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OPTIMIZATION OF THE CONSTRUCTIVE FORM OF A Ti-6Al-4V ACETABULAR PROSTHESIS

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In some medical cases, depending on the development of bone tumours, it is necessary to design and manufacture customized prostheses. The present paper proposes to present the results regarding the design optimization of a customized acetabular prosthesis made of titanium alloy and obtained using the rapid prototyping process. In order to optimize the design, two bone-prosthesis assemblies were designed and their in-vitro stability was studied using finite element analysis (FEA). The paper also presents studies on the optimization of the shape of prosthetic models, following which the mechanical stresses and the overall displacements in the bone-prosthesis assembly were reduced by eliminating the stress concentrators. The simulations demonstrated that both models can withstand the normal stresses that occur during the normal use of the prosthesis, but the model with additional ears showed superior stability.

Keywords: prostheses, titanium, FEA

1. Introduction

Statistically, it was found that 15% of all primary malignant bone tumours involve the pelvis. Advances in systemic and local disease control through effective chemotherapy treatment have improved survival rates and have led to the development of surgical methods which allow the maintenance (as far as possible) of the integrity of the limbs in anatomical and functional terms. The patients' overall survival rate after such surgery is good when appropriate excision margins are selected.

The specific anatomy and the usually large size of pelvic tumours make the setting of the appropriate excisional margins while maintaining limb integrity a discouraging challenge. Saving lower limbs in malignant tumours can be achieved in many situations, thus contributing to reducing the social and

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psychological costs associated with amputation. Surgical excision of periacetabular malignant tumours often involves the complete removal of the acetabulum and the partial or total removal of the pubic bone and ischium (Fig. 1) [1].

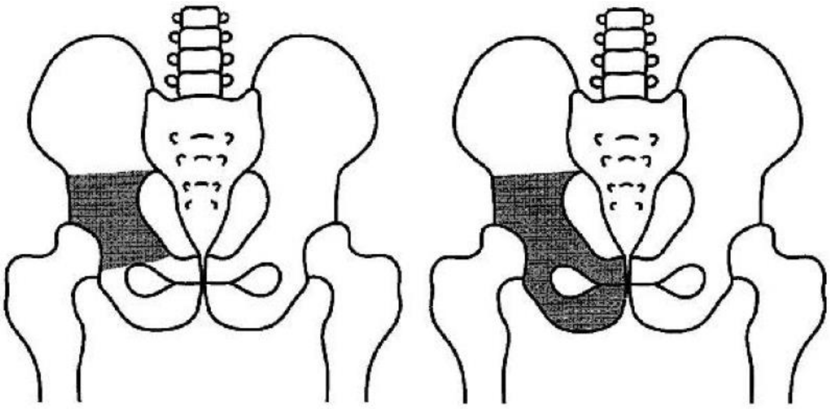


Fig. 1. Areas excised in the case of periacetabular tumours

Complete excision of the acetabulum may often be necessary, which results in a non-functional hip (pseudarthrosis), but femoral arthrodesis to the rest of the bones (ilium, pubis, ischium or sacrum) can provide improved stability. The non-functional hip, pseudarthrosis and arthrodesis, all lead to considerable limb shortening, inclination of the pelvis, impaired walking, and back pain.

Modern treatment involves pelvic reconstruction by biological or mechanical means. Biological reconstruction uses allografts or reimplantation of excised bone after autoclaving and sterilization. Allografts may be combined with endoprostheses (APC system - **A**llograft **P**rosthesis **C**omposite) [2]. The most commonly used method is the mechanical reconstruction of the pelvis using customized prostheses, which allow maintaining the length of the lower limbs and restoring the natural function of the hip.

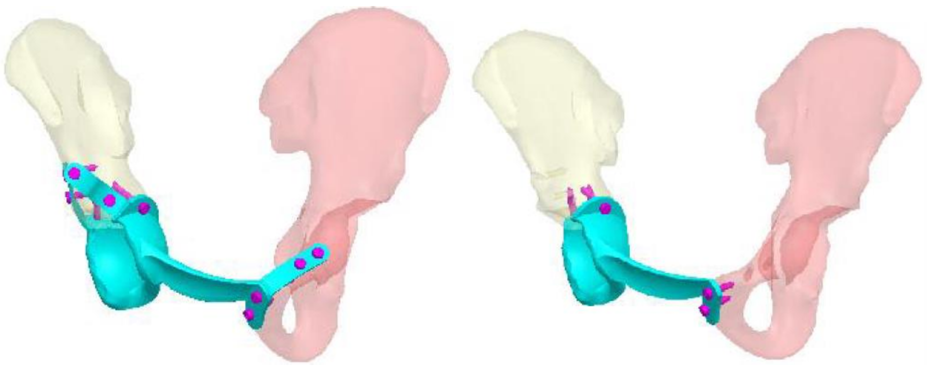
The course of the operation differs from patient to patient depending on the severity of the condition, but in principle after the resection level is determined, the affected bone portion is removed while preserving the integrity of the sciatic nerve and its ramifications. In most cases, it is necessary to design a customised prosthesis to replace the resected bone portion, which is fixed on the remaining intact bone with bone cement and/or with orthopaedic screws. A total hip prosthesis (a commercial model) is usually used together with this customized prosthesis, so that the normal function of the affected lower limb is restored [3].

2. Experimental procedure

The main purpose of this paper is to optimize the design of a customized prosthesis made of titanium alloy Ti-6Al-4V, which was designed using the medical images obtained from a CT scan. Following the design of the optimal 3D model, the prosthesis can be made using a CNC manufacturing process or by applying an additive manufacturing process.

Taking into account the complexity of the prosthesis design, two models of bone fixation (Fig. 2) were taken into consideration. To facilitate the selection of the design, and since the hip joint area involves extreme mechanical stress, the in-vitro stability of the two models was studied using the finite element analysis before manufacturing the prosthesis using rapid prototyping.

Computational models of the mechanical structures have been successfully applied for a long period of time in the study of biological systems. Due to irregular three-dimensional geometry, material inhomogeneity, complex loads and movements and non-linear behaviour, the finite element method represents the optimal approach to bone structure analysis [3].



a) b)

Fig. 2. The 3D models of prosthesis proposed for analysis:
a) – the version with additional clamping ears, b) – the simple version

Maximum stresses occur in the hip joint in the unipodal support position as well as during normal walking. Walking is the daily activity that generates the highest loads in the hip joint, inducing forces which act cyclically on the system, with a period imposed by the walking cadence (frequency). The loading of the femoral joint (Fig. 3) is given by the weight of the patient (G) and the action of the abductor muscles (M). The resultant of this concerted action of the patient's weight and the muscles of the area is a force (R) that compresses the joint and is oriented at an angle of 72°-74° to the horizontal, respectively 16 °-18 ° to the vertical axis [4].

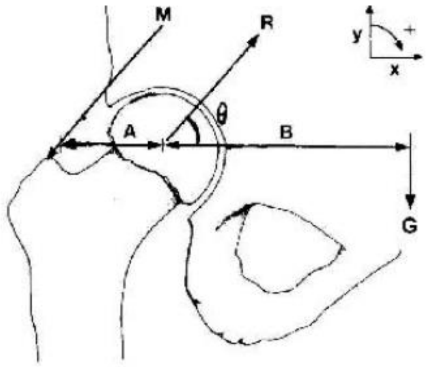


Fig. 3. Forces acting on the joint in equilibrium

According to this scheme, the dynamic loading of the coxofemoral joint leads to the generation of forces with a magnitude of 2.8 ... 5 times the body weight [5, 6].

For the computer simulation, the three-dimensional model of the pelvis obtained in MIMICS 18.0 (Materialise, Belgium) [7], was imported into SolidWorks (2015 Edition, Dassault Systemes, USA) [8] and the two models of the customized prosthesis were designed. The models were subsequently loaded with a force of 1350 N, uniformly distributed over the acetabular surface and oriented at a 16° angle to the vertical (Fig. 4).

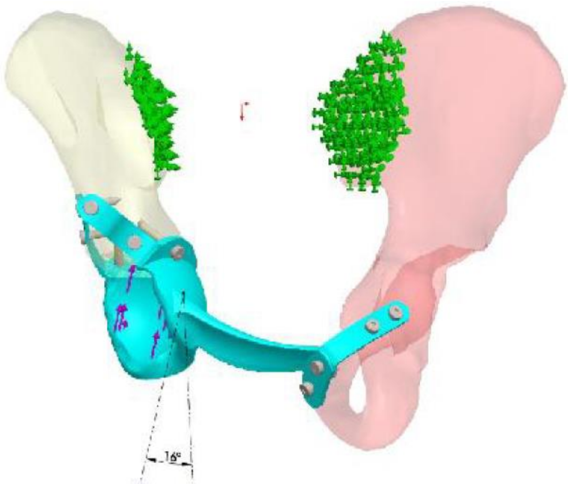


Fig.4. Loading force orientation and bearing surfaces

The finite element analysis was run in SolidWorks using the COSMOSXpress module. The simulation was focused on: analysing the influence of various external stresses on the elements of the assembly, determining the safety factor for the constitutive elements of the assembly and obtaining animations illustrating the evolution of von Mises stress (MPa) and displacements (mm) during articular mechanical solicitation, in order to better understand how load is acting upon the assemblies.

For the components of the assembly, specific materials were assigned: bone for the portion of the pelvis to be preserved, titanium alloy Ti-6Al-4V for the customized prosthesis and fastening screws. For the simulation the materials used are considered homogeneous and isotropic.

The characteristics attributed to the materials used in the analysis are presented in Table 1 [11, 12].

Table 1

Characteristics of the materials used in the finite element analysis

Material / Material property	Bone	Ti-6Al-4V
Modulus of elasticity [N/m^2]	1.71 x 10^{10}	1.048 x 10"
Poisson Coefficient	0.3939	0.310
Transverse modulus [N/m^2]	3.189 x 10^8	4.102 x 10^{10}
Density [Kg/m^3]	500	4428.784
Tensile strength [N/m^2]	10^8	8.274 x 10^8
Yield strength [N/m^2]	33.9 x 10^6	105 x 10^7

The contacts between the surfaces and their type were established for the whole assembly, using an adherent global contact with no clearance and no friction forces. Assignation of restraints was made by blocking the surfaces considered as fixed according to figure 4, thereby obtaining the locking of the surfaces on the coxal bone, thus simulating the transmission of the stresses throughout the bone mass, similar to the support of the assembly on the spine.

For meshing, a standard mesh with fine elements was used, having a mesh size of 1.460 mm and a tolerance of 0.290 mm. The use of such a fine mesh leads to an increase in the static analysis runtime with the improvement of the accuracy of the obtained results. The settings for the mesh size of the component elements of the assembly were identical for all the conducted simulations, so that all the obtained results could be compared.

Prior to initiating the static analysis, both the desired results and the units of measurement in the international system were set. Thus, the following elements were selected for the analysis:

- von Mises stress [MPa];
- global displacements in the bone-prosthesis assembly [mm];
- design insight diagram [-];
- factor of safety [-];
- fatigue check diagram [-].

3. Results and discussions

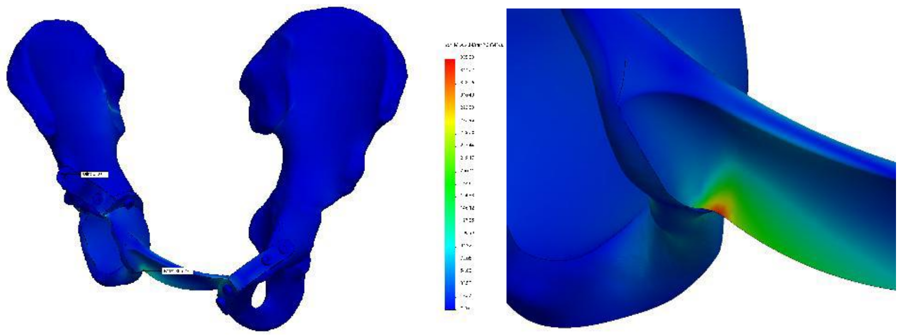
For ease of study and comparison, the results of the simulation were summarised in Table 2 for the bone-prosthesis assembly, with the maximum/minimum value corresponding to each result.

Table 2

The results of the finite element analysis

Desired result	Direction (X,Y,Z)	Type	Value	
			Implant with additional clamping ears (fig. 2.a.)	Implant - simple version (fig. 2 b)
von Mises stress	Global	Min [MPa]	0	0
		Max [MPa]	365.28	523.21
Global displacements	Global	Min [mm]	0	0
		Max [mm]	0.26	0.34
Factor of safety	Global	Min [-]	0	0
		Max [-]	1.82	1.27

Von Mises stresses or equivalent tensile/compression stresses are used in computerized design to predict when the constituent materials of an assembly begin to deform plastically and can be used for uniaxial tensile-compression loads [13, 14].

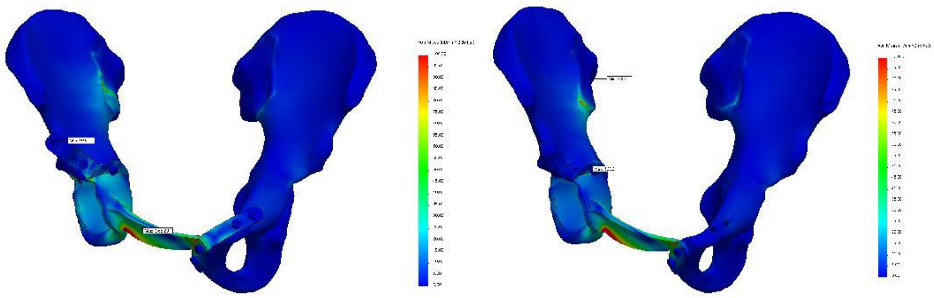


a) b)

Fig. 5. Von Mises diagram: a) – general view, b) – detail

In this context, it should be noted that during the first simulation attempts we obtained very high values for the stresses (1123.67 MPa), which exceeded the yield strength of the titanium alloy. The study of the diagrams showed that these stresses appeared in several areas with stress concentrators (sharp edges, no connecting fillets). Following the remodelling of these areas by inserting connecting fillets/chamfers, the analyses were run again; the diagrams obtained are shown in figure 6.a for the implant model with additional clamping ears and figure 6.b for the simple version.

By analysing the values presented in table 2 as well as those in figure 6, we can see that the stresses in the whole bone-prosthesis assembly are within acceptable limits, the highest value (523.21 MPa for the simple version) being reached in the vicinity of the fixing screw on the acetabular area. This value is well below the yield strength of the titanium alloy Ti-6Al-4V (820 MPa) [15], the material the acetabular endoprosthesis is expected to be manufactured from. It should be outlined that in the simple version model, the maximum stress was located in the connecting area between the acetabular cup and the pubic tubercle, as it is shown in figure 6.a.



a) b)

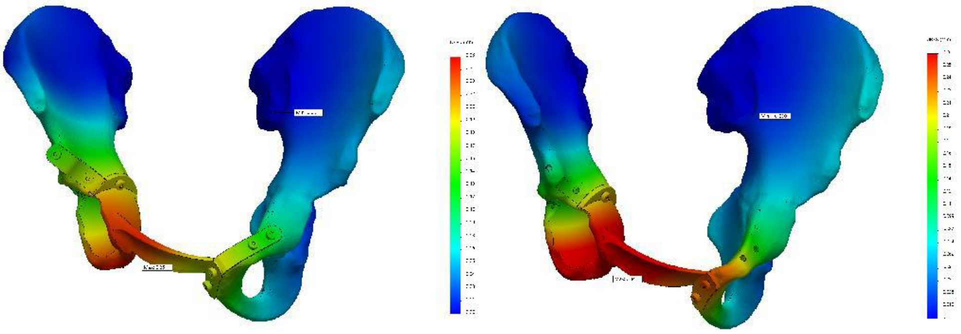
Fig. 6. Von Mises stress diagrams of remodelled endoprosthesis: a) – with additional clamping ears, b) – the simple version

Also, following the analysis of the results presented in figure 6, we can conclude that larger stresses also occur in the support area on the coxal bone. Stresses are reduced in the rest of the assembly, which means that the shape of the implant should be revised in this connecting area, in the sense of increasing the connection fillets or modifying the shape of the area that replaces the upper branch of the pubic bone.

The displacements within the endoprosthesis assembly were materialized by plotting both the total displacement diagrams (Fig. 7.a and b.) and also the displacements on the 3 axes (X, Y, Z) for both implant variants.

The study of the displacement values reveals maximum deformations in the lower part of the prosthetic acetabular cup and in the lower part of the healthy ischium, both for global and also for uniaxial displacements.

Minimal displacements - as expected - occur in the supporting area on the coxal bone, which is the area considered fixed by assignation of restraints. The size of the deformations can easily be seen directly on the diagrams, the blue shades corresponding to null or small displacements, and the red ones to maximum displacements (0.34 mm for the simple version).



a) b)

Fig. 7. Displacement diagrams: a) – with additional clamping ears, b) – the simple version

The qualitative assessment of the endoprosthesis design in terms of resistance to simulated loads can be conducted by studying the design insight diagram (Fig. 8.a and b.), which highlights in blue the regions that bear the highest loads.

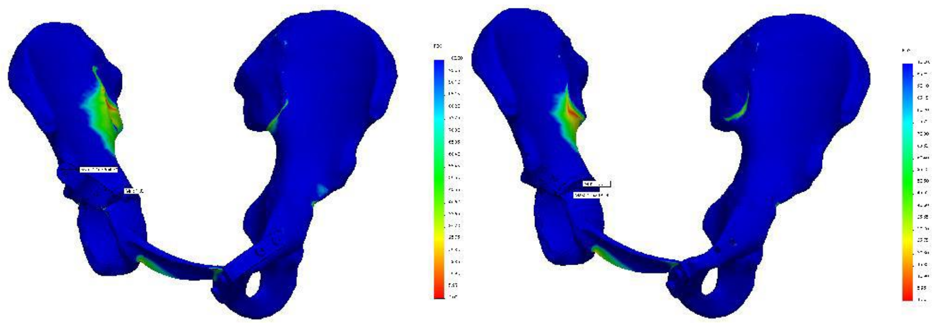
Transparent areas in the diagram indicate the contours of the original model, and in these areas the designer can further reduce the sections in order to optimize the parts of the assembly. Similarly, in the areas highlighted in blue, one can consider the stiffening of the sections, in our case - in the area between the acetabular cup and the pubic bone, where the von Mises stresses are higher for both implant models.

a) b)

Fig. 8. Design insight diagrams: a) – with additional clamping ears, b) – the simple version

Following the finite element analysis, information regarding the factor of safety - FOS (safety coefficient) was obtained for the elements of the assembly. FOS is obtained by dividing the admissible material resistance, respectively the yield strength, to the equivalent stresses in that point (von Mises Stress or Equivalent Tensile Stress).

On the FOS diagrams for the simulated models, we can visualize the areas where problems can arise by looking at the obtained results. Thus, blue areas are for FOS> 100, while the surfaces highlighted in red are for FOS> 1.27 (Fig. 9.a and b).



a) b)

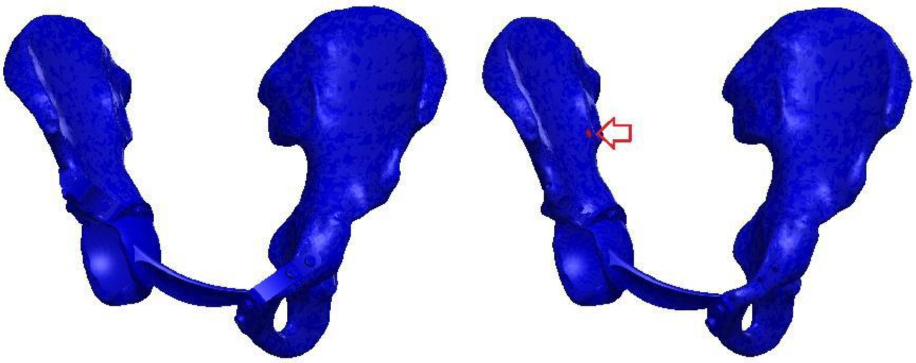
Fig. 9. Factor of safety diagrams: a) – with additional clamping ears, b) – the simple version

Since in engineering it is recommended to use a safety factor FOS > 1.5, it results that the simple version (model without additional ears) is at the limit of stress resistance, and it is possible that it will yield when used in-vivo.

It can be seen that the lowest factor of safety corresponds to the area of the fastening screws on the acetabular zone for both conceptual models, which is explained by the fact that the yield strength of the cortical bone is lower than that of the titanium alloy. Thus, we can conclude that the additional fastening with clamping ears has a favourable effect on the stability of the endoprosthesis, which can also be noticed by observing the value of the minimum safety coefficient (FOS = 1.82) for this model.

Regarding the design of the endoprosthesis, after studying the stresses, displacements and the factor of safety diagrams, it results that the endoprosthesis can be redesigned, especially in the connection area that supports the upper branch of the pubic bone, in the sense of increasing the radius for the fillet of the lower edge of the connection (Fig. 5.b) to reduce stresses in this area. Also, taking into account the results obtained from the finite element analysis, it results that it is possible to reduce the section of the endoprosthesis in certain areas where it would not affect the resistance to the emerging stresses. The reduction of the sections leads to additional material savings (with corresponding reduction in manufacturing costs) as well as increased elasticity of the part, the ultimate goal being to ensure a behaviour that is closest to that of the natural bone.

Finally, for verifying the long-term endurance of the endoprostheses, the Fatigue Check Plot was generated - a tool used for warning the designer if the verified assembly can yield to cyclic mechanical stress with repeated loadingunloading cycles. The diagram identifies the regions of the virtual model which can be subjected to fatigue cracking, by marking them in red. The initial settings for this check allow the designer to choose the loading type (pulsating or alternating cycle) as well as the desired factor of safety. In the conducted simulation, a positive pulsating loading cycle was selected (during the leg balancing phase, the force in the hip joint is considered zero) and a minimum factor of safety of 1.5 (FOS>1.5) was considered. Using these settings, the fatigue check diagrams presented in figure 10.a and b were obtained.



a) b)

Fig. 10. Fatigue check diagrams: a) – with additional clamping ears, b) – the simple version

Analysing the results presented in figure 10, we can conclude that there are no areas with the possibility of fatigue cracking for the model with additional clamping ears, while the second model shows an extremely small area (highlighted with a red arrow in Fig. 10.b.) that would be susceptible to be overloaded in case of cyclic loading. Since the natural bone of the pelvis has the ability (in healthy individuals) to withstand normal cyclic loading, it results that this model of endoprosthesis introduces additional stresses in comparison with the natural bone architecture, which could create in-vivo problems.

The occurrence of areas with possible fatigue cracking may be caused by the different rigidity of the titanium alloy from that of the natural cortical bone and also by the fixing method of the endoprosthesis on the remaining bone. For this model, the factor of safety was reduced to FOS = 1.4 and the finite element analysis was run again, following which it was determined that the area with the possibility of fatigue cracking disappeared, which means that the implant can be used intraoperatively.

4. Conclusions

The main objective of the paper was to analyse the possibility of using the finite element analysis in the design of customized prostheses made of titanium alloys.

Following the analysis of the obtained results we can outline the following conclusions:

- both models can withstand in-vivo stresses, but the endoprosthesis with additional clamping ears for fixing on the remaining bone provides better stability of the implant;
- it is more difficult to manufacture the model with additional clamping ears by using an additive manufacturing process; it is also more difficult to post-process/finish it - facts which may suggest the necessity to conduct an extended analysis of using hybrid manufacturing possibilities (rapid prototyping followed by welding or welding depositing);
- the analysis of the initial results of the simulations allowed the reduction of the stresses and displacements by studying the optimization of the shape of the prosthetic models, which resulted in the modification of the values of the connection fillets in the area of the implant that replaces the upper branch of the ischium which initially presented sharp edges representing stress concentrators.

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