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ZYGOMATIC IMPLANTS MANUFACTURED BY SLM

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Abstract: *Selective laser melting (SLM) is widely gaining popularity as an alternative manufacturing technique for complex and customized part. The main advantages of customized implants made by SLM process are: the precise adaptation to the region of implantation reduced surgical times and better performance over their generic counterparts. This technique has eliminated the constraints of shape, size, internal structure and mechanical properties making it possible for fabrication of implants that conform to the physical and mechanical requirements of implantation according to CT images. The purpose of this research was to improve the design and manufacturing process of customized zygomatic implants.*
Key words: *selective laser melting, titanium, zygomatic implant, roughness, lattice structure*

1. INTRODUCTION

Additive Manufacturing (AM) technology applications are very diverse and can be used in many fields, from industry to design or medicine. Applications of AM in medicine are reported since 1994 [1]. These applications have led to the development of customized implants that are physical prosthetic models made for each individual case in order to accurate reconstruction of bone structure. Custom implants are presurgicaly constructed based on medical data acquired by computer tomography (CT) using virtual 3D models and CAD/CAM techniques. Custom implants fabricated with AM have been used by different surgeons mainly for rebuilding post-traumatic in the neocranium (cranioplasties) for reconstruction of viscrocranium defects, but also for other defects and dislocations of the human skeletal system [2, 3].

In recent years, the Selective Laser Melting (SLM) technique part of AM, has become a practice in the area of customized medical implants from different biocompatible alloys. Through the use of laser melting process, implants can be made accordingly to the CT images of the patients, resulting in higher accuracy and therefore disappear postoperative medical complications. In the past, the doctors had to use combinations of old techniques (casting, milling) to build up customized implants. Moreover, fewer production steps are required to produce the implants resulting in time-saving. On the other hand, internal structures can be integrated in the material file such as lattice structure in order to lighten the final component with regards to the mechanical properties and for ingrowth osseointegration [4].

The main objective of this study was to design and to manufacture customized midface implants via SLM and to analyze the results. In addition, to improve the surface quality of parts after SLM fabrication it was grid-blased with alumina and ultrasounds cleaning. Finally, the surface was analyzed by SEM and EDS.

2. MATERIAL AND METHODS

2.1 Material

The material used for manufacturing was especially gas-atomized titanium powder named TILOP 45 provided by Osaka Titanium Technologies. This power has a medium 45 µm particle diameter, the melting point temperature around 1670°C, 4.51 g/cm^3 density and it can be include in category of Titanium Grade I (UNS R50250). The main reason why Ti is often used in the body is due to titanium's biocompatibility with surface modifications and bioactive coatings [5].

2.2 Equipment

SLM ReaLizer 250 system (MTT Technologies, Germany) uses selective laser melting technology and provide 3D CAD data as a digital information source and energy in the form of a high-power laser beam (ytterbium fiber laser with 200W maximum power) to create three-dimensional metal parts by fusing fine metallic powders together under a protective high-purity argon atmosphere. In the present work, all the process parameters are unified into one single factor to understand their influence on the density of customized parts. The total energy input per volume of each track/scan (E) as a function of processing parameters was evaluated from [6]:

$$E = \frac{L}{v * h * t} \quad [\mathrm{J/mm^3}] \qquad (1)$$

Where L is laser power, v is scan speed, h is hatch distance or scan line spacing (usually 0.1-0.12 mm) and t is layer thickness (usually 50µm).

2.3 Dimensional measurements, porosity and roughness

After the parts were produced by SLM process, it was measured with a Mitutoyo caliper (Absolute Digimatic IP67), according to ISO 13385-1:2011. The dimensional error D_e was introduced in order to perform an analytical study of the accuracy (Equation 2). In this equation N_d and M_d represent the nominal and respectively the measured dimension.

$$D_e = \left(\frac{M_d - N_d}{N_d} \right) * 100 \quad [\%] \qquad (2)$$

The parts were weighed with an analytical balance (Partner AS 160.R2) with ± 0.2mg precision and porosity P was calculated.

In SLM technology, the surface quality is not only a primary concern to the users, but also a key issue in completion of the component during the fabrication. The obtainable surface quality of SLM parts is considered as one of the major drawbacks of the process and has been the subject of many studies in recent years [7, 8]. The roughness was measurement using a digital apparatus for roughness (Mitutoyo SJ-2010) according to ISO 4288:1998, where R_a is arithmetic average of absolute values and R_z is calculated by measuring the vertical distance from the highest peak to the lowest valley. Outer boundary is the process parameter for controlling the surface roughness and Table 1 listed below do not contain this parameter only the measurement results (in order to not complicate them).

2.4 Reconstruction of model upon patients CT images

For customized implants, the common path is to reconstruct the model via scan-to-part: a cloud of points is reconstructed upon computed tomography (CT) images and subsequently converted into a 3D model using MIMICS software (Figure 1). The model can then be manufactured through SLM technology. Currently, CT imaging has improved, in terms of resolution and 3D details, obtaining very accurate information from the patient. With this information, implants can be designed taking into account patient's anatomy, type of injury and surgical technique.

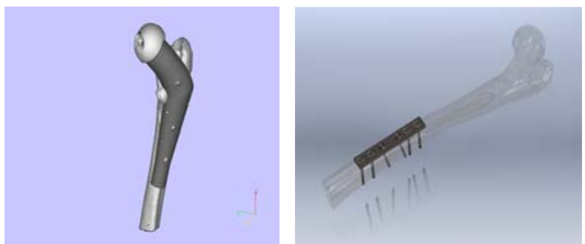


Fig.1. 3D-CAD reconstruction of femur and two types of customized prosthesis designed and fabricated by SLM

In order to show above explained benefits of implant customization and fabrication with additive technologies, two case studies have been made with customized parts. In this case study, all the parts were designed in Solid Works software, CT reconstruction was performed in MIMICS. The SLM process can provide with success the obtaining of porous metallic implants and the pore size obtained by this technique allowed the necessary nourishing to cell survival, proving that pores and channels form a high interconnectable network represented by the osseointegration and osteoconduction feature of the porous Ti [9].

3. CASE STDY: CRANIOFACIAL RECONSTRUCTION

Reconstruction of the orbital wall by mirroring data from the normal side has been described by several authors [9, 10, 11], and a methodology for computer assisted surgical planning and custom Ti plates or mesh for midfacial reconstruction. SLM fabricated models have been used as a template to presurgically adapt a Ti plate to precisely fit the defects of the orbital wall a procedure that helps to reduce surgical time [12, 13].

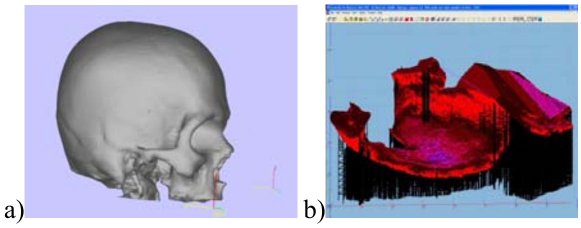


Fig.2. a) 3D reconstruction of patient specific skull, b) 3D zygomatic implant on SLM equipment

To develop the best cosmetic and functional outcome some critical considerations for treatment of larger defects of the midface, orbito-zygomatic complex reconstruction and alveolar ridge reconstruction for dental implant placement, it was designed customized midface implants following the steps presented above, 3D CAD design for the implant was derived from the CT scan data and zygomatic orbital implant was designed as presented in Figure 2.

Three pieces of zygomatic implant was fabricated by SLM with different process parameters (Figure 3).

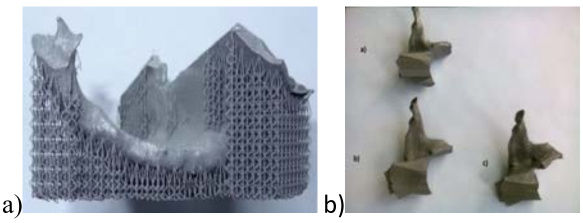


Fig.3. a) Zygomatic implant with supports after SLM process, b) A_a, A_b, A_c implants manufactured with different internal structure (porosity)

In Table 1 it can see the process parameters and characteristics obtained and the main difference between implants was the internal structure. So, A_a and A_b implants were designed and manufactured to have an thin exterior contour (A_a have 0.2mm and A_b have 0.8 mm thickness of exterior contour) and the inside have a special lattice structure manufactured with 39%, respectively 34% porosity (Figure 4 a, b) similar to real human trabecular bone [14]. Trabecular bone is much more porous with porosity ranging anywhere from 50% to 90% (Figure 4 c). The cord-supported of lattice structure has a diameter around 200 μm and the pore size is around 280μm (Figure 4 b). In general, implants with pore sizes in the range of 100-500 μm are suitable for bone ingrowth and was reported direct connectivity of macropores with bone[15]. It has also been suggested that the degree of interconnectivity is more important for new bone formation than the pore size itself [16], and this internal lattice structure manufactured by SLM have interconnections pores. This internal structure makes implants lighter in comparison with those without lattice structure (full dense).

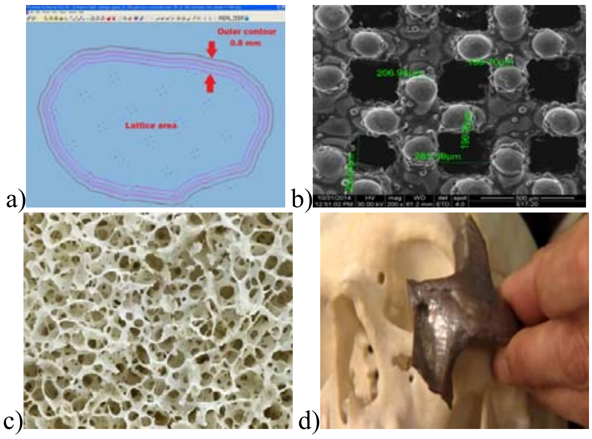


Fig.4. a) 3D cross section of A_b implant with 0.8 mm outer couture and lattice structure inside, b) SEM image with internal lattice structure (200 x magnifications), c) Cross section of human trabercular bone, d) A_c implant after grit-blasting by alumina and ultrasounds cleaning

A_c implant doesn't have any open porous structure (full dense part) just surface microporosity obtained using the suitable SLM process parameters. All these parts were completed with high precision (D_e under 1%).

Table 1

Characteristics of implants fabricated by SLM

Properties		Zygomatic Implants		
		A_a	A_b	A_c
Process Parameters	Scan Speed [mm/s]	375	375	400
	Power [W]	88	100	120
Energy Input, E [J/mm^3]		46	55	25
Dimensional Error, D_e [%]		+ 0. 6	+ 0. 5	+ 0.9
Porosity, P [%]		49.8	44.4	1.3
Roughness	R_a [µm]	11.8	10.2	1.4
	R_z [µm]	55.3	54.7	6.2

Adhered and unmelted powder particles on the component surface during the manufacturing process are not avoidable. A special attention is given to the surface of implants that are in direct contact with bone, and where removal adhered and melted powder particles are necessary because these particles can create problems after the surgical intervention.

In recent years there were developed different removal by cleaning-processes, and in this article A_c implant was grit-blasting with abrasive alumina and ultrasounds cleaning. Ultrasounds cleaning have the following advantages: accessibility to hard-to-reach areas, economically and material careful removes of particular soilings and cannot enter other particles into gaps which can harm the patient's health. The difference between a part before and after grit-blasting with alumina and ultrasounds cleaning in distilled water at 40°C for 30 minutes can see in Figure 5, where the initial surface contains several particles of titanium partially unmelted or anchored in micro-crevices. Average R_a, R_z roughness after SLM manufactured were around 10 µm respectively 55 µm and it depends on the orientation of the component surfaces in the process chamber and the exposure parameters (Table 1). On A_c model was applied this post-processing treatment and the roughness R_a, R_z were decreased at 1.4 µm respectively 6.2 µm (Table 1). This final porous surface obtained by SLM has been demonstrated to be favorable for cell adhesion, migration and ingrowth, and these properties result in strong bone-implant contact. When an implant is populated with osteogenic cells, these cells not only migrate on the surface of the implant but also inside the pores of the implant [17].

a)

b)

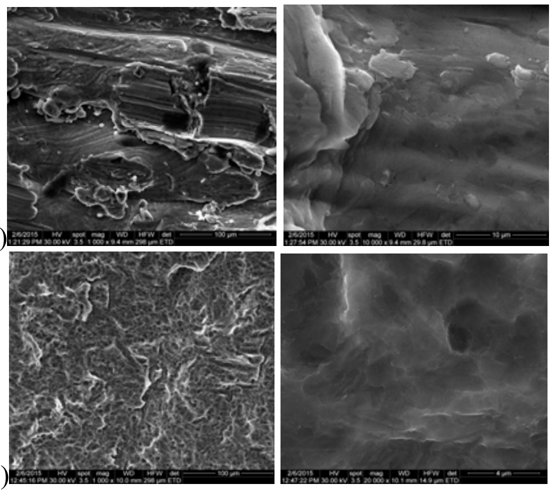
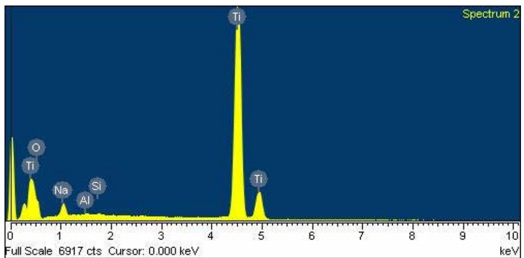


Fig.5. SEM images of A_c before post-processing (a) and (b) after grit-blasting with alumina and ultrasounds cleaning (1000x and 20 000x magnification)

Chemical composition of surface after this treatment is present in EDS spectrum (Fig. 6), where the it can see that the zygomatic implant was not contaminated by alumina after this surface processes. Finally result of this post-processing method it can see in Figure 4 d.



Element	O	Na	Al	Si	Ti
Weight [%]	21.48	2.67	0.16	0.16	75.54

Fig.6. EDS spectrum of A_c implant after grit-blasting with alumina and ultrasounds cleaning

The zygomatic bone is a paired bone which articulates with the maxilla, the temporal bone, the sphenoid bone and the frontal bone. It is situated at the upper and lateral part of the face and forms the prominence of the cheek, part of the lateral wall and floor of the orbit, and parts of the temporal and infratemporal fossa

A similar implant was implanted to a patient (45 years old male) in distress, who suffering a car accident and the left side of midface was completely destroyed in zygomatic bone area (Figure 7). The advantage of this Ti implant compared to implant made from plastic (polymethyl methacrylate) is that Ti is more stable and is integrated into the bone structure. The surgical act and implant method for manufacturing was an international premier because, so far such customized titanium implants were used only to reconstruct the mandible.

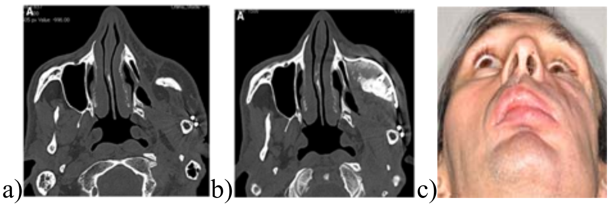


Fig.7.a) CT scan confirming the left zygomatic deficiency, b) Postoperative CT scan showing the restoration of the zygomatic bone, c) Patient after 4-month post-operative [18]

The surgery team was conducted by Dr. H. Rotaru and the result of the implantation was a success, and after four months the implant was perfectly integrated in the body without any signs of rejection [18]. Psychological condition of the patient was also greatly enhanced by reintegrating into the community and a one-year follow-up revealed a stable outcome with no complications.

This article presents the initial test of zygomatic implant, to manufacture the final implant for surgical act was used Titanium Grade 2 powder, and the mechanical properties were similar to those for biomedical implants (ASTM F67, Unalloyed Titanium for Surgical Implant Applications). Using this type of fabrication and virtual surgical planning, the surgeon could better have planning the patient specific implants and this fact helps to precise placement of the bone graft in an optimum position for rehabilitation.

4. CONCLUSION

Globally the production of customized biocompatible medical implants from titanium via SLM is gaining importance. Titanium implants manufactured by SLM might be a promising alternative approach to alloplastic craniomaxillofacial bone reconstruction due to their geometrical, biological, and mechanical properties. SLM allows an efficient and customized production of the complex framework with some specific post-processing. Proper process parameters and an appropriate production strategy guarantee an accurate fit between the framework and the implants, needed to avoid mechanical or biological failures of the prosthetic system. This technology opens a new era enabling the customized production of medical implants. In this study, using pure titanium powder and SLM manufacturing was demonstrated that it could be fabricated customized implants with proper roughness for osseointegration process, comparable to those of conventionally fabricated ones. The surface quality was improved using grit-blasting with alumina and ultrasounds cleaning.

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Implanturi zigomatice fabricate prin SLM

Rezumat Procesul de topire cu laser selectiva (SLM) castiga popularitate pe scară largă fiind o tehnica de fabricatie alternativa pentru piese complexe si personalizate. Principalele avantaje ale implanturilor personalizate realizate prin procesul SLM sunt: adaptarea precisa a implantului la regiunea de implantare, reducerea timpului interventiei chirurgicale si performante mai bune in comparatie cu cele generice. Aceasta tehnica a eliminat restrictiile de forma, marime, structura interna si proprietati mecanice, facand posibila fabricarea de implanturi conforme cu cerintele fizico-mecanice necesare implantari in functie de imaginile obtinute de la CT. Scopul acestei cercetări a fost de a imbunatati proiectarea si fabricarea implanturilor zigomatice personalizate.

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