# DIRECT FABRICATION OF METAL ORTHOPEDIC IMPLANTS USING ELECTRON BEAM MELTING TECHNOLOGY

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Reviewed, accepted August 13, 2003

## Abstract

Metal orthopedic implants have been used for many decades with great success. Replacement joints and plates for bone fractures are usually made from titanium, cobalt-chromium or stainless steel. Through recent advancements in biomodeling, custom orthopedic implants can be designed. However, fabrication of these custom implants can be prohibitively expensive with traditional processes. With the introduction of Electron Beam Melting (EBM), direct fabrication of fully dense metal components is possible. In this paper, the development of titanium for the EBM-process will be discussed, and direct fabrication of custom designed orthopedic implants made out of steel and titanium will be demonstrated.

## Introduction

Over 500,000 Americans undergo joint replacement surgery each year, with hip and knee implants being the most common. The number is predicted to exponentially increase over the next couple of decades[1]. Many different types of bone plates are used to fixate bones after a severe fracture or after an osteotomy. Joint implants and bone plates are usually made out of stainless steel, titanium or cobalt-chromium and come in standard sizes and generic shapes. Even though total joint replacements have been successfully used for several decades, the longevity of the implant components is not satisfactory in many cases, especially in younger patients [1, 2]. One of the most common causes for implant revision is loosening of the component, which is mostly caused by bone remodeling [3]. Bone is a living tissue that is constantly changing due to external forces to optimize its structure and minimize its weight [4]. Bone will increase in density when experiencing a dynamic load, and it will decrease in density when experiencing a static load or no load at all. This is a common problem for astronauts when spending an extended amount of time in microgravity. Older people experience the same problem when they become less active, and their condition is referred to as osteoporosis.

When implanting a joint replacement, the affected portion of the joint must be removed to provide healthy bone to interact with the implant [5]. Modern implants are coated with a porous titanium coating on the bone-implant interface surface to enhance and promote bone ingrowth. These implants do not use any type of adhesive to secure the implant component to the bone and solely depend on the bone ingrowth to provide a secure and stable attachment. This is the preferred approach to be used on all healthy patients with sufficient bone growth. Due to the current manual surgical tools available to the surgeon, the bone-implant interface on a standard knee implant is designed with straight, flat surfaces (see figure 1.) [6].

[1] Data provided by American Academy of Orthopaedic Surgeons, Dept. of Research and Scientific Affairs

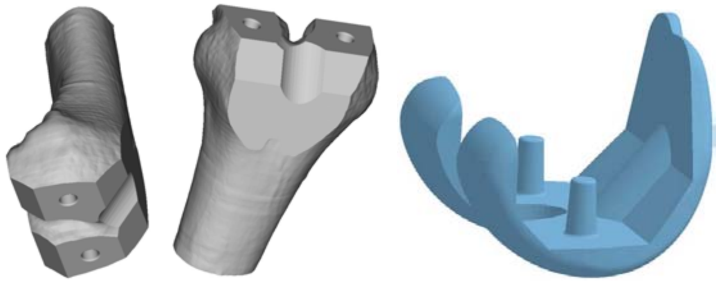

Figure 1. Computer models of a human distal femur prepared for implantation and a generic femoral implant component.

The geometry limitations cause areas with increased pressure and areas with decreased pressure, which causes bone remodeling and finally loosening of the implant components. To further increase the problems, all humans are different, and standard implants only come in 5-7 sizes with generic shapes. The longevity of the implant is highly dependent on the initial fit and how well it resembles the natural shape of the joint [7]. Hip and knee implants have had the same basic design for several decades, which have been limited by the hand tools available to the surgeons. The manual saws and drills can only produce straight cuts and holes, and the precision is highly dependent on the surgeon's skill. Recently, two robotic surgical systems have been commercialized that can perform the cutting and drilling operations with far better precision using end mills as actuators [8, 9, 10]. A robot also has the ability to easily machine freeform surfaces, which eliminates the previous design restrictions on implant components.

The articulating surfaces of a knee implant have a generic shape that might change the gait for many patients. These have been well-known problems for a long time, and in the '70s, several attempts were made to develop custom-sized implants that would fit better. However, the fabrication technologies available at that time made it prohibitively expensive to produce custom parts. The custom sized implants were based on radiographs, which was a fairly inaccurate method due to the 2-dimensional limitations. Most modern orthopedic implants are manufactured through investment casting, which is an excellent fabrication technology that provides high precision parts with good surface finish. Unfortunately it is expensive in small quantities. Solid freeform fabrication (SFF) technologies have enabled manufacturers to produce small quantities through investment casting at a reasonable price, opening up new possibilities for custom design and fabrication of orthopedic implants.

Recent advancements in medical imaging and image processing have enabled custom design of biomedical implants based on patient specific Computed Tomography (CT) data [11,12]. The CT data is edited, and an accurate 3D-model of the joint is created and exported as an stl-file. A different software is used to convert the stl-file into a CAD-model that can be used as the base for the custom designed implant components. Several SFF-technologies can be used to produce a master pattern for investment casting, but producing a finished implant component is still time consuming and labor intensive. With the introduction of the Electron Beam Melting (EBM) machine by Arcam (Sweden), a new possibility for fabrication of custom implant components has become available. Initially, the EBM technology was only available with tool steel, which is not a biocompatible material. In theory, the EBM machine can process most materials that are electrically conductive, and a collaborative effort between North Carolina State University and Arcam AB was initiated to develop titanium for the EBM process.

To enable clinical testing of the custom designed implants, an animal study is the first step, and collaboration between the Industrial Engineering Department and the Veterinary School at NCSU was initiated [13]. Surgeons at the veterinary school have developed generic hip implants for canines that are currently being implanted on a weekly basis. At this time, no commercial knee implants for canines are available due to the number of sizes that would be needed to accommodate most patients. However, the demand is present. The idea of custom designing and fabricating knee implant components for canines became an interesting solution for the veterinary surgeons at the same time as it would serve as a clinical trial for humans. A CT-scan of a potential patient was acquired, and a custom femoral component was designed in collaboration with the orthopedic surgeons. Both the articulating surface and the bone-implant interface surface were custom designed based on the CT-data.

This paper describes the development of the titanium powder for the EBM process as well as the initial fabrication of the first custom implant components. The traditional investment casting process of implant components is compared to the EBM fabrication.

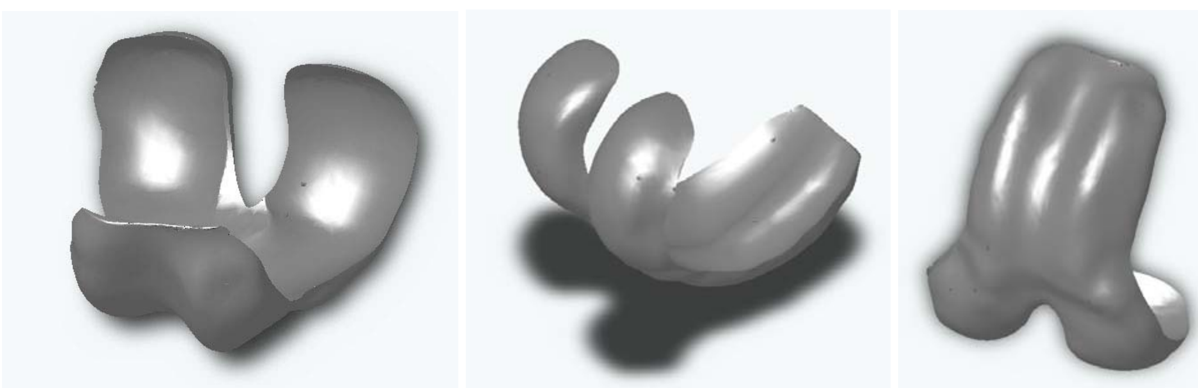

Figure 2. Computer models of a custom designed implant component for a canine stifle joint.

## Material and Methods

As a first step to enable direct fabrication of custom designed orthopedic implants using the Electron Beam Melting technology, the process parameters for titanium (Ti6Al4V) were developed. North Carolina State University partnered with Arcam AB in the development, which took place at Arcam's facility in Mölndal, Sweden. Both Ti6Al4V and pure titanium are commonly used for biomedical implants. Pure Ti is softer and less suitable for high impact applications. The first challenge was to find a supplier that offers a Ti powder with the right composition and particle size, which cannot be disclosed at this time. The particle size is very important for the final result and affects the flow of the powder and the melt pool behavior. For each new material, a long list of processing parameters must be developed through experimentation. The initial parameters are calculated based on material dependent factors such as melting temperature and flow characteristics. Each parameter is optimized through an iterative process based on testing and evaluation. To further complicate matters, the process parameters are geometry dependent as well and require a vast amount of testing to fully develop. At the present time, parameters for many types of geometries have been developed and successfully fabricated, however no custom designed implant component has been fabricated in titanium. The processing parameters and the powder composition for the Ti6Al4V is proprietary and cannot be disclosed at this moment but the processed material properties are reported in the next section.

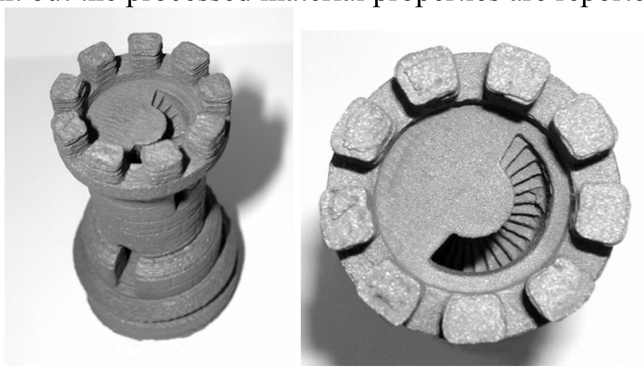

Figure 3. Chess piece built of Ti6Al4V in the EBM S12

The Electron Beam Melting process is powder based, and the excess powder supports the structure during the build phase. It does not eliminate the need for support structure, however. The parts are built on a substrate, and the part and start plate are kept at an elevated temperature throughout the build to minimize residual stresses. When the build is completed, the part and substrate will cool down and a shrinkage of 1.4 % for tool steel will take place that has been compensated for through the software prior to the build. The part tends to shrink towards the center causing a curling or bending motion of the edges. To prevent distortion, support structure is used to secure the part to the substrate and to secure overhanging structures to the underlying structure. The orientation of a part is very important considering the amount of support structure needed and the surface finish of the final part. On thin features with down facing surfaces, "icicles" can form that will affect the surface finish and complicate the finishing of the part. At the present time, no automatic support generation for the EBM process is available. If Magics from Materialize is used to generate support, substantial editing is needed since excessive support is generated. For this project, the implant component was oriented on its side, and support structure was manually created directly in SolidWorks. When building parts with very thin cross sections, it is difficult to effectively transmit enough heat through the part to keep the elevated temperature without over melting the powder. To solve this problem, a "dummy" structure was added as an artificial means to impart more heat to each. In this case, a large diameter cylinder was added to increase the total melting area for each layer.

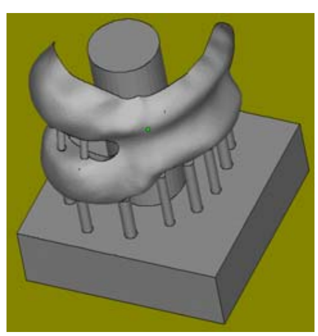

Figure 4. Computer model showing the implant with support and heat sink

As a time and cost comparison, a canine stifle joint component was fabricated using the Electron Beam Melting machine and was compared with traditional investment casting using an RP-pattern as a master. It was decided to use an SLA-190 to fabricate the master pattern to be used for the investment casting process and a QuickCast model of the implant was produced. Due to the small and thin geometry of the canine femoral component, it was difficult to drain the resin from the model leaving an almost solid RP-pattern. Several attempts of reorienting the component and creating drain and vent holes still did not deliver a hollow structure sufficient for the QuickCast process. To complete the investment casting process, an RTV-mold was created using the SLA-pattern and a wax pattern was cast.

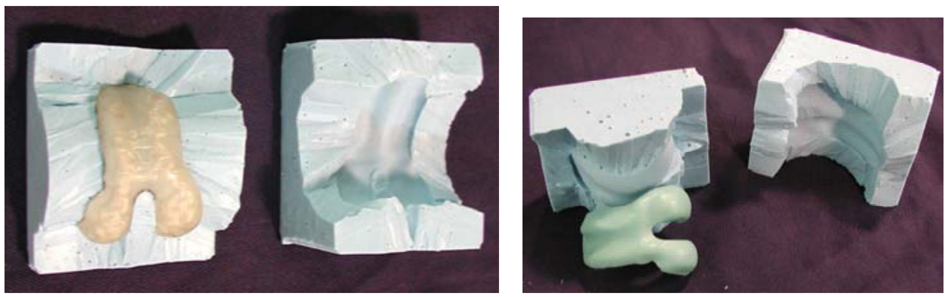

Figure 5. RTV mold with SLA RP-master (L) and resulting wax pattern (R)

The wax pattern was attached to a wax sprue and placed in an investment-casting flask. Quikvest was used as the ceramic media and poured around the wax pattern. The flask was placed in a convection oven to remove moisture and later fired in a high temperature furnace according to the manufacturer's recommendation. For this comparison, aluminum was used for the casting.

## Results

The material properties of the EBM processed titanium powder are very similar to conventionally processed titanium. The processed titanium is fully dense and is biocompatible in accordance with FDA regulations. The Ti6Al4V parts fabricated in the EBM process feature good machinability and can be machined as stock Ti6Al4V parts. Pure titanium is under development but the material properties are not publishable at this time. The chemical composition of the EBM processed Ti6Al4V is as follows:

| Element | Weight- % |
|---|---|
| Nitrogen (N) | 0.01 |
| Oxygen (O) | 0.19 |
| **Aluminum (Al)** | **6.2** |
| **Vanadium (V)** | **4.5** |
| Iron (Fe) | 0.45 |
| Nickel (Ni) | 0.037 |
| Chromium (Cr) | 0.03 |
| Sulphur (S) | < 0.01 |
| Manganese (Mn) | 0.04 |
| Tin (Sn) | 1.3 |
| Zirconium (Zr) | < 0.02 |

Table 1. Typical chemical composition of EBM processed Ti6Al4V (Source: Arcam Ti6Al4V Data Sheet)

The mechanical properties of the EBM processed Ti6Al4V are as follows:

| Property | |
|---|---|
| Hardness HRc | 30-35 HRc |
| Tensile Strength, $R_m$ | 930 MPa<br>135 000 psi |
| Yield Strength, $R_{p0.2}$ | 880 MPa<br>120 000 psi |
| Elongation | 10% |

Table 2. Mechanical properties of Ti6Al4V (Source: Arcam Ti6Al4V Data Sheet)

At the time of writing this paper, the processing parameters for the Ti6Al4V were not fully developed for thin walled structures like the stifle joint component. As a proof of concept, the custom designed stifle joint implant was fabricated on the EBM machine using the commercially available tool steel H13. The total building time for the implant was 5 hours. After the part had cooled down to room temperature, the support structure was removed using a rotary cutting tool and the articulating surface was polished to a mirror finish. The total finishing time was approximately 2 hours, which would be similar if it had been fabricated out of titanium. The total setup time for the EBM machine was approximately 2 hours and the implant was left to cool down over night.

Figure 6. Custom designed knee implant processed on EBM S12

The investment-cast implant took considerably longer time to complete with many more steps. The total time for the investment cast implant from stl-file to finished product was 78 hours compared to 25 hours for the EBM process. A considerable amount of time was spent waiting for the RTV mold to cure as well as drying the investment. A total time of 11 hours of labor was spent on the investment cast version compared to 7.25 hours for the EBM version. The total machine time for the EBM machine is 8.25 hours as compared to 8.5 for the SLA machine. The hourly rate for an EBM machine is slightly higher than a modern SLA machine, but the investment cast version requires additional equipment such as a convection oven, a furnace for firing the investment, as well as melting the metal, and additional tools needed for the mixing of investment and RTV rubber.

| Investment Casting | Hours | EBM | Hours |
|---|---|---|---|
| Start with STL | | Start with STL | |
| Prepare SLA Build File | 1 | Prepare EBM Build File | 1.5 |
| Startup SLA | 0.5 | Startup EBM Machine | 2 |
| SLA build time | 8 | Draw Vacuum | 0.75 |
| Clean and postcure | 3.5 | Heat Start Plate | 0.5 |
| Sand SLA pattern | 0.5 | EBM Build Time | 5 |
| Prepare to Pour Silicone | 1 | Cool down | 12 |
| Silicone Cure time | 24 | Remove sintered powder | 0.25 |
| Finish silicone mold | 0.5 | | |
| Wax casting | 1 | | |
| Build wax tree | 0.5 | | |
| Mix and pour investment | 0.5 | | |
| Dry investment | 24 | | |
| Fire investment | 10 | | |
| Pour metal | 0.25 | | |
| Cool down | 1 | | |
| Cut off tree | 0.25 | Cut supports/ remove start plate | 1 |
| Clean/Polish | 1.5 | Clean/Polish | 2 |
| **Total** | **78** | **Total** | **25** |

Table 3. Time comparison between investment casting and EBM processing of custom designed implant

## Discussion and Conclusions

It is the authors' opinion that the EBM technology can successfully be used to fabricate custom designed implants for knees, hips, elbows, shoulders, fingers, and bone plates in titanium. Even though the initial results appear promising, additional material development will be necessary to optimize the processing parameters for Ti6Al4V and Ti. There are differences between processing steel and titanium using the EBM technology. The build time for titanium is approximately half of that for steel, however the cool down must take place under vacuum inside the build chamber. There are other potential advantages with using the EBM technology to fabricate custom designed orthopedic implants that can not be achieved through traditional processes such as investment casting. In the case of a knee implant component, it is desired to have a very hard and smooth surface finish on all articulating surfaces and a soft and porous bone-implant interface. To achieve this through investment casting, a porous coating is applied to the bone-implant interface surface through a sintering process. Similar coatings are applied to hip, elbow, and shoulder implants to promote the bone ingrowth in selected areas. The Electron Beam Melting technology has the prospect of fabricating parts with functional gradient microstructures, which would be very useful for orthopedic implants. This would allow for the porous surfaces to be directly designed into the components. Further, the EBM technology lends itself to deposit multiple materials that is of highest interest to the orthopedic implant industry as well. Often orthopedic implant components are made out of several materials to achieve the desired properties. Modular hip implant systems are often combined out of both titanium and cobalt-chromium components.

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