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Design of a hybrid artificial hip joint using finite element analysis

تصميم هجين لمفصل مخروقة إصطناعي بإستخدام تحليل العناصر المحدودة

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الآيـة

"ولا تقفُ ما ليس لك بهِ علمٌ إن السمع والبصر والفؤادَ كل أُوْلئك كان عنهُ مسئُولًا*
ولاتَمْشِ فِي الأَرضِ مرحاً إِنكَ لن تخرِق الأَرض ولن تَبْلُغَ الْجِبال طولًا"

الإسراء (37-35)

Dedication

To who is my life, my mother,,,,,,,,

To who is my support and guide, my father,,,,,,,,

To her pure soul, my grandmother,,,,,,,

To my beloved brothers,,,,,,,,

To my lovely sister,,,,,,

To my dear friends,,,,,

And everyone who supported me to move forward.

Acknowledgement

My grateful thanks to Allah for guiding me and giving me the strength to complete this project with HIS mercy, kindness and blesses. Thanks are progressed specially to D.Elias Sidieg at Sudan University of science and technology (SUST) for his wise supervisory and guidance, D. jaafar abd-alhameed at SUST, E.ahmed taha at Giad group , E.mohamed abas at SUST, E Zoelnoon nasraldeen at advanced design and manufacturing center-defence industry system , E.Ezaldeen at 3Max workshop and finally ms. Reem at Sudanese foundation group Isidor 3D printing.

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Abbreviations	Core
AHJ	Artificial hip joint
CFRP	Carbon-fiber-reinforced polymer
COC	Ceramic-on-ceramic implant
CoCrMo	Cobalt-chromium-molybdenum alloys
COM	Ceramic-on-Metal
COP	Ceramic-on-Polyethylene
FEA	Finite element analysis
MOP	Metal -on- polyethylene
PEEK	Poly-ether-ether-ketone
PMMA	Poly-methyl-meth-acrylate
PTFE	Poly-tetra-fluor-ethylene
QFD	Quality Function Deployment

THA	Total hip arthroplasty
Ti6al4v	Titanium 6 Aluminum 4 Vanadium alloy
UHMWPE	Ultra High Molecular Weight Polyethylene
X-UHMWPE or XLPE	Crosslinked UHWMPE
Y-TZP	Yttrium stabilized tetragonal polycrystalline zirconia

Abstract

Rehabilitation is an important branch of biomedical engineering specializations that is exceedingly related to the healthcare delivery and its improvement, one of the most important topics of rehabilitation is prosthesis that is related to resolving the problems of the amputations and artificial joints. The later has been widespread recently due to the bone diseases and traumas.

Subsidence, stress shielding, fatigue fracture, stiffness mismatching and expensive prices are the most common problems with metallic artificial hip joint, which led to presence of different artificial joints modalities with different qualities. This research aims to enhance the healthcare by providing an artificial hip joint that proposes a reasonable solution for these problems, and that through design a hybrid joint composed of hybrid stem that consist of core and coat with two different materials CoCrMo and PEEK for each of them respectively. The CoCrMo core exhibits elevated mechanical properties and optimal corrosion resistance under friction condition and has an elliptical geometry that permit handling the maximum load that is applied on the joint. On the other hand the S-shape PEEK coat provides high flexibility and osteointegration that makes it able to handle the rest of the load that is applied on the joint. For the suggested design, special mechanical analysis tests using finite element analysis methods were carried out then repeated 10 times with gradient of 12.8º in the range of motion angle to check the efficiency of the proposed design, it was observable that the highest value of the maximum stress presented in the model analysis was 345.34 MPa, this means the suggested materials and dimensions provides efficient of 64%. Finally, the proposed design was printed as 3D prototype to verify the reasonability of the model dimensions.

المستخلص

إعادة التأهيل من الفروع المهمة جداً في تخصصات الهندسة الطبية الحيوية التي ترتبط إرتباطاً وثيقاً بتقديم الرعاية الصحية وتحسينها،ومن أهم محاورإعادة التأهيل هي الأطراف الإصطناعية التي ترتبط بحل مشاكل البتر والمفاصل الإصطناعية ، والأخيرة أصبحت منتشرة بسبب أمراض العظام والحوادث.

الخمود ، إجهاد التدريع ،كسور الإجهاد ، الإختلاف في الصلابة وإرتفاع الأسعار تعتبر أكثر مشاكل مفصل الورك اللاإصطناعي المعدني ، مما أدى إلى ظهور العديد من التصاميم ذات الكفاءة المتباينة . هذا البحث يهدف إلى تحسين الرعاية الصحية وذلك بتوفير مفاصل ورك إصطناعية تقترح حلول معقولة لهذه المشاكل ، وذلك بتصميم مفصل هجين يحتوي على جذع هجين يتكون من قلب وغطاء من مادتين مختلفتين هما الكوبالت كروميوم موليبديم و البولي إيثر إيثر كيتون على الترتيب .قلب التصميم ذو مادة الكوبالت كروميوم موليبديم يمتاز بخواص ميكانيكية متقدمة ومقاومة تآكل مثالية تحت ظروف الإحتكاك وكما يتمتع القلب بشكل إهليجي يمكنه من تحمل أقصى الإجهاد الواقع على المفصل.على النطاق الأخر فإن الغطاء ذو شكل حرف S يدعم التصميم بالمرونة والتكامل العظمي الذي يمكنه من تحمل ما تبقى من قوى مسلطة على المفصل.

تم إجراء إختبارات ميكانيكية متخصصة للتصميم المقترح وذلك بإستخدام طرق تحليل العناصر المحدودة وتم إعادة هذه الإختبارات 10 مرات وذلك بتدريج زاوية نطاق الحركة بمقدار 12.8^{o} للتأكد من كفاءة التصميم المقترح. من نتائج تحليل التصميم المقترح ،لوحظ أن أعلى قيمة لأكبر إجهاد ظهرت على التصميم كانت 345.34 ميقا باسكال وهذا يعني أن المواد والأبعاد المقترحة ذات كفاءة 64%. تمت طباعة التصميم المقترح كنموذج ثلاثي الأبعاد للتحقق من واقعية الأبعاد .

Chapter one

Introduction

1.1 General view:

Medical implant is a medical device that is designed to replace body missed part, for function or shape restore. They are manufactured from different materials according to the purpose of the implant, due to the biological environmental that medical implants would be exist in, their materials should be biocompatible, such like Titanium, silicon, apatite, Ploy-Ether-Ether-Ketone (PEEK), polymers and carbon fibers. Many implants are prosthetics intended to replace missing body parts; other implants deliver medication, monitor body functions, or provide support to organs and tissues. Due to the different types of tissues, bones and vascular diseases, and since these diseases causes painful sensation and function lose, the necessity of the prosthetics is increased widely, leading to produce different types of them with different qualities, one of these prosthetics is the artificial joints, which are used to replace the damaged joints. Hip joint is one of the most important joint in the human body that plays a major role in ambulation and load bearing. Total hip arthroplasty (THA) is a procedure where the damaged hip joint is removed and replaced with artificial one, the number of people undergoing hip joint replacement surgery has increased over the past decades. In the UK alone, more than 60,000 THA are performed annually, 15 % of which are performed in the younger age group (less than 57 years old) [1], and to produce appropriate cost verses quality artificial hip joint (AHJ), sequential studies will be carried out.

1.2 problems statement:

Subsidence, stress shielding, fatigue fracture, stiffness mismatching and expensive prices are the most common problems with metallic AHJ, which led to presence of different artificial joints modalities with different qualities.

1.3 Hypothesis:

Enhance the healthcare by providing AHJ with appropriate cost and quite enough quality.

1.4 Objectives:

1.4.1 General objectives:

The general objectives of this research are to:

1- Provide local manufactured with high durability AHJ.

2- Introduce fresh idea in designing and material usage by triggering a modern biomedical industrial horizon.

3- Reduce the cost of the AHJ (minimum cost vs. best quality).

1.4.2 Specific objectives:

The Specific objectives of this research are to:

1-Use price acceptable, biocompatible and mechanical suitable materials for AHJ manufacturing.

2- Implement finite element analysis and 3D designing methods

3- Design a composite AHJ model.

1.5 Thesis layout:

The first chapter outlines the general view of the project followed by the problem definition and the suggested hypothesis to reach the objectives behind this research. The second chapter states a rich theoretical fundamental of the anatomy, physiology and biomechanics of the hip joint, and includes the biomaterials and its biocompatibility for the artificial hip joint. The third chapter gives a background study of designing methods and materials those were adopted and used in the AHJ designing. The fourth chapter presents the methods those were adopted to achieve the final design. The fifth chapter deals with the necessary description and schemes for the final design. The sixth chapter includes the results. The seventh chapter presents the discussion. The eighth chapter highlights the main conclusions and recommendations. Finally, the used references and the needed appendices were added.

Chapter two

Theoretical fundamental

Hip joint is one of the free movable, synovial joints that belong to the ball and socket joints categories. in a simplest discerption of the Hip joint, it consists of acetabulum which is called the socket, and femoral head that is called the ball. This chapter presents the essential structure and function of the hip joint, including the replacement mechanism for the damaged joints due to the different reasons, while discussing the designs, material and fixations mechanisms of AHJs.

2.1 Definition of the hip joint:

The hip is a synovial joint formed by the surface of the acetabulum and the head of the femur. These form a ball-and-socket joint with two highly congruent juxtaposed articular surfaces, lubricated by fluid from the synovial lining and surrounded by a strong capsule and ligament complex. The architecture of the joint provides a nearly exact match between the cup-like acetabulum and spherical femoral head and makes the freely mobile articulation perfectly suited for weight-bearing locomotion. In addition, the configuration of the bony architecture provides inherent stability and limits total range of motion, while allowing multiaxial articulation and minimizing the need for soft tissue constraint. Due to these characteristics, the hip joint plays a pivotal role in lower extremity gait advancement and bears up to four times the body weight during walking.

2.2 Anatomy of the hip joint:

The basic structure of the hip joint is three major parts, and for better understanding for the complex anatomy, it will be described in three sections:

1. Bone and articular surface anatomy.

2. Capsules and ligaments.

3. Muscles Surrounding the Hip

2.2.1 Bone and articular surface anatomy:

Here it is possible to palpate different bony landmarks such as the greater trochanter, anterior superior iliac spine, iliac crest, posterior superior iliac spine, pubic symphysis, pubic tubercle and ischial tuberosity. The greater trochanter can be seen and palpated as a flattened, depressed area as shown in figure (2.1) [2].

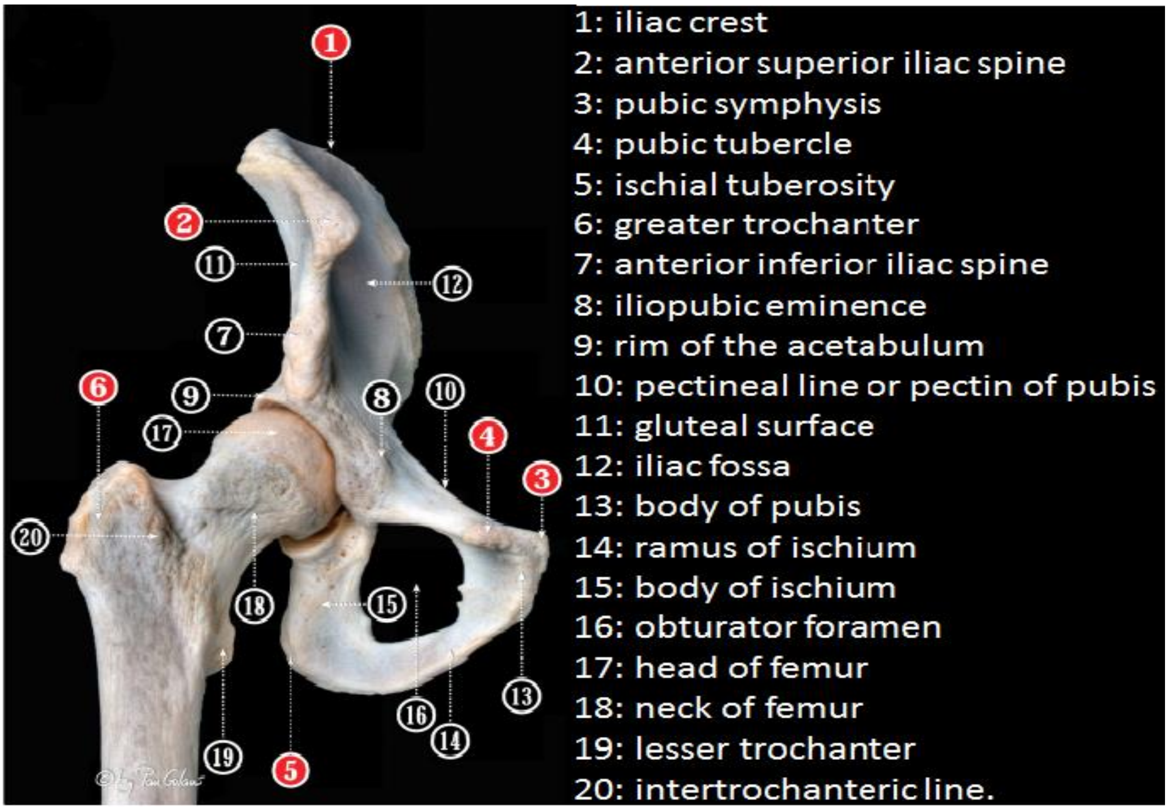

Figure (2.1):a. anterior view of the osseous components of a right hip joint

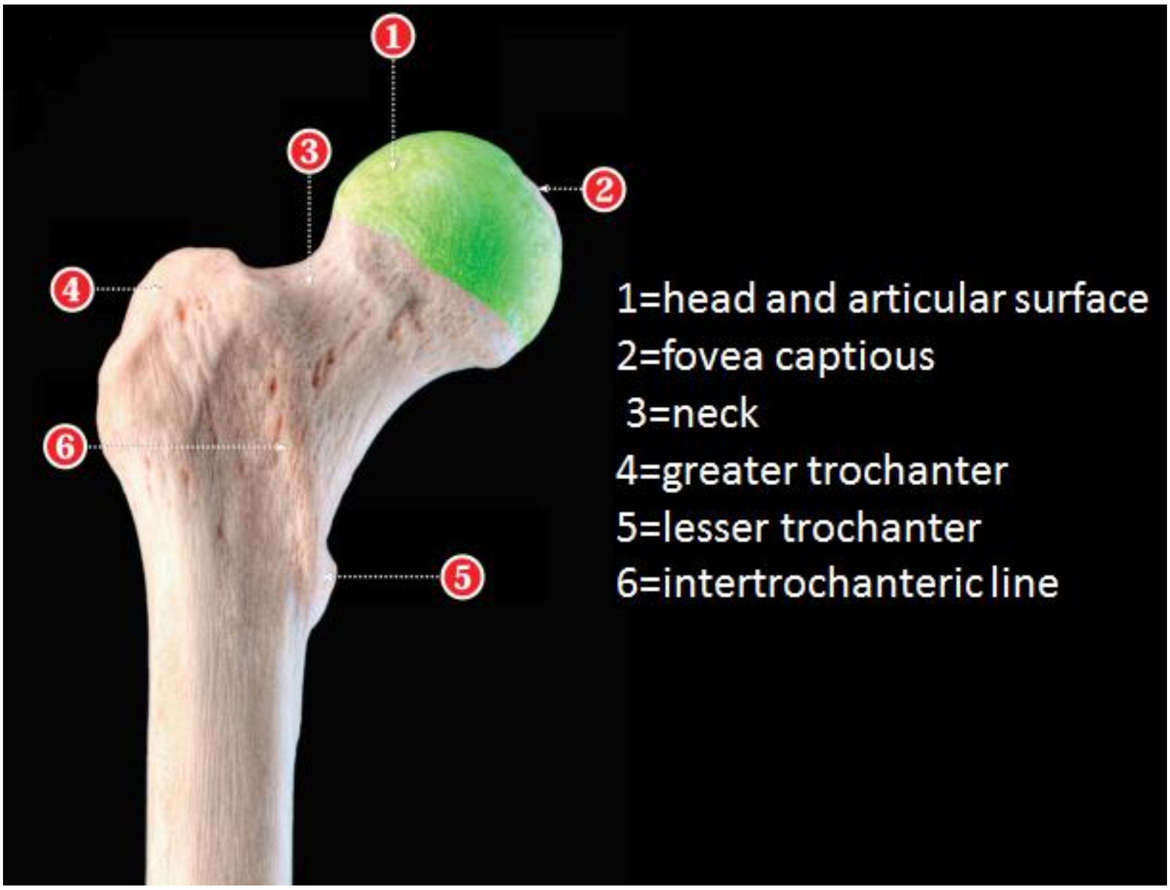

Figure (2.1):b. anterior view of the proximal epiphysis of a right femur

2.2.2 Capsules and ligaments:

The capsule of the hip joint is the most important stabilizer of the joint. It encases the hip joint from the acetabulum to the base of the femoral neck. It is intimately related to the intrinsic ligaments and together with them forms a strong capsule-ligamentous complex that can reach a thickness of 0.5 cm in some parts. Anatomically, the posterior capsular insertion on the femur is more proximal than the anterior insertion. Despite the stability provided by the osseous anatomy, the soft tissues surrounding the hip joint are important for stability. There are four ligaments surrounding and reinforcing the capsule joint. Classic descriptions establish that there is one ligament for each component of the coxal bone (iliac, ischial and pubic bones) that connects it to the femur and another ligament called the zona orbicularis. The ilio-femoral and pubo-femoral ligaments and the zona orbicularis are found in the anterior region of the hip joint, whereas the ischio-femoral ligament is located in the posterior region. Furthermore, the hip contains an intra-articular ligament, the ligamentum teres the ilio-femoral ligament is the largest and thickest of the three capsular ligaments and one of the strongest ligaments in the human body. It is comprised of two bands of fibers, one medial and one lateral. The medial band originates between the anterior inferior iliac spine and the iliac portion of the acetabular rim. It runs distally in a nearly vertical course and inserts in a protuberance in the distal intertrochanteric line of the femur. The lateral band originates proximal to the anterior inferior iliac spine. This band has a more horizontal course than the medial band and inserts in the anterior region of the crest of the greater trochanter. The configuration of these two bands is classically described as an inverted Y. The medial band tightens in external rotation and extension, whereas the lateral band tightens in external rotation and flexion or in internal and external rotation during extension of the hip. Relaxation of this ligament facilitates access to the hip joint during arthroscopy of the peripheral compartments, creating an anterior working area. The pubo-femoral ligament is comprised of a single band of fbres that originate from the superior pubic ramus and inserts on the distal region of the intertrochanteric line of the femur, blending with the medial band of the ilio-femoral ligament. Although the pubo-femoral ligament tightens in external rotation and extension of the hip, it has a less important limiting role in the joint and acts more as a reinforcing element of the antero-inferior joint capsule. The zona orbicularis is a thick bundle of fibers, circularly arranged in the medial, deep region of the capsule that form a reinforcing ring around the femoral neck. This structure is thought to act as another ‘check rein’ to aid in maintaining the head within the acetabulum. A portion of the orbicular fibers are derived from deep tendons of the gluteal region and the reflected head of the rectus femoris muscle. The zona orbicularis of the anterior capsule is easily seen in the arthroscopic view of the peripheral compartment of the hip joint and should not be confused with the acetabular labrum. The inner surface of the capsule and the intra-articular femoral neck are covered by the synovium. This synovial tissue forms a series of folds that descend along the neck of the femur. The ischio-femoral ligament is located at the posterior part of the hip joint capsule and consists of an upper and lower band. These bands have a common origin at the ischial part of the acetabular rim. The upper band inserts at a site medial to the antero-superior base of the greater trochanter. The lower band inserts at a posteromedial site at the base of the greater trochanter, at the posterior intertrochanteric crest. Internal rotation of the hip in flexion and extension tightens both bands of the ischio-femoral ligament. The ligamentum teres or ligamentum capitis femoris is an intra-articular ligament that attaches the femoral head to the acetabulum. It arises in the inferior part of the acetabular fossa and runs inferiorly and anteriorly across the joint space to insert into the fovea capitis of the head of the femur. The ligamentum teres is trapezoid; its base, which is thickened into two bands, inserts onto the border of the acetabular notch and onto the transverse acetabular ligament. As it runs towards the femoral head, it becomes progressively round or ovoid in shape before inserting into the fovea capitis at a site slightly posterior and inferior to the true centre of the head. It is important to remember that the ligamentum teres inserts in the antero-superior area of the fovea capitis, a fact that allows the fovea capitis to accommodate the proximal part of the ligament when it is tensed. In cross section, the ligamentum teres is pyramidal, with a fascicular appearance formed by an anterior and a posterior bundle; it follows a spiral course from its acetabular attachment to its femoral insertion.

2.2.3 Muscles Surrounding the Hip:

The hip joint is completely surrounded by muscles. The functions of the muscles can be inferred on the basis of their paths. The points of origin and attachment of the muscles surrounding the hip are illustrated in figure (2.2) [3].

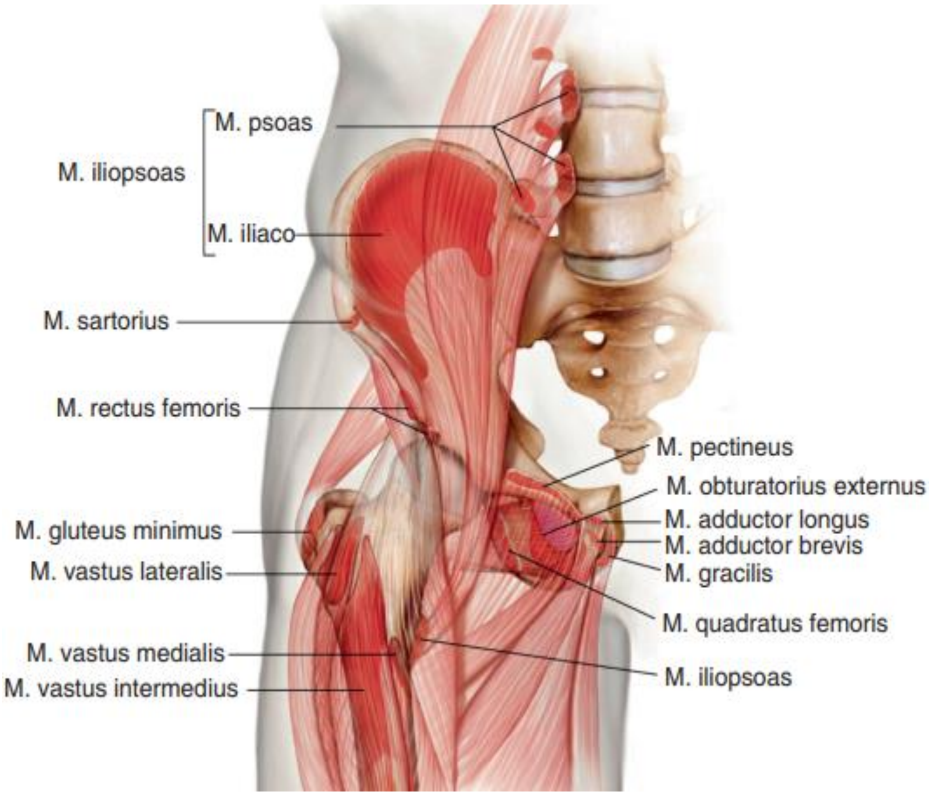

Figure (2.2):a. ventral aspect of the hip joint

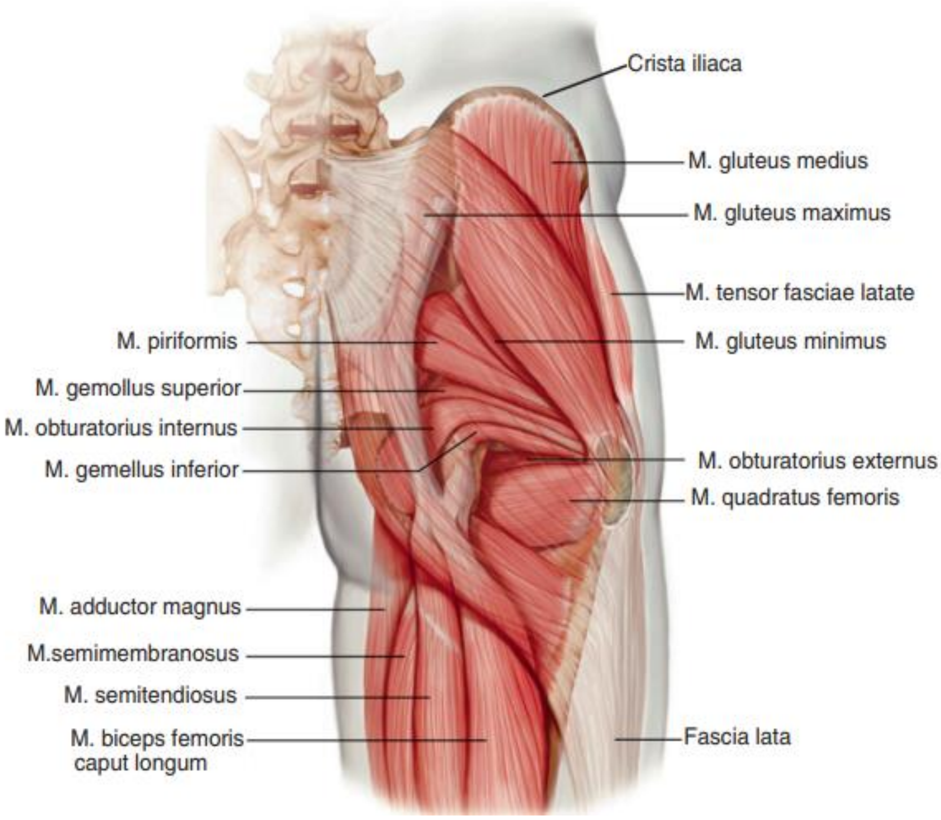

Figure (2.2):b. dorsal aspect of the hip joint

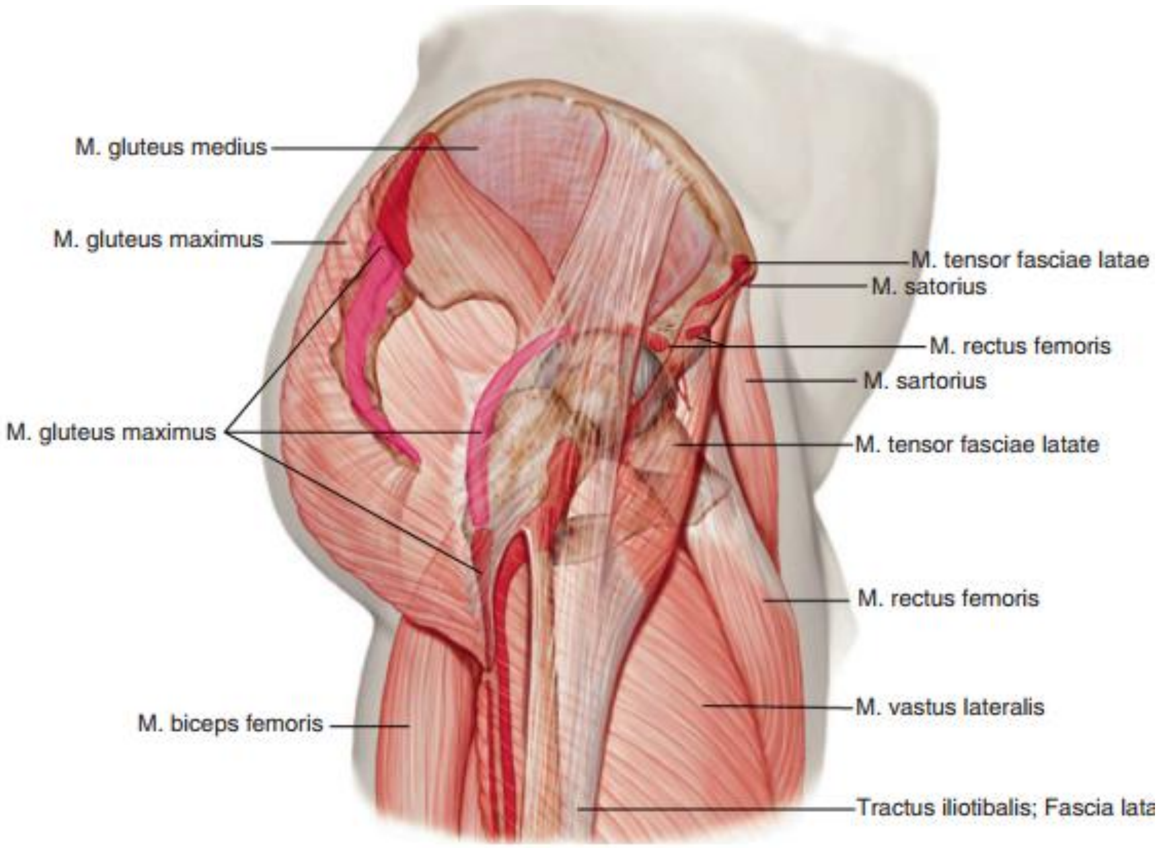

Figure (2.2):c. lateral aspect of the hip joint

2.3 Function and biomechanics of the hip joint:

In the field of biomechanics, the mechanics part needs to be explained in detail by drawing the free body diagrams and obtain equilibrium equations to try to resolve forces; also, by taking moments, some unknown forces may be obtained.

2.3.1 Degree of freedom of the hip joint:

A three-dimensional musculoskeletal model was used to estimate the hip joint forces. The model was based on a bilateral model developed by Carhart, which then was simplified to include only four segments: the pelvis, thigh, shank and foot of the right leg. The model contained six Degrees of Freedom (DOF) to represent the primary motions at the hip, knee and ankle. In general, the muscle forces play a key role in the movements of human body; these forces should be considered as tensile forces. Figure (2.3) Illustration of the segmental reference frames in the frontal and sagittal plane for the pelvis (A), thigh (B), shank (C) and foot (D) with the subject standing in the anatomical position. In the pelvic reference frame, the superior/inferior axis is in line with the trunk when in a standing posture. The anterior/posterior axis is perpendicular to the superior/inferior axis and in line with the progression of movement in the anterior direction. The medial/lateral axis is defined as the cross product of the other two axes [4].

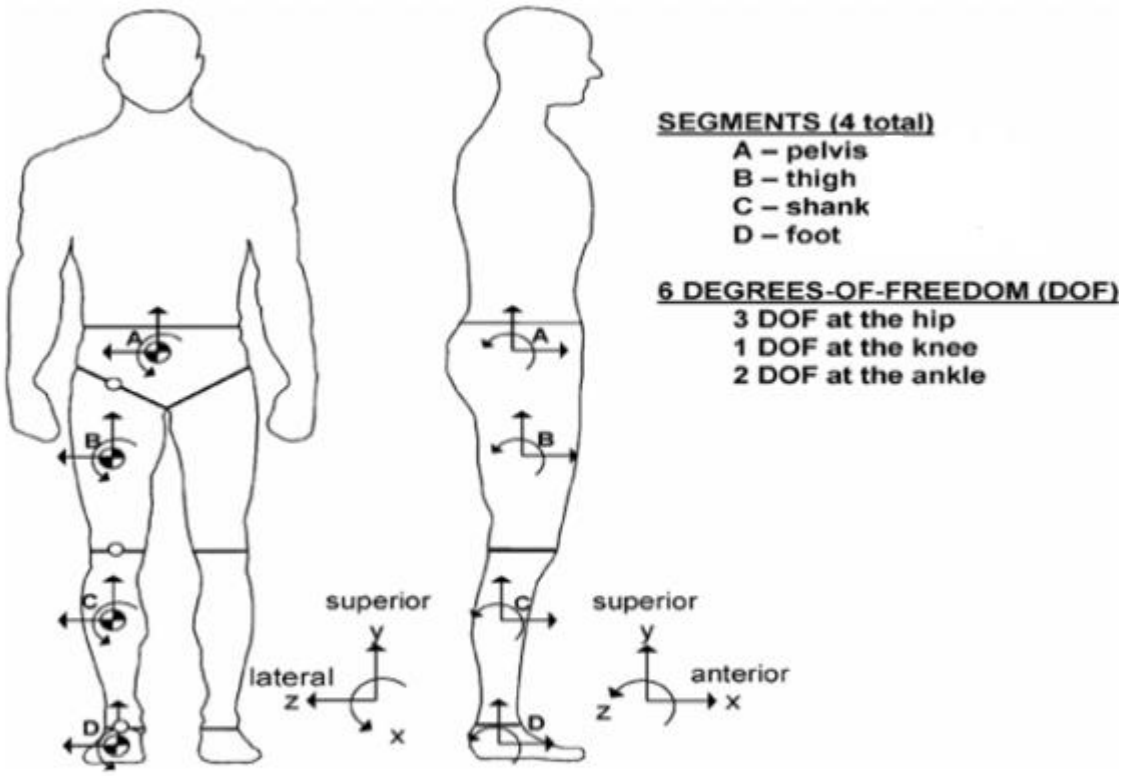

Figure (2.3): the musculoskeletal model

2.3.2 Mobility and stability of hip joint:

The mobility of human joint is indicated by the relative motion between bones connected by the joint. This relative motion depends on the contact between bones and the maximum strains of tissues surrounding the joint. If a natural joint is replaced, the joint replacement should be able to achieve the minimum movement of the natural one. The types of joint movement are flexion, extension, abduction, adduction and rotation. Flexion is the movement to bend the joint and extension is to straighten the joint. Abduction is the movement of joint member outward the body axis and adduction is the movement toward the body axis. Rotation is the movement of joint member around its center.

Stability in joint is defined by its ability to maintain position of the members during body movement. A stable joint manages to perform movement in its range of motion while carrying load. From biomechanics point of view, hip joint is one of lower extremities parts those bear high load. Mostly, hip joint is subjected to moment loading, except for rotation motion, the load is torsion. As moment and torsion, loads depend on the distance or radius from center of axis, the longer the distance the higher the load on the joint. During normal body movements, such as: walking, running, stair climbing, the load on a hip joint was about 2.5 to 3.0 times of the body weight. While running, the joint load might reach 6 times of the body weight because legs position during running was farther from joint center, figure (2.4) below depicts the loading on a hip joint. Body weight W worked on the centroid of human body was transferred to the hip bone by the ligament and results abductor force F_A. F_A was produced due the tissue contraction of the ligament positioning on the shoulder part of femoral (thigh) bone. From figure (2.4) it can be seen that the femoral bone was subjected to bending moment and the neck part of the femoral were the critical area due to stress concentration. The acetabulum of the hip bone contacted with the head of thigh bone and it caused a normal force F_R in the interface. As a consequence, friction force occurred during body movement and wear failure might take place if lubrication was not sufficient [5].The abductor force F_A and reaction force F_R were expressed as:

$$F_A = \left(\frac{5}{6}\right) W \frac{l}{r} \tag{2.1}$$

$$F_R = \left(\frac{5}{6}\right) W \sqrt{725 + 5cosA} \tag{2.2}$$

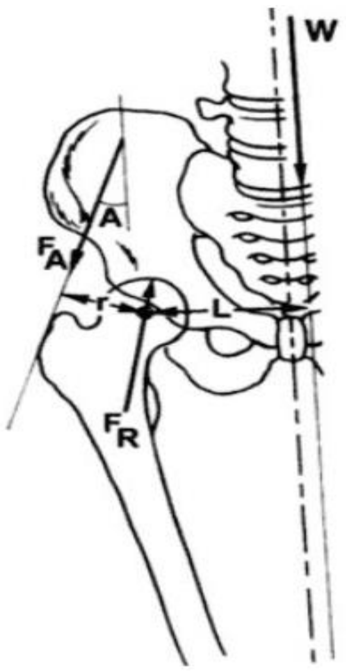

Figure (2.4): loading in the hip joint

Large forces and moments are developed within the hip joint during normal activities, including walking, running, and stair climbing, and rising from a chair. Using instrumented hip prostheses, several investigators have reported in vivo measurements of hip joint forces for periods of up to 3 years after implantation. These studies show that during normal gait, the peak force developed across the hip ranges from 2.6 to 4.1 times body weight (typically, 390-620 lb), whereas the torque acting on the hip prosthesis ranges from 74 to 189 in-lb, with peak values of up to 291 in lb. The in vivo readings show that joint forces increase with walking speed, body weight, and stride length, with forces of up to eight times the body weight during strenuous activities. The effect of individual parameters on loading of the hip joint can be appreciated from a simplified mechanical model of the hip joint during one-legged stance Figure (2.4). In this model, the forces acting across the hip are represented in the sagittal plane. The weight of the body supported by the hip joint is represented by a single force (WI) passing through the center of gravity of the body. Typically, the hip joint supports five-sixths of the total body weight (BW) (ie, WI = 5/6 BW). This force is balanced by muscle contraction, which stabilizes the pelvis by counteracting the leverage developed by the weight of the body. In this model, a net abductor muscle force (FA), which acts in the direction of the glutei muscles represents the sum of these muscle forces. A stable mechanical equilibrium is reached when the abducting effect of the forces equals the adducting effect of the body weight acting around the hip joint fulcrum. This balance is expressed mathematically by the equation this indicates that the abductor force necessary to maintain hip joint stability is proportional to the ratio between Land r. For a typical value of this ratio (eg, L/r = 2.5), the estimated value of the abductor force is 2.1 times body weight. From this expression, it can be seen that the abductor force (and thus the total joint force) may be decreased by either leaning over the hip joint (decreasing L) or maximizing the distance of the abductor insertion from the center of the femoral head (increasing r). Moreover, the more valgus the femoral neck, the larger the ratio L/r and, thus, the greater the abductor force necessary to balance body weight. It is also possible to calculate the total force (FR) acting on the hip joint by adding the vertical and horizontal components of the joint reactive force. If the ratio Lfr = 2.5, this leads to the expression in equation (2.2) [5].

2.4 Hip joint diseases:

There are many diseases affect the normal functional hip joint, from cartilages breakdown to muscle inflammation, problems to blame for painful hip. Many forms of arthritis and related conditions that affect the joint, muscle and or/ bones can cause hip problems like pains, stiffness and swelling here are some possible diseases-related hip problems:

2.4.1 Osteoarthritis (OA):

The most common form of hip arthritis, osteoarthritis is a chronic condition characterized by the breakdown of the cartilage that cushions the ends of the bones where they meet to form joints. In hip osteoarthritis, the cartilage that lines the acetabulum and/or covers the surface of the femoral head breaks down causing the bones to rub against each other. This may result in pain, stiffness, the loss of movement and the formation of bony overgrowths called spurs. Pain from hip osteoarthritis is often felt in the groin area and front of the thigh. Stiffness may be worst after periods of inactivity. all that is illustrated in figure (2.5).

Figure (2.5): Osteoarthritis

2.4.2 Rheumatoid arthritis (RA):

Rheumatoid arthritis is a chronic inflammatory disease of the joints that occurs when body's immune system – which normally protects us from infection – mistakenly attacks the synovium, the thin membrane that lines the joints. Symptoms of hip rheumatoid arthritis include pain, redness, swelling and warmth of the affected hip joints. Unchecked, inflammation can lead to hip joint damage loss of function and disability. In addition to the hips, rheumatoid arthritis commonly affects the knees, hands, wrists, feet, elbows and ankles all that is shown in figure (2.6)

Figure (2.6): rheumatoid arthritis

2.4.3 Juvenile arthritis:

Juvenile arthritis is the term used to describe arthritis when it begins before age 16. There are several different types of juvenile arthritis. Many can cause hip joint pain and swelling. Figure (2.7) depicts the Juvenile arthritis.

Figure (2.7): juvenile arthritis

2.4.4 Ankylosing spondylitis:

Ankylosing spondylitis is a form of arthritis that primarily affects the spine, causing inflammation in the spine that can lead to chronic pain and stiffening of the spine. Often other joints are affected. Aside from the spine, the hip is the joint most commonly affected by ankylosing spondylitis.

2.4.5 Lyme disease:

Lyme disease is an infectious disease characterized by a skin rash, joint swelling and flu-like symptoms. The disease is caused by the bite of a tick infected with a bacterium called B. burgdorferi. Lyme disease can affect the hip.

2.4.6 Lupus:

Lupus is a chronic autoimmune disease, meaning the body's immune system creates antibodies that attack and damage healthy tissues. Lupus can cause inflammation of the joints, including the hip, as well as the skin, heart, lungs, and kidney.

2.4.7 Gout:

Gout is a form of arthritis that occurs when excess uric acid, a bodily waste product circulating in the bloodstream, is deposited as needle-shaped monosodium urate crystals in tissues of the body, including the joints. For many people, the first symptom of gout is excruciating pain and swelling in the big toe – often following a trauma, such as an illness or injury. Subsequent attacks may occur off and on in other joints, primarily those of the foot and knee. Gout less commonly causes hip pain.

2.4.8 Psoriatic arthritis:

Psoriatic arthritis is a form of arthritis accompanied by the skin disease psoriasis. The skin disease often precedes the arthritis; in a small percentage, the joint disease develops before the skin disease. The arthritis can affect both large and small joints, including the hip.

2.4.9 Infectious arthritis:

Also called septic arthritis, infectious arthritis refers to arthritis that is caused by an infection within the joint. Infectious arthritis is often cause by bacteria that spread through the bloodstream to the joint. Sometimes it is caused by viruses or fungi.

2.4.10 Polymyalgia rheumatic:

An inflammatory disorder that causes widespread muscle pain and stiffness, polymyalgia rheumatica mainly affects the neck, shoulders, upper arms, thighs and hips. The disease often comes on suddenly and resolves on its own in a year or two.

2.4.11 Osteonecrosis:

Also called avascular necrosis or aseptic necrosis, this condition occurs when diminished blood to an area of bone causes it to die and eventually collapse. Blood flow may be blocked due to a number of causes including a clot, blood vessel inflammation or use of corticosteroid drugs. The hip is one of the most commonly affected joints.

2.4.12 Paget's disease of the bone:

Paget’s disease is a chronic disorder in which excessive breakdown and formation of bone causes the bones to become enlarged, misshapen and weakened. The disease usually does not affect the entire skeleton, but just one or a few bones. If the pelvis is affected the disease can cause hip pain.

2.4.13 Sciatica:

This is inflammation of the sciatic nerve. The largest nerve in the human body, the sciatic nerve runs from the lower part of the spinal cord, through the buttock and down the back of the leg to the foot. The most common causes of sciatica include compression of the nerve where it exits the spine by a herniated disc, or a rupture of one of the structures that cushions the vertebrae in the spine. Sciatica may be felt as a sharp or burning pain that radiates from the hip [6].

2.5 total hip arthroplasty:

Which is called Total Hip Replacement (THR) is an operation that replaces the damaged hip joint with an artificial one called a prosthesis. In a problem hip, the worn cartilage no longer serves as a cushion and exposes the underlying bone. This causes roughening of the bones and they rub together like sandpaper. The ball grinds in the socket when you move your leg, causing pain and stiffness. The affected leg may become shortened, muscles may become weaker and a limp may develop. Hip replacement removes damaged bone and cartilage and provides smooth working surfaces. The most important goal of THR is to decrease pain, improve function and make the hip more stable or reliable. During surgery, skin and muscles are cut, and the hip joint is opened. The ball of the femur is removed and replaced with a new ball and stem that goes down into the center of the femur. Damaged cartilage and bone are removed from the socket and a metal shell with a liner is inserted.

The replacement pieces can be made of metal, plastic, or ceramic. Once the new hip joint is in place, the muscles and skin are stitched together and the incision is closed with staples. This is shown in figure (2.8) [7].

Figure (2.8): total hip arthroplasty

2.6 Designs of AHJs:

As a simplest description of the artificial hip joints parts:

1. Acetabular component (socket): The bowl shaped piece that represents your new socket. This bowl or "cup" shaped piece is fit into your resurfaced socket. This piece is usually made of metal but is occasionally made of ceramic or a combination of plastic and metal.
2. Acetabular liner: The plastic liner fits into the acetabular component and allows the femoral head (ball) to glide easier and more naturally in the socket. This piece is usually made of high-quality plastic.
3. Femoral head (ball): The ball that will fit directly into the new, plastic lined socket and is attached to the femoral stem. There are many shapes and sizes of "heads". These are made of durable metal, plastic, ceramic, or a combination of materials.
4. Femoral stem: The stem attaches to the ball and supports the new hip joint. Usually, this metal piece if porous, allowing for natural bone to grow and attach to this piece, which replaces your femur. As shown in figure (2.9).

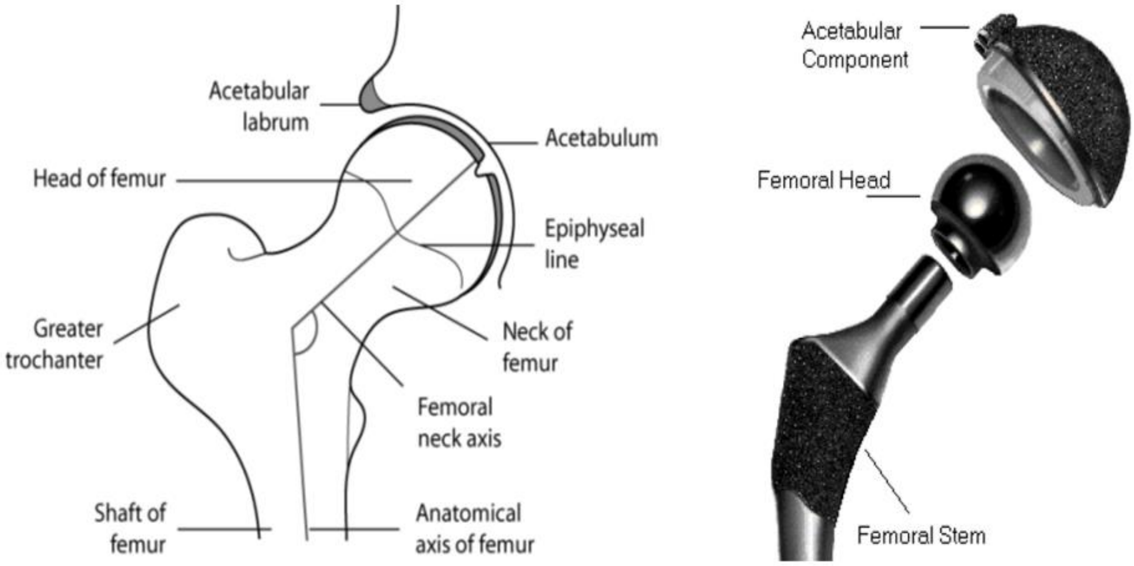

Figure (2.9): the fundamental components of hip joint, compared to the fundamental components of artificial hip joint

Artificial replacement parts can be made of strong plastic, metal, or ceramic. In most cases, the femoral stem component is built from titanium, titanium cobalt, stainless steel, cobalt-chromium alloys, or a titanium and cobalt mixed metal. The head, liner and acetabular parts can be made of either metal, plastic or ceramic, or a combination of the above. Implant materials have to be strong but flexible in order to allow for everyday movement. They also must be biocompatible. In spite of harmonization between the AHJ designs, but they differ from each other in the materials of each part. According to this, there are different designs.

2.6.1 Metal-on- plastic implant:

Both the ball and the socket of the hip joint are replaced with a metal prosthesis, and a plastic spacer is placed in between. The metals used include titanium, stainless steel, and cobalt chrome. The plastic is called polyethylene. The implant is secured to the bone by one of two methods; it is either press-fit or cemented into place. In the press-fit method, the implant is fit snuggly into the bone, and new bone forms around the implant to secure it in position. When an implant is cemented, special bone, cement is used to secure the prosthesis in position. This is shown figure (2.10) .

Figure (2.10): metal-on-plastic artificial hip joint

2.6.2 Metal-on-metal implant (MOM):

This is when the socket and the ball components are all made of metal. The metal components can be a combination of metals like titanium, cobalt-chromium alloys, or cobalt mixed metals. There is no plastic piece inserted between. Metal-on-metal implants do not wear out as quickly as the metal and plastic materials. The metal and plastic implants wear at a rate of about 0.1 millimeters each year. Metal-on-metal implants wear at a rate of about 0.01 millimeters each year, about 10 times less than metal and plastic. Despite the low wear rates, it is not known that metal-on-metal implants will last longer. There are also concerns about the wear debris that is generated from the metal-on-metal implants. Metal ions are released into the blood, and these metal ions can be detected throughout the body. The concentration of these metal ions increases over time. There are no data to show that these metal ions lead to increased rates of cancer or disease, but no one knows for sure. As illustrated in figure (2.11)

Figure (2.11): metal-on-metal artificial hip joint

2.6.3 Ceramic-on-ceramic implant (COC):

Ceramic-on-ceramic implants are designed to be the most resistant to wear of all available hip replacement implants. They wear even less than the metal-on-metal implants. Ceramics are more scratch resistant and smoother than any of these other implant materials. Unfortunately, there are also problems with ceramic implants. Again, there is no long-term data available on how well these implants work over time. In addition, there are concerns that these ceramic implants can break inside the body as shown in figure (2.12)

Figure (2.12): ceramic on ceramic artificial hip joint

2.6.4 Ceramic-on plastic:

Ceramic-on-UHMWPE (Ultra High Molecular Weight Polyethylene) is a good combination of two very reliable materials. Ceramic heads are harder than metal and are the most scratch-resistant implant material. The hard, ultra-smooth surface can greatly reduce the wear rate on the polyethylene bearing. The potential wear rate for this type of implant is less than Metal-on-Polyethylene. Ceramic-on-Polyethylene is more expensive than Metal-on-Polyethylene, but less than Ceramic-on-Ceramic. In the past, there had been incidents of fractures in ceramic components, but newer, stronger ceramics have resulted in considerable reduction of fracture rates (0.01%) compared to the original, more brittle ceramics. Some ceramic-on-polyethylene implants utilize a vitamin E-stabilized, highly cross-linked polyethylene bearing material. Vitamin E, a natural antioxidant, is expected to improve the longevity of the implant bearings used in total joint replacements. In laboratory testing, these liners have demonstrated 95-99% less wear than some other highly cross-linked polyethylene liners. Ceramic-on-Polyethylene implants have a potential wear at a rate of about 0.05 millimeters each year, i.e. 50% less than Metal-on-Polyethylene. The newer, highly cross-linked polyethylene liners have shown potential wear rates as little as 0.01 millimeters each year. Newer, highly cross-linked polyethylene liners have shown potential wear rates as little as 0.01 millimeters each year. This all is illustrated in figure (2.13).

Figure (2.13): ceramic on plastic artificial hip joint

2.6.5 Ceramic-on-Metal (COM), Ceramic-on-Polyethylene (COP):

Ceramic hips are less common, and a material not used by all surgeons. Ceramic material is often used in combination with special metal components or plastic components for those allergic to metals. Although ceramic parts are durable, historically, they have been more fragile than metal components. However, this is changing. Today's ceramic parts are argued to outlast metal part.

2.6.6 Metal -on- polyethylene implant (MOP):

Polyethylene is a high quality metal-free plastic. The socket or acetabular liner is usually made of this plastic. In addition, other components can be made of metal and covered with plastic. When a socket is plastic and the ball is metal, this is considered MOP [8].

2.7 Materials used in AHJs:

There are many materials those used in hip replacement devices, which are considered as biocompatible materials. A biocompatible material can be defined as any material used to make devices to replace a part or a function of the body in a safe, reliable, economic, and physiologically acceptable manner. The biocompatibility of a material has therefore to be assessed in function of its specific application. Its interaction with the body environment can range from no interaction, i.e. the bio-inert case, to a maximum for bio-active or bio-resorb-able materials.The term bio-inert refers to any material that, once placed in the human body, has minimal interaction with its surrounding tissue. Examples of these are stainless steel, titanium, alumina, partially stabilized zirconia, and UHMWPE. As a consequence of initial inflammatory response on the foreign material, a fibrous capsule can be formed around a bio-inert implant. Hence its bio-functionality relies on tissue integration of the implant. Bio-active materials interact with surrounding tissue through a time-dependent kinetic modification of the surface after implantation. An example for such a material is synthetic hydroxyapatite [$Ca_{10}(PO_4)6(OH)_2$] used as a coating on metals to improve and/or accelerate their osteointegration. An ion-exchange reaction between the hydroxyapatite and the surrounding body fluids results in the formation of a biologically active carbonate apatite layer on the implant that is chemically and crystallographic ally equivalent to the mineral phase of bone. Bio-resorb-able refers to a material that starts to dissolve after implantation and is slowly replaced by advancing tissue, for example tri-calcium phosphate [$Ca_3(PO_4)_2$].In order to take over thephysiological function of a hip joint, a hip prosthesis must feature three different compatibility requirements:

1. Structural requirements: Since the hip is, after the knee, the body’s second largest weight-bearing joint, the material must exhibit adequate mechanical strength and fatigue strength, i.e., it must resist millions of mechanical loading cycles without fracture.

2. Tribological requirements: The articulating surfaces must ensure the correct relative motion of the musculoskeletal system without being compromised by wear.

3. Biological requirements: Stem and shell must provide good osteointegration, all components must resist the highly corrosive body environment, and the inevitably released wear particles and corrosion products must not harm the organism. Thus, the structural and bearing components should be bio-inert, whereas, in the case of cement less fixation, stems and shell of the acetabulum cup should exhibit bio-active surfaces for good osteointegration at the same time. To reduce wear, load bearing surfaces must be hard, whereas stem and shell should be as elastic as possible to better match the mechanical properties of the surrounding bone. These contradicting requirements require a modular design of hip prostheses. Additionally, coatings and surface modifications are frequently applied in order to stimulate bone growth and promote osteointegration for stable and durable fixation.

4. Corrosion and wear effects: the human body is a chemically very aggressive environment and foreign implant materials are permanently exposed to extracellular tissue fluids, which are aqueous solutions of complex organic compounds, oxygen, sodium, chloride, bicarbonate, potassium, calcium, magnesium, phosphate, amino acids, and other corrosive species, such as peroxides. Only gold and a few other metals like platinum are electrochemically sufficiently resistant to corrosion under such conditions, but they are mechanically not strong enough for orthopedic applications. From an electrochemical point of view, all metals currently used for orthopedic implants can be oxidized by body fluids and become protected against further corrosion by an oxide layer. In electrochemistry this effect is called

passivation. It is the ability of a metal to form an ultra-thin surface layer of corrosion products, usually insoluble oxides, on its surface acting as a barrier to further oxidation. Stainless steels, cobalt-chromium-molybdenum alloys (Co-Cr-Mo), pure titanium (Ti) and titanium alloys feature such passivation capabilities. Their corrosion resistance depends on the stability of the oxidized surface layer. Any chemical or mechanical breakdown of this layer causes localized corrosion phenomena such as crevice, pitting, fretting or tribo-corrosion. Compared to stainless steel and Co-Cr-Mo alloy the adhesion of the oxide layer on Ti alloys is the weakest. Therefore, Ti alloys are suitable for manufacturing of structural components but they cannot be employed for Tribological applications since the oxide layer would be quickly scraped off. Galvanic corrosion occurs when two different metals are in electrical contact with each other and are immersed in a common electrolyte. This kind of corrosion may be an issue for modular prosthesis, wherever components made of different metals are put in contact e.g. at taper junctions between stem and femoral head. Corrosion results in release of ions and/or debris particles especially when passivation layers are scraped off from surfaces exposed to wear or fretting. These corrosion products may cause adverse tissue reactions, which are among the most prominent clinical complications and may compromise the outcome of THA.

2.7.1 Metallic materials:

Metals are required in orthopedic applications because they exhibit elevated mechanical strength and fracture toughness, i.e. the ability to contain a crack and to resist fracture. Today three groups of metals are prevailing for applications in joint replacements:

1. Stainless steels: Contain as main alloying elements chromium (Cr), nickel (Ni), molybdenum (Mo) and nitrogen (N) and in general exhibit good corrosion resistance. Stainless steel alloys are economic but have limited resistance against localized crevice corrosion. Moreover, their relatively high content of Ni represents a possible source of Ni sensitization for patients who have received a stainless steel hip implant.

2. Cobalt-chromium-molybdenum (CoCrMo) alloys: Fall under two main categories: cast alloys (ISO 5832-4) and wrought alloys (ISO 5832-5,6,7,8,12). Cast CoCrMo exhibits elevated mechanical properties and

optimal corrosion resistance under friction condition. Its main drawbacks are related to their poor fatigue resistance and their high cost. Wrought CoCrMo is even more expensive than cast material, but the higher cost can be justified by the enhanced corrosion and fatigue resistance. The presence of Ni creates some concerns regarding possible nickel sensitization. In contrast to cast CoCrMo, the Tribological properties of wrought CoCrMo are too poor for bearing surfaces.

3. Titanium (Ti): is considered one of the most biocompatible metals, which has determined the success of pure Ti (ISO 5832-2) in dentistry. However, the poor mechanical properties of pure Ti, such as small Young's elastic modulus and low fracture stress, have limited its application in joint replacement. However, titanium alloyed with aluminum (Al), vanadium (V) and niobium (Nb), mainly Ti6-Al4-V (ISO5832-3) and Ti6-Al7-Nb (ISO-5832-11), are best suited for the production of un-cemented femoral stems. The numbers in the formulas present the weight percentage of the alloying elements. The improved Mechanical properties of Ti alloys are at the expense of a reduced biocompatibility due to the presence of potentially toxic elements, such as aluminum and vanadium. Another limitation of Ti and Ti alloys is the drastic reduction of its outstanding corrosion resistance under friction conditions.

2.7.2 Ceramics:

Despite the critical brittleness of ceramics, both the hardness and the wet ability of ceramic surfaces result in excellent abrasion and wear resistance, resulting in low wear rates. Three types of ceramic materials are used for hip prosthesis:

1. Alumina: short for aluminum oxide (Al_2O_3) Alumina (ISO 6474-1) represents the gold standard for ceramics in THA thanks to its high compression strength, high hardness, and its resistance to abrasion and chemical attack. Its hydrophilicity plays an important role in the wet ability of its surface and consequently on the lubrication efficiency under friction.

However, aluminum oxide is a brittle material and cannot stand elevated tensile and impulsive stresses.

2. Zirconia: short for zirconium oxide (ZrO_2) It exhibits lower hardness than alumina but higher fracture toughness. Zirconia has three stable crystallographic phases: monoclinic, Tetragonal and cubic. Zirconia is commonly mixed with yttria (yttrium oxide, Y_2O_3) to stabilize its tetragonal crystal structure at room temperature. The tetragonal phase has the most suitable mechanical properties, and thus the fabrication processes have been optimized to maximize this phase in the finished component. Standard ZrO_2 used in orthopedic applications is therefore yttrium stabilized tetragonal polycrystalline zirconia (Y-TZP).

4. Alumina-Zirconia: composite Ceramics have been developed in order to improve the ageing behavior of Y-TZP and to reduce the brittleness of Al_2O_3. They are commonly referred to as alumina-toughened zirconia. The martens tic phase transformation of tetragonal ZrO_2 into monoclinic ZrO_2 is exploited to improve the mechanical properties of the composite material.

2.7.3 Polymers ultra-high molecular weight polyethylene:

Ultra high molecular weight polyethylene UHMWPE is a subset of semi-crystalline thermoplastic polyethylene materials. UHWMPE is a very tough material, with very high impact strength. It is highly resistant to corrosive chemicals with the exception of oxidizing acids, exhibits a very low friction coefficient, is self-lubricating and highly resistant to abrasion. Its friction coefficient is similar to that of Poly-Tetra-Fluoro-Ethylene (PTFE), but UHMWPE has better abrasion resistance than PTFE.

2.7.4 Carbon-fiber-reinforced polymer (CFRP):

Is an extremely strong and light fiber-reinforced polymer, which contains carbon fibers. CFRPs can be expensive to produce but are commonly used wherever high strength-to-weight ratio and rigidity are required. The binding polymers often a thermoset resin such as epoxy, but other thermoset or thermoplastic polymers, such as polyester, vinyl esteror-nylon, are sometimes used. The composite may contain other fibers, such as Ultra-high-molecular-weight polyethylene UHMWPE or glass fibers, as well as carbon fiber. The properties of the final CFRP product can also be affected by the type of additives introduced to the binding matrix (the resin). The most frequent additive is silica, but other additives such as rubber and carbon nano tube scan be used. The material is also referred to as graphite-reinforced polymer or graphite fiber-reinforced polymer [9]. All these material and their application in the THA is summarized in table (2.1)

Table (2.1): summary of material selection for THA components

Component	Material class	Most used material
Femoral stem	Metal	Co-Cr-Mo wrought, Ti alloy, stainless steel.
Femoral head	Metal	Co-Cr-Mo cast stainless steel.
	ceramic	Alumina, zirconia.
Acetabular cup liner	polymer	UHMWPW, XLPE.
	Metal	Co-Cr-Mo cast.
	ceramic	Alumina, zirconia.
Acetabular cup shell	metal	Commercially pure titanium, stainless steel.

2.7.5 Poly-Ether-Ether-ketone (PEEK):

PEEK is a poly-aromatic semi-crystalline thermoplastic polymer with mechanical properties favorable for bio-medical applications. Poly-ether-ether-ketone forms: PEEK-LT1, PEEK-LT2, and PEEK-LT3 have already been applied in different surgical fields: spine surgery, orthopedic surgery, maxillo-facial surgery etc. Synthesis of PEEK composites broadens the physicochemical and mechanical properties of PEEK materials. The possibility to use these materials in 3D printing process could increase the scientific interest and their future development as well [10].

2.8 Fixation mechanisms of the AHJs:

Fixation of the stem and acetabular cup component in THA can be achieved by using acrylic bone cement (cemented prosthesis) or by press-fitting against the bone (non-cemented prosthesis).

2.8.1 Cemented prostheses:

The cement fixes the implant to the bone and assures uniform load transfer on the whole contact area between implant and bone in order to optimize the load-bearing capacity of the prosthesis-bone and the cement-bone system. Poly-Methyl-Meth-Acrylate (PMMA) is the standard material used as bone cement. Bone cement does not bond the prosthesis to bone. It rather acts as filler occupying the space between prosthesis and surrounding bone; thereby it fixes the prosthesis in its position and creates a stable interlayer allowing a uniform mechanical load transfer between bone and prosthesis. A homogeneous and complete layer of bone cement between implant and bone is required to achieve this and to prevent high local stresses, leading could lead to local crushing of the bone (per prosthetic fractures), and implant loosening. Cemented stems and acetabular cups must exhibit smooth surfaces in order to avoid stress concentrations that may crack the PMMA layer. Moreover, they must be sufficiently stiff to avoid mechanical loading of cement by elastic deformation of the metal. The disadvantages of acrylic bone cements are related:

1-To its dense polymerized structure, this does not allow osteointegration for improved bone fixation.

2- To its exothermal polymerization reaction. A temperature peak during positioning of the implant may cause necrosis of surrounding bone tissue resulting in loosening of the implant.

3- Necrosis of bone tissue can also be caused by released unreacted monomer molecules.

4- Moreover, shrinkage during polymerization of MMA may compromise the fixation of a component.

The timing of the preparation of bone cement, the injection technique and achieving a homogeneous thin layer completely filling up the space between implant and bone requires high surgical skills. The surgeon must also have experience in the preparation of the bone cement from the solid and liquid components, which is done in a short time window just before the cement is needed to fix the implant. A slightly too low monomer content may reduce both toxicity and polymerization peak temperature, but it increases cement viscosity, reduces the available working-time before cement consolidation and makes it difficult to achieve a homogeneous and complete cement layer around the implant. A slightly too high monomer content makes the cement too liquid and it distributes in homogeneously because it has the tendency to flow. Both deviations may compromise fixation.

2.8.2 Non-cemented prostheses:

Non-cemented prostheses characterized by a direct press fit contact between implant components and surrounding bone. The close surface contact between bone and implant shall facilitate bone integration. In order to promote long-term osteointegration of non-cemented components their surface exhibits porous coatings or a porous surface finish, which are intended to be filled by newly forming trabecular bone tissue. Frequently the surfaces are coated with plasma-spray deposited hydroxyapatite, Ti sintered beads or plasma sprayed Ti that shall facilitate integration into hosting bone tissue. The shape of un-cemented stems exhibits edges and grooves, which are meant to mechanically enhance primary fixation. Since the long-term stability relies on the patient’s health status, factors reducing the capability of bone growth, such as age or pathological conditions, limit the application of un-cemented THA. In older patients with less vital bone tissue, cement filling allows for a lower degree of accuracy in bone shaping and can compensate for bone defects. Since younger patients have biologically more active bone tissue, un-cemented THA is preferred in younger patients. Moreover, this group will more likely undergo revision surgery, which is complicated by the presence of cement and cement debris. The more sophisticated surface requirements for un-cemented devices complicate their fabrication, which is reflected in the higher price compared with cemented prosthesis [11].

2.9 Solidwork and ANSYS:

Solidwork and ANSYS are a solid modelling computer aided-design and computer –aided engineering computer program that runs on Microsoft. They are a solid modeler, and utilizes a parametric featured –based approach by PTC (Creo/Pro-engineer) to create models and assemblies .The software is written on parasolid-kernel.Parameters refer to constrains whose values determine the shape or geometry of the shape or the model or assembly .parameter can be either numeric parameter such as line lengths or circle dimeters, or geometric parameters, such as tenget,parallel,concentric,horizontal or vertical ,etc. Numeric parameters can be associated with each other through the use of relations, which allows them to capture design intent. Design intent is how the creator of the part wants it to respond to changes and updates. For example, you would want the hole at the top of beverage can to stay at the top surface, regardless of the height or size of the can.solidwarks allows the user to specify that the hole is a feature on the top surface, and will then honor their design intent no matter what height they later assign to the can .features refer to the building blocks of the part. They are the shapes and operations that construct the part .shapes and operations that construct the part .shape-based features typically begin with a 2D or 3D sketch of shapes such as bosses, holes, slots, etc. This shape is then extruded or cut to add or remove materials from the part. Operation-based features are not sketch-based, and include features such as fillets, chamfers, shells, applying draft to the faces of a part, etc.

Chapter three

Background studies

A. Fiorentino et al., in (2013), in order to correlate performance characteristics and design choice, tools like Quality Function Deployment (QFD) were used. In particular, these tools used results of market investigations on existing products and market requests to identify the improvement areas, to correlate them with design specifications so outlining the features of new products able to satisfy the market requests. This approach ended up with a new design of the prosthesis stem, which were then subjected to mechanical resistance testes using finite element method (FEM) simulations. This design provides a concept that is based on a new geometry able to improve the osteointegration and reduce the risks of bad stress distributions on the femur bone [12].

Shantanu Singha in (2014), developed a design of cemented AHJ with specified stem cross section and appropriate material, that was accomplished through studying the properties of the Titanium alloy (Ti-6Al-4V) and compared it to Chromium alloy (Co-Cr-Mo) properties, also Comparison between trapezium and circular cross section of the femoral stem was carried out, and that resulted in model made of Chromium alloy because of large displacement in case of Ti-6Al-4V which caused the stem to bend inside the cement mantle, thus destroying it, and with trapezium cross-section because Trapezoidal stem resulted in lower interfacial micro movements, and developed lower peak stresses in different femoral components [13].

López Galbeño in (2015), designed an un-cemented total hip prosthesis for a middle-aged person to find a system very similar to the real joint in order to minimize the wear, and that through the principle of the revere engineering and mechanical analysis test using finite element analysis (FEA) software. The design used Titanium Alloy (Ti6-Al4-V) as a material for the Acetabulum, with three holes on it for fixation through screws. The insert was made with ultra-high molecular weight polyethylene (UHMWPE), Ceramic Alumina and Zirconium Oxide were the materials used for the head, and Titanium Alloy was used for the stem. In these tests, Zirconium Oxide was proven more adequate than Alumina in improving the safety factor and the wear of the polymer, where Yttrium oxide is usually added to improve the material properties of Zirconium as well. That resulted in a new strategy called "Zirconium toughened Alumina." The combination of the two materials results in a composite with high strength and thermal stability Zirconium Alumina [14].

Mohammad Rabbani et al in (2015), studded the biomechanical influence of different load type on the stress distribution through a hip implant, and that through using FEA methods; to explain the influence of speed and contribution of torsional load in different activities of living life on the hip prosthesis, nine routine activities using FEA were included. In each activity, different forces of varying magnitude and orientation were applied on the prosthesis during a period of time to examine the critical points developed in the entire 3D model. This includes a full description of the geometry material properties and the boundary conditions. The activities considered comprise slow walking normal walking, fast walking, upstairs, down stairs, standing up, sitting down, and standing on 2-1-2 legs and knee bending. The hip endo-prosthesis examined was an un-cemented implant. The material assigned to the femoral stem was titanium. The material for acetabular cup and femoral head was considered to be (Co-Cr), and the plastic liner was (UHMWPE).All this enabled them to found that loading conditions have more influence than implant geometry or surface coating type on the implant design [15].

Ryan Kamal et al in (2015), proposed a press fit composite design for AHJ that composed of three parts acetabulum, head and stem. The stem is then decomposed to core and coat parts. The core was made of (Ti6-Al4-V) to handle the maximum load, and (PEEK) was used as coat to reduce both the fatigue strength and cost. The head was made of (Co-Cr-Mo), and the (UHMWPE) was the material of the acetabulum. The aim behind the design was to enhance the healthcare through reducing the cost of the AHJs, so the local synthesis for the joint would be possible. The composite design was subjected to the mechanical stress and strain tests using FEA methods and the obtained results was discussed to show that the cost reduction was about 49.37%. Since, the suggested composed design was compared with pure metal on metal design for the same geometry [16].

Sachin G. Ghalme1 et al in (2016), with a review study aimed to present an overall evaluation of biomaterials mainly developed for a hip joint replacement, they presented a solution of two serious problems related to the artificial hip joint materials, the first problem is ‘stress shielding’ that raising from unevenly load distribution between implant and bone while walking, which is also called as stress protection. in such cases low modulus material like polymer are suitable, but low modulus associated with little strength restricts the potential use of polymers, so for long term application research, itis suggested reinforcing of UHMWPE with carbon fibers. The second problem is mismatch of stiffness in the commercial hip joint where stems made of metal alloys, which are 5 to 6 times stiffer than bone. leads to aseptic loosening and failure of joint. This implant loosening and failure could be reduced with improved prosthesis design and using a less stiff material with mechanical properties similar to bone. The researcher found that with the requirement of high strength for hip prosthesis design, polymer composite offers good strength comparable to metal and more flexibility than metal [17].

Rohit Khanna et al in (2017), suggested high wear resistance, mechanical reliable and hybrid ceramic/metal artificial hip joint, which was proposed as 10-15 µm thick dense layer of pure α-alumina formed onto Ti-6Al-4V alloy by deposition of Al metal layer by cold spraying or cold metal transfer methods with 1–2 µm thick Al3Ti reaction layer formed at their interface to improve adhesion. This was carried out through tribological testing as well as transmission electronic microscopic (TEM) analysis of the interfaces between the alumina layer-reaction layer-Ti alloy, and corrosion testing of the reaction layer, which finally concluded that combination of cold spray or cold metal transfer and micro-arc oxidation methods will be effective in forming an adherent layer of dense α-alumina and is expected to enable advances in the field of artificial hip joints [18].

Abdulrahman Al-sanea et al in (2018), designed a 2D/3D CAD model of an AHJ using FEA software. Biocompatible and strong enough materials such as Titanium alloy Ti6-Al4-V and Alumina ceramic Al2-O3 were used in the designing process, where acetabulum and stem were made of Ti6-Al4-V, and Al2-O3 was used to design the head and the liner of the joint. FEA method was used to obtain a solution for the stress and strain distribution throughout series of adjacent elements, further the design was analyzed using computer aided engineering (CAE) software after it was loaded with static loads 250N, 350N, and 450N to see the durability of the design. The stability of the model was verified by static test. Finally, the Von Misses stress, strain, and displacement distribution are obtained from static analysis results are within the acceptable range, but if the static load was increased to values higher than 450N the stress, strain and displacement of femoral head are directly proportional with the static load so the risk ratio of hip joint damage will increase.

Chapter four

Methodology

To fulfill the aim of this research specified steps were done, firstly all the data related to biomaterials of the artificial joints, designing methods of the artificial joints, anatomy and physiology of the hip joint, biomechanics of the hip joint and the different modalities of the AHJ, were collected from different references, papers and websites to prepare the necessary knowledge and science for the topic. Through the knowledge that was acquired from the theoretical background, the desired model ,dimensions and materials for designing the joint were prepared and chosen according to the mechanical, biocompatibility and cost conditions.

The chosen model for the joint was consisting of four parts, the acetabulum (the cup or the socket), the head (the ball), the insert (the liner) and the stem. The chosen dimensions were according to ISO-7206 standard, with specific modification for specific dimension according to the Sudanese dimensions, which were taken from, applied and used model in Sudan, this model for LINK Company, which is a Germany company that supply AHJ for Sudan according to the Sudanese specifications.

After determining the model type, its dimensions and specifications, CoCrMo was assigned as the used material for the acetabulum, for the head and for the inner part of the stem, UHMWPE was used for the insert, and PEEK was applied to the outer part of the stem. After that a test design using the suggested dimensions was designed using Solidwork software which is a finite element analysis software that is used to design and analysis 3D models by firstly sketching the geometries as distinct parts, assemble all the parts and then applying the suitable forces and fixations points with the right directions on the assembled model. After sketching, the joint geometry with Solidwork software and setting the angle on 0^{o} the design was imported to Ansys software, which is parallel to the Solidwork software, but more efficient in object analysis than Solidwork. The analysis process started with fixing the geometry on specific points and applying the forces on other points. The fixation points, the forces points and their amount were determined from the biomechanics of the hip joint, after alignment of the forces and the fixation points the chosen materials were assigned to each part of the model as they were firstly chosen, after that the model was subjugated to special mechanical analysis tests which were stress, strain and total deformation using static structure library on the Ansys. The analysis process was repeated 10 times, each time the angle was increased with 12.8^{o}, until the angle reached 128^{o} and this is the total angle of the implant.

For conducting the study special visits for hospitals were done to conclude the most used model in the hip joint replacement surgery ,which were found as metal on metal and metal on polymer models, also special visits for workshop and companies were done, seeking for the best technique for execution the model. 3Max workshop in the El_rimelah industrial area shows that the model needs a 5-axis CNC machine or 3D printer to be executed, according to that the plan was redirected to Sudanese foundation group Isidor 3D printing where the model was printed.

The used technique to print the prototype was 3D printer. The prototype materials were poly latic acid (PLA) for the acetabulum, PLA for the head, Acryloitrile butadiene stayrene (ABS) for the insert, PLA for the inner part of the stem and ABS for the outer part of the stem. The total cost of the printing the prototype was about 800 Sudanese pound.

Since the suggested design needs about 0.19561Kg of PEEK, 0.30511 Kg of CoCrMo, and 0.022Kg of UHMWPE,and from the market investigation the cost of 1Kg from PEEK is 12$,and for 1Kg of CoCrMo is 50$, and 1Kg of UHMWPE is 20$, the total cost will be :

$$(0.19561*12) + (0.30511*50) + (0.022*20) = 18.04282 \$$$

Since the total cost of the used model in the hospital ranging from 20,000 up to 80,000 Sudanese pound which about 425.5 to 1702.12$,the design offer a great chance to reduce the cost, because the total cost of the suggested design about 35.064 $,which about 1648.01254 Sudanese pound. All that is illustrated in table (4.1).

Table (4.1): comparison between the models

The cost of the used model		The cost of the suggested design	
In dollars	In Sudanese pound	In dollar	In Sudanese pound
425.5	20,000	35.064	1648.01254

Finally the sketched design was executed as a prototype with materials which are differ than the materials used in the analysis and that because the materials those were used in the analysis aren’t found in Sudan because they are not used, and also cannot be imported for individual projects, so the printed prototype just to verify that the model dimensions are reasonable and acceptable and can be printed and executed in the reality. All that is illustrated in figure (4.1).

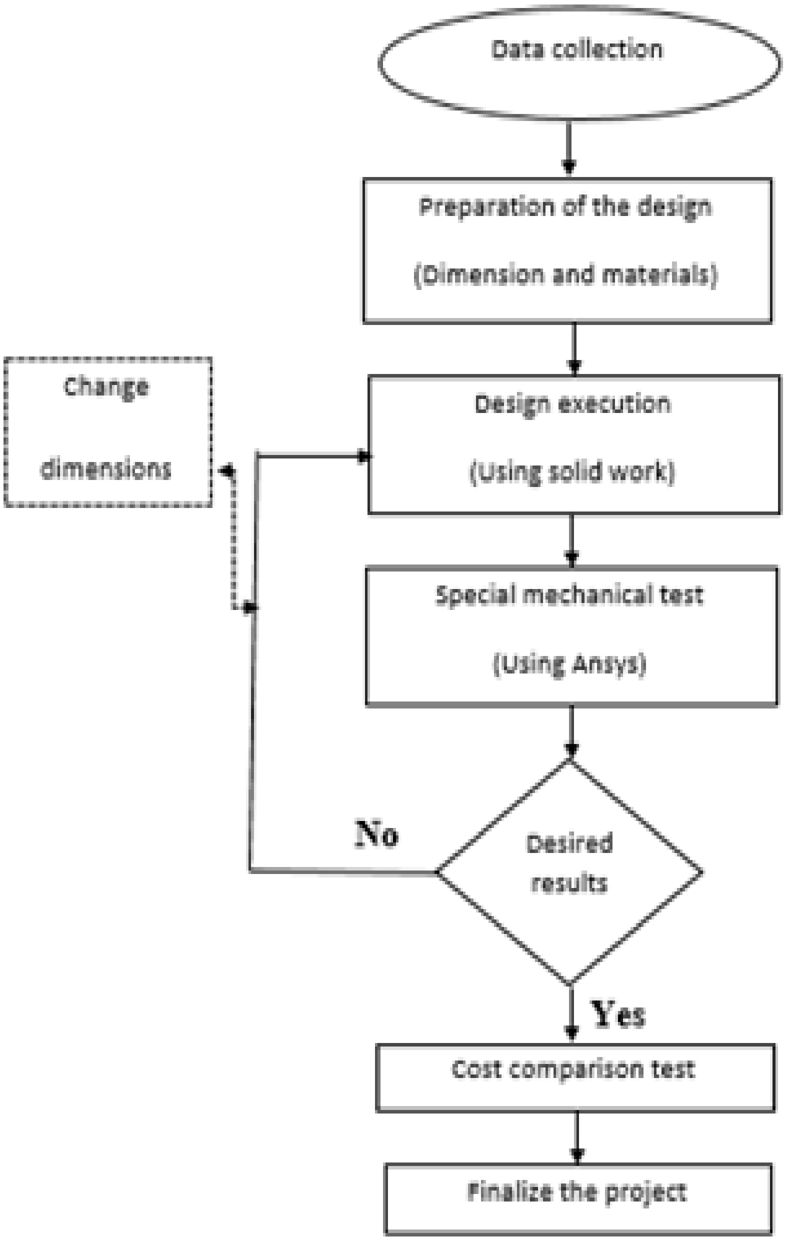

Figure (4.1): flow chart for the methodology

Chapter five

The design

To accomplish the final design, specific calculation and measurement were done; here the most important point is to make a design that satisfy a reasonable solution of the problems of the AHJ models.

5.1 Basic concept of the design:

5.1.1 Stress shielding:

This problem arises from unevenly load distribution between implant and bone while walking. This can be solved using low module materials such like polymers.so bone will not reclines on the implant and then loose its stiffness by the time.

5.1.2 Stiffness mismatching:

Metal alloys are 5 or 6 times stiffer than bone leads to aspect loosing and failure of joint .This can be solved by using less stiff materials with mechanical properties.

5.1.3 Subsidence:

Sinking or settling in bone ,as of a prosthetic component of a total joint implant .It can be solved by designing the outer surface using an Integrable material such like PEEK that has a high ability to integrate with bone.

5.1.4 Fatigue fracture:

Fracture rise from high stress and high repeated cyclic loading [19].It can be solved by using a combination of metallic-polymeric materials with the aid of good bone integration.

5.2 The construction of the design:

This design for the AHJ consist of four major parts:

1. The acetabulum (the cup).

2. The liner.

3. The head of the stem.

4. The stem.

5.2.1 The acetabulum:

It is a screw fixed cup, with an outer diameter of 44 mm and spherical gap in the middle with 37 mm to allow the head of the stem to fit inside the gap. The cup is made of CoCrMo and it is an integrated spaced cup, with five screw holes for fixation. All the necessary dimensions are illustrated in figure (5.1).

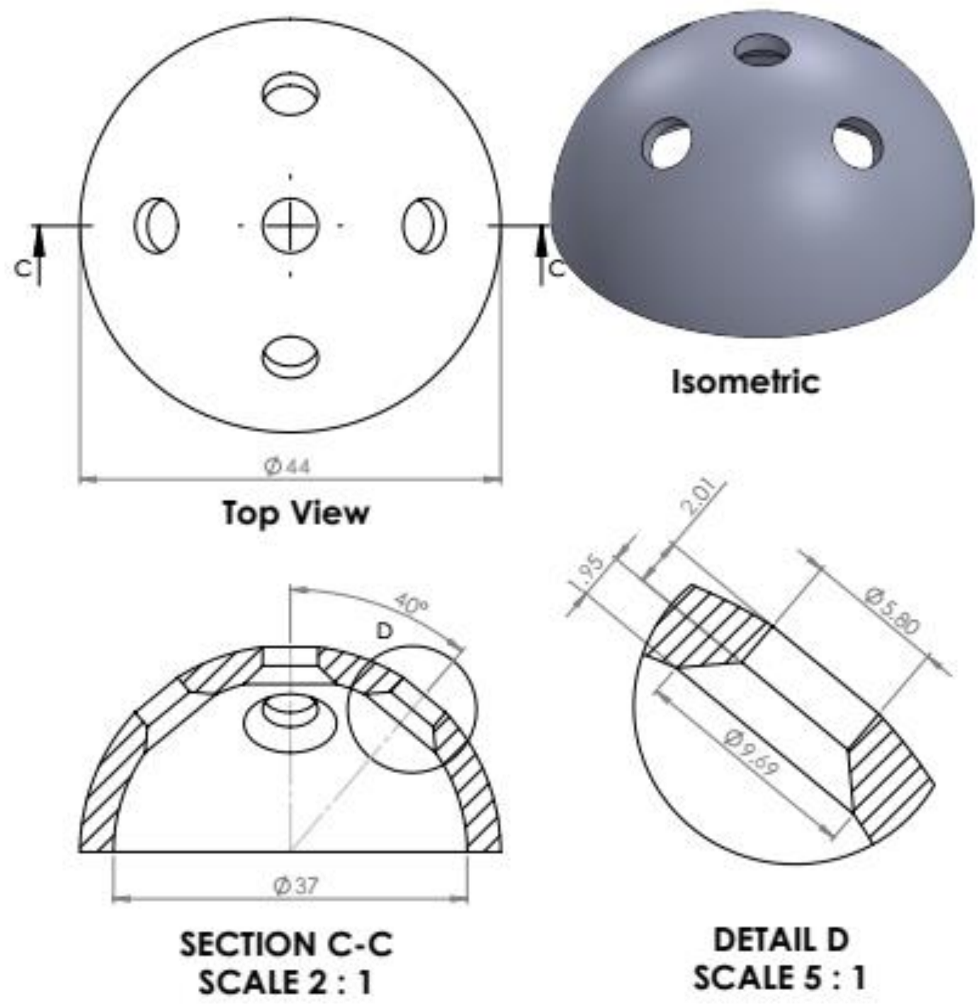

Figure (5.1): CoCrMo acetabulum with five fixation holes

5.2.2 The liner:

The design is metal casing, by means that behind the metallic cup the UHMWPE insert lined, with 36 mm outer diameter and 33 mm inner diameter. As illustrated in figure (5.2).

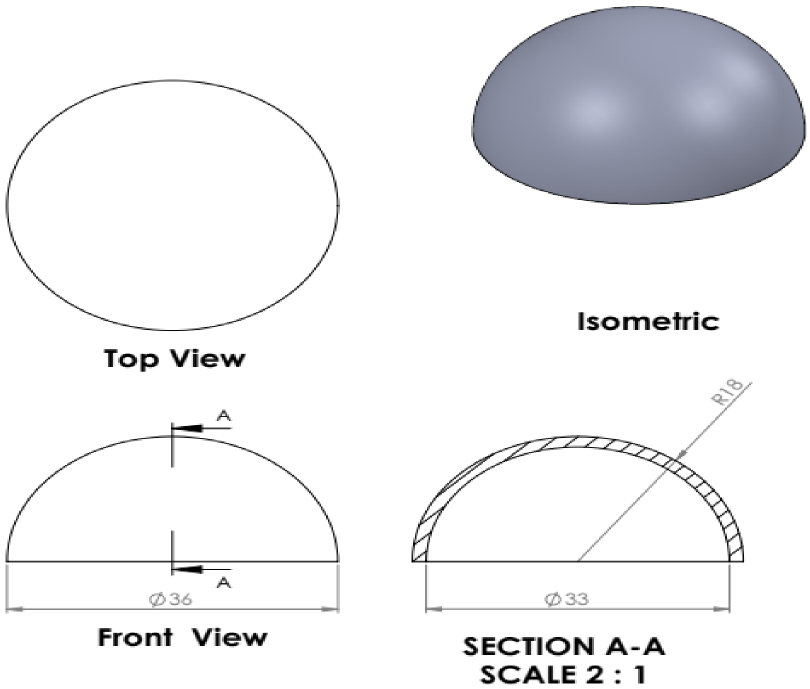

Figure (5.2): UHMWPE liner

5.2.3 The head:

It is metal rounded semi ball with height of 28 mm, outer diameter of 32 mm and inner taper diameter 14-12 mm. The used metal is CoCrMo. All the descriptive dimensions are shown in figure (5.3).

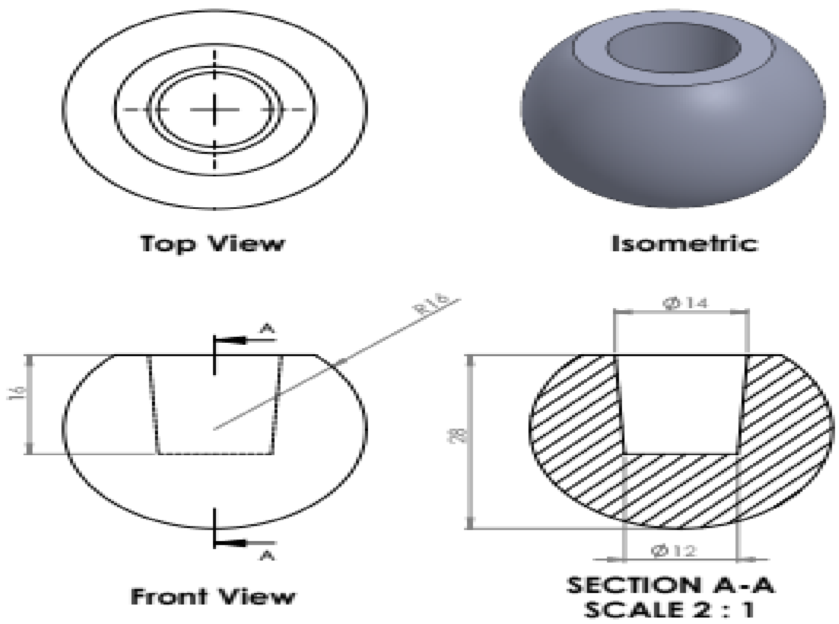

Figure (5.3): CoCrMo head of the stem

5.2.4 The stem:

It is press fit stem that is centered position in the femoral canal due to the anatomically shaped .preserves in the intramedullary bone substance .S-shape stem to resist rotational force .Large collar 30 mm support achieve reintroduction physiological forces in the femur .Stem length 147.5 mm with offset 29 mm which has a thickness of 1mm.

It is important to mention that the stem consists of two major parts, the core that is made of CoCrMo to handle the maximum load figure (5.4) depict the schematic geometry of the core, and the coat, which is made of the PEEK to handle the minimum load it is important to mention that PEEK unique of its reliability, high fatigue strength and design flexibility. Figure (5.5) depict the schematic geometry of the coat.

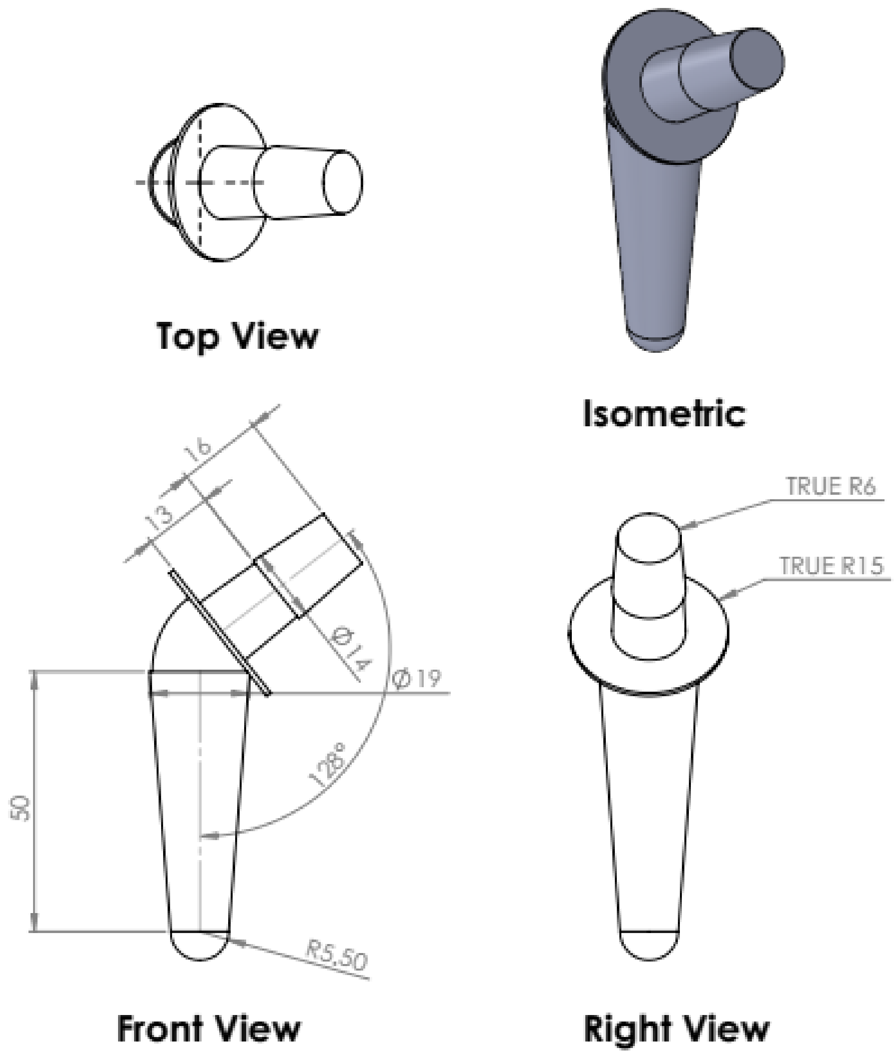

Figure (5.4): CoCrMo core of the stem

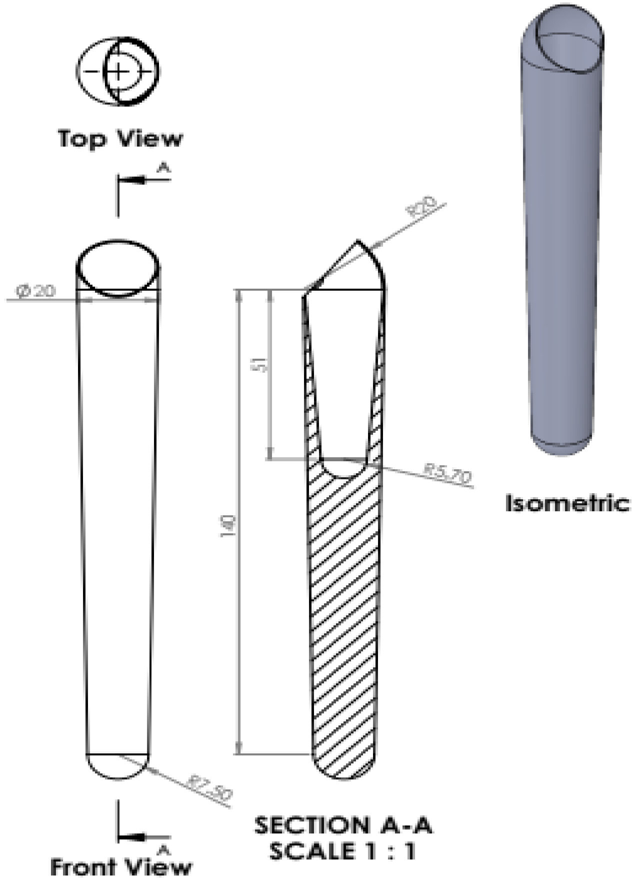

Figure (5.5): PEEK coat of the stem

5.3 Force generation and their concentration points:

As mentioned before in chapter two in equations (2.1) and (2.2) if L, A, r and W were substituted with:

L=8.75cm, A=5˚, r =4cm and W=59.407kg.

Then:

$FA = 5/6 * \ 59.4107 * (8.75cm \ /4cm)$

$$FA{=}108.28N$$

$FR = 5/6 \ * 59.4107 * \sqrt{725 + 5cos5}$

$$FR{=}1337.4N$$

Taking in account the maximum force that is presented on the hip during running these values must be multiplied by 6 and that gives:

FA= 649.68N , FR=8024.4N

Chapter six

Analysis of the design

Mechanical analysis for the suggested model was carried out, every region in the design is colored with one of these colors: red, orange, yellow, green (3 degrees) and blue (3 degrees) and the corresponding values are denoted beside each test.

Firstly the design was assembled as one model using solidwork, and then it was imported to Ansys to analyze the model, these steps were repeated 10 times with different angles and the results were denoted as shown below.

6.1 Mechanical analysis tests:

6.1.1 Maximum Principal Elastic Strain:

Maximum principle strain is the most reliable parameter to use for predicting failure in FEA methods; strain means that change in shape or size resulting from applied forces (deformation), elastic strain is a type of strain where the body returns to it is original shape after removing the deforming force .maximum principle strain is a theory states that the failure occurs when the maximum shear strain energy component for the complex state of stress system is equal to that at the yield point in the tensile test .

6.1.2 Maximum principal Stress:

They are essentially the maximum normal (tensile or compressive) stresses that element will ever see under the specified applied loads after any transformation.

6.1.3 Total Deformation:

Since the directional deformation is defined as the displacement of the system in particular axis, total deformation is the vector sum all directional displacements of the system.

6.2 Mechanical analysis results for angle 0º:

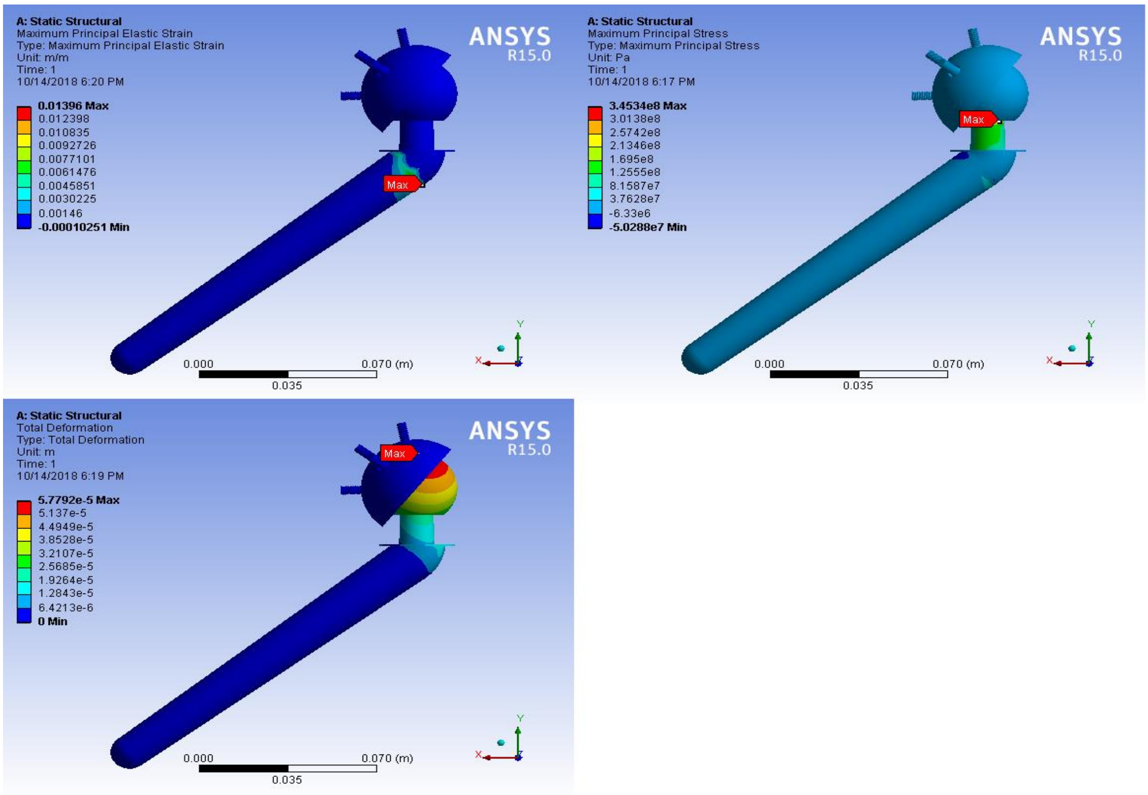

Figure (6.1): mechanical analysis results for angle 0º

6.3 Mechanical analysis results for angle 12.8º:

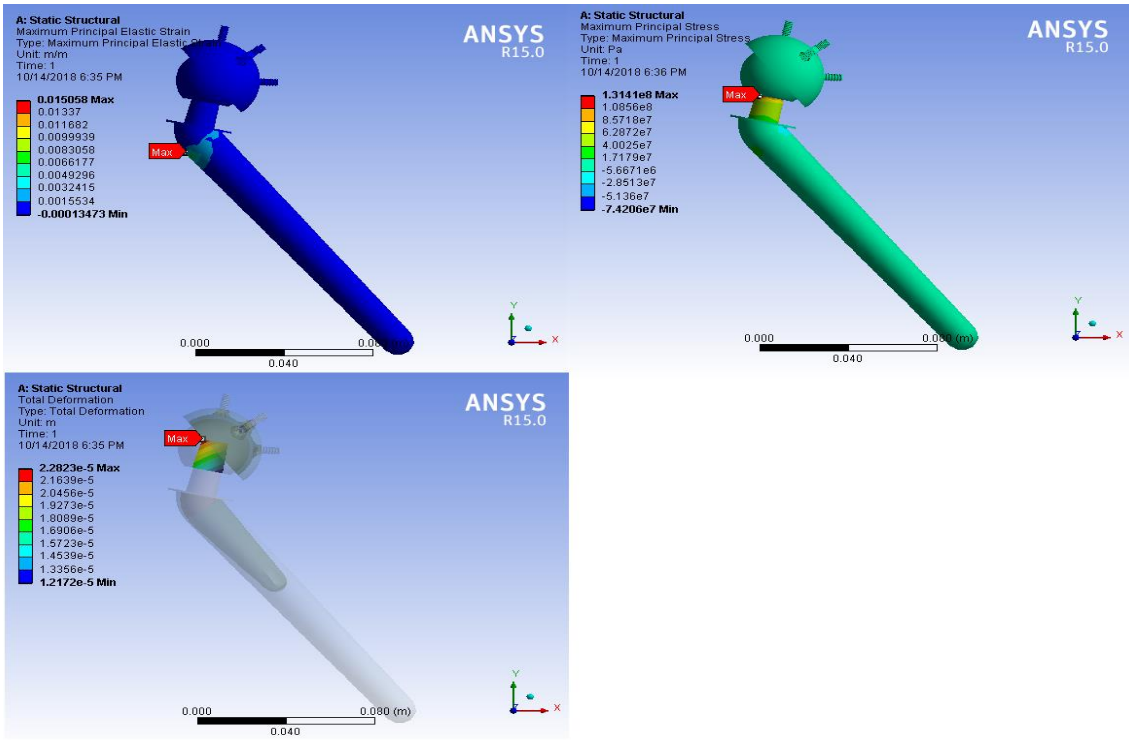

Figure (6.2): mechanical analysis results for angle 12.8º

6.4 Mechanical analysis results for angle 25.6º:

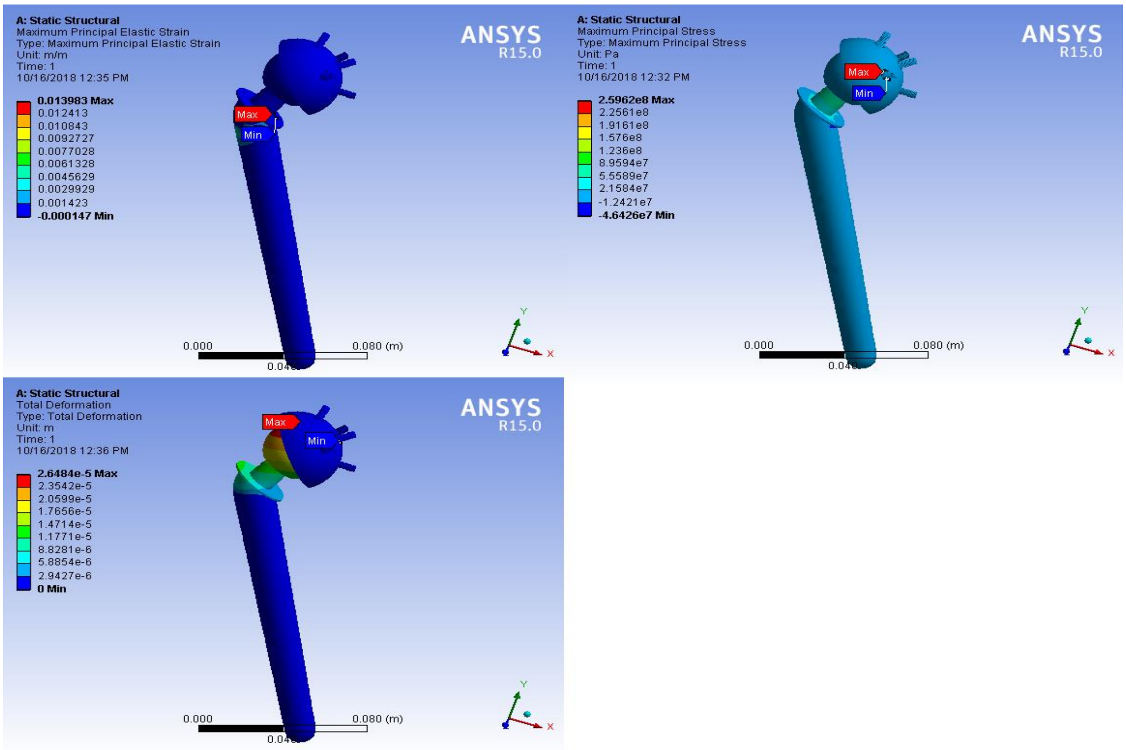

Figure (6.3): mechanical analysis results for angle 25.6º

6.5 Mechanical analysis results for angle 38.4º:

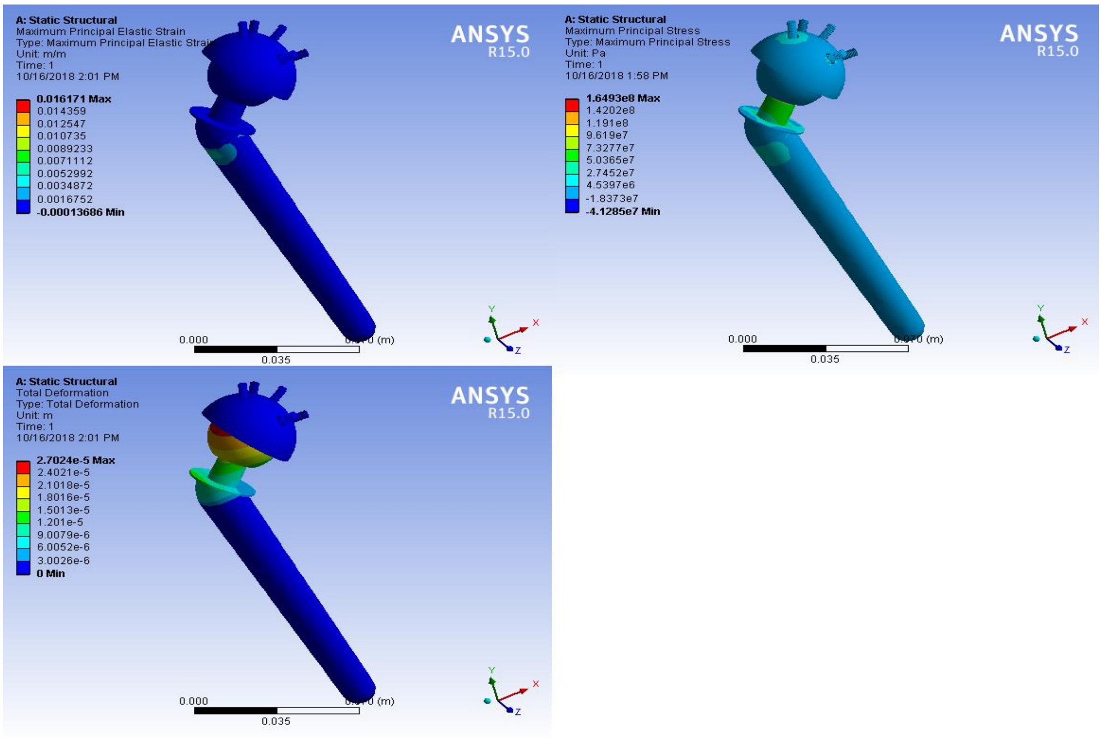

Figure (6.4): mechanical analysis results for angle 38.4º

6.6 Mechanical analysis results for angle 51.2º:

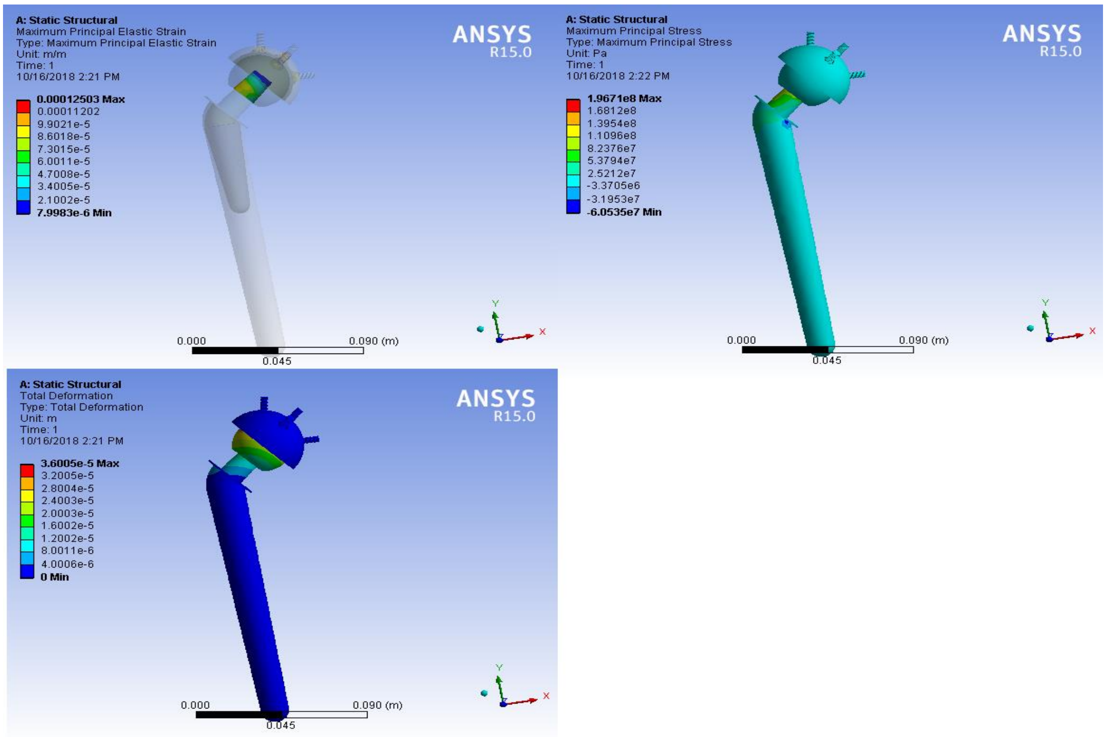

Figure (6.5): mechanical analysis results for angle 51.2º

6.7 Mechanical analysis results for angle 64º:

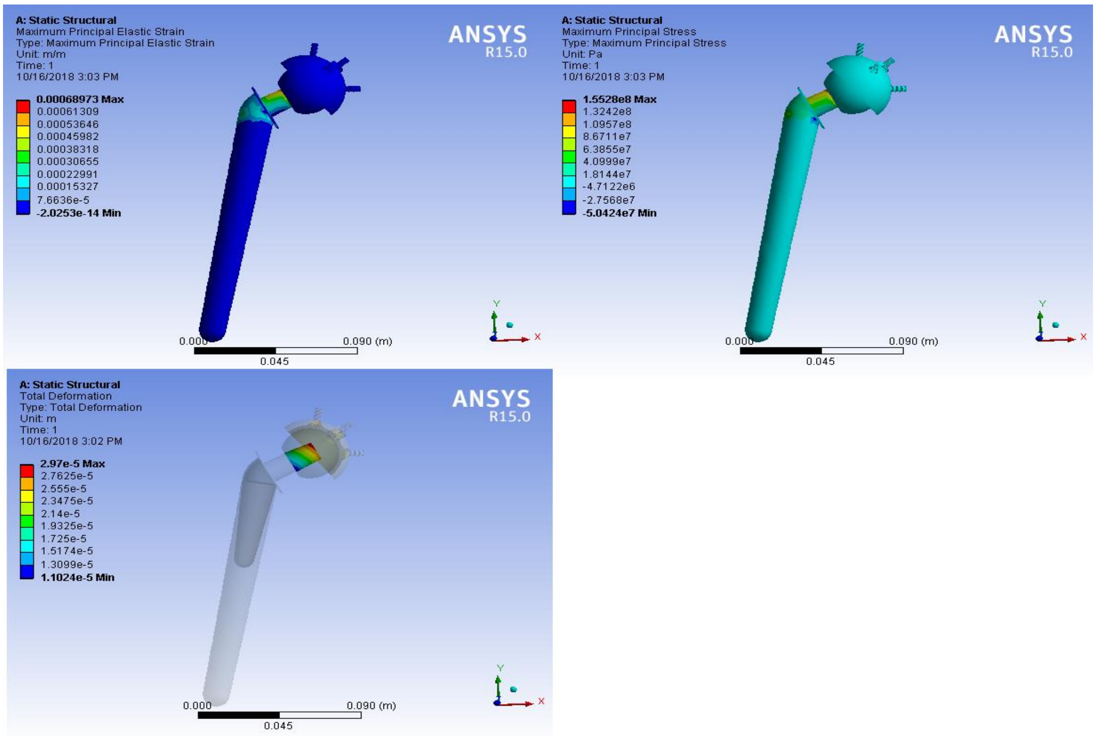

Figure (6.6): mechanical analysis results for angle 64º

6.8 Mechanical analysis results for angle 76.8º:

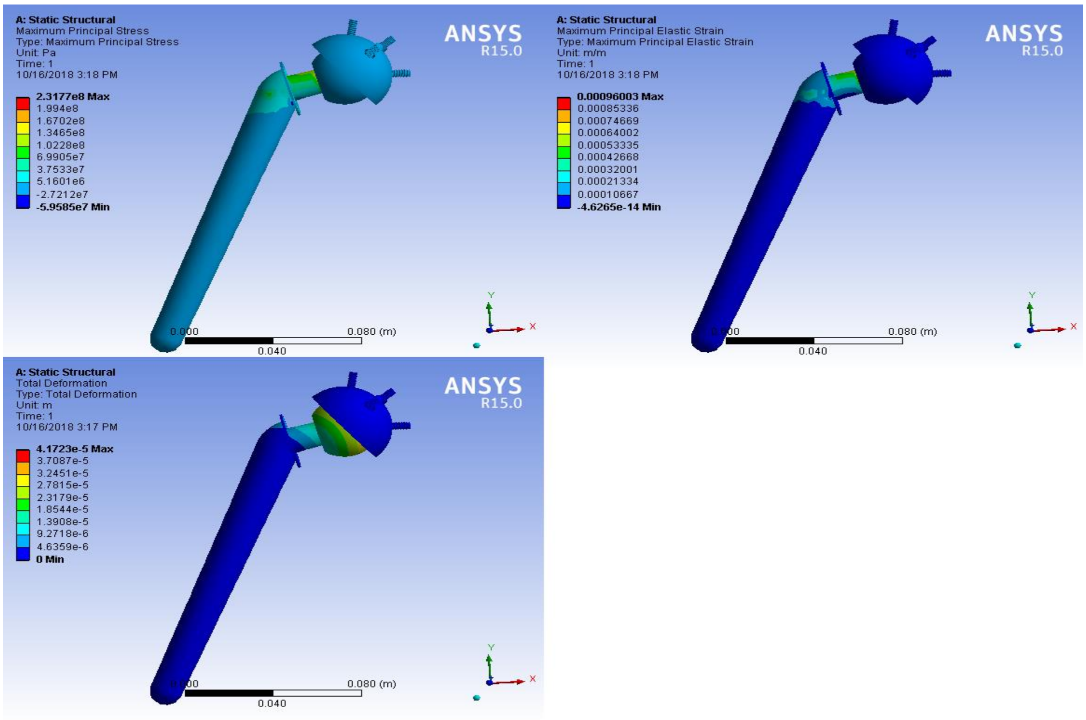

Figure (6.7): mechanical analysis results for angle 76.8º

6.9 Mechanical analysis results for angle 89.6º:

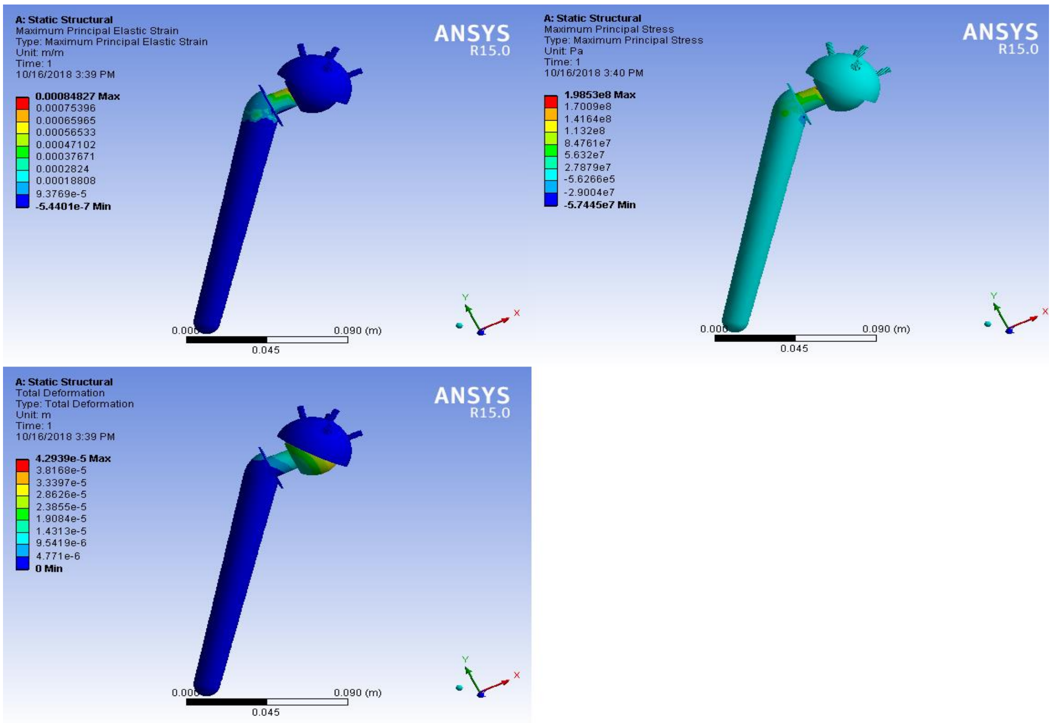

Figure (6.8): mechanical analysis results for angle 89.6º

6.10 Mechanical analysis results for angle 102.4º:

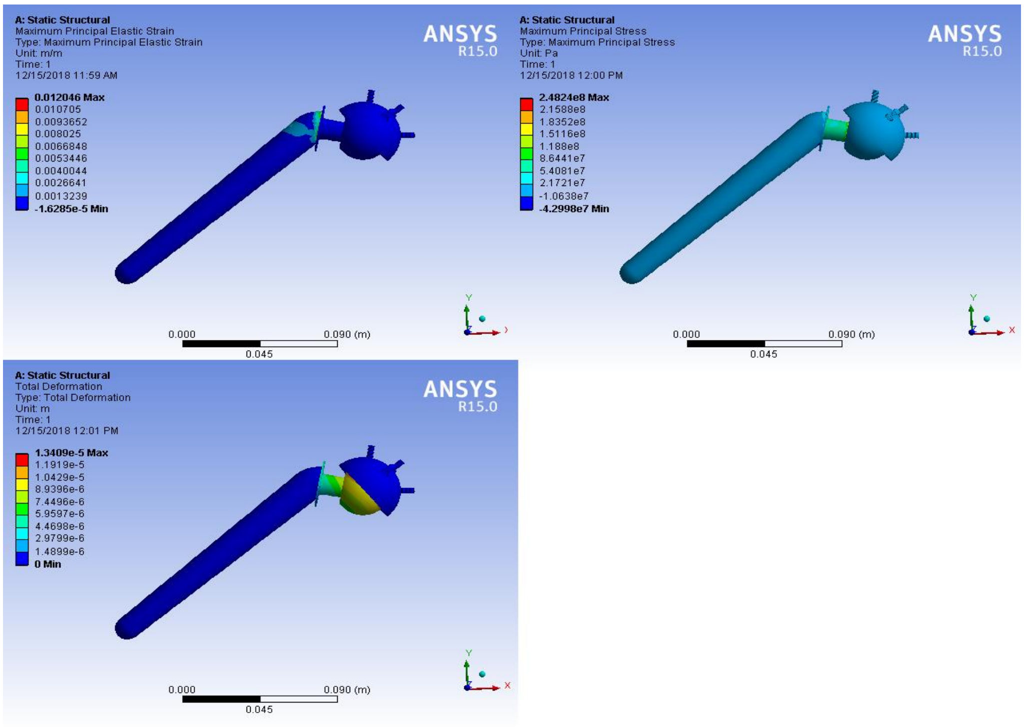

Figure (6.9): mechanical analysis results for angle 89.6º

6.11 Mechanical analysis results for angle 115.2º:

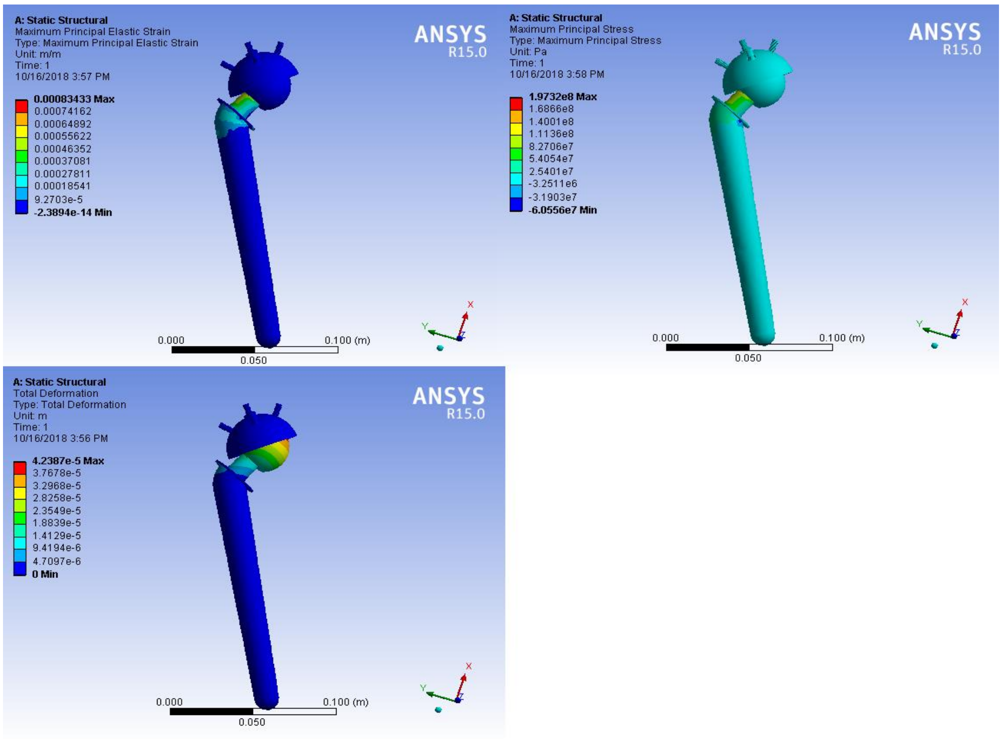

Figure (6.10): mechanical analysis results for angle 115.2º

6.12 Mechanical analysis results for angle 128º:

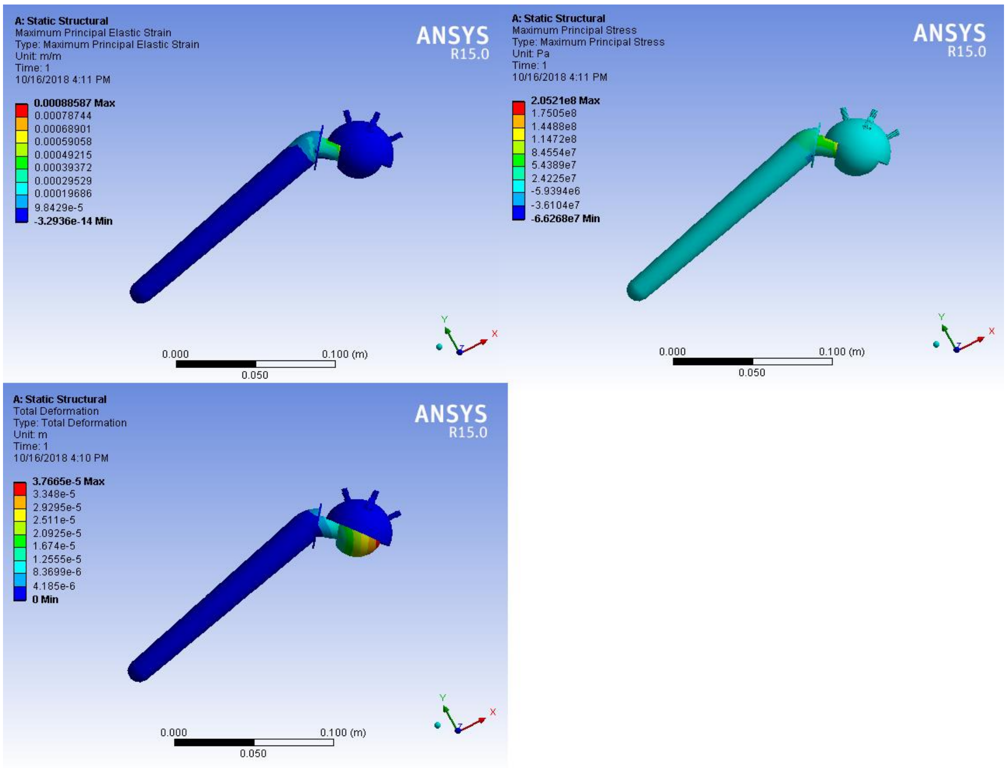

Figure (6.11): Mechanical analysis results for angle 128º

Starting with figure (6.1) through figure (6.2), (6.3), (6.4), (6.5), (6.6), (6.7), (6.8), (6.9), (6.10) until figure (6.11) 3.4534e+008 Pa was the highest value of the maximum stress that was presented in the model analysis, and since the tensile strength, present the maximum amount of tensile stress that the material can take before failure, and yield strength present the stress of a material can withstand without permanent deformation. This verify these results are accurate, because 3.4534e+008 Pa less than the tensile yield strength of the CoCrMo [20][21], which is 8.4e+008 Pa.

Since the tensile yield strength for CoCrMo is 840 MPa,UHMWPE is 16.99 MPa and PEEK is 100MPa, the total tensile yeild strength for the geometry is 956.99 MPa. so the accuracy of the design under the subjected load is:

((956.99-345.34)\956.99)*100% =64%

Chapter seven

Discussion

From the knowledge that was concluded from the Theoretical fundamental, the standard dimensions were prepared and executed according to the required assumptions using solidwork software and specific modifications in the dimensions were done according to Sudanese standards .The model type is four pieces acetabulum, insert, head and stem, CoCrMo was assigned as the used material for the acetabulum, for the head and for the inner part of the stem, UHMWPE was used for the insert, and PEEK was applied to the outer part of the stem. The assumption behind the material choosing is that the metallic parts handle the maximum load and the polymeric materials handle the minimum load and that because the load is reduced from the top to the bottom of the design according to the biomechanical principle that is used. In addition, the suggested dimensions able to distribute the applied force and their reaction according to the geometry of the design, also the designed geometry has S-shape stem which able to resist the rotational stress. All this was followed by mechanical analysis tests using Ansys software, which are Maximum Principal Elastic Strain, Maximum principal Stress and Total Deformation, with different angle starting with 0º and ending with 128º, having 12.8º step. This analysis showed that the model provide an accurate solution for the four metallic problems. The results also showed that the maximum stress that appeared in the model is 3.4534e+008 Pa which is higher than the tensile yield strength of the metallic parts with 2.6 times; this mean the design provide an excellent solution for stress shielding; stiffness mismatching, subsidence and fatigue fracture all together. Finally, the model was executed as a prototype using 3D printing technique to verify the reasonability of the suggested dimensions.

Chapter eight

Conclusion and recommendation

8.1 conclusion:

The project was completed according to the suggested plan; ending up with a hybrid model for AHJ.The factors, those causes the problems with the metallic joints were enclosed and emphases take place for material choosing and force distribution through the model geometry. Also special mechanical analysis tests were performed to examine the design and it passed successfully through it, the results of the test were illustrated and discussed, and it showed that the selected materials and geometry are successful .however, there still some challenges faces the local manufacturing, which need more searching and visibility study to be established, and since the hybrid model provide a a great chance for cost reduction ,the opportunity of establishment of local manufacturing is great too.

8.2 Recommendations:

The metallic and cost problems of the AHJ models led to presence of different artificial joints modalities with different qualities; since this research suggested a hybrid design, local manufacturing could solve these problems so solving these problems could be enclosed in these categories of recommendations:

- Since the local manufacturing of the AHJ needs metallic 3D printing or 5-axis CNC techniques, emphasis should take place on establishing workshops and factories those have these techniques.
- Since the used materials are not available in Sudan, emphasis should be on how to import these materials with the minimum cost and how to overcome all the obstacles on the way to make a mass production.
- Training courses are needed to qualify the necessary staff with the enough ability to carry out the job this thing will lead to breakdown all the fear against the obstacles that might be faced.
- Emphasis must take place on the biomedical engineer job description, especially in rehabilitation field to enhance the healthcare.
- Conducting of feasibility study to know the possibility of installing a factory for prosthesis in the Sudan.
- Conducting a study that aims to find the standard Sudanese dimensions for the hip joint.

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Appendices

Appendix (A)

Analysis details

1. Material characteristic:

1.a PEEK:

Density	1320 kg m^-3
Coefficient of Thermal Expansion	1.2e-005 C^-1
Specific Heat	1700 J kg^-1 C^-1
Thermal Conductivity	0.25 W m^-1 C^-1
Resistivity	1.7e-007 ohm m
Compressive Ultimate Strength	3.e+008 Pa
Compressive Yield Strength	1.179e+008 Pa
Tensile Yield Strength	1.e+008 Pa
Tensile Ultimate Strength	2.3e+008 Pa
Isotropic characteristics of PEEK:	
reference Temperatu3.re C of Thermal Expansion	22
Young's Modulus Pa	3.6e+009
Poisson's Ratio	0.4
Bulk Modulus Pa	6.e+009
Relative Permeability	10000
Shear Modulus Pa	1.2857e+009

1.b CoCrMo:

Density	8300 kg m^-3
Coefficient of Thermal Expansion	1.2e-005 C^-1
Specific Heat	450 J kg^-1 C^-1
Thermal Conductivity	13 W m^-1 C^-1
Resistivity	1.7e-007 ohm m

Compressive Ultimate Strength	5.e+009 Pa
Compressive Yield Strength	2.7e+009 Pa
Tensile Yield Strength	8.4e+008 Pa
Tensile Ultimate Strength	1.28e+009 Pa
Isotropic characteristic	
Reference Temperature C of Thermal Expansion	22
Young's Modulus Pa	2.5e+011
Poisson's Ratio	0.3
Bulk Modulus Pa	2.0833e+011
Relative Permeability	10000
Shear Modulus Pa	9.6154e+010

1.c UHMWPE:

Density	0.93(g/cm-^{3})
Coefficient of Thermal Expansion	11 e-5 in/in/°F
Specific Heat	1.81e3 j/Kg °C
Thermal Conductivity	2.9 in/hr.ft^{2}. °F
Resistivity	1e+023 (10^{-8} ohm.m)
Compressive Ultimate Strength	80000 PSI
Compressive Yield Strength	3000 PSI
Tensile Yield Strength	2465 PSI
Tensile Ultimate Strength	5800 PSI
Isotropic characteristic	
Reference Temperature C of Thermal Expansion	22
Young's Modulus Pa	0.45 GPa
Poisson's Ratio	0.355
Bulk Modulus Pa	0.51724

Relative Permeability	10000
Shear Modulus Pa	0.16605

1.d Cortical bone:

Density	1.85(g/cm^3)
Coefficient of Thermal Expansion	12 e-06/°C
Specific Heat	200-390 K
Thermal Conductivity	0.53+/-0.030 (W/mK)
Resistivity	2-5*105 ohm-cm
Compressive Ultimate Strength	205 MPa
Compressive Yield Strength	170 MPa
Tensile Yield Strength	114 MPa
Tensile Ultimate Strength	133 MPa
Isotropic characteristic	
Reference Temperature C of Thermal Expansion	37
Young's Modulus Pa	20 GPa
Poisson's Ratio	0.3
Bulk Modulus Pa	15 GPa
Relative Permeability	0.86
Shear Modulus Pa	14.8GPa

2. Units:

Unit System	Metric (m, kg, N, s, V, A) Degrees rad/s Celsius
Angle	Degrees
Rotational Velocity	rad/s

Temperature	Celsius

3. Model:

3. a Geometry :

Object Name	Geometry
State	Fully Defined
Definition	
Type	Parasolid
Length Unit	Meters
Element Control	Program Controlled
Display Style	Body Color
Bounding Box	
Length X	0.12638 m
Length Y	0.18358 m
Length Z	4.7284e-002 m
Properties	
Volume	6.751e-005 m^3
Mass	0.36573 kg
Scale Factor Value	1.
Statistics	
Bodies	11
Active Bodies	11
Nodes	58903
Elements	29721
Mesh Metric	None

Basic Geometry Options	
Solid Bodies	Yes
Surface Bodies	Yes
Line Bodies	No
Parameters	Yes
Parameter Key	DS
Attributes	No
Named Selections	No
Material Properties	No
Advanced Geometry Options	
Use Associativity	Yes
Coordinate Systems	No
Reader Mode Saves Updated File	No
Use Instances	Yes
Smart CAD Update	No
Compare Parts On Update	No
Attach File Via Temp File	Yes
Analysis Type	3-D
Mixed Import Resolution	None
Decompose Disjoint Geometry	Yes
Enclosure and Symmetry Processing	Yes

3.b Coordinate system:

Object Name	Global Coordinate System
State	Fully Defined
Definition	

Type	Cartesian
Coordinate System ID	0.
Origin	
Origin X	0. m
Origin Y	0. m
Origin Z	0. m
Directional Vectors	
X Axis Data	[1. 0. 0.]
Y Axis Data	[0. 1. 0.]
Z Axis Data	[0. 0. 1.]

3.c Connection:

Object Name	Connections
State	Fully Defined
Auto Detection	
Generate Automatic Connection On Refresh	Yes
Transparency	
Enabled	Yes

3.d Connections Contacts:

Object Name	Contacts
State	Fully Defined
Definition	
Connection Type	Contact
Scope	
Scoping Method	Geometry Selection

Geometry	All Bodies
Auto Detection	
Tolerance Type	Slider
Tolerance Slider	0.
Tolerance Value	5.6959e-004 m
Use Range	No
Face/Face	Yes
Face/Edge	No
Edge/Edge	No
Priority	Include All
Group By	Bodies
Search Across	Bodies

4. Mesh:

Object Name	Mesh
State	Solved
Defaults	
Physics Preference	Mechanical
Relevance	0
Sizing	
Use Advanced Size Function	Off
Relevance Center	Coarse
Element Size	Default
Initial Size Seed	Active Assembly
Smoothing	Medium
Transition	Fast

Span Angle Center	Coarse
Minimum Edge Length	7.6256e-007 m
Inflation	
Use Automatic Inflation	None
Inflation Option	Smooth Transition
Transition Ratio	0.272
Maximum Layers	5
Growth Rate	1.2
Inflation Algorithm	Pre
View Advanced Options	No
Patch Conforming Options	
Triangle Surface Mesher	Program Controlled
Patch Independent Options	
Topology Checking	Yes
Advanced	
Number of CPUs for Parallel Part Meshing	Program Controlled
Shape Checking	Standard Mechanical
Element Midside Nodes	Program Controlled
Straight Sided Elements	No
Number of Retries	Default (4)
Extra Retries For Assembly	Yes
Rigid Body Behavior	Dimensionally Reduced
Mesh Morphing	Disabled
Defeaturing	
Pinch Tolerance	Please Define
Generate Pinch on Refresh	No

Automatic Mesh Based Defeaturing	On
Defeaturing Tolerance	Default
Statistics	
Nodes	58903
Elements	29721
Mesh Metric	None

Appendix (B)

Equations

$$F_A = \left(\frac{5}{6}\right) W \quad \frac{L}{r} \tag{1}$$

$$F_R = \left(\frac{5}{6}\right) W \sqrt{725 + 5cosA} \tag{2}$$

Appendix (C)

Isidor 3D Printing

ايزيدور للطباعة ثلاثية الابعاد

ISIDOR 3D PRINTING

To whom it may concern

This certificate to verify that ms.Ryan Kamal Saidahemed mohemed , and through the facilities of Isidor 3D printer company, printed 3D model for artificial hip joint using 3D printer ,and she was very collaborated with sketching and designing .

Reem ahmed madni

Executive Manger

Isidor3D

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