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Joint Master in Manufacturing 4.0

ÉCOLE CENTRALE LYON

# COURSE: INTERACTION/OUTIL MATIERE

**Ecole Centrale de Lyon, France**

**Master of Science in Mechanical Engineering and Advanced Technologies**

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| Programme | Meta 4. O/REGULAR |
| Course Module | INTERACTION/OUTIL MATIERE |
| Project | Design and Manufacture of a hip prosthesis |

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## 1. Abstract

The design and development of Hip Implant Prostheses (HIP) represent a pivotal advancement in orthopaedics care, aiming to enhance the quality of life for individuals grappling with hip joint issues. This comprehensive review delves into the multifaceted considerations involved in HIP prosthesis design, encompassing crucial factors such as materials selection, shape and function, and patient-specific parameters. The convergence of engineering accuracy, biomechanical understanding, and materials science has ushered in a new era in orthopaedics care, leading to the development of cutting-edge prosthetic devices. Notably, the review emphasizes the significance of surface roughness as a critical criterion in evaluating the quality of machined surfaces, particularly focusing on the femoral head, impacting factors such as friction, wear, and biological response in medical implants. Furthermore, the challenges posed by degenerative diseases such as osteoarthritis and the need for innovative solutions in orthopaedics care are thoroughly examined. The review underscores the pivotal role of HIP prosthetic implants in sustaining the functionality and longevity of the hip joint, shedding light on the intricate interplay between design intricacies and patient outcomes.

## 2. Introduction

The design and development of Hip Implant Prostheses (HIP) is a tribute to the unwavering goal of improving the quality of life for persons suffering from hip joint problems in the field of orthopedic breakthroughs. As an important weight-bearing joint, the hip frequently develops degenerative diseases such osteoarthritis, which calls for the use of cutting-edge prosthetic devices. A new age in orthopedic care has been ushered in by the convergence of engineering accuracy, biomechanical understanding, and materials science in the progress of HIP prosthesis design. As it connects the femur to the pelvis, the hip is one of the most vital joints that sustain our body. The femur's smooth, round head fits perfectly into the cup-shaped acetabulum's natural seat; the entire joint is covered in extremely resilient ligaments that make the joint stable. Because the hip joint must support the weight of the upper body, it is subjected to tremendous everyday loads. Thus, especially with advancing age, these pressures can jeopardize its functionality (Merola & Affatato, 2019).

The vital role that HIP prosthesis design plays will be examined in this review, along with the complex interactions between materials selection, shape and function, and patient-specific factors that all play a part in the longevity and success of these implants.

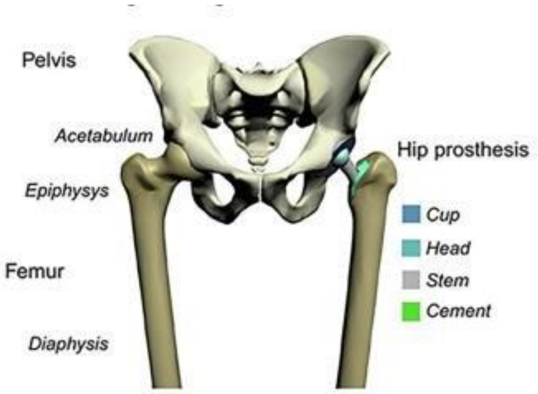


*Fig. healthy HIP joint and the main components of a total hip replacement (Guo et al., 2022).*

The femur, the body's longest and primary weight-bearing bone, articulates with the pelvis at its proximal end and the tibia at its distal end. Its length, approximately 25% of an individual's body length (averaging 45–50 cm), can vary among people. In contrast to immobile (synarthrosis) or partially mobile (amphiarthrosis) joints, the hip joint holds significant importance owing to its ball-and-socket configuration. This unique joint structure plays a crucial role in facilitating everyday activities like sitting, walking, jumping, and squatting(Delikanli & Kayacan, 2019). The hip joint is a crucial weight-bearing and shock-absorbing structure in the human body, supporting various motions such as normal gait, running, and jumping. Understanding stress distribution in this joint is essential for both preoperative and post-operative rehabilitation. Comprising components like the femoral stem, femoral head, liner, and acetabular cup. The hip joint undergoes total hip replacement procedures to alleviate pain and restore normal gait. In the market, two types of femoral stems, modular and non-modular, are available. Implants are manufactured using diverse materials, including stainless steel, cobalt-chromium alloy, and titanium alloys (Joshi et al., 2020). This review details the design and manufacturing of a hip prosthesis and more particularly the femoral head.

## 3. MATERIAL SELECTION CONSIDERATIONS

Different materials can be used in the design of HIP prosthesis. This materials include metal alloys, ceramics, polyethylene, composite materials and others.

The biocompatibility of different materials, such as stainless steel, cobalt-chromium alloys, titanium alloys, and nickel alloys, and their reactions to the human body and surrounding body fluids have been reviewed from different papers. The fundamental of an implant material are high biocompatibility, low wear, compatibility with the bone, and minimum reactivity with the body fluid. Titanium alloys exhibit outstanding biocompatibility, impressive corrosion resistance, and dependable mechanical performance, making them suitable for replacements (Joshi et al., 2020). The mechanical properties of different materials, such as modulus, strength, fatigue, and corrosion resistance, and their effects on the performance and longevity of the implant have been analysed. The implant material should have a modulus close to that of the bone, high strength and fatigue resistance, and excellent corrosion resistance. Titanium alloy is a common choice for hip implants due to its favourable properties. The material properties can be controlled by adjusting the processing parameters, such as laser power, scanning speed, and hatching distance, in additive manufacturing techniques. Titanium and its alloys have advantages such as high strength, low density, corrosion resistance, biocompatibility, and osseointegration. However, they also have some drawbacks such as high cost, low wear resistance, high modulus mismatch with bone, and potential toxicity of some alloying elements.

Also, Cobalt-chromium-molybdenum alloys are recognized for their superior corrosion resistance compared to other metals. However, cobalt and chromium, essential trace elements in the human body, can become toxic when concentrated. Individuals with Co-Cr metal-on-metal pairings, particularly in joint replacements, face wear-related issues leading to the release of cobalt and chromium into the synovial fluid. These elements may migrate to the bloodstream before eventual expulsion through urine. The effects of circulating cobalt and chromium remain poorly understood, potentially impacting biological and cellular functions, with implications for the immune system, mutagenesis, and carcinogenesis (Merola & Affatato, 2019). Moreso, although Titanium alloys have some drawbacks.

*Table 1.0 Highlight of Titanium alloys & other materials for hip implants(Meena et al., 2023; Sarraf et al., 2022)*

| Material | Strengths | Drawbacks |
|---|---|---|
| **Titanium Alloy** | High Strength to weight ratio.<br>Outstanding resistance to corrosion by body fluids<br>High bio-compatibility<br>Capacity for osteointegration | Sensitive to contact in friction couple leading to fretting and reduced fatigue life.<br>Potential embrittlement by interstitial elements like hydrogen and oxygen.<br>Formation of titanium hybrids in the presence of hydrogen, decreasing fracture resistance<br>Nonmagnetic Properties. |
| **Cobalt--Chromium** | Excellent wear resistance | Potential for allergic reactions in some individuals |
| **Alloys** | High strength and stiffness<br>Good corrosion resistance | Higher density compared to titanium alloys.<br>Potential for ion release and metallosis |
| **Austenitic Stainless** | Excellent formability and response to deformation | Nickel content may cause allergic reactions in some individuals |
| **Steel** | Non-Magnetic Properties | Magnetic alloys should not be used in the human body due to dislodgement in MRI fields |
| **UHMWPE** | Low friction and wear in articulating surfaces<br>Good impact strength and toughness | Potential for wear debris-induced osteolysis<br>Susceptibility to oxidative degradation and aging |
| **Hydxyapatite** | Bioactive porous coating promoting bone ingrowth | Potential for coating delamination and wear |

Titanium alloys are the most suitable material for hip implants due to their high strength to weight ratio, outstanding resistance to corrosion by body fluids, high biocompatibility, capacity for osteointegration, an acceptable tissue tolerance and nonmagnetic properties. While titanium alloys may be sensitive to contact in friction couple leading to fretting and reduced fatigue life, these drawbacks can be mitigated through proper surface treatments and design modifications. Additionally, the potential for embrittlement by interstitial elements like hydrogen and oxygen can be avoided through careful fabrication processes(Choroszyński et al., 2017). Overall, titanium alloys offer a combination of mechanical, chemical, and biological properties that make them an ideal choice for hip implant and the titanium fatigue properties of the load bearing device are not reduced through contact with body fluids containing aggressive ions(Choroszyński et al., 2017).

## 4. EXPECTED LIFE

The paper titled “in vitro study of the reduction in wear of metal-nonmetal hip prostheses using surface-engineered femoral heads.” estimates the expected lifetime of the prostheses by using the ISO 7206-4:2010 standard, which specifies that the prosthesis should withstand at least 5 million load cycles without any damage. The paper also uses the stress-life fatigue criterion and Goodman mean stress theory to calculate the fatigue life of the prostheses. The paper reports that the CrN-, CrCN-, and DLC-coated heads have significantly longer fatigue lives than the clinical MOM prosthesis, while the TiN-coated head has a similar fatigue life to the clinical MOM prosthesis.

Another paper titled “Fatigue Life estimation of Artificial Hip joint model using Finite Element Method” analysis for the loadings to which HIP prosthesis are subjected considering the average weight of the person 70Kg.

In our case Titanium alloy emerges as an optimal selection due to its excellent mechanical properties, corrosion resistance, and biocompatibility. Specifically, Ti-6Al-4V is a commonly employed alloy for its high strength-to-weight ratio and compatibility with additive manufacturing processes.

Hip prosthesis lifetime is fundamentally influenced by patient demographics, particularly age and sex. Patients who are younger and more physically active may put the implant under more mechanical stress, which could shorten its lifespan. And also, it is dependent on Changes in health service delivery, implant design, and patient characteristics over time implant selection as reviewed in the papers titled “On the design evolution of hip implants (review article)” and “How long does a hip replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up”. Considering all the criteria indicated above we estimated the tool life to be 15-25 years.

# 5. MANUFACTURING TECHNIQUES

Ti-based alloys, characterized by their high hardness, encounter challenges related to cutting-induced temperature variations, high strain rates, and subsequent phase transformations (Uddin et al., 2017).

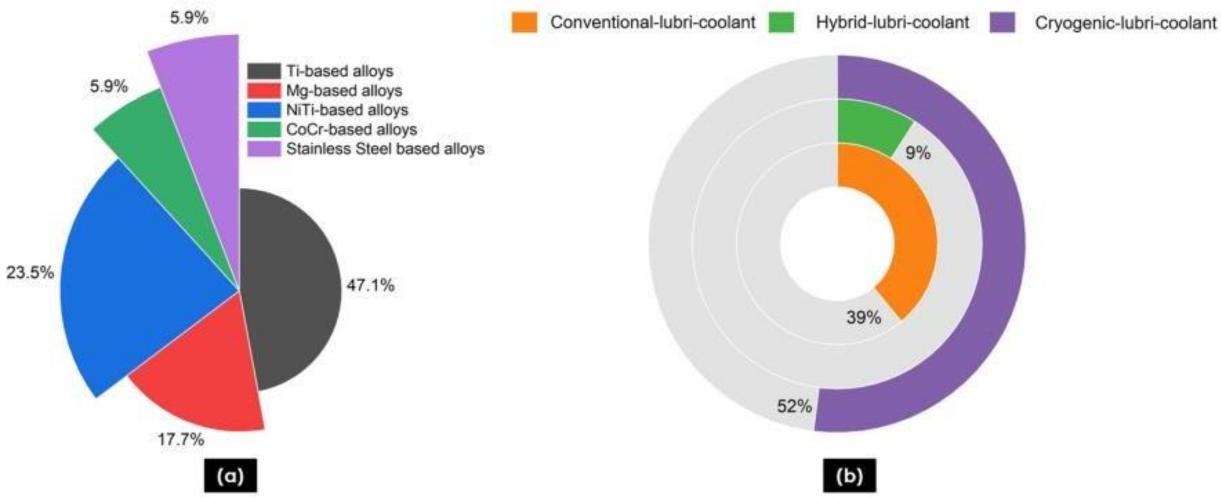


*Figure 2. The proportion of research articles published in the past two decades focusing on conventional machining of metallic implant biomaterials employing various lubricants and machining environments.*

To address these issues, advanced manufacturing processes, including non-traditional subtractive manufacturing techniques like SLS, etc, have been explored, however due to the issues surrounding fatigue life, this study aims at using machining.

## 5.1. CRYOGENIC TURNING PROCESS

Titanium alloys can be machined using carbide and nitride, although their chemical resemblance limits their practical application. Cryogenic machining, however, stands out as a dual-purpose solution, providing chemical stability and temperature reduction during the machining of challenging metallic biomaterials(Sun et al., 2015). This approach significantly enhances the efficiency of titanium machining. (Davis et al., 2022) discusses the turning process, a carbide insert (CNMX1204A2-SMH13A) was employed with an approach angle of 45°, a rake angle of

+15°, an effective rake angle of +9°, and an inclination of -6°. The utilization of this inserts significantly reduced chip and flank wear due to cutting forces, especially at various cutting speeds, attributed to the dimensions of the built-up edge. Consequently, cryogenic compressed air cooling emerged as a more favourable option. Investigating the orthogonal cutting of Ti-6Al-4V alloy, the study focused on dynamics and chip geometry generation, particularly with a more effective feed rate (0.1–0.25 mm) at high speeds. The manufacturing of implants involved turning, employing a displaceable cutting plate made of coated cemented carbide (Davis et al., 2022).

## 6. SURFACE FINISH

The femoral head implant must have a smooth, biocompatible surface finish in order to function properly. A variety of finishing methods, such grinding or polishing, are used to remove flaws and improve the biocompatibility of the implant. The surface finish not only impacts the aesthetics of the implant but also plays a significant role in its functionality and biocompatibility.

After manufacturing by machining, it is important to post process the material to get the required material property.

The post-processing of Hip Implant Prostheses (HIP) produced by CNC machining heavily relies on surface finishing procedures. By following the right procedures, one can attain the required level of surface quality, minimize roughness, and guarantee that the implant satisfies all biocompatibility requirements. Polishing helps in smoothing out the surface, reducing the Ra (0.1-0.5μm) value, and providing a more uniform appearance. Polishing can reduce surface friction and wear, which is critical for medical implants like hip prostheses. A smoother surface may contribute to better wear resistance and long-term functionality. A polished surface can also contribute to improved biocompatibility, reducing the risk of adverse reactions or irritations when the implant is in contact with biological tissues.

*Fig.2 surface finished femoral head (https://www.sandvik.coromant.com/en-gb/industry-solutions/medical/hip/femoral-head)*

## 6.1. SURFACE INTEGRITY

A crucial component of the design of a femoral head that is machined is its surface integrity. The surface roughness is one important metric that's utilized to evaluate surface integrity.

## 6.2. SURFACE ROUGHNESS

Surface roughness provides insights into the quality of the machined surface and affects issues such as friction, wear, and biological response in medical implants. Different surface roughness parameters can be utilized including Ra(arithmetic average roughness), Rz(Average Maximum Height), Rk(core roughness), Rpk(peak roughness), Rvk(valley roughness) and Rq (Root Mean Square Roughness). For our case we selected Ra (arithmetic average roughness) which is a standardized parameter, and its measurement is well-defined by international standards (e.g., ISO 4287). Standardization enhances consistency and facilitates comparisons across different industries and applications.

Surface roughness, in particular, can act as stress concentrators and initiate fatigue cracks. High surface roughness can lead to increased stress concentrations, reducing the fatigue strength and decreasing the fatigue life of the component. On the other hand, smoother surfaces with lower roughness values can distribute the applied stress more evenly.

## 6.3. SURFACE ROUGHNESS MEASUREMENT

Measurements of surface roughness are normally performed to understand the surface quality and to quantify and describe the patterns of material flow and the effects of tool chipping, if any, along the cutting edge. Therefore, the measurement is typically carried out parallel to the cutting edge. As indicated on the figure below which is taken from the published paper on surface integrity for different conditions (Chen et al., 2022).

To measure the surface integrity of the part we can use optical interferometer, different types of profilometer.

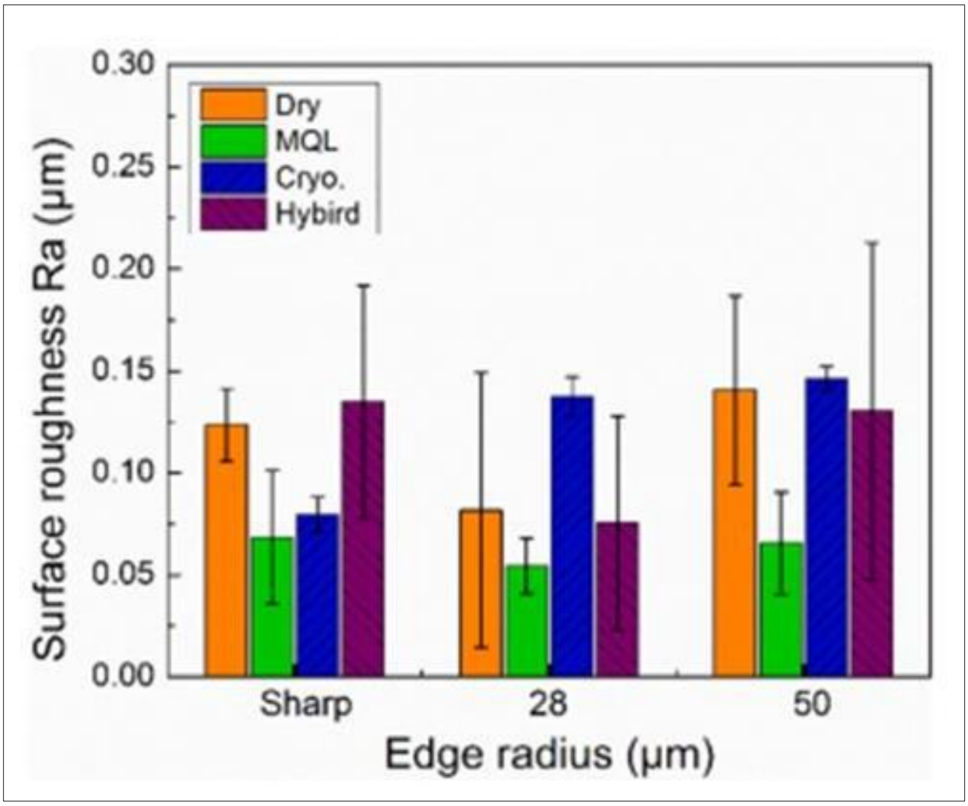


Figure. Surface roughness for different conditions (Chen et al., 2022).

## 6.4. RESIDUAL STRESS

A material's internal state of stress that persists following machining or other manufacturing procedures is known as residual stress. Compressive residual stress is preferred for titanium femoral heads because it can prolong the life of the implant by shielding the surface from fatigue fracture start. Compressive residual stresses between -300 and -600 MPa are typically preferred. In order to examine the influence of edge radius and cooling/lubrication on the mechanical behaviors, the micro-hardness of machined surface and the subsurface micro-hardness at different depths from machined surface. The bulk hardness for the as-received Ti-6Al-4V alloy was determined to be approximately 325 HV (Chen et al., 2022).

## 6.5. MICROSTRUCTURE

Microstructural characterization of the machined subsurface is conducted using scanning electron microscopy (SEM). Titanium alloys are widely used in the medical field due to their excellent biocompatibility, corrosion resistance, and strength. One of the most common titanium alloys used in hip prostheses is Ti-6Al-4V, which exhibits a microstructure consisting of alpha grains and lamellar alpha plus beta grains. The microstructure of Ti-6Al-7Nb is slightly different, with spherical and acicular grains within a matrix containing equiaxial grains. The microstructure of a titanium implant has a significant impact on its properties. For example, the spacing between the alpha grains in Ti-6Al-4V affects its fatigue strength, while the amount of beta phase in Ti-6Al-7Nb affects its stiffness.

To optimize the properties of titanium implants, it is important to understand the relationship between microstructure and properties. This can be done through a combination of experimental and computational techniques. Microhardness

Microhardness is a measure of the resistance of a material to plastic deformation. It is typically measured using a Vickers indenter, which is pressed into the surface of the material. The hardness of a material is inversely proportional to the size of the indentation.

The microhardness of Ti-6Al-4V is typically between 300 and 400 HV, while the microhardness of Ti-6Al-7Nb is typically between 350 and 450 HV. The higher microhardness of Ti-6Al-7Nb is due to its higher content in the beta phase.

### 6.5.1. Microstructure Characterization

The microstructure of a titanium implant can be characterized using various techniques, including optical microscopy, scanning electron microscopy (SEM), and energy-dispersive X-ray (EDX) spectroscopy.

Optical microscopy provides a general overview of the microstructure, while SEM provides more detailed information about the size and shape of the grains. EDX spectroscopy can be used to identify the chemical composition of the grains.

### 6.5.2. Controlling Microstructure

The microstructure of a titanium implant can be controlled by several factors, including the alloy composition, the processing temperature, and the cooling rate.

The alloy composition can be used to control the relative amounts of alpha and beta phases in the microstructure. Higher temperatures promote the formation of the beta phase, while lower temperatures promote the formation of the alpha phase. Faster cooling rates can also lead to the formation of the beta phase.

### 6.5.3. Optimizing Microstructure for Implants

The microstructure of a titanium implant is particularly important for biomedical applications, as it can affect the biocompatibility, corrosion resistance, and strength of the implant.

For example, a fine, equiaxed microstructure is preferred for biocompatibility, as it is more likely to promote bone ingrowth. A lamellar microstructure is preferred for corrosion resistance, as it is less likely to pit. A fine, equiaxed microstructure is also generally preferred for strength, as it is less likely to crack.

## 7. CONCLUSION

The design and manufacture of hip prostheses stand as a critical frontier in orthopedic care, addressing the challenges posed by degenerative diseases such as osteoarthritis and striving to improve the quality of life for individuals grappling with hip joint issues. This intricate process involves a comprehensive evaluation of various factors, including materials selection, shape and function, and patient-specific considerations, all of which play a pivotal role in the success and longevity of the implants. The convergence of engineering accuracy, biomechanical understanding, and materials science has revolutionized the field, paving the way for the development of advanced prosthetic devices that are tailored to meet the diverse needs of patients.

Of particular significance is the emphasis on surface roughness as a critical criterion in evaluating the quality of machined surfaces, with implications for factors such as friction, wear, and biological response in medical implants. This underscores the meticulous attention to detail and precision required in the manufacturing process to ensure optimal functionality and biocompatibility of the prostheses. Furthermore, the review sheds light on the challenges inherent in orthopedic care, highlighting the pressing need for innovative solutions to address hip joint problems and sustain the functionality of the hip joint, especially in the face of increasing demands due to aging populations.

In essence, this review underscores the pivotal role of HIP prosthetic implants in not only restoring but also sustaining the functionality and longevity of the hip joint. By delving into the intricate interplay between design intricacies and patient outcomes, it provides valuable insights into the evolving landscape of orthopedic care and the critical advancements in prosthetic implant technology.

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