DIRECT MANUFACTURING OF CUSTOMIZED IMPLANTS FROM BIOMETALS, BY 3D PRINTING

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ABSTRACT: The article highlights the main steps in directly obtaining of customized medical implants made of biometals, starting from computer tomography scanning of the patient up to the proper individualised implant, fabricate by Additive Manufacturing. To detail the entire design-manufacturing method, a 3D model was designed with specific software's, the osseous reconstruction was manufactured by selective laser melting (SLM) and post-processed. In order to investigate the surface of titanium implant, scanning electronic microscopy was used. The research exhibits a good SLM manufacturing practice regarding a zygomatic reconstruction implant. The advantages of customized implants are accurate, having aesthetic and functional results. This procedure described bellow could reduce the surgery and recovery time, and it could significantly improve the patient's life quality.

KEY WORDS: designing, zygomatic reconstruction, selective laser melting, titanium, post-processing

1 INTRODUCTION

The technologies of processing material have evolved distributive since their apparition. From among the most advanced technologies developed over the last years, the Additive Manufacturing (AM or 3D Printing) is the one that best meets the demands of the fourth industrial revolution (Berce et al., 2015). Among the most innovative AM of metals is the Selective Laser Melting (SLM). The SLM process appeared in 1994 as a result of a complex research elaborated by the Fraunhofer Institute (Germany), led by Dr. Fockele and Dr. Schwarze (DE 19649865 patent). The technology is eco-friendly, it does not pollute the environment, as its manufacturing process does not lead to toxic waste (Baumers et al., 2011; Rusko et al., 2013).

The technological evolution has greatly contributed to the modernization of the medical field, through the improvement of the quality of products as well as of the medical act (Benea et al., 2016). This trend is triggered by an aging society, with a higher life expectancy. The implants commercialised currently do not cover the multitude of medical cases that deal with individual osseous problems that appeared as a result of traumas, malformations or osseous tumours.

For the support of the surgeons in such cases, different research Centre's have developed the preparatory CAD model corresponding to the osseous area affected, starting from the computer tomography image (CT), they have designed the customized implant and they have manufactured it directly with AM technologies from biocompatible metals (Kroonenburgh et al., 2012; Nakano et al., 2015; Murr at al., 2012). The entire designing and manufacturing through SLM of customized implants is a present-day international topic. The customized implants are precisely adjusted to the implant area, eliminating the restrictions of shape, reducing the length of the surgical intervention through preparatory simulations, and they can have physical-mechanical features similar to those manufactured through conventional technologies (Rotaru et al., 2015; Parthasarathy, 2014; Tunchel et al., 2016). All these aspects lead to the diminishment of the chances of infection or rejection by the body, as well as to the more rapid recovery of the patient.

In the field of SLM, the first research had done in Department of Manufacturing Engineering (DME) at the Technical University in Cluj-Napoca appear in the year 2008, when the department purchased the equipment Realizer 250 (Leordean et al., 2015). The main products and services developed in DME are: ▶Designing and manufacturing custom implants made of biocompatible materials using 3D printing technologies, such us cranioplasties, maxillofacial

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reconstructions, orthopaedic prostheses, titanium mesh (for midface defects) and other special medical devices; ▶Custom products used in dentistry such as dental crowns and bridges, abutment bar, titanium membrane (to secure the implant and graft material); ▶Anatomic or complex prototypes manufactured by 3D Printing from plastics and metals; ▶3D scanning and digitalization products; ▶Medical data processing and adjustments; ▶Optimizing the design of custom implants using Finite Element Analysis (FEA); ▶Verification and validation of medical products; ▶Science and research in the field of biomedical engineering.

The aim of this article is to present the main steps in 3D printing of custom-made implants, manufactured from biometal powder. Also, it exhibits some good SLM manufacturing practice regarding a zygomatic reconstruction implant.

2 MATERIAL AND METHODS

2.1 Biometal powder

Currently, to manufacture medical products via SLM process, the main biometals used are pure Titanium (Ti), Ti6Al7Nb, Ti6Al4V, CoCr alloys or Stainless Steel (Armencea et al., 2015; Cosma & Balc, 2015; Buican et al., 2017; Ardelean et al., 2016). The present research was done by using powder of pure Ti furnished by Osaka Titanium Technologies (Japan). This metallic powder corresponds from the point of view of its composition to the standard Ti Grade 1, having a purity of 99.5% and a density of 4.5 g/cm^3 for full parts with porosity less than 0.5%. Ti powder has spherical granules with a diameter of 25 µm and a high biocompatibility (Santos et al., 2004; Wang et al., 2016).

2.2 Infrastructure

For the manufacturing of the customized implants the SLM REALIZER 250 equipment was used (SLM Solutions GmbH, Germany). The system uses selective laser melting technology and could manufacture three-dimensional metal parts by fusing fine metallic powders together slice by slice, under a protective high-purity Argon atmosphere. This technology has a solid-state laser type Nd:YAG (neodymium-doped yttrium aluminium garnet) and the maximum power of laser is 200 W.

For additive manufacturing of low cost prototypes was used a Selective Laser Sintering equipment (DTM Sinterstation 2000) and polyamide powder. The 3D Reconstruction of patient specific bone models was done in MIMICS software. To design the customized implant, the virtual model was performed in SolidWorks. The finite element analysis (FEA) of virtual implant was elaborated in SolidWorks Simulation.

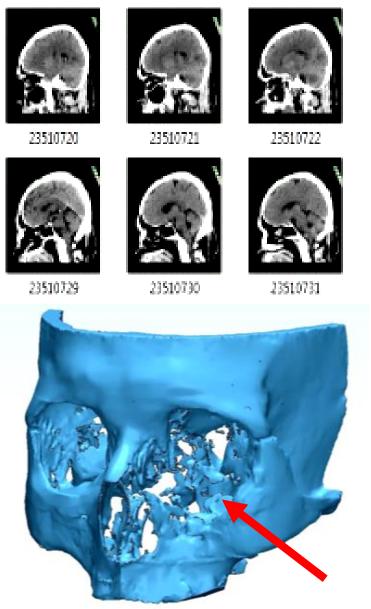
3 RESULTS AND DISCUSSION

3.1 Process flow for designing and manufacturing of customized implants

The complete process flow for designing and manufacturing of customized implants is shown in Figures 1-6 and is described briefly below.

The first step in this method consists the scanning of the patient using a CT or a micro-CT, the digitization and processing of the images (Figure 1a). Using the CT images, the surgeons could establish the diagnosis and suggest a treatment method (Tarcolea & Semenescu, 2016).

The second step was to operate the CT images which lead to the precise 3D reconstruction of the patient's bones. An example for this is rendered in Figure 1b, where is represented a 3D reconstruction of the cranial bones who had suffered a trauma in the area of the left zygomatic bone. The CT images were imported and processed in the MIMICS software, and for the fixation and repairing of the errors the Autodesk Meshmixer software was applied. After the processing of CT images, the zygomatic osseous model was obtained in .STL format file (Figure 2a).



a)

b)

Figure 1. a) CT images of defect (sagittal view), b) 3D reconstruction of the patient cranium defect

The third step was to design the CAD model of implant, focused on the affected area. This transformation from .STL file into a solid one is necessary because a solid model can be mathematical analyzed by finite element method (FEM). Usually, the affected area that is to be treated with the customized implant is malformed, therefore it calls for an implant that is precise for the affected area. The CAD model of implant was designed in SolidWorks software. Generally, the designing of the customized implant is done in the mirror with the healthy bone.

The fourth step consists the optimization of implant design through finite element analysis (FEA). The simulations that could be done on an implant can be static, dynamic or cinematic, and they are elaborated according to the biological conditions and the physical-mechanical features of each tissue. Moreover, for the adequate designing of the implant, the physical-mechanical properties are defined in accordance with the results obtained on standard samples manufactured by SLM process. It is well known that the implants SLM-manufactured have physical-mechanical properties that vary much according to the process parameters, as compared to those processed conventionally (Chen et al., 2014).

In this study, the design of zygomatic implant was optimized through static simulations in SolidWorks software (see Figure 2b). The FEA study was done by applying a force of 100 N. Also, the physical-mechanical characteristics of Ti implant were set up as follow: 100 GPa Young Modulus, 0.35 Poisson ratio, 4.4 g/cm^3 density, 410 MPa ultimate tensile strength and 210 MPa yield tensile strength. These physical-mechanical properties were obtained in previously research on standard samples SLM-manufactured with optimum process parameters for pure Ti powder (Ispas et al., 2016).

The fifth step was to manufacture the prototype of implant and patient's cranium by SLS process. These models were rapidly manufactured out of polyamide, and the processing costs were reduced (Pradel et al., 2017). They could be used for the preparatory analysis of the affected osseous structure, namely for testing the fixation of the implant and the adjacent bone. Figure 3 illustrates the zygomatic implant fabricated via SLS process as well as the patient's cranium.

According to the area where the implant will be applied, the engineers and surgeons could establish the proper metallic material that will be used in SLM manufacturing. The fabrication will be done with processing parameters whose physical-mechanical features are determinate and which had been applied in FEA simulations (e.g. Young modulus, density, yield strength and Poisson ratio).

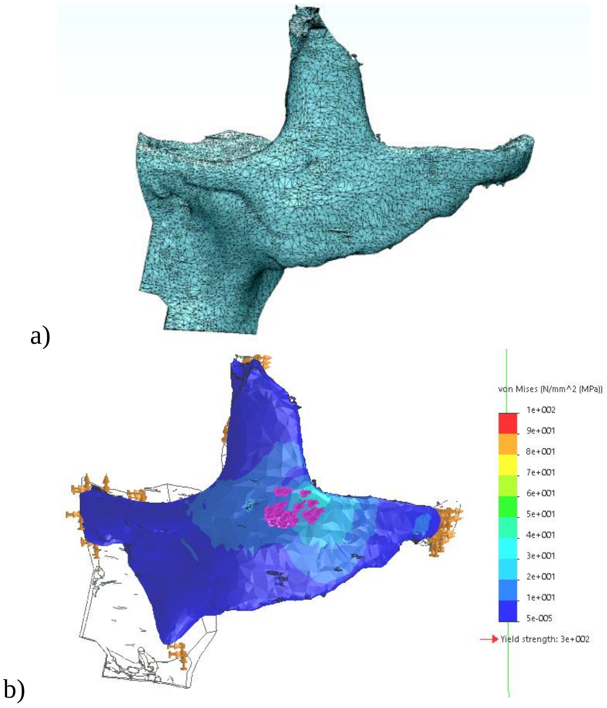


Figure 2. a) Zygomatic implant in .STL format file, b) Design optimization by FEA

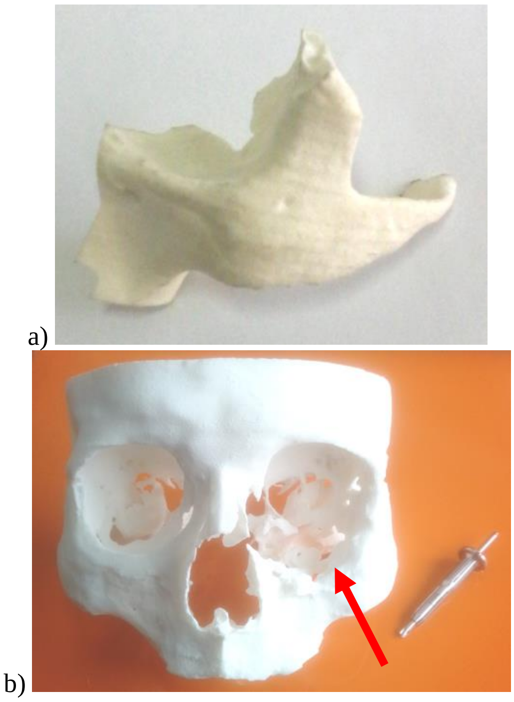


Figure 3. a) Prototype manufactured via SLS, b) Patient cranium SLS processed with affected area

The sixth step lies the manufacturing by SLM process from pure Ti. Figure 4 illustrates an image during the SLM processing and the zygomatic implant manufactured. The processing parameters set up were: 120 W laser power, 500 mm/s scan speed and 0.1 mm hatch distance, totalling a 48 J/mm^3 energy density, according to equation from literature (A. Laohaprapanon et al., 2012). The slice powder thickness was configured at 50 µm, and the laser scanning strategy was „x/y", being recommended by certain authors (Lu et al., 2015). These SLM parameters lead to the manufacturing of certain parts with tensile strength of 441 MPa, which is a higher level compare to other studies that used the same pure Ti powder (Laoui, et al., 2006).

Moreover, in order to obtain a better quality of the surfaces, the optimum parameters for the scanning of the outer boundaries of the implant were: 133 W laser power and 344 mm/s scanning speed of laser (Balc et al., 2015). With these processing parameters associated to the outer boundaries scanning, the R_a roughness of the implant was varied between 4-6 µm according to the shape complexity (see Figure 4b). These values of surface roughness are comparable with those obtained through other non-traditional technologies (Harničárová et al., 2013).

The seventh step was the post-processing of processed customized implant. The techniques of post-processing the SLM-manufactured parts have advanced rapidly starting from CNC milling, blasting with alumina, silicon nitride, CO_2 or dry ice blasting, abrasive flow machining and electro-polishing (Brusilová et al., 2017; Ceclan et al., 2015; Yang et al., 2016; Bergmann et al., 2013). Generally, the implants fabricated by SLM have a R_a roughness between 6-8 µm, and after an adequate post-processing the roughness can be reduced to 0.8 µm. To achieve the surface quality, the zygomatic implant illustrated in Figure 4b was post-processed using OTEC technology for surfaces finishing (Ferreira et al., 2016). Thus, the complex surface of the implant was polished at a speed of 10 m/s in abrasive granulated powder.

The eighth step lies the microscopically investigation of the implant surfaces. The result of these analyses details the structural and morphological aspects of the post-processed surfaces. Figure 5a illustrates an image obtained by Scanning Electron Microscopy (SEM) with the initial surface of the zygomatic implant SLM-manufactured. This image clearly renders the fact that the surfaces have micro-pores or granules of Ti partly anchored.

For the thorough cleaning of these surfaces, apart from the post-processing detailed during the seventh step, chemical treatment like acid-etched was also applied (Herrero-Climent et al., 2013).

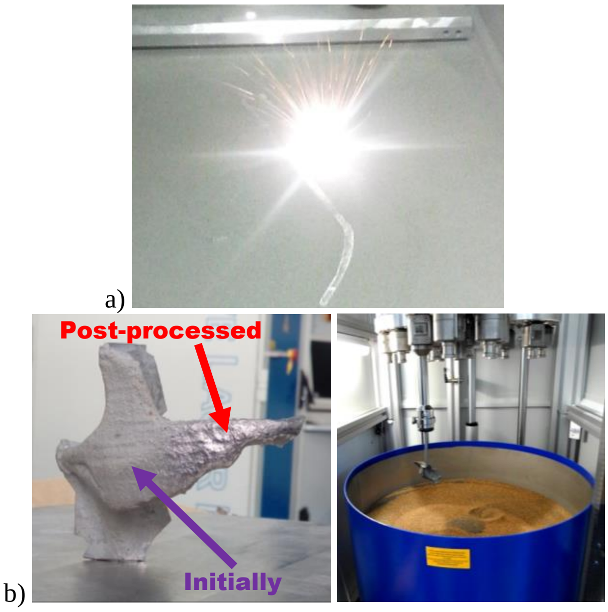


Figure 4. a) SLM manufacturing of zygomatic implant, b) Implant post-processed via OTEC technology

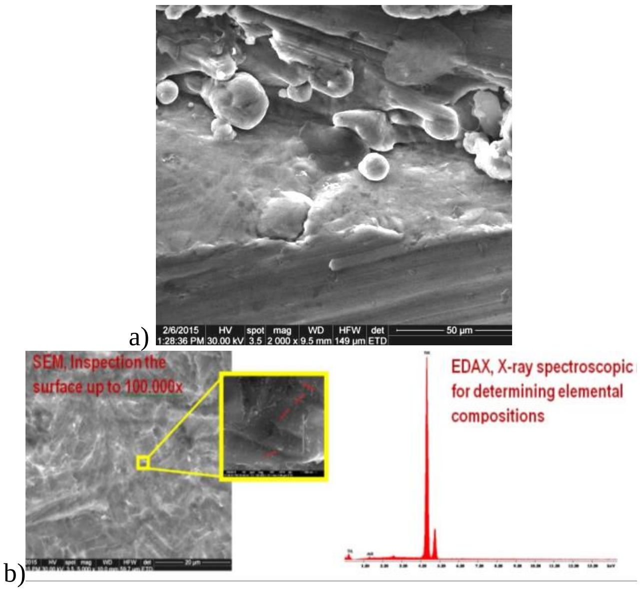


Figure 5. SEM and EDAX investigation: a) Initially surface, b) Surface after post-processing

Thus, the resulting surface corresponds to medical requirements regarding the quality of implants (Figure 5b). In order to analyze if the implant was contaminated during post-processing operations, the implant surface was investigated by Energy Dispersive Spectroscopy (EDAX). Figure 5b points out the fact that, on the implant surface of pure Ti there are no other chemical elements. In conclusion, the implant was not contaminated with other materials.

The ninth step lies in the geometrical inspection, meant to check the accuracy of the implant. To develop this task, the manufactured implant was 3D scanned and packaged as a CAD model. The designed implant was then set as a reference model, and the scanned real implant was set as a contrast model (Song et al., 2014; Krolczyk et al., 2016). After automatic overall alignment, the existing geometrical deviations were determined and are shown in Figure 6a. While analyzing the accuracy, the geometric deviations are between ±0.30 mm and the mean is -0.04 mm. The cranium processed via SLS in the fifth step and the zygomatic implant SLM-manufactured could be used by the surgeons to develop preparatory simulations of the bone-implant assembly (see Figure 6b). Also, they can thoroughly plan the intervention (including the area where the affected bone will be substituted) and they can calculate the operating times. Appling these preparatory simulations on each patient, the surgeons can particularize the surgery, reducing the length of the intervention and improving the inter-operating fixation between the implant and the host bone.

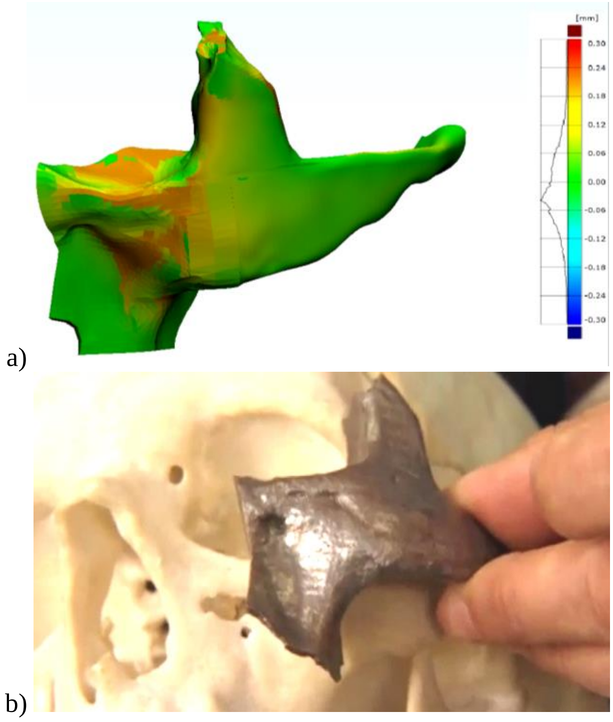


Figure 6. a) Comparison diagram between 3D model and SLM-manufactured, b) Pre-operatory simulation

The tenth step is the surgical intervention itself. A similar bone reconstruction was implanted to a 45-year old male in distress, who suffering a trauma (car accident) and the left side of his midface was completely destroyed in zygomatic bone area (Rotaru et al., 2015; Cosma & Miron, 2015). The surgery team was conducted by Dr. Rotaru and the result of the implantation was a success. After 1 year post-operative, the implant was perfectly integrated in the body without any signs of rejection. The psychological condition of the patient was also greatly enhanced by reintegrating into the community and after one-year revealed a stable outcome with no complications. Also, it's reported a difficult medical case treated with bespoke implants (cranioplasty recovery) processed by AM from biopolymers, following similar procedure (Tarcolea & Doicin, 2016).

3.2 Future perspectives

The stiffness of Ti or CoCr implants directly affects the cellular response. In order to modify the elasticity modulus of the implants, new design methods are developing to vanish this disadvantage. To significantly reduce the Young modulus of implants, lattice structure or scaffolds could be applied directly in specific areas.

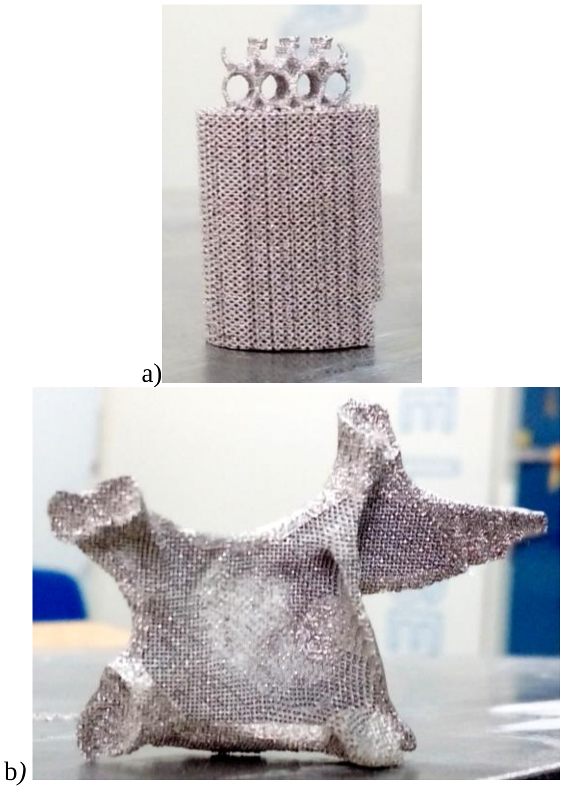


Figure 7. Future perspective: a) Medical grafts with variable porosity (2 types of lattice structures), b) Macro-porous implant with solid outer boundary SLM-manufactured

In Figure 7 are illustrated two different applications, developed currently by the authors. The first application presented in Figure 7a is a graft that could be used in regenerative medicine, to support the growing of new bone tissues or to be infiltrated with bioactive materials or drugs. This graft contains two different designed lattice structures with 52% and 83% porosity (Figure 7a).

The second model is a maxillofacial reconstruction implant with solid outer boundary and macro-porous area in the middle (Figure 7b). All these parts with complex and interconnected porosity were SLM-manufactured, and it represents a novelty in this field. In addition, these lattice structures could create a strong mechanical retention between the metallic substructure and other veneering materials like composites or ceramics, specific in dental field (Ispas et al., 2016; Burde et al., 2016).

4 CONCLUSIONS

Using the CAD systems for design and simulations, as well as the AM technologies, personalized implants can be done with complex anatomic shapes. The AM process (SLM and SLS) could allow the surgeons the preparatory visualization of the implant-bone assembly so as to be able to establish the surfaces of fixation in the damaged area of the osseous system.

The establishing of the physical-mechanical features of the parts obtained by SLM process contributes to the completion of certain medical personalized implants with adequate mechanical properties. In addition, these implants can be optimized using FEA simulations, and at the end they can be re-designed by greatly reducing their weight. In addition, it's presented two new applications of macro-porous structures in regenerative medicine and maxillofacial surgery.

The benefits that make patients satisfied with customized implants manufactured directly by SLM process from biometals are: a personalized implant fits suitable, the aesthetic and functional results are proper, the total cost-of-ownership is reduced, and the surgery is more quickly and safe. With reduced surgery time and therefore shorter recovery, the patient could be integrated into society sooner. This fact will significantly improve the patient's life quality.

5 ACKNOWLEDGEMENTS

This research was supported the OpTi-DeP Project (no. BG101/2016) financed from the UEFISCDI by the Romanian Government and also by the HORIZON 2020 AMaTUC project (GA 691787) financed from EU.

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7 NOTATIONS

The following abbreviations are used in this paper:

AM - Additive Manufacturing
CAD - Computer-Aided Design
CT - Computer Tomography
EDAX - Energy-Dispersive X-ray Spectroscopy
FEA - Finite Element Analysis
R_a - Roughness parameter
SEM - Scanning Electron Microscopy
SLM - Selective Laser Melting
SLS - Selective Laser Sintering
STL – Stereolithography file format
Ti – Titanium