

MSE452 – Biomaterials & Biocompatibility

Term Project

“Nanoporous Alumina-Coated Femoral Stems for Use in Total
Hip Arthroplasty Applications”

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Introduction

The total hip arthroplasty is one of the cheapest and safest of all joint replacement procedures. Modern artificial joints typically have a modular design consisting of: (1) an acetabular cup; (2) a femoral head; and (3) a femoral stem¹.

In total hip replacement, the femoral component can be secured to bone in one of two ways: (a) using bone cement as a grout to fix the implant to the bone (“cemented”); or (b) using a “cementless” implant specifically designed to allow natural bone to grow into and affix it. The “cementless” design paradigm is a relatively new one, but has fast gained the favor of orthopedic surgeons because it provides the same durability and performance as cemented designs, while avoiding potential complications arising from the use artificial bone cement²⁻⁴.

In this paper, we will develop a novel design for the femoral stem component of an artificial cementless hip joint. We will attempt to incorporate state-of-the-art technology in component shape, surface, and synthesis in order to maximize performance and comfort at the minimum cost. Finally, a proposed development schedule for a prototype will be provided for the benefit of the executive committee.

Design Parameters

Stem Geometry

Cementless femoral stems come in a variety of shapes and styles. Primarily, there exists a choice between distally fixed cylindrical and tapered stem designs. The difference between the two designs is illustrated in (FIGURE 1(a) and (b)).

The difference in stem shape between the two designs has important consequences for their application. While both designs are abundantly used, the cylindrical distal fixation design has one very well-known drawback: the uneven stress distribution (concentrated particularly at the tip of the stem) leads to the phenomenon of stress-shielding. Osteolysis in the surrounding bone then reduces the extent of bone ingrowth resulting in poor fixation and thigh pain⁵⁻⁷.

The tapered stem design, on the other hand, has shown a markedly lower incidence in stress-shielding and thigh pain^{3,8}. As shown in (FIGURE 1(c)) the tapered design follows the natural shape of the femur, resulting in uniform loading of the implant over its entire profile along the metaphysis⁹. This uniform stress transfer results in lower stress-shielding and better long-term bone biology.

Core-Shell Design

A cementless implant presents some unique challenges for the design of the femoral stem component. The lack of an external adhesive to fix the implant to the bone means that the implant must be designed to allow bone matter to grow into it and lock it in place. For this to happen, fibroblasts, osteoblasts, and other supporting bone-building cells must be able to migrate into the implant. It has been shown that this is most easily done in a porous material^{10,11}, and so one possible design consists of a femoral stem made entirely of a porous biocompatible material.

The femoral stem must also be able to withstand the compressive stresses upon loading of the artificial joint. For this application, an all-porous material is *not* the best choice, since the large volume fraction (often >50%) of air in the material will greatly reduce its yield strength. This may lead to brittle failure (cracking) in the stem that will require painful revisional surgery. For this purpose, it is best to use a solid metal implant since this will have the highest yield strength. However, the stiffness (Young's modulus) mismatch between a solid metal stem and the surrounding bone may lead to increased stress-shielding and bone resorption.

In light of these considerations, a compromise was chosen between the all-porous and solid metal designs for the stem. For our application, we decided to use a solid metal core with a nanoporous bone contact surface. In addition to being able to robustly withstand axial compressive forces (since the largest volume fraction will be that of the core), such an implant can also easily recruit bone-building cells into its porous surface, allowing bone ingrowth to a certain depth inside the implant (sufficient for fixation). In addition, since the surrounding bone only comes in contact with the porous surface (which has a relatively low Young's modulus compared to the solid core), the effect of stress-shielding is greatly reduced, leading to better overall performance.

Materials Selection

In order to fulfill these design parameters, we propose a structure premised on a Ti-alloy core and a porous coating made of anodized alumina. Under the appropriate conditions, anodized alumina presents a columnar porosity that provides the opportunity for profound three-dimensional bone in-growth and biochemical functionalization to enhance osteosynthesis.

Molded Ti-alloy

Ti-alloy is an ideal choice for the implant bulk-core due the combination of its robust mechanical properties and long-term inertness with respect to biochemical reactions and wear. As discussed previously, it is important for the core to emulate the mechanical behavior of bone in order to obviate stress-shielding¹²; Ti-alloys have the closest elasticity to bone of any metal allowing for the absorption and transmission of energy most similar to what occurs naturally.

Furthermore, Ti is highly resistant to the wear that degrades implant-materials under the working stresses of human locomotion and the biochemical environment. Not only has it been shown to release little in terms of particulate from mechanical abrasion and chemicals from leaching, it has also been demonstrated to have little reactivity within the biochemical environment and negligible electrochemically-induced corrosion.

Beyond selecting the alloy composition that is ideally suited for implant, one must have the Ti piece tailored exactly for the patient. The supplier must thus offer not only design in term of material composition but formation.

Anodized Alumina

Surrounding the Ti core with anodized alumina not only improves the biomaterial's character mechanically, but also represents a novel approach to ameliorating osteointegration. The ceramic has a remarkably high wear and corrosion resistance that

has been shown to outperform traditional materials especially in the most active and demanding implementations¹³. In addition, they offer a nanoporosity that serves a dual purpose: a site for deep, three-dimensional osteointegration beyond the superficial topography of surface coating and etching techniques and cells for loading compounds that will enhance osteosynthesis and mitigate infection.

Furthermore, the exact character of these pores can be designed through the control of various synthesis parameters thus giving complete control to the doctor to design the implant to maximize the success of surgery according to the patient's specific needs. Furthermore, the nanoscale periodicity and controllable nature of the pores allow for a highly uniform fixation-character while maintaining mechanical strength through a low volumetric porosity.

Deposition-quality silver bead

In order to guarantee predictable behavior in evaporation and purity, standard thermal deposition beads will be used (mounted along a conductive wire).

e-beam deposition-quality aluminum

Again, ensuring the quality and regularity of evaporation is paramount and so a high-quality source is needed to prevent contamination and irregular heating. A defect-free porous structure requires an exceptional film purity ~99.99%.

Functionalization of Surface and Pores

Biochemical functionalization through combined surface treatment and pore loading improves the integration of the BM by diminishing the opportunity for infection while enhancing integration by promoting bone in-growth. Surface functionalization and pore-loading provide for a combined effort of differing effects over varying time-spans: surface preparations act as continuous, high-surface area (thus interaction area) catalysts; pore-packed species are layered such that they release in a given order over time.

- Collagen: coated on a surface, collagen improves the adhesion of osteoblast cells and suppresses neutrophil activation¹⁴
- Ag⁺: Silver ions are a commonly-used antibacterial agent; as ions dissolve into the biological solution, they act acutely within the immediate environment. Bacterial infection and biofilm formation is an issue that, though minimized by the protected location of the hip, still causes immense complications when it does occur in operation and is especially likely in revision surgery¹⁵

In addition to providing a more profound mechanism for bone in-growth, the nanopores of the anodized alumina will be used to mitigate infection and encourage osteointegration. By packing the pores with porous hydroxyapatite, the synthetic precursor to the inorganic matrix on which bone develops, bone growth is accelerated and fixation is ultimately stronger¹⁶. Furthermore, a thin coating of silver will be thermally deposited into the pores in order to provide an initial, local antibacterial dose to fight infectionⁱ.

Ease and Cost of Synthesis and Application

Synthesis is premised on a four-step procedure beginning with the custom-shaped Ti-alloy implant core:

1. Steam sterilization of Ti-alloy

Ti-alloy is resistant to thermal warping or moisture corrosion and thus steam is a cheap and safe method for sterilization.

2. E-beam deposition of aluminum on Ti-alloy

Al has a high boiling temperature of 2740 K and is thus evaporated for deposition using an electron-beam. Instead of passing current through the metal in order to induce resistive heating, electrons are accelerated into the material at energies high enough to result in local sublimation. The outgoing metal atoms are deposited on the Ti implant to a uniform thickness of 200 μm .

3. Nanoindentation of aluminum to direct pore growth

Though the anodization process ensures order in the nanoscale pores, uniformity can be ameliorated by prefabricating nucleation points through indentation¹⁷; pores will develop where high-surface energy crevices exist.

- Generate SiC master of hexagonal array of convexes through e-beam lithography and wet-etching
- Electropolish Al in 1:1:2 weight-ratio of phosphoric acid : sulfuric acid : distilled water at 25-30V for 1-2 minutes¹⁸
- Anneal Al at 900° C for 1h
- Imprint in an oil press

4. Anodization of aluminum to generate oxidized porosity

With pressed indentations to serve as focal points for growth, the oxidization process develops highly-ordered pores that run parallel through the material.

The electrochemical process that oxidizes the Al-layer is a simple anodization, but the instrumentation required is complicated by the large size of the subject and the high voltage of 160V needed to ensure a high-quality induced porosity. Accordingly, the standard anode/cathode arrangement will be complemented with a 15 L bath that will use one of: 0.4M phosphoric acid, 0.3M chromic acid, 0.3M oxalic acid, or 1.5M sulfuric acid as an electrolyte.

The choice of acid is critical to the anodization process as it dictates the precipitation and growth of the pores. *Ono et al* performs a combinatorial assessment of the importance of the primary parameters in anodization: electrolytic acid, applied voltage, and process length¹⁹.

- Anodize from 0-5° C:
 - Stability of temperature ($\pm 0.1^\circ\text{C}$) is key to high-quality order²⁰
 - Stir solution at ~ 60 rpm
- Dip alumina in phosphoric acid solution at 30 °C to open pores

5. Fill pores with thermally-deposited Ag and biochemical agents / bioactive glass to selectively enhance cell growth and bone integration

- Thermal deposition for Ag
- Soaking/Spin-coating for surface collagen
- Nanoscale patterning can be effectuated by soft-lithography²¹

A competitive analysis shows many other solutions being used and in development, but a strict cost comparison with these products would be misleading. Due to the critical nature of the prospective advantage of this design and the *de facto* vertical market that it occupies, a successful product could be introduced at a price substantially above the

market average of \$4000 to \$6000 in the US²² or a mean cost of around \$7000 USD in the UK²³. Under the current environment where price capitation continues to grow in popularity²⁴, such a specialty line will have the added advantage of outmaneuvering larger, swelled commercial lines where prices have been rising according to function and not unit.

Development Schedule

- 1. Review of literature and commercially available solutions**
- 2. Design and materials selection**
- 3. Call for suppliers; sub-contracting negotiations**
- 4. Materials testing / Prototyping**
 - Al₂O₃: verify safety through post-anodization cleaning
 - Mechanical (strength and wear) and biological testing
 - Functionalization
 - Immobilization and denaturation
 - Relative binding potentials of biochem
 - Ti
 - Mechanical and wear testing
 - Ti → Coat with Al → Anodize
 - Biological and mechanical testing
 - Full product
 - Effectiveness / Toxicity of confluence of biochem / Ag
- 5. Materials testing / Prototyping**
 - Implant w/ chronic monitoring and anti-inflammatory / immuno-suppressive medicating

Figures

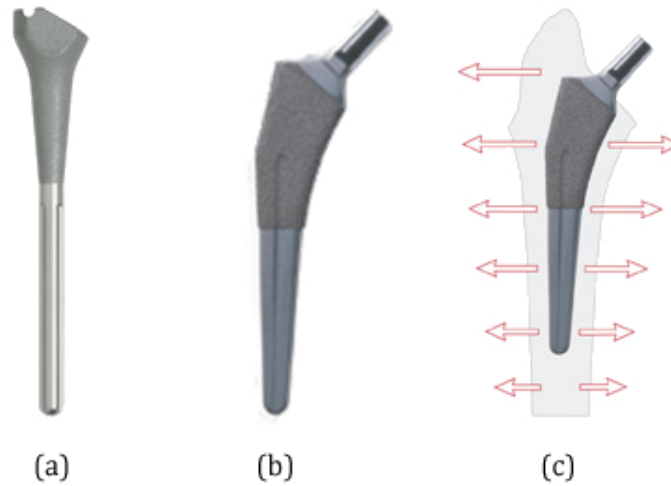


FIGURE 1: Design of (a) a cylindrical stem (b) tapered stem. (c) Stress distribution in a tapered stem

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