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The mechanical behavior of a dynamically stressed customized skull implant made from different types of biomaterials by Additive Manufacturing technologies

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Abstract. The main objective of the research consists in the determination of the mechanical behavior of a customized implant that is dynamically stressed, especially the way the implant takes external loadings, as well as its influence on the adjacent areas that are destroyed, in close connection with the shape of the implant (solid or perforated) and the type of biomaterial the implant is made from (metallic or non-metallic). The assessment of such a hypothetic situation has been considered in order to determine which material is adequate to be used for the manufacturing of the implant and to determine also if some shape modifications are required to be realized in such a way that the impact shock will be much better resisted and the effect of the impact will be diminished especially in the vital areas, where the implant is in contact with. Such a complex analysis can be realized since the virtual generation of the medical implant, by conceiving different virtual models within the design stage and by performing complex analysis by the using finite element method as well. Our studies showed that the stress state of the assembly components is strongly influenced by the type of material from which the implant is manufactured, The decrease of the implant stiffness by realizing some perforations leads to an increase of the stress state of the implant simultaneous with a decrease of the stress level that is transmitted to the surrounding structures, the implants made from PMMA material have isolating properties superior as compared to the ones of the metallic material.

1. Introduction

It is well known the fact that customized medical implants made by using Additive Manufacturing (AM) technologies are physical elements which are conceived and realized in order to restore different biological structures that were destroyed by

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different reasons, such as accidents, malfunctions, etc, in which case, initial treatment assumed a surgical operation [1-6].

The geometrical shape of the implant must be adapted to the particular conditions of the patient to be operated. In general, these implants do not have a well-known and regular geometrical shape, which can be rigorously defined by simple geometric primitives, but their shape is of free-form type, that can be approximated by a collection of Spline, B-spline and NURBS surfaces, that are interconnected and must complete the anatomic shapes, which are adapted and specific to a particular case [7-12]. The virtual shape of the customized implant can be obtained by using dedicated 3D CAD programs, which use Reverse Engineering techniques (in which in most cases, the starting element is represented by a product of a 3D scanning system) or by generating symmetrical models by mirroring a model considering a plane which is selected in a convenient way or by using boolean subtraction operations between the two models [13-17]. Taking into consideration the role and the importance of these implants, it is necessary to assess their behavior in particular situations (theoretical and real) that may be really faced, in real life situations. Such a particular situation is the strike of the implant area with different objects, leading to a dynamic stress, with high impact especially in the region where the mounting of the implant has been realized [18-20]. For the safety of the patient it is expected that the destruction will appear only at the level of the implant before the stresses transmitted by the loadings will destroy the life tissue that is surrounding the medical implant. In other words, after the strike it is expected that the medical implant will not transmit further on stresses that will cause fracture of the neighboring bone area, such fractures in case of appearance causing an increasing of the destroyed area and in an implicit way, the necessity of producing a new implant, following all the manufacturing stages, starting from a new Computer Tomography image as well [21-22].

2. Experimental design

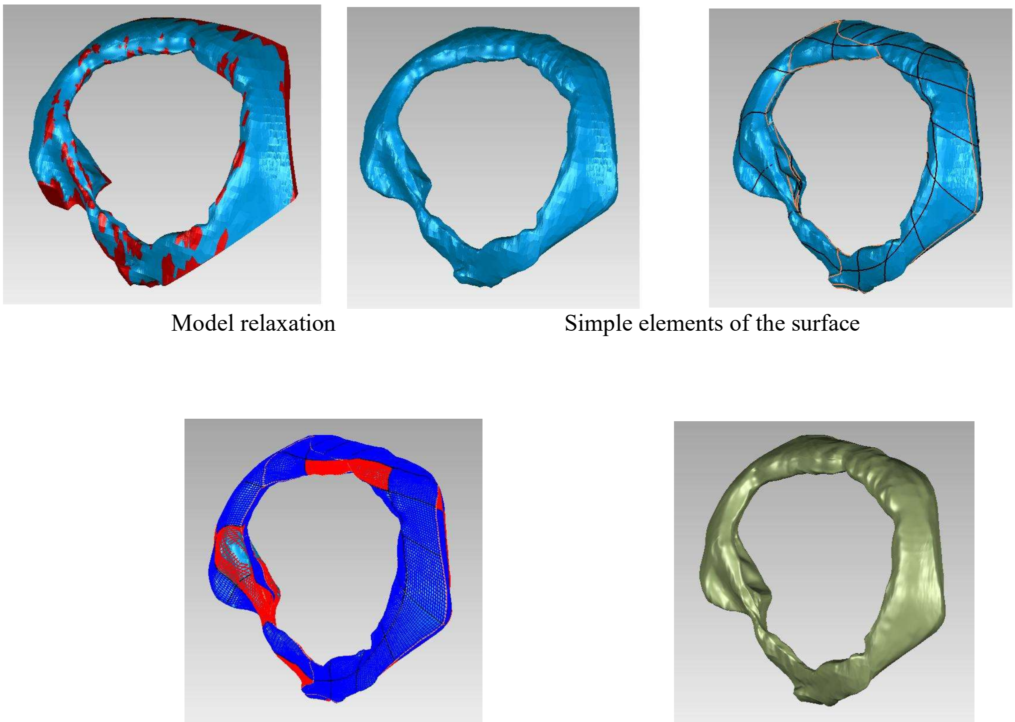
The aim of the present experiment was to determine the behavior of the customized implant, considered as being assembled inside a living patient, being surrounded by “living” neighboring areas, in the context when the medical implant is realized from different types of materials, with different shape variations and stressed in the same dynamical conditions. For a virtual evaluation of such a hypothesis the ANSYS finite element analysis program was chosen, which allows the construction and running of different types of projects that may include practically any type of possible stress that can be considered for such an implant. The experimental project that has been designed consists in striking a customized implant, in assembly state, with a gravitational pendulum. The pendulum consists of a steel ball having a diameter of 100 mm and the weight of 4.11 kg, its length being 1000 mm. The initial position of the pendulum is horizontal, parallel with the terrain, traveling while by free falling, before the impact with an angle of 90 degrees in total. The velocity of the pendulum at the impact moment was determined by using the energy conservation law and had a value of 4.47 m/s.

Three virtual models were considered for the realized experiments, their geometry being defined in a CAD format that it is accepted and recognized by the ANSYS finite element analysis program. The model of representing the ball pendulum has not been difficult to achieve, due to the fact that it was virtually generated by using the SolidWorks CAD program, the model being easily converted in any CAD format required for the made analysis.

The model of the customized implant was realized by using a CAD system as well, by not using boolean operations, being possible to be represented in any format that is required for the made analysis.

The model of the destroyed area is constituted by a native medical model which was obtained by processing the data collected from a Computer Tomograph, its representation in "stl" format being simple and easily realized with a dedicated software - MIMICS [23], software which was specially designed for processing medical models. The "stl" model being not adequate to the aim that has been defined, there were several trials performed during our studies in order to convert the model in a format that is acceptable for the proposed assessment, using some particular CAD programs that are commercially available. The obtained results proved to be unusable at the end, in all cases, the converted files having very high dimensions (hundreds of MB). The use of Geomatic Studio program was a reliable choice in this case, due to the fact that this program allowed obtaining reliable results at the end, even if the resulted models were represented only by an approximation of the initial "stl" models that were used for the made analysis.

With the aim of simplifying the model structure to be analyzed, the model that resulted from the processing of the data taken from the Computer Tomograph (an "stl" model of a skull implant) was "cut", by using the MAGICS program, the resulted model containing at the end the destroyed area and just a small area of the skull structure that is surrounding the destroyed area. This decrease of the model is justified not only by its simplification in the assembly context, but also by the fact that in real applications, the single role of the model in the destroyed area is to check the shape of the implant to be realized. Figure 1 shows the stages that are required to be followed in order to realize the simplified model, with the observation that one stage is considered to be adequately realized if at its end, the model results with no errors.



Model relaxation　　Simple elements of the surface

u and *v* familly curves　　Complete surface of the model

Fig. 1. The main stages required for the conversions of an “stl” model into a CAD model.

By considering the way the final surface of the model is generated and built, it is easy to notice that the resulted surface is only an approximation of the initial model considered for the analysis. The errors which result in comparison with the initial model were determined by the overlapping of the considered models (initial and final), the dimensional differences between the models being in terms of tenths of microns, the average errors being less than five hundreds of a micron. The model conversion (the approximation of the model) was considered as being adequate due to the fact that in the case of medical models, the dimensional errors are in the size of ± 1 micron, values that are considered acceptable in this case.

The final validation of the model correctness was given by the finite element analysis program, the checking being validated by its possibility to recognize, import and meshing the respective model (Fig. 2).

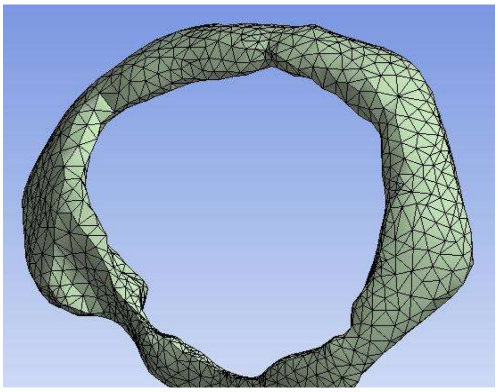


Fig. 2. Model validation.

Once the CAD models of the components involved in the experiment were defined in an adequate manner, the next step consisted in the assembly generation which was made using the Assembly module of the SolidWorks program (Fig. 3).

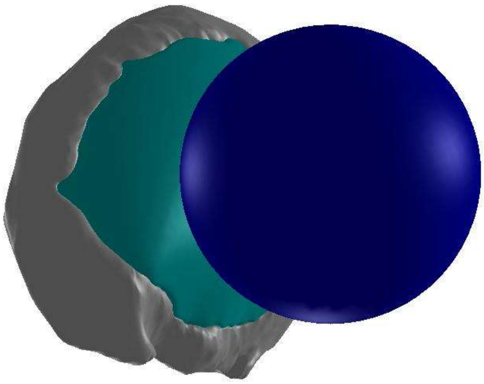


Fig. 3. Generated assembly.

In the stage of defining the models there were considered the options of the ANSYS program regarding the stiffness of all the models involved in the experiment. In this sense, in the case of the ball it was selected the Rigid option and for the destroyed area and the customized implant was selected the Flexible option.

- The ball of the pendulum was considered as being rigid, the maximum dimension of a discretized element being limited to 50 mm. Of course, such a high value, as compared with the size dimensions of the ball has not been used in the case of any other finite element, these elements having variable size, much lower in size and established in close connection with the conditions imposed regarding the approximation accuracy of the shape and the surface quality. By considering that the ball has been defined as being a rigid element, the high value of the size for the elements to be discretized in the case of the ball do not have a significant influence on the accuracy of the obtained results. On the other hand, the large dimension of these finite elements shortens the computation time, due to the lower number of nodes, requiring complex successive calculus for their positions at every stage of the analysis.

- The destroyed area and the customized implant were considered as being flexible elements, the determination of the way of deforming and the stresses accumulated in these components being one of the main objectives of the simulation. The maximum size of the finite elements was maintained at default values, very restrictive conditions being imposed regarding the accuracy of model approximation and the surface quality of these elements.

Figure 4 shows the final and adequate shape of the discretized assembly, with respect to the conditions that were previously detailed.

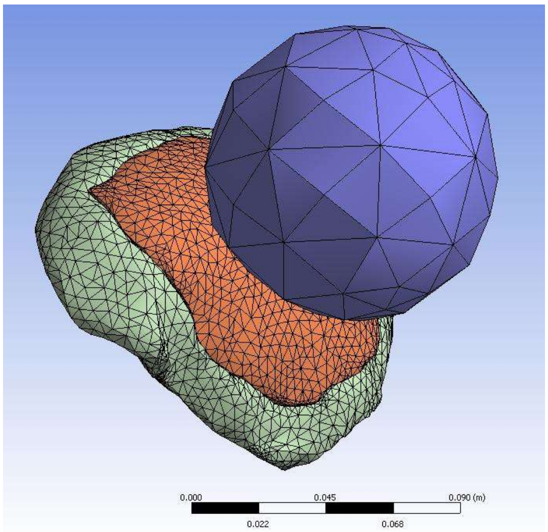


Fig. 4. Meshed assembly.

3. Materials and methods

In the experiment that was conceived and presented previously, the materials which are involved in the analysis are the human bone, the material from which the implant is made and the material of the ball pendulum.

a) Ball. The material of the ball is common steel, the mechanical properties of the material being not important from the experimental point of view, due to the fact that after the analysis, the stresses are no evaluated in the ball, but only the effects of the striking of the ball against the implant – destroyed area assembly region. The only characteristic which is important in this case is the weight of the ball (4.11 kg), this property defining its dynamical characteristics.

b) Human bone. Most of human bones are represented by a complex natural structure which consists of an external dense and compacted layer, namely the compacted bone or cortical bone and a porous core, which is represented by the trabecular zone. The bone material is a composite material that consists in a mixture of collagen and hydroxylapatite. The crystal apatite is very rigid and resistant. Young's modulus of these crystals is 165 GPa, this value being comparable to the one of steel (200 GPa). The collagen does not respect precisely Hooke's law, its Young modulus being in this case about 1.24 GPa. The Young's modulus of the assembly is 17 GPa, this value being an intermediate value of the apatite and the collagen. Like in the case of any composite material with high quality, the strength of the bone is higher as compared to the elements from its composition (separately considered), its properties being improved due to the fact that by the soft component (collagen) the stiffness is being decreased and the occurrence of the small cracks caused by the fragility of the bone is prevented, while the rigid component (the apatite) is maintaining the shape of the assembly in a compacted state [24].

Research that was made in this field indicates that the bone tissue is an orthotropic material, its anisotropy being given by the flat shape of the hydroxylapatite crystals and their partial alignment in a direction considered as being longitudinal, direction which determined the most rigid and most stress-resistant direction of the material If the bone is dry, the Young's modulus increases and the yield strength and fracture strength decrease due to the fact that the content of the collagen is also decreased. A bone which is completely dried, in the case of performing a tensile test, has a linear-elastic behavior [24, 25].

The bone material is not defined in the existing database of the ANSYS FEA program that can be directly accessed and used for different types of analyses. as a consequence, in order to perform the simulation of the experiment, a new type of orthotropic material has been defined, by assigning all the mechanical characteristics of the bone tissue in this case. By considering the hypothetic analysis, as well as the fact that in this case it is aimed to analyze the effect of the mechanical stress in the case of a live organism, in the case of defining the properties of the material there were used the values which are characteristic to a human live tissue (wet) in the end. Table 1 presents the characteristic values of the defined material, these values being taken into consideration in the case of the analysis. the values presented in this table are critical for the defined material and are not sufficient to describe the behavior of the analyzed material while testing. in order to describe and completely define the behavior of this material, in the database of the program were introduced the pair of values presented by Gibson l [25]. It is important to specify at this stage the fact that the properties of the bone tissue are highly influenced by certain biological factors (age, sex, type of analyzed bone), the values considered and used for the analysis in the case of this research being average values.

Table 1. Properties of the compacted bone.

Characteristic	MU	Value
Density	**Kg/m³**	**2000**
Young's modulus E	**GPa**	
longitudinal		17
radial		11,5
tangential		11,5
Elastic modulus G	**GPa**	
longitudinal - radial		3,3
longitudinal - tangential		3,3
radial - tangential		2,3
Poisson's ratio	**-**	
longitudinal - radial		0,41
longitudinal - tangential		0,41
radial - tangential		0,41
Compression strength	**MPa**	
longitudinal		193
transversal		133
Tensile strength	**MPa**	
longitudinal		148
transversal		49

In order to check if the bone material was defined in a correct way, we made a simulation of a collision between the pendulum ball and a medical model which is represented by a piece of skull having the mechanical characteristics and the properties of the new type of material which was defined. Figure 5 shows the assembly involved in this simulation, in the initial position before the ball of the pendulum was starting to move. For the boundary condition, the model has been considered in a bounding box, the bounding surface being formed by the patch surface reunion, which delimits the analyzed model. The made analyses had the main aim to theoretically determine the areas in which the fracture of the medical model is expected to occur.

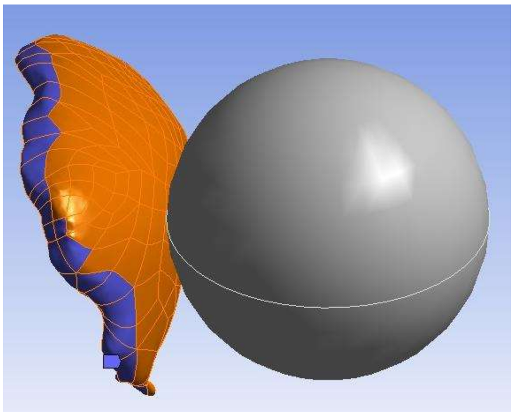


Fig. 5. Assembly subjected to impact.

As a criteria for estimating the fracture zones, we used the assessment of the main maximum stresses variation (traction and compression stresses) and the comparison of these stresses to the ones given by the fracture stresses given by traction and compression tests in longitudinal direction and transverse directions, as well (see Table 1). As it is possible to notice from the variation diagram shown in Fig. 6, the main maximum stresses had a value of 380.71 MPa in the case of traction, an 387.62 in the case of compression, these values being above the limit values given for the traction and compression stresses presented in Table 1, no matter which type of direction is considered (longitudinal or transverse). The first conclusion that was drawn was that in the case of a real load, similar with the one that was simulated, it will result at the end for sure the fracture of the analyzed model. In the same time, the analysis of maximum stress area propagation (areas marked in red on the figure) allowed an estimation of the areas where the cracking would occur in the case of a real experiment to be done (Fig. 6).

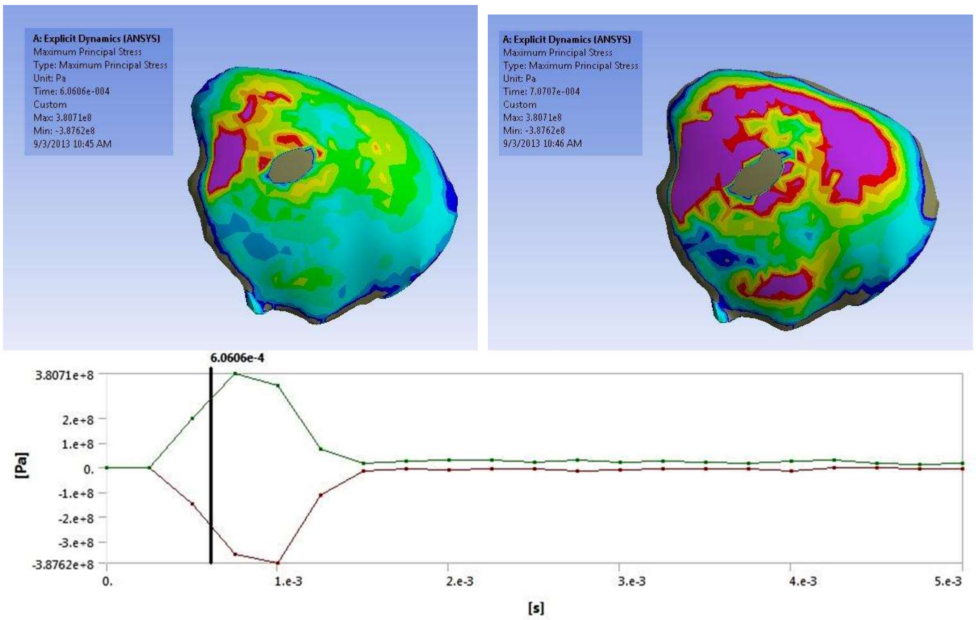


Fig. 6. Variation of the maximum principal stress.

In order to check the theoretical model presented above, we evaluated a collision between the ball and a skull which was presumed from a body. In order to visualize the striking effects, the experiment was filmed with a high speed camera (8000 frames / second), the analysis made after the experiment allowing to precisely locate the cracks and their propagating directions. After the analysis of the frames filmed during this procedure it was possible to notice that the fracture lines are following the direction of apparent displacement of the particular zones with maximum stresses, which means that the material that was considered for the virtual analysis has been correctly defined. Materials considered to be used in the

case of the implant. The materials used for the manufacturing of the customized implants where polymethylmetacrilate (PMMA) in the shape of a bone cement and titanium alloy TiAl6V4 type, which is delivered in powder state, in order to be processed by selective laser melting, technology which is available at the Rapid Manufacturing laboratory from the Technical University of Cluj-Napoca.
The most important mechanical characteristics of the materials used for the fabrication of implants used for the experiments and analyses are presented in Table 2. The behavior of these materials for different types of stresses is completely described by stress-strain curves and state equations that are available in the material database of the ANSYS FEA program.

Table 2. Properties of the implanted materials.

Characteristic	MU	Value	
		PMMA	Ti6Al4V
Density	Kg/m^3	1170 - 1200	4430
Fracture strength (traction)	MPa	38 - 70	950
Yield strength (traction)	MPa	38 - 70	880
Elongation	%	2-10	14
Elasticity modulus E	GPa	2,5 – 3,5	113,8
Poisson's ratio		0,35 – 0,4	0,342
Specific heat	J/kgK	1466	526,3
Thermal conductivity	W/m.K	0,167 – 0,25	6,7

3.1. Choosing the type of interaction between models

As previously mentioned, the hypothetic experiment assumes the dynamic analysis of an assembly which consists of three components, to determine the effects that are caused by the dynamical loads induced by the pendulum ball. The source of these effects is the pendulum ball, the effects on the other components being generated by subsequent interactions that occur between the ball and the implant, the implant and the destroyed area and between the assembly and the environment. The definition of these subsequent interactions has a similar importance as the other planned operations of the experiments, due to the fact that in this case, through this operation will be defined the way how the stresses will be transmitted within the experiment. The order in which these interactions are defined can be freely established by the user, the only conditions being to adequately define these interactions in accordance with a possible real experiment.
A first interaction consists in the interaction between the assembly and the environment, and mainly between the boundary conditions of the assembly, which must be realized in such a way that the model will be statically defined during the entire experiment. In this sense, the surface elements which limits the destroyed area (Fig. 7) are considered as being locked (a constraint that does not allow any degree of freedom and which generates within the fixed element reactions that are oriented along all three directions Ox, Oy and Oz of the reference frame). The

surface elements on which the boundary condition is applied are manually selected by the user.

The interaction that stressed the assembly was given by the collision of the pendulum ball against the implant (Fig. 8). The value of the ball velocity was determined by the energy conservation law (4.47 m/s), its direction being considered for the most disadvantageous situation, along a direction which is perpendicular to the surface of the implant, in such a way that there will not be any tangential components to produce a decrease of the impact energy and by consequence an attenuation of the striking effects. With the aim of maintaining the impact energy at a constant level it was considered that the contact between the ball and the implant is realized with no friction.

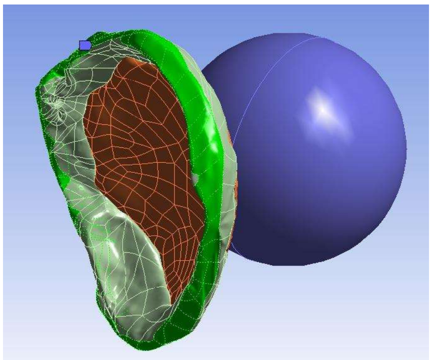


Fig. 7. Clamping of surface elements.

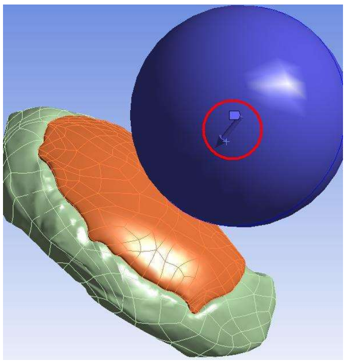


Fig. 8. Impact between the sphere and the implant.

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that after the decimal point, the first five significant numbers will be zero, otherwise it can be considered that the surfaces are not in contact. As it was previously presented, from the practical point of view, the dimensional deviations of 1 mm do not have a significant influence on the functionality of the implant. By taking into consideration the geometrical shape of the patched surfaces, a manual selection of those which are in contact was practically impossible, the best option being the automatic selection (Fig. 9) as it was done with the finite element analysis program, the type of the contact being defined at the end by the user.
From the type of contacts which are possible to be used within the dynamical explicit analyses, such as the presented one, just two were adequate and recommended to be used in this case. The first type was the bounded type contact, which presumes the assumption by the finite element analysis program of different internal conditions which does not allow the displacement of the components during the simulation, which at a superficial analysis seems to correspond to the contact conditions that are required to be imposed in this case for such a type of analysis.

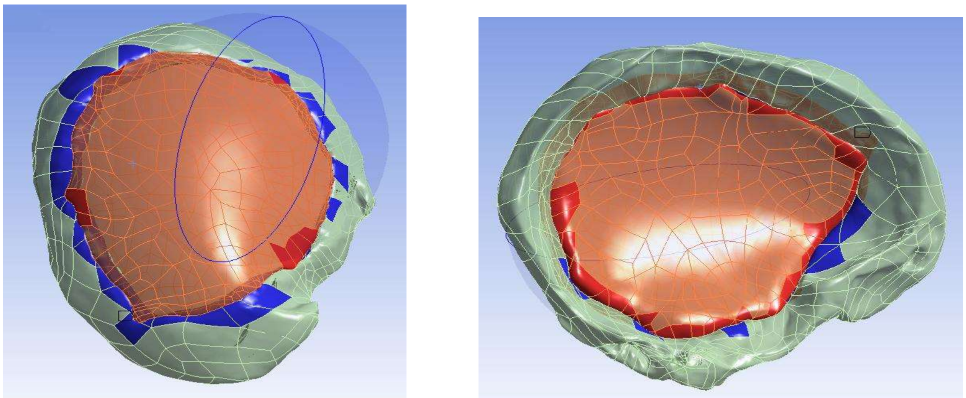

Fig. 9. Surface elements of the implant and destroyed area being in contact.

The interaction that stressed the assembly was given by the collision of the pendulum ball against the implant (Fig. 8). The value of the ball velocity was determined by the energy conservation law (4.47 m/s), its direction being considered for the most disadvantageous situation, along a direction which is perpendicular to the surface of the implant, in such a way that there will not be any tangential components to produce a decrease of the impact energy and by consequence an attenuation of the striking effects. With the aim of maintaining the impact energy at a constant level it was considered that the contact between the ball and the implant is realized with no friction. The most important interaction was between the implant and the destroyed area, due to the fact that through this contact region the stresses from the implant to the surrounded life area are transmitted. The definition of this interaction was limited to the definition of the contact type which exists between the surface elements that exist at the boundary, on the implant and on the destroyed area, as well. Due to the shape errors that occur during the CAD

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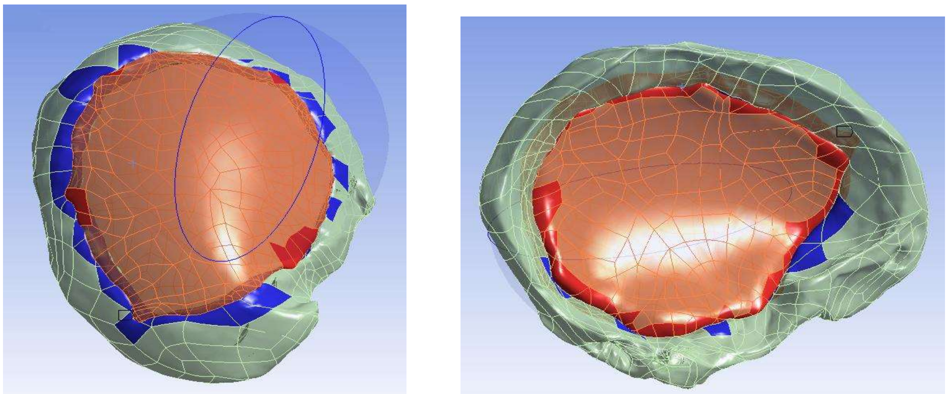

Fig. 9. Surface elements of the implant and destroyed area being in contact.

With all these specifications set, during the simulations that were made with the aim of planning the experiments, it was possible to notice that the implant is being displaced from the destroyed area that is considered as reference, without producing any mechanical stress in this area (Fig. 10). Such a behavior is generated by the fact that, due to the shape error, during the stress period it is allowed the deformation of the implant, leading to a final effect that consists in the separation of the components and their simultaneous displacement.

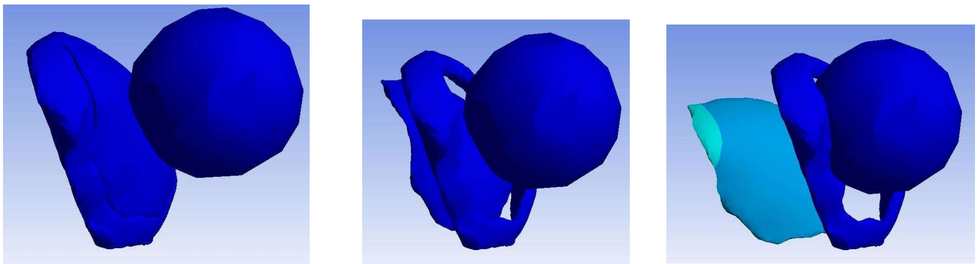

Fig. 10. “Bounded” contact type.

The problem related to the displacement of the components while stressing has been solved by imposing a contact with friction between the components. The following equation is already well known:

$$F_f = \mu \cdot N \tag{1}$$

where: F_f is the friction force, μ – friction coefficient, and N – normal force on the surface on which the friction acts.

If in this relationship, the friction coefficient is considered as having a unit value (μ = 1), i.e. the friction force which acts on any surface becomes equal to the normal force on that surface, which means in this case there is an integral transfer of the forces to the surface area of interest.

So as that the stresses generated by the impact between the ball and the implant will be transferred as adequate as possible, the value of the friction coefficient μ between the implant and the destroyed area has been imposed at 0.99, this value being the maximum value which is allowed by the program.

The previous experiment shown in fig. 10 was repeated in similar conditions, the only difference consisting in the way the contact between the two components is realized.

Figure 11 shows the results obtained in the case of the new experiment that was made, the differences compared to the previous experiment that was analyzed being clearly visible. The ball representation was removed from this figure for a better view and to ease the evaluation of the results.

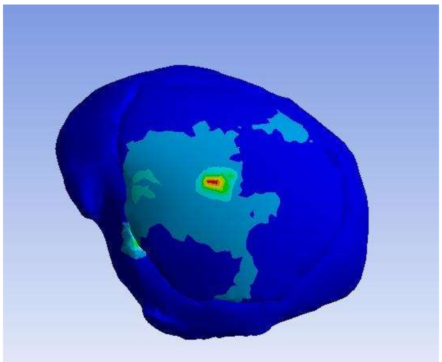

Fig. 11 Friction contact.

3.2. Determination of the experiment period

The simulation period is influenced by the time required for the development of the interaction between the pendulum ball and the assembly formed by the implant and the destroyed area, value that has been loaded as input element in the program in which the simulation is realized. In the following the time of the interaction will be named as the period of the experiment, period which is influenced by the initial relative positions between the ball and the assembly formed by the implant and the destroyed area, this period representing the time while the ball of the pendulum is in motion. In order to determine the optimum periods for the experiments, we made simulations by keeping the geometrical shapes of the models involved, models that comprise simplified hypotheses that were imposed in this sense. The materials that were tested were the generic ones, their behavior being defined as purely elastic (materials with zero plasticity and which do not present residual deformations after the stressing), without being introduced a common value of the fracture stress.
The value of the fracture stress (a mechanical characteristic that is mandatory to be used for defining the behavior of a material) that has been considered for the analysis had two higher size orders as compared to the one of the materials involved in the real simulation (the fracture stress of the generic material was approximately 100 times higher as compared to the one of the real material.
By taking into consideration the simplified hypotheses that were considered it is possible to state that in the case of testing experiment, the pendulum ball is moving along the incident direction until its total energy becomes equal with the potential energy of elastic deformation that it is stored in the impacted assembly, the ball being rejected at this time period, its displacement being continued in the opposite direction, this moment being the one in which the analyzed assembly is considered as being stressed with a maximum force. the appreciation of the moment in which the two energies are equal was realized by analyzing the stress diagrams that resulted at the end of the testing experiments (fig. 12). as one may notice in fig. 12, the value of stresses that are stored in the analyzed assembly presented an increasing tendency until a critical value was reached, followed by a decrease of the stresses, which correspond to the overlapping of the moment in which the values of the two energies are equal, when the ball already changed the direction of its motion.

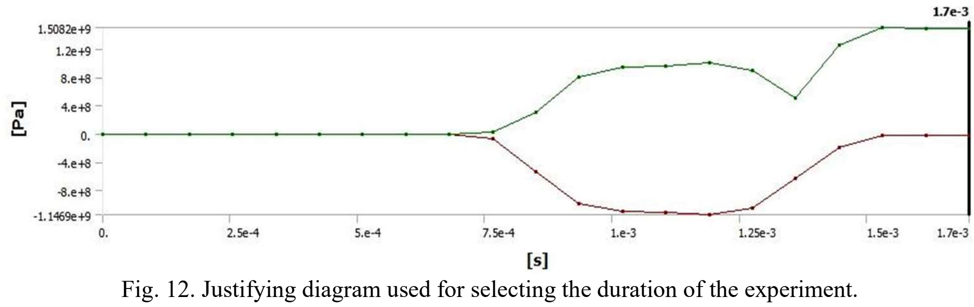

Fig. 12. Justifying diagram used for selecting the duration of the experiment.

In order to determine the optimum period of the experiment there we made simulations with different time periods that were varied between 0.5 ms and 2.5 ms (the precise values were: 0,5; 0,7; 1; 1,2; 1,5; 1,7; 2; 2,5 ms). By analyzing the stress diagrams corresponding to these testing experiments it was possible to notice that the two resulted energies were equal at 1.2 – 1.3 ms time period. The optimum value of the experiment period was 1.7 ms, this value being considered a covering period that allowed the rejected ball to be displaced to the initial position and to get out from contact with the analyzed assembly. Figure 12 shows only one of the analyzed cases, this analysis being realized with respect to the aspects that were presented above and justifying meantime the selected choice. The realization of the experiment tests with variable periods was required to fulfill the initial objective, allowing on the one hand the realization of the analysis without the time limitation of the interaction period, and on the other hand, allowing the possibility to determine simulation time periods as lower as possible at the end. During the experiments, the time required for performing the simulation varied from 6 hours for a 0.5ms time period of interaction to 28 hours for 1.7 ms time period and 48 hours for 2.5 ms time period, the differences being in all these cases, as one may notice, significant in the end. It can be specified the fact that the period of the experiment which was selected is specific to the designed experiment, being influenced by the relative position that has been imposed between the ball and the assembly that formed by the implant and the destroyed area considered in the analysis. For any other relative position of the models involved in the experiment, the time period selection for the experiment assumes the repetition of the experiment tests and the re-interpretation of the stress diagrams obtained in this way after the analysis.

4. Results

The virtual analysis of a hypothetic impact between the customized implant and a tough body was realized for 4 distinctive cases, by considering different shapes of the customized implants (solid and compact implants and perforated) and different types of materials for the manufactured implants made by SLS and SLM (PMMA in the bone cement state and TiAl6V4 powder alloy material). The assemblies implant- destroyed area realized in this way, were impacted by a pendulum in in a similar way with the situations previously described. Figure 13 illustrates the schematic representation of these simulations in the initial position. The effects of the dynamic stress were evaluated in close connection with the stresses stored in the implant and those transferred by the implant to the destroyed area due to the fact that from the stressing point of view, there is a comparison term given by the fracture strength (at traction and compression) of the analyzed material.

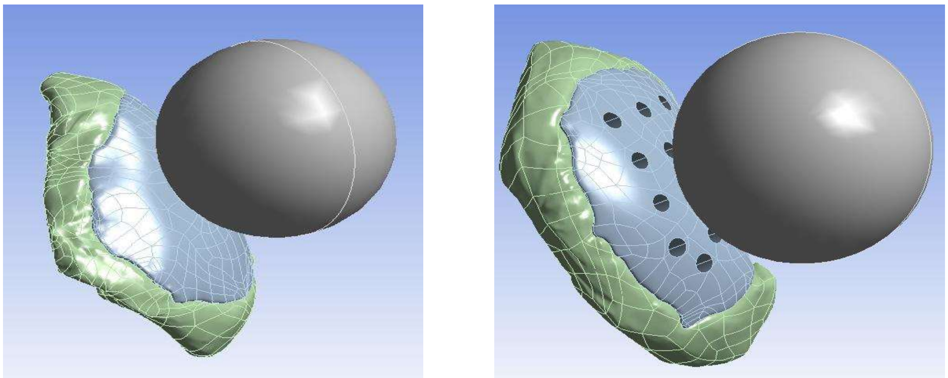

Fig. 13. Assemblies considered for the analysis.

The analysis of the strains generated by the dynamic stress is purely informative. The size of the strains is difficult to be evaluated due to the fact that the results that are obtained are expressed in percent and the determination of the effective size of the deformations raise difficult problems due to the irregular shape of the analyzed models and their non-uniform thickness as well.

As evaluating criteria for the determination of the stresses there were considered the von Mises equivalent stress and the maximum main stresses, the realized analysis being similar with the one realized for the validation of the material models. The stress distribution in the case of the 4th analysis case is presented in the following images, for the assembly implant- destroyed area and for the destroyed area in particular, as well:

1. Implant with solid structure made from PMMA (Fig. 14 and Fig. 15).

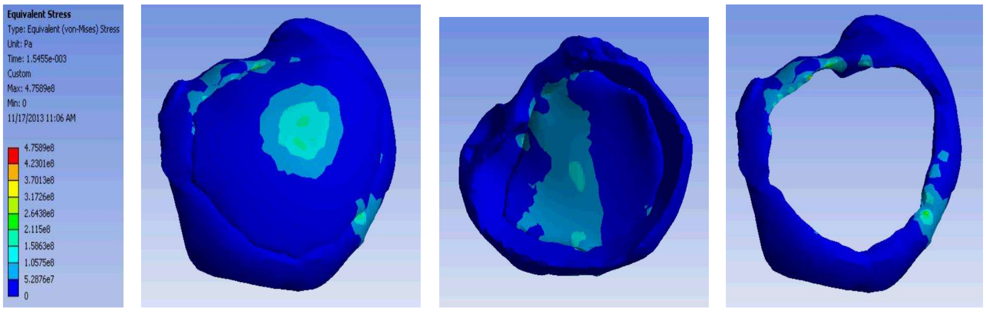

Fig. 14 Equivalent stress.

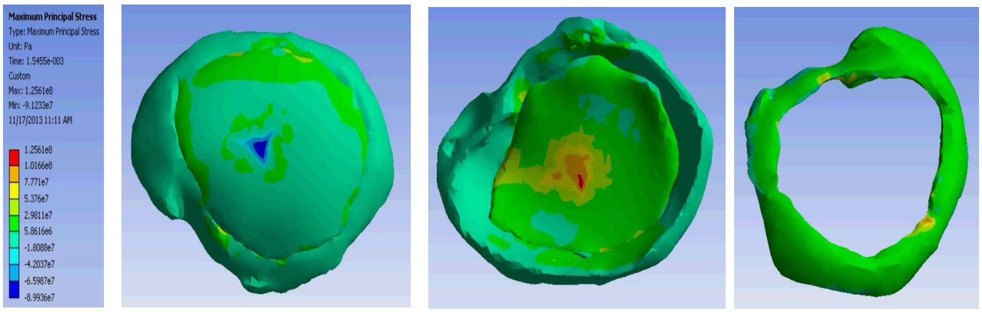

Fig. 15. Maximum principal stress.

2. Perforated implant made from PMMA (Fig. 16 and Fig. 17).

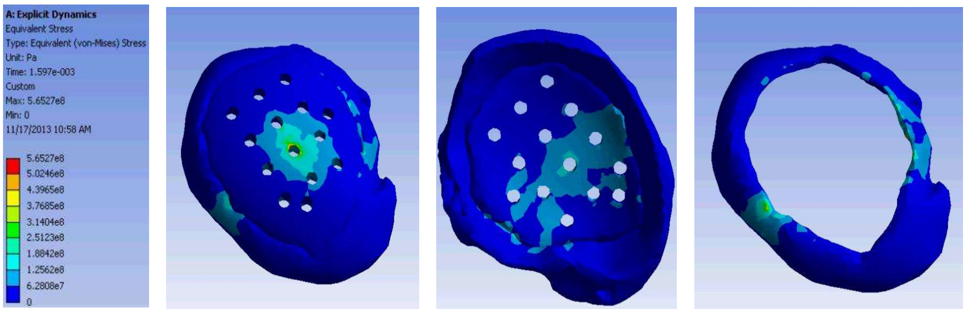

Fig. 16. Equivalent stress.

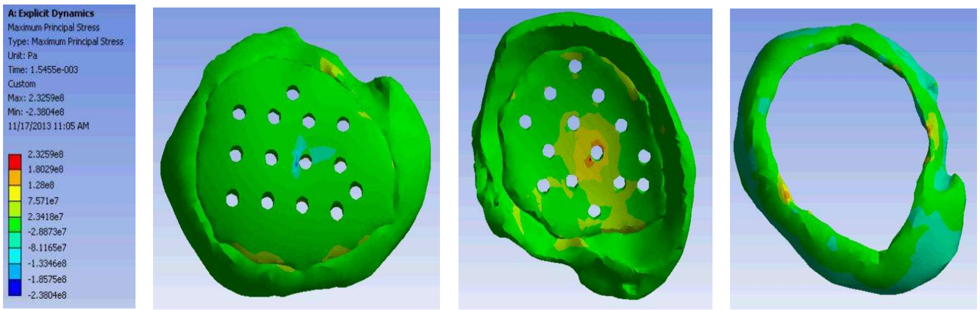

Fig. 17. Maximum principal stress.

3. Implant with solid structure made from TiAl6V4 (Fig. 18 and Fig. 19).

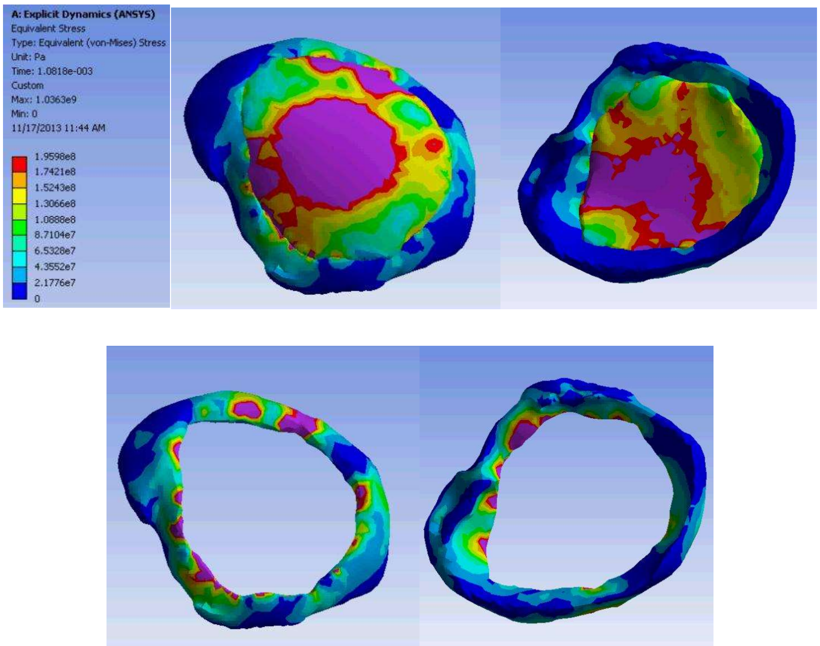

Fig. 18. Equivalent stress.

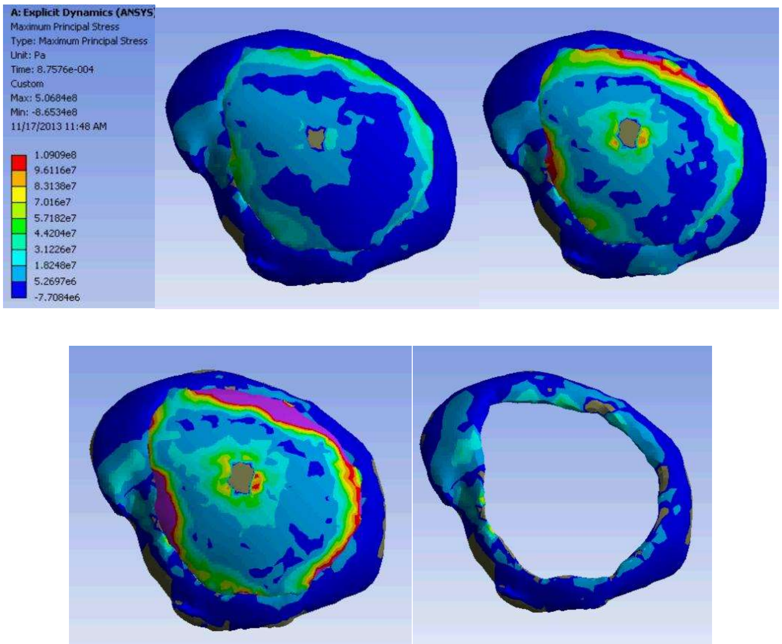

Fig. 19. Maximum principal stress.

4. Perforated implant made from Ti6Al4V (Fig. 20 and Fig. 21).

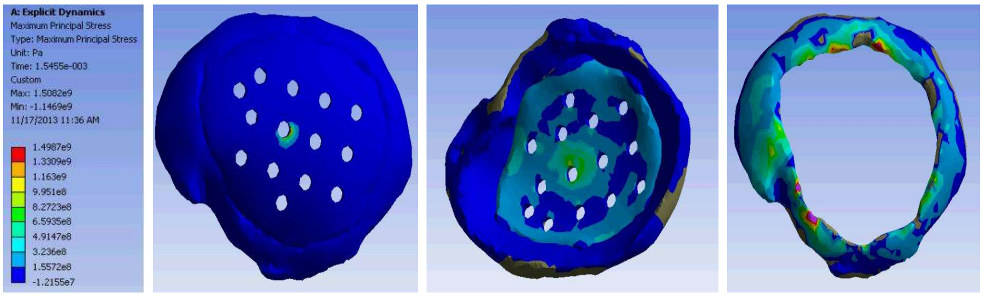

Fig. 20. Equivalent stress.

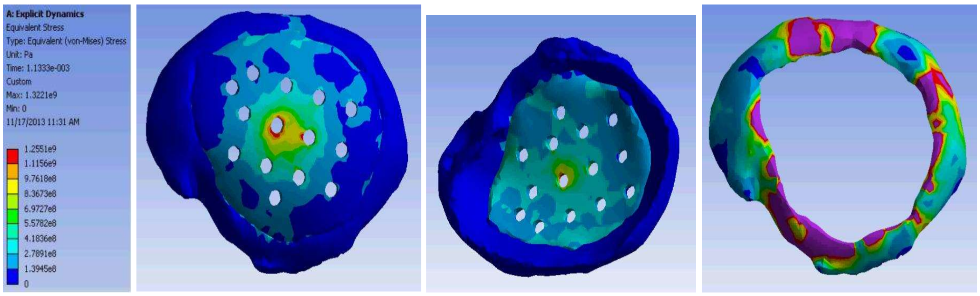

Fig. 21. Maximum principal stress.

By taking into consideration the conditions in which the impact simulation was realized it was considered that in all cases the general stress of the assembly generated by the ball of the pendulum is identical, the value of the stresses stored in the components of the assembly only depending on the properties of the materials from which these components are made from. Table 3 lists the value of these stresses sorted out by considering the analyzed component and the experiment which was simulated.

Table 3. Stress values.

	PMMA		**Ti6Al4V**	
	Implant	**Destroyed area**	**Implant**	**Destroyed area**
Solid	σ_{echiv}= 475 MPa σ_{min}= -89,9 MPa σ_{max}= 125 MPa	σ_{echiv}=435 MPa σ_{min}= -46,8 MPa σ_{max}= 103 MPa	σ_{echiv}=195 MPa σ_{min}=-77 MPa σ_{max}=109 MPa	σ_{echiv}= 509 MPa σ_{min}= -79 MPa σ_{max}= 195 MPa
Perforated	σ_{echiv}= 565 MPa σ_{min}= -238 MPa σ_{max}= 232 MPa	σ_{echiv}= 408 MPa σ_{min}= -38 MPa σ_{max}= 98 MPa	σ_{echiv}= 125,5 MPa σ_{min}= -120 MPa σ_{max}= 149,8 MPa	σ_{echiv}= 470 MPa σ_{min}= -39,5 MPa σ_{max}= 412 MPa

5. Discussions

The present research has underlined yet again the utility of AM technologies in the manufacturing of personalized implants out of biocompatible materials which can reproduce the shapes and sizes of a native bone with a very high fidelity. This provides a maximum contact surface between the implant and the live bone, which in result will lower specific pressures in the case of static or dynamic stresses.

Our results have shown that the stress state of the assembly components is strongly influenced by the type of material the implant is realized from (Table 3). As a consequence, in the case when the implants are made from PMMA, the stress stored in the implant is high, but due to the elastic behavior of this type of material, the action of the implant on the destroyed neighboring area is significantly reduced as compared to the case when the customized implant is realized from titanium alloy material. The stress state of the implant made from Ti alloy material is reduced, but the destructive effect of the implant on the surrounding tissues is highly superior in this case.

In the same time, it was possible to notice a decrease of the stress that results in the destroyed area in the case when the implant is realized with a perforated structure, the supplementary machining operations leading to a decrease of the component stiffness, this allowing the storage of higher value of stresses in the structure of the implant and therefore a stressing highly diminished on the surrounding components (in the analyzed case, of the destroyed area). By analyzing the previous cases presented from the strain point of view, it is possible to notice in the case of the implants made from PMMA that these values are much higher as compared to the reached values obtained in the case when the implants are made from metallic materials. In terms of size, the strain differs with approximate one order, from the physical point of view, these values being approximate 5 mm in the case of the implants made from PMMA as compared with 0.5 mm, that were obtained in the case when the implants are made from metallic materials. By comparing the resulted stresses stored in the components of the assembly with the maximum strength of the involved materials, it was possible to notice that the theoretical values that were determined by calculus were much higher, indicating the fact that in the case of a real stressing in accordance with the one presented by simulation, the analyzed components will be destroyed. This aspect can be explained by the fact that the simulation of the experiments cannot be stopped in the moment when the value of stresses reaches a critical level, the element of control being only the period of the experiment in this case and not the possible mechanical destruction of the analyzed components, as well. From the point of view related to the period after which in the destroyed area cracks occur, in the case of the implants made from plastic materials, this period is 1.5 to 2 times higher as compared to the one reached in the case of the implants made from metallic materials.

By connecting this period with the stress levels are reached in the case of the components of the analyzed assembly, in the case of implants made from PMMA, the moment when the cracks occur in the destroyed area is after the braking or destroying of the implant, which represents a hypothesis that can be a real benefit in a real situation, being desirable in this case that the major effect of the stressing to be recorded at the level of the implant and not at the level of the life surrounding tissues (the level of the destroyed area).

6. Conclusions

The virtual simulations that were made had the main objective to determine the optimum geometrical shape of the customized implants and the adequate materials from which these implants should be made, in such a manner that the realized implants would exhibit a maximum safety for the patient to be operated at the end. In the simulating processes, as material to be used in the case of the implant, there were considered two types of materials with mechanical characteristics that are completely different. These type of materials were polymethylmetacrilate (PMMA) in the bone cement state and TiAl6V4 alloy in the powder state. As regarding the shape and structure of the implant, there were considered for the analyses two cases: one in which the implant has been considered in compact state (with a fully solid structure) and other in which the implant presents perforations. The presence of the perforations can be medically justified, these perforations blocking the accumulation of liquid between the implant and the soft surrounding tissues, this liquid if present generating an unwanted pressure on these type of structures. After the analyses and after the interpretation of the results it was possible to draw some important conclusions, such as:

- The stress state of the assembly components is strongly influenced by the type of material from which the implant is manufactured. In this sense, the implants made from PMMA material stores stresses that are much higher as compared with the case when the implants are made from metallic material, the Young's modulus that has lower values in the case of plastic material leading to a decrease of the stress transferred to the surrounding structures as compared to the case when the implant is made from metallic materials.
- The decrease of the implant stiffness by realizing some perforations leads to an increase of the stress state of the implant simultaneous with a decrease of the stress level that is transmitted to the surrounding structures, without being influenced by the state of the material from which the implant it is made with.
- The weight of the implant made from PMMA is three times lower as compared to the weight of the implant made from titanium alloy material.
- By considering the thermal properties (specific heat and thermal conductivity) of the two types of materials considered for the analyses it was possible to notice that the implants made from PMMA material have isolating properties superior as compared to the ones of the metallic material, leading to the patient increased comfort in the end.

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