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DESIGN AND CONSTRUCTION OF A CUSTOM IMPLANT OF THE TEMPOROMANDIBULAR JOINT PRODUCED BY ADDITIVE MANUFACTURING IN TITANIUM ALLOY FROM COMPUTED TOMOGRAPHY

Rafael Ferreira Gregolin
Felipe Estevão da Silva
Faculty of Engineering, Mechanical Engineering Course, Federal University of Grande Dourados (UFGD), Dourados (MS), Brazil
rafaelgregolin@ufgd.edu.br, felype_estevao@hotmail.com

Reginaldo Ribeiro de Sousa
Faculty of Engineering, Energy Engineering Course, Federal University of Grande Dourados (UFGD), Dourados (MS), Brazil
reginaldosousa@ufgd.edu.br

Cecília Amélia de Carvalho Zavaglia
Dept. of Materials Engineering, State University of Campinas (UNICAMP), Campinas (SP), Brazil
zavagl@fem.unicamp.br

Ruís Camargo Tokimatsu
João Antônio Pereira
Dept. of Mechanical Engineering, Paulista State University (UNESP), Ilha Solteira (SP), Brazil
ruis@dem.feis.unesp.br, japereira@dem.feis.unesp

Abstract. *Biomodels are physical reproductions of anatomical structures of regions or organs of the human body used for diagnosis and surgical planning. The use of tomographic images for generating 3D models and manufacturing of biomodels has been awakening a great interest in the medical area. It is possible, with the use of medical images, to generate representative computer models, thus enabling several simulations and biomechanical analysis of the region or organ of interest, aiming at the manufacture of customized prosthesis or orthesis. In this work we present the project of a customized implant of the TMJ, mechanically ordered and manufactured in titanium alloy by the additive manufacturing process of DMLS. Through the model created for the TMJ region, computer simulations of stresses and deformations were performed on the mandible virtually implanted in the patient, considering severe stresses of human chewing applied to the frontal teeth. With the data from the computer simulations the prosthesis was analyzed through a conventional analytical design process to verify the fatigue failure resistance. The implant was fabricated in titanium alloy by additive manufacturing and was realized physical simulations of the coupling of the prosthesis in the biomodel of the mandible fabricated by three-dimensional printing.*

Keywords: *Three-Dimensional Modeling, Biomodels, Finite Elements, Medical Images, Customized Prosthetics.*

1. INTRODUCTION

Studies of the behavior of implanted joint replacements, known as arthroplasties, are scarce and rarely performed in academic community. The study of experimental simulations of the prostheses in representative conditions of the human anatomy is a difficult task to perform and has a high cost, as a result is little applied. There are numerous studies of failure, which leads us to understand the importance of previously analyzing the behavior of the interaction between human body and prostheses, in order to minimize cases of failure [1, 2]. A solution to this question is to use a three-dimensional modeling that enables computational simulations of the implanted region, showing an interaction between the prosthesis and the human body and its limitations.

A three-dimensional digital image allows the creation of customized prostheses and orthesis from an identical copy of the patient's anatomy. Furthermore, it also allows the development of an implant from the generated biomodel, in order to find a perfect adaptation to the region of the tissue, organ or body functions that need to be replaced.

Multidisciplinary is required for a proper development of a biomodel. Professionals from different areas are required in order to complete the process efficiently. It is very important to share information between professionals in the computer science, medicals and engineering. In some cases, is essential for medical staff to plan the surgery using a biomodel, as this allows a real verification of the area that will be operated and replaced by the implant. In addition to this, the professionals involved can also manipulate the object and perform simulations of the surgery, handling all required surgical instruments and the implant itself. As well, the surgeons can perform the connections of the prosthesis with the region of interest of the human body that needs to be replaced [3].

In the construction of implants some manufacturing processes are used, among them, we can mention the foundry, the machining, the forging and more recently the additive manufacturing or rapid prototyping. The manufacturing process chosen depends on the type of prosthesis material and its respective geometry. Each manufacturing process has its limitations and advantages, and the designer is responsible for analyzing the best option for the construction of the intended implant. In the case of custom (personalized) prostheses of metallic material the foundry is impracticable because molds would have to be made for each patient in order to be implanted, which would make this type of manufacturing process very expensive. This situation also applies to forging. Manual machining processes are also not practicable, since the use of three-dimensional models depends on the reading provided by the software in the manufacturing equipment. Therefore, for efficient manufacturing of custom metal implants, there are only two manufacturing processes, CNC machining and additive manufacturing. The additive manufacturing has the advantage of having minimal geometric restrictions due to the type of process used in these equipments, which often can be considered as a problem during the CNC machining process [4-8].

Biomaterials are already used in additive manufacturing equipment and allow the construction of implants by this innovative technology. One of the current metal additive manufacturing technologies is known as direct laser metal sintering (DMLS); this process provides the construction of metal implants from a 3D drawing by sintering a metal powder using a high power laser [9, 10 ,11].

The DMLS technology uses a high-power CO2 laser. In this process the metal is sintered directly without addition of binders (Agglutinative substances). The atmosphere of the building chamber is controlled by an inert gas, usually argon or nitrogen. The chamber is heated to reduce residual stresses generated during solidification and the laser strikes the material causing its heating in the right proportion in order to obtain a fusing puddle, where the material of the lower melting point alloy will be liquefied to provide an adequate wettability of the solid by the liquid, which will constitute the solid piece in the geometry desired for the construction of the physical model or customized implant. All additive manufacturing processes are made layer by layer and a roller spreads the powder in each vertical movement of the building chamber. Lastly, the piece that was prepared in 3D design or obtained by three-dimensional scanning by some technological process like computed tomography, magnetic resonance imaging or ultrasonography is ready [7].

The generation of mathematical models through computed tomography is a consolidated process already done in several countries of the world. The improvement of the mathematical models created through this process has been studied by several authors, showing the potential of this technique in the analysis and modeling of the regions of the human body [9, 11, 12].

The innovation of the work presented is the creation of a custom implant specific to the Temporomandibular Articulation (TMJ) region through an anatomical geometric model generated with the help of a computed tomography and afterwards constructed in titanium alloy by the DMLS additive manufacturing process. This method allows the production of biocompatible titanium alloy pieces that have been used in the manufacture of prostheses for decades.

2. MATERIALS AND METHODS

The powder used during the additive manufacturing process of the implant was the Ti-6Al-4V titanium alloy and the manufacturing equipment used was the DMLS type, EOSINT M270 model. The materials and equipment were supplied by the INCT-BIOFABRIS/UNICAMP Laboratory.

The study was carried out from computed tomography (CT) files of an individual's skull performed on a Cone Beam i-CAT tomograph. The tomographic files were received in DICOM format.

All parameters used in the tomograph followed standard procedure for generating files in the DICOM format. Computed tomography generated 577 two-dimensional images in shades of gray in the size of 800 x 800 pixels. The thickness between the slices (two-dimensional images) of the skull was 0.30 mm.

The creation of the computational model of the mandible, its analysis and validation, are presented in the article by Gregolin et al., 2017 [13]. This work shows about evaluating a patient's healthy jaw through the application of forces that simulate severe conditions of human chewing. All boundary conditions, muscular forces and constraints are presented in the article [13], the figure 1 shows the steps of the work described.

In the healthy mandible model, two types of simulations were performed, at where the mechanical properties of the interface between the condyle and the joint fossa were altered, that is, the articular disc. The simulation of two conditions for the representation of the interface between the condyle and the joint fossa (articular disc) showed the versatility that the designer would have for the development of customized prostheses, being able to portray the synovial fluid and the real articular disc with elastic characteristics, which can lead to several reanalyzes involving different efforts. It is also important to note that comparing the two models created in this stage of the work (articular disc of elastomeric material and bone disc) showed small differences in the results of tensions and deformations, indicating that simpler models, used in works present in the current literature, also provide consistent results that can be used in simulations [13, 14].

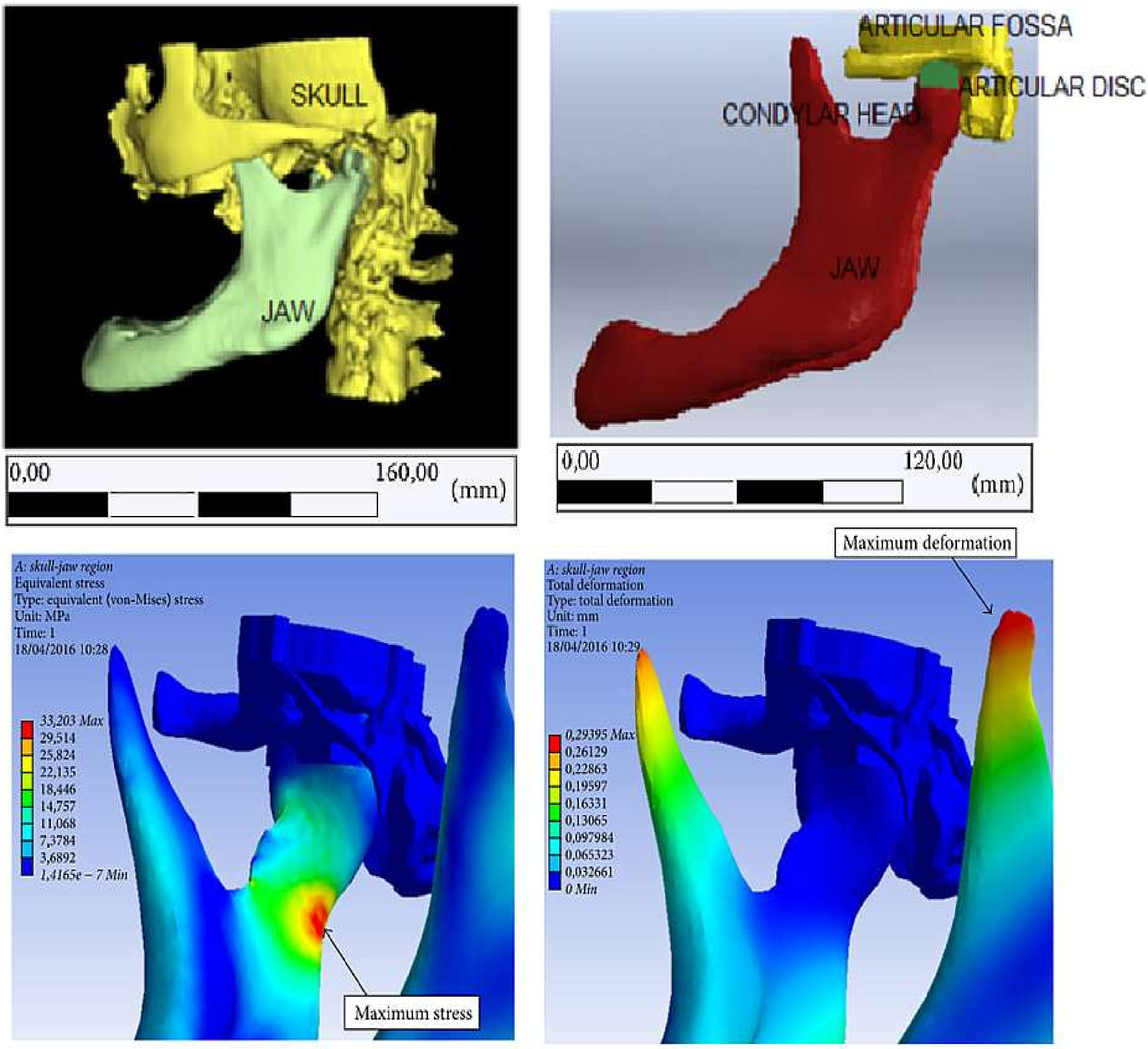

Figure 1 - Development of the Computational Model of the Healthy Jaw.
Source: Author data.

For finite element simulation the element SOLID187 (Ansys Software) was used, which is an element with 10 nodes and 6 degrees of freedom at each node, allowing translations and rotations in the x, y and z axes. The element is composed of 10 nodes distributed as shown in figure 2. This element allows simulating plasticity, hyper elasticity, deformation, stiffness, large deflection and high stress capacities. Used often in structural analysis of complex solid geometries [13, 15].

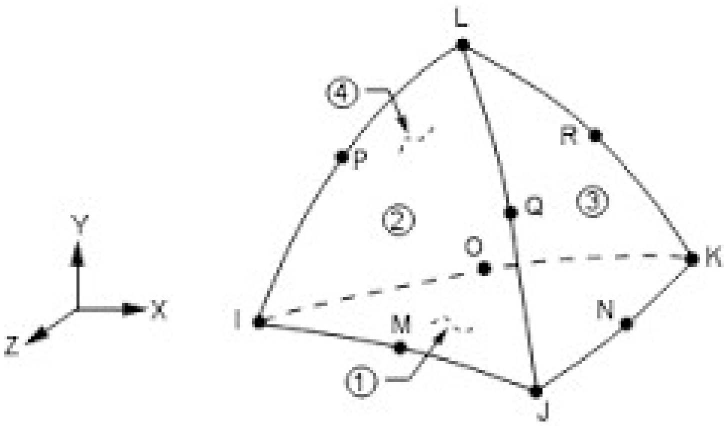

Figure 2 – Solid Tetrahedral Element - SOLID187.
Source: [15].

The development of the model and simulation of the healthy jaw, presented in the work of Gregolin et al., 2017 [13], can be used to elaborate a new computational model that simulates a fracture of the left mandible condyle, allowing the introduction of an alloplastic implant in titanium alloy.

The simulation and previous acceptance phase of the implant geometry, stress and strain analysis and creation of the TMJ prosthesis is described in the second paper elaborated by Gregolin et al., 2017 [16], figure 3 illustrates the mentioned work in this paragraph.

To create the implant, the left surface of the mandible face was copied through computational tools, producing the same outline of the implantation region for the developed prosthesis. At this point a thickness was applied to the created surface because it is only one face without depth, in the case of the custom implant was defined thickness of 2.0 mm for generating a solid 3D from the surface [16].

The titanium implant called the TMJ Condyle Plate was introduced only on one side of the mandible, thus creating an asymmetry in the mathematical model with the objective of simulating a critical stress condition, ensuring the strength of the prosthesis in extreme cases of loading [16].

After introducing the materials properties in the Ansys software, the next step was to generate the finite element mesh with enough richness to present, after the simulations, clear convergence of the stresses. The finite element mesh created has the number of nodes of 804.595 and the number of elements of 538.307 [16].

Through the model developed for the TMJ region, computational simulations of tensions and deformations were performed in the patient's mandible, considering the severe efforts of human chewing applied to the front teeth (incisors) of the mandible. The maximum tension found in the implanted mandible, located in the prosthesis, was $191.10\,MPa$ and the maximum deformation found in the mandible was $0.28\,mm$ [16].

After the simulations and acceptance of the implant geometry the construction of custom prostheses in titanium alloy by additive manufacturing process of the type DMLS was started.

In some cases, such as the implant designed in this study, the DMLS process can perform a densification of the material in an efficient manner and for this to happen the machine must have a favorable environment, where the liquid phase must be present in sufficient quantity to ensure a fast filling of the pores, since it is known that the laser generates energy to the material in fractions of seconds and this soon will cool since the process is fast and punctual. The wettability of the solid by the liquid must be high and the energy absorbed will be transmitted by conduction during the process. The higher the specific area of the powders (the lower the powder particle size), higher be the denser of the material [7].

Table 1 - Construction parameters used in the EOSINT M270.

DMLS Machine Parameters	
Laser Power	170 W
Scan Speed	1250 mm/s
Layer thickness	30 microns
Line spacing	100 microns
Construction strategy	Zigzag (rotating 45° at each layer)

Source: Data provided by Biofabris laboratory (Unicamp) [16].

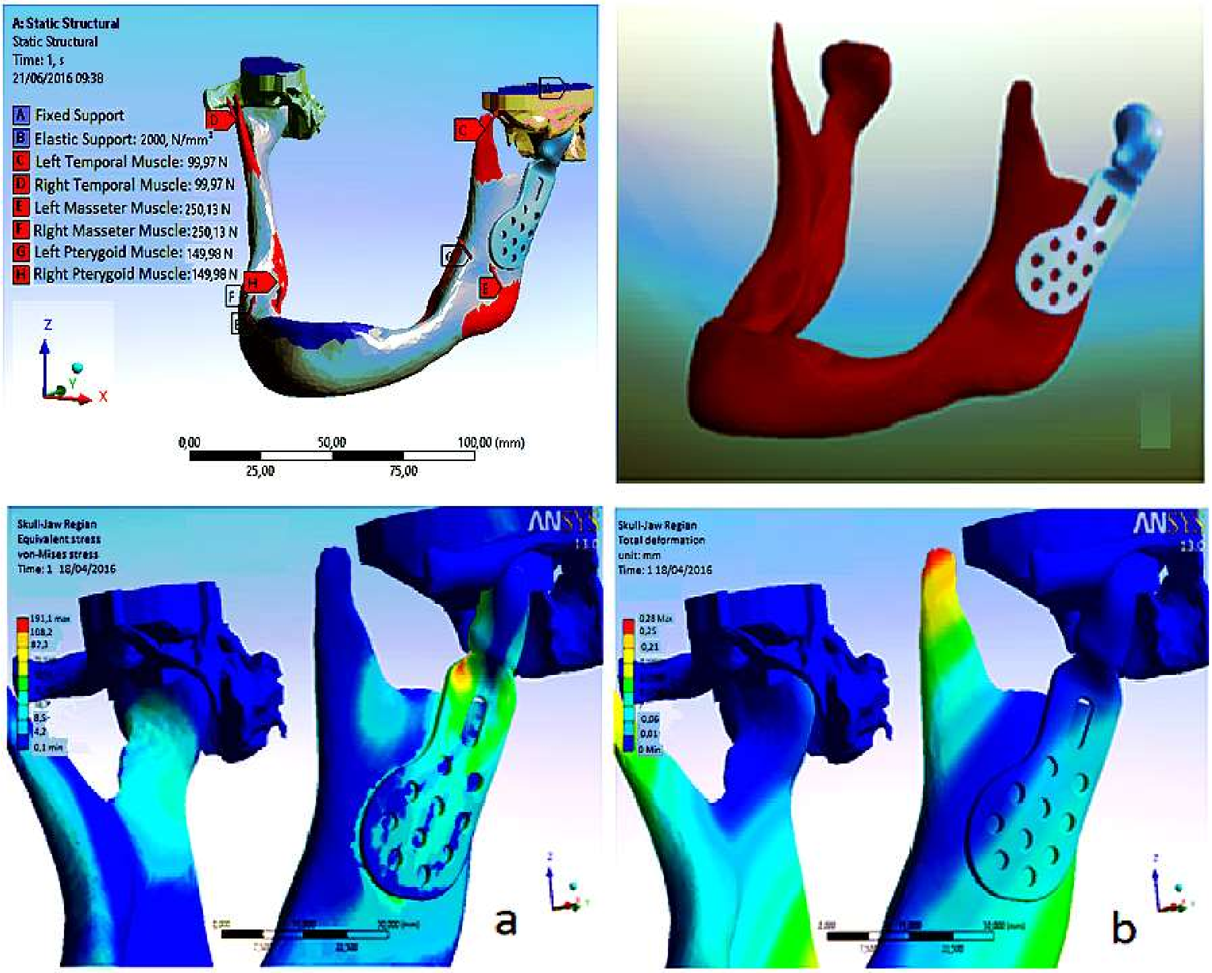

Figure 3 - Implant creation and analysis of stress and strain in the jaw implant.
Source: Author data.

The machine parameters defined in the construction of the custom implant by additive manufacture are those recommended by the equipment manufacturer, when the objective is to produce parts with maximum densification. The manufacturing parameters are shown in table 1.

3. RESULTS AND DISCUSSIONS

In this stage, the analytical simulation of the implant resistance to fatigue failure will be approached through the results obtained by the numerical computational simulation. Also, the manufacture of the prosthesis is described in DMLS type additive manufacturing equipment. Finally, the physical simulation of the personalized TMJ implant will be discussed, reporting the fixation of the metallic prosthesis in a polymeric material mandible biomodel.

3.1 TMJ Implant Fatigue Resistance Calculations

Through mechanical tests in the alloy manufactured by additive manufacture it was determined that the yield limit of the implant constructed by DMLS in titanium, tested in traction, is $957.00\,MPa$ [17]. The result obtained is greater than the value of the maximum stress found in the computational simulation of the TMJ Implant that was $191.10\,MPa$. Statically the safety factor (n_y) for loading applied in the simulation is calculated by dividing the yield stress ($s_y = 957.00\,MPa$) by the maximum stress in the implante ($s_{max} = 191.10\,MPa$).

$$n_y = s_y / s_{max} \tag{1}$$

Applying equation 1, n_y is equal to 5.01. An acceptable factor for a titanium implant which can be considered a material with safe characteristics for biomechanical structural functions.

For the calculation of the endurance limit, in a conservative way, the ultimate strength was used as follows [18].

$s_{ut}=1172.00\,MPa$ (ultimate strength) [17].

$se'=0,5\,x\,s_{ut}$ (endurance limit) (2)

Using equation (2) and the ultimate strength [17] is possible to find the endurance limit of the order of $se'=586.00\,MPa$.

It is important to emphasize that the use of this equation is more usual for steel alloys, however, since it is a custom implant, it assumes high safety parameters, which can be obtained by the use of conservative boundary conditions such as the use of this equation.

Applying the modifying factors of the endurance limit, the new stress value will be [18].

$$se=k_a\,x\,k_b\,x\,k_c\,x\,k_d\,x\,k_e\,x\,k_f\,x\,se' \tag{3}$$

Where,
k_a= surface condition modification factor
k_b= size modification factor
k_c= load modification factor
k_d= temperature modification factor
k_e= reliability modification factor
k_f= miscellaneous-effects modification factor
se'= rotary-beam test endurance limit

For the implant proposed in this work, the factors k_d and k_f were considered equal to unity, since there were no high temperature variations end the modifications due to varied effects were not considered.

The k_a factor is calculated as follows [18].

$$k_a=a\,s_{ut}^{\;b} \tag{4}$$

Where a and b are parameters for the **Marin** modification factors. As the result of the calculation of the endurance limit will be performed for more critical region, ie, in the region of highest von Mises, this area has ideally a polished surface finish. For this type of finish the value of k_a is considered equal to 1.

The k_b factor is calculated as follows [18].

$$k_b=\left(\frac{d_e}{7,62}\right)^{-0,107} \tag{5}$$

Where d_e is calculated as follows in equation (6) [18].

$$d_e=0,808\,x\,(hxb)^{0,5} \tag{6}$$

Where, (hxb) is the cross-sectional area of the maximum von-Mises stress, point of greatest criticality. Measuring the dimensions of the geometric model we have the value of $(hxb)=18.80\,mm^2$.

Applying the value of $18.80\,mm^2$ in equation (6) and then recalculating to equation (5) we have the value of $k_b=1.08$.

Considering an axial load of repeated stress the value of k_c will be equal to 0.85. And then, stipulating a reliability of 95% for the result of the endurance limit, the value of the coefficient k_e will be equal to 0.87. Thus, the final result of the value of the endurance limit calculated using equation (3) is given bellow.

$$se = 1\,x\,1{,}08\,x\,0{,}85\,x\,1\,x\,0{,}87\,x\,1\,x\,586 = 468{,}01\,MPa.$$

Applying the modified Goodman's failure criterion, the value of the fatigue safety coefficient for the developed TMJ implant should be calculated from equation (7).

$$n_f = \frac{1}{\frac{\sigma_a}{S_e} + \frac{\sigma_m}{S_{ut}}} \tag{7}$$

Where, σ_a and σ_m are respectively the amplitude and average stress. Since the simulated load in this analysis is repeated, ie, it goes from zero to the maximum load and returns to zero cyclically, the amplitude and average stress are equal and can be calculated as follows.

$$\sigma_a = \sigma_m = 191.10\,MPa/2 = 95.55\,MPa.$$

Thus applying all the values in equation (7) we obtain the result for the safety coefficient to the fatigue by Goodman Modified equal to $n_f = 3.55$.

Calculating the safety factors for the **Soderberg, Gerber and ASME-elliptical** criteria, the results obtained are shown in table 2.

Table 2 - Static and fatigue safety factors for the Implant.

Condition	Failure Criterion	Safety Factors
Static	von-Mises	5,01
Fatigue	Goodman modified	3,55
Fatigue	Soderberg	3,29
Fatigue	Gerber	4,37
Fatigue	ASME-elliptical	4,47

Source: Author data.

Note that in table 2 that all safety factors were above the value two (2) demonstrating that the resistance of designed prosthesis has a failure static protection and by fatigue above 100%. In addition to this, is also important remember that the calculation were performed considering a situation with highly critical loads, and real chewing conditions of human mandible that are innumerable times softer.

3.2 Construction of the custom prosthesis in titanium and the physical jaw polymeric biomodel for surgical simulation

In the construction of the customized physical model for verification and simulation of the implantation of the prosthesis was used the own implant made in titanium, produced by three-dimensional impression of the type DMLS, coupled to the patient's mandible constructed of ABS polymeric material (Acrylonitrile Butadiene Styrene)**,** also in three-dimensional printers.

In figure 4 the five titanium implants manufactured in the additive manufacturing equipment are identified.

Figure 4 - Titanium prostheses manufactured by DMLS additive manufacture in the EOSINT M270 .
Source: Author data and EOS Info.

The image of the prosthesis coupling verification procedure and surgical simulation is shown in figure 5. In Figure 5 (c) is illustrated the custom implant coupled with the jaw in perspective view. In figure 5 (d) are evidenced all the components of the assembly performed in the surgical simulation. The screws have been adapted to the length of the jaw and do not exceed the thickness of the model.

The diameter of the TMJ prosthesis fixation holes was idealized with a dimension of 2.8 mm, providing the jaw coupling by commercial titanium screws with an external thread diameter of 2.7 mm. The author proposes a polished finish and a nitriding coating on the condyle of the implant. The polishing of the head aims to provide perfect articulation for the TMJ region by reducing the friction. The nitriding coating reduces the wear on the prosthesis joint, avoiding the release of particles in the region.

Figure 5 - Surgical simulation in a mandible with resection of the condyle on the left side.
Source: Author data.

The surgical simulation was performed using commercial stainless-steel screws. In the attempt to introduce the screws without drilling with the drill was noticed the appearance of some cracks in the mandible, procedure not indicated by the author of this work during the surgical act.

In the simulation of the implantation the plate fitting in the jaw worked perfectly, the geometry of the custom board fastening body easily coupled to the geometry of the jaw.

In addition to the implant used in the procedure described, four replicas of the prosthesis were fabricated in order to enable, in future works, the validation of the computational model through experiments.

4. CONCLUSIONS

One limitation of prosthesis analysis is in the model created that does not consider the different densities and types of structures of the bone of jaw. The template developed in the *Invesalius* software and exported in the STL extension assumes a totally homogeneous structure of compact density of the human bone.

In the final model, where the titanium implant was linked, which replaced the area of the left condyle of the mandible, a safety factor of 5.01 for the static analysis was obtained and for the analysis of fatigue failure resistance the most critical condition occurred when the ***Soderberg*** criterion was applied, obtaining a safety factor of the order of 3.29. As the safety factors found are high, this leads to the understanding that the implant developed has excellent indications of the mechanical requirements for the function to which it was idealized.

However, it is necessary to consider that the function of the TMJ implant in the human body has been proven by numerical and analytical simulations, requiring experimental evaluations, making possible the final basement of trust in the development of the prosthesis.

The manufacture of 5 TMJ implants using the DMLS three-dimensional printing technology performed in this study makes it possible to use these parts in experiments simulating conditions similar to human chewing. As future work, static (monotonic) and dynamic (fatigue) loading analyzes can be performed on the customized implant, aiming to experimentally validate the analyzes performed in the presented work.

The results show that this work can be a tool to assist the process of manufacturing, study and analysis of customized prostheses and orthoses from the use of computed tomography.

5. REFERENCES

[1] R. M. Trommer, M. M. Maru, , C. A. Achete, Simulação de desgaste em próteses de quadril. In: congresso latino americano de órgãos artificiais e biomateriais, 2012, Natal. **Proceedings…** Natal: [s. n.], pp. 1-10, 2012.

[2] N. Celebi, E. C. Rohner, J. Gateno et al., "Development of a mandibular motion simulator for total joint replacement," Journal of Oral andMaxillofacial Surgery, vol. 69, no. 1, pp. 66–79, 2011.

[3] J. V. Silva, A. Santa Barbara, M. F. Gouveia, M. C. Reis, and C. A. Zavaglia, "Aplicación del prototipaje rápido al tratamiento de defectos cráneo faciales", Revista CENIC: Ciencias Biológicas, vol. 37, no. 3, pp. 214–218, 2006, Recuperado de http://www.redalyc.org/articulo.oa?id=181220529019.

[4] C. B. L. Ulbrich, Inspeção por digitalização em aplicações de prototipagem rápida na medicina [thesis], Campinas: Universidade Estadual de Campinas, 2007.

[5] G. A. Soares, **Fórum de biotecnologia biomateriais.** 2005. Rio de Janeiro: Universidade Federal do Rio de Janeiro, 2005. Programa de Engenharia Metalúrgica e de Materiais – Instituto Alberto Luiz Coimbra de Pós–Graduação e Pesquisa de Engenharia. Disponível em: <http://www.anbio.org.br/pdf/2/tr10_biomateriais.pdf>. Acesso em: 12 abr. 2013.

[6] A. Santa Barbara, Processamento de imagens médicas tomográficas para modelagem virtual e física: o software InVersalius [thesis], Universidade Estadual de Campinas, São Paulo, Brazil, 2006.

[7] L. Esperto, A. Osório, Rapid tooling, sinterização directa por laser de metais. **Revista da Associação Portuguesa de Análise Experimental de Tensões**, Lisboa, v. 15, p. 117-124, 2008.

[8] M. de F. Gouveia, **Aplicação da prototipagem rápida no planejamento de cirurgias craniofaciais**. [thesis], Faculdade de Engenharia Mecânica, Universidade Estadual de Campinas, Campinas, Brazil, 2009.

[9] X. F. Shan, H. M. Chen, J. Liang, J. W. Huang, and Z. G. Cai, "Surgical reconstruction of maxillary and mandibular defects using a printed titanium mesh," **Journal of Oral and Maxillofacial Surgery**, vol. 73, no. 7, pp. 1–9, 2015.

[10] E. H. Kim, D. H. Lee, S. M. Kwon, and T. Y. Kwon, "A microcomputed tomography evaluation of the marginal fit of cobaltchromium alloy copings fabricated by newmanufacturing techniques and alloy systems," **The Journal of Prosthetic Dentistry**, vol. 22, no. 6, pp. 30352–30353, 2017.

[11] A. Al-Ahmari, E. A.Nasr, K.Moiduddin, S. Anwar, M. A. Kindi, and A. Kamrani, "A comparative study on the customized design of mandibular reconstruction plates using finite element method," Advances in Mechanical Engineering, vol. 7, no. 7, pp. 1–11, 2015.

[12] A. Tarsitano, S. Battaglia, L. Ciocca, R. Scotti, R. Cipriani, and C. Marchetti, "Surgical reconstruction of maxillary defects using a computer-assisted design/computer-assisted manufacturingproduced titanium mesh supporting a free flap," **Journal of Cranio-Maxillofacial Surgery**, vol. 44, no. 9, pp. 1320–1326, 2016.

[13] R. F. Gregolin, C. A. C. Zavaglia, R. C. Tokimatsu, J. A. Pereira, "Biomechanical Stress and Strain Analysis of Mandibular Human Region from Computed Tomography to Custom Implant Development," **Advances in Materials Science and Engineering**, vol. 2017, Article ID 7525897, 9 pages, 2017. doi:10.1155/2017/7525897.

[14] L. S. Bertol, Contribuição ao estudo da prototipagem rápida, digitalização tridimensional e seleção de materiais no design de implantes personalizados, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil, 2008.

[15] Ansys Workbench, 2006. "Ansys 11.0 Program Documentation, SAS IP, Inc."

[16] R. F. Gregolin, C. A. C. Zavaglia, R. C. Tokimatsu, J. A. Pereira, Desenvolvimento de prótese personalizada da articulação temporomandibular através da geração de imagem tridimensional biomecânica a partir de tomografia computadorizada. **14° Congresso da Sociedade Latino Americana de Biomateriais, Orgãos Artificiais e Engenharia de Tecidos,** Article ID 01-002, 8 pages, 2017.

[17] M. A. Larosa, A. L. Jardini, C. A. C. Zavaglia, P. Kharmandayan, D. R.Calderoni, and R. M. Filho, "Microstructural and mechanical characterization of a custom-built implant manufactured in titanium alloy by direct metal laser sintering," Advances in Mechanical Engineering, vol. 6, pp. 8–16, 2014.

[18] R. G. Budynas, J. K. Nisbett, Shigley's Mechanical Engineering Design. [S. l.]: Tata McGraw-Hill Education, 2011.

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