# STUDIES ON DESIGNING AND TESTING OF A CUSTOMIZED MEDICAL IMPLANT FOR THE MAXILLOFACIAL AREA

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**ABSTRACT**: This paper presents the designing and testing of a customized medical implant for the maxillofacial area of a biocompatible alloy (Ti6Al7Nb). In order to create the plan for this implant, CT images were required, they were analyzed and processed to obtain a 3D model of STL type. This was transformed into a solid model so boolean operations could be done (3D). After obtaining the 3D solid model, a series of finite element analysis were made to identify areas with high tension rate which are necessary in the design of the new implant from the alloy. A series of finite element analysis were performed in different areas of the zygomatic bone which show cases of blows or accidents. Considering these tests, several types of implants have been designed. In developing, constructive variants was aimed to achieve a weight close to the zygomatic bone and to the maximum mechanical strength of the alloy. Following the tests with finite elements analysis, an optimal customized implant was redesigned.

**KEY WORDS**: customized implant, maxillofacial, titanium alloy, CREO Parametric, FEA.

## 1 INTRODUCTION

Today's manufacturing of custom medical implants poses a big challenge for both engineers and doctors. The difficulty stands in both the level of material and manufacturing technology. The appearance of new nonconventional technologies and materials opens a lot of possibilities in the implant manufacturing area.

Researchers from King Saud University, Saudi Arabia, have created a customized medical implant for the maxillofacial area of an individual who had a tumor. The researchers started from the tomographic images of the damaged area and created a 3D model of the implant. The implant, after the design, was fabricated by the EBM method (Electric Beam Machining) from biocompatible alloy Ti6Al4V ELI (extra low interstitial) with the following chemical composition: 6.04% Al, 4.05% V 0.013% C, 0.0107% Fe, 0.13% O and Ti [Khaja 2016]. In order to reduce the weight of the implant a porous structure was applied (the pore diameter was 0.70 mm) [Khaja 2016; Harrysson 2007].

Another study in this field was done by two researchers from Germany. In this experiment, a customized implant had been created for the maxillofacial area under the eyes.

In this study the process started from the tomographic image analysis which lead to a 3D implant design and manufacturing using selective laser sintering method (SLM). [Ranaa 2015; Vandenbroucke 2007]

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## 2 WORKING CONDITION

To elaborate this article, the Creo 2.0 package was used, which is a program that helps 3D CAD design and manufacturing products, according to industry standards. This being a program with embedded systems, Creo enables users to use the CAD, CAM or FEA without wasting time transferring and converting data into other programs. The Creo Parametric software was used, in this case, for the design of the implant and for the finite element analysis, the Creo Simulate.

Ti6Al7Nb alloy (www.atimetals.com) is the metal alloy used in the implementation of the project. It is created by the SLM process using a laser beam power of 160 W, as shown in Table 1.

**Table 1**. **Ti6Al7Nb alloy's caracteristic at 160 W [Leordean 2011; Leordean 2015].**

| LASER power [W] | Rm [MPa] | E [Gpa] | ρ [g/cm$^3$] | υ |
|---|---|---|---|---|
| 160 | 500 | 90 | 4.4 | 0.38 |

To identify the concerned areas the mechanical properties of the human bone was analyzed. After examining the specific literature, it was decided to take into account the following mechanical characteristics of the human bone (Table 2): bone density: 1.6 g/mm^3 [Cowin 2001]; the Young module E1, E2 and E3 [Mpa]; transversal module

G12, G13 and G23 [Mpa]; the Poisson coefficient υ23, υ31 and υ32 [Leordean 2011; Cowin 2001];

**Table 2. The spring constants of the human bone [Leordean 2011; Cowin 2001].**

| Spring constant | Measure unit | Central zone | Margins |
|---|---|---|---|
| E1 | GPa | 10,93 | 11,77 |
| E2 | GPa | 14,78 | 16,25 |
| E3 | GPa | 18,89 | 20,42 |
| G12 | GPa | 4,24 | 4,80 |
| G13 | GPa | 5,13 | 5,72 |
| G23 | GPa | 6,27 | 6,67 |
| υ12 | - | 0,224 | 0,157 |
| υ13 | - | 0,295 | 0,292 |
| υ23 | - | 0,275 | 0,273 |
| υ23 | - | 0,276 | 0,211 |
| υ31 | - | 0,501 | 0,500 |
| υ32 | - | 0,280 | 0,33 |

The finite element analysis was done with a force of 5000 N. This force was considered the maximum force the implant can support.

This 5000 N being the equivalent force of a 10 kg object moving at the speed of 5 m/s.

The estimated force of impact was analytically determined by the kinetic energy equation.

$$E_c = \frac{m * v^2}{2} \quad \text{[J, Nm]} \qquad (1)$$

Where: m - weight (10 kg); v - speed (5 m/s). In this case, the estimated Ec is 125 J.

The necessary energy to damp the impact is:

W= Fi*d [Nm] (2)

Where: Fi – impact force and the friction wasn't taken into consideration;

W=Ec;

d – damping distance (0,025 m)

From these equations, (1) and (2), it was concluded that: a 5000 N impact force can be applied for all of the tests.

## 3 CASE STUDY PRESENTATION AND WORKING METHODOLOGY

The subject chosen for the zygomatic bone case study has suffered trauma in the maxillofacial area. The aim of the paper is to design personalized implant created with additive manufacturing technology by analyzing the bone structure with FEA.

The zygomatic bone (Zygomaticum), also known as the cheekbone (figure 1), which is a paired bone, is situated at the upper and lateral part of the face. It forms the prominence of the cheek and it presents a malar and a temporal surface. [Papilian 2006]

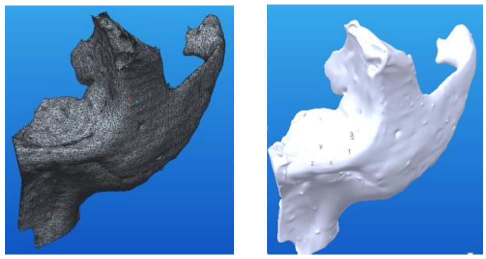


**Figure 1. 3D model of the zygomatic bone: (left) STL model; (right) Solid model**

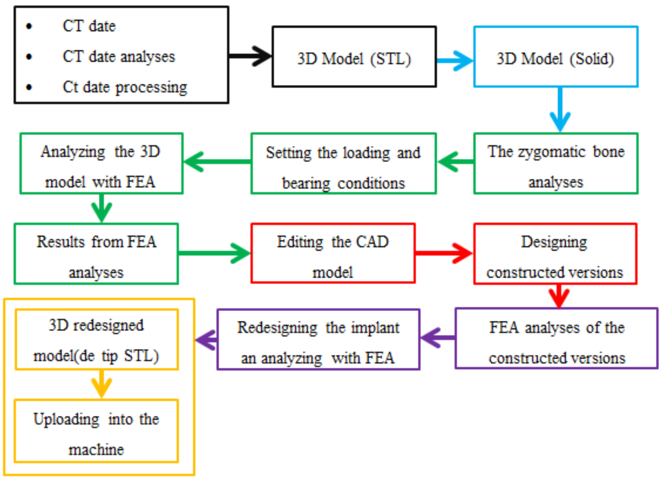



**Figure 2. Work stages of the implant created by the SLM technology**

Figure 2 presents the work stages of this study: design, finite element analyses and entering the data to SLM equipment.

## 4 THE ZYGOMATIC BONE ANALYSIS

This chapter focuses on identifying the high tension areas, which concern the zygomatic bone, conformed after the finite element analyses. A series of finite element analyses were conducted on different parts of the zygomatic bone. These cases represent various types of impact of 5000 N force (Fig.3-10).

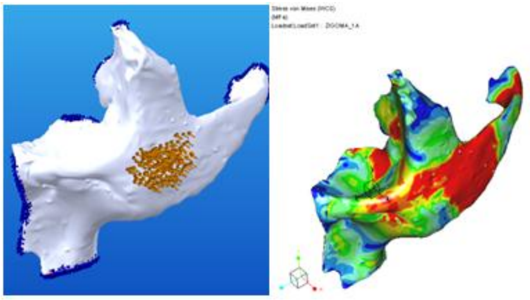


**Figure 3.Test.1. Applying the force in the center area.**

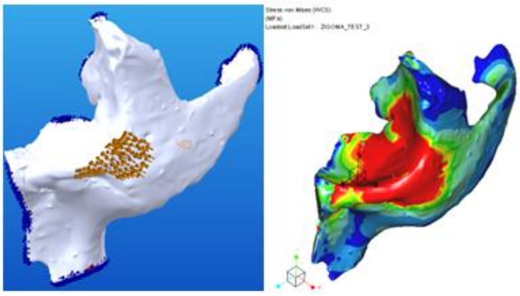


**Figure 4.Test.2.Applying the force under the eye area.**

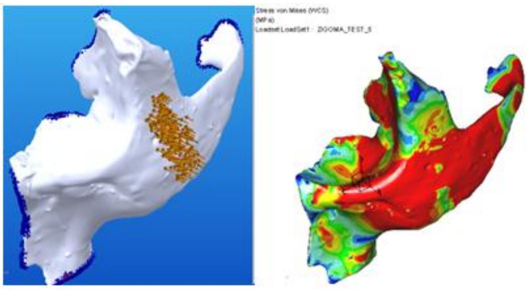


**Figure 5. Test.3. Applying the force in the center area vertically.**

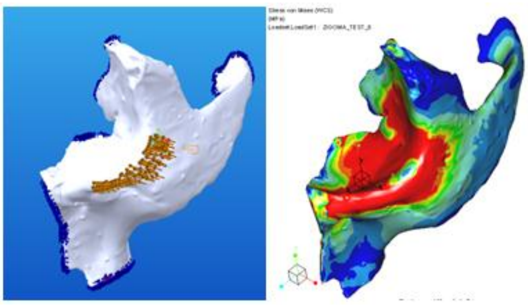


**Figure 6. Test.4. Applying the force under the eye area with an extended surface.**

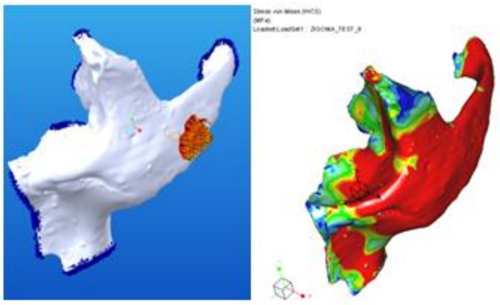


**Figure 7. Test.5. Applying the force in the margin of the temporal mastoid area.**

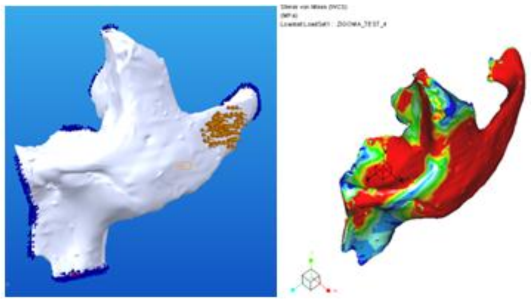


**Figure 8. Test.6. Applying the force in the temporal mastoid area.**

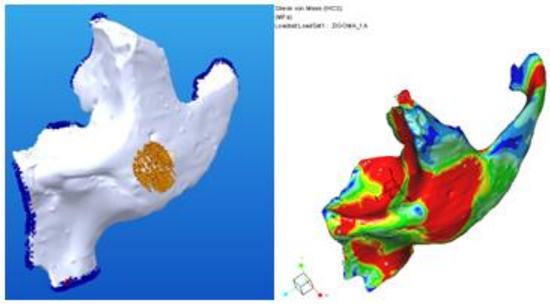


**Figure 9. Test.7. Applying the force on the surface with 45 grade angle.**

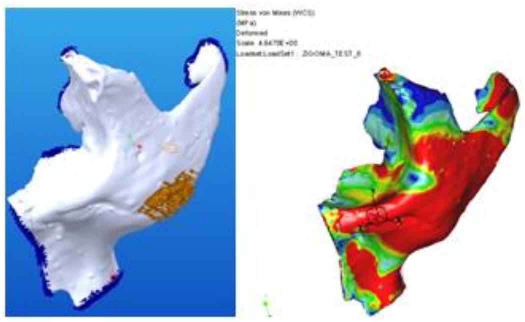


**Figure 10. Test.8. Applying the force in the maxillary process area.**

The finite element analysis was conducted with the Creo Simulate 2.0 software from the PTC Creo package. To succeed in the finite element analyses the 3D model has to be solid. Because the model from the MIMICS soft was STL type (Fig.1 left), it had to be converted into solid 3D model (Fig.1 right).

## 5 IMPLANT DESIGN

This chapter follows the design and the finite element analysis (FEA) of a personalized implant for the maxillofacial area with the help of the Creo Parametric software, taking into consideration the analyses from the previous chapter.

The aim of this chapter is to design a customized medical implant with similar mechanical characteristics like natural bone, which will be manufactured from the Ti6Al7Nb alloy.

The virtual model of the zygomatic bone was obtained from the CT data, which allowed for designing the model with the mechanical properties of the cortical bone, weighing 26 g. The new customized implant designed for this case study has to fulfill the biocompatibility conditions (and mechanical resistance) as well as nearing the weight of the actual bone. But it has to mechanically withstand a maximum force of 5000 N. The Figures 11 and 12 present the constructed versions designed for the medical implant.

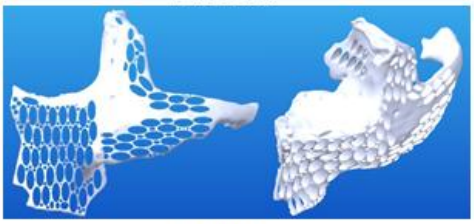
Version 1.

Version 2.

Version 3.

**Figure 11**. **Frontal and isometric view of Constructed version 1, 2 and 3**.

Version 4.



Version 5.

**Figure 12**. **Frontal and isometric view of constructed version 4 and 5**.

Figure 13 and 14 present a detailed analysis of the 3rd constructed version. In this version, holes with elliptic and round shape were used, same as in the previous versions. The only difference being that the distance between the holes was reduced in order to increase their number in the temporal mastoid area.

The elliptic holes were situated vertically as well as horizontally with a length from 6 to 12 mm and thickness from 2.5 to 3 mm. In the area under the eye, holes with a depth from 3 to 7 mm, were used to avoid the zygomatic arch.

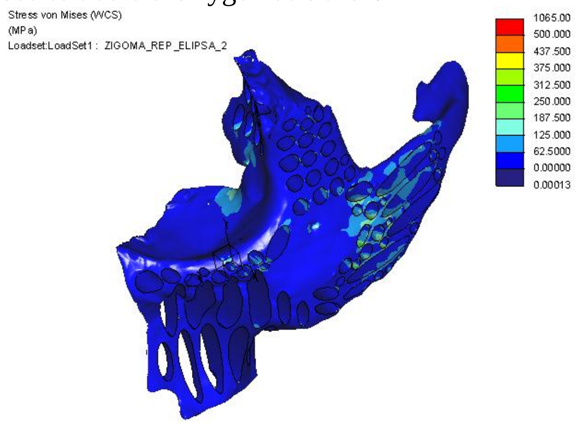



**Figure 13**. **Von Mises tensions**.

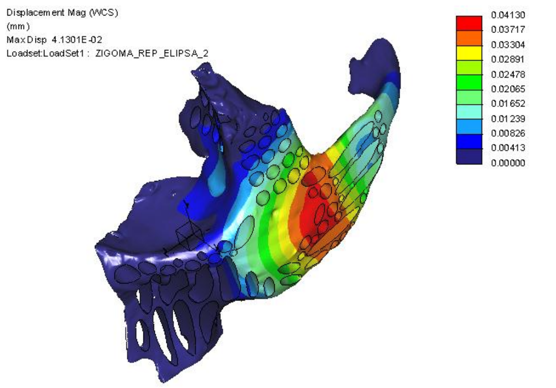



**Figure 14**. **Deformation diagram after the force was applied**.

It was observed, after the analyses, that the third version had a weight of 44.7 g (figure 15). On the tension diagram on figure 13 it can be observed that the maximum tension value is under the maximum resistance value of the Ti6Al7Nb alloy, made by 160W laser beam power. The maximum deformation rate, after the force was applied, was 0.04 mm, as shown in figure 14.

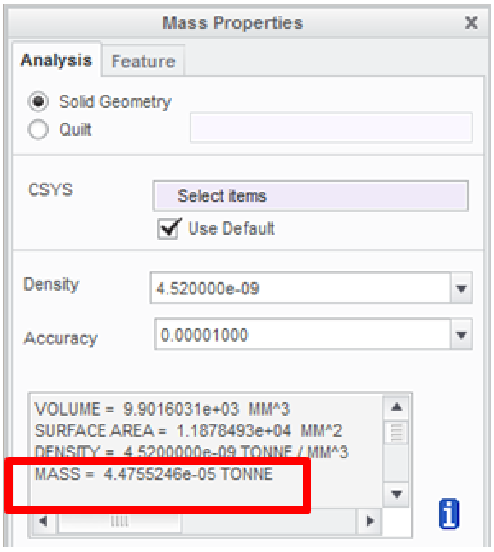



**Figure 15. The weight of the constructed version 3rd.**

## 6 RESULTS AND DISCUSSION

The finite element analyses, on different areas of impact showed the zones which need more attention in the designing stage: the central, the temporal mastoid, under the eye and the zygomatic arch area. These areas need to be taken into consideration in terms of mechanical resistance to redesign the customized implant.

It can be observed from the design and analyses of the different customized implants that every constructed version has a different weight value. It became obvious that it wasn't enough to only use elliptical and round shaped holes but also the distance between them had to be diminished.

It is important to mention that, in order to obtain an implant with the lowest weight possible and to maintain the conditions of biocompatibility and mechanical strength, blind holes were used in the marginal and temporal mastoid areas besides reducing the distance between the holes. The results of the analyses can be observed in Table 3.

**Table 3**. The results of the analyses.

| No. | Variant | Weigth [g] | Max. Tension [MPa] | Max. Deformation [mm] |
|---|---|---|---|---|
| 1 | V1 | 49.99 | 450 | 0.04 |
| 2 | V2 | 47.66 | 401 | 0.03 |
| 3 | V3 | 44.75 | 437 | 0.04 |
| 4 | V4 | 37.2 | 1200 | 0.11 |
| 5 | V5 | 35.63 | 1073 | 0.09 |

After analyzing the results obtained, the implant was redesigned. In this version the weight and the structure resistance was optimized with the help of holes of different diameters (from 1 to 2 mm) as seen in figure 16. It can be observed that the distance between the holes was reduced to the minimum to efficiently reduce its weight.

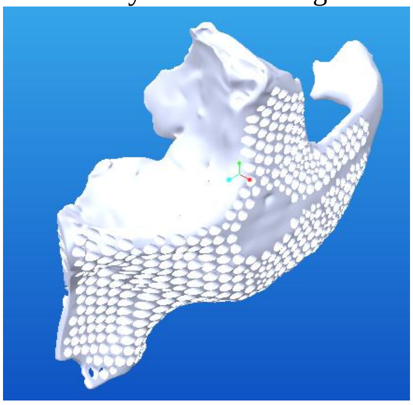


**Figure 16. Isometric view of optimalized version.**

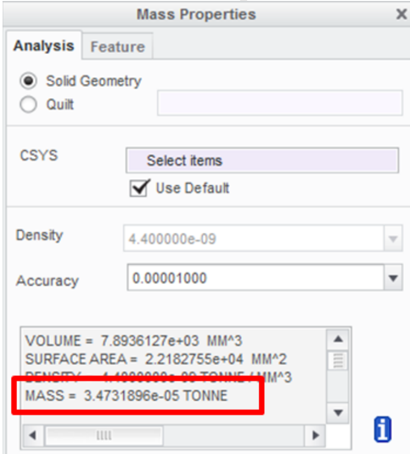



**Figure 17. The weight of the optimalized version.**

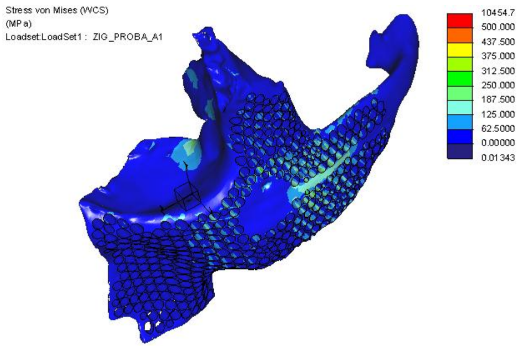



**Figure 18. Von Mises tensions of optimalized version.**

In the marginal and temporal mastoid areas blind holes with different depth were used (from 2 to 4 mm), without affecting these areas and reducing the weight of the implant. In the temporal mastoid zone the distance between the holes was 2 mm, slightly larger than the other areas to keep the mechanical stiffness of the implant. The holes were made only in a single direction normal to the frontal surface of the implant.

With all the modifications done to this version of the implant, the total weight of it was reduced to

34.73 g (Figure 17). It can be observed that using only round shaped holes and minimizing the distance between them has a major effect in reducing the weight of the customized implant.

Analyzing the tension diagram of the redesigned version of the implant in figure 18, can be seen that the values are under the maximum yield stress (500 MPa). The maximum value of 1045 MPa on the tension diagram is due to the local tension concentration. Also, it can be observed that tensions over 63 MPa appear only in the margins of the temporal mastoid and the zygomatic arch areas. Therefore the 0.05 mm value in figure 19 represents the maximum deformation of the redesigned implant after the impact at 5000 N force, which is very close to the versions analyzed in the previous chapters.

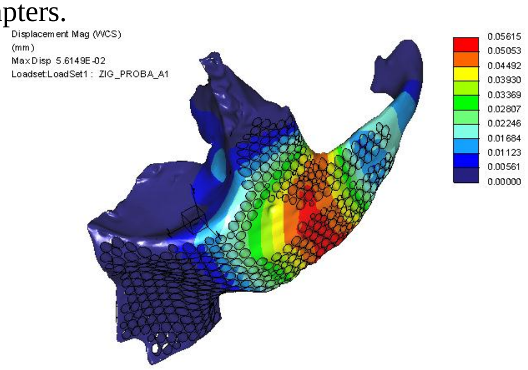



**Figure 19**. **Deformation of the optimalized version**.

## 7 CONCLUDING REMARKS

The finite element analyses highlighted the areas of impact that need more attention in designing a customized implant such as the central, the temporal mastoid, under the eye and the zygomatic arch area. These areas need to be taken into consideration in terms of mechanical resistance at the redesign stage.

It was established that to obtain the sufficient mechanical resistance and the optimal weight, the use of round shaped holes and the reduction of the distance between them was necessary.

The analyses and the design completed in this paper resulted in a redesigned and optimized maxillofacial implant.

To conclude, the new redesigned and analyzed implant can be an optimal solution to replace the damaged zygomatic bone of an individual, because it not only has a weight of 34.7 g, which is very close to the original bone weight (27 g), but it also respects the mechanical and biocompatibility conditions as well.

## 8 ACKNOWLEDGEMENTS

This research was supported by the AM-CIR project, PN-II-RU-TE-2014-4-1157, no. 37/01.10.2015 financed from the UEFISCDI by the Romanian Government.

## 9 REFERENCES

► Khaja Moiduddin, Abdulrahman Al-Ahmari, Mohammed Al Kindi, Emad S. Abouel Nasr, Mohammed Ashfaq, Sundar Ramalingame (2016). *Customized porous implants by additive manufacturing for zygomatic reconstruction*, Nałęcz Institute of Biocybernetics and Biomedical Engineering of the Polish Academy of Sciences. Published by Elsevier Sp. z o.o;

► Harrysson, O.L., Hosni, Y.A. and Nayfeh, J.F. (2007),*Custom-designed orthopedic implants evaluated using finite element analysis of patient-specific computed tomography data: femoral-component case study*, BMC Musculoskeletal Disorders, Vol. 8, p. 91, available at: www.biomedcentral.com/1471-2474/8/91;

► M. Ranaa, M.-M. Gellrichb, N.-C. Gellricha, (2015), *Customised reconstruction of the orbital wall andengineering of selective laser melting (SLM) core implants*, British Journal of Oral and Maxillofacial Surgery 53 (2015) 208–209;

► Vandenbroucke B, Kruth J (2007) *Selective laser melting of biocompatiblemetals for rapid manufacturing of medical parts.* Rapid Prototyp J 13(4):196–203, ISSN 1355-2546*;*

► Leordean D. (2011) PhD Thesis: *Theoretical and experimental research regarding of RP Technologies in the manufacture of customized orthopedic implants*, Technical University of Cluj-Napoca, Romania;

► Leordean, D., Radu, S.A., Fratila, D., Berce, P., (2015) *Studies on design of customized orthopedic endoprostheses of titanium alloy manufactured by SLM*, International Journal of ADVANCED MANUFACTURING TECHNOLOGY, Volume: 79, Issue: 5, 2015, ISSN: 0268-3768, DOI 10.1007/s00170-015-6873-0, pp. 905-920, FRI: 1,779;

► Cowin, S.C. (2001), *Bone Mechanics Handbook*, Informa Healthcare, New York, NY;

► Victor Papilian, (2006), *Anatomia omului*, *Aparatul Locomotor* , Ediția a XII-a., Editura ALL, ISBN: 978-973-571-690-5;