

COMPUTATIONAL SIMULATION OF BONE- PERSONALIZED HIP PROSTHESIS ASSEMBLY

Adrian PACIOGA¹, Doru D. PALADE², Stanca COMŞA³

Artroplastia de șold este cel mai utilizat procedeu de reconstrucție a șoldului și chiar dacă procedura are o rată mare de succes, prezintă unele limitări care conduc la realizarea unor compromisuri și la apariția unor complicații postoperatorii, care pot afecta calitatea vieții pacientului și durata de viață a implantului. Utilizarea unui implant personalizat permite restabilirea anatomiei originale maximizând suprafața de contact os-proteză, ceea ce conduce la optimizarea distribuției încărcării. Autorii au realizat modelarea 3D a unui femur proximal, au proiectat o proteză personalizată adecvată și au realizat simularea computerizată a ansamblului în vederea anticipării comportamentului la solicitările statice.

The total hip arthroplasty is the most common procedure for hip reconstruction, but even if it has a great success rate it also has some limitations regarding compromises that must be made, which can lead to post operative complications and could affect patient's life quality and implant's lifetime. Utilization of a personalized implant permits restoration of the original anatomy with maximization of the contact surface between bone and prostheses, which leads to the optimization of load distribution. The authors realized a 3D proximal femur modelling, designed an adequate personalized prostheses and realized computational simulation of the assembly, in order to anticipate the behaviour to static loading.

Keywords: personalized prostheses, static simulation, geometric optimization.

1. Introduction

The idea of a personalized hip implant is not so new on the international scale and there are some preoccupations regarding personalized implant manufacturing, using classic and non-conventional technologies. The new laser sintering machines have brought an unexpected excitement among researchers in this domain. There have been some international programs aiming realization of

¹ PhD. Student Eng., National Institute for Research and Development in Mechatronics and Measurement Technique, Romania, e-mail: pacioga@yahoo.com

² Prof. PhD. Eng., Department for Mechatronics and precision Mechanics, University POLITEHNICA of Bucharest, Romania

³ PhD. Eng., National Institute for Research and Development in Mechatronics and Measurement Technique, Romania

software capable of reconstructing bone anatomy using CT and MRI images like Prometeo Project, Titanium Bone Implants Project and HipOp Project.

In Romania there have been preoccupations regarding realization of prostheses with standardized sizes and studies regarding the manufacturing of a personalized hip implant, but without materialization in an experimental model. Studies in this domain have been made at Technical Universities from Bucharest and Timisoara, and also at INCMDTM.

The final target of 3D bone modelling is to design an implant adapted to patient's specific anatomy and realization of finite element analysis studies for determination of bone – implant interactions. The computational models of mechanical structures have been successfully used in the past years in the study of the biological systems. The finite element analysis analyses is the optimal choice for bone structures study, because of their irregular shape, non linear behaviour, complex movements and because bones are inhomogeneous.

2. Determination of the loading force

For the computational simulation, the authors have used the morphological data of the patient A.M. (see table 1), whose 3D model of the proximal femur was obtained using the commercial software 3D DOCTOR, and importing the obtained surfaces in SolidWorks 2009, in order to compute the solid model.

Table 1

Morphological parameters of patient A.M.

Patient	Age	Height	Weight	Distance between femoral heads	Femoral head diameter	Angle of neck on shaft
	[years]	[cm]	[kg]	[mm]	[mm]	[°]
A.M.	57	179.2	82	199.65	49.1	127.8°

The loading of the femoral joint is given by the patient's weight and the action of the abductors muscles, their resultant being a force R (see fig. 1) that compresses the joint and is orientated at $\theta=72^\circ-74^\circ$ related to horizontal, which means $16^\circ-18^\circ$ related to the vertical axis [1].

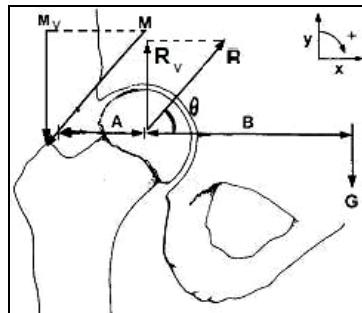


Fig. 1. Forces distribution in hip joint

The position of the body centre of mass is situated approximately at 30-40mm from the vertical axis (sitting on one leg). The lever arm of the body weight $A=148.7\text{mm}$ and the lever arm of the abductor muscles force $B=50.6\text{mm}$ - were measured on the medical image (see fig.2) [2].

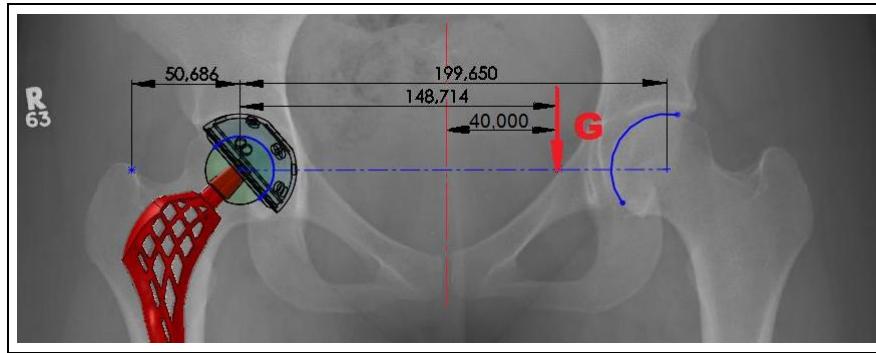


Fig. 2. Measurement on radiography of the force's lever arm

Using these values and considering the weight of a single leg being $1/6G$ (which means that sustained weight is $5/6G$) from the moment equilibrium equations we obtain [1]:

$$M_V \cdot A = \frac{5}{6}G \cdot B \Rightarrow M_V = \frac{5}{6}G \cdot \frac{B}{A} = 2008.13N \quad (1)$$

The total force on the hip joint is obtained from the equilibrium of forces in the vertical direction:

$$R_V = \frac{5}{6}G + M_V = 2520.63N \quad (2)$$

The final value for the force R is obtained by correcting R_V with $\cos 16^\circ$:

$$R = \frac{R_V}{\cos \alpha} = 2622.62N \approx 2700N \quad (3)$$

3. Establishment of the loading parameters

The static analysis was carried out in COSMOSXPress and no simplifications were made to the three-dimensional model so that the simulation should be more realistic. The purpose of the analysis was to determine the influence of the exterior loading upon the parts of the assembly, to establish the overstressed areas, and to make a comparative study between two models of personalized implants and a standard Medin prosthesis in order to evaluate the opportunity of manufacturing the dedicated implants. The study had several stages as follows [3]:

- Establishment of the 3D geometry of the constitutive elements;
- Assignation of materials to each part;

- c. Establishment of the global contact between surfaces;
- d. Determining loading;
- e. Assignment of restraints;
- f. Meshing the parts of the assembly;
- g. Designation of the desired results.

a. We've already mentioned the way of obtaining the three-dimensional models. Here we must say that two prosthetic models were designed using the natural interior architecture of the bone, the difference between them being the dimension of the fenestrations made in the implants body. The idea of those fenestrations belongs to a collective of Romanian researchers who assumed that reproducing the internal arciform structure of the original femur would help the bone in growth and to the final implant stability and would contribute to a closeness between bone and prosthesis elasticity [4]. The spherical joint, the liner and the acetabular cup are standardised and the dimensions are taken from Medin Product Catalogue, being identical for all three prosthesis.

b. Assignment of materials was made as follows: bone for the femur, titanium Ti6Al4V alloy for the implants and acetabular cups, stainless steel for the spherical joint and UHMWPE (Ultra High Molecular Weight Poly Ethylene) for the liner. The characteristics of the materials are entirely taken from SolidWorks 2009 materials library, for most of them the properties being well known. The problem is more complex when talking about bone properties which are different, depending on the bone position in the skeleton, on bone mineral density, and the bone type: cortical or cancellous. One of the bone properties which differ from an author to another is the yield strength, with values between 27.7 - 35.9MPa. For the present simulation the authors used a value of 33.9MPa for the yield strength [5].

c. Establishment of the contacts between the parts was made for the entire assembly and an adherent global contact with no clearance and no friction forces have been chosen [3]. From the available options we used "Compatible mesh", because its use in the static analysis leads to more precise results at the contact surfaces between parts.

d. For loading the bone-implant assembly, the resultant force $R = 2700\text{N}$ determined in section 2 was used. As mentioned above, the force direction was 16° related to the vertical axis, and for its materialization the assembly was set in anatomical position (as measured on the plain radiography), and the resultant was applied on the spherical surface of the acetabular cup (see fig.3) [1;2].

e. Assignment of restraints means choosing the fixture type [3] and consists in blocking the inferior part of the 3D femur, simulating the force transmission. It's obvious that such supporting is not in total accordance with the real situation, but in the carried researches the authors didn't have a CT scan for a full femur, but only for the proximal femur. However, we appreciate that this

approximation does not influence much the global results of the simulation. The chosen fixture type “Fixed geometry” leads to the blocking of all translations and rotations of the designated surface (see fig. 3)



Fig. 3. Establishement the loading and fixture type

f. The mesh of the components was made using the „Create mesh” command and the „Standard mesh” option checked. For the mesh elements a dimension of 1.355mm was used and a tolerance of 0.11mm, which leads for sure to an increase of the duration of the static analysis but also to an improvement of the accuracy of the obtained results [3]. The ratio time/accuracy is not so significant, but the meshing of the 3D assembly couldn’t be obtained with bigger element sizes, because of the very complex surfaces of the model.

g. The results that the user wants to be obtained can be defined before the beginning of the study, but the user can start the analysis, and, after obtaining the computational model he can choose what results to be displayed. In our study we selected the following results to be displayed:

- Stress von Mises [MPa]- sectioned with a plane passing through the neck and shaft axes;
- Global displacements [mm];
- Axial displacements (UX,UY,UZ) [mm];
- Factor of safety (FOS);
- Design insight.

4. Results of static simulation

For the easy comparison of the results, these are presented in table 2, for each type of prosthesis the maximum and minimum value being mentioned for every result category. We must outline that in order to facilitate the graphic comparison the maximum/minimum value of the scale of each result diagram was modified as it can be seen in table 2, in the column shaded in red. Because the maximum stress is attained only on small areas (especially in the neck areas) for a better view of stress distribution, the maximum value for this scale was set 115MPa instead of 900.7MPa as it should be expected.

The von Mises stress or equivalent tensile stress is utilized in computational simulation to anticipate the moment when plastic deformation occurs in the materials from which the parts of an assembly are made [6].

Table 2

The results of static simulation

Result	Direction	Value	Medin prosthesis	Prosthesis with big fenestrations	Prosthesis with small fenestrations	Scale values
Von Mises stress	Global	Minimum [MPa]	0	0	0	0
		Maximum [MPa]	900.7	761.2	822.2	115
Total displacement	Global	Minimum [mm]	0	0	0	0
		Maximum [mm]	2.33	3.49	1.44	3.49
X Displacement	X Axis	Minimum [mm]	-1.776x10 ⁰	-2.995x10 ⁰	-1.229x10 ⁻¹	-1.229x10 ⁻¹
		Maximum [mm]	4.784x10 ⁻³	6.131x10 ⁻³	1.121x10 ⁻³	6.131x10 ⁻³
Y Displacement	Y Axis	Minimum [mm]	-1.498x10 ⁻²	-1.902x10 ⁻²	-0.932x10 ⁻²	-0.932x10 ⁻²
		Maximum [mm]	1.407x10 ⁰	1.706x10 ⁰	6.138x10 ⁻¹	1.706x10 ⁰
Z Displacement	Z Axis	Minimum [mm]	-1.431x10 ⁰	-1.601x10 ⁻¹	-1.009x10 ⁻¹	-1.009x10 ⁻¹
		Maximum [mm]	6.507x10 ⁻²	9.710x10 ⁻²	2.798x10 ⁻²	9.710x10 ⁻²
Factor of safety	Global	Minimum	2.98	3.44	3.12	2.98
		Maximum	100	100	100	100

The study of table 2 and von Mises stress diagram (see fig. 4) shows that in the same loading conditions, the stress in the three implant models are different, the greatest stress being 900.7MPa for the standardized Medin prosthesis.

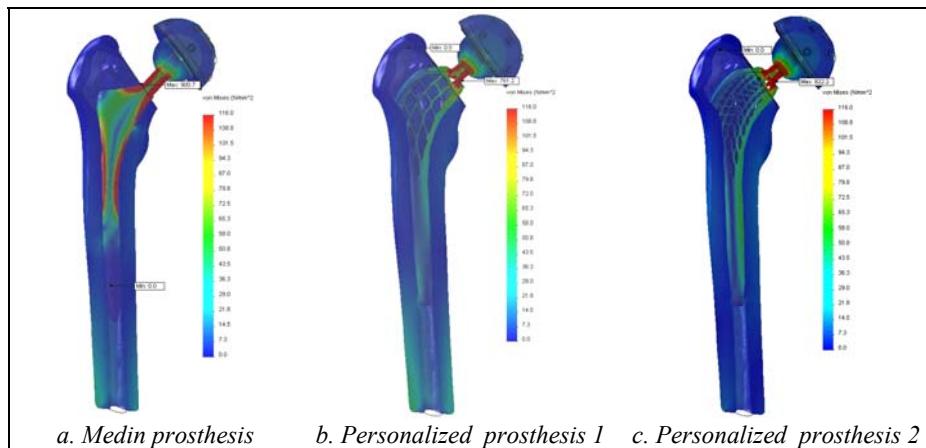


Fig. 4. Von Mises stress diagrams

The maximum stress is located to all the three models in the neck area and at first sight it's surprising that bigger stress appears at the prostheses with small

fenestrations, but the phenomenon can be explained by the increased elasticity conferred by the bigger fenestrations which leads to a better load transfer. It can also be observed that stress distribution in the case of the personalized implants is similar, with an exception in the inferior part of the bone which is more stressed in the case of the implant with big fenestrations because of the bigger displacements that occurs in this case. For a better understanding of the stress distribution in the area of the implant's neck, the authors determined the stress in seven sampling points, using the "Probe" command available in COSMOSXpress module (see fig. 5 and table 3), and plotted the chart of the stress variation (see fig. 6).

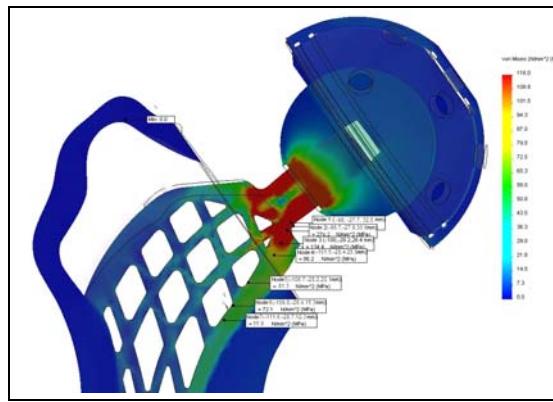


Fig. 5. Taking the probes in seven sampling points

Table 3

The stress values in seven sampling points

Point nr.	Position of the sampling point			Prosthesis with big fenestrations	Prosthesis with small fenestrations
	X (mm)	Y (mm)	Z (mm)	[N/mm ² =MPa]	[N/mm ² =MPa]
1	-98.069	-27.721	32.559	393.9	618.8
2	-98.794	-27.928	30.978	278.2	247.0
3	-100.05	-28.231	28.419	134.4	88.2
4	-101.56	-28.417	25.941	86.2	65.4
5	-106.72	-28.237	20.101	81.3	55.6
6	-109.85	-28.497	15.36	72.1	53.9
7	-111.65	-28.729	12.35	55.9	51.7

From the table it can be observed that the stress decreases dramatically when passing from the neck to the stem of the implant and even if in the first sampling point the efforts are 50% bigger at the prosthesis with small fenestrations, in the following points they are smaller and finally the values are comparable. The observation is more obvious when looking at the chart of the stress variation from fig. 6 and this means that a more elastic implant improves the way the implant responses to normal loading.

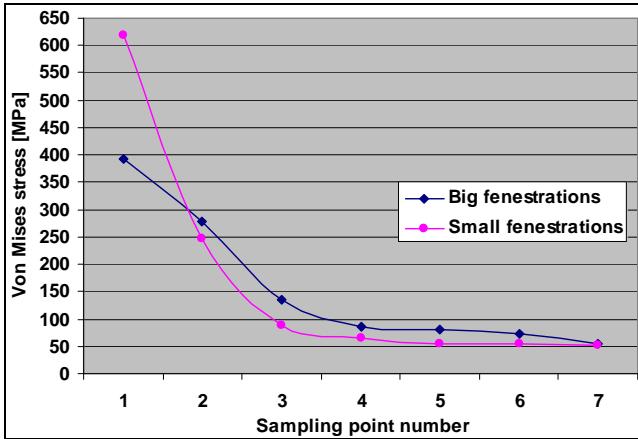


Fig. 6. Stress variation in the neck area at the two models of prosthesis

The displacements in the bone-prosthesis assembly were materialised by the global (URES) and axial (UX, UY, UZ) displacement diagrams. The study of the displacement values (see fig. 7) shows maximum deformations in the case of the big fenestrations model, the observation being valid for both global and axial displacements.

At all the three models, the maximum displacement occurs in the superior part of the assembly, and the minimum - as expected - at the base, which is a fixed area. The differences between displacements can be easily seen on the diagrams, the blue colour tone corresponding to null or small displacements while the red one to maximum ones.

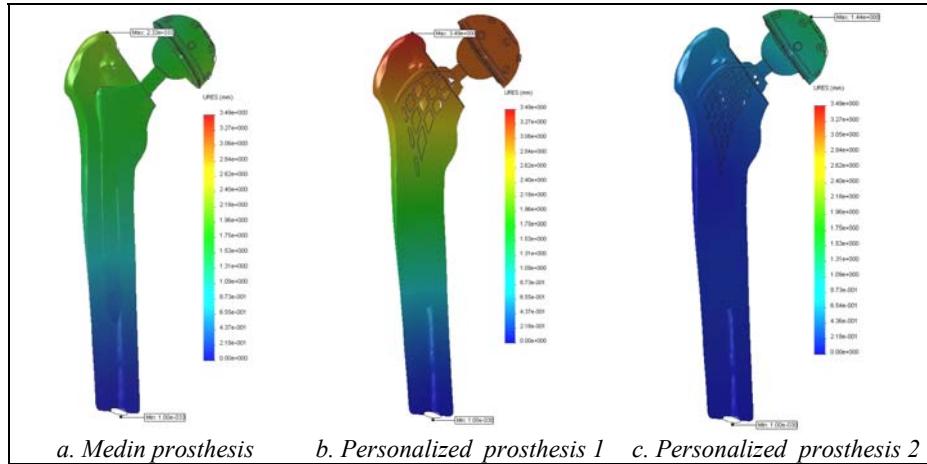


Fig. 7. Global displacements diagrams

Because of the lack of space, the axial displacements are not presented in this paper, but their aspect is similar to the global displacement.

The maximum displacement of 3.49mm in the case of the first personalized prosthesis is in accordance with the specifications of ISO 7206-4: 2002 [7], which indicate a maximum allowable 5mm displacement, for a hip implant.

The qualitative evaluation of the implant's design regarding the bending stress durability can be made using the Design Insight diagram (see fig. 8). This plot shows the most stressed areas of the assembly shaded in blue colour tones. The transparent areas indicate the contours of the original model, and in these areas the designer can reduce the cross sections in order to optimize the assembly parts. Similarly, in the areas shaded in blue, the designer can think to a cross sectional stiffening – in our case the neck area at all three implants.

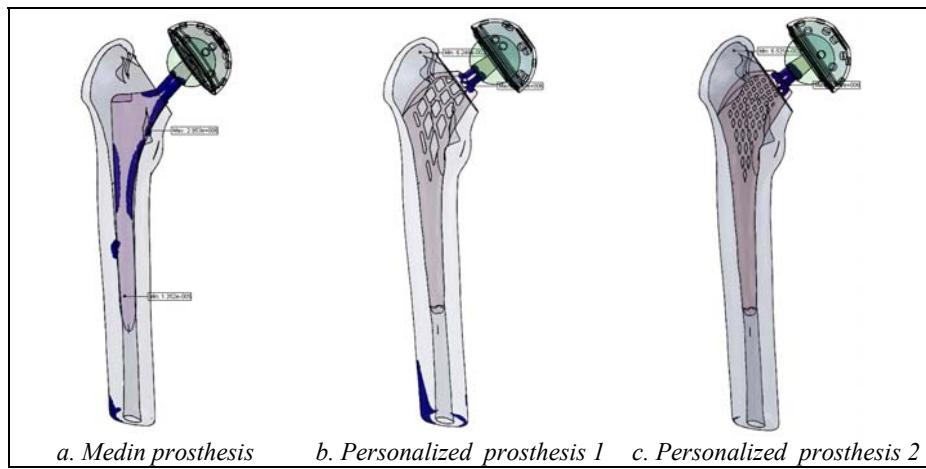


Fig. 8. Design Insight diagrams

A supplementary stress can be observed in the base of the assemblies with bigger displacements, the phenomenon being already outlined at the von Mises stress diagram study.

The quantitative evaluation of the prosthesis design regarding the bending stress durability can be made using the factor of safety values. COSMOSXpress module calculates this value for a certain point by dividing the yield strength of the material to the von Mises stress in that point. The following theoretical considerations are applicable:

- FOS<1 in a certain point means that in that point the material is yielding, and for sure problems will arise in that zone;
- FOS=1 in a certain point indicates that in that point the yielding begins in the material and plastic deformation starts in that area of the part;
- FOS>1 means that application of a supplementary force in that specific point leads to yielding for forces with values equal to the current value multiplied with the FOS value [8].

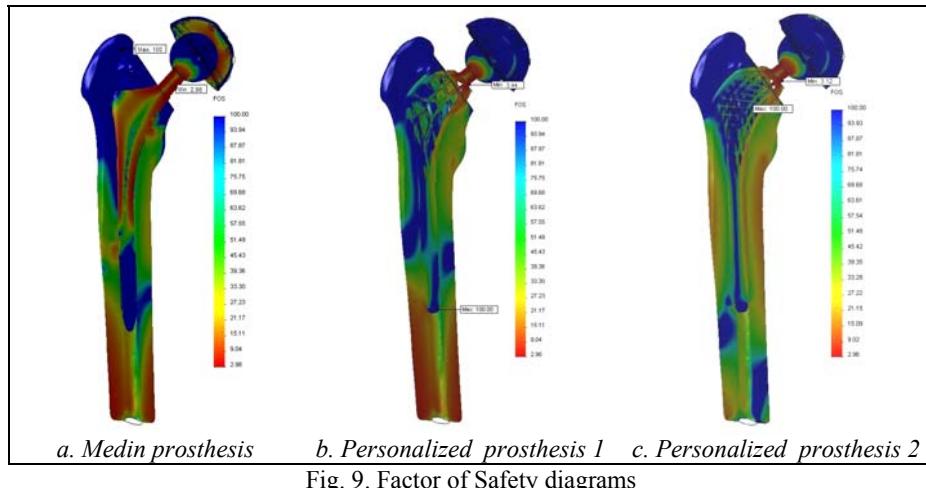


Fig. 9. Factor of Safety diagrams

The zones where problems can arise in the case of our simulations can be seen through a colour tone study (see fig.9), knowing that the blue zones corresponds to $FOS=100$ and the red ones to $FOS=2.98$ which is the lowest factor of safety corresponding to Medin prosthesis. Because in engineering design a $FOS \geq 1.5$ is recommended, it results that all three models resist to the static loading. The personalized implant with small fenestrations contributes to bone stress diminution in detriment to stress rising in the neck area of the prosthesis.

5. Optimization of the prosthetic models

The static study of the bone-personalized prosthesis assembly showed an already known fact: the most stressed zone of total hip prostheses is situated in the neck area. Taking into account the results of the static simulation, a reinforcement of the prosthesis neck is not obligatory but it can be done with a certain influence on stress decrease in this perimeter [9].

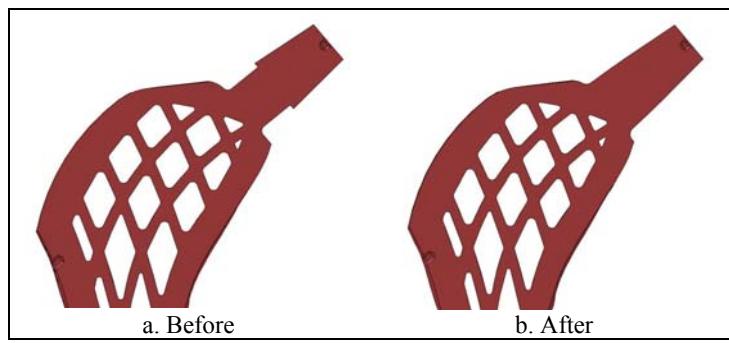


Fig. 10. Reinforcement of the prosthesis neck

The maximum diameter which can be used in the case of keeping the 12/14 taper for spherical joint fixture, is 12mm (this is the base diameter of the taper). For a better reinforcement, the authors chose to use a tapered neck, having an angle of 5°, which is smaller than the angle of the taper for spherical joint fixture (5°43'30''). The fillet corner between neck and stem was also increased from 1.5mm to 2mm, a larger radius being impossible to use due to lack of space. Before and after these modifications, the superior part of the implant looks like in Fig. 10.

With the mentioned modifications, the static simulation was carried out again, the new numerical values being presented in table 4. Due to lack of space, von Mises stress, displacements, FOS and Design Insight diagrams are presented only for the small fenestrations prosthesis (see fig.11), but the quantitative modifications for the other model can be observed in the results table. The dramatic decrease of the maximum stress can be easily observed. In the case of the big fenestrated model the maximum value was 427.1MPa (corresponding to a percentage decrease of 43.8%), while a higher value resulted for the second model: 449.8MPa (45.3% reduction). On the stress diagram this decrease is remarked as a reduction of the red shaded zone from the neck.

Table 4
Results of static simulation after neck reinforcement

Result type	Orientation	Value	Prosthesis with big fenestrations	Prosthesis with small fenestrations
Von Mises stress	Global	Minimum [MPa]	0	0
		Maximum [MPa]	427.1	449.8
Displacement	Global	Minimum [mm]	0	0
		Maximum [mm]	3.32	1.18
Factor of safety	Global	Minimum	3.94	4.33
		Maximum	100	100

The displacements decrease is not so significant in the case of the first model (0.17mm), which is normal because most of the deformations were due to the stem elasticity conferred by the special design with big fenestrations. A more significant decrease is shown by the results for the model with small fenestrations (0.26mm) but these modifications are hard to be seen on the global displacements diagrams.

The improvement can be also detected when studying the FOS values. For the model with big fenestrations the minimum value not only increases to 3.94 but the area where this minimum value is changed from the prosthesis neck to the inferior area of the bone, which is subjected to greater deformations. On

FOS/Design Insight diagrams, the reduction of the red/blue shaded zones can be observed.

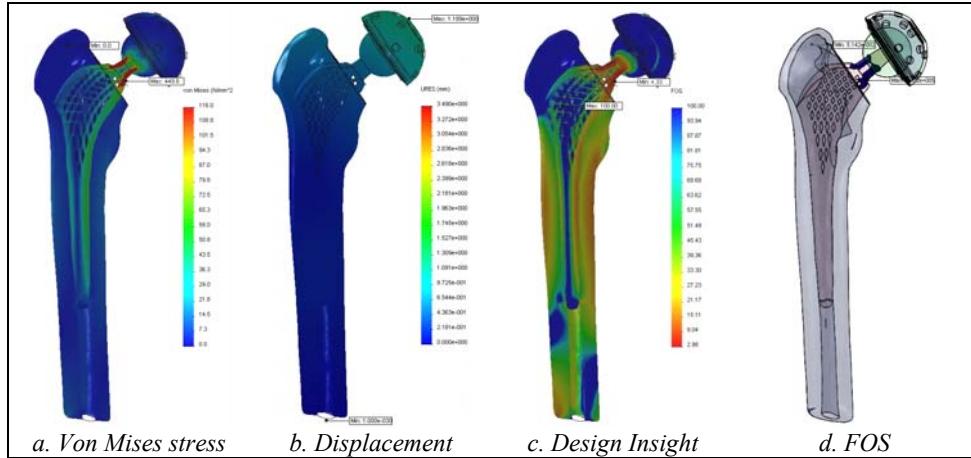


Fig. 11. Diagrams for small fenestrated model with reinforced neck

A value of $FOS=4.62$ was obtained utilizing the “Probe” command for taking a sample from the area where the minimum FOS value was situated at the model with thin neck, which outlines the positive effect of the tapered neck with a greater fillet radius.

In order to illustrate the positive effect of neck reinforcement, we've proceeded again to sampling from the same points as the first time and the new results were superimposed on the stress variation curves for the models with thin neck (see fig. 12).

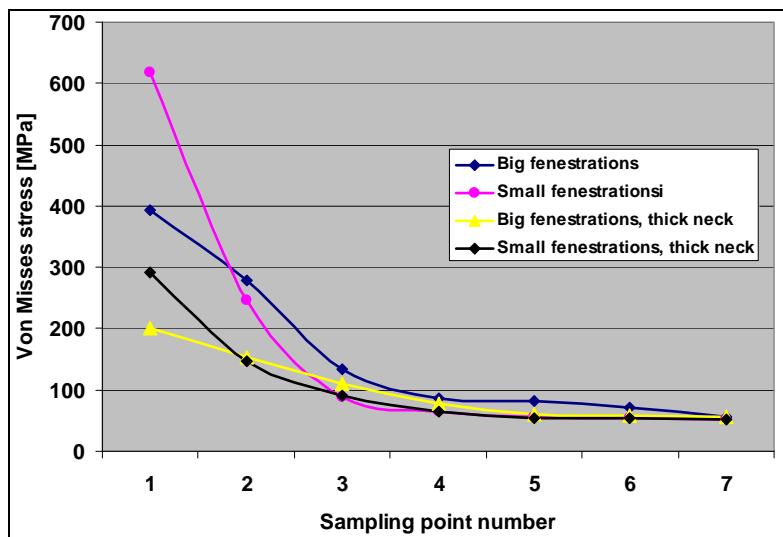


Fig. 12. Stress variation curves for implants with thick neck

From the figure we can see that the tapered neck with greater fillet radius has a benefic effect resulting in decrease of the curves slope and in diminishing the great discrepancies between stress values at the neck to stem transition. The smallest variations are for the prosthesis with big fenestrations, but here we must outline that the stress variation is almost similar at both personalized stems at the stem level, which makes difficult a choice between the two models.

However it's obvious that the adopted constructive modification improves the behaviour of the implants to the static loading, a favourable effect being foreseen also for the behaviour to fatigue tests where the sudden variation of the efforts can reduce the implant's life, characteristic which is very important for the long term success of the implant.

6. Conclusions

The authors realized a 3D model of the proximal femur of a 57 years old patient using the commercial software 3D DOCTOR, and imported the surfaces in SolidWorks 2009, in order to obtain the solid model. Using previous results regarding forces distribution [1] in the hip joint we determined the loadings which appear in normal anatomic conditions, measured the force's lever arm and computed the static loading in hip joint for the patient A.M. On the same three-dimensional model of the proximal femur, 3 prosthetic models were mounted: a standardised commercial Medin implant and two personalized implants having the interior contour of the femur. These two models were fitted with fenestrations with two different sizes in order to imitate the natural internal architecture of the bone [4]. The three assemblies were submitted to static studies in the same loading conditions and having assigned the same materials. The results showed an evident improvement of the personalized implants behaviour in comparison with the commercial one through the decrease of stress values and increase of the factor of safety values. Regarding the displacements, the model with big fenestrations had greater deformations and thus increased elasticity with smaller stress values. These bigger displacements induced more stress in the bone, lowering the FOS values in its inferior part. The bigger values for von Mises stress were found to all three models in the neck area and with a sudden decrease at the neck to stem transition. These observations lead to a constructive modification of the prostheses neck consisting in a new tapered shape and an increase of the fillet corner radius. The static simulation was carried out again and a significant improve of all results could be observed. The stress decreased with almost 50%, the displacements with approximately 0.2mm and the minimum FOS value increased from 3.44 to 3.94 for big fenestrations model and from 3.12 to 4.33 for the second model.

So as final conclusions we can say that:

- A personalized prosthesis is preferable to a standardised one because all possible anatomic mismatches are avoided. The discussions about stem anteversion (0°-12°) are so avoided;
- Personalization of the hip implant contributes to stress reduction and FOS increasing, and finally the implant's life is so improved;
- Realization of a model with big fenestrations increases the implant elasticity but induces more stress in the inferior part of the bone, so it's recommended that such kind of implant should be used in patients with high bone mineral density:
 - The small fenestration model decreases the bone stress but the efforts in the neck area are bigger and could affect implant's lifetime. We assume that such kind of prosthesis should be used in patients suffering of osteoporosis;
 - It is expected that the use of fenestrated implant model would improve not only the mechanical behaviour (as the authors of the patent assumed [4]) but also the long term fixation because of the bone in growth through the fenestrations;
 - The authors didn't have a fatigue simulation module in the SolidWorks 2009 software, but from the review of the results it's expected that the implant's lifetime is increased by the use of a personalized fenestrated model with reinforced neck [9].
 - The personalized prosthesis price is higher than of the commercial one, but in our opinion, customization is the future in implantology.

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