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Additively manufactured femoral stem topology optimization: case study

Sorin Munteanu^a, Daniel Munteanu^a, Bogdan Gheorghiu^b, Tibor Bedo^a, Camelia Gabor^a, Patrizio Cremascoli^c, Fabio Alemani^c, Mihai Alin Pop^{a,*}

^aTransilvania University of Brasov, Materials Science Department, 29 Eroilor Blvd., 500036 Brasov, Romania

^bSC Mind Four D SRL, Str. Nicolae Titulescu, 4, 500010 Brasov, Romania

^cAdler Ortho SpA, Via Dell'Innovazione, 9, 20032 Cormano, Italy

Abstract

The main problem of femoral stem prostheses is their primary stability after implantation, which is assured by the so-called press-fit implantation. After implantation, the second requirement is to achieve a secondary stability, due to the osseointegration of the prosthesis in the bone of the femur. Additive manufacturing (AM) allows the designer to create tridimensional models that can have a diffused porosity in the contact area with the bone, which could confer significantly higher osseointegration. Furthermore, through topology optimization, the shape of the prosthesis can be improved, in conjunction with significant mass reduction. This work presents our results concerning the topology optimization of a medium length femoral stem, intended to be manufactured by powder bed fusion (PBF). The CAD models have been analyzed through computer-aided simulations concerning their mechanical characteristics, according to the ISO 7206/4 and ISO 7206/6 standards, and were topologically optimized using commercially available software. The CAD models, both original and optimized, have been analyzed concerning their mechanical characteristics. An optimized femoral stem has been obtained, which answers to the ISO 7206/4 and ISO 7206/6 standards, but with a 15% mass reduction.

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* Corresponding author. Tel.: +40744687408.

E-mail address: mihai.pop@unitbv.ro

1. Introduction

The prostheses used for medical applications must meet a number of conditions such as: i) the condition regarding the compatibility of the materials used in regards to the living tissue (biocompatibility); ii) operational conditions which refer to stress during use and duration of operation in optimal conditions. The proper use of various materials and technologies is a constant concern in both the medical field and the manufacturing technologies.

Studies on the applicability of AM in regards to medical applications are found in the scientific literature, with good results. Obtaining medical implants directly from CAD models is a practical necessity due to the individual characteristics of each patient [1]. These technologies open the way towards making customized prostheses according to the anatomical features of patients. Consequently, the topological modeling and optimization of prostheses is of great importance.

AM technologies allow the use of specific biocompatible materials (metals and alloys, ceramics, plastics, composites) [2, 3, 4]. One of the AM technologies is PBF (Powder Bed Fusion), which has the advantage that by using pulverous materials one can obtain products directly from CAD models, with mechanical properties close to or even superior to the ones of bulk materials.

The current femoral implants are made of fully solid materials which all exhibit stiffness considerably higher than that of bone, and this can cause serious complications, such as implant loosening and bone resorption [5]. In the field of prosthetic components, in particular those intended for hip and knee reconstructive surgery, PBF processes are already applied.

Using CAD models enables one to optimize the design of elements to be further built by AM. Topological optimization allows shape adaptation taking into account only the functional properties (mechanical) without constraints related to the processing technology. From this perspective, AM technologies allow for complex geometric shapes which can be similar to biological shapes, which are difficult or sometimes impossible to manufacture by means of conventional technologies (casting, plastic deformation, machining). Significant implant design improvements have been possible only due to the advances in additive manufacturing [6].

Regarding the materials used for the manufacture of femoral prostheses, titanium alloys are heavily used due to their good biocompatibility and high mechanical strength [7, 8, 9, 10].

Femoral stems are classified as short, medium or long depending on the dimensions [11]. While short stems are successfully produced by PBF, medium and long ones are still challenging, mainly due to the strict requirements which they have to pass, according to the ISO 7206/4 - Implants for surgery, Partial and total hip joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components and ISO 7206/6 - Implants for surgery, Partial and total hip joint prostheses - Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components standards [11].

This paper is presenting the development of a new medium length femoral stem CAD model, intended to be manufactured by PBF, with the main objective of weight reduction, while complying to the conditions imposed by ISO 7206/4 and ISO 7206/6 standards. Other reports mention the possibility of improvement of these types of parts, achieved by simulating static and fatigue resistance coupled with reduction of the mass of the prosthesis, using finite element software [12, 13, 14].

An important tool for additively manufactured structures is advanced design optimization and variable density lattices in particular. The topology optimization allows a designer to assess the optimal layout in a structural and/or mechanical sense [7, 15, 16, 17].

2. Experimental details

The study was performed on a medium length femoral stem model, pictured in Figure 1. The work was carried out taking into account all the stipulations of the ISO 7206/4 and ISO 7206/6 standards. In order to realize the stress/strain simulations on the femoral stem model, the SolidWorks software package was used. The topology optimization was conducted with TruForm (GRM Consulting) software as an extension of SolidWorks. The dark grey area, pictured in Figure 1, is meant to provide the secondary stability, therefore, that would be the region where a certain pattern must be built, which should mimic the trabecular bone structure.

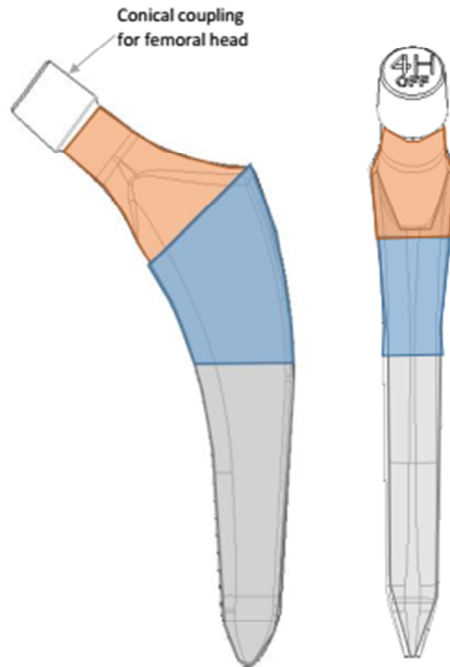


Fig. 1. Non-optimized femoral stem model.

The initial simulations, performed on the non-optimized femoral stem CAD model, have sought to show that the prosthesis fulfills the requirements imposed by ISO 7206/4 and ISO 7206/6. The simulations took into account the characteristics of titanium Ti6Al4V powder ($R_m = 860$ MPa, $R_{p0,2} = 780$ MPa, percentage elongation after fracture $A_{min} = 8\%$), as well as the characteristics of Co-Cr-Mo alloy, generally used for the femoral head (Table 1).

Table 1. Mechanical properties of Co-Cr-Mo alloy, used for the femoral head

Condition	Tensile strength	Proof stress	Percentage elongation
	$R_{m,min}$, MPa	$R_{p0,2,min}$, MPa	A_{min} , %
Annealed	897	517	20
Hot worked	1000	700	12
Warm worked	1172	827	12

According to the ISO 7206/4 specifications, which is concerned with the mechanical behavior of the femoral stem body, a 2300 N force acting on the prosthesis head was considered. Figure 2 represents the constraint points and the loading points, for the original femoral stem design, and the stress results, shown in the tensile stress region, as well as the compression stress region.

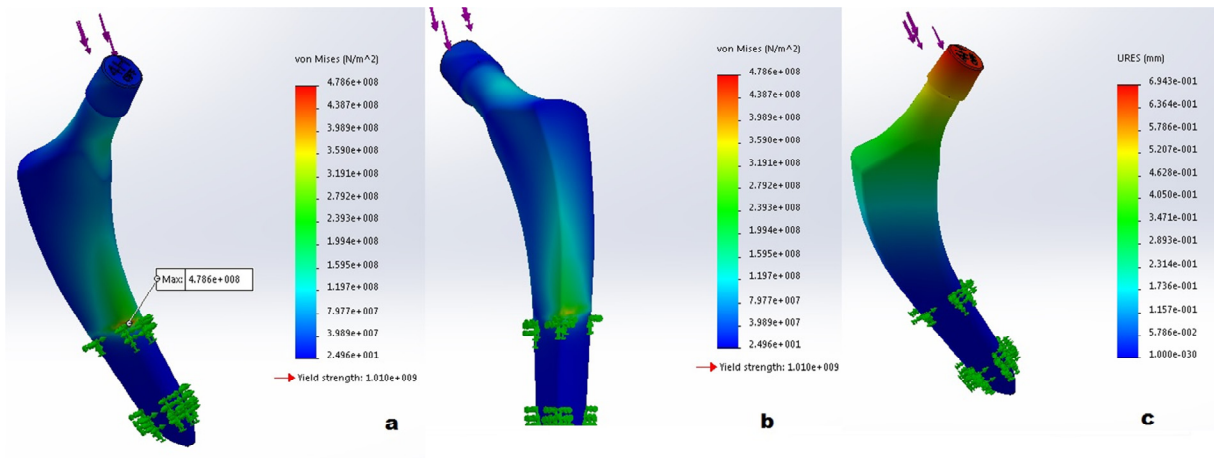


Fig. 2. Simulation results obtained on the non-optimized femoral stem, compression stress zone (a), tensile stress zone (b) and displacement (c).

The simulation results showed a maximum stress value of 478.6 MPa, much lower compared to the permissible resistance of the material, which is 860 MPa. The applied 2300N load produces a maximum displacement of the prosthesis of less than 1 mm.

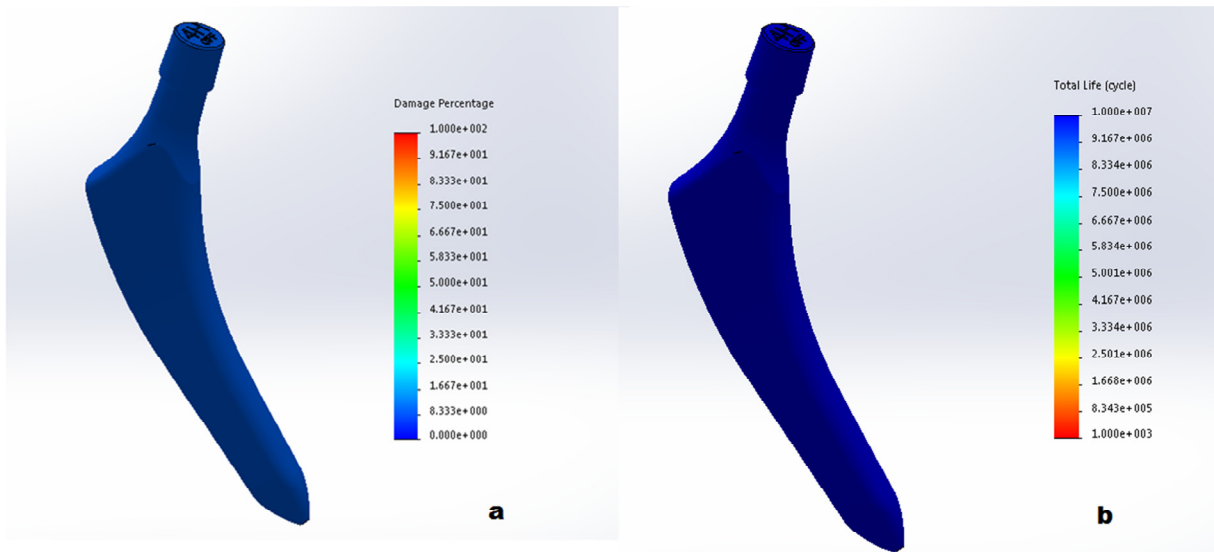


Fig. 3. Damage plot: it shows the percentage of the life of the structure consumed by the defined fatigue events (a), Life plot: it shows the number of cycles that cause fatigue failure at each location (b).

Based on the previous tests, namely fatigue resistance imposed by the ISO 7206/4 and ISO 7206/6 standards (Figure 3), the shape optimization was performed with a target of 15% mass reduction using an extension of SolidWorks, namely TruForm. One of the many variants that were generated by the optimization software is presented in Figure 4.



Fig. 4. TruForm-generated optimized femoral stem.

Since TruForm renders as a result a parametric form and not a solid, the part model was then created to be again subjected to strains simulations. The model was recreated considering both topological optimization results and functional surfaces required for the prosthesis. A new femoral stem model was proposed (figure 5) - a model with 15% weight reduction.



Fig. 5. Weight optimized femoral stem

The simulations were repeated on the model shown in Figure 5, according to ISO 7206/4 and ISO 7206/6 standards. The results are presented hereinafter (Figure 6).

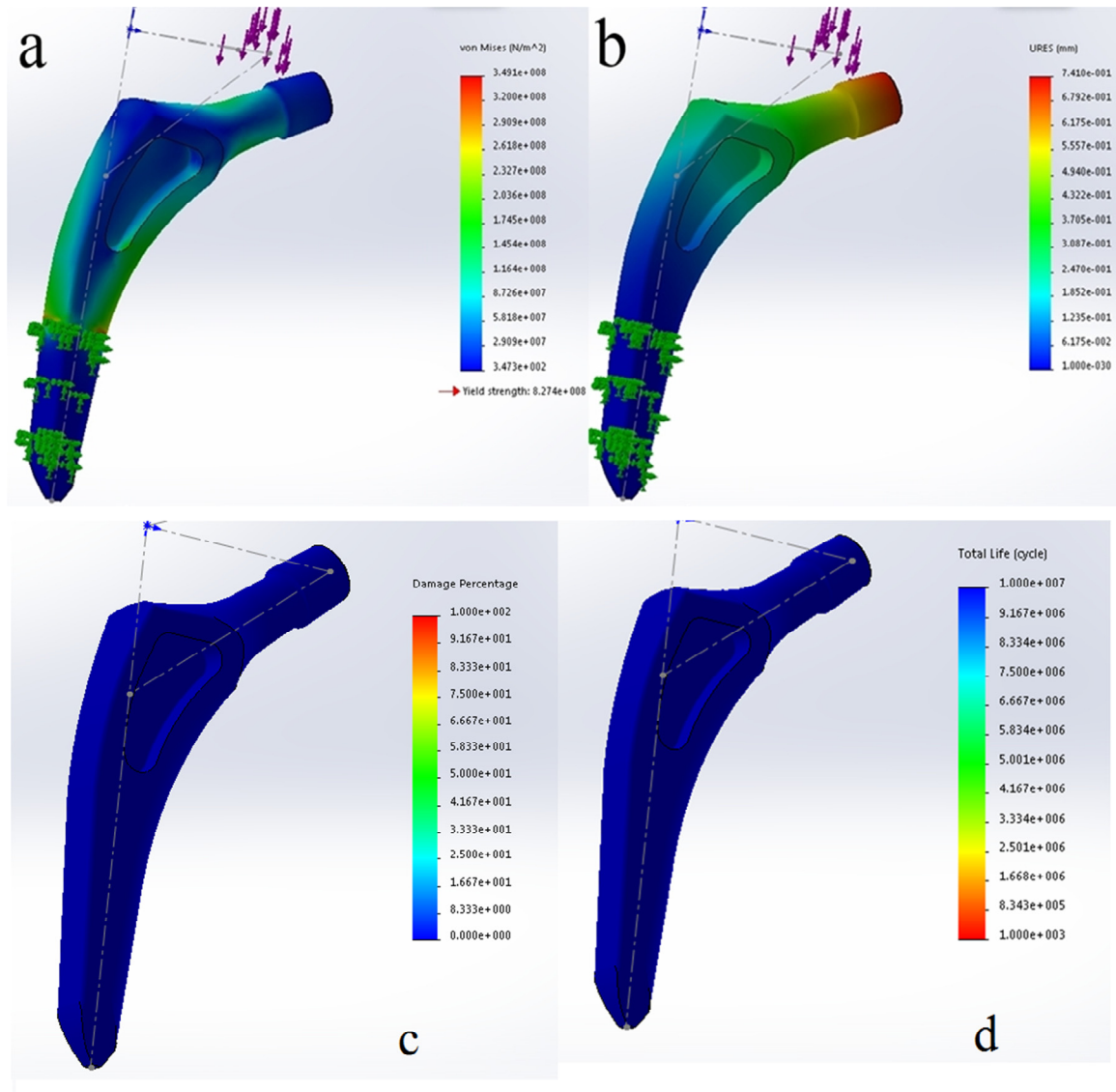


Fig. 6. Simulation results obtained on the optimized femoral stem: compression stress zone (a), tensile stress zone (b); displacement (c); life plot: the number of cycles that cause fatigue failure (d).

To synthesize, the results obtained at simulation are presented in Table 2. The simulation results showed a maximum stress value of 349.1 MPa (for the optimized stem), situated with more than 50% under the standard imposed resistance of the material, which is 860 MPa. The maximum displacement of the prosthesis was less than 1 mm. (0.741 mm), greater than in the initial stem (0.694 mm), but in the parameters imposed by the ISO 7206 standard.

Table 2. Values obtained by simulation.

	Stress [MPa]	Displacement [mm]
Initial stem	478.6	0.694
Optimized stem	349.1	0.741

3. Conclusions

A medium length femoral prosthesis model was analyzed in order to create it using PBF. The above presented simulations prove that the proposed model totally fulfill the ISO 7206/4 requirements regarding the fatigue and mechanical strains specific for femoral prosthesis.

Our research highlighted that through topology optimization one can obtain a completely functional prosthesis shape reducing, in the same time, its weight with more than 15%.

The research should be validated with data obtained from testing on real additively manufactured models.

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