ADDITIVE MANUFACTURING IN THE DEVELOPMENT OF AN INTRAMEDULLARY NAIL: STUDY OF CLINICAL CASE

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ABSTRACT

The additive manufacturing is currently an indispensable tool in different areas. Its application in orthopaedic area has been essential in the development of surgical procedures, visualization of anatomical structures and especially in the new implants design to improve the conditions for patients’ treatment. The present study considered different techniques of additive manufacturing applied in design, diagnosis and planning of a locked intramedullary nail used in the femoral diaphysis fractures (type A). This study was complemented with the follow-up of a surgery case to the femoral diaphysis fracture. It was performed a biomechanical analysis using the finite element method and 3D models through a printing in full colour, allowing to obtain the colour levels related to von Mises stresses. All the studied techniques have proved to be important, since they allow a three-dimensional view of real dimensions of the implant by helping health professionals to do a more accurate and safe surgical planning.

Keywords: additive manufacturing, femur, fracture, locked interlocking nail, finite elements.

1 INTRODUCTION

In orthopaedic surgery, the femoral diaphysis fractures are the most common occurrence. These surgeries are considered serious injury as result of violent forces and, most of the times derived from car or motorcycle accidents, road kill and falls from height, usually involving young adults (Poozzi, 2011).

There are different systems of classification which identify the types of fractures that can occur in a particular anatomical region or specific bone. This work was based on the classification system developed by Swiss Group AO, which includes the fractures classification of the long bones (Muller, 1991). The AO classification developed by Muller (Muller, 1991) organizes the fractures of each bone segment (proximal, middle and distal) in three different types (A, B and C), in accordance with the injury severity. Thus, simple fractures are classified in type A, wedge fractures are classified in type B and complex fractures are type C. The Figure 1 shows the three classifications.

Depending on the type of fracture, it is necessary to understand the best way of treatment to allow the creation of a biological environment that maximizes the normal processes of bone repair. The advances in technology allowed a wide variety of instruments, materials for implants and various techniques for the internal fixation of femoral diaphysis fractures.
The intramedullary fixation with intramedullary nail is one of the possible treatments for this type of fracture. These implants have a locking system through surgical screws that allow the intramedullary nail remains attached in the bone on the proximal and distal zone (Rodrigues, 2008; Stiffler, 2004). However, the main objective is to design an implant that decreases rehabilitation time and offers better results for patients. The additive manufacturing coupled to the medicine has proven to be a great tool in the improvement and planning of this type of surgeries (Costa, 2011). Through medical images in DICOM format, from a computed tomography (CT), it is possible to obtain three-dimensional (3D) digital models. After file image processing, it is possible to obtain physical models that allow the handling of patient anatomical parts and the surgical guides manufacture.

The main goal of this study was to evaluate the potential of the additive manufacturing technique in design, diagnostic and planning of implants used in femoral diaphysis fractures (type A). The study was complemented with the follow-up of a surgery case to the femoral diaphysis in a specialized Hospital from Brazil (Fernandes, 2013).

2 METHODOLOGIES OF STUDY

2.1 Study of clinical case

The accompanying a surgery case to the femoral diaphysis was performed to better understand all procedures used of this type of treatment. The followed surgery, was carried out in a male patient, which had an open fracture in the femoral diaphysis on the right lower limb, resulting from a motorcycle accident. The treatment of the fracture was performed through the intramedullary fixation with the insertion of an intramedullary nail of stainless steel, and opening of the medullary canal. The lock of intramedullary nail was performed with three locking screws, increasing the stability of fixation. In distal zone of femur, the lock was performed using two 3.5mm diameter screws, placed in parallel. The proximal locking was performed through the proximal guide and with a 6.5mm diameter screw placed in the diagonal position (Fernandes, 2013). The images presented in the Figure 2 show two x-rays exams of the patient before and after the insertion of the intramedullary nail. Following this treatment, the 3D physical solid model (biomodel) was performed to be used in numerical simulation, as close as possible to the real situation.
2.2 Description of Biomodel

Following the method used in the clinical case, a 3D model of the femur-implant-screws was created. The femur model was obtained from digital medical images (DICOM) of a computed tomography exam. The segmentation and the treatment of the interested regions were performed using the InVesalius program (Figure 3).

The CAD model of the intramedullary nail was built through SolidWorks program and with the same dimensions of the intramedullary nail used in the clinical case. Figure 4 shows the real intramedullary nail and the CAD model, with a diameter equal to 11mm and 360mm of length. The locking screws, without thread, two for the distal zone femur with 3.5mm of diameter and one for the proximal femur with 6.5mm of diameter, were also developed in SolidWorks program.
The *CAD* model of the intramedullary nail was assembled with the femur biomodel. In *SolidWorks* program a simple fracture (type A) in the femur model was developed and also incorporated the locked intramedullary nail and locking screws (Figure 5). The stresses analysis in this type of fractures was performed using the finite element method with the *Ansys* program (v14.5).

### 2.3 Finite Element Analysis of Biomodel

In the numerical analysis a 3D finite element (*Solid45*) was used (Figure 6). It was considered an elastic modulus equal to 210GPa for stainless steel material of the intramedullary nail and screws (Rodrigues, 2008). The elastic modulus for femur bone was assumed equal to 21.1GPa (Currey, 2009). For all materials Poisson’s ratio was 0.3. In this study, the numerical simulations were performed assuming a perfect contact among all materials. Considering that the patient has a body weight of 70kg, a compression force equal to 700N was applied on the femoral head at a distance of 40.5mm to the intramedullary nail. The resulting forces from the muscular action were not considered and proceeded to the femoral fixation in the distal part (Figure 6). In this study was considered a static linear analysis and isotropic materials.
The numerical analysis allowed to study the biomechanical effect of the intramedullary nail (stainless steel), the osteosynthesis of the fractured bone and the effect on the femoral diaphysis fracture, type A (Fernandes, 2013). The stresses in the biomodel were analysed before and after placing the intramedullary nail, Figures 7 and 8, respectively. The results are displayed in a colour scale, representing different levels of stresses. The analysis in the model was performed after the insertion of the intramedullary nail, at an early stage of osteosynthesis, which means that the fractured zone of the bone is represented by a continuous model in only some nodal points of the respective model. After analysis and interpretation of the von Mises stress distribution, it was observed that when the bone has a diaphysis fracture, there is a stress concentration with more critical values along the fracture zone (74MPa), creating instability along the all bone. The applied load in the femur head caused a bending moment along the diaphysis, which created compressive stresses of the medial side of the femur (shortening) and tensile stresses on lateral side (elongation).

The insertion of the intramedullary nail caused a significant reduction of von Mises stresses in the femur model and also decreased the mechanical stresses in the bone. This fact allowed a greater stability along the bone, promoting its consolidation. After the intramedullary nail insertion, the fractured zone remains as the critical one but the von Mises stresses decreased (29MPa). Before placing the intramedullary nail in the fractured zone, a value equal to 74MPa was reached. In the external and adjacent areas to the fracture, there are lower values compared with the fractured zone, in the order of 17 MPa. Regarding the stresses obtained on the intramedullary nail, it is observed that the distribution along the intramedullary nail is relatively greater than in bone, around 80MPa.
The results obtained in this study were consistent with the results from Pauwels (Pauwels, 1980), which describes the concepts of load transfer within the bone. The placement of the intramedullary nail allowed the neutralization of the forces and prevented the shortening and lengthening generated along the femur.

3 RAPID MANUFACTURING OF THE INTRAMEDULLARY NAIL

There are various prototyping technologies that allow manufacturing physical models. The high speed with which these models are obtained in different materials and degrees of complexity allows to health professionals: reduction the time of surgical intervention, creation of custom tools, improve the dialog with the patients and explore the potentialities of custom prosthesis by additive manufacturing (Dvorak, 2006; Foggiato, 2006).

This study presents some additive manufacturing processes applied to the manufacture of a locked intramedullary nail and the set femur-implant-screws. Different processes were used with the purpose of evaluating the models and the manufacturing quality in the diagnosis and planning of implants placement. CAD models (intramedullary nail and femur-implant-screws) were converted in STL format for further production of physical models.

3.1 Stereolithography

The Stereolithography (SL) was performed in the Viper si2 equipment, from 3D systems. In pre-processing stage, the intramedullary nail was put on a virtual platform in conjunction with supports to sustain it while was constructed, Figure 9. The manufacture was performed through the photopolymerization of an epoxy resin, resulting in a prototype with $22.04cm^3$ of volume and with 131.655 layers of approximately 0.1mm thickness.

After total construction of the model it was necessary to clean the prototype and remove all support material (Figure 10). The model was subsequently cured in an ultraviolet oven.
The prototype was subjected to sanding operations to remove all imperfections and irregularities created by supports. Finally, the piece was painted to obtain an appearance similar to the real intramedullary nail (Figure 11). All process stages lasted approximately 540 minutes.

### 3.2 Fused Deposition Modelling

The Fused Deposition Modelling (FDM) was performed in a *Fortus 250mc* equipment. The *Fortus 250mc* works with Insight software that allowed to build the virtual model of the intramedullary nail and the supports, Figure 12. The model was manufactured by extruding ABS polymer filaments (*ABS plus 430*) through a printing head. This polymer was heated (310°C) and melted when going through the printing head and each layer was deposited over the previous one melting it, partially, and becoming a continuous structure, with 20.37cm³ of volume.

### 3.3 3D Printing

The 3D Printing (TDP) is an additive manufacturing that stands out because can produce monochrome and colour models, in reduced time and competitive costs.

In this study, two different 3D Printers were used: *Zprinter 310 Plus* and *Zprinter 650*, for building monochrome and colour models, respectively.

- **TDP Monochrome**

The model was built layer-by-layer with powder composite (*zp130*) bonded through an aqueous base binder (*zb58*). Figure 13 shows the several phases from model manufacturing, going from the layer impression until the cleaning of the residual dust. The cleaning
operations consist in the global remove of excess material by the compressed air action to obtain a rough surface. After that, model surface consolidation was done by applying the cyanoacrylate layer which strengthens the connection among particles and increase the mechanical resistance. The final prototype presented a $22.04 \text{cm}^3$ volume and 2234 layers, each one with 0.0889mm thickness. The total duration of the procedure was approximately 90 minutes.

![Fig. 13 - Main steps to fabricate the intramedullary nail using monochrome TDP](image)

- **TDP Chromatic**

The TDP chromatic process was applied in the production of two models. This process was used to print the intramedullary nail and the femur-implants-screws, with the respective colour levels associated with the von Mises stresses. Through this printing process, a direct visualization and physical distribution of the stresses field throughout the model was possible, allowing the evaluation of the more critical regions in this type of orthopaedic surgeries. This technique was performed in a Zprinter 650 equipment with a ceramic material. It is important to note that, unlike previous techniques, this process requires the conversion of the 3D CAD file for the VRML format, in order to obtain models with colour. The models were manufactured with approximately 930 layers, each one with 0.0875mm of thickness (Figure 14).

![Fig. 14 - Main steps to fabricate the colour models](image) ![Fig. 15 - Models manufactured by colour TDP](image)

As in the previous process, the models removed from the printing machine need a surface treatment based on the application of a cyanoacrylate resin (Figure 15). The total duration of the manufacturing process was approximately 450 minutes.

Table 1 presents the summary of the all different additive manufacturing processes and their characteristics used in this study.
Table 1 - Comparison of different additive manufacturing processes (Chua, 2010; Volpato, 2007)

<table>
<thead>
<tr>
<th>RP Processes</th>
<th>SL</th>
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<th>TDP</th>
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<td>Zcorporation</td>
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</tr>
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<td>Post processing</td>
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<td>Yes. Removal of supports</td>
<td>Yes. Air jet and infiltration with resin</td>
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<tr>
<td>Total time of manufacture (minutes)</td>
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<tr>
<td>Prototype cost</td>
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<td>Medium-high</td>
<td>Low Low-medium</td>
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CONCLUSION

The additive manufacture applied in the medical area has been revealed to be essential powerful tool for visualization and direct manipulation of prototypes, offering several advantages, such as simulation, surgical planning and exposure of clinical case to the patient.

In this work, some additive manufacturing techniques available on the market were applied to manufacture a locked intramedullary nail and the femur-implant-screws. The application of these different techniques allowed to evaluate the final quality of each model, as well as the duration of the different procedures and the involved costs.

Through the numerical analysis of the femur-implant-screws, it was possible to visualize the distribution of von Mises stresses throughout the model and understand which regions considered most critical in this type of surgery. The addition of an intramedullary nail, in this type of situation, allows a load distribution, resulting always in the sharp decrease of the stresses in the bone, especially in the fracture region, promoting greater stability.

The colour printing of intramedullary nail and femur-implant-screws, allowed the actual view of physical models with the respective colours related to the involved stresses. All the discussed techniques are essential in orthopaedic area by 3D view, the real dimensions of the implant and the intended location for the placing, helping health professionals for a more accurate and safe surgical planning.

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