Product Design and Prototyping

(BM5193)

MINI PROJECT REPORT

"Prosthetic Hip Implant"

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ABSTRACT:

Hip replacement surgery is one of the most frequent surgeries performed worldwide. In the next ten years, it is expected that the number of hip replacement operations performed annually would double, to more than 1 million. The bone-healing process begins after the worn-out or injured hip joint is replaced with an artificial hip joint or prosthesis.

Current trends in prosthesis design emphasize the use of biocompatible materials that are strong enough to withstand the more active lifestyles of many patients, whilst generating minimal wear debris. The thermoplastic filament material polylactic acid (PLA) is used in our case. Its ease of use and minimal warping issues make PLA filaments the perfect starting point for 3D printing. PLA is also one of the most environmentally-friendly 3D printing materials and, unlike ABS, is biodegradable. Among other PLA advantages are also its low cost and a wide assortment of colors and blends.

We proposed a 3d CAD model of prosthetic Hip implant. The analyzed models were created using a computer aided design (CAD) software i.e. CATIA software. CATIA provides the best solutions for the entire shape designing, styling, and surfacing workflows. Reverse Engineering of the 3D model was performed using CATIA software. The 3D model or prototype was printed using an FDM printer. Speed and Material flexibility are some of the reasons to use FDM 3D printing. It is important to introduce some modification to our 3D model such that it can resist wear and tear. High friction and consequent wear of artificial hip implants after 10–15 years of implantation are the major issues leading to revision surgery. Therefore, surface modification techniques can be developed to improve the implant quality. Surface modification techniques improve biological, chemical and mechanical properties of implant surfaces. Surface modeling techniques like surface texturing and roughness parameters are added to the standard model to improve their quality.

Keywords: *prosthesis design, Hip replacement, PLA filaments,3D CAD model, FDM*

INTRODUCTION:

Femur is an important load-bearing bone that supports the total body's weight during activities such as standing, walking, running, and jumping. Fracture and damage to the hip can result from a variety of causes, such as traffic accidents, falls, osteoporosis, or diseases that affect joint tissues. Hip injury is an extremely serious and common event that can be highly damaging, leading to permanent disability and even death. Worldwide, the number of hip fractures is expected to increase to over 6.26 million by 2050

Many patients with hip disease have difficulties carrying out daily activities; hence, hip replacement surgery has become a common procedure. Hip replacement involves replacing the diseased hip with a new artificial joint called prosthesis, which is used to transfer the load from the acetabulum to the femur by inserting a metal stem into the latter.

Total hip replacement is a more mature and reliable treatment method to replace the damaged joint and recover its normal function. It is one of the most common surgical procedures, during which a surgeon replaces a diseased or damaged hip joint with a prosthetic hip implant. A hip prosthesis is a medical device that replaces a damaged hip joint. The hip consists of a convex femoral head inserted into a concave acetabulum within the pelvis, cushioned by articular cartilage within a synovial joint capsule. The long-term stability of implanted prostheses is strongly related to the stress transfer between implants and bone

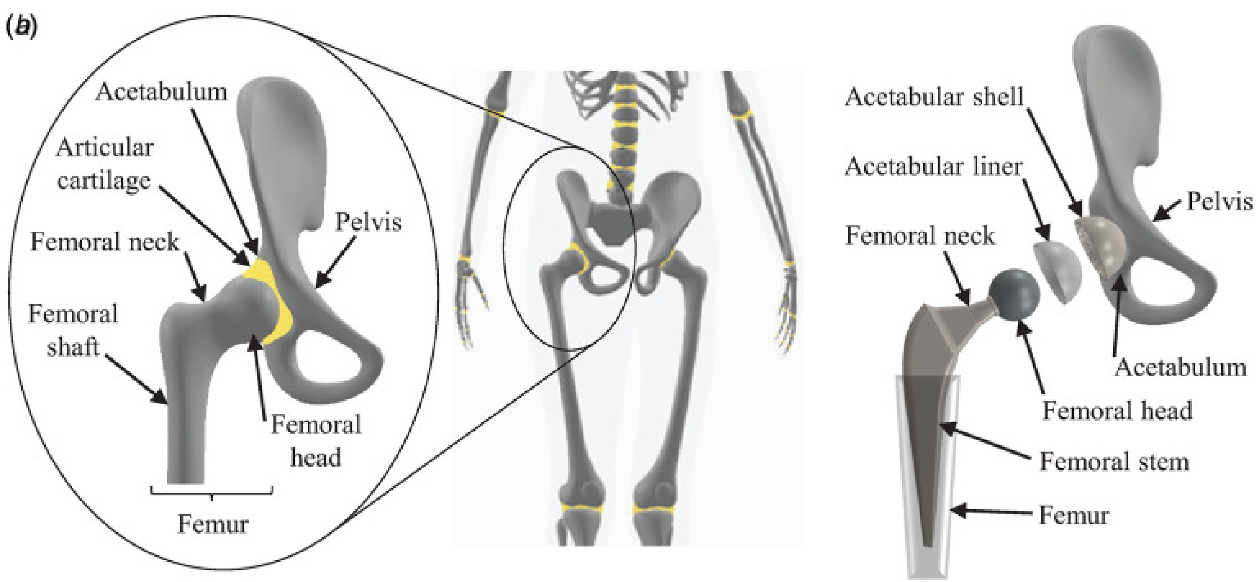

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Fig 1: Schematic of (a) the human hip and (b) a typical prosthetic hip implant

A prosthetic hip implant comprises a femoral head that attaches to a femoral neck and stem, which anchors in the femur (thigh) bone (see Fig. 1). The femoral head articulates with an acetabular liner, which sits in an acetabular shell that is implanted in the pelvis. The articulation between the femoral head and acetabular liner/shell replaces the natural hip joint motion

Prosthetic loosening is a failure mode caused by movement of the prosthesis in bone or bone cement. The most common cause of this problem is a loss of bone mass due to stress shielding .The latter process occurs in the femur, where the prosthesis bears part of the load and thus shields the bone. Under normal circumstances, the femur itself is subjected to an external load, which is then transmitted from the femoral head through the neck of the femur to the proximal cortical bone. After implanting a hip prosthesis in a patient, the loading conditions on the cortical bone become much different. When a more rigid component is inserted into the medullary canal, it shares the load with the femur. Owing to the large mismatch between the stiffness of the prosthesis and that of cortical bone, a significant amount of the stress is absorbed by the hip implant, which only leaves a small amount of the load to be transferred to the surrounding host cortical bone. The loading thus shifts from the femur alone to the prosthesis and femur together. As a result, the bone is subjected to less stress, and stress shielding occurs. The upper part of the femur receives a lower load, but the femur around the distal part of the femur is overloaded.

Bone areas that are subjected to high load or stress develop an increased mass to resist the load, while those under low load or stress response by reducing their mass, that is, by becoming less dense and weaker, owing to the absence of stimulation . In other words, bone grows where it is needed and is resorbed where it is not. The growth, absorption, and remodeling of bone are all related to the stress applied on it. In the case of the stress shielding effect of hip implants, it was reported that the surrounding host cortical bone initiates the progression of osteoporosis and remodels itself to become less dense over time.. As the bone becomes less dense, the hip implant starts to undergo micromotion, which then increases over time and causes stem loosening. Other causes of implant loosening include osteolytic particle debris.

The recent advances in 3D printing technology now enable significant improvements in implant design. Three-dimensional (3D) printing offers significant potential as an efficient fabrication technique on personalized organs as it is capable of biomimicking the intricate designs found in nature. **Fused Deposition Modeling (FDM)** is a form of 3D printing that involves the use of thermosensitive polymers that undergo heating above its glass transition temperature and a solid medium deposition occurs. FDM is closely similar to SLA, and it was initially used for only 3D polymer structures. The FDM has been developed to produce ceramic, ceramic/polymer composites which is termed a fused deposition of ceramics. For this technique, a word thermoplastic polymeric filament is used by unwinding and extruded via a hot nozzle onto a fabrication base.

On settling on the platform, the polymer cures. After a series of the layer on layer deposition, the final **CAD structure** is produced. The key advantage of FDM is that there is a low possibility of toxicity from organic solvent when they solubilize polymers; for example, dichloromethane is used for solubilizing PLGA. They can also be applied on scaffolds without cells or any bioactive molecules which have gradients in x, y and z directions. However, the limitation in the requirements used for determining the right thermoplastic material hinders its versatility and application range concerning scaffold fabrication with the result being that PolyLactic acid (PLA) is the most commonly used material.

Several regions are important in the design of the hip implant and these regions include geometry, materials, stress distribution along the stem and micro-motion between the implant and the bone. The geometry suitability between the human bones and implant is one of the most key factors for a positive outcome. 3D CAD model of Hip Prosthetic Implant can be designed using various CAD softwares. The hip-bone joint design has been generated using CATIA V5 software. Once the CAD file is generated it can be converted to stl file for further printing. The STL format is usually obtained by triangulating an exact model using CAD software. A STL data file is defined from triangular facets defined by the coordinates of the three vertices and its normal directed to the free side of the object. The 3D point cloud format conversion operation in STL format is performed by Catia V5 software

NEED/PURPOSE OF THE DEVICE:

The hip joint plays an important role in our daily activities, such as walking, cycling, driving, and playing. Unfortunately, there is no guarantee that this articulation will always be in good condition: damage to it can occur in many unexpected ways, such as accidents or osteoporosis-like diseases.

The damaged femur needs to be replaced by total or hemi hip arthroplasty. The **insertion of a prosthesis into the femur** can lead to effects such as **stress shielding and rejection**. Therefore, the design of the prosthetic Hip implant must be optimized to minimize these effects.

Hip implants can be necessary in following conditions:

- Osteoarthritis or Rheumatoid arthritis - severe hip pain and inflammation
- Osteonecrosis - Blood supplied to the ball portion of the hip joint is not enough
- Bone dislocation
- Bone collapse and deform.
- Hip fracture and natural wear-and-tear

High friction and consequent wear of artificial hip implants after 10–15 years of implantation are the major issues leading to revision surgery. Therefore, **surface modification techniques** can be developed to improve the implant quality considering the lifespan of younger patients

WORKING MECHANISM:

A standard total hip replacement consists of five individual component, and each has its own function –

a. **Acetabular cup**

The acetabular (cup) socket structure fits into pelvic

b. **Acetabular liner**

The acetabular liner fits into the cup and serves as the new “cartilage”. Much like the cartilage in the hip, it is susceptible to wear and historically this has been the “weak link” of total hip replacement.

c. **Femoral head**

The femoral head (ball) fits on the top of the stem (trunnion). This end of the stem is taper shaped to allow the ball to wedge into position and be held tightly in place with friction.

The ball comes in many different diameters often related to the size of the cup and liner that fits into the pelvis

d. **Femoral neck**

Portion of the replacement between femoral head and femoral stem

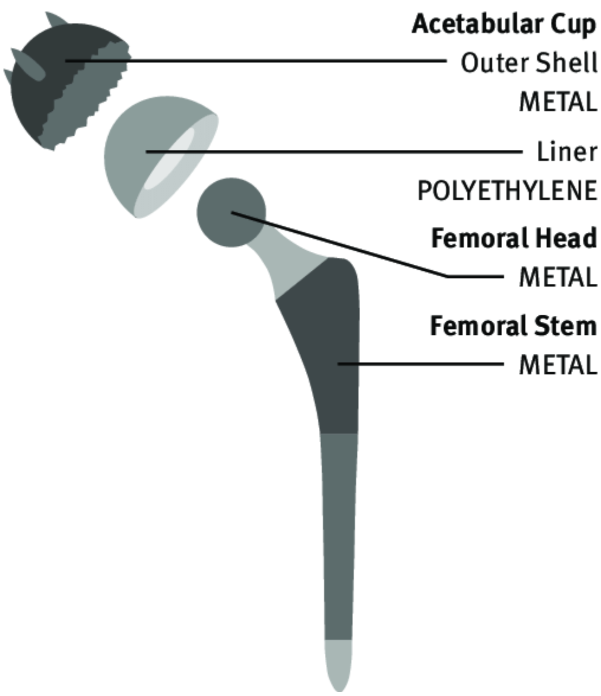
e. **Femoral stem**

Portion of the replacement that fits into thigh bone

<u>CAD MODELING: (Using CATIA Software)</u>

<u>Graphic Picture :</u>

(Dimensional : Sketch)



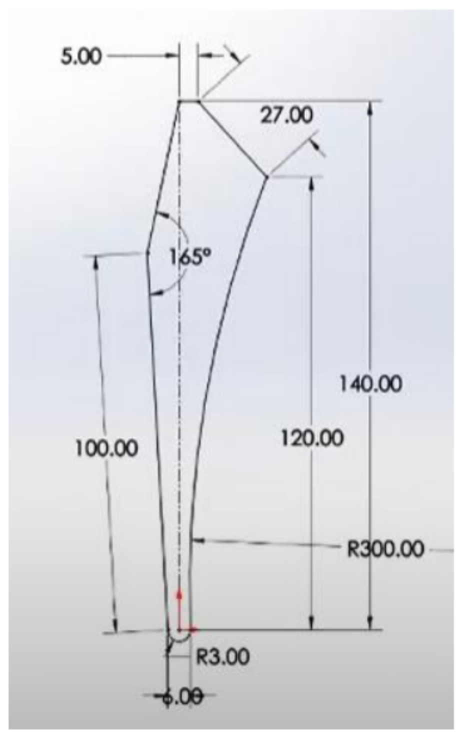


Image Source – Arun, S. & Sreekanth, P S & Subramani, Kanagaraj. (2013). Polymer composites for cemented total hip replacements. 10.1515/9783110267488.53.

Sketching

Description: Sketching is the fundamental step in CAD design. It involves creating 2D profiles or drawings on a 2D plane (usually called a sketch plane) using various sketching tools like lines, arcs, circles, and polygons.

Usage: You start by sketching the basic shapes and profiles that will serve as the foundation for your 3D model. These sketches can then be extruded or manipulated to create 3D objects.

Revolve:

Description: Revolve is a feature used to create 3D objects by revolving a 2D profile (usually created through sketching) around an axis. This creates a solid 3D object with rotational symmetry.

Usage: You can use the Revolve command to create objects like cylinders, cones, or even more complex shapes by rotating a profile around a central axis.

Padding:
Description: Padding, also known as extrusion or extrude, is a command used to give thickness or depth to a 2D sketch. It takes a 2D sketch and extends it along a specified direction to create a 3D solid.
Usage: Padding is often used to convert 2D sketches into 3D objects, such as turning a flat rectangle into a rectangular prism.

Rotating Instances:
Description: This command allows you to create multiple copies or instances of a 3D object and arrange them in a circular or rotational pattern.
Usage: Rotating instances are handy when you need to create symmetrical patterns or arrays of objects around a common axis or center point.

System Level Design

Acetabular Cup

The Acetabular Cup is designed using the catia software generative shape design feature. This feature is excellent when it comes to surface designing.

The operations performed during modeling includes

- Sketching
- Revolve
- padding
- Rotating Instances
- Pocketing

Pocketing:
Description: Pocketing is a subtractive operation in CAD. It involves removing material from a 3D object by cutting or hollowing it out. Think of it as creating holes or cavities within a solid object.
Usage: Pocketing is used for creating spaces, voids, or internal features within a 3D model. For example, you can use pocketing to create holes for screws or to hollow out the interior of a part.

3D printing of an acetabulum through Fused Deposition Modeling (FDM) with acrylonitrile butadiene styrene (ABS) polymer or Polylactic acid (PLA) can be considered.

Polyethylene Insert/Liner

The part is modeled using the Catia's Part modeling feature. The part is made of polyethylene to avoid

The operations performed during modeling includes

- Sketching
- Revolve
- Pocketing
- Chamfer

Chamfer:
Operation: Chamfering is a modification made to the edges or corners of 3D objects. It involves cutting or beveling away a portion of the edge to create a flat, angled surface between two adjacent surfaces. Chamfers are typically applied to reduce sharp edges, making parts safer and more aesthetically pleasing.

Result: The result of chamfering is a 3D object with beveled edges, typically defined by specific dimensions or angles. Chamfers can be applied to the exterior edges of a part or even to internal edges or corners.

Use Cases: Chamfers are commonly used in engineering and product design to improve the durability and safety of components. They are often applied to edges of mechanical parts, electronic enclosures, and architectural elements to prevent stress concentration and facilitate assembly.

Femoral Head and Neck

The part is modeled using the Catia's Part modeling feature. The part is applied with titanium Material.

The operations performed during modeling includes

- Sketching
- Revolve
- Padding
- Chamfer
- Surface Drafting (to give angles)

Surface Drafting:

Operation: Surface drafting, sometimes referred to as draft analysis, is a process used to analyze and modify the angles of surfaces within a 3D model. It's particularly important in processes like injection molding or casting, where the removal of a mold or die from a part is easier if the part has draft angles.

Result: The result of surface drafting is to adjust the angles of surfaces to facilitate their removal from a mold or die. It ensures that the part can be ejected without causing damage or getting stuck in the mold.

Use Cases: Surface drafting is crucial in industries like manufacturing and product design. For example, when designing plastic parts for injection molding, engineers use surface drafting to ensure that the molded part can be ejected smoothly from the mold, reducing production issues.

Femoral Stem

The part is modeled using Wireframe design feature for multi sections solid profile. The part is applied with titanium Material.

The operations performed during modeling includes

- Sketching
- Padding
- Surface Drafting
- Multi Sections Solid Connect using spline

REVERSE ENGINEERING OF THE DEVICE :

Reverse Engineering (RE) is a process of redesigning, reassembling and restructuring of an existing part. Though it had been a great use in the development of many new designs, products and concepts, it has now been very much utilized in the design and development of the medical implants, prosthetics, and orthopedic components and also in the tissue engineering

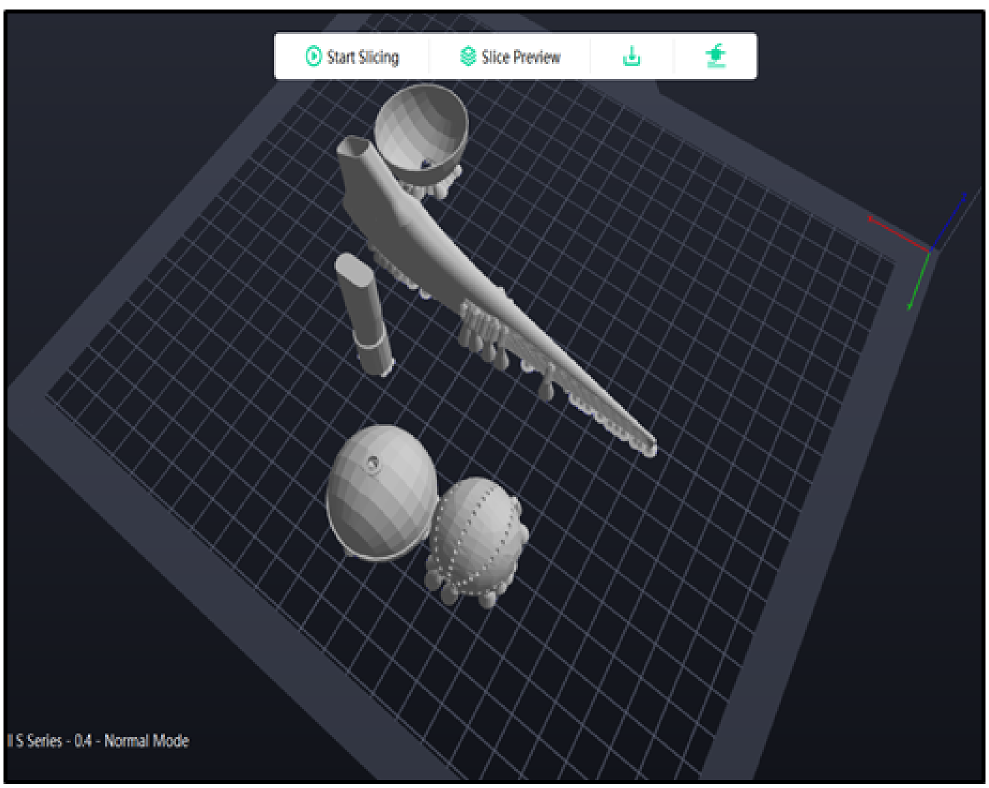


Figure: The Slicer orientation level

slicing is a useful feature that allows you to visualize and analyze cross-sectional views of 3D models. It helps you examine the internal details and geometry of a 3D object by creating 2D cross-sections at specified planes or angles.

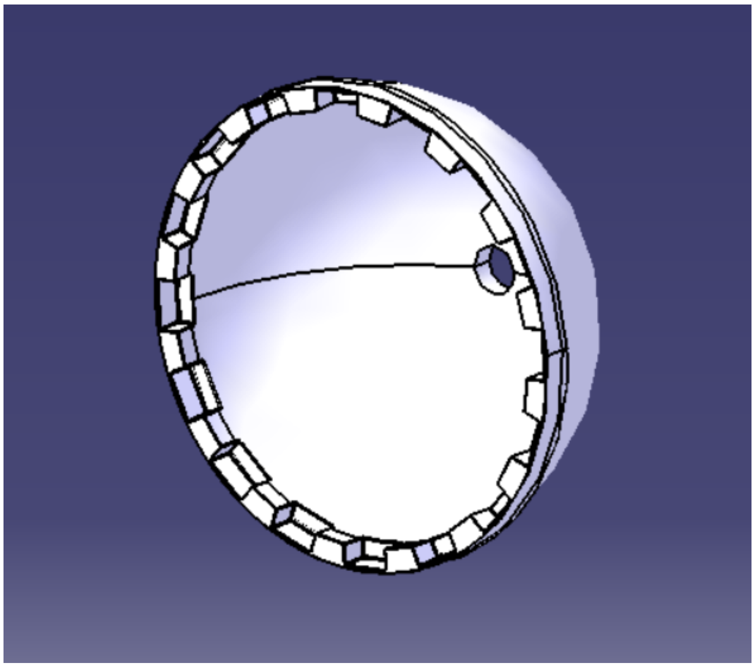
The geometric modeling of the scanned images can be well termed as Bio modeling which is used in the fresh preparation of the personalized implants may be hip implant. Reverse Engineering in medical (RIM) is a new dimension to research and development in the medical field. It is a challenge to the engineers as well as the surgeons to utilize it for proper shape, geometry and structure of the biomedical objects and take the challenge ahead. In this work a methodology for designing personalized human hip prosthesis using Reverse Engineering methods has been proposed.

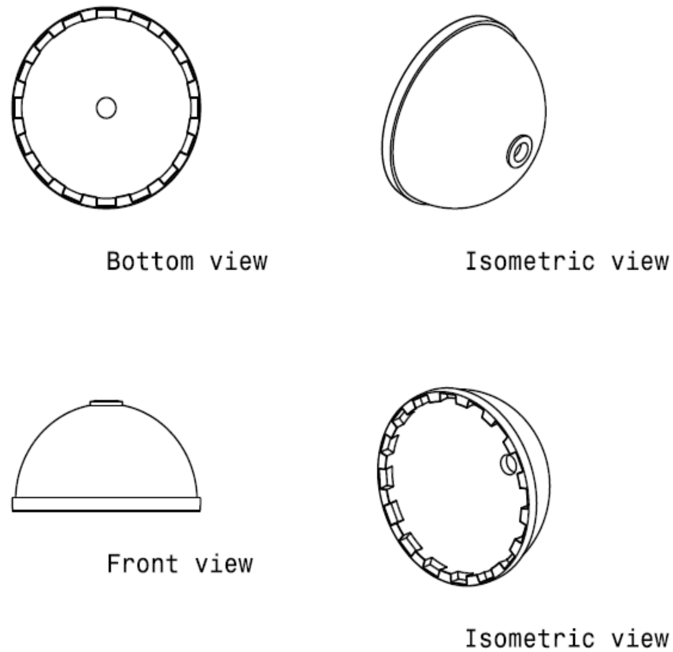
figure: FDM printed hip implant

It is important for the design and implementation of a personalized denture to adapt to the patient's anatomical dimensions. To meet these requirements, one should get the exact dimensions of the damaged joint. For this purpose, it is convenient to use a CT test, based on which a personalized prosthesis can be designed in CAD programs.

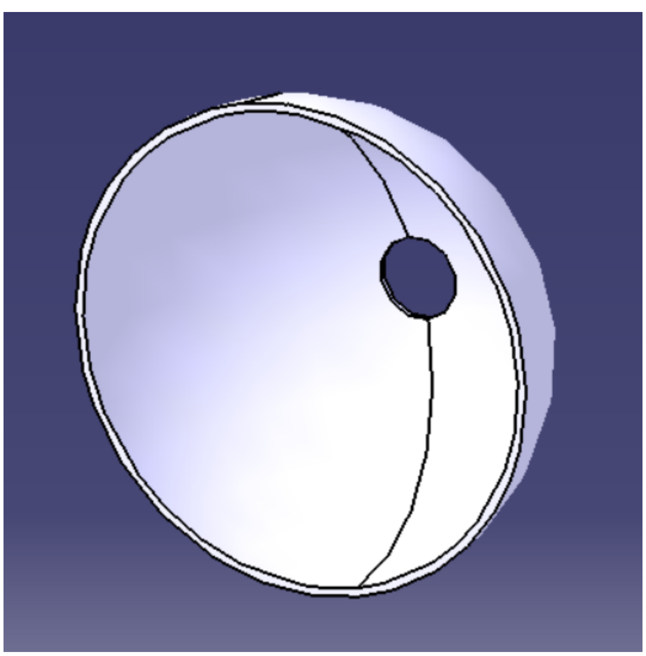
- **CAD MODEL OF THE COMPONENTS AND ASSEMBLY:**

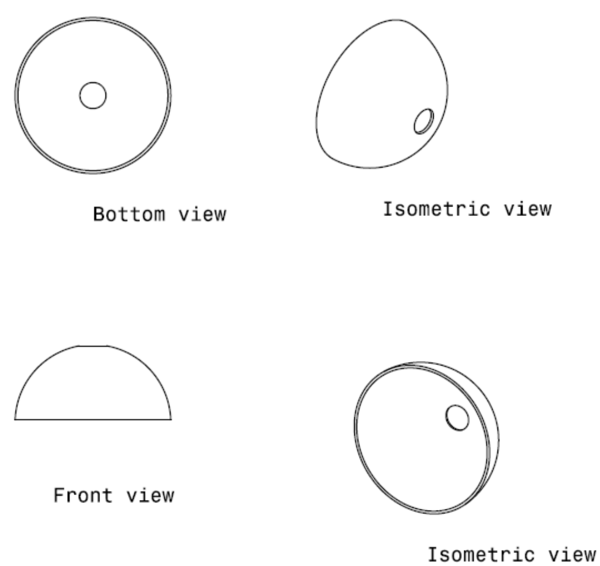
  - **Acetabular Cup**



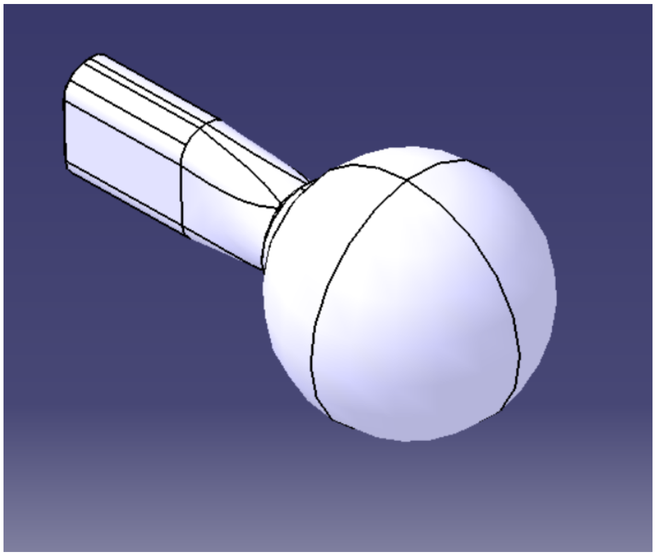


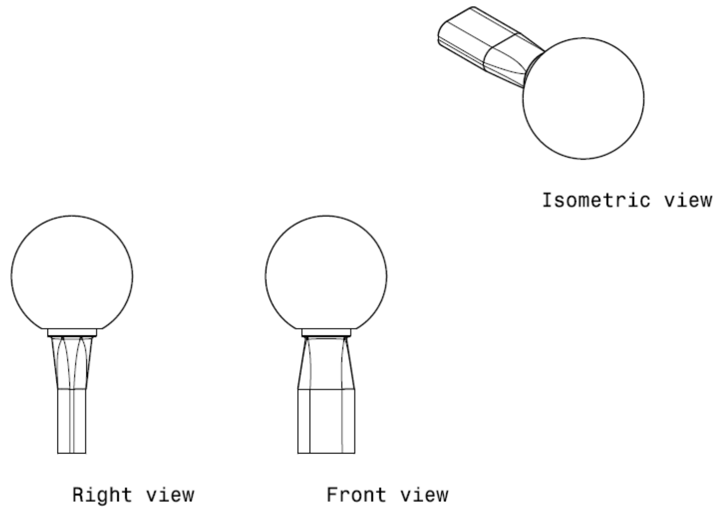
- **Polyethylene Insert/Liner**



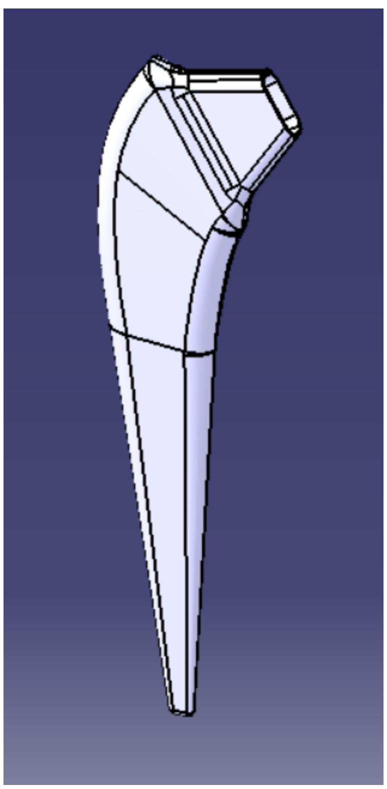


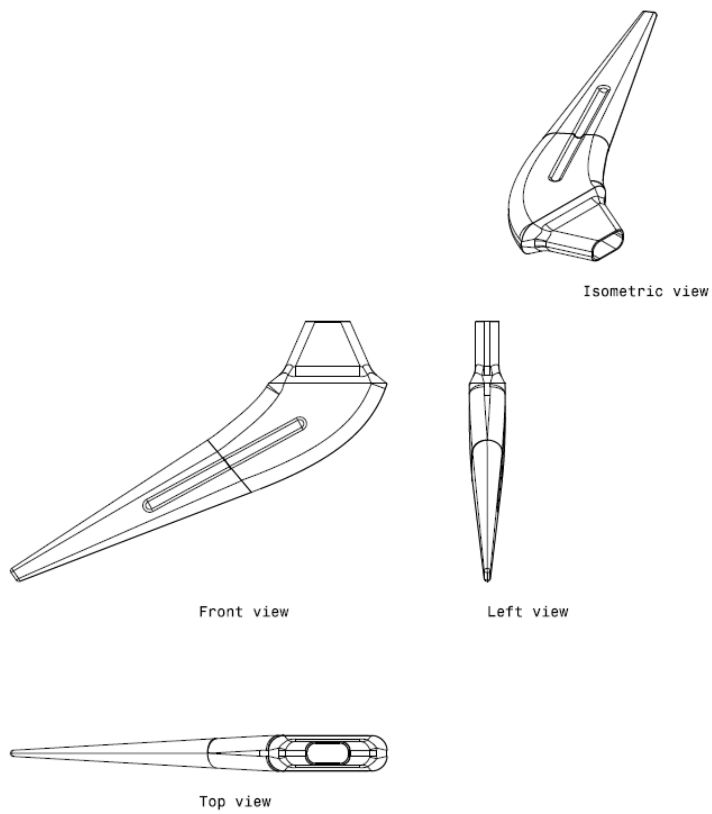
- **Femoral Head and Neck**





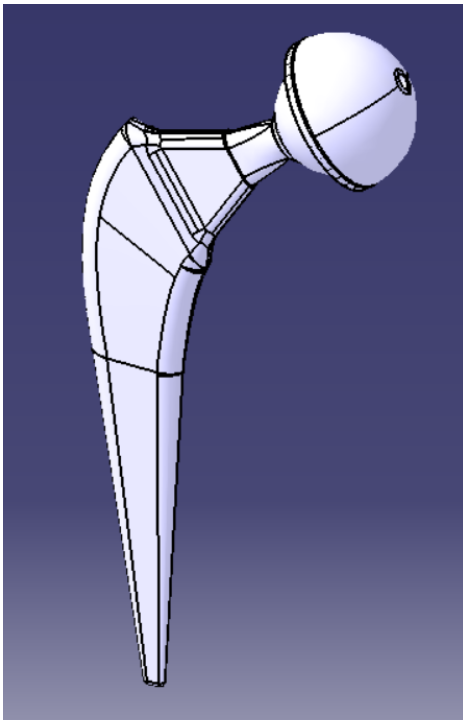
- **Femoral Stem**

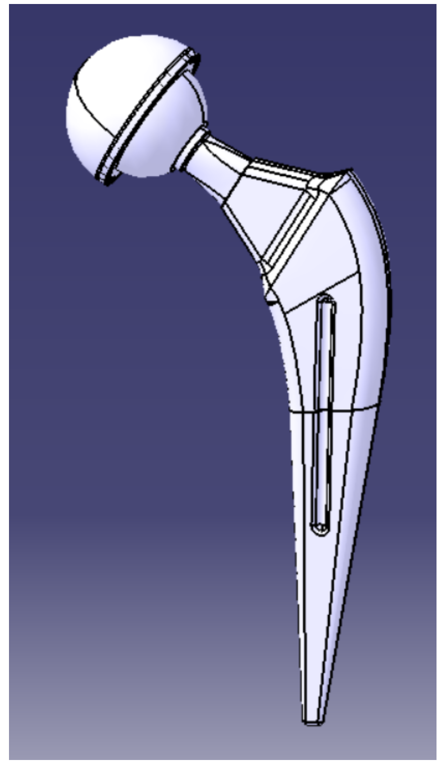


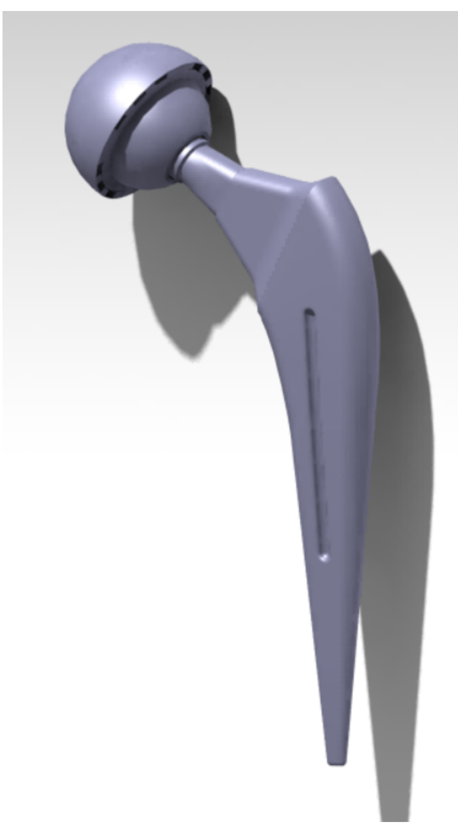


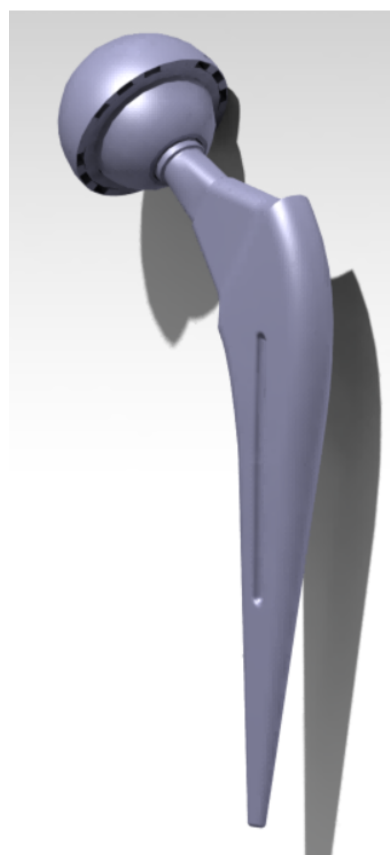
Complete Assembly of Hip Prosthetic Implant

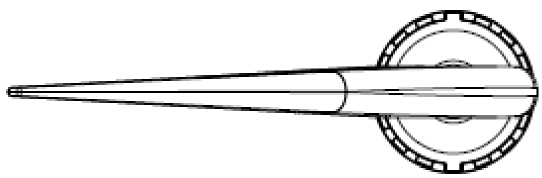
Cad Assembly model and rendered View



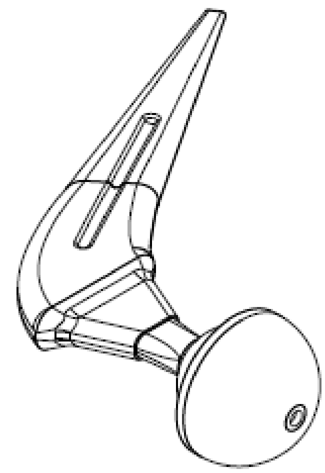




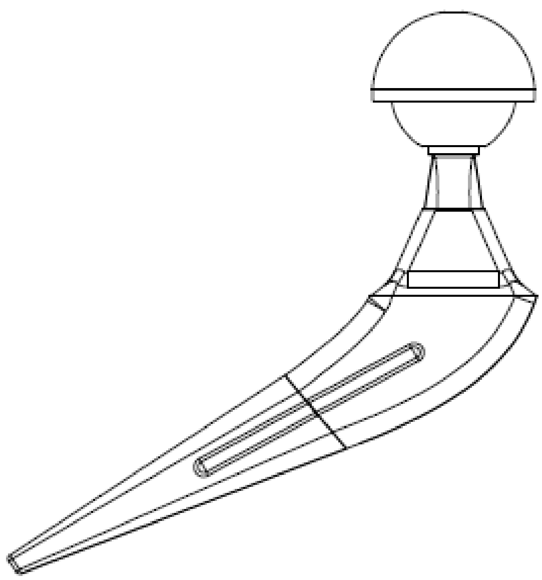




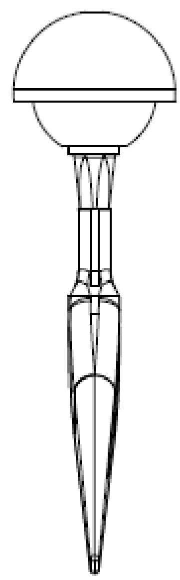
Bottom view



Isometric view



Front view



Left view

LIMITATIONS & CHALLENGES :

- Using PLA material as an acetabular liner is subject to limitations concerning mechanical properties.
- Surface Finish of the Prototype was not good.
- Use of support structure: adds additional printing time
- Rigid edges on surface of the part
- The layer thickness is not strong
- Durability cannot be guaranteed

DESIGN ANALYSIS:

Two major issues with current Hip implants are :

- Stress Shielding effect
- Integration of prosthesis with surrounding bone tissue.

Redesign:

High friction and consequent wear of artificial hip implants after 10–15 years of implantation are the major issues leading to revision surgery. Therefore, **surface modification techniques** can be developed to improve the implant quality considering the lifespan of younger patients.

Surface Modification : (In our Case)

- Surface modification on Femoral Head Surface (circular pattern)
- Surface Modification on Femoral Stem Surface

Femoral Head Surfaces:

The surface texturing technique has been introduced in implant design to obtain the benefit of the lubricating effect. This technique is popular in implant design due to the improved friction and tribological performances. It produces micro-textures on implant surfaces that have a number of benefits over smooth surfaces:

(1) they act as a lubricant reservoir

(2) they increase hydrodynamic pressure under sliding condition

(3) they store the produced wear debris or foreign materials in dimples

(4) they decrease the contact area

(5) they minimize friction and wear

A major concern for the longevity of prosthetic hip implants is wear debris that can affect the tissue surrounding the prosthetic implant. It is important to design micro/texture features for the specific bearing operating conditions to reduce wear and improve prosthetic hip implant longevity. Surface modification techniques are generally applied on femoral head surfaces.

Surface texturing improves tribological performance. It increases the film thickness between the mating components by acting as a lubricant reservoir. This film thickness provides an additional lift effect by generating hydrodynamic pressure between the converging surfaces. Thus, it protects the surfaces from coming into contact and therefore prevents the generation of solid friction. The tribological performance of the implant surface does not depend only on the surface texturing technique but also on the **geometrical parameters** such as dimple diameter, dimple depth, dimple shape, dimple pattern and dimple density. **Circular shaped grooves/dimples** are commonly applied because they can be easily fabricated with high precision. They can also reduce the friction coefficient and wear of the bearing surfaces.

Femoral Stem Surface:

The construction of femoral stems for artificial hip joints is no longer restricted to traditional designs, but has been optimized (in our case) to change in femoral stem's surface modification .

A flexible stem was found to reduce stress shielding and bone resorption compared to a rigid one but increases proximal stress at the prosthesis/bone interface, which can lead to implant failure. Introducing a rigid/ rough surface (i.e optimizing surface of the stem body)

Although patients can return to activity after hip replacement, revision surgery may still be needed. **Revision surgery** is an extremely risky procedure, especially for older patients, and complications may include heart/lung problems or death . Therefore, it is important to minimize the likelihood of such complications.

Adaptive design analysis:

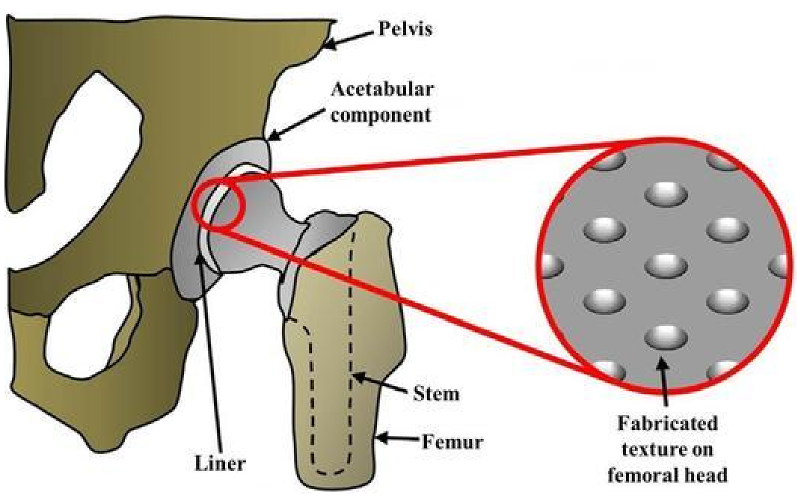


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Figure , show the fabricated **surface texturing on articulating femoral heads.**

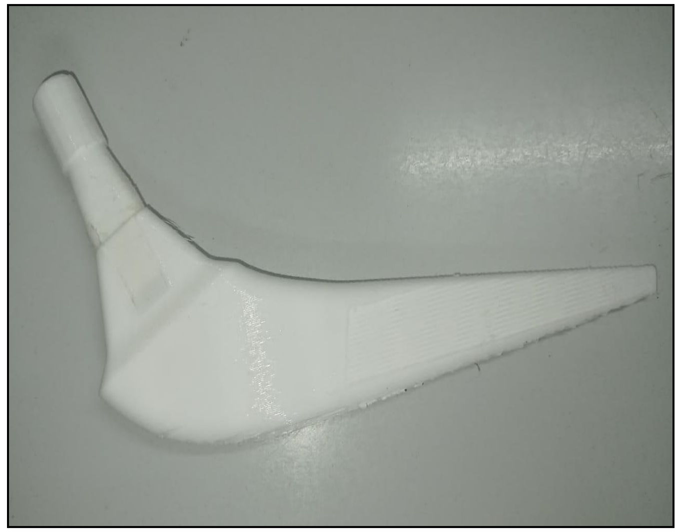

Figure: Grooves on Femur Head　　**Figure: Rough surface on femur stem**

Figure shows surface modified images (i.e. grooves on femur head and rigid surface (or patterns) on femur stem, to improve the implant quality considering the lifespan of younger patients.

Surface modification techniques are generally applied on femoral head surfaces. Surface texturing improves tribological performance. It increases the film thickness between the mating components by acting as a lubricant reservoir. This film thickness provides an additional lift effect by generating hydrodynamic pressure between the converging surfaces. Thus, it protects the surfaces from coming into contact and therefore prevents the generation of solid friction. The dimples produced by surface texturing can trap wear debris in boundary lubricating conditions. Further, it decreases the contact area and thereby reduces adhesion.

Two major issues with current hip implants are the stress shielding effect and the integration of the prosthesis with the surrounding bone tissue. The further development of different types of materials and constructions would allow optimizing and enhancing the performance of hip implants and extend their lifetime.

Various stem geometry designs can be used to create a load transfer system through the proximal femur that closely mimics the natural process. According to some studies, a femoral stem with rectangular cross section, sharp corners, and curved design may provide better stabilit. The stiffness of the stem can be adjusted by modifying its section, with a thicker stem bearing a higher load than a thinner one. Laine et al. found that an anatomical design could improve the fitting and filling of a metaphyseal femoral stem; the shaft could be tightly fitted with a straight stem for good stability. However, good bone growth and remodeling around the distal stem indicated that stress was transferred through this region and increased the stress shielding of the proximal metaphyseal femur.

CONCLUSION:

The insertion of a prosthesis into the femur can lead to effects such as stress shielding and rejection. Therefore, the design of the prosthetic stem must be optimized to minimize these effects; many solutions have been proposed and applied over a long period of time.

Surface texturing techniques significantly reduce the friction coefficient by generating hydrodynamic pressure between the contact interfaces. However, the entrapped wear particles may be released from the dimples owing to the effect of associated vortex flow during hydrodynamic lift of working lubricant, and thus it could increase the wear particle generation. A suitable dimple depth with lower densities may lead to better tribological outcomes. Therefore, it is essential to develop theoretical models to optimize the surface geometry and to predict the lubrication mechanism depending on the operating conditions.

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