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Custom Hip Stem Additive Prototyping Using Smart Materials

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Abstract: *Although a standardized hip joint prosthesis is a quick and easy solution to repair most diseases related to the hip joint, it never satisfies the patient's personal needs due to the uniqueness of the human anatomy. Femoral hip stem geometry is one of the factors that have an important impact on prosthesis lifespan or the revision surgery frequency that occurs due to postoperative complications, such as impingement or dislocation after THR (Total Hip Replacement). In this sense, the development of a custom hip stem prosthesis starting from a standardized femoral stem can bring benefits to the patient in time, being able to reduce the failure percentage of THR. The purpose of this article is the development of a custom prosthesis based on patient's CT (Computer Tomographic) scans in order to be 3D printed with biocompatible materials, being able to serve as a study model in both engineering and medicine. Also this study represents a first step in understanding how to apply the unique distribution of mechanical properties in human bone, in order to manufacture a hip prothesis that can mimic them.*

Keywords: *hip stem, femur, additive prototyping, THR, smart filler ABS*

1. Introduction

The optimization of the femoral component using the patient's femoral parameters leads to the personalization of the hip prostheses and thus to hip mechanics improvement, trying to avoid revisions and early replacement of worn hip joint prosthesis. These issues motivate researchers to constantly improve prosthetic components in terms of design, biocompatibility and especially durability, such that the surgery revisions, to which most probably a young patient will have to undergo, will become as rare as possible, avoiding patient discomfort and invasiveness. Parameters which influence hip joint wear should be taken into account to improve the patient's condition after surgery, making the need for implant personalization increasingly important [1]. The greatest challenge is to decrease the manufacturing cost of these personalized medical products [2].

Because of the laborious work from designing to production and implantation implicitly, the manufacturing involves high costs and extended time compared to selecting a standard prosthesis. For this reason it was chosen to develop a CAD femoral stem template that could be modified according to the certain patient’s morpho-anatomical landmarks. This contributes to the semi-automation process of making a femoral stem and can reduce the time, but also the costs of production, giving the possibility of using additive manufacturing. The modeling work from which was started and that was carried out as part of this article is the modification of the existing Linéa® anatomical femoral stem model marketed by the Tornier© company. The development of anatomical femoral stem was chosen because the contact between the femur and the stem is made along the curvature of the femoral cavity, thus leading to better distribution of the external loads or patients’ body weight compared with a straight femoral stem that creates a three point contact (Figure 1).

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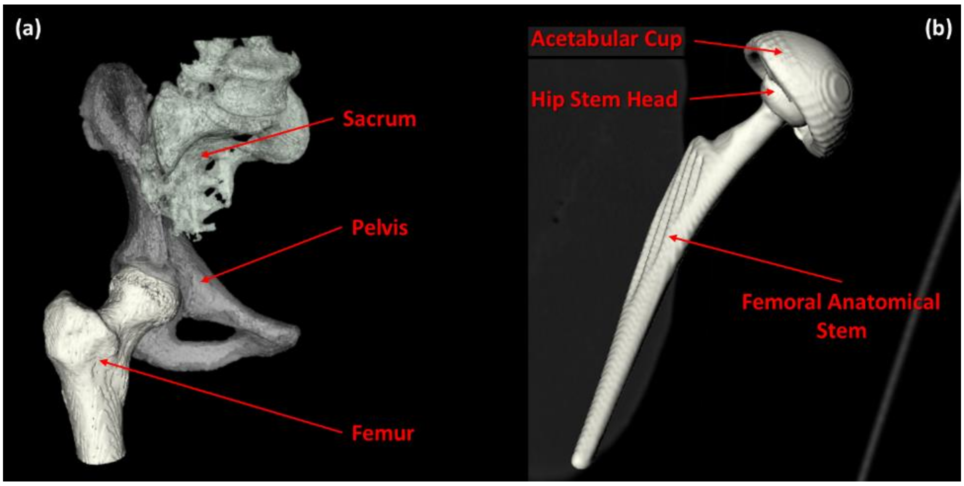


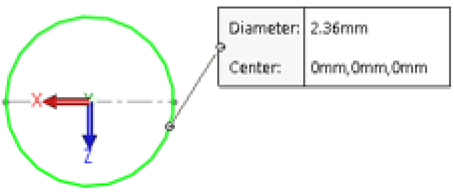
Figure 1. (a) Hip joint anatomy; (b) Hip prosthesis components for THR (Bone segmentation realized with the VTK library in Python)

In preoperative THR planning, orthopedic surgeons use X-Rays or CT scans of patients that are going to undergo surgery to replace the damaged hip, in order to determine femoral morphological parameters such as: diaphyseal axis, femoral neck axis, shaft angle, anteversion angle, femoral cavity width, femoral head center [3]. Based on this morphological landmarks surgeons are choosing the most appropriate standard femoral stem model in an attempt to meet the patients' needs [4]. Following the same approach the anatomical landmarks were used in designing the custom hip stem prosthesis.

2. Materials and methods

The custom femoral stem design was performed in Solidworks software following the femoral stem model from Linéa® anatomical Tornier© in order to generate a custom geometry by taking into account patient's femoral landmark. Because of the complex geometry of the femoral stem, and also due to the anteversion angle (the angle created by the femoral neck axis and the line made by joining the two protuberances from the femoral bottom), which need to be recreated, the femoral stem it was divided into thirteen sections. In order to be able to construct the sketches of each initial profile, thirteen reference plans were constructed, each of them being located at a certain distance from each other and at certain angles, following the standard hip stem cross sections. The first plane was created coincident with the top plane in Solidworks, from the second reference plane until the fifth one offset planes were created at the first one, from the sixth reference plane begins to be tilted in order to form the femoral stem neck.

The diaphyseal axis (represents the axis that passes through the center of two cross sections of the prosthesis) was realized and the neck axis of the hip stem (represents the axis that passes through the center of two cross sections of the neck prosthesis) [5]. After the reference planes, the following step was to proceed by realizing first stem profile sketch in the first plane using as a reference the diaphyseal axis and having the center origin in (0, 0, 0). The other hip stem cross section profiles were built by using the standardized hip stem as a model (Figure 2 (a); (b); (c); (d); (e); (f)).



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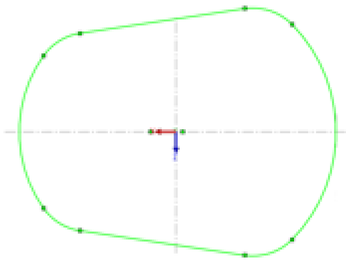

b

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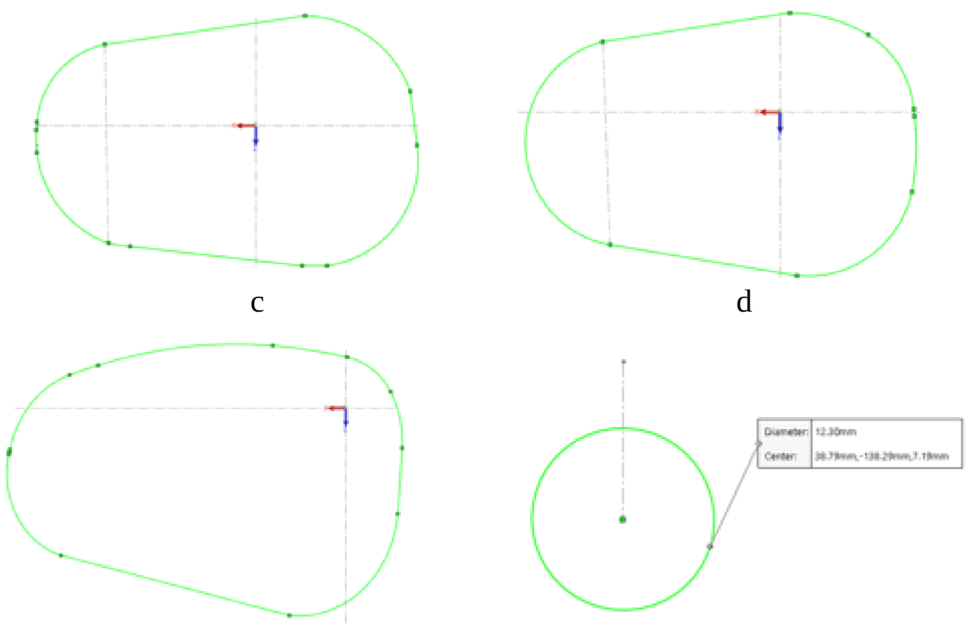


Figure 2. Cross section hip stem profiles. (a) First profile; (b) Third profile; (c) Forth profile; (d) Fifth profile; (e) Seventh profile; (f) Thirteenth profile

The angle created by the diaphyseal and neck stems axis is called neck shaft angle, and usually supposed to match with the patient's femoral shaft angle before the surgery (the angle created by the femoral diaphyseal axis and femoral neck axis). This angle helps the patient to have a normal walk, as close as possible to the initial one, before the hip was affected by the disease, still, depending on the severity of the diagnosis and other pathologies, in some cases the shaft angle cannot be restored.

The shaft angle was measured on a patient's femur that was obtained from CT scans and segmented by using Simpleware ScanIP medical image segmentation software. In this particular case the patients' neck shaft angle resulted to be of 135°, which places the patient in the category of femurs with a normal shaft angle (120°-135°), but surgeons are often carry on another two type of cases called coxa vara (<120°) and coxa valga (>135°) [6].

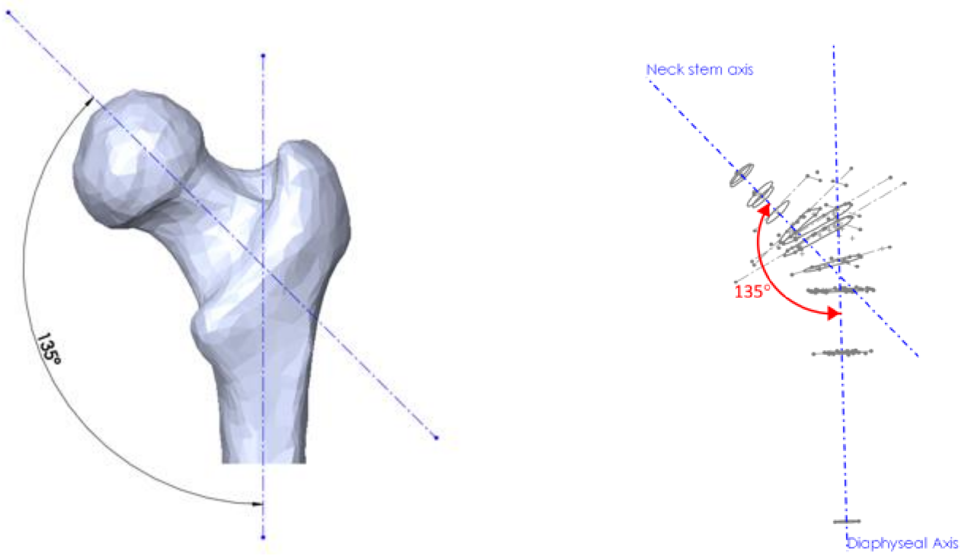


Figure 3. (a) Measuring patient's femoral shaft angle; (b) Hip stem cross section profiles and axis with the neck shaft angle

To obtain the final curvature of the femoral stem two curves tangent at the stem profiles were realized, generically called paths, which serve as a guide for the final instrument applied in order to obtain the final model, called loft (an instrument that adds material between all the profiles in order to create the final feature). The radii of these curves that coincide with the curvature of the femur shown in Figure 4 can be modified according to the femoral morphological landmarks of the patient by accessing the 3D sketch from the template file. A femoral stem with a geometry that tends to fuse on the femoral inner canal may facilitate a better fixation and thus reduce postoperative complication such as impingement after THR.

Femoral patients' curvature radius can be determined by creating a tangent circle at the femur's outline in longitudinal section in the area of lesser trochanter and greater trochanter, this radii can be used in order to change the curvature of the femoral hip stem geometry so that it can be customized according to each patient needs.

At the same time, by accessing the 2D sketches, we can change the total length of the stem according to the size of the patient's femur, neck diameter, neck shaft angle and hip stem offset. Depending on the patient's femoral landmarks we can customize a hip stem prosthesis that it fits much better with the patient's needs. Adaptive geometry and a suitable surgical approach can reduce post-operative complications, increase the life span of the femoral stem, and thus reduce the number of THR revisions during the patient's lifetime.

The geometry of a hip stem prosthesis can be a determining factor in reducing the percentage of THR failure with the orientation of the prosthetic components made by orthopedic surgeons during the THR surgery.

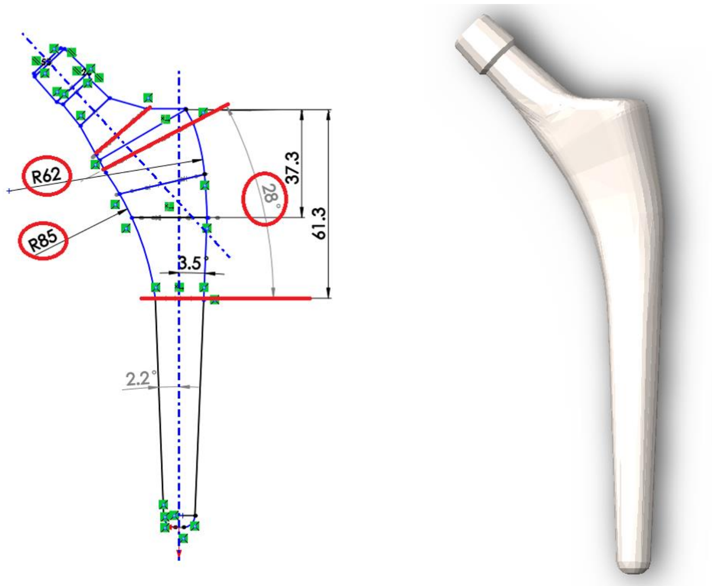


Figure 4. Custom hip stem in 2D sketch and 3D model

3. Results and discussions

Using the custom hip stem design, a prototype was obtained using additive manufacturing. The material used was the smart 3D filament, an ABS (Acrylonitrile Butadiene Styrene), with high quality material specially designed for medical applications [7]. The filament has the ISO 10993-1 certification, that guarantees its biocompatibility with the human body [8, 9]. The printing properties for the smart filler ABS are listed in Table 1.

Table 1. Printing properties for smart filler ABS biocompatible material

Printing properties	Typical value
Printing temperature	240°± 10°C
Hot pad	80°-100°C
Printing speed	40-50 mm/s

CREATOR PRO Flash Forge (Figure 5) was used to manufacture the custom hip stem. In order to obtain smooth surfaces, the model mesh containing 1212 vertices and 4091, was refined and prepared by using MeshLab software. This process involved the use of filters (refining mesh algorithms) to clean and repair the model mesh by removing the duplicate faces or vertices. Two faces are considered equal if they are composed by the same set of vertices, regardless of the vertices order. By applying this different filter, the number of faces decreased to 2567. A high mesh quality was created to have a smooth surface. This is preferable in order to obtain more accurate model, instead of reducing the mesh.

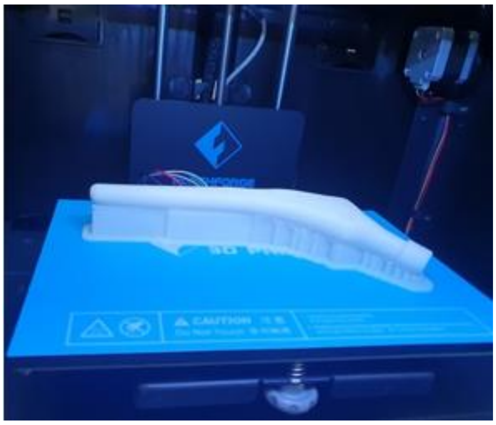
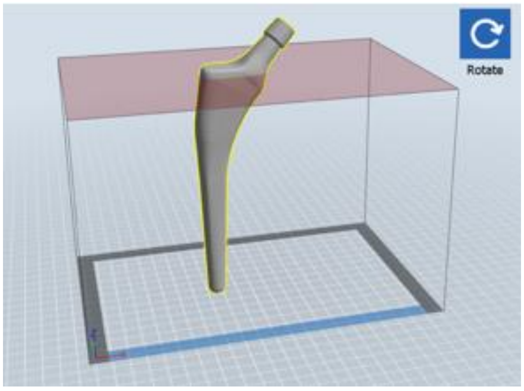


Figure 5. Finished prototype inside CREATOR PRO Flash Forge with the final generated raft support

The model was imported in Flash Print Software (Figure 6 (a)). Then it was rotated with 90°, to position it parallel with the machine platform on, which will be manufactured (Figure 6 (b)).



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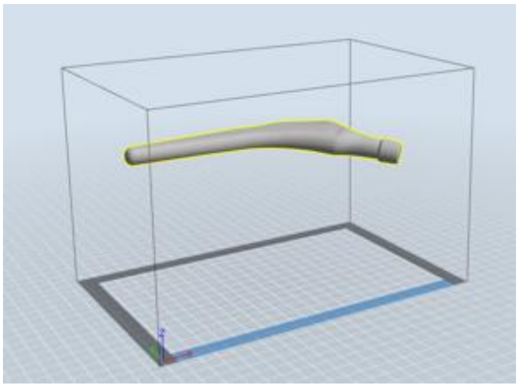
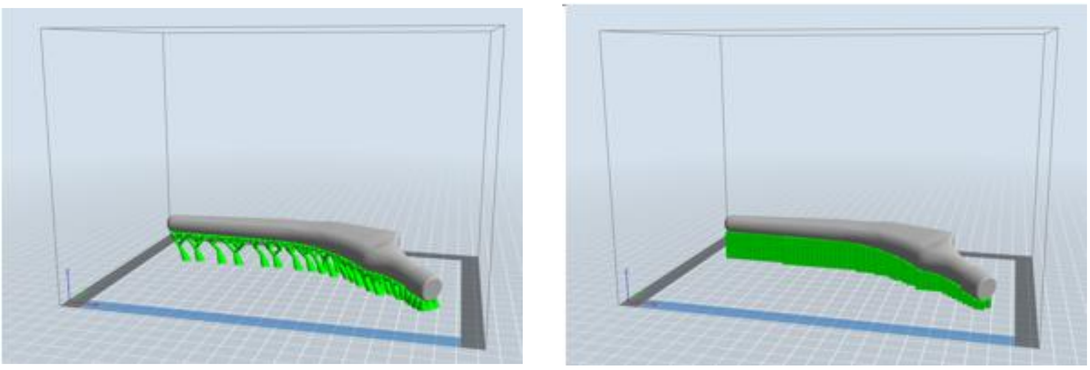


b

Figure 6. Positioning the model on the platform using Flash Print Software
(a) Initial position; (b) Position after 90° turn in relation to the machine platform

The model was centered on the platform and position at 4 mm above it. This was done to create a raft support in order to eliminate the sticking of the material to the platform (Figure 7 (a)), due to the irregular shape of the model. The sticking of the material can affect the printing of proper layers. The raft support contained pillars of 3 mm in size and an overhang threshold of 45° (Figure 7 (b)).



a b

Figure 7(a) Generating a raft support with minimal use of material;
(b) Generating a raft support allowing the layers, printing without problems
and the easy detachment of the hip stem prototype after printing

An important step was the printer settings input, because the material can be optimally printed under certain condition [10]. The layer height was about of 0.18 mm and the first layer height was set to 0.27 mm. The shell setting was chosen as follows: 2 perimeter shells, 3 top solid layers and 3 bottom solid layers.

a b

Figure 8. (a) The manufactured prototype; (b) Comparison of the
manufactured prototype and a commercial hip stem (Tornier©)

The infill was chosen as follows: fill density of 30% and hexagon fill pattern. The print speed was 60 mm/s and the travel speed 80 mm/s. The temperature at extruder level was 240°C (this temperature allows the optimal melting of the material, so that the layers can be built without problems) and at platform level 90°C (this temperature allows the material shelf so that it does not come off during the printing). The prototype manufacturing process took 3 h and 50 min and was used 14.852 m of smart filament.

The final prototype is slightly larger than a commercial hip stem, as it can be observed in Figure 8. By using the smart filler material for additive manufacturing of the custom hip stem a well-defined prototype was obtained.

4. Conclusions

Even if the protheses currently available on the market has reached an all-time level of development, the unique anatomy of each individual is still a challenge. More than that, injuries of different degrees of complexity in young people, arise the necessity to use a prothesis that can function properly for a long period of time, so the need to advance the research on custom protheses is paramount.

In this study, a custom hip stem design was obtained using Solidworks; the initial outline shape was prelevated from Linéa® anatomical Tornier© then addapted and individualised after the pacient`s femural landmarks. The custom geometry was made by taking into account the patient's femoral landmark. Patient's CT (Computer Tomographic) scans were used to create the custom hip stem, thus highlighting the individual anatomy.

A prototype of the custom hip stem with 30% fill, using the hexagon pattern of deposition was obtained by additive manufacturing with smart filler ABS, which represents an ideal option due to its properties. When compared to a commercial hip stem, the manufactured prototype a slightly difference in dimension can be observed. The well defined form of the prototype is a result of the good compatibility of the use of smart filler ABS and printing settings.

Future studies will focus on studying the mechanical behavior of custom hip stems manufactured by additive prototyping. The future goal will be to analyze the geometry impact and percentage of pattern filling on the mechanical behavior of the custom hip stem. This will represent a second step in developing a custom hip stem similar to the bone, in terms of its mechanical behavior.

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