic material for its property. This type of model mainly is not accurate to do analysis on the femur because the dimension itself does not obey the dimension and nature of the bone. The advanced and robust methods which are CT-scan (Computed Tomography) and MRI (Magnetic Resonance Imaging) data[26] can be used to model a 3-D femur bone because there are relatively reliable and has high accuracy. The model is developed based on different in HU-units in human body composition. Since this method follows the nature dimension of the femur, more study can be conducted and adopted for further analysis with 3-D femur bone model.

3.2 Materials and methods

3.2.1 Computed Tomography (CT) Dataset

The CT-scan images of geometrical data of real implanted femur and contralateral femur bone were stored in 512X512 pixels, with a pixel size of 0.9 mm X 0.9 mm and slide thickness of 2.0 mm in the form of Digital Imaging and Communications in Medicine (DICOM) format contains binary data elements. A single DICOM file contains header that stores information about the patient`s biodata (Female, 73-year-old, with an implant on her right femur), which contains information in three dimensions. A total number of 363 slices of image was obtained to define the whole femur (head to shaft of femur, the distal epicondyle is not included).

3.2.2 Generation of surface model

The CT images were used for subsequent image processing and analysis. The images were processed using a medical imaging software package (MIMICS 17.0, materialize Leuven, Belgium) and used to convert 2-D CT scans into a layered of 3-D Stereolithographic (STL) image. A lossless compression (a class of data compression algorithms that allows the original data to be perfectly reconstructed from the compressed data) was applied to convert the CT scan images to 3-D bone model. CT scan data in the form of DICOM consist of two dimensional gray-scaled images. A thresholding was used to map the variation of HU value in human body where compact bone (CT, adult) was used as predefined threshold set with specified HU scale range (min=1686, max=3012). The images was edited slice per slice starting from the head of femur to distal end of the shaft by filling the empty region inside the femur that was not included during the threshold setting (Figure 3.1).

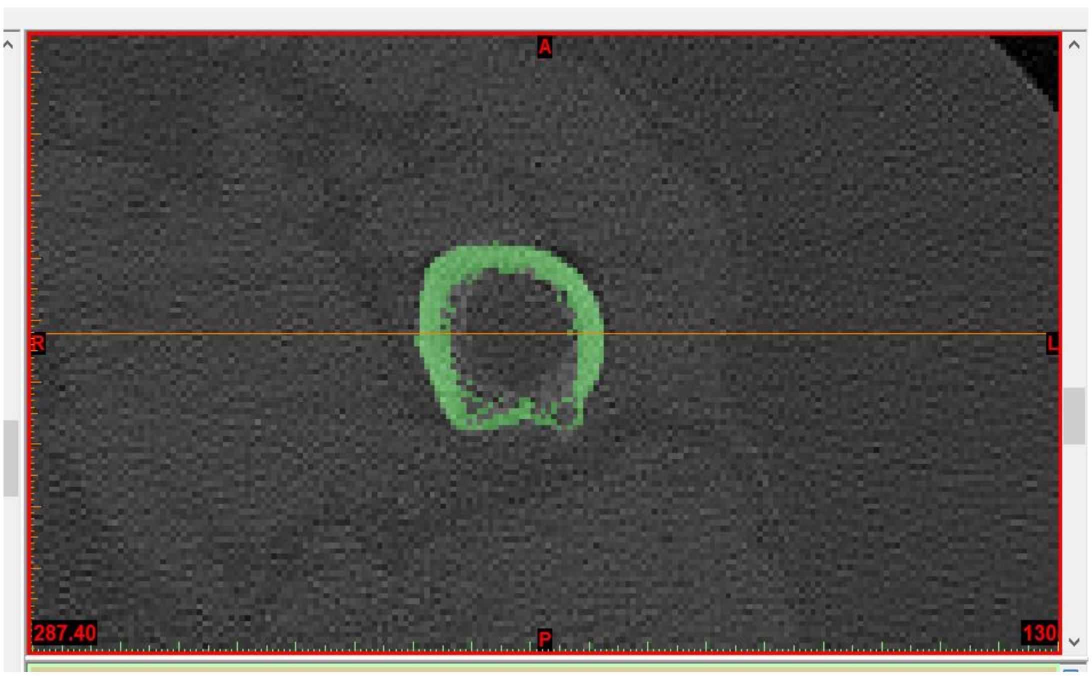


Figure 3.1 Top view, at slice no. 130, the inner region of the femur shaft was not filled with pixels

The other important process is the removing the excess threshold region surrounding the femur that may effected our 3-D model development. This effect arise due to the `artefact effect' that come the implanted femur when the CT-scan was conducted. In this study, artefact effect reduction/elimination software or algorithm was not used due to limitation of currently used software. So, the removal process was done manually per slices by deleting some of the unwanted pixels. The artefacts effect can be seen clearly if present of implant materials shown in Figure 3.2.

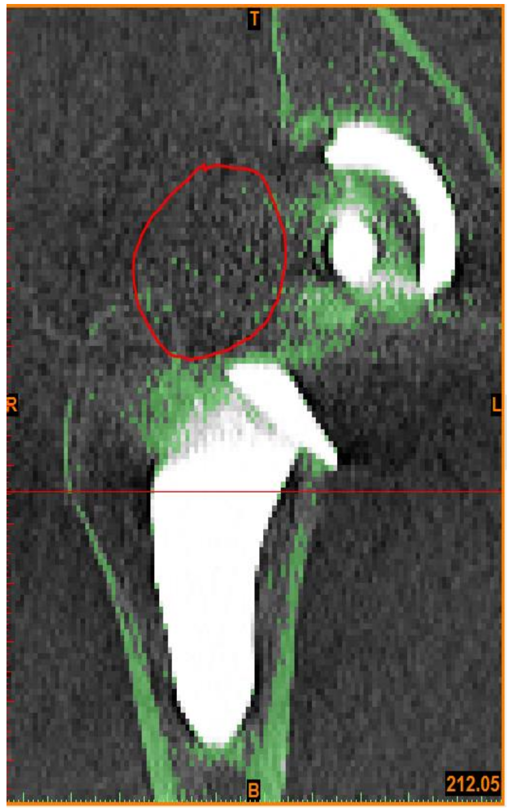


Figure 3.2 Artefect effect (shown in red circle) due to the presents of implant material on right sided femur

The general summary of whole process of developing 3-D femur bone in MIMICS 17 done by the following steps:

- Thresholding based on HU value scale which is compact bone (CT, adult) was done at the early stages of the process to ensure the segmentation object which contains only those pixels of image with defined value. Trimming process was executed in order to get the good model shape of the femur itself. However, there were certain pixels that not be filled during the threshold process due to variation of HU value in human body composition and filling process was done manually to filled the gap. Besides, the unwanted pixels due to artefact effect, surrounding the femur that may affect the 3-D shape of the femur should also be deleted in early stage process.

- The region growing process allows splitting the segmentation in different and separated part[23]. The generated region mask basically was used to develop 3-D model for the bone which is based on 3-D interpolation technique that transform 2-D images to 3-D model.
- The 3-D femur bone model was converted and exported into stereolithographic (STL) file for meshing and FE Analysis.

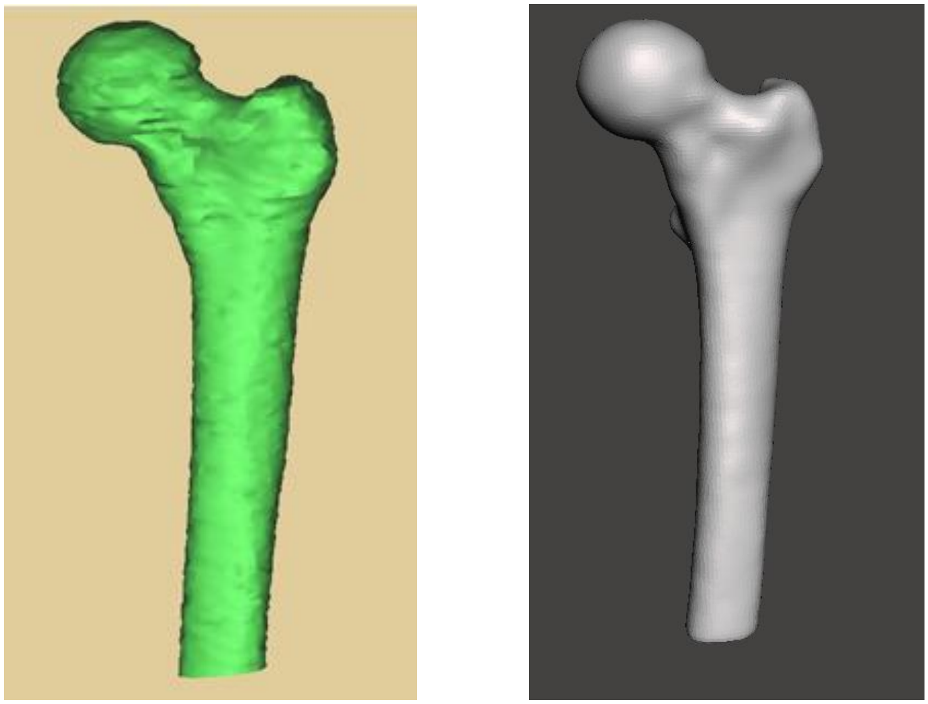
The following steps can be repeated for the implanted femur which are shaft and also implant.

3.2.3 Model smoothing

After generating the model (Figure 3.3 (a)), the STL file from the MIMICS was imported into an Autodesk, Inc. an open-source software (Autodesk Meshmixer Version 3.2.27) for development and modifying to get smoother and good dimension of femur. The model has undergo smoothing and remeshing process where the remesh mode was set to `Target Edge Length' and the edge length was adjusted to maintain according to the desired size (Figure 3.3 (b)). The model was then saved as STL file. Generally, in defining and smoothing following actions were performed:

Amount of uneven and roughness of surface are reduced significantly.

- The nature dimension of femur is maintained with robust smoothing process being executed.
- Amount of details are added and outliers are reduced.



(a) (b)

Figure 3.3 Anterior view of reconstructed femur model (a) before and (b) after smoothing process

The whole process of reconstruction of the model was repeated for the right implanted femur.

3.2.4 Generation of solid models

After that, the STL file was imported to (ANSYS Workbench Version 16.0) for further process. In this sub-process, certain elements correction can be done and some errors may be reduced and get a better model for further FE analysis.

All the bone models were saved as STL file and exported to MSC.MARC-MENTAT 2010, MSC Software Corporation, and Santa Ana, CA, USA to generate FE models.

In remeshing and certain operations in Marc Mentat 2010, the following actions were performed according to the type of model:

3.2.4.1 Intact femur

Based on Chaudhary et al. study[27], convergence considerably reached at a 2 mm mesh size which is based on 5 percent change in mean stresses between a mesh size of 2 mm and 1.5 mm. In the present study on the femoral component, the element size was set up to 1.5 mm (Figure 3.4) in surface meshing while coarsening factor was set to 1 in volume meshing, which resulted to 47,480 number of nodes and 257,613 number of elements Figure 3.4. The coarsening factor basically to compensate the element size between the outer surface and inner volume, so both of it will have more likely equal in element size (Figure 3.5). The FE model used 4-node linear tetrahedral element (TETRA134).

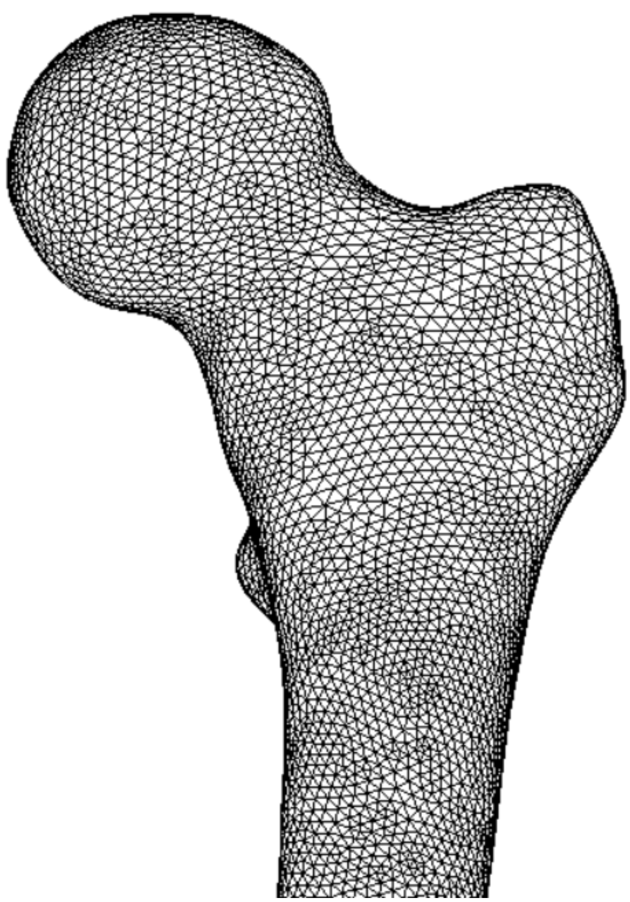


Figure 3.4 Anterior view of left femur with 1.5 mm element meshing size

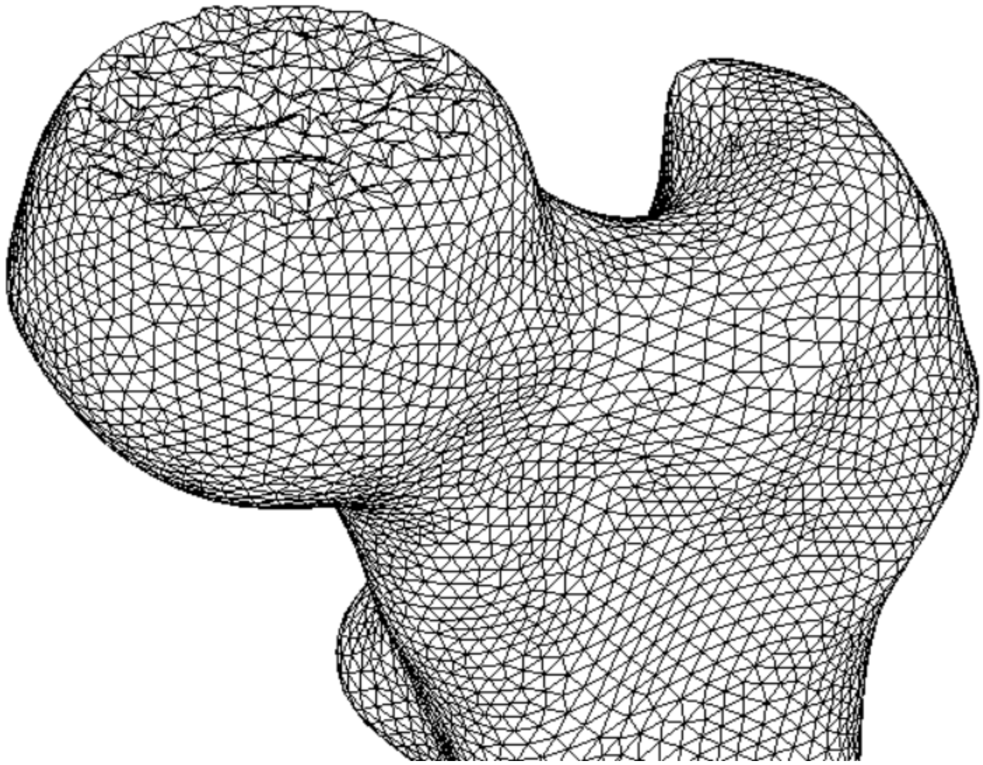
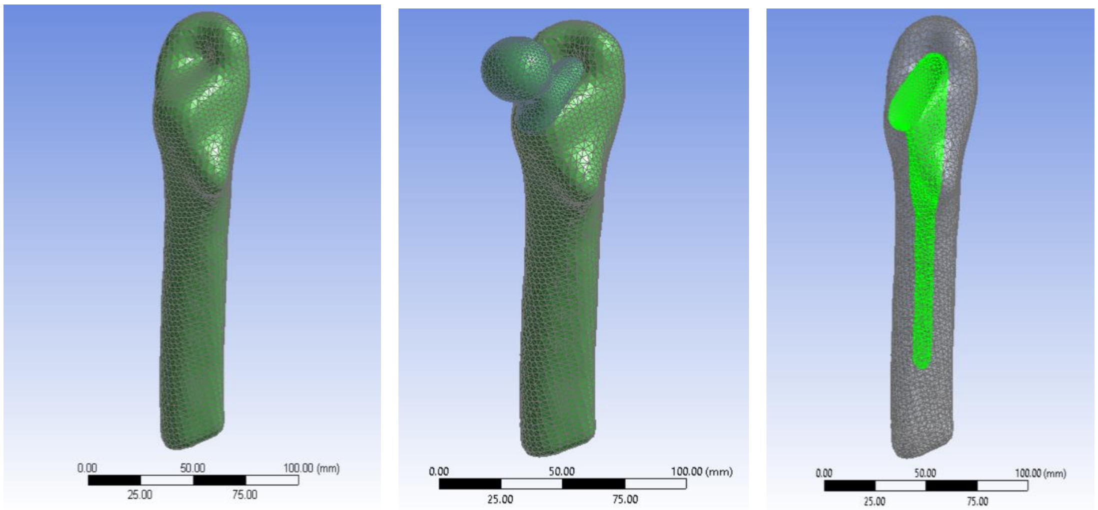


Figure 3.5 Cross-sectional view of femur head; the element size within the volume and the surface are likely the same due to coarsening factor 1.

3.2.4.2 Right Shaft

The right femur and implant model was edited in `Design Modeller' for an important process which is Boolean operation. The aim for this process was to create two different solid model for FE analysis. The `Boolean Subtraction' operation was performed to make the femur become a hollow as preparation for implant position (Figure 3.6 (a)). The position of the implant was automatically placed inside the femur when it was imported based on position algorithm set in DICOM file (Figure 3.6 (b)). So, the position orientation was not changed to prevent in position error when doing certain operation and analysis.



(a) (b) (c)

Figure 3.6 Isometric view of (a) right femur before Boolean operation, (b) the femur and implant were merged together, and (c) hollowed femur was generated using `Boolean Subtraction' operation

The merging process between the femur and implant were perfectly located within their position which is based on CT data scan algorithm. This eventually will smoothen the Boolean operation task because no need alignment need to be done between the shaft and implant, thus preventing any error when doing FE analysis.

After the hollow shaft has been generated (Figure 3.6 (c)), the model was then saved as (stl. File) and it was imported in Marc 2010 software for meshing procedure. The steps involved was similar as in previous steps executed for the left femur. The FE model of implanted femur consisted of 32,565 number of nodes and 171,626 number of elements.

3.2.4.3 Implant

Inside `SPACECLAIM’, the implant model was saved as (stl. File) for another operation in Marc 2010 software. The FE model of implant consisted of 14,714 number of nodes and 76,562 number of elements (Figure 3.7).

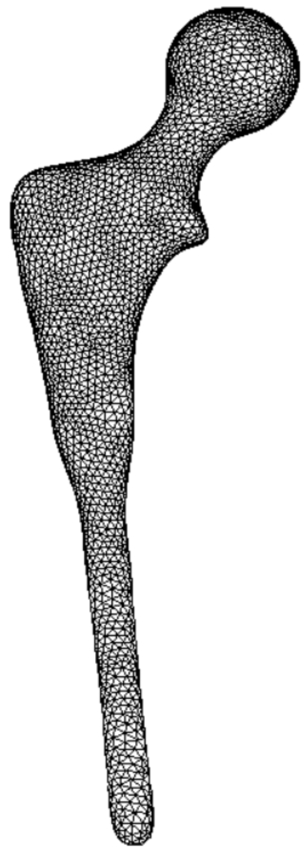


Figure 3.7 Anterior view of implant with element meshing size 1.5 mm

3.2.5 Material properties assignment

Generally, the femur models were assumed to be linearly elastic with heterogeneous material. For the implant, linear elastic behavior of a material was used, as a function of two elastic constant – Young`s modulus (depends on type of material used for the implant) and constant Poisson`s ratio 0.3[16].