

DESIGN FOR ADDITIVE MANUFACTURING OF CUSTOMIZED IMPLANTS CONSIDERING THE PREDICTABILITY OF THE MECHANICAL BEHAVIOR AND DIMENSIONAL STABILITY

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Abstract: *The anatomy of each patient is unique. This statement explains the growing demand for personalized treatments and, therefore, the supply of services and customized products within the medical devices area. The main demands are in orthopedic, maxillo-facial and endovascular implants, and surgical guides and surgical instrumental. These devices are designed according to the patient's anatomy and the surgical technique selected by the health team for treatment. In such cases, medical images are used as 3D ultrasound (3DUS), computed tomography (CT), magnetic resonance imaging (MRI) to obtain a geometric three-dimensional virtual model of the patient's region of interest. From this model, in a virtual environment, the implants and guides are designed and the surgical planning is performed by health team. After that, the devices are manufactured, sterilized and taken to the surgical procedure. The purpose of this article is to contextualize and emphasize the importance of the differentials that the use of the selective laser melting (SLM) process brings to the area of implants customized design. Technical issues related to the parameters and constraints within this additive manufacturing process were addressed. This work aims to reduce the gap between design and manufacturing of custom implants made by SLM using Ti6Al4V. It presents the basic idea of a new method within the Design for Additive Manufacturing focusing on manufacturing of custom metal implants. This new method will take into account the microstructural and dimensional predictability of the implant to the end of the manufacturing process. It should also explore the ability of SLM process build complex and porous geometries. These issues are important for the restoration of function and promote regeneration of damaged bone.*

Keywords: *design for additive manufacturing, selective laser melting, implant, Ti6Al4V.*

1. INTRODUCTION

The main goals of an implant (orthopedic or buco-maxillofacial) are to restore function and promote the regeneration of bone tissue in the damaged region. According to Hollister (2009), the implant design must meet certain requirements such as:

- biocompatibility;
- have a surface that allows cell attachment, proliferation and differentiation;
- contain porous regions with interconnected pores that allow cell growth and transport of nutrients and metabolic residues;
- have mechanical properties close to the tissues of the damaged region to reduce or eliminate bone resorption in the vicinity of the implant (a phenomenon known as Stress Shielding);
- withstand the region's natural loading, avoiding mechanical failures.

There are basically two types of bone: cortical (more compact) and trabecular, with elastic modulus close to 30 and 0.3 GPa, respectively. Due to the requirement to have a mechanical behavior similar to the damaged bone region, titanium alloys stand out as compared to chromium-cobalt alloys. The Ti6Al4V alloy has an elastic modulus around 110 GPa, while the CoCrMo alloy around 210 GPa. This more flexible alloy also stands out for the good resistance to corrosion and it is no coincidence that there are processes of Additive Manufacturing (AM) such as Selective Laser Melting (SLM) already using it as raw material. This use allows the construction of customized porous implants that meet aforementioned requirements and also allows the use of optimization methods to design the topology or geometric parameters of the implant. These features substantially increasing the implant performance and the chances of success of the surgical procedures (COSMA; LEORDAN, 2015; CRONSKÄR, 2011; REGIS *et al.*, 2015).

2. DESIGN FOR ADDITIVE MANUFACTURING

According to ISO/ASTM 52900: 2015 (E), the term Additive Manufacturing (AM) is defined as any process that join materials to make parts layer upon layer from a three-dimensional model data, as opposed to the subtractive and forming manufacturing methods. In AM the component can be constructed from the raw material in various formats (filament, powder, liquid or gel) and materials (metals, polymers, ceramics and composites).

The main benefits of using AM processes are the ability to fabricate components with a high complex geometry without incurring a considerable increase in the time and end cost of the part compared to the traditional manufacturing methods. In this way, the designer has more freedom to materialize structures inside the component and freeform surfaces without the need for additional processes, molds or specific tooling. In addition, AM processes associated with mathematical methods such as Topological Optimization allow the fabrication of components with the topology (distribution of one or more materials in the part domain) and the properties of one or more functionalized materials over a specific objective (or an objective function within the optimization vocabulary) and its constraints (THOMPSON *et al.*, 2016). For example, in a structural problem this function can have varied objectives and natures such as maximization of stiffness in certain regions of the component or mass minimization with deformation-constrained, varying the topology of the component according to the established objectives and constraints, as well as satisfying the boundary conditions of the equilibrium problem.

The freedom to build complex or functionalized forms within the same process layer by layer, justified the creation of a new area of study within the engineering, called Design for Additive Manufacturing (DfAM). This new way of to think and to materialize products has a direct impact on the methodology of Design for Manufacturing and Assembly (DfMA), which has been widely used in the last three decades by the product development engineering teams of the automotive, naval, aerospace and medical devices industries. The DfAM methodology, when compared to the DfMA, allows a considerable reduction in the number of parts of a component, assemblies and fasteners, as well as providing a higher level of customization and substantially modifying the way of designing and idealizing products (GIBSON; ROSEN; STUCKER, 2010; KUMKE; WATSCHKE; VIETOR, 2016; THOMPSON *et al.*, 2016).

3. ADDITIVE MANUFACTURING BY SELECTIVE LASER MELTING

Among the processes of AM, Selective Laser Melting (SLM) is one of the most promising. This can be concluded when we observe its rise in the last two decades, the investments of the medical and aerospace industries and for its ability to manufacture metallic components with complex geometries and with mechanical properties similar to the traditional processes such as casting and forging (YADROITSEV; SMUROV, 2010).

In the SLM process, the raw material (in the form of a metallic powder) is melted by a laser beam that passes in the upper region of powder-bed, solidifying a thin layer of powder. After melting of this layer, the substrate plate descends the thickness equivalent of the solidified layer and a new layer of powder is distributed and the laser again passes on the top of the powder-bed to melt a new superimposed layer and a metallurgical connection with the previous layer. These steps are repeated until all the slices of the geometry are solidified in layers and stacked, thus reproducing the three-dimensional model that had been sliced.

The quality of the component manufactured by SLM is dependent on characteristics of the raw material (powder) such as purity, physical and geometric properties (humidity, size and shape). It also depends on process parameters such as laser wavelength, beam size, laser power, laser scan speed and strategy, hatch distance in each layer and layer thickness, see Figure 1a.

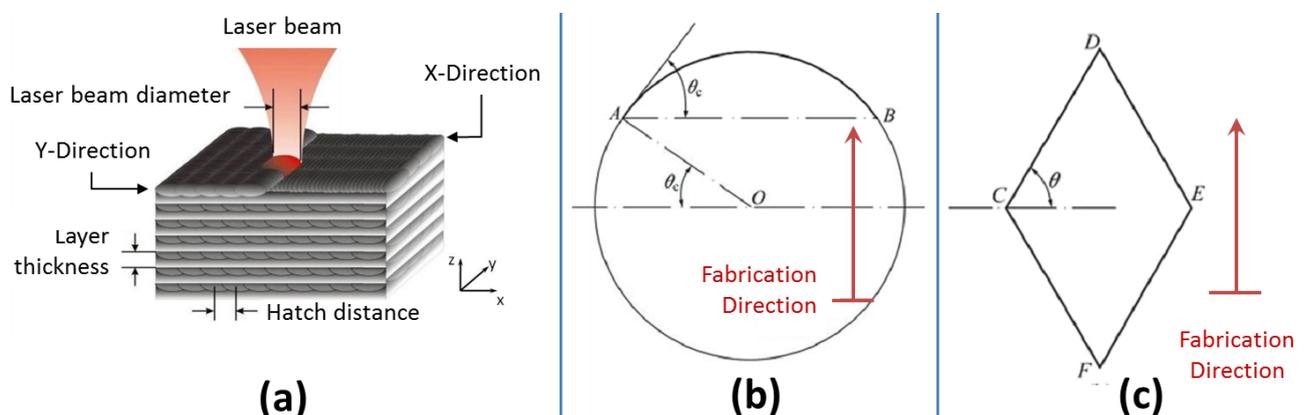


Figure 1. Illustration of some parameters that influence the quality of the component manufactured by SLM (a) and two examples of the critical angle between layers for the need or not of support structure in relation to the manufacturing direction (b and c). Adapted from Meiners (2012) and Su et al. (2012), respectively.

In addition to the parameters already mentioned, the choice of the direction of stacking of the layers also influences the presence or absence of support geometries. These structures create a base for the overlap of layers in case the geometry of the part has a variation from one layer to the next layer which does not allow the overlapping of the lower layer with the upper layer. The supports are removed after the manufacturing process which ends up impacting the finishing quality of the regions that were in contact with these structures. The dimensional stability of these regions also is impacted when compared to the initial three-dimensional model (YADROITSEV; BERTRAND; SMUROV, 2007).

In order to facilitate the understanding of the need or not of support structures, it can be observed that in Figure 1b the geometry of an \widehat{AB} arc with diameter \widehat{AO} needs support to be constructed because in the point A the angle of inclination of the tangent of the arc \widehat{AB} - with respect to the horizontal line \widehat{AB} - is smaller than the critical angle θ_c . However, if we wish to fabricate the structure of Figure 1c following the indicated manufacturing direction, both the initial CFE patch and the CDE patch will not require support since the angle θ between the layers is greater than the critical angle θ_c . This critical angle θ_c is influenced by the process parameters such as layer thickness, laser scan strategy and distance hatch (SU *et al.*, 2012). The possibility of constructing self-supporting structures as parts with internal trabecular geometries, interconnected and dimensionally controlled similar of the substituted bone region are great differentials of the use of SLM in the manufacture of implants using Ti6Al4V alloy.

4. ADVANTAGES OF SLM FOR DESIGN OF IMPLANTS

Osseointegration in the interface regions of implants with respective bones is a phenomenon of fundamental importance for the bone consolidation and consequently for the success of the surgical procedure. With the insertion of the implants replacing the bone tissue, there is a considerable change in the stiffness of the replaced regions, since in the vast majority of cases the metal implants have a higher modulus of elasticity than the bone. This change may cause the body to transfer bone mass from a more rigid region to a less rigid one during the process of bone remodeling, a phenomenon known as Stress Shielding. This phenomenon causes two serious and high-risk problems for the patient: the lack of bone mass in the implant-bone interface region, with consequent instability or even implant release, and the weakening of bone regions, increasing the risk of bone fracture near the implant. These two problems require surgical corrections that are much more complex than the first, from a clinical and patient recovery point of view (BOSCHIN; ALENCAR, 2007).

In this scenario, the SLM process presents itself as a tool that makes possible the construction of implants that perform much better than conventional one (the first generation of implants), often massive, with pre-determined sizes and much more rigid than bone tissues which they will replace or reinforce. Thus, with the aid of computational tools and experimental studies (in-vitro and in-vivo tests) it is possible through the SLM to manufacture implants that mimic the bone region to be replaced. In others words, this process allow the reducing of implants weight with internal porous and interconnected structures which can also accelerate the osseointegration process. This type of research is already underway as shown in the Taniguchi *et al.* (2016) study which aims to determine which geometric and interconnectivity parameters of these internal structures are more adequate for osseointegration of the implant for a given region of the body, in the case for the cortical region of the rabbit tibia.

Another line of research that aims to promote a substantial increase in the performance of implants manufactured by SLM is what uses mathematical methods such as Finite Elements and Topological Optimization. These methods can insert a objective function of a optimization problem that have stiffness constraints in the domain of implant structure and process constraints such as the construction of self-supporting internal structures which excludes the need for supports and improves the dimensional stability and uniformity of the roughness of the component. To better illustrate the benefits of using SLM process in the AM of implants using the Ti6Al4V alloy, two applications will be presented in designs of distinct orthopedic components, but which are part of the same type of surgical procedure, Total Hip Arthroplasty (THA).

4.1. Femoral Stem

THA is a type of surgical procedure aimed at replacing the articular surfaces of the hip joint. It is performed when the patient presents severe pain due to wear in the joint region in the hip, formed by the surface of the femoral head and the region of the acetabulum. The replaced bone mass in the femur gives rise to the femoral stem and femoral head components. In turn, the acetabular region is subtracted and replaced by the acetabular component which in contact with femoral head forms a spherical joint. Figure 2a shows two radiographs: one with the hip joint before the procedure and another after a THA procedure with a set of conventional implants, respectively. Still in the post-surgical image, the insertion of two screws can be observed helping the fixation process (osseointegration) of the acetabular component in the hip region. In addition, can be seen how the femoral stem inserts into the femur, acting as a support for the head component of the femur. Figure 2b exemplifies the region of critical osseointegration for the femoral stem design.

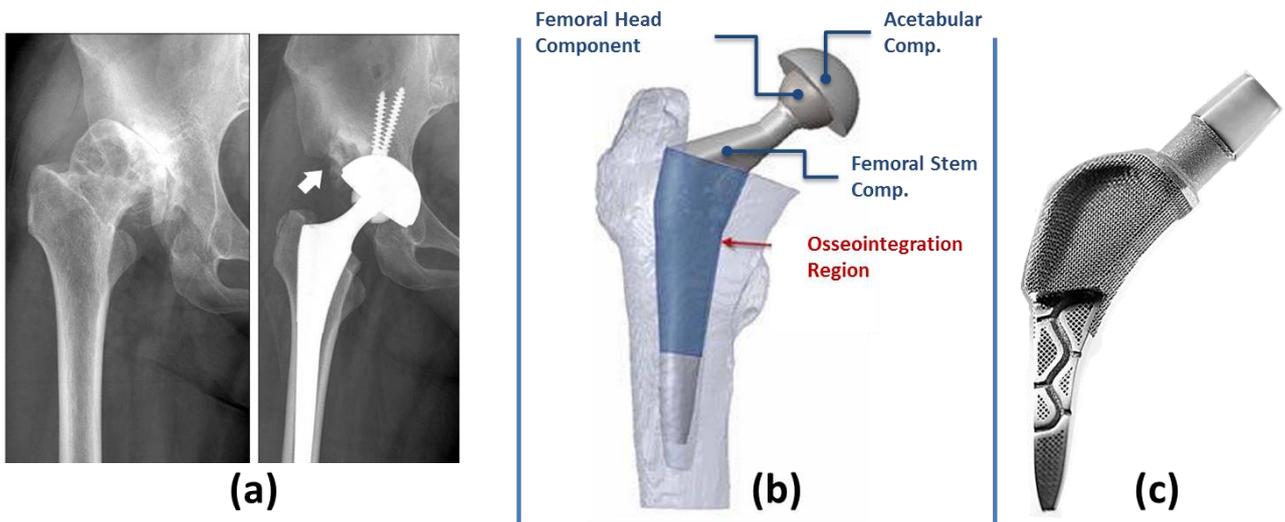


Figure 2. Images of two pre and post-surgical X-rays of THA (a), an illustration of the region of osseointegration of femoral depression (b) and an image of a femoral stem design made by SLM with lattice structures and internal channels in the region of osseointegration interface implant-femur (c). Adapted from Yoon et al. (2013), Cronskär et al. (2014) and Fraunhofer Institute (2016), respectively.

In order to demonstrate the advantages of the use of AM process in the design of femoral stems, researchers at the Fraunhofer Institute IWU (located in Chemnitz, Germany) developed the project called MUGETO. This femoral stem has internal channels that can serve as reservoir and drug delivery medium for the regions of bone-implant interface as well as cellular structures in the region of osseointegration interface implant-femur.

4.2. Acetabular Implant

The second example of application, unlike the first, is a real case and implanted in 2014. It is a 71 year old patient with a history of six THA surgeries, in others words, five revision surgeries. These successive complications were responsible for reducing left leg length by more than 5 cm and for years on crutches and medical follow-up. The implant design was conceptualized, modeled and detailed by the company Mobilife® (based in Belgium). In this implant, internal structures were used to contain a binding substance made with cells from the patient's own bone marrow. Surgical planning was performed with the medical staff of the Southampton General Hospital (in the United Kingdom) and using polymer anatomical models from the patient's acetabulum region (manufactured by Selective Laser Sintering, SLS, and derived from a CT Scan), see Figure 3a. The three-dimensional model of the implant was manufactured by the company Orthodynamics®, also located in the United Kingdom. Figure 3a and b show the two parts of the implant already finished in the anatomical model.

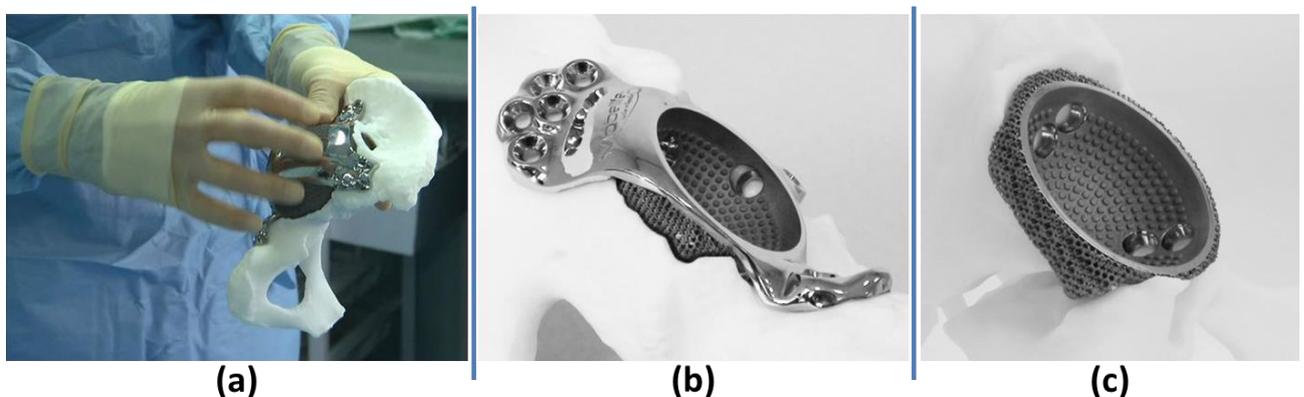


Figure 3. Images of the custom acetabular implant manufactured by SLM using Ti6Al4V alloy. Adapted from Kemel, B.L. (2016).

5. A NEW METHOD FOR DIAM OF CUSTOMIZED IMPLANTS

The process of conceptualizing, modeling, designing and manufacturing an implant is something that has been studied for at least five decades and several studies have contributed to the evolution and level of success reached by the current implants (LOPES *et al.*, 2006; PAPER, 2015; RAHMATI; ABBASZADEH; FARAHMAND, 2012). However, these designs are based on methodologies that have been developed to be manufactured by conventional manufacturing processes such as machining, forging and casting. As already shown and exemplified throughout this text, AM brings new possibilities and constraints to implant design. This fact justifies the creation of new methodologies or the adaptation of existing ones.

The following is an example of the work done by Rahmati, Abbaszadeh and Farahmand (2012) they developed a femoral stem implant design methodology already considering the use of additive manufacture, but without taking into account the influence of process parameters on the implant.

The development of a new method that takes into account the prediction of the mechanical behavior and the dimensional stability of custom implants manufactured by SLM and using Ti6Al4V alloy is the first step in a line of research that aims to study the benefits and constrains of additive manufacturing processes applied in the design of medical devices. This methodology also intends to incorporate mathematical methods such as Finite Elements (FEM) and Topological Optimization into the implant development cycle. These tools have been used for years in implant design, but their integration with the SLM process is extremely new and complex, due to the influence of the process variables on the microstructure and the dimensional of the component at the end of manufacturing process.

In this design methodology, as shown in Figure 4, there are several steps into development, surgical planning and manufacturing cycle of customized implants and surgical instruments. These steps start with a 3D Anatomical Virtual Model of Region of Interest from a patient’s medical image protocol specific for customized implants and instruments (Medical Image Protocol for AM) as an input of medical consultation for this first step. This protocol is very important and specific according with anatomical region and details of interest for three-dimensional reconstruction. These medical images are used as CT and MRI to obtain a geometric three-dimensional virtual model of the patient's region of interest. From this model, in a virtual environment, the implants and instruments are designed and the surgical planning is performed by health team.

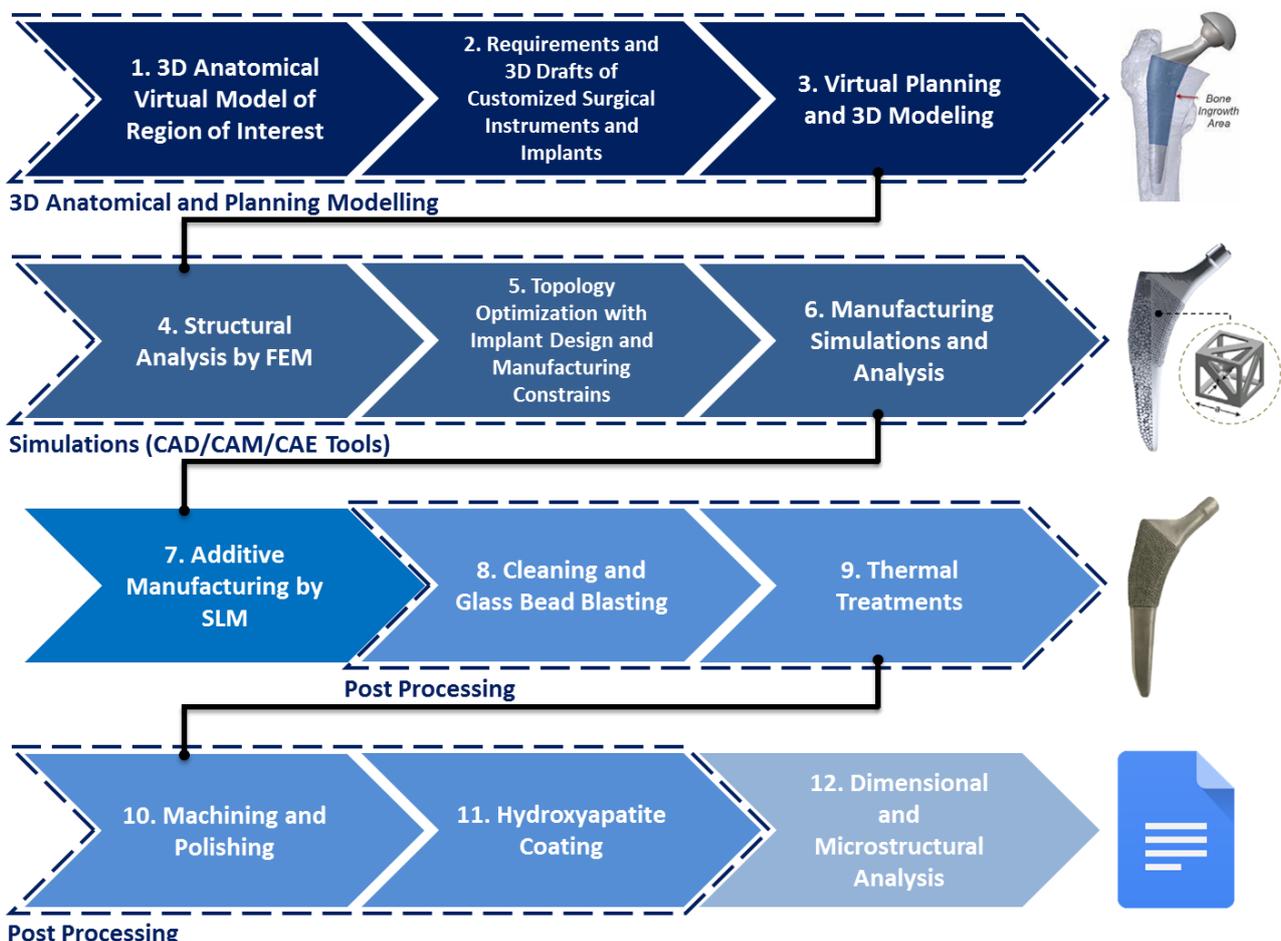


Figure 4. Femoral stem implant design methodology.

The manufacturing process has two phases (Additive Manufacturing and Post Processing) and five steps (Additive Manufacturing, Cleaning/Glass Bead Blasting, Thermal Treatments, Machining/Polishing and Hydroxyapatite Coating) starts soon after Simulations phase (consisting of Structural Simulation, Topological Optimization and Manufacturing Simulation), as shown in Figure 4. Thus, when three-dimensional model of implants and surgical instruments are completed, the construction phase of these geometries begins. It is important to emphasize that simulation of the manufacturing process is very recent within this specific product development cycle with focus in additive manufacturing process. This stage is very relevant for prediction of mechanical behavior and dimensional stability of implants and surgical instruments at the end of the manufacturing process as well as substantially increases safety for patient and surgical procedure.

6. COMMENTS AND WORK IN PROGRESS

The process of Selective Laser Melting brings new possibilities for the design of implants such as the construction of implants with interconnected pores, less weight and with structures that accelerate osseointegration process. In addition, the use of SLM allows problems such as Stress Shielding to be substantially minimized compared to conventional implant designs (massive and pre-determined sizes).

The advantages of using titanium alloys such as Ti6Al4V associated with the use of SLM have moved from a research level (as in the case of the MUGETO project) to the application in a real case (as in the case of acetabular implants) which demonstrates a relevant potential for the treatment of complex cases and consequently a new area of activity in the market of medical devices.

Additionally, additive manufacturing presents itself as a method that guides several processes (such as Selective Laser Melting) that applied to the area of medical device development offer a potential for innovation and a very broad competitive differential. This statement can be justified by the simple fact that a single Selective Laser Melting (SLM) machine supplied with a single type of raw material, a titanium alloy powder (Ti6Al4V) for example, allows the manufacturing of practically all types of orthopedic implants and according to different types of requirements such as patient anatomy, selected surgical technique and standardized design requirements. Once established this design methodology could be used to other 3D printing processes, such as, Laser metal deposition (LMD) or Electron beam melting (EBM) and other materials (Ti6Al7Nb and commercial pure titanium).

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