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Numerical analysis of loading on the implant of a threaded osseointegrated transfemoral prosthesis

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Abstract. Between 2010 and 2020, 292,198 amputations of superior and inferior members were done in Brazil, taking into consideration only the ones carried out through the Unified Health System (SUS - Sistema Único de Saúde), being the majority of it of inferior members and as consequence of diabetes complications. The most common type of transfemoral prosthesis is the conventional one which connects to the residual limb through a socket. However, several studies reported volume alterations of the residual limb, which lead to discomfort, pain and skin injuries on patients, besides them presenting difficulties with its adaptation. With the objective of avoiding movement complications and health problems, a new type of prosthesis has been studied and improved in recent years, known as osseointegrated prosthesis. With this type of prosthesis, the prosthetic leg is connected to the residual limb through a fixture which is previously implanted and osseointegrated to the patient femur. This technology still presents a limited commercial use, but has been gaining space because of its advantages regarding the conventional socket prosthesis. Therefore, deeper studies and research of this type of prosthesis is necessary for a broader knowledge and spread of this model in Brazil. The objective of this work was to carry out a CAD modeling of a threaded osseointegrated transfemoral prosthesis and to conduct a numerical stress analysis of a falling scenario in three different time frames. Results showed high probability of implant failure, but no bone fracture.
Keywords: transfemoral prosthesis, titanium, finite element method, osseointegration, implants

INTRODUCTION (HEADING 1, HELVETICA 11PT BOLD ALL CAPS)

The first cases of amputations are dated to the time of Hippocrates and the use of the first tourniquets are mentioned in the time of Ambroise Paré (1575) (Ferreira, 2017). Amputation can be defined as the total or partial surgical removal of a limb. According to o Baraúna *et al.* (2006), amputations can lead to the loss of the efferent and afferent neural control mechanism. The first is related to the motor function of the nervous system and the second is related to the sensory function of the nervous system, that is, the receptors that detect internal and external stimulus. Meaning that the loss of these mechanisms occurs due to the lack of synchrony of muscle activity that does not receive adequate proprioceptive information.

Amputations have several nomenclatures based on the removed limb. According to the literature, lower limb amputation patients, the main focus of this work, are classified in different categories according to the amputation level. The main categories are: transtibial, which consists of the partial or complete removal of the tibia and fibula, that is, bones located close to the calf area; knee disarticulation, which occurs when the knee joint is cut, removing the calf; transfemoral, which occurs between the hip and knee disarticulation and can be divided into three levels: proximal (short), medial and distal (long); and, finally, hip disarticulation, which occurs around the area of the hip joint. In these cases, the control of the prosthesis is performed through the pelvis.

Patients who undergo the amputation process need to develop new skills in order to adapt to the physical disability, and this can negatively influence the physical and mental health as well as the quality of life of these citizens. In addition, it needs to be properly understood and put into practice in daily treatment that patients who are subjected to this sudden modification in routine often go thorough changes in their behavior and in the way they act with other people (Resende, 1993).

Throughout medical history, it is known that prostheses are used to facilitate mobility and independence of amputees. Currently, there are two main types of prosthesis fixation: the most known method is the conventional fixation that works by connecting the prosthesis to the residual limb with a prosthetic socket. In this way, the person can control their prosthesis by the movement and position of the amputation stump (Li and Felländer-Tsai, 2021). However, some studies have reported changes in the stump volume, which generated discomfort, pain and skin lesions on the stump patients in addition to they presenting difficulties in its use.

In order to avoid movement complications and health problems, a new type of prosthesis has been studied and improved in recent years. In the 60's, the concept of osseointegration emerged through research on the healing patterns of bone tissue. With the development of this technique, it was possible to create an osseointegrated prosthesis, which provides a stable mechanism for fixing the prosthesis directly to the residual limb without the need for a prosthetic fitting. According to Hagberg *et al.* (2005), patients who undergo this process reported improved quality of life, better movement and greater comfort in using the prosthesis. Its operation occurs through the connection between the bone tissue and the surface of the selected implant. This technology still has some negative points, such as skin problems and failures of the connecting device. These points presented reinforce the idea that the osseointegrated prosthesis needs improvement and accessibility to the Brazilian population. Thus, further studies are necessary for greater knowledge and dissemination of this model of prosthesis.

The osseointegrated prosthesis is a recent device in the academic and health areas and, therefore, has not reached the patients who could benefit from its use. In Brazil, research on this subject is scarce and it is not in use in the hospital environment, which generates low development of this mechanism in the country.

It is possible to view the low number of research on this topic on the Scopus website (B.V., 2021), which is a database of abstracts and citations of articles for academic journals. On this site, in addition to collecting the raw materials for the construction of this work, data from the numbers of research on osseointegrated were also collected. With this, it was possible to evaluate that since its inception, only 16 studies were developed in Brazil and 745 researches around the world. It is worth mentioning that when using the search tool, the term ”dental” was excluded, as it belongs to the subject of osseointegration and there is a range of research about it, but it is not the focus of this work.

Thus, the present study aims to contribute to the advancement of studies on the subject, performing a bare simulation of stresses for different time frames of a falling scenario on an osseointegrated threaded fixation prosthesis (OPRA) system using finite element method (FEM). A CAD model was also developed for this research.

METHODOLOGY

This section details the methodology that was used for the development of this study. It is presented the steps for prosthesis system geometry definition, CAD modeling as well as the numerical analysis.

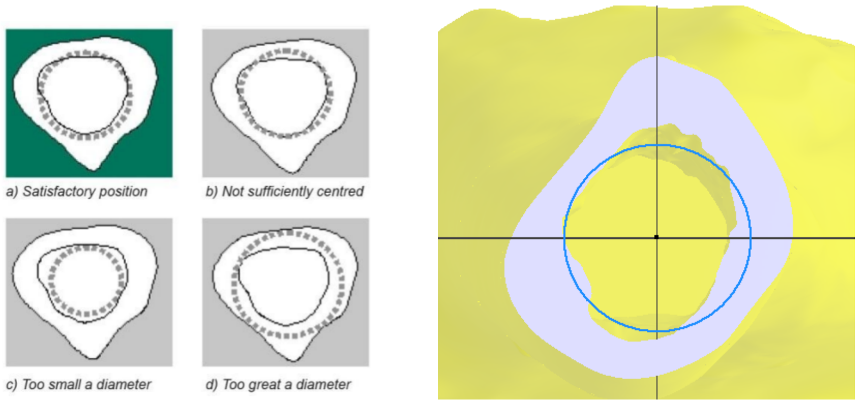
Cad modeling

The assembly of the prosthesis system to the amputated femur was developed using the CAD software Autodesk Inventor Professional 2020. The main object of this work is a prosthesis system which is fixed to the femur by a threaded implant. This type of osseointegrated prosthesis is patented by Integrum. Therefore, there is little information available regarding its internal or external geometry. However, from the few images and some data found on the literature and by analyzing its mechanical and biological working, it is possible to define the geometry and to estimate the dimension of the three parts that integrate the system: the fixture or implant which is screwed to the femur; the abutment screw which fixes the fixture to the abutment and has the role of connection between the system and the prosthetic leg; and the abutment that keeps contact with patient skin. In general, all the parts are fabricated using the titanium alloy Ti-6Al-4V.

The first step was to get a 3D model of a femur so the diomensioning of the prosthesis and the hypothesizing of the loading conditions could be done. As it was not possible to scan a patient femur, the CAD model was obtained from another study (Mahmoudi and Mahbadi, 2020) in which authors rebuilt the femur of a person from computerized tomography (CT) images using the 3D Slicer software. According to the authors, the femur is from the left leg of a 44 years old male, with 85 kg and 1.85 m. The femur was cut to simulate a transfemoral amputation at 250 mm height above the knee based on works by Tomaszewski (Tomaszewski *et al.*, 2012b; Tomaszewski, 2012; Tomaszewski *et al.*, 2012a).

The dimensions of the parts were initially based on documents from Integrum (Integrum, 2020), the company that owns the OPRA prosthesis patent, and Food and Drugs Association - FDA (FDA, 2020) and from papers that had also modeled threaded osseointegrated prosthesis systems (Mirulla *et al.*, 2020; Brånemark *et al.*, 2014)

Integrum presents the image from Fig. (1a) to detail the ideal position of the fixture in relation to the bone and also shows the general thickness of cortical bone necessary for the fixation of the fixture and a successful osseointegration. The first image represents the satisfactory position between fixture and cortical bone; the second image shows a decentralized positioning between fixture and bone; on the third image, the fixture diameter is too small and the fixation would not happen adequately; and the last one shows a fixture that is too large which would cause too much bone loss. Moreover, from the 3D femur model, it was defined a 18 mm diameter for the fixture. The thread pitch was specified by ISO standards for metric profile thread: 2.5 mm. Besides, geometric alterations were also modeled for osseointegration improvement and system stability like radial holes and lateral grooves. Figure (1b) shows the section view of the amputated bone and the position of the fixture adopted in the study.



v

(a) Ideal relation between femur and fixture (adapted from .

(b) Final relation between femur and fixture.

Figure 1 – Position between the amputated femur and the prosthesis fixture.

CAE analysis

The numerical analysis of stress was carried out using Ansys 2019 software through the *Static Structural* toolbox. The prosthesis system parts were considered manufactured of titanium alloy Ti-6Al-4V with the properties taken out from the literature. To the femur, it was assigned cortical bone properties as showed in Tab. 1.

Table 1 – Cortical bone properties.

Cortical bone properties	
Young Modulus (E_x)	$1,15 \times 10^{10}$ Pa
Young Modulus (E_y)	$1,15 \times 10^{10}$ Pa
Young Modulus (E_z)	$1,70 \times 10^{10}$ Pa
Poisson Ratio (V_{xy})	0,51
Poisson Ratio (V_{yz})	0,31
Poisson Ratio (V_{xz})	0,31
Transverse Young Modulus (G_{xy})	$3,6 \times 10^9$ Pa
Transverse Young Modulus (G_{yz})	$3,3 \times 10^9$ Pa
Transverse Young Modulus (G_{xz})	$3,3 \times 10^9$ Pa

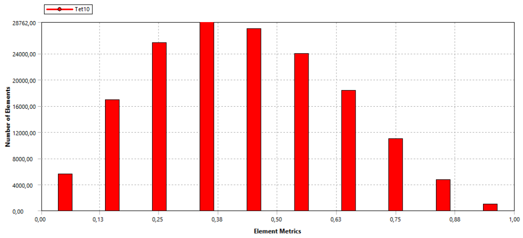
For failing possibility analysis, it was considered the titanium alloy Yield Strength (850 MPa) for the prosthesis parts. As for cortical bone, because of the nature of the material, it was considered the method of strength computation detailed by Keyak and Falkinstein (2003) and Mirulla *et al.* (2020) that uses the density ρ_{ash} of the elements of the scanned bone model for the bone strength calculation according to Eq. 1, where density was assumed to be 1.22 g/cm^3. Bone strength was computed to be 160.5 MPa.

$$S_{osso} = 114 \times \rho_{ash}^{1,72} \tag{1}$$

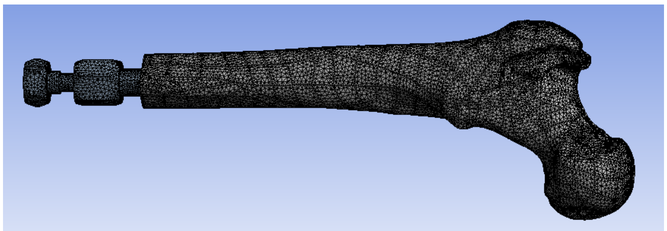
The support of the bone and prosthesis assembly was defined at the proximal head of the femur and loading (forces and moments) was applied to the face of the head of the abutment screw. These definitions were made based on the literature and on that femur loading occurs as a reaction of the surface on that the patient is walking on.

It is important to highlight that the thread of the surfaces was removed, leaving them with the major diameter for external threads and minor diameter for internal threads. This procedure is standard and was made because thread geometries consume severe computational resources and, in the present work, the threads are not the main focus of study. The system was considered to be fully osseointegrated so contact relations were not modeled.

The convergence analysis for the mesh size of the assembly was determined by a mesh refinement test, considering a 5 % variation on the peak of the von Mises stress result as the limitation. Also, the quality of the mesh was analyzed using the skewness. Figure shows the distribution of the elements along skewness value and it can be seen that most elements have skewness lower than 0.5, that is, with quality between good and excellent. The mesh was generated with tetrahedral elements of 1 mm. Mesh data is showed in Tab. 2 and Fig. shows the meshed bodies.



(a) Skewness distribution between mesh elements: average 0.37.



(b) Mesh generated for FEM model.

Table 2 – Mesh data.

Mesh data	
Elements shape	tetrahedral
Elements size	1 mm
Quantity of nodes	283.876
Quantity of elements	163.278

Loading condition was based on two papers by Frossard *et al.* (2010) and Tomaszewski *et al.* (2012a). The first work carried out an experimental measurement of loading on a falling scenario using a patient who was amputated and was using an osseointegrated prosthesis. The second study adapted these results of forces and moments to use on their research. The present work analyzed the falling scenario in three different time frames as in Frossard *et al.* (2010):

- Time 1 - It starts with the last heel contact with the floor before the fall and ends with the decline of the resultant force;
- Time 2 - It starts with the decline of resultant force and ends with the start of impact on the floor;
- Time 3 - It starts with the impact and ends with the stabilization of forces.

Loading forces and moments were calculated when resultant force was maximum for each time frame. Therefore, three loading conditions were analyzed, but all of them are different moments of a falling scene. Directions of force and moments are as showed in Fig. : direction x is the medio-lateral direction with lateral being positive; direction y is the long axis of the femur; and y is the anterior-posterior direction with anterior being positive. Loading values are showed in Tab. 3.

Table 3 – Finite element analysis loading conditions.

Direction	**Time 1**	**Time 2**	**Time 3**
Fx (medio-lateral)	93.56 N	109.04 N	238.62 N
Fy (long axis)	580.47 N	599.83 N	1012.94 N
Fz (antero-posterior)	-81.00 N	-188.45 N	-266.17 N
Mx	2.25 N.m	-6.96 N.m	135.72 N.m
My	2.98 N.m	-1.49 N.m	26.56 N.m
Mz	-16.64 N	-18.47 N.m	9.26 N.m

Finite element model was analyzed by means of the equivalent von Mises stress and it was compared with yield strength of titanium alloy and bone strength as calculated.

RESULTS AND DISCUSSION

This section provides the results found throughout the development of the study and also the discussion lead by them. It is included the results of CAD modeling and FEM analysis.

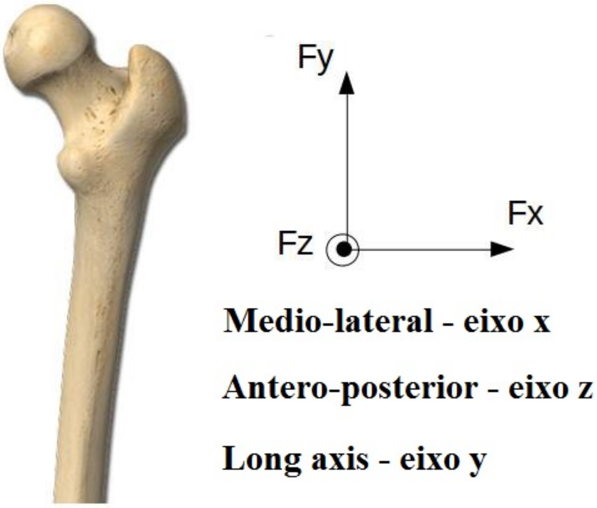


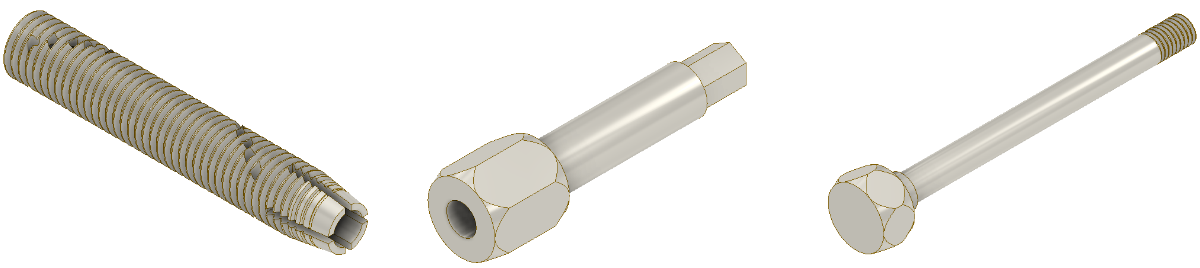
Figure 2 – Position between the amputated femur and the prosthesis fixture.

3D model of osseointegrated prosthesis system

The results of CAD modeling for each part are showed in Fig. 3. As it can be seen in Fig. 3(a), the fixture has some surface modifications to improve osseointegration and this was done using lateral grooves and small radial holes. Also, the surface of this component does not need to present an excellent finishing with very low roughness as it can also help to improve osseointegration. This can be taken into consideration during manufacturing processes.

Besides, it is possible to observe in Fig. 3(b) that the abutment geometry is used as a connection between the abutment screw and the fixture (implant), which is something essential to the functionality of the system. Thus, it is possible to affirm that the components are in compliance with their initial functionality. Last, in Fig. 3(c), it is seen the part that is linked to the fixture and the prosthetic leg: the abutment screw. As observed, the geometry of this part is according to the last parts.

In Fig. 4(a), it is possible to see the final result of the assembly of the osseointegrated prosthesis, based on the three parts showed before. The last result of this subsection is the assembly of the system with the amputated bone (Fig. 4(b).

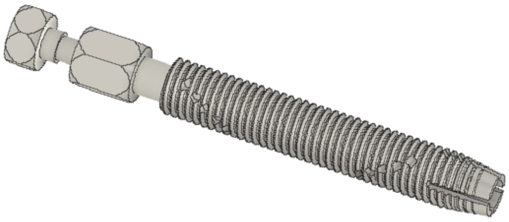


(a) Fixture (implant). (b) Abutment. (c) Abutment screw.

Figure 3 – Osseointegrated prosthesis parts.

FEM analysis

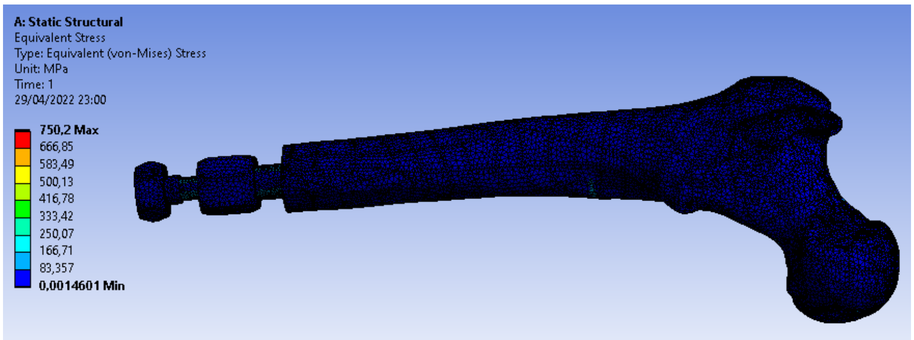
As detailed in the works of Tomaszewski (2021) and Tomaszewski *et al.* (2012a, 2012b), numerical stress analysis of threaded implants which work osseointegrated are often developed without the threads in the model. The consideration of a fully osseointegrated implant leads to the possibility of considering the prosthesis-bone system as one body. Nevertheless, it is important to point out that when studying the process of osseointegration and how the stress relates to bone remodeling during this period, the thread will play an important part and should be considered in the analysis.



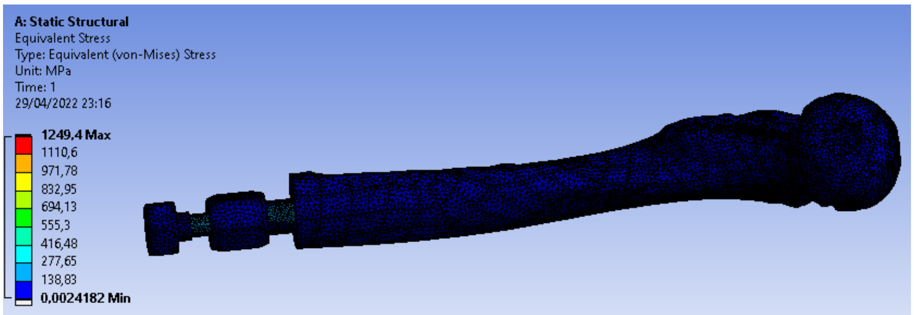
(a) CAD model of prosthesis system.

(b) CAD model of prosthesis assembled on amputated femur.

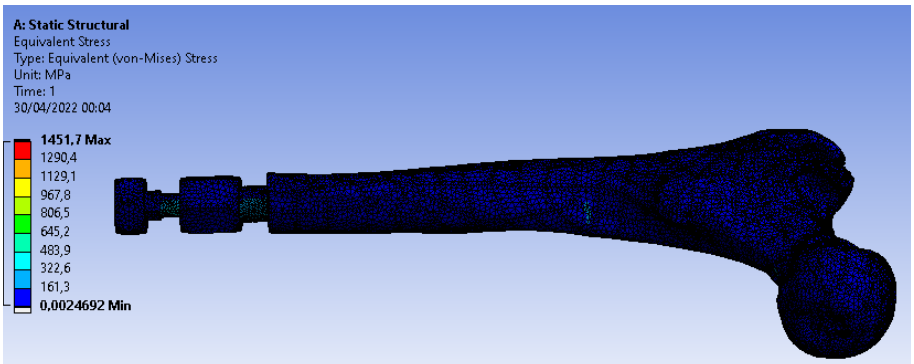
Figure 4 – CAD assembly femur + prosthesis system.



(a) Time 1.



(b) Time 2.



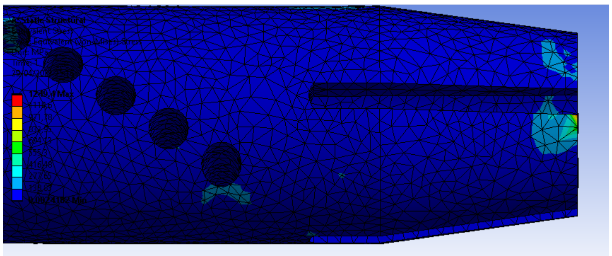
(c) Time 3).

Figure 5 – Equivalent von Mises Stress results for falling scenario for osseointegrated prosthesis.

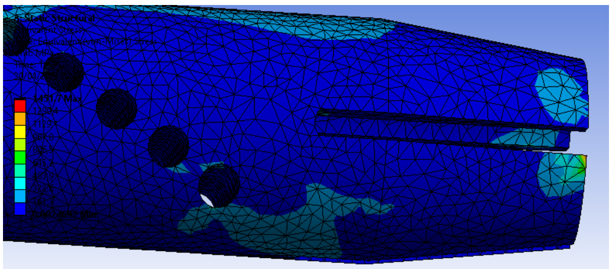
Figure 5 represents the results for the equivalent von Mises stress from the numerical analysis of the assembly prosthesis-amputated bone considering the support and loading conditions described. As it can be seen, the maximum stresses for all time frames happen on the prosthesis parts and not one the bone which is a positive thing as any possible rupture would occur first on the implant and not on the bone. This situation is predicted by this type of osseointegrated prosthesis: the implant failing before the bone.

The maximum von Mises stress (750 MPa) for Time 1 is smaller than the yield strength of the implant material (850 MPa). However, for Time 2 and Time 3, maximum stress exceeds it. This shows high possibility of implant failure and it is in accordance with other studies as Mirulla *et al.* (2020). According to the results, failure could occur on the abutment screw, right above the abutment as showed on the images. It is important to notice that the amputated femur is almost fully blue which means that the failure of bone would be improbable.

Another important point to highlight is the presence of stress concentrations points on the implant, specially as a consequence of the geometrical modifications. Figure 6 shows the images of high stress locations in Time 2 and Time 3 analysis. They show that the tip of the implant as well as the radial holes are points of concern. The geometry design of these parts can be improved in order to avoid the concentration of stress at these positions.



(a) Time 2.



(b) Time 3.

Figure 6 – Detail of concentration of stresses and maximum von Mises stress locations.

CONCLUSIONS

This paper deals with osseointegrated prosthesis with threaded fixation which presents several advantages regarding the conventional socket prosthesis. The objective was to develop a CAD model of the system assembled in an amputated femur and to carry a numerical analysis of stress on a falling scenario using finite element method.

The following conclusions can be taken from this study:

- 3D model of the osseointegrated prosthesis system was developed based on the literature and it was possible to reproduce the assembly using a CAD model of a femur. Even with little information available regarding dimension and geometry, the system was modeled accordingly;
- Three different time frames during the falling of a patient were analyzed. The main conclusion is that the prosthesis system could fail during a fall. However, patient femur would not fracture, meaning that the implant would rupture first. This security system is typical for this kind of prosthesis;
- Implant showed stress concentration points which could be avoid with a redesign of the parts and an improvement on the geometry;

For future studies, the redesign of the implant to avoid stress concentrations is in order. Also, a better understanding of the loads happening during a fall is mandatory as the work used by this study carried out an experiment with a single person.

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