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PhD THESIS

RESEARCH ON OPTIMIZING CUSTOMIZED PROSTHESES

(Thesis Summary)

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Eng. Patricia Isabela Brăileanu

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INTRODUCTION

1.1. Presentation of the doctoral thesis field

1.1.1. PhD thesis structure presentation

This research work was carried out between two university partners, *University "Politehnica" of Bucharest* and *Institut National des Sciences Appliquées de Lyon* as part of a "*cotutelle*" contract. To conclude the research work carried out during the doctoral years, it was then structured and divided into chapters as described below.

Chapter I offers a medical view of the human hip joint anatomical morphology and the determinative causes of hip pain with related or degenerative diseases which can occur in a patients' life, but also an engineering point of view which describes the evolution of the hip joint prostheses.

Chapter II presents the Total Hip Replacement surgery with its postoperative complications after THR, the hip joint prosthetic components with the type of bearings and categories, the traditional 2D preoperative planning that most of the orthopedic surgeons are using nowadays, and the transition trend to 3D virtual preoperative planning.

Chapter III describe a methodology of rapid prototyping of a custom femoral stem by using the patients' CT scans. The chapter goes through all the steps from the description of the medical files (DICOM files), through a bone segmentation process done in SimpleWare ScanIP and the specific algorithms used to extract the bone tissue. The refining surface preparation of the femoral CAD model, was concluded by obtaining patients' femoral landmarks in order to be used in the 3D virtual preoperative planning approach.

Chapter IV aims to analyze the mechanical behavior of a patient's hip joint that suffers of arthritis disease at different loads which may describe the patient's weight in order to observe how a poor quality bone tissue reacts to external solicitations, but also a comparative analysis between a standard femoral anatomical stem and a custom femoral anatomical stem at different loads to observe their mechanical behavior.

Chapter V aims to develop a medical software, based on the information specified in the previous chapters, using VTK libraries to create a Multiplanar view with a perspective view of the patients' bone tissue by choosing the level of Hounsfield Units. A bone segmentation module was developed by using image processing algorithms to extract the desired bone tissue in a CAD model that can be used in the 3D virtual preoperative planning and also a changeable script of the femoral stem used as a template, in which by introducing specific dimensions can generate geometrical transformations that permits the femoral customization.

Chapter VI presents the flexibility of this customization and optimization method of the femoral stem by integrating it into the additive manufacturing sector, which represents the future and the tendency in bioengineering, offering the possibility of fast manufacturing of custom medical products. Compression tests performed on the custom prostheses made of biocompatible natural material show the possibilities, which can be exploited in future, when it comes to customization of femoral stem and AM fabrication.

Chapter VII represents the final chapter where the conclusions regarding the theoretical and practical part obtained from this research study are expressed together with future directions and possibilities to use this study in different future research works, which will take place in this orthopedic field.

At the end of the thesis are presented the reference sources used as a theoretical basis in this research study, which also includes the author's publications in specialized journals and conferences.

1.1.2. PhD thesis proposed objectives

This thesis aims to develop a virtual surgery planning methodology starting from the traditional Total Hip Replacement preoperative planning and having as final goal the realization of a template prosthesis that can be customized according to the femoral landmarks of each patient. Starting from the traditional preoperative planning of THR, which is done on the patients' X-Ray and using the same principles of obtaining femoral landmarks, the CT scans of a patient with hip joint related disease that need to undergo a THR surgery were segmented by using specific algorithms in order to extract the patients' femur and after that was imported in dedicated CAD software in which, with the help of evaluation instruments, all the patients' femoral landmarks were identified. These femoral landmarks were used to develop a custom prosthesis starting from a standard anatomical femoral stem, which was validated using FEA simulations.

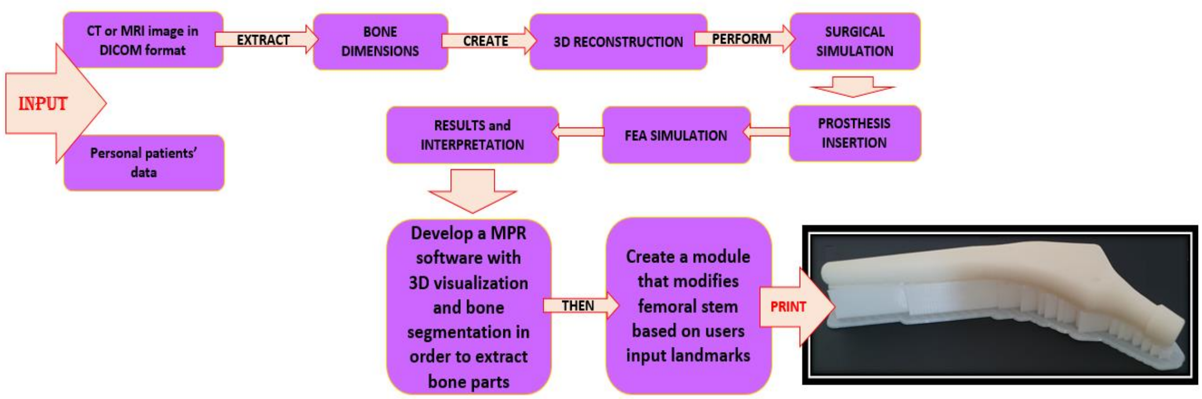

Figure 1.1. Project aim chart with its objectives

Based on the information obtained, the development of a software coded in Python language was done to create somehow a tool that allows the analysis of patients' CT scans in MPR view, but also in 3D view. It allows the bone segmentation of the affected area in order to obtain a CAD model file and perform the virtual preoperative planning in a CAD dedicated software, and finally use some of these dimensions in order to personalize a custom hip stem based on a pre-existing stem model used as basis for the desired geometrical transformations.

The work is completed by printing it with FDM technology, using a biocompatible material to demonstrate the potential of this study, the versatility and the possibility of orienting the femoral stems used in THR towards personalization and AM, avoiding the use of standard prostheses that can lead to postoperative complications and thus leading to the elimination of prostheses “banks” due to the fact that they would no longer be necessary.

Following those described above, these objectives have been set for this research thesis:

O_1: Description of a methodology for geometric customization of the femoral stem according to patient’s anatomical landmarks who is subjected to a THR surgery.

O_2: Development of a medical software meant to analyze the condition of the patient that will be subjected to a THR surgery, offering a visualization module, a segmentation module and a personalization of the femoral stem module.

O_3: Manufacture of the customized hip stem with the help of AM in order to emphasize the possibilities offered by this technology, too little exploited in the orthopedic endoprostheses field.

The results obtained from the study led to the achievement of secondary objectives, as follows:

OS_1: Bone extraction methodology applying specific image processing algorithms in Simpleware ScanIP.

OS_2: Finishing and remeshing the surfaces that define organic forms to simplify them in order to carry out FEA studies.

OS_3: Performing THR surgical simulation in a dedicated CAD software.

OS_4: Virtual simulation at different loads by using FEM having as purpose to obtain a characterization of the mechanical behavior of the prosthetic hip stem and the bone tissue interface to validate the custom femoral stem geometric shape.

OS_5: Developing a semi-automatic bone extraction code in Python language by using the Region Growing algorithm.

OS_6: Development and design of a medical software in Python coding language and proposing a user-friendly interface by using QT Designer software and library.

1.1.3. The current state of femoral stem in the orthopedic field

Nowadays, most of the orthopedic surgeons are using the traditional preoperative planning or surgical technique which consists in three main stages: the evaluation step, the anticipation step and the selection step.

In the evaluation stage the orthopedic surgeon are using an X-Ray of the patient that includes both hip joints in a 2D coronal view [1], begins to determines hip pathology (this can mean, for example, measuring the difference between the lower limbs), then is marking the femur center and observe its location in relation with the greater trochanter, to determine if the patient falls into a case of coxa valga or coxa vara. After the preliminary evaluation, the surgeon is drawing the diaphyseal axis of the femur and evaluates the bone support quality (sometimes uses also a left or right side X-Ray to gather information about the anteversion of the femur).

After the surgeon is concluding the first stage of the preoperative planning is starting to reconstruct the hip acetabulum by choosing an acetabular cup that fits better with the patients’ needs from a standard catalog offered by the companies that produce this type of prosthesis. The same procedure is repeated in the case of the femoral component, the surgeon using a transparent template over which a femoral stem of different sizes is drawn, and overlaps it with the patient's X-Ray to find a standardized solution, as optimal as possible, to solve each patient orthopedic medical problem.

The step is concluded by adjusting the hip joint reconstruction and choosing the size of the prosthetic components from the catalog furnished by the company and finally planning a surgical technique approach that fits best with the patients' needs.

Standardized prostheses are kept in "prostheses banks" and they have an expiration date that usually is around 5 years. The orthopedic surgeon that is following to perform a THR surgery on a patient, use this "banks" every time to procure the prosthetic components and transport them in the hospital where it will perform the surgery.

Customized prostheses are used in exceptional situations, in which the patient has a special medical condition through which the implantation of standard prostheses would not solve or improve his medical condition. They are rarely used due to the difficult process of obtaining them, the number of specialized people involved and the production costs.

1.1.4. Current trends and research directions in THR and hip stem prostheses production

Nowadays, due to technology produced in the recent years as a result of technological advancement, researchers working in the bioengineering field together with orthopedic doctors, are forming research teams to improve prosthetic implants that meet better the patient's needs.

People are much more prone to orthopedic surgery such as THR from an early age and this happens due to the fact that in the recent years the population has begun to eat unhealthy food that predisposes them to obesity, or even they perform activities that strains excessively the hip joint articulation. For this reason, researchers are constantly trying to optimize the endoprosthesis either geometrically or the manufacturing material, to reduce the number of postoperative revisions of a patient, and thus, increase the lifespan of the endoprosthesis.

Periprosthetic osteolysis is one of the most common postoperative complications for which many patients have to undergo THR revision surgery, this taking place due to the detachment of wear particles from the polymeric components that in time eliminate proteolytic enzymes and cytokines enzymes that eventually lead to the implant failure [4]. To slow down this wear process, the researchers realized that they can irradiate the polyethylene components with gamma rays, thus subjecting them to a treatment that makes them more resistant to wear.

Subsequently, the use of metal-on-metal couples was thought to reduce the probability of producing periprosthetic osteolysis, but this type of bearing couple also produces metal ions or metallosis, these being metal wear particles, which studies have shown to be carcinogenic, especially for patients with sensitivity and medical predispositions in this regard [5].

Due to the fact that lately more and more young patients need orthopedic interventions such as THR, engineers and doctors have created implants coated with hydroxyapatite to prevent bone loss. It is usually used uncemented, and their fixation is done in time because this material allows the ingrowth of bone tissue on its surface [6].

The directions in orthopedic surgery and implicitly in THR surgery is to minimize the invasiveness of the surgery, this involves optimizing surgery time to reduce blood loss, optimizing the materials from which endoprosthesis are made, and, of course, finding optimal geometric solutions to reduce the number of surgical revisions after THR. In this sense, software engineers have started to produce software capable of performing computer-assisted surgeries in order to prepare future orthopedic surgeons, but also to prepare virtual THR surgery depending on each patient case. This can come as a solution to preview a THR intervention surgery and gives surgeons the opportunity to choose the most suitable solution for the patient who is about to undergo THR, in a virtual environment. One such software is Osso VR that allows surgeons to perform virtual surgeries that look very real because they use VR headset [7].

Designing geometric models that represent prosthetic components, which imitates or reproduce the anatomical landmarks of the patient, represents another direction of development in the orthopedic field. Because of this, researchers are trying to use femoral landmarks in order to customize prostheses and achieve better osseointegration. Among the first prostheses made by Bohlman and Moore in the 1939 [8] were custom prostheses manufactured specifically for the patient who underwent surgery. Over time, however, with the increase of the orthopedic surgery interventions and due to limited technology, custom manufacturing has collapsed in favor of standardization of the prosthetic components because of the high production costs.

Due to technological advancement produced in recent years and especially because of the additive manufacturing industry development, researchers are performing VPPs to obtain patients' femoral landmarks directly from their CT scans, trying to customize the design of hip joint prostheses. In this sense, the trend is to use software that allows the user to choose anatomical landmarks dimensions and then generate the geometry of the implant based on algorithms. Finally, the design obtained can be manufactured using AM technology.

Recent research studies on materials used in the manufacture of prostheses try to reproduce the bone tissue to recreate a material that has the same mechanical properties and characteristics with the human bone tissue [9]. At first, both engineers and doctors considered that the use of metal prosthetic components biocompatible with the human body will solve the problem of wear, so implicitly the lifespan of the prosthesis. The introduction into the human body of a metal alloy bearing couple that has different properties from the bone tissue, with a high density, can cause damage to both femoral bone and pelvis due to high stress, which a human hip joint is exposed daily, and making patients more prone to postoperative complications, that includes also femoral bone fractures. Thus, research studies are carrying on this field to obtain a material that can be used in 3D printing and that has gradient property characteristics.

In this sense, all directions in the orthopedic field and implicitly in THR are made to obtain prosthetic components that have a design as close as possible to the anatomical structure of the human hip joint, but also at the material level, trying to imitate spongy bone tissue or cortical bone tissue, to obtain a medical product that better meets the needs of each patient who need to undergo such surgery.

1.2. Human hip joint anatomical morphology

The hip joint, or sometimes referred as *coxa* in specialized medical terminology is the human body biggest joint. The hip joint occupies a vital position and role in the body, which, without it locomotion would not have been possible. Being a synovial and spherical joint because the spherical head of the femur fits in the pelvic concave cavity, thus forming the hip joint capsule. The femur's head surface and the concave part (acetabulum) of the pelvis are "*coated*" with a layer of hyaline cartilage or articular cartilage, having the role of reducing the friction between the two joint elements during movement, but also of absorbing shocks that may occur during more demanding activities or even in the event of an accident.

The coxal bone it is an irregular shape bone often likened to a propeller formed by three smaller bones called ilium, ischium and pubis, which all connect in the acetabulum and sutures between them at puberty, the connection lines having the appearance of a "Y" letter. The two coxal joint anteriorly forming the pubic symphysis and posteriorly with the sacrum, forming the sacroiliac joint. In the center it is located the acetabular cavity, and above it is the external face of the ilium on which is located the anterior and posterior gluteal line. Between these two lines the three gluteus muscles have the origins.

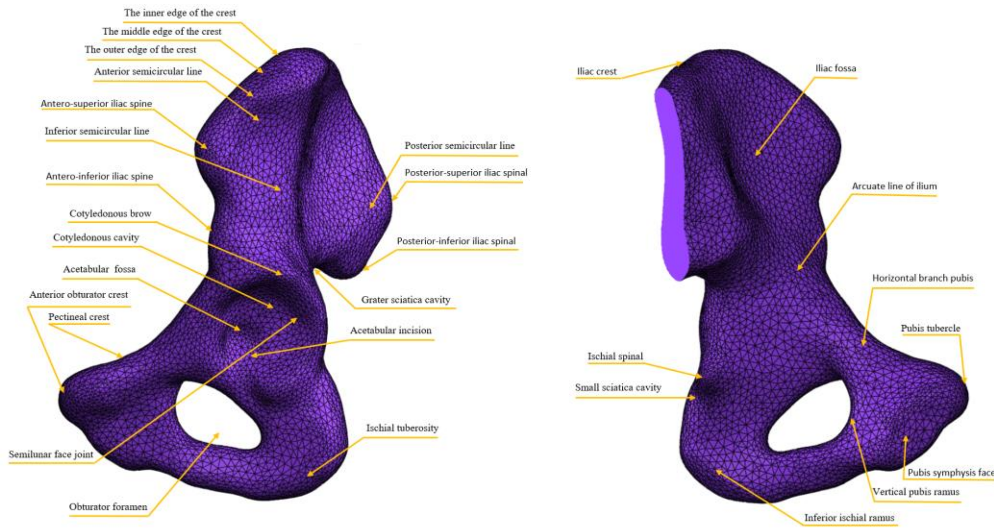

Figure 1.2. Pelvic girdle

The upper margin of the ilium is represented by the iliac crest, which has the shape of a rotated S. The inferior margin presents an anterior segment that joints with the other coxal forming the pubis symphysis and a posterior segment represented by the ischiopubic ramus. Anterior margin presents antero-superior iliac spine, antero-inferior iliac spine, the iliopubic eminence, the pectineal line and the pubis tuberosity. The lower margin of the pelvis shows the posterior-superior iliac spinal, the posterior-inferior iliac spinal, the large ischial cavity, ischial spine, the small ischial cavity and the ischial tuberosity.

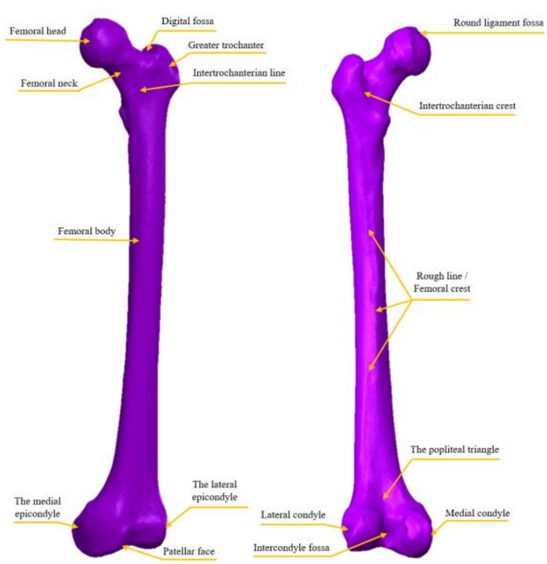

Figure 1.3. Femoral bone

The diaphyseal bone, commonly known as femur is compounded by three parts: one named diaphysis, an extremity called proximal epiphyses and another one called distal epiphyses. The proximal epiphysis contains the femoral head, the femoral neck and the two tuberosities, the greater and the lesser trochanter. The femoral head is 2/3 of the sphere and articulates with the acetabular cavity of the coxal bone. The greater and lesser trochanter are united posteriorly by the intertrochanteric crest and anteriorly by the intertrochanteric line.

The diaphysis has a prismatic geometry, having an anterior face, a medial and a lateral one. At the union of the medial and lateral faces, the rough line is observed, which, at the top is divided in three and at the bottom in two.

The distal epiphyses presents two articular surfaces called femoral condyles. Between the two condyles the patellar surface is located and posteriorly the intercondylar fossa. Above the medial part is the medial epicondyle and above the lateral condyle, the lateral epicondyle.

1.3. Chapter conclusion

All human beings are complex and unique organisms, each one presenting anatomic particularities that need to be considered if the patient must undergo a surgery. Although hip prostheses evolved later than exoprostheses due to the limited knowledge of the human body that scientists knew at that time, starting with surgeon Carnochan, who in 1840 came up with the idea of replacing an affected hip joint with an artificial one, hip prostheses are experiencing a relatively rapid rise that has taken place with technological advancement and the understanding of biocompatibility. Nowadays, the technology promises countless directions for the development and modernization of this field of orthopedics, and THR surgery can now be planned in a virtual environment. Along with the AM technology, the ways to personalize the prosthetic components can be opened, trying to imitate as well as possible the anatomy of each patient in an attempt to reproduce a model as “*biofidel*” as possible.

CHAPTER 2

TOTAL HIP REPLACEMENT SURGERY AND PREOPERATIVE PLANNING

The total hip prostheses consist of three elements that connect with each other, usually by press fit, meant to make a spherical contact that allows the movements of flexion, extension, abduction, adduction and external or internal rotation of the hip.

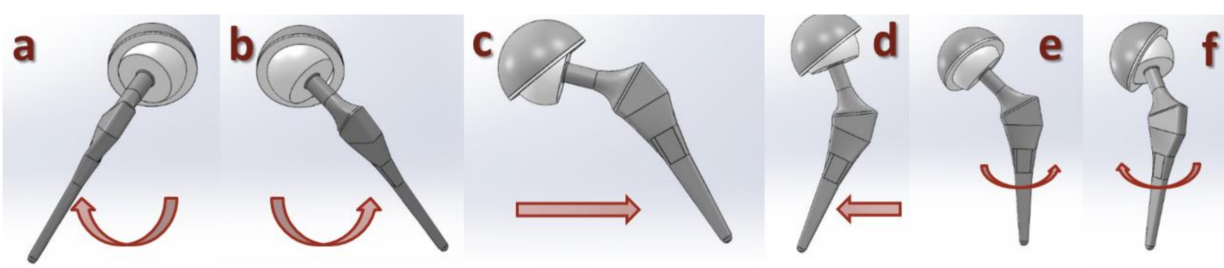

Figure 2.1. Hip joint prosthesis allowed movements (a. Flexion; b. Extension; c. Abduction; d. Adduction, e. External rotation; e. Internal rotation)

Both the hip joint prostheses and the surgical approach are performed based on the particularities related to the patient’s hip joint morphology and the medical history, so surgeons look for the best standardized hip prosthesis type for each individual patient and the most appropriate surgical medical technique to achieve a successful intervention without postoperative complications.

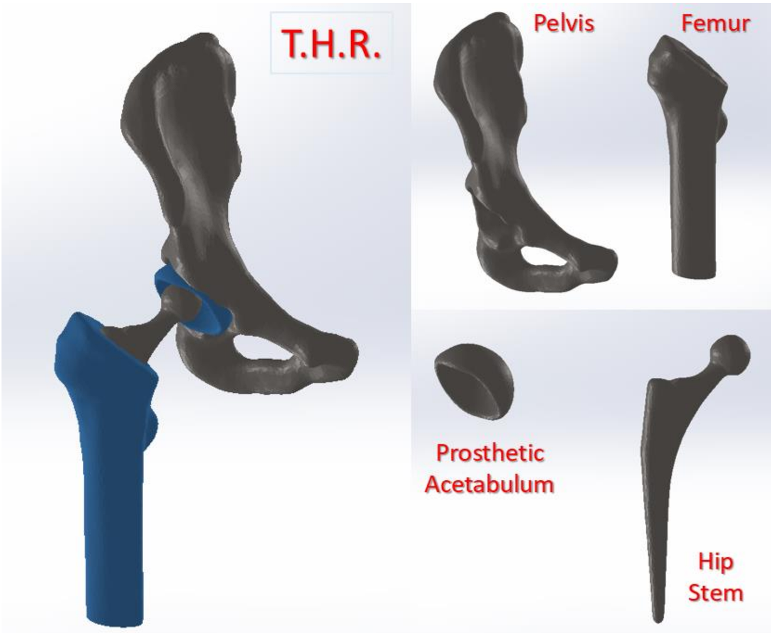

Figure 2.2. THR prosthetic main components

The hip stem is the component inserted into the patient's femoral canal after the femur has been sectioned to remove the damaged area. It is made of special alloys, such as titanium, to ensure the best biocompatibility. Usually they are coated with hydroxyapatite to facilitate the growth of bone tissue on the load-bearing surface which leads to a better osseointegration and implicitly a good stem fixation. Also, the femoral stem can be cemented (usually used for patients with poor bone quality, such as elderly patients who have bone tissue demineralization) or uncemented (commonly used for young patients, or active patients who may subsequently undergo hip replacement surgery in order to replace the old hip prosthesis without damaging the femur) [44].

2.1. Categories of hip joint prostheses

Depending on the geometric shape of the femoral stem, it is divided into two categories:

a. *Straight hip stem* it is most often used for elderly patients with poor bone quality and who have suffered a femoral neck fracture, requiring a special fixation of the prosthesis [57]. After analyzing the contact between the straight hip stem and the patient’s femoral canal, the researchers established that in the case of this typology of prosthesis the contact is made in three points, thus, the load distribution is not uniform and in the event of intense activity or accidents may occur cracks that may lead to femur fractures. Usually, these types of hip stem are cemented and have holes through which they can be reinforced by clamping it with the femur, as well as having standard removable necks.

b. *Anatomical hip stem* it is a prosthesis that follows the morphology of the human femur, having a curvature that molds on the inner femoral canal. Due to this fact the contact surface between the stem and the inner femoral canal is determined by a curved surface, which evenly distributes the loads in the hip joint [58]. This type of hip stem is one of the most commonly used in the recent years, especially for young patients with good bone quality. They can be used cemented or uncemented, and are usually coated with hydroxyapatite to facilitate bone growth on the prosthesis surface.

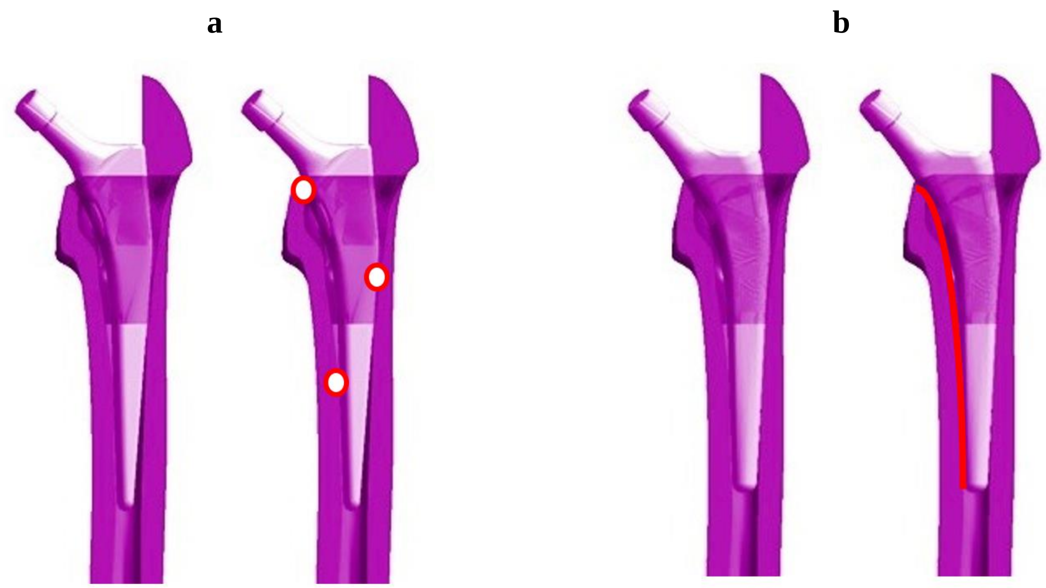

Figure 2.3. a. Contact between the right hip stem and the femoral canal; b. Contact between the anatomical hip stem and the femoral canal

2.2. Postoperative THR surgery complications

One of the largest human body articulations is the hip joint, and is designed in such a way to resist repetitive movements. The bones are making a perfect fit, allowing the synovial fluid to continuously lubricate the articulation. Because of the increase in outdoor sports activities, junk food consumption, and body trauma, or just because of ageing, hip pain is a commonly encountered problem that occurs in the case of many people nowadays. The exact location of hip pain can provide valuable clues about the hip pain causes. Depending on the hip joint affection or illness, the patient can be prescribed a treatment, or in more serious situations, has to undergo a THR surgery [59], which can be partial (hemi-arthroplasty) or full (bipolar hemi-arthroplasty), hip resurfacing surgery, arthroscopy or osteotomy.

Focusing on Primary Total Hip Replacement, engineers and surgeons identified the main postoperative complications, which are faced by a large number of patients: early and late intraprosthetic dislocation, periprosthetic osteolysis, after THR impingement and heterotopic ossification. Postoperative complications may appear due to various reasons, but some of them are directly related to the prosthetic component design, such as early and/or late intraprosthetic dislocation, and after THR impingement [60].

2.3. Total Hip Replacement preoperative planning

Nowadays, more and more surgeons prefer a virtual alternative for preoperative planning which involves bone segmentation and working with Computer Aided Design files that offer a three-dimensional overview of the surgical and virtual preoperative planning. In order to obtain the femur CAD is mandatory to make a bone segmentation from the patient's scans by using dedicated software, such as Simple Ware ScanIP.

After obtaining the femoral model, it is imported in a CAD software and VPP is performed by determining the femoral parameters that orthopedic surgeons use to determine which prosthesis suits the patient's needs. Thus, the landmarks needed to achieve a complete VPP are: femoral shaft angle, femoral neck axis, center of the femoral head, diaphyseal axis, femur's neck diameter, femur length, the femur's anteversion angle and the width of the femoral canal.

a. Femoral neck axis

Starting from the middle of the femur's head, two points were identified, one in the convex area of the femoral neck and another one in the concave area of the femoral neck, in this way the femoral neck axis can be determined in a more accurate manner, obtaining more exact representation as in the case of 2D preoperative planning.

b. Femoral head center

Because the femur's head is an irregular form, it can be approximated with a sphere tangent at the femur's surface. The femoral head center is a femoral landmark which determines the new motion center of the artificial joint and can give natural lower limb movement.

c. Femur neck diameter

The diameter of the femoral neck can be compared to a cylindrical form, having the base perpendicular to the axis of the femoral neck, for example, in this case the diameter of the femoral neck is ~ 47.5mm.

d. Femur's diaphyseal axis

The femur can likewise be approximated with a cylindrical shape whose tallness is the diaphysis axis, it can be identified by determining two points in various zones along the femur, situated in the femoral width center of the picked area.

e. Neck shaft angle

The CCN angle is identified at the convergence between the neck axis and the diaphyseal axis of the femur. The neck shaft angle can determine in which case the patient is situated: coxa valga, normal shaft angle or coxa vara. Many patients who have a dimensional difference between the lower limbs are in one of the cases outside the normal range of the angle.

f. Total length of the femur

The femoral total length can be measured in its entire length, in this care is ~505mm, which normally can be identified as a male femur due to its dimensions.

g. Anteversion angle of the femur

In order to determine the angle of anteversion it must be built an axis by joining two points located in the posterior femoral condyles, the angle formed between this axis and the axis of the femoral neck determines the angle of anteversion, which in this case is about 15°.

One of the most common causes of postoperative complications that produce after THR pain to the patient, increase the wear degree between the prosthetic components and causes unnatural walk to the patient, is the incorrect identification of the anteversion angle, and implicitly defective positioning of prosthetic components, which determine the patient to undergo new revision surgeries to resolve the problem.

h. Femur width above the lesser trochanter

This femoral landmark can be identified by creating a construction axis at 20mm above the lesser trochanter and determine the width of the femoral canal in the section, by measuring it on the construction line.

i. Femur width at the lesser trochanter level

This femoral landmark can be identified by creating a construction axis at the level with the lesser trochanter and determine the width of the femoral canal in the section, by measuring it on the construction line.

j. Femur width below the lesser trochanter

This femoral landmark can be identified by creating a construction axis at 20mm below the lesser trochanter and determine the width of the femoral canal in the section, by measuring it on the construction line.

Once the femoral morphological parameters have been determined, the 3D models of the standardized prostheses can be inserted using the previously determined axes as a guideline and seek the best solution regarding the recreation of the hip motion center and the anteversion angle.

2.4. Chapter conclusion

The human organism is a very complex organic machine with subsystems that work in perfect harmony one with each other conserving energy and protecting us from potential interferences that may emerge from the outside. The use of the particular landmarks which are unique for any individual that must undergo a THR orthopedic surgery, helps to increase not only the eventual prosthetic life, but also to reduce postoperative complication such as early intra prosthetic dislocation, related also to prosthesis geometry.

VPP is a modern method of measuring the femoral parameters of the patient that must undergo a THR surgery. By performing this THR planning in a virtual, three-dimensional environment, the orthopedic surgeon can plan the surgery approach, choose a suitable prosthesis for the patient and better understand his medical condition.

Each patient must be treated in an individual manner and the reverse engineering method can help us establish the femoral parameters of each patient, helping to change the standard procedures, treating each patient case differently because all of us has unique particularities, although they may seem similar at first glance.

CHAPTER 3

VIRTUAL PROTOTYPING FOR CUSTOM FEMORAL STEM PROSTHESIS

Bone segmentation is the particular operation with which we can reconstruct body parts, usually organs by overlaying the voxels and separating the soft tissue of bone tissue in order to extract the parts, which this study needs. Today, there are multiple dedicated software programs which realize bone segmentation in an automatic way by applying multiple image processing algorithms and extracting directly the bone tissue, or in semi-manual way, requiring user's intervention, usually prepared or trained to use the specific software [90]. In this chapter the femur of a patient, which suffers of arthritis need to be extracted and because of the patient condition an automatic bone segmentation software will not extract only the femur, but also the pelvis in a same CAD file due to the hip joint wearing, the threshold algorithm couldn't identify the difference between the two bone parts. Because of this condition this study was realized in Simpleware ScanIP Version 7.0 +FE software, dedicated to the processing of medical images, having a complex basis of image processing algorithms which can be applied to obtain a better surface and a better CAD model in order to perform virtual analysis or even preparing a 3D printing model.

The principle of bone tissue extraction from medical images is based on voxels (is the equivalent of a pixel in a three-dimensional space) identification from region of interest by applying various image processing algorithms on each CT scan, slice by slice, so that the 3D anatomical model can be recreated [91].

The model accuracy obtained after image processing can also be influenced by the digital image quality, which are often affected by a specific phenomenon called noise. Noise in images occurs due to imperfections of medical capture devices, scanning systems or optical systems when transferring data and can be of several types: additive, Rician, multiplicative, Gaussian or white etc. [92] If the situation requires, these images can be processed with the purpose of imperfections and noise reduction, thus, the following algorithms can be applied: histogram equalization by adaptive filtering with contrast limitation or CLAHE, linear contrast adjustment, image filtering, Wavelet transform, Fourier transform, image binarization etc. [93] All these medical image adjustments can help clinicians to better isolate and identify the patient's medical problem by increasing the visibility of the studied areas.

To start the image process the DICOM images were imported by selecting the DICOM directory and add all the frames: a crop and resample window will pop-up where the user can choose a pixel rescaling, a pixel skip and if the user wants to crop the files or not. After importing the data, a four windows view called generically MPR view (Multi Planar View) will appear and in this way the user has the possibility to work in axial view, coronal view or sagittal, and verify the applied algorithms by refreshing the perspective view.

The main important steps performed in order to obtain the CAD femur file are:

a. *Threshold* image processing algorithm (perform segmentation based on lower and upper greyscale boundaries, by creating a histogram in order to extract only the bone tissue and prosthesis components) with a lower value of +400 HU and an upper value of +2000 HU, this value allows to extract specific tissue. In radiology each voxel from the CT scan has a value which is measured in Hounsfield units, a quantitative unit scale used to describe the radio density, every voxel having a number of 4096 possible values that it can take, this value being arranged on a scale from -1024 HU to + 3071 HU [94]. In DICOM files, a value is directly related to the linear attenuation coefficient for the X-Ray and is usually calibrated and set to 0 HU for water and to -1024 HU for air, studies have shown that values around -120 HU corresponds to fat, +40 HU corresponds to muscle and +400 HU corresponds to bone tissue [95].

b. *Region growing* algorithm (growing a region from a voxel by using statistics) is used to identify neighboring voxels and to select whether they belong to the region of interest. If voxels belonging to the region are still not selected *Paint with threshold* tool can be chosen so each DICOM can be repaired separately.

c. *Island removal* algorithm is applied because of residues remained from other organs around the main part, thus applying this algorithm the user can eliminate island size threshold or isolated voxels.

d. *Close morphological algorithm* which is closing the small holes inside the mask part by uniting the voxels.

In order to extract the femur more accurately, the image processing was done in two MPR views (in the horizontal plane/axial view and in the vertical plane/coronal view), starting by using the *Threshold* tool, choosing a lower and an upper value and selecting the option *Profile line* with, which two points can be selected along the entire hip and the software will automatically separate most of the soft tissue from the bone tissue. In order to isolate the femur and eliminate the body part that we don't need the *Crop tool* can cut the 3D image by using reference planes, so in this way the user can focus on the specific area that wants to extract it from the CT scans.

In most cases after the *Threshold* algorithm residues of other tissues that interfere with the profile line will appear, and this effect was eliminated by using the *Island Removal* tool with a specific voxels size that we can choose depending on the situation, in this way *Island Removal* algorithm helps us to "clean" the 3D image of small residual particles.

Usually we can notice that the algorithm applied selects also the femoral arteries, the user can proceed through processing the image by using a *Region Growing* tool, and selecting the femur in a particular view, which offers good visibility such as the axial view in our case, where we can distinguish well the femur. By using this tool in the active view area and creating a new mask overlapped on the initial mask, the entire femur can be isolated and recreated in all the frames by applying the algorithm a several times, until the bone is fully covered by the mask.

After checking the other frames we can observe that the new mask didn't cover all the bone tissue and there were still pixels in the initial mask that weren't covered by the new created mask: in order to fix this problem, the user can increase the multiplier and the initial neighborhood (voxels), and select the areas where the second mask didn't cover the initial one.

Since the need to obtain a model as accurate as possible is high, Simpleware ScanIP offers the *Paint with Threshold* tool which helps the user to select each voxel, in order to cover all the bone tissue for every DICOM image frame.

Anatomical surfaces of any kind have a high complexity due to the irregular geometric shape, which therefore directly affects the analysis time of the CAD model, but also the requirements regarding the performance of the computer. For this purpose, the models are simplified, re-meshed and refined, in order to obtain a surface with reduced geometry model complexity, thus optimizing the model analysis times [96]. To simplify mesh from the toolbar the re-meshing option can be selected, simplification and reconstruction category, the Quadric Edge Collapse Decimation filter was used to reduce the number of faces. As the number of polygons increases, the simulation accuracy or details increases, but the model complexity increases as well, so as a repercussion the virtual simulations, for example, tends to be as simple as possible by keeping the essential parts with an agreeable number of elements.

In order to provide a more refined surface with MeshLab software, the user can also reconstruct surface decimation, in this way it can reduce the number of elements by using the algorithm of Taubin Smooth in order to remove residuals as in E. P. Ravera et al. study [97]. After the surface optimization and finishing process was concluded, the model was exported in the extension *.stl, after it can be imported in CAD software programs that can perform finite element analysis (FEA).

3.1. Identification and measurement of patient's femoral landmarks

The foremost imperative part in characterizing the geometry of a hip stem prosthesis is represented by the femoral landmarks of the patient, which were presented in the previous chapter. These landmarks offer support to adjust the standard geometric shape of a femoral prosthetic component so that it matches with patient's morphology. Each landmark has a purpose in the construction of the hip stem prosthesis, but also in its orientation when inserted into the femoral canal.

The performance of a virtual preoperative planning can be realized in most CAD type software that allow the import of a 3D file and which can be manipulated (Catia V5, Solidworks, Solid Edge, Inventor). In this study, Solidworks 2017 software was used in order to measure patient’s femoral parameters.

After the *.stl file has been imported in Solidworks 2017 it was proceeded by determining the femoral diaphyseal axis by creating first a reference plane coincident with the lower sectioned surface of the patient's femur. In this plane, a tangent ellipse was made at the transverse contour of the femur and its center is becoming the first reference point that will be used in the achievement of the diaphysis axis. In the same manner, the second reference plane was realized which includes the second ellipse tangent to the transverse contour of the femur and which is parallel to the previous plane. The two ellipse centers were used as reference points to construct a reference axis, namely femoral diaphyseal axis.

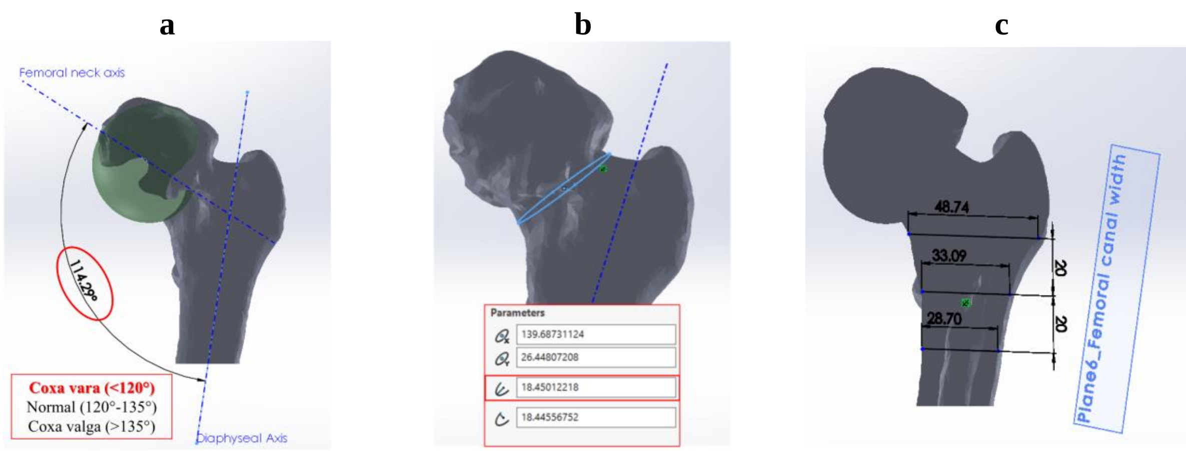

Figure 3.1. a. Patient's neck shaft angle determination; b. Patient's femoral neck width determination; c. Patient's femoral canal width determination

For the femoral neck axis determination, the same principle as the previous one was used, but this time the first reference plane was constructed using two collinear edges at the base of the femoral neck. In order to facilitate the construction of the ellipse, a section of the femur was created by the respective plane. After constructing a plane and an ellipse tangent to the transverse profile of the femoral neck the process was repeated in another parallel plane that was created at the opposite end of the femoral neck. By joining the two centers of the ellipses, the axis of the femoral neck is determined.

In order to determine the new patient’s motion a new reference plane coinciding with the axis of the femoral neck and being perpendicular to one of the reference planes used to determine the axis of the femoral neck was needed and inside this plane was made a sketch of a half sphere that is approximately tangent to the surface of the patient’s femoral head. Using the *revolved boss/base* command we generated a spheroid that is approximately tangent to the femoral head, but it is worth mentioning that the femur is damaged due to arthritis and because of this the surface of the femur cannot be perfectly enclosed in a sphere. The center of this spheroid is the femoral head center or the new center of motion.

To determine the neck shaft angle, it just needs to be measured the angle between the femoral diaphyseal axis and the femoral neck axis, which were constructed before. In this case the CCN angle measures ~114.29°, which includes the patient in a coxa vara case.

The femoral neck width was measured by constructing an ellipse in a reference plane situated approximately in the middle of the femoral neck the parameters of the ellipse determining the neck width of ~36.9mm.

In order to determine the thickness parameters of the femoral canal, it was proceeded by constructing a reference plane that passes through the femoral diaphyseal axis and the femoral neck axis and perpendicular to one of the diaphyseal axis reference planes. The femur was sectioned with the help of the new reference plane created that cuts the femur in two pieces and next to the lesser trochanter were measured the femoral canal width.

In order to determine stem’s offset, it was proceeded by measuring the distance between the femoral neck center and the diaphyseal axis, which in this case measures approximately 39.64mm.

After determining the patient's femoral landmarks, the next step on virtual prototyping of a custom stem is to build a personalized hip stem prosthesis using patient's landmarks and trying to mold it as much as possible on the femoral canal surface.

3.2. Developing a custom hip stem *[98]*

The foremost commonly femoral stems utilized in THR surgeries, if we take into account the stems geometry, are the anatomical and the right hip stems shape. The considerable distinction between them is the contact mode realized between the hip stem and the femoral inner wall cavity that clearly is influencing the way in which the loads are distributed.

Since the anatomical stem shows a curved contact surface along the femoral internal cavity, which implicitly helps to a better load distribution that can occur in hip joint, it was decided to develop a customized anatomical stem model, according to the patient's femoral landmarks.

Once the primary step of the femoral landmark determination was done, the femoral prosthetic stem’s length was chosen to be about 130mm in accordance with the patient's femoral geometric shape. An inappropriate choice of the femoral stem total length can cause postoperative complications and over time a very long stem can cause fracture of the femur, therefore the length of the femoral stem is chosen taking into account the anatomical landmarks of the patient and his age.

The femoral stem offset is determined, being about 40mm in this studied case. Then, by using a construction line angled at about 45°, the femoral cutting line is marked, this practically represents the line marked by the orthopedic surgeon to determine which part of the patient’s femur is removed in order to insert the femoral hip stem. This reference line is necessary because the anteversion angle of the femoral prosthesis component changes its inclination in this area, achieving an anteversion of ~16°.

Using as reference the patient's femoral cavity in section, three widths A, B, C and D are identified, these being necessary to mark the width of the femoral hip stem in different areas of it (the dimensions are measured in the area of the lesser trochanter, below and above it).

Each of us presents unique features of the body, implicitly the curvature of the femur has a distinct radius that gives us a certain way of walking, different from one individual to another. In this study was assumed that the patient has a healthy hip joint and a damaged one, for which he must undergo THR surgery. If a femoral prosthesis is implanted with a standard CCN angle of 135° that is completely different from the patient's healthy hip joint, it can create a difference between his hip joints and obviously between their kinematics, and although it may seem unimportant it may be one of the factors that triggers postoperative complications. In order to optimize the femoral component of the hip prosthesis and to create the possibility to reduce eventual postoperative complications that a patient could go through, but also in an attempt of trying to restore the patient's initial kinematics, it was decided to develop a prosthetic femoral component using these patient's landmarks.

Because it was wanted to reproduce the femoral curvature of the patient in an attempt to make a prosthesis as "*biofidel*" as possible, a construction circle tangent to the outer surface of the femur, in the area of the lesser trochanter was drawn, which was offset until its intersection with the construction line represented by the B segment. Was proceeded in the same manner with the outer part of the great trochanter to acquire the outer part of the femoral stem prosthesis. By joining the segments, the thickness of the femoral prosthetic component was determined, its curvature being obtained through the circle arches made with the help of the construction circles.

By constructing the two curvatures of the prosthetic femoral component so as to imitate those of the patient, but also using these radii to produce a gradual transition from the body of the prosthesis to its neck, a personalized prosthesis can be developed according to the patient's anatomical landmarks.

To transform this sketch into a 3D model, the two spline curves and a profile perpendicular to these curves and tangent at the same time is used. In order to achieve the anteversion angle of 16°, a tilted reference plane is created at the same angle, in which the transition profile is inserted. With the help of the loft tool from the Solidworks software, material can be added between the created profiles, respecting the guidance of the curves that define the thickness of the femoral prosthetic component.

Postoperative complications such as impingement after THR can also be determined by the design of the femoral prosthetic component, and making customized prostheses can reduce some of the factors that lead to these complications. Orthopedic surgeons are aware of this determining factor, and having only standardized prosthetic components at their disposal tries to avoid the occurrence of such postoperative complications by positioning them so as to create a compromise in the patient's favor.

3.3. Developing a femoral stem template with changeable parameters *[99]*

The greatest challenge is to decrease the manufacturing cost of these personalized medical products. Prosthesis standardization is a quick and permissible way to restore the hip joint of a patient who is suffering from hip pain or has related joint disease, but although these prostheses are developed to restore an initial patient's condition, unfortunately it does not fully meet the needs of the patient because each bone system contains unique features depending on the individual.

That is why orthopedic surgeons and engineers are motivated to develop prostheses that faithfully mimic the human femur through their design, increase the lifespan of the medical product, and being manufactured from a biocompatible material to reduce the percentage of patients who have to undergo a revision surgery shortly after THR.

Thus, the femoral parts that lead to the prosthetic components wear can be modified and improved so that the patient is less exposed to postoperative complication, so the need to customize the prosthetic femoral component becomes more and more important.

Making a custom prosthesis as by following the steps explained in the previous sub-chapter takes time, trained personnel and of course it involves validating the prosthesis once it is built. Because of this 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 that we carry out as part of this thesis is the modification of the existing Linéa® anatomical femoral stem model marketed by the company Tornier©.

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 3.2* 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.

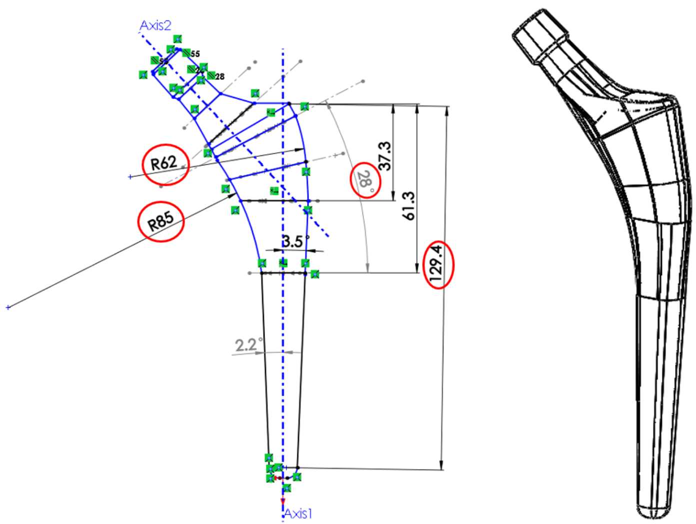

Figure 3.2. Hip stem template with adaptive geometry

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.

3.4. Chapter conclusion

One of the main causes that increase the early prosthesis dislocation is the geometrical aspect of the hip stem and acetabular components. In order to create a more suitable anatomical hip stem that tends to fuse with the patient's femur, patient's femoral landmarks and femoral curvatures were used to develop a personalized hip stem prosthesis. The difference between the standard hip joint prosthesis and a personalized one is that in case of personalized hip joint prosthesis the shaft angle and the anteversion angle (which influence the probability of early intra prosthetic postoperative complication) can be the same as the initial one that the patient had when the hip joint was healthy; instead if we talk about the standard hip joint prosthesis we can choose between a limited number of angles.

With the help of Additive Manufacturing Technology, the costs of manufacturing personalized hip joint prosthesis can be decreased, and the opportunity to develop specific medical products for any individual becomes more and more possible and feasible.

Because of a significant improvement of pre-clinical validation in the last years, numerical models and experiments in vivo can replicate nowadays most of failure scenarios of hip joint prosthesis. However, there are still many factors that are very difficult to consider like: patient's anatomy, bone and muscles characterization and activity level or other biological interferences. In this sense, in the next chapter, a virtual validation was performed with the help of FEM in order to observe the mechanical behavior of a standardized prosthesis and a customized prosthesis.

CHAPTER 4

FINITE ELEMENT ANALYSIS OF HIP JOINT FEMORAL STEM

4.1. Mechanical behavior simulation of a standard femoral stem

The simulations were carried out on Solidworks 2017 CAD software with a finite element extension called *Solidworks Simulation*, because is particularly recognized for its excellent contact management. In this part, the images used to illustrate the method come from the assembly of the standard femur and the standard anatomical hip stem.

The standard anatomical femoral stem was built based on a *Linea Anatomica Tornier* femoral hip stem, to use it as a benchmark in the study of a custom hip stem prosthesis. In order to perform the assembly and perform a virtual THR surgery, a new assembly file was created and the femur was imported and used as a basis geometry. Orthopedic surgeons are using femoral landmarks to choose the most suitable hip stem prosthesis. Using the same idea the diaphyseal axis and femoral neck axis of the femur was used in order to create a mate with the diaphyseal axis and the neck axis of the hip stem. After constraing both parts the virtual surgery is performed by cutting the femur with a reference plane at the same level with the angled femoral stem. Depending on the bone quality, or patient's medical condition, surgeons can cut all the superior femoral part, or usually they let a part of the grater trochander, following the same procedure a small part of the grater torchander was still kept in this study. The stem insertion was created by using the create cavity feature, which practically is creating a gab inside the femur that fits with the geometry of the femoral stem inserted. At the same time, separate static simulations were performed on the femur and on the femoral hip stem in order to observe the individual mechanical behavior of each part.

4.1.1. Contact definition

Within this model one contact type was consider, the contact between the cortical bone (of a young patient and of an older patient) and the femoral stem. The management and definition of these contacts are detailed below. Defining constraints between the parts of an assembly is possible in Solidworks Simulation, *Connections*, *Contact Sets*. In this study, the femoral stem is in contact with the cortical bone, contact must therefore be defined between the cavity of the cortical bone and the femoral hip stem. In this sense, the interfering faces were identified automatically and set up a contact which allow penetration between the femoral cavity and the femoral hip stem with a global bonded contact between both parts, assuming that the contact between parts is a dry, ideal surface contact.

In the case of individual static studies for the femur and standard hip stem the contact were bonded because we do not have other parts involved in the simulation.

4.1.2. Fixing geometry

When modeling the femur involving only the upper part of the diaphysis and the proximal end, the boundary conditions are applied directly to the lower face of the sectioned femur. Since this face does not constitute a real limitation and the diaphyseal part is continuously up to the distal end, there is no possible translation or rotation at this face relative to the rest of the bone. In the same way for individual studies the geometry of the femur was fixed as in the assembly, but the femoral standard stem was fixed on the entire surface which is in contact with the cortical bone.

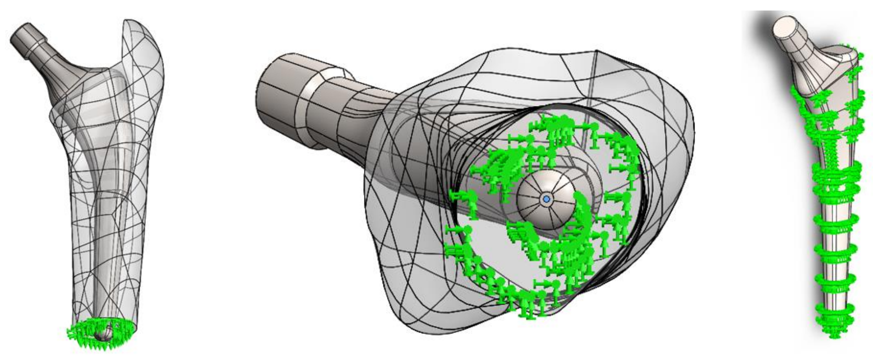

Figure 4.1. Femur and standard prosthesis assembly fixture and standard hip stem fixture for the individual part study

4.1.3. Boundary condition

Table 4.1. Forces applied in the FEA study

Load	**Value [N]**	**Equivalent in kgf**
F_1	686.46	70
F_2	784.53	80
F_3	882.59	90
F_4	980.66	100
F_5	1078.73	110
F_6	1176.79	120
F_7	1274.86	130
F_8	2000	204
F_9	2500	255
F_{10}	3000	306

In order to model the application of the loads in a realistic way, it was chosen to distribute the efforts evenly on the upper part of the femoral head, corresponding approximately to the bipedal position of a patient who undergo a THR surgery. Ten types of load were applied (*Table 4.1*), as a normal to the femoral head faces, and distributed over the entire surface on which it acts. For the study performed on the assembly between the femur and the standard stem, the loads were applied to the femoral head of the stem, as well as on the individual study of the standard femoral hip stem, but for the individual study of the femur the force was applied to the entire cavity created by the standard stem insertion.

A pressure distributed on the entire outer surface of the femur equal to 24MPa was applied, representing the external pressure exerted by soft tissues such as muscles on the femoral bone. Determining the value of this pressure to apply is overly complex and would require carrying out a much more in-depth bibliographic study, which was carried out on the subject within the framework of this project. This study was based on the articles of Bensamoun et al. (2006), Debernard et al. (2011) and Larsen et al. (2008), from which we can conclude that the muscle stiffness of the thigh muscles used in 20% of the voluntary muscle contraction was around 8MPa on average. In addition, knowing that during a climb of stairs, the muscles are stressed at around 60% maximum, was decided to raise this value to 24MPa, with the specification that this value is only an approximate order of magnitude because muscle behavior is far from being so linear. However, we still wanted to keep this boundary condition which seemed essential for the modeling as realistic as possible.

4.1.4. Material assigning

Table 4.2. Mechanical properties of the material used in the FEA study

Property	**Healthy cortical bone tissue**	**Elder cortical bone tissue**	**Titanium alloy (Ti_6Al_4V)**	**Units SI**
	Value	**Value**	**Value**	
Elastic Modulus	15000	11600	115000	MPa
Poisson's Ratio	0.3	0.26	0.3	N/A
Shear Modulus	3300	3300	44000	kg/m^3
Mass Density	1800	1440	4400	MPa
Tensile Strength	133	21.13	950	MPa
Compressive Strength	205	97.19	970	MPa
Yield Strength	114	114	880	MPa

This study was performed with two types of bone tissue, one with healthy cortical bone tissue and one with cortical bone tissue having a lower quality, equivalent to the elderly patients, in order to compare the results and to observe how different both tissues behave in certain conditions.

Regarding the FE analysis performed on the whole femur and the standardized femoral stem, the material applied to the standard stem was the same in both types of study, the one performed with healthy cortical bone and the lower quality cortical bone tissue. To test the femoral prosthetic component, a biomaterial widely spread in medical applications called TC4 was used, a titanium alloy containing between 3.5 and 4.5% vanadium and between 5.5 and 6.5% aluminum and other impurities [113]. It was considered to implement the hypothesis that this material is homogeneous and isotropic with an elastic and linear behavior.

4.1.5. FEA stress results

In *Figure 4.2* we can observe the stress distribution on the assembly, but also in all individual parts, in case of F_{10} load application.

In *Figure 4.3* we can observe the graphic evolution of stress results in the assembly study, in the femur for both, healthy and elderly patient cortical bone tissue and for the standard femoral stem.

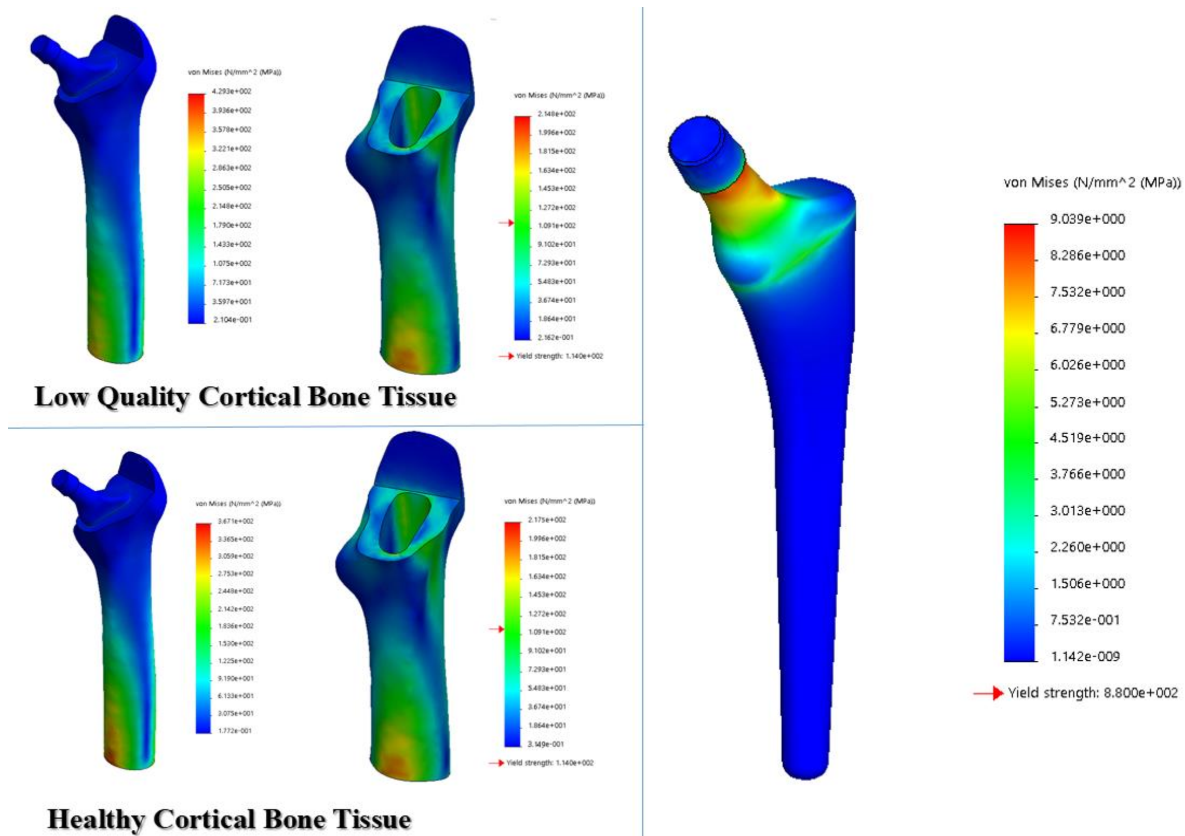

Figure 4.2. Stress results distribution in case of 3000N load applied

4.2. Mechanical behavior simulation of a custom femoral stem

Following the same principles as in the case of finite element analysis of a femur and a standardized hip stem, a new set of simulations was performed in order to observe the mechanical behavior of the prosthesis and whether its geometry can effect a better load discharge in case of healthy cortical bone tissue and in case of low quality cortical bone tissue. In this sense, the contact was defined as in the subpoint *4.1.1*, fixing the geometry was done as well as in the subpoint *4.1.2*, the boundary condition was the same established in *4.1.3* subpoint, and the material assign was done in the same way as in the anterior simulation.

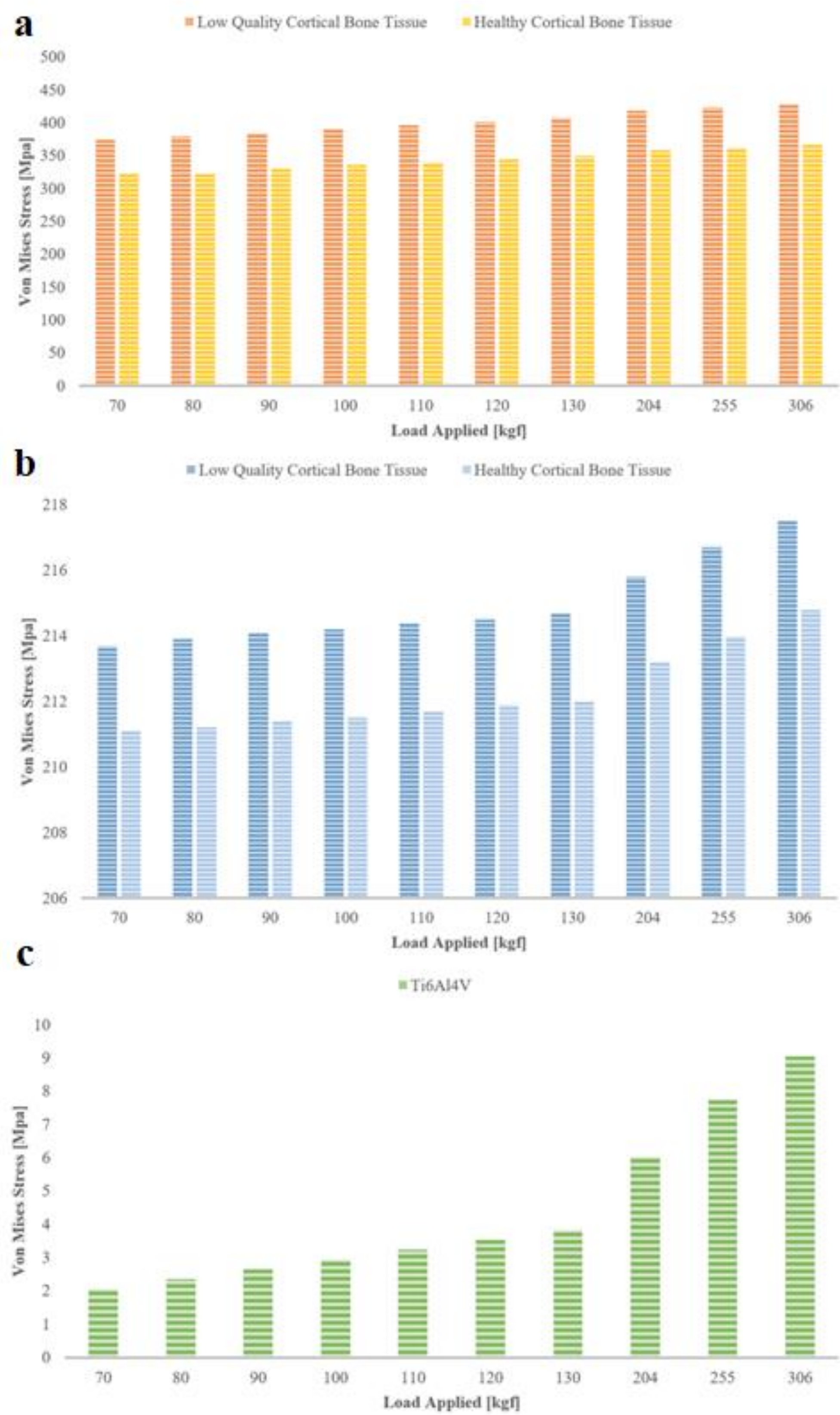

Figure 4.3. Simulation stress results. a. standard femoral stem assembly; b. femur model; c. standard femoral stem

4.2.1. FEA stress results

In *Figure 4.4* we can observe the stress distribution on the assembly, but also in all individual parts, in case of 3000N load application. In *Figure 4.5* we can observe the graphic evolution of stress results in the custom femoral hip stem study in case of each load.

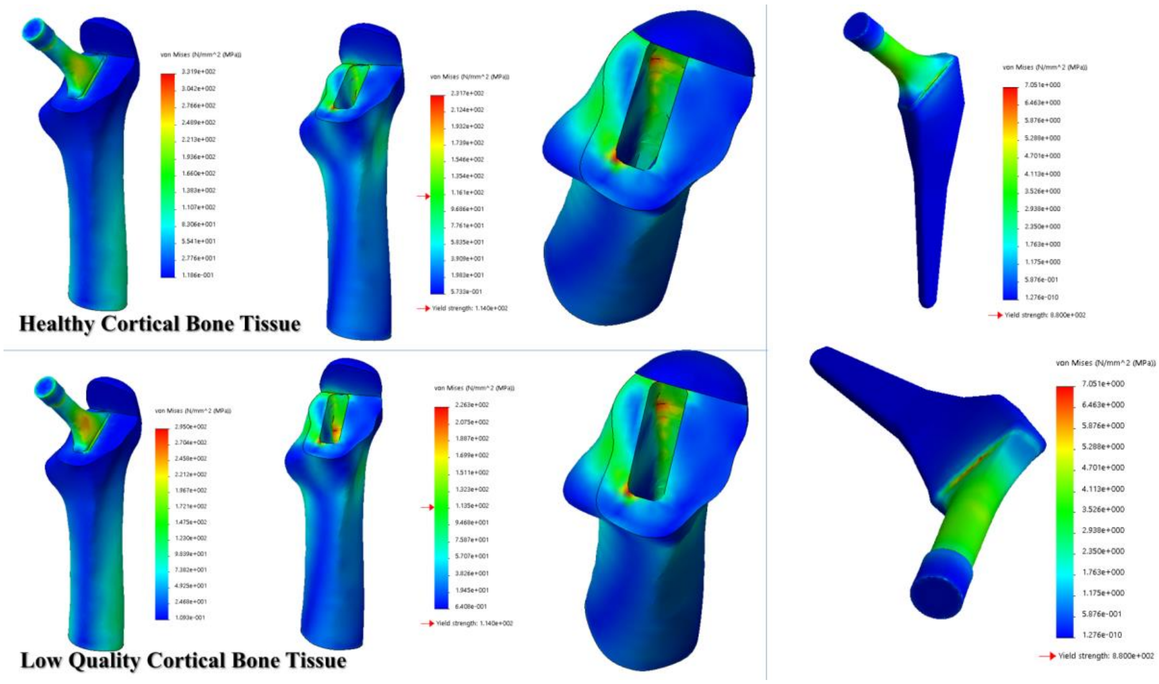

Figure 4.4. Stress results distribution in case of 3000 N load applied

4.3. Chapter conclusion

Comparing the results obtained from the FEA studies between the assembly that contains standard hip stem and custom hip stem we can notice a considerable improvement in the stress results following the femoral custom hip stem. A personalized geometry may discharge in a more optimal way the loads that can occur inside the hip joint articulation. At the same time we can observe also that the bone quality influences the results and the stress at the joint level, young patients responding better to external loads than elderly that can suffer of bone loss or other associative pathology.

Although virtual simulations can provide significant information on the mechanical behavior of prostheses they cannot accurately reproduce real situations due to the complexity of the human body and the uniqueness of each individual. However, they are especially used in the prototyping phase of a design, helping the concept engineer to decide which design can be studied further and in which design should invest for the in vivo experiments.

Due to the large number of THRs performed in the last decade, but also due to the increasing number of surgeries expected to be realized in the coming years, the use of the patient's femoral landmarks to develop femoral prosthetic components can be an important stage in orthopedics, and the implementation of an accessible manufacturing method for such prostheses can generate a new approach in this medical sector.

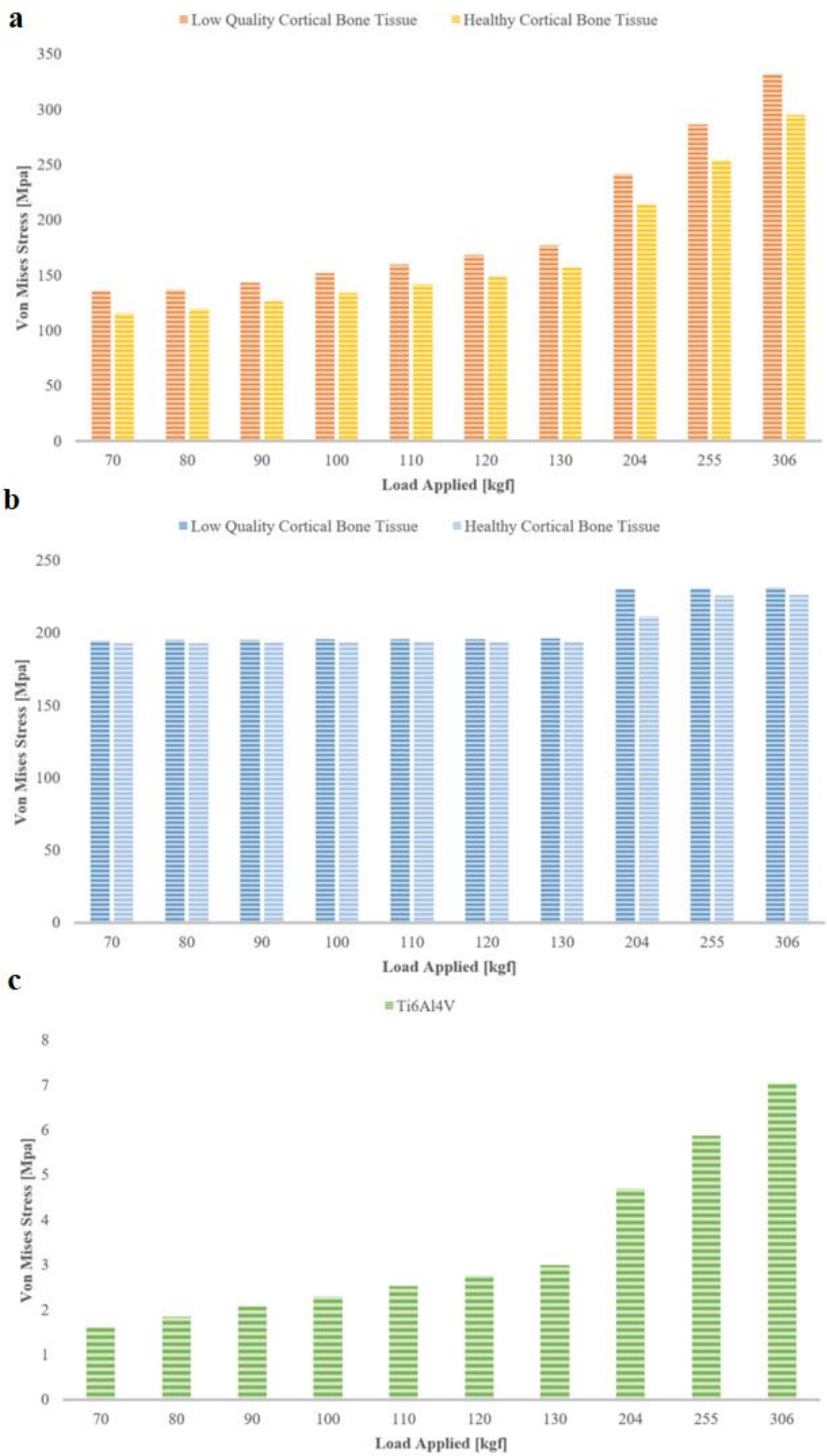

Figure 4.5. Simulation stress results. a. custom femoral stem assembly; b. femur model; c. custom femoral stem

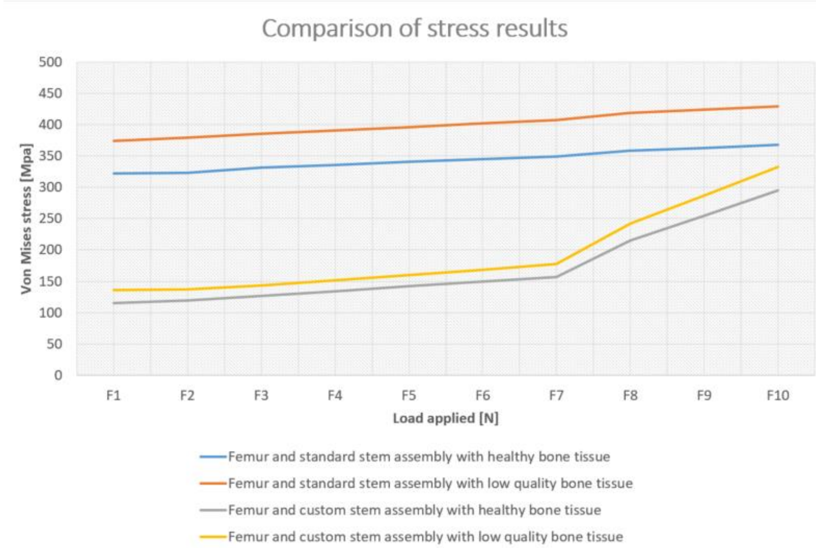

Figure 4.6. Comparison of stress results

CHAPTER 5

DEVELOPING BONE SEGMENTATION AND VIRTUAL PROTOTYPING MEDICAL SOFTWARE

The project aim was to develop a software that allows the user to upload DICOM files obtained by MRI or CT patients' scan and performing bone segmentation by displaying a CAD model of the bone structure which allows the user to manipulate it in order to perform image processing operations. The development of this software was done in collaboration with doctors from *Imagerie Médicale Clinique du Parc*, Lyon, France, which provide CT scans of patients with various health conditions regarding the hip joint, but also useful information from the orthopedic surgeon and radiologist point of view.

The software will be used for didactic purposes, as a tool, for teaching students in medicine (future orthopedic surgeons in particular), but also for students in biomechanical engineering bone segmentation process in THR and virtual preoperative planning. For future doctors it is a way of planning THR surgery, to learn how to choose the most suitable hip prosthesis according to each patient's case.

In order to give an identity to the project a logo was made starting from the abbreviation of the project name NAOS (Numerical Analysis for Orthopedic Surgery), but also a motto to create a greater impact, "Predicting orthopedic future".

The software must perform the following main functions: opening DICOM files, bone segmentation, 3D control, MPR view (coronal plane, axial plane, and sagittal plane), contrast control for MPR view, 3D pelvis visualization and rotation.

The software that follows the functions listed above can enter very difficult on this market segment, because the number of open source platforms and software that allows simple bone segmentation studies are quite a lot, but by implementing the idea of custom THR with custom hip joint prostheses may increase the interest of potential developers, and the introduction of additional 3D printing module for hip stem based on the femoral landmarks that the user identify can position this project in an area of interest. This project can become an impact in terms of speculating "custom" THR idea in the orthopedic field and also in creating links with Additive Manufacturing Industry.

5.1. Developing the software's MPR view in Python language

In order to control better the bone segmentation process based on the patients' medical condition and what the user need to extract, a Housfield Units slider widget was added so in this way the user can select a minimum and a maximum value in which the bone extractor can action.

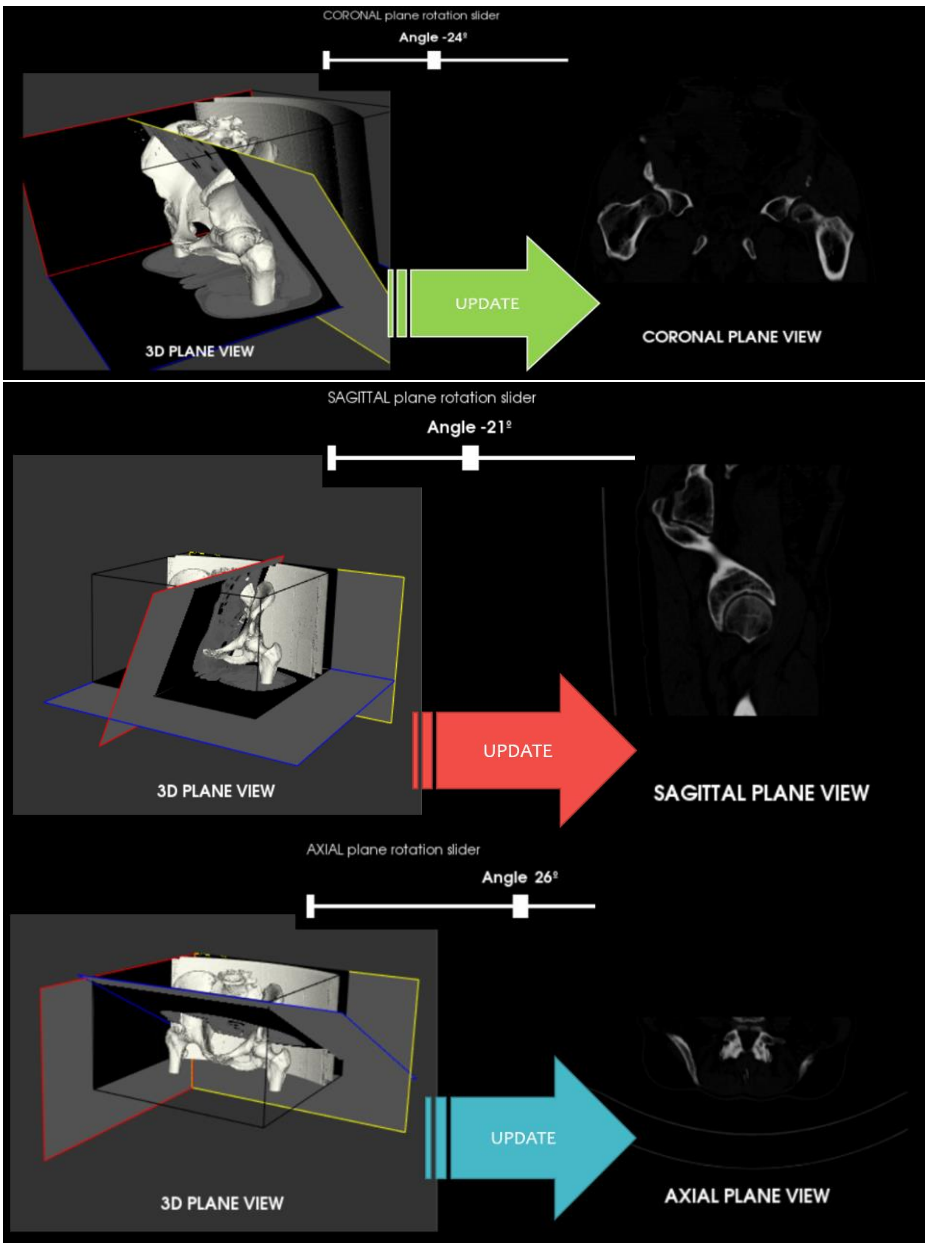

Figure 5.1. Coronal plane rotation slider interaction, sagittal plane rotation slider interaction and axial plane rotation slider interaction

Following the same code flow as in the previsions case the oblique MPR view was created for each plane view, in this way the user can eventually correct the patient posture during the tomography examination, helping him to evaluate better the patient medical condition. In order to correlate the MPR views with the slider and also with the 3D view, for each axis the plane views were resliced with the help of *vtkImageReslice* class reference and create a 3D display for each plane view.

5.2. Developing the bone isolation module

This software module was made with the help of image processing algorithms, namely bone segmentation based on region growing, this method being a contour-based segmentation, which find the boundaries between different regions and connect the threshold if they share similarities. One of the most important property of a region is the homogeneity and consists of main criterion in region growing bone segmentation process because it divides in different areas of homogeneity. In this case because was considering for CT scans, the homogeneity criterion is based on gray level. It starts with a selected voxel or a selected group of voxels and increases all the neighboring voxels, if one of these voxels meets the same criterion as the selected one, it will be added to the group of voxels already formed. The process is repeated until there are no voxels add into the group because they don't share the same criterion with the other voxels.

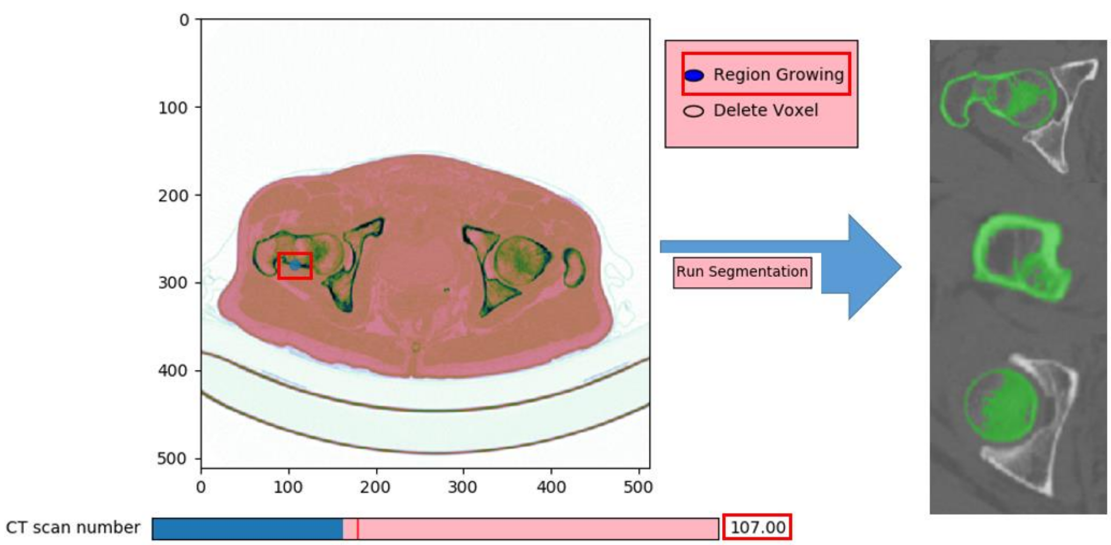

Figure 5.2. Bone segmentation with Region Growing method

Following the code testing, certain limitations can be observed in the case of patients with poor bone quality (case b. and c. from *Figure 5.3*) because of the mechanical wear of the hip joint, the femur and pelvis appearing connected to each other, so the algorithm perceives the pelvis as part of the same group of voxels. The obtained results can be subsequently exported and used in dedicated software, in which the surface can be refined with other algorithms, it can be used in virtual biomechanical studies, or it can be used to perform a 3D virtual preoperative planning for the patient.

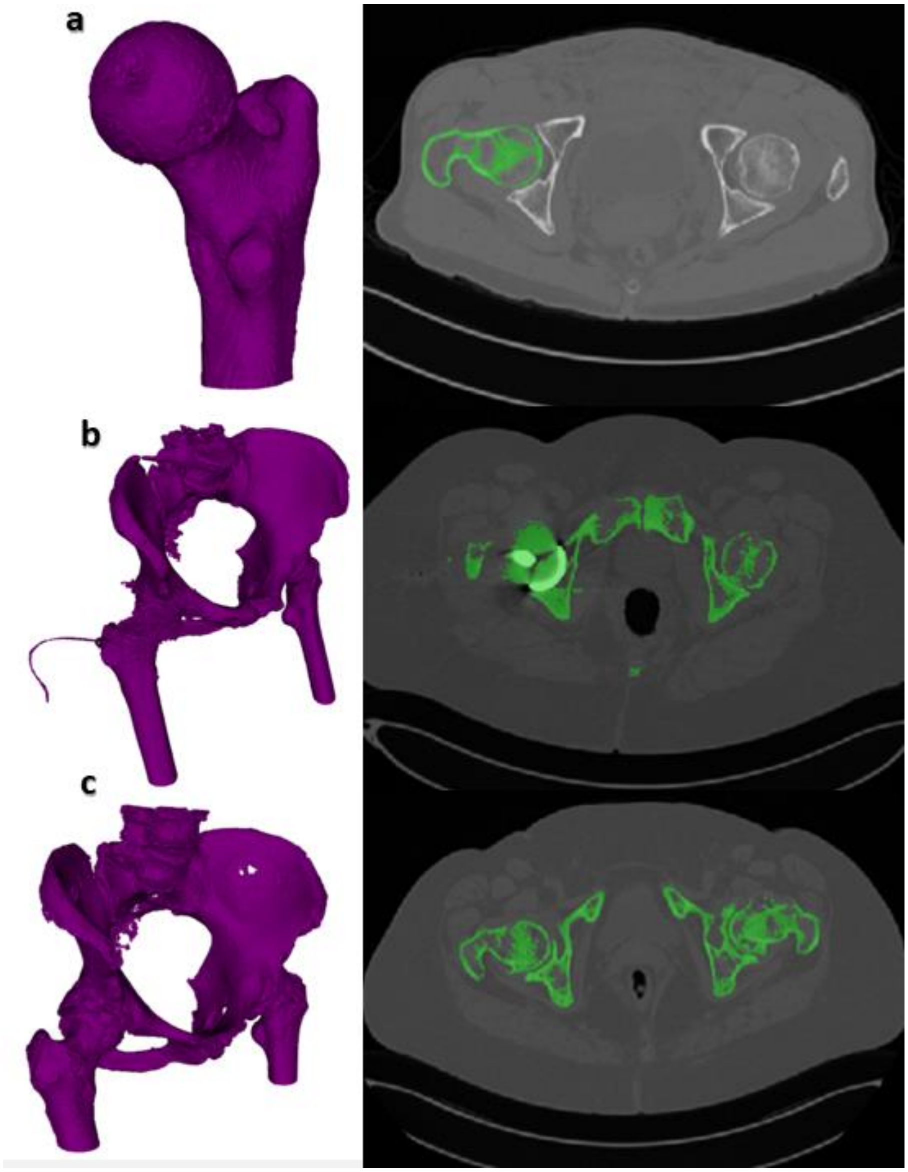

Figure 5.3. a. Healthy hip joint; b. Patient with THR surgery; c. Patient with arthritis

5.3. Developing the custom hip stem geometry code

For the hip stem geometry modification Gmsh open source software was used, which is a software that generates three-dimensional meshes. The software contains instruments that allows to transform the imported CAD model, but also can generate the model's script, allowing the users to modify it and generate the model based on the changes that the user made in the script. In this sense the 3D model of a hip stem was used as a template to be modified and make possible a geometrical personalization based on patient's femoral landmarks. The file extension used to import the femoral stem model was *.stp, a three-dimensional graphic extension used by CAD software to collect the image data in format ASCII, as the standards are defined in ISO-10303-21.

To transform the geometry of the stem, it was necessary to identify the vertices that can be modified and those that will remain unchanged, more precisely to which vertices will be applied changes of the coordinates in order to obtain the desired transformation.

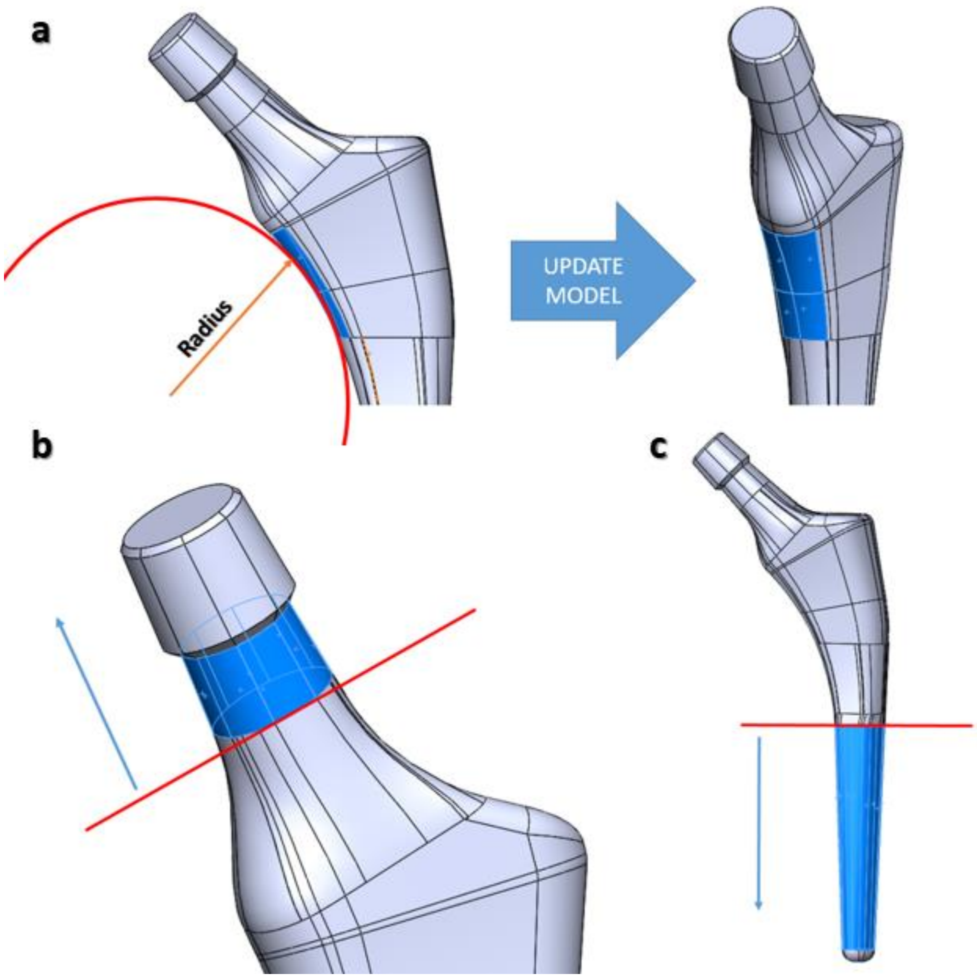

Figure 5.4. Hip stem geometrical transformation. a. Femoral stem anatomical radius; b. Femoral stem neck length; c. Femoral stem length

5.4. Chapter conclusions

The development of a software[1] that can be used for a didactic purpose can be a laborious work that which combines project management knowledge with software engineering, biomechanics, industrial engineering, and a minimum of medical knowledge. The MPR view offers the possibility to examine patients' CT scans and generate the 3D view in order to analyze the perspective of the bone segmentation, the bone segmentation code apply the region growing algorithm and permits the bone extraction in a semi-automatic way and the stem customization script permits the user to create personalized hip stem geometry in each patient case.

[1] This chapter contains passages from the original code to prevent intellectual theft.

Such a software can build the way for customization in terms of hip stem prostheses, and can offer an alternative to analyze patients, but also a cheaper manufacturing way due to additive manufacturing appearance, and due to the continuous technological development process.

CHAPTER 6

ADDITIVE MANUFACTURING OF A CUSTOM FEMORAL STEM

The additive manufacturing or commonly known as 3D printing is a technology that is not as new as we think, but which, in the last decades, has become increasingly accessible to most people, allowing, and stimulating the innovation by increasing efficiency in many areas due to the design freedom and sometimes for low production costs.

3D printing technology can be used as a rapid prototyping in medical education also, both in veterinary medicine and in human medicine, orthopedics, dentistry, ophthalmology, etc. In order to be used successfully, the 3D printing in medicine uses a 3D scanned model by high-performance equipment such as CT scanners or tomography medical equipment.

6.1. Custom hip stems additive manufacturing *[99]*

Using the custom virtual hip stem model described in the previous chapters, a prototype was obtained using additive manufacturing with the help of fused deposition modelling process technology. The FDM 3D printing technology is one of the most commonly used in rapid prototyping process because of the accessible cost of the equipment and the large possibility of material printing.

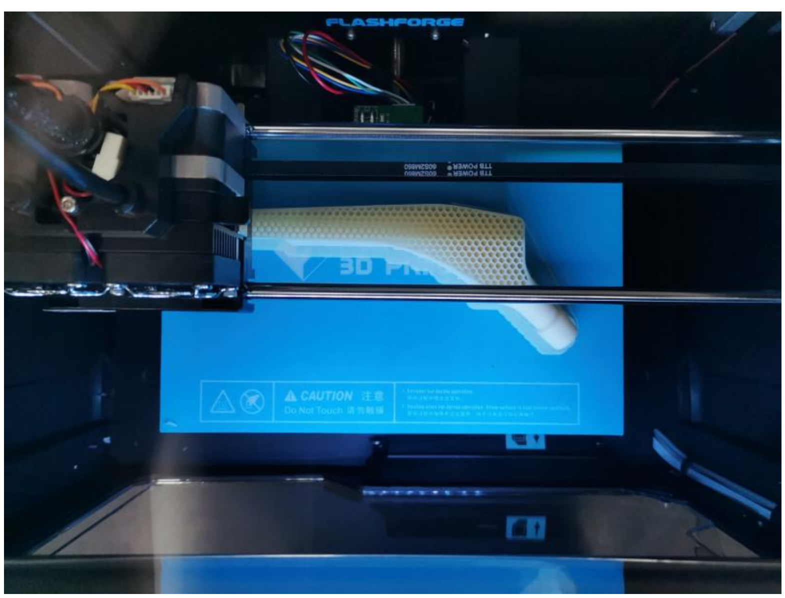

Figure 6.1. Custom hip stem prototype 30% hexagon fill pattern

The material used in this process was the natural Smartfil Medical 3D filament produced by Smart Materials 3D company, an ABS, high quality material specially designed for medical applications [124]. This filament is a USP class VI or ISO 10993-1 certified, which guarantees that this filament is biocompatible with the human body [125, 126]. This class allows the material to enter in contact with the human body for a certain period of time.

6.2. Custom hip stem compression test

In order to perform the compression test, the Instron® 8872 equipment was used, being one of the most used servo-hydraulic testing equipment that allows users to test products at static or dynamic testing simulations demands.

The results showed a maximum force supported by custom hip stem sample made of PLA material (specimen 1) of 0.796kN, for the custom hip stem sample made of Medical Smartfil (specimen 2) of 0.753kN and for specimen 3 of 0.749kN. This means that specimen 1 can support the equivalent body weight of 79.6kgf, specimen 2 of 75.3kgf and specimen 3 of 74.9kgf with only 30% material infill. The graphic results of the compression test for all samples are shown in *Figure 6.2*.

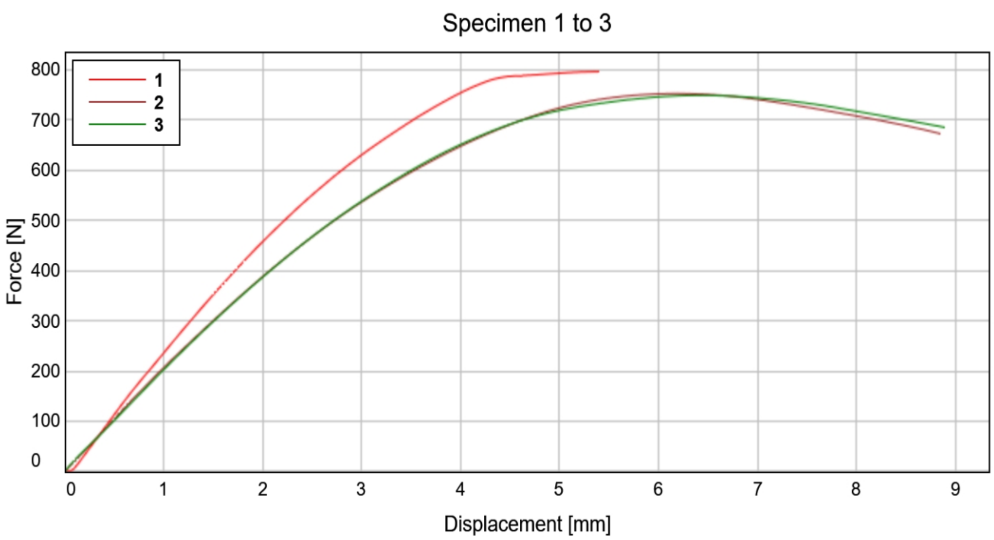

Figure 6.2. Custom hip stems compression test results

The results of the compression test indicate the appearance of a buckling phenomenon in the lower part of the custom femoral stem because it presents cracks in that solicited area of the stem.

The samples were not destroyed during the compression test and a rapid return to the initial geometry of the samples was observed, especially in the case of samples printed with the Medical Smartfil material, a material that can withstand large deformations.

Although the maximum force may appear small comparing to standard hip stem prosthesis manufactured with titanium alloy we should take into consideration that the custom stem infill was set to 30%, with hexagon pattern type, the possibilities can be multiple in order to increase the resistance of the product to external loads.

6.3. Chapter conclusion

Even if the prostheses 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 prosthesis that can function properly for a long period of time, so the need to advance the research on custom prostheses are paramount.

A prototype of the custom hip stem with 30% fill, using the hexagon pattern of deposition was obtained by additive manufacturing with Medical Smartfil 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 Medical Smartfil 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.

CHAPTER 7

FINAL CONCLUSIONS

Nowadays, virtual prototyping is gaining more and more importance in the field of bioengineering and medical sector due to facility that offers in terms of analyzing patients' conditions, simulating different daily life activities and surgery planning. The human body is a complex organic machine which although it may have common features, seen up close, it has so many peculiarities that give us uniqueness both as an individual and as an organism, peculiarities that can make a difference if we talk about the surgical approach in the orthopedic field.

This work is based on medical studies of the anatomical morphology of the human hip joint, but also causes of the hip joint pain and related illnesses in order to provide a complex understanding of how the quality of a patient can be improved from an engineering point of view. Due to the frequency with which the number of Total Hip Replacement surgeries is increasing in the last years either due to pathology, an unhealthy lifestyle that involves a poor diet or morbid obesity, even due to excessive physical activity, the age at which patients may undergo THR surgery decreases each year. This causes doctors and engineers to work together to improve the life quality of the patients who have undergone a THR, by increasing the life of a prosthesis so that the patient goes through fewer revision surgeries during his life.

In this study, a 3D preoperative planning of THR surgery methodology was presented using specific algorithms for extracting bones from patients' CT scans to measure the femoral landmarks that are used to template and choose a suitable femoral stem. Based on these patients' morpho-anatomical landmarks a femoral stem was geometrically optimized so that it can fuse on the patient's femoral curvature and present its anatomical features, in order to restore the function and the motion center of the hip that the patient had initially. Such optimization can reduce post-operative complications that have as cause stem geometry and prosthetic component placement inside the human body. The virtual prototyping methodology of the custom femoral stem presents a clear and explicit approach through which a custom femoral stem can be obtained from the CT scans of a patient which has to undergo a THR surgery.

The results of the FEA simulation show better mechanical behavior for the custom hip stem, how the loads are discharging, and small displacement compared to a standardized prosthesis and can be a start in terms of geometric validation of custom hip prostheses. Although FEA analyzes are still limited in terms of simulating the complexity of the human hip joint, however, they can provide vital information about prosthesis failure or the appearance of cracks, fracture subsequent, in the patient's femur.

The thesis also aimed to develop a preoperative planning medical software coded in Python with the help of VTK library which is intended for use in academia or research as a tool in analyzing patients medical condition at the joint level by importing CT scans and using the bone segmentation algorithms in order to obtain patients' femur from which the femoral landmarks can be subsequently obtained with the purpose of using this landmarks in order to change the geometry of a femoral stem and customize it for the patient.

Such a process can pave the way for personalization in the prosthetic industry by using it simultaneously with the additive manufacturing process in order to decrease the fabrication costs and make it more affordable for the patients that needs to undergo THR. Simplifying the customization process by developing medical software that works simultaneously with industrial equipment and technologies such as additive manufacturing printing machines can lead to a new approach in the field of orthopedics.

7.1. The contributions brought into the doctoral thesis

Following the approach of a virtual preoperative planning (VPP) of THR surgery, it was aimed to develop a methodology of bone segmentation process by using dedicated medical software. In this sense, starting from patients' CT scans obtained from Imagerie Médicale Clinique du Parc clinic, Lyon, the DICOM files were imported in Simpleware ScanIP. The use of specific image processing algorithms described in the thesis conducts to a fast bone segmentation process by obtaining optimal bone models that can be used in virtual research studies. By using the *Threshold* image processing algorithm with a lower value that corresponds to +400HU and an upper value that corresponds to +2000HU allows the extraction of bone tissue only, eliminating most of the soft tissue, the *Region Growing* algorithm allows the user to select other voxels which belongs, for example, to the femoral bone region, the *Paint with threshold* instrument select the voxels manually, that the previsions algorithms didn't identified them in order to create a full solid model, the *Island removal* algorithm eliminates the residual voxels around the model and the *Close morphological* algorithm unifies the eventually gabs that may occur between the voxels. The use of these image processing algorithms listed above leads to a rapid bone segmentation of the femoral bone and pelvis from the CT scans.

The process of identifying patient's femoral landmarks by using VPP and their implementation in order to develop a custom stem prosthesis that fits to patients' needs from the geometrical point of view, it aimed to emphasize the uniqueness of each human body and treating each individual as a unique different case, focusing on his personal medical needs from this point of view. Although the process of obtaining a standardized prosthesis using patients' femoral landmarks may seem difficult a hip prosthesis was made starting from a standard one with changeable parameters, which can be modified according to the medical situation of the individual in dedicated CAD software.

Creating a code meant to read and import data from patients' CT scans, allowing to analyze the medical condition of the individual in coronal, sagittal and axial view, but also allowing to generate a 3D representation by choosing a minimum and a maximum value on the Hounsfield unit scale allows a fast three-dimensional generation and update of the view. The oblique MPR view can be used to solve visualization problems regarding the incorrect positioning of the patient on the tomographic table, so that the analyzed parts are located in the same plane.

Based on the image processing algorithm called *Region Growing* a code was developed for a semi-automatic bone extraction. The patients' CT scans are imported and read by the code after choosing the optimal DICOM slide. The user can click on a voxel and apply the algorithm that as a result will include all neighboring voxels that have the same properties as the selected voxel into a region. This helps to obtain a femoral or a pelvic model that can be used in virtual studies.

The bone segmentation software together with the extraction and identification module for the patient's bone part was performed by consulting accredited medical staff from the orthopedic and radiological field, developing a progress monitoring plan for the medical software. In this sense a software feasibility analysis was conducted in order to establish the software performing functions, such as: opening DICOM files, the bone segmentation process and the 3D control, the MPR view that contains the coronal plane, the sagittal plane and the axial plane, the brightness and contrast control inside the MPR view and the 3D pelvis visualization and rotation. For analyzing and determine the software requirements constant meetings were held with medical staff to evaluate and suggest different medical approaches.

To decide the best approach a marketing study was conducted to analyze and extract the best options in terms of software development. Software development and design were performed in the Python programming language used with Visual Code Studio, and for the software interface proposal was used PyQT5, a software used to design interface widgets and buttons that can be exported in Python language further. In order to measure and track the software progress a project plan was used, where the approximate timings for developing each function were inserted and discussed at each meeting with the medical staff. The automation of the bone segmentation and extraction process was semi-automated, developing a code based on the Region Growing image processing algorithm, which runs in the software background.

Transforming the custom stem used as template into a script and the individualization of vertices, Cartesian points used as control points, spline lines and surfaces created between them, which can be included in certain geometric transformations meant to customize a hip stem prosthesis is a way to implement a patient's femoral landmark in an attempt to automate this laborious customization process and to make it accessible so that a future implementation in this field can be attempted.

The software codes were tested for several medical cases in order to observe the segmentation capacity, according to the patients' medical conditions and satisfactory results were obtained. In the future, a gradual implementation in the academic environment is desired to be tested by medical students studying radiology and orthopedic surgery.

The 3D printing of human organs and prosthesis in the experimental environment, it is not a new concept in the orthopedic field, but the realization of a study meant to unify the development of medical software in order to prepare a THR surgery by using the virtual environment, the customization of the stem according to the individual femoral landmarks which can be fabricated by using the AM technology can improve a patient's life after THR intervention by reducing postoperative complications related to stem geometry, that occurs due to the choice of an inappropriate standard stem or the bad positioning of the femoral component. It can also be a cheaper alternative for the manufacture of customized prostheses for special cases of THR and the eventual implementation of such a system of production can lead to the elimination of "*prostheses banks*", the production of only necessary stem prostheses not leading to product expiration and possible recycling of the medical products.

In *Table 7.1* a summarized presentation of the main thesis objectives along with personal contributions exposed in publications are shown.

Table 7.1. Summarized presentation of the main thesis objectives

Objectives	Obtained Results	Results published in relevant scientific papers and/or presented in the academic environment
O_1	Method of personalizing of a hip stem by using patient's femoral anatomical landmarks.	REM 2018, German-French-Moroccan Summer School 2018 *Custom hip implant optimization*
O_2	Development of a software dedicated to the analysis and planning of a THR surgery in the orthopedic field.	Rapport du doctorant au Comité de suivi de thèse 4^{eme} année
O_3	Manufacturing of the customized hip stem prosthesis using FDM technology.	Materiale Plastice (Mater. Plast.) 2020 *Custom Hip Stem Additive Prototyping using Smart Materials*
OS_1	Bone segmentation methodology using specific image processing algorithms.	U.P.B. Sci. Bull. 2019 *Method of extracting hip joint bones from C.T. images in order to perform static F.E.A. study*
OS_2	Method of finishing organic virtual model surfaces obtained from bone segmentation process to reduce the complexity of the model and to simplify virtual simulations.	Séminaire TMI du 5 Juillet 2018 *Optimization of personalized prostheses*
OS_3	Methods of performing virtual THR surgical simulations using CAD software with FEA extension module and VPP.	5th SGEM Conf. 2018 *Reducing early intraprosthetic dislocation by using personalized hip joint prosthetic design and virtual preoperative planning*
OS_4	Virtual simulation performed in order to describe the mechanical behavior of an organic model by using Reverse Engineering methods.	IMSCI 2019 *F.E.A. study of a patient's prosthetic hip by using Reverse Engineering Method*
OS_5	Development of a bone extraction code by using specific image processing algorithms in Python programming language.	Scientific Report N°4
OS_6	Development of a user-friendly interface proposal for a medical software.	Scientific Report N°5

7.2. List of the original works published in international indexed journals or conferences

1. **19th International Conference on Research and Education in Mechatronics (REM), Delft, Netherlands**, 7-8 June 2018, Date Added to IEEE Xplore: 31 July 2018, Publisher: IEEE, Information: Electronic ISBN: 978-1-5386-5413-2, USB ISBN: 978-1-5386-5412-5, Print on Demand (PoD) ISBN: 978-1-5386-5414-9.
Authors: **Patricia Isabela Brãileanu**, Ionel Simion, Benyebka Bou- Saïd, Nicoleta Crişan
Paper: *Custom hip implant design optimization*
DOI: 10.1109/REM.2018.8421805
Indexing: IEEE Xplore

2. **5th International Multidisciplinary Scientific Conference on Social Sciences & Arts SGEM**, Albena, Bulgaria, August 24 - September 2 / 2018.
Authors: **Patricia Isabela Brăileanu**, Loredana Manasia, Ionel Simion, Benyebka Bou- Saïd, Gina Florica Stoica
Paper: *Reducing early intraprosthetic dislocation by using personalized hip joint prosthetic design and virtual preoperative planning*
DOI: http://doi.org/10.5593/sgemsocial2018/5.3
Currently WOS indexing pending
Indexing: Clarivate Analytics, Scopus - Elsevier international indexing database, Google Scholar, Proquest, EBSCO, Crossref DOI, Russian citation SCI, British Library, Mendeley Elsevier

3. **U.P.B. Sci. Bull., Series D, Vol. D, Iss. 2, 2019, pp. 153-164.**
Authors: **Patricia Isabela Brăileanu**, Ionel Simion, Benyebka Bou-Saïd, Gina Florica Stoica
Paper: *Method of extracting hip joint bones from C.T. images in order to perform static F.E.A. study*
ISSN 1454-2358
Indexing: Ulrich's International Periodicals Directory, Scopus, INSPEC, Metadex, Elsevier Sciences's Bibiliographic Database, Engineering Village, Cambridge Scientific Abstracts, Compendex.

4. **ICEGD 2019, Craiova Romania, published in JIDEG, May 2019, Vol. 14, no. 1, pp. 221-226**
Authors: **P. I. Braileanu**, I. Simion, and B. Bou-Said
Paper: *Researching and trends in optimizing hip joint prosthesis*
Indexing: ROAD Directory of Open Access scholarly Resources, DOAJ Directory of Open Access Journals, Copernicus, Applied Science & Technology Source (EBSCO), Applied Science & Technology Source Ultimate (EBSCO), Engineering Source (EBSCO), STM Source (EBSCO), ProQuest SciTech collection, ProQuest Technology collection, Google Scholar.

5. **13th International Multi-Conference on Society, Cybernetics and Informatics (IMSCI 2019),** July 6-9, 2019, Orlando, Florida, USA, Conf. Proceedings, **Vol. I, pp. 65-70.**

Authors: **Patricia I. Brăileanu**, Ionel Simion, Benyebka Bou- Saïd, Maria Gratiela Ianoș, Oliver Tayot, Bertrand Bordet
Paper: *F.E.A. study of a patient's prosthetic hip by using Reverse Engineering Method*

Indexing: Scopus - Elsevier international indexing database, DOAJ - Directory of Open Access Journals

6. **Materiale Plastice (Mater. Plast.), Vol. 57 No.2,** June 2020, **pp. 152-158**
Authors: **Patricia I. Brăileanu**, Ionel Simion, Benyebka Bou- Saïd, Delia Alexandra Prisecaru, Nicoleta Crișan
Paper: *Custom hip stem additive prototyping using Smart Materials*
ISSN 2668-8220
DOI https://doi.org/10.37358/MP.20.2.5361
Currently WOS indexing pending
Indexing: Web of Science, Scopus - Elsevier international indexing database, LetPub Boston, SCImago Journal & Country Rank, CAS – division of the American Chemical Society, Electronic Journals Library, ROAD - the Directory of Open Access scholarly Resources, developed with the support of the Communication and Information Sector of UNESCO.

7. **JIDEG, June 2020, Vol. 15, Iss. 1, pp. 35-40**
Authors: F. Harmon, **P. I. Brăileanu**
Paper: *Rapid prototyping of a custom upper limb bionic prosthesis*
Indexing: ROAD - Directory of Open Access scholarly Resources, DOAJ - Directory of Open Access Journals, Copernicus, Applied Science & Technology Source (EBSCO), Applied Science & Technology Source Ultimate (EBSCO), Engineering Source (EBSCO), STM Source (EBSCO), ProQuest SciTech collection, ProQuest Technology collection, Google Scholar.

7.3. Seminars and Poster Sessions participation not indexed

1. **German-French-Moroccan Summer School 2018, TRIBOLOGY TODAY – From Research Labs to Industry, Marrakesh, Morocco**, April 8-14, 2018
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Poster Title: *Optimization of personalized prostheses*

2. **Séminaire TMI, LaMCoS, INSA Lyon**, July 5, 2018
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Presentation Title: *Optimization of personalized prostheses*

7.4. Scientific Reports

1. **Scientific Report n°1, UPB**: "*Notions regarding the optimization of custom prosthesis*"
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: Prof. PhD. Eng. Ionel Simion, Conf. PhD. Eng. Victor Adîr, Conf. PhD. Eng. Daniel Dobre, Prof. PhD. Eng. Sorin Cănănău

2. **Scientific Report n°2, UPB**: "*Research on custom prosthesis optimization*"
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: Prof. PhD. Eng. Ionel Simion, Conf. PhD. Eng. Victor Adîr, Conf. PhD. Eng. Daniel Dobre, Prof. PhD. Eng. Gina Florica Stoica

3. **Scientific Report n°3, UPB**: "*Reducing THR postoperative complications by using customized femoral stems*"
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: Prof. PhD. Eng. Ionel Simion, Conf. PhD. Eng. Victor Adîr, Conf. PhD. Eng. Daniel Dobre, Prof. PhD. Eng. Gina Florica Stoica

4. **Scientific Report n°4, UPB**: "*Bone density extraction from DICOM files in order to develop a femoral bone density map*"
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: Prof. PhD. Eng. Ionel Simion, Conf. PhD. Eng. Victor Adîr, Conf. PhD. Eng. Daniel Dobre, Prof. PhD. Eng. Gina Florica Stoica

5. **Scientific Report n°5, UPB**: "*Considerations regarding the research of customized prosthesis*"
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: Prof. PhD. Eng. Ionel Simion, Conf. PhD. Eng. Victor Adîr, Conf. PhD. Eng. Daniel Dobre, Prof. PhD. Eng. Gina Florica Stoica

6. **Rapport du doctorant au Comité de suivi de thèse 4eme année, INSA Lyon** : *Optimization of personalized prostheses*
Authors: **Patricia I. Brăileanu**
Scientific coordinators: Benyebka Bou- Saïd, Ionel Simion
Evaluation Committee: MdC. Jarir Mahfoud from LaMCoS, DCS and Prof. PhD. Eng. Nicolas Riviere from LMFA

7.5. Perspectives and research directions

The methodology of optimization and customization of the femoral hip stem presented in this work can be used as a basis in future research studies for automating the process so that it becomes an accessible option when planning a THR surgery. Software development can continue to become more user-friendly with medical users and containing more femoral landmarks that can be implemented to change the geometry of the femoral stem so that the traditional preoperative planning methods of THR surgery will completely move into a virtual environment. Thus, the virtual environment being much more permissive, it can be used for planning and simulating a THR intervention, making it much more suitable for everyone.

The customization of the femoral stem can continue moving from the geometric side on the part of the material used to be fabricated with the help of AM technology. The human femur contains a variety of densities along it, being a nonhomogeneous material of two bone tissues which is reinforcing where the femur is more solicited during various activities and thins where the external loads are not high. A study on the extraction of the femoral density from patients' CT scans can be used as a basis in developing a new material that can present gradient properties and can be 3D printed on a custom prosthesis. Continuation of this hip stem customization study by creating a smart material that mimics human tissue can revolutionize the medical field by opening a new era regarding orthopedic prostheses.

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