

Design Specification and Material Selection Of Total Hip Implants

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1.0 INTRODUCTION

The purpose of this paper is to explore the design specifications and material selection of human hip implants. Section 2.0 will discuss the anatomy of the human hip, which will give a basis of the design of the implant. Section 3.0 takes a look into the brief history of the implant. Section 4.0 discusses the material selection and design specifications of the femoral stem, while Section 5.0 will discuss the material selection and design specifications of the acetabulum. Section 6.0 shows the future plans and current experiments of the materials used for the implant.

The two types of femoral implant fixation used today are cement fixation and biological fixation. This paper will concentrate on biological fixation due to the fact that it is seen as the choice of fixation for today and the future.

2.0 ANATOMY OF THE HUMAN HIP

The human hip is a ball and socket joint, which allows for movement in all directions. The femur is the bone of the upper leg. At the top of the femur is a mass of bone known as the femoral head. The femoral head fits into the acetabulum, which is a cavity in the pelvis. The synovial fluid moves throughout the pores of the cartilage to reduce the friction between the bones. The goal of the design of the hip implant is to mimic the design of the hip. To accomplish this, a total hip implant is composed of three sections, the acetabulum, femoral head and femoral stem, similar to that of the hip.

3.0 HISTORY OF THE HIP IMPLANT

Hip implants are performed to replace arthritic joints. Arthritis is a disease caused by the cartilage between the bones wearing away. Arthritis usually affects people between the ages of 50 and 60 years, but people past the age of adolescence are susceptible to arthritis.

Arthritis in younger people is most commonly caused by a defect in the hip from birth.

The first attempted surgical correction of arthritis was to place a material between the bones of the arthritic joint. At this time, there was very little knowledge of the hip, so the results of the implanted material varied greatly. Philip Wiles of London introduced total hip implants in 1938 [1]. He used all stainless steel components in the implant, including screws to hold the implant in place. These implants produced poor results due to premature loosening of the implant. Since the introduction of these primitive implants, many materials and designs have been investigated. Currently, a Cobalt-Chromium alloy, known as Vitallium, is widely used in the United Kingdom, while a Titanium alloy (Ti-6Al-4V) is most predominantly used within the United States.

4.0 FERMORAL STEM AND HEAD

4.1 Loads Applied

Throughout normal activity there are a variety of loads acting on the femoral stem and the acetabulum. The femoral stem is a loaded column, and the loads applied to it can be resolved into orthogonal loads acting along vertical, mediolateral, and anteroposterior axes. The vertical force fluctuates between three and six times body weight depending on the action of

the body and the orientation of the leg. The mediolateral force component acts in a lateral direction and varies between one and two times body weight. The anteroposterior force component primarily acts on the femoral head in a posterior direction and can range between two and five times body weight. The anteroposterior component creates torque on the bone-implant interface. Also, since the same amount of load that enters the femoral head must eventually exit below the implant, if the femur is understressed due to load carrying by the implant, the femur will be overstressed in another region [2].

4.2 Material Selection

There are many factors that come into play in deciding which material to use for the implant. The first and foremost criterion is biocompatibility. Biocompatibility is the measure of interaction between the foreign material with the tissues of the human body. If a material is biocompatible, there will be no discoloration, irritation, infection or inflammation of the tissue in contact with the material. In past studies, stainless steel, Ti-6Al-4V and Vitallium were inert when introduced to bone, thus it was concluded that these materials are biocompatible.

Another criterion for material selection is the similarity of mechanical properties between bone and the material. Loads placed on bone alone allow the bone to deform and be stressed, but when the bone is attached to a metal implant with a much larger modulus of elasticity, the bone is limited to the deformation in the metal. Figure 1 shows the stress vs. strain relationship of bone [2]. Figure 2 shows the relationship of the stresses in the metal and bone with an applied load perpendicular to the contact interface [2]. Figure 3 shows the stress

relationship between the bone and metal with an applied load parallel to the contact interface [2]. The figure shows that the stress in the metal is much greater than the stress in the bone. If there were no difference between the properties of bone and the implant material, the response to the loads applied to the hip would be similar to that of pure bone, which is the goal of the implant. A material of identical mechanical properties to human bone has not been found, but as can be seen in Table 1 [3, 4], Ti-6Al-4V and Vitallium have similar properties.

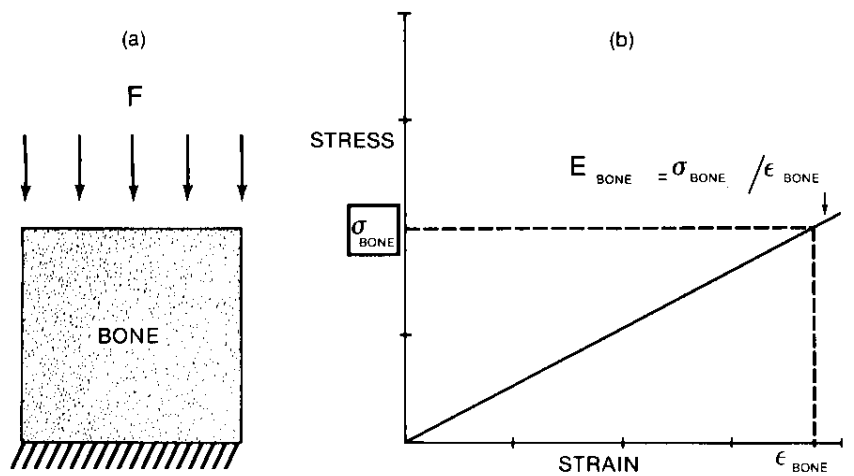


Figure 1. Stress vs. Strain Plot of Human Bone [2]

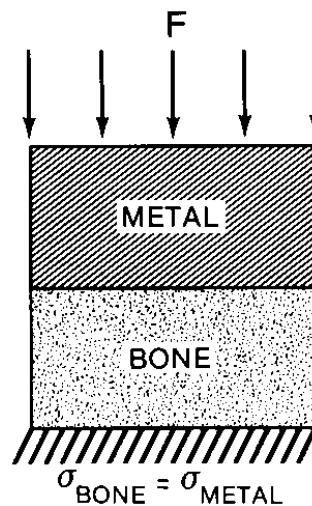


Figure 2. Stress Relationship with Perpendicular Load [2]

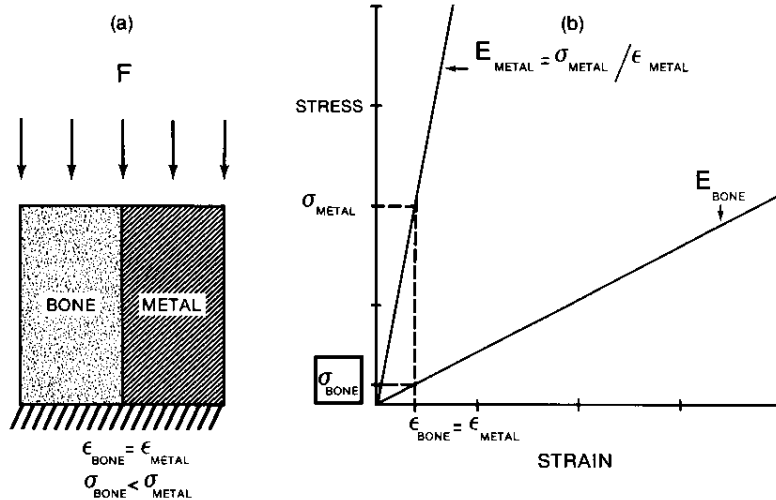


Figure 3. Stress Relationship with Parallel Load [2]

Table 1. Comparison of Material Properties [3, 4]

Material	Elastic Modulus (GPa)	Tensile Strength (MPa)	Elongation at Fracture (%)	Fatigue Strength, 10^7 cycles (MPa)
Parallel to Bone Axis	17.4	135	3 – 4	---
Perpendicular to Bone Axis	11.7	61.8	---	---
Ti-6Al-4V	120	1075	13	580
Vitallium	230	1200	13	500

Another property to consider during material selection is corrosion resistance. The body fluid consists of an aerated and warm solution containing approximately 1 wt% NaCl in addition to other salts and organic compounds in relatively minor concentrations [5], Vitallium has a difference of 0.37 V between the breakdown potential and the resting potential in 0.17 M NaCl [6], while Ti-5Al-4V has a difference of 24.77 V between the breakdown potential and the resting potential in 0.17 M NaCl [7]. The large differences indicate that the oxide film formed on the alloys protects against corrosion.

4.3 Design Specification

Biological fixation is the process of living bone growing within the pores of a metallic implant. Biological fixation is used mainly for young patients whose bones are still growing and require longer fixation. The pores are created during the sintering process and the pore size varies greatly. For mature, calcified bone to consistently develop uniformly within the pores of a sufficiently inert material, the following must be true [8]:

1. Overall pore size must be approximately 50 μm or greater.
2. Porous implant must be sufficiently stabilized at the time of surgery so as to eliminate or at least minimize movement at the bone-porous surface interface.
3. Bone essentially treats pores in the approximate range of 50 to 500 μm in an equivalent manner with respect to ingrowth rate, maturity of the ingrown tissue, and bone-implant interfacial strength.
4. A porous implant should initially be placed in direct contact with bone in order to achieve the fastest rate of bone ingrowth.
5. Substantial bone ingrowth occurs by 3 weeks and can reach a maximum by 6 to 8 weeks after implantation.
6. Bone is capable of filling every space that is available to it, probably, within reasonable limits, to whatever depth the porous network exists.
7. Bone will grow into a porous implant whether it is situated within cancellous or cortical bone, or against endosteal or periosteal cortical bone. There is also a certain osteoinductive potential for cone growth into a porous implant that is not in actual contact with bone.
8. Only the surface of an implant need be made porous for substantial fixation strength to develop and, as expected, this developed strength is greater for implants situated within cortical bone than for those situated within cancellous bone.
9. Once established, biological fixation can cause or enhance bone modeling (either bone formation or resorption, densification or osteoporosis) by altering the degree of stress transfer from the relatively stiff implant to the relatively compliant bone.
10. Fixation of a functional, dynamically loaded implant by bone ingrowth is certainly possible and has often been demonstrated in long term studies.

The implant used for biological fixation is fabricated using two heating methods. The Ti-6Al-4V is heated at 900°C for 1.5 hours, then quenched to increase the strength of the material. The implant is then aged at 500°C for 8 hours to increase the ductility [9]. The

particles are then sintered to the substrate. After sintering, the implant is allowed to slowly cool in the furnace and once removed, is passivated in a nitric acid solution to promote development of a corrosion-resistant oxide film [10]. The slow cooling produces a porous implant that has good strength and ductility.

The femoral stem is a straight rod with constant diameter [11]. This design makes fitting the implant and adjusting the implant after implantation easier. There is also a collar where the neck meets the stem. This collar is used to disperse the load applied to the stem. Currently there are three lengths for the neck of the implant; short, regular or long [12]. The neck is the section of the implant that connects the femoral head and the femoral stem. The size of the neck is selected to make both legs of equal length [12]. The femoral head can be either 22 or 32 mm in diameter [12]. The size selected is dependent on the patient's size and the size of the acetabulum. A larger head will be used for larger patients to help distribute the load from the patients body weight.

Many experiments have been completed to investigate the dependence of pore size after sintering on particle size prior to sintering. These studies have indicated a proper range of pore size, particle size and amount of porosity. Today, the Co-Cr alloy particles range in size from 187 to 250 μm and produce pores ranging from approximately 50 to 400 μm with an average pore size of about 200 μm [13]. Figure 4 shows the comparison between particle sizes and contact surface area [11]. As can be seen, small particles provide a much larger contact surface area. There are many arguments today about the proper pore size. Larger pores will allow for bone growth at greater ranges of movement of the bone-implant

interface, while small pores allow for quicker ingrowth. The porosity throughout the implant and average pore size changes with distance from the substrate as can be seen in Figures 5 and 6 [14], respectively.

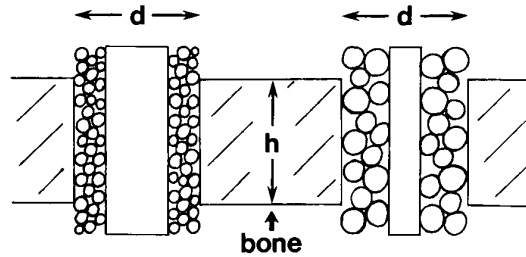


Figure 4. Particle Size Comparison [11]

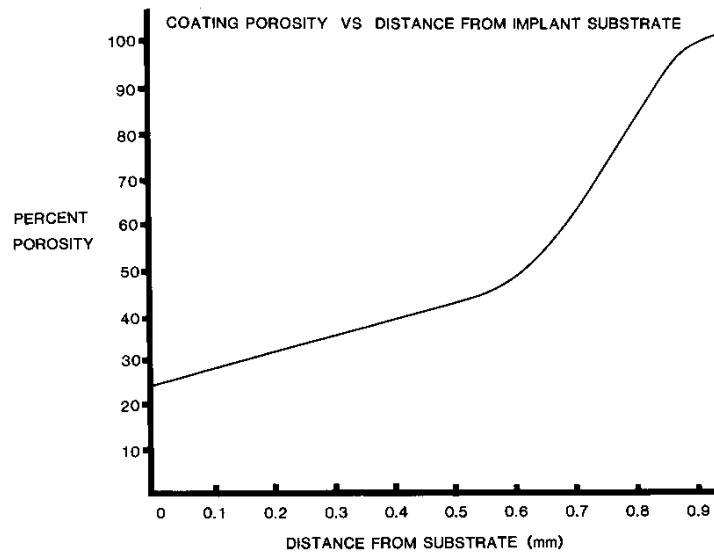


Figure 5. Percent Porosity vs. Distance From Substrate [14]

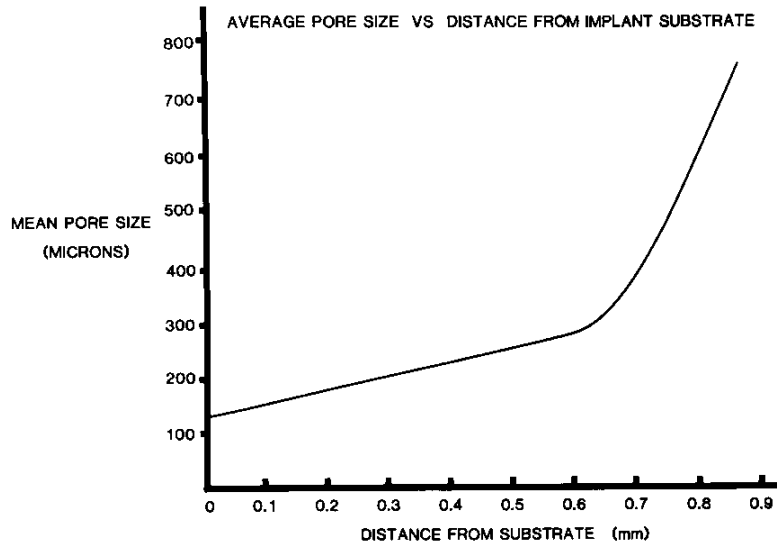


Figure 6. Mean Pore Size vs. Distance From Substrate [14]

The complex loads applied to the hip joint create many problems with consideration to the fixation of the implant. For example, if only the distal portion of the prosthesis becomes fixed by bone ingrowth, the load would enter the femoral head, bypass the proximal section of the femur without fixation and transfer to the cortex at the distal region of contact. The proximal portion of the femur would be prone to atrophy due to load bypass [2].

It can be argued that biological fixation is advantageous to cement fixation. Biological fixation is capable of forming a much stronger bond through the growth of living bone in the implant. Also, with biological fixation, a large number of fixation points can be achieved by tissue ingrowth and loads transmitted from the prosthesis to bone can be distributed over a large surface area, thereby minimizing the stress applied to the bone-implant interface.

Biological fixation is thought to be the ultimate solution to loosening in joint replacement.

5.0 ACETABULUM

5.1 Loads Applied

The loads applied to the acetabulum are much simpler to understand. Since the acetabulum is hemispheric, the load is transferred over a greater surface area than in a normal hip. Also due to the shape of the acetabulum implant, the loads applied to the acetabulum are applied to the implant and compress the bone [2]. There are no long arms present in the acetabulum, so there is minimal bending, tilting and rotating moments [15].

5.2 Material Selection

Within the acetabulum implant there are at least two types of materials present. A metal piece, usually the same material used in the femoral stem and head, is used as the base of the acetabulum. This material is chosen on the same basis as the femoral stem and head, and also with consideration to anodic/cathodic corrosion with the femoral stem implant. The base also needs to have similar mechanical characteristics to bone for the same reasons as the femoral stem.

The other material needed in the acetabulum is usually ultra high molecular weight polyethylene (UHMWPE). This material is used to replace the synovial fluid and cartilage. The UHMWPE needs to have a very low coefficient of friction and a high resistance to wear. The UHMWPE would ideally have a coefficient of friction between 0.0135, which is the coefficient of friction of synovial fluid during various actions [16]. The interface of Ti-6Al-4V and UHMWPE produced a coefficient of friction between 0.01 and 0.01 [17]. The

UHMWPE must have a very low wear rate to avoid loss of material and to increase the life of the implant. The small particles from the loss of material could cause a reaction of the tissues.

5.3 Design Specification

The acetabulum implant is hemispheric in shape to minimize bone removal, allow retention of natural weight bearing load plate, and to make slight adjustments easy without more bone removal. As previously stated, there are three parts to the acetabulum implant. The base is made of the same metal used in the femoral stem. The base is metal to produce precise threads. The metal base needs to be secured in place using spikes, studs or screws. The small thread of the screw help with easy insertion into the pelvis by minimizing the amount of torque needed to insert the screws and provides for maximum fixation. In the apex of the metal base there is a small hole. This hole is used to guarantee proper seating of the acetabulum implant in the pelvis and provides a position for a bone graft if it is needed. The UHMWPE is screwed into the threads of the metal base to allow for easy removal and replacement since UHMWPE currently has a life expectancy of 14 years [18].

6.0 CONCLUSION

Total hip implants have evolved since the first experiments to cure arthritic hips. The implants have gone through design changes, material changes and size changes. Our advances in medicinal and materials science have helped us get to the point we are at today, but there is more to come. The experiments to improve implants are searching for options to improve the current materials used and to find new materials. One process being tested to

improve the current materials is ion implantation. Ion implantation has been found to increase wear resistance, increase strength of material and decrease friction. New materials being investigated are ceramic implants. Another experiment is looking into a smooth surface along the distal portion of the femoral stem. The reduction in the porous surface will make implant removal easier and it will help to disperse the loads throughout the bone-implant interface. Since most hip implants are implanted into people between the ages of 50 and 60 years, the current lifespan of the implants is allowable, but in the future the implants lifespan will be much longer.

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