CUSTOM KNEE PROSTHESIS DESIGN FOR ADITIVE MANUFACTURING

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ABSTRACT*: This work aims to develop a customized knee joint prosthesis, starting from the traditional preoperative planning of total knee arthroplasty surgery and using morpho-anatomical parameters extracted from the patient's CT scans. The customized model of the knee prosthesis is made using a three-dimensional virtual preoperative planning method, similar to the traditional preoperative planning performed by surgeons. The CT scans of a patient were segmented, using specific algorithms to extract the bone tissue that forms the knee joint, and then the obtained model was imported into the CAD application software, where, with the help of evaluation tools, all the femoral and tibial patient's landmarks were identified. Based on these morpho-anatomical landmarks, a 3D model of the knee prosthesis was built, which was used in additive manufacturing of the prototype.*

KEYWORDS*: custom knee prosthesis, additive manufacturing*

1 INTRODUCTION

A prosthesis is an artificial device intended to replace a limb, organ or affected joint. The word prosthesis comes from the Greek word pro, meaning in place, and tilhemi, meaning placement, therefore indicating a device to replace the lack of an organ, limb or joint.

Knee arthroplasty or knee replacement is a surgical intervention in which the degenerated articular surfaces of the femur and tibia are replaced with a total or partial (unicompartmental) prosthesis to relieve pain and functional impotence. The first attempts of knee replacement date back to the end of the 19th century (Gluck), but the "*modern*" period began with the introduction of articulated prostheses in 1954 (Walldius, Shiers) and later the Guépar prosthesis in 1970. Since then, knee joint prostheses have evolved considerably in terms of materials used, intervention success rate, patient satisfaction, and preoperative planning. The prosthesis process involves a major change in the life of any patient, allowing him to carry out daily activities with ease, thus improving his quality of life.

The knee is one of the largest and most complex joints in the body. The knee joint is part of the lower extremity, is the junction of the thigh and leg being a hinge joint type (bends back and forth in one plane).

In terms of bone systems, there are three important bones that form the knee joint:

- Tibia or leg bone
- Femur or thigh bone
- Patella

A fourth bone, the fibula, is located right next to the tibia and knee joint and can play an important role in some knee conditions.

Knee replacement surgery can help relieve pain and restore function in severely affected knee joints. The most common cause of chronic knee pain and disability is arthritis. Although there are many types of arthritis, most knee pain is caused by just three types: osteoarthritis, rheumatoid arthritis, and post-traumatic arthritis.

Arthroplasty involves cutting and removing the damaged bone and cartilage from the thigh, tibia and patella and replacing it with an artificial joint (prosthesis) made of metal alloys or high-quality plastics and polymers. To determine if a knee replacement is appropriate, the orthopedic surgeon evaluates the mobility, stability, and strength of the knee with the help of X-rays to determine the extent of damage.

The knee is a joint with a single degree of freedom, that is, the movements are performed in one plane, namely the sagittal plane, and its main movements are flexion and extension, that is, bending and straightening the knee. There are also secondary movements, namely the movements of internal and external rotation, which are sometimes involved in the execution of complex movements. [1]

2 METHODS

Preoperative clinical evaluation is important in assessing the current medical condition and determining the patient's relative risk profile. Preoperative planning begins with selecting an appropriate candidate for total knee replacement (TKR) surgery. Patient expectations and general risk factors play an important role in this decision. An appropriate musculoskeletal radiological study is essential in preoperative planning. In this way the presence of bone issues can be detected and with the help of this information a decision can be made about the type of implant that is suitable for the patient. Determining the joint line is also important in determining flexion/extension space and ligament balance.

Most knee replacement systems offer many options for treating conditions that are encountered during surgery. Different systems serve surgeons with different implant sizes in a wide range. Intraoperative determination of implant dimensions was found to be more accurate than preoperative template. However, the preoperative template is useful to achieve correct implant positioning. Working with templates is a widely accepted approach that can help determine component dimensions, predict the amount of bone resection, and anticipate surgical steps. Still, with the widespread use of digital medical imaging, the use of digital models has recently increased due to advances in reducing errors associated with X-rays and template manipulation. [2]

2.1 Bone segmentation process

The bone segmentation technique enables improved diagnosis, disease characterization and treatment monitoring using CT scans [3]. There are numerous software applications dedicated to performing bone segmentation automatically by applying several algorithms of direct bone tissue extraction and image processing. In this study, Simpleware ScanIP software was used, which is a software dedicated to the processing of medical images. Moreover, the mentioned software has a base of complex image processing algorithms in this way, a better surface and a more finished model can be obtained. The bone segmentation begins by importing DICOM files into the software used. The DICOM set used in this study case contains 1563 whole-body CT images of a 43-year-old male.

Threshold–based techniques can be used to separate bone tissue from soft tissue using higher levels of HU values (Hounsfield units) in CT scans. The HU values attributed to bones in other studies are found between 150HU and 3000HU [4]. A threshold will be set for both the lower and upper limits of the gray levels identified in the histogram. The lower limit will have the value of +200HU, and the upper one the value of 2000HU. After setting the thresholds, the region of interest is selected for the actual bone segmentation).

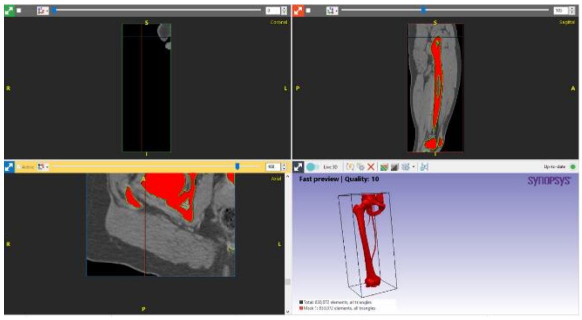

Fig. 1 Automatic segmentation of the femur and pelvis

Fig. 1 shows the selection of the right femur in all MPR windows in Simpleware ScanIP software.

To separate the femur from the pelvis, the *Split regions* function was used, through which different masks can be created, and the regions of interest can be manually selected to make the segmentation more precise. In this case, a mask for the pelvis (blue color) and a mask for the femur (purple color) were created.

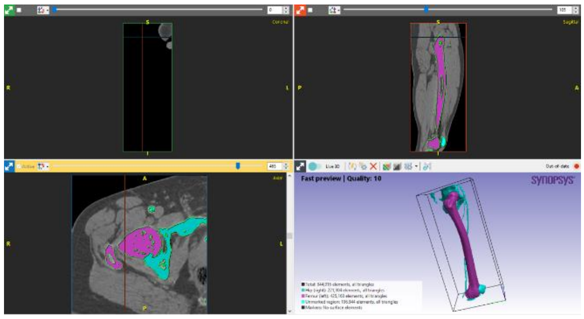

Fig. 2 Separation of regions (femur and pelvis)

After the regions were well defined, the mask corresponding to the pelvis was removed, leaving only the mask corresponding to the femur. The segmentation of the femur was successfully completed, but gaps can be observed in the viewing window of the axial plane (Fig. 2). They must be removed, as they can influence subsequent measurements. The *Paint with threshold* tool is used to cover the bone tissue.

Finally, the model can be exported with the **.stl* or **.step* extension, which can later be used in CAD software applications to create virtual simulations or to prepare surfaces for additive manufacturing. The same steps are followed for the segmentation of the tibia and patella.

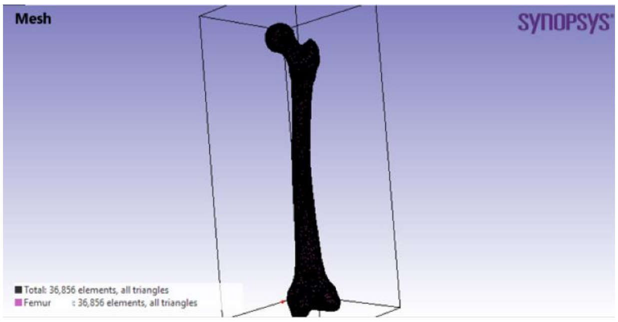

Fig. 3 Exported 3D model as **.stl* extention

2.2 CAD model surface finishing

Anatomical surfaces possess irregular geometric shapes with a high complexity. This affects the processing time and analysis of the CAD model, but also the computer performance requirements. To avoid the disadvantages of anatomical surfaces, the models resulting from the processing of CT images in Simpleware ScanIP software are simplified, to optimize the analysis and processing time. This is possible by obtaining surfaces with reduced complexity of the model geometry.

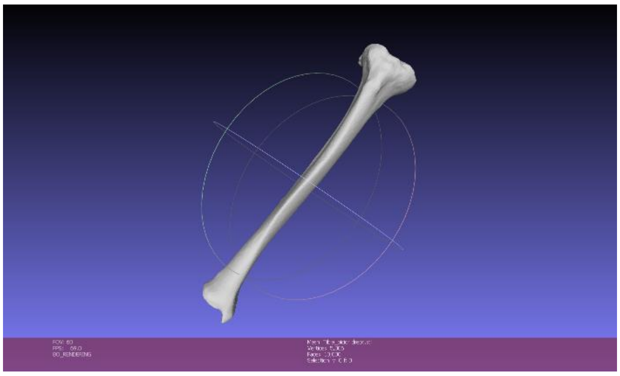

Fig. 4 Tibia simplified 3D model

The software used to simplify the models is MeshLab. From the MeshLab toolbar software application, in the *Filters* category, the re-meshing, simplification and reconstruction option can be selected to reduce the number of faces (*Simplification: Quadric Edge Collapse Decimation*). Thus, a simplified model is obtained, with an optimized analysis and processing time.

2.3 Identification and measurements of patient's femoral and tibial landmarks

In order to generate the geometry of a knee prosthesis, the identification of the femoral and tibial landmarks is a mandatory step. They offer support in the virtual prototyping process of the personalized knee prosthesis geometry, made according to the morpho-anatomical parameters of the patient.

The measurement of the mentioned parameters was carried out with the help of Inventor software, but this process can be carried out in most CAD software applications that allow the import of a 3D model.

After importing the 3D model in Inventor, a frontal plane was created to divide the femur in half, the goal being to determine the anatomical femoral axis. Perpendicular to this and immediately below the deepest point of the medial codylus, a line will be drawn to reveal the section of the femur that will be cut, at 12.5 mm (Fig. 5 b.).

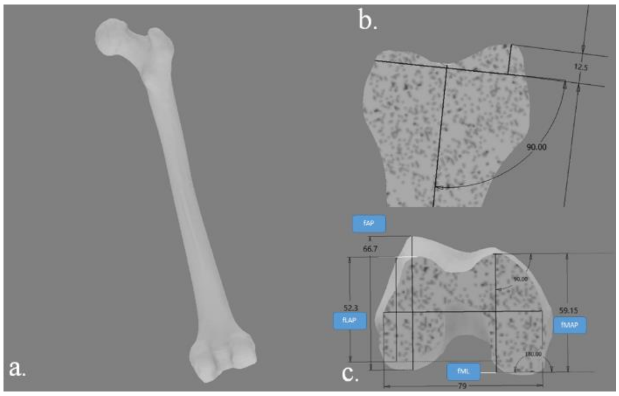

Fig. 5 Femoral anatomical landmarks. a. Femoral 3D model used in this case study; b. The femoral anatomical axis and the section that will be cut; c. The necessary parameters for designing the femoral component

Through the last drawn line, a transversal plane will be created to determine the necessary parameters for sizing the femoral component according to methods used by F. Bo et all and H. Yazdi et all. The measurements resulted are the following dimensions (Fig. 5 c.):

- Femoral mediolateral length (fML) measured as the width of the resected surface of the femur in the mediolateral (ML) axis, in this case ~79 mm.
- Femoral anteroposterior length (fAP) was defined as the total width of the lateral condyle in the anteroposterior (AP) axis, in this case ~66.7 mm.
- Anteroposterior medial femoral length (fMAP), the length of the line drawn parallel to fAP and passing through the most posterior anatomical point of the medial femoral condyle, in this case ~59.15 mm.
- Anteroposterior lateral femoral length (fLAP) the length of the line drawn parallel to fAP and passing through the most posterior anatomical point of the lateral femoral condyle, in this case ~52.3 mm.

The same steps are used for the tibia. The 3D model is imported into Invetor (Fig. 6), then a frontal plane is created to identify the tibial mechanical axis and the section that will be cut, respectively 9.5 mm (Fig. Fig. 6 b.). Then the transversal plane is created to determine the necessary parameters for sizing the tibial component (Fig. 6 c.). They have the following dimensions:

- Tibial mediolateral length (tML) the greatest mediolateral length of the proximal tibial cut surface, in this patient case ~77.4 mm.
- Tibial anteroposterior length (tAP), the length of a line drawn perpendicular to tML and passing through the midpoint of the tML line, in this study is ~46.12 mm.
- Medial tibial anteroposterior dimension (tMAP), the length of the line drawn parallel to tAP and passing through the most posterior anatomical point of the medial tibial condyle, in this case ~49.71.

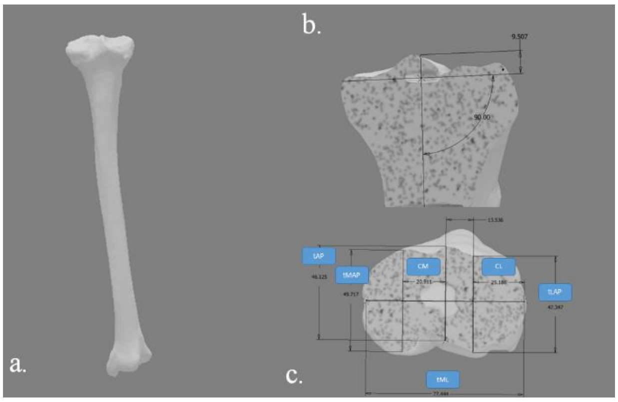

Fig. 6 Tibia anatomical landmarks. a. Tibia 3D model used in this case study; b. Tibial axis and the section that will be cut; c. The necessary parameters for sizing the tibial component

- The lateral tibial anteroposterior dimension (tMAP) is the length of the line drawn parallel to the tAP and passing through the most posterior anatomical point of the lateral tibial condyle, in this case ~47.34 mm

2.4 Tibial and femoral prosthetic component design of a customized knee prosthesis

The 3 components of the knee prosthesis (tibial component, spacer and femoral component) were built in Inventor software. For each individual component, the first step towards obtaining a well-defined 3D model was the creation of a 2D sketch.

In the case of the tibial component and the spacer, 2D sketches of the geometry were created with a length equal to the tibial mediolateral dimension (tML). In the lower part of the sketch, an arch is created that represents the posterior intercondylar space. The two sketches are then extruded using the *Extrude* command of the software.

Both upper parts of the tibial component, as well as on the lower part of the spacer were generated in a new sketch in which a circle is represented. This circle is extruded in both components case, but in different directions, its purpose being their join. The tibial component is fixed in the tibia by inserting a stem into the bone [5]. In the 3D model, this stem is created on the lower part of the tibial component.

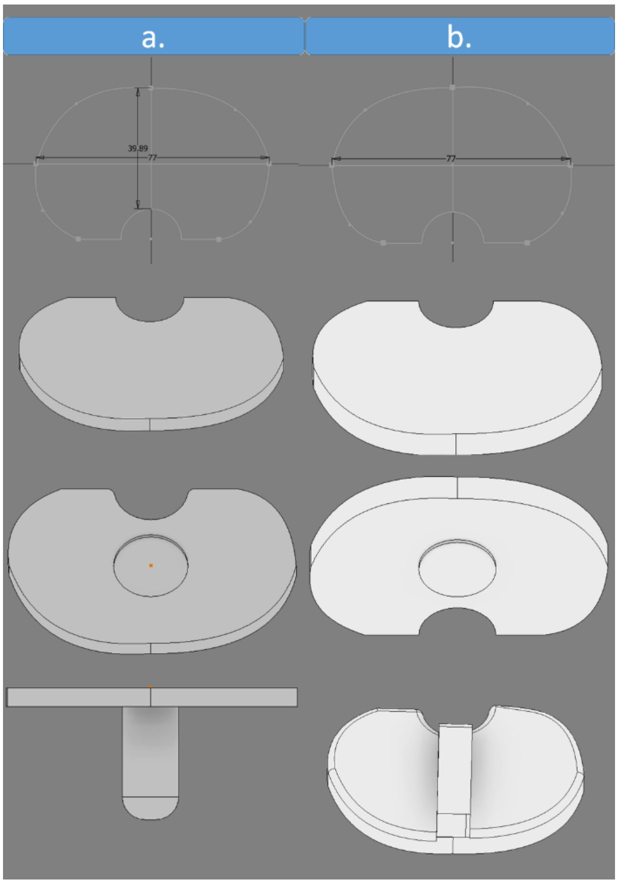

Fig. 7 Rapid prototyping of the tibial components. a. Tibial stem prosthesis; b. Prosthesis spacer

Static spacers maintain the knee joint in full extension or minimal flexion [6]. In order to make this possible for the 3D generated model, a geometry is built on the upper surface of the spacer that will prevent the femoral component from making unwanted movements.

To obtain the 3D model of the femoral component, the starting point is also represented by the 2D sketch. Following this sketch, only the right side of the component will be obtained (Fig 8), and to obtain the left side as well, a plane parallel to the initial plane will be created on which a similar sketch will be built. The right side of the femoral component is thicker than the left one, because the medial femoral shaft is shorter than the lateral one.

Fig. 8 Design stages of the custom femoral component

The two sketches are extruded, then connected to create the front face of the femoral component. Two small stems are created on the upper surface, with the role of fixing the femoral component in the bone. After completing all the prosthetic elements, an assembly with all 3 components is created in the Inventor software, which will represent the custom knee prosthesis (Fig. 9).

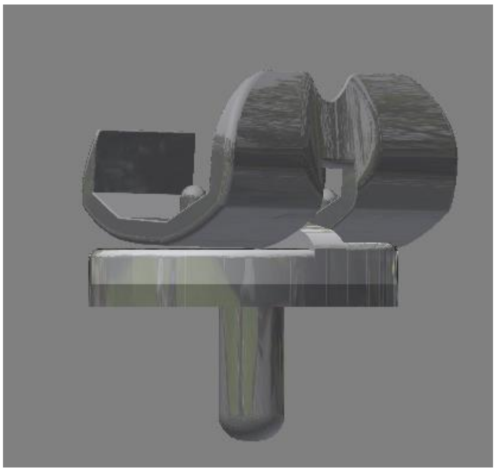

Fig. 9 Assembly of the customized total knee prosthesis

3 ADITIVE MANUFACTURING OF CUSTOM KNEE PROSTHESIS

The Using the personalized virtual model of the knee prosthesis described previously, a prototype was obtained with Creator FLASHFORGE Pro 3D printer based on the FDM additive manufacturing process. Thermoplastic extrusion (Fused Deposition Modeling) is an additive manufacturing process that belongs to the material extrusion family. This process based on the extrusion of materials uses a wire made of different materials, which is heated to a temperature at several degrees below the melting temperature point, after which, its diameter is reduced to 0.12 − 0.15 mm by extruding it in a deposition device. The device moves in the XOY plane to render a section of the 3D virtual models. In FDM technology, an object is built by selectively depositing material in a predetermined shape layer by layer [7].

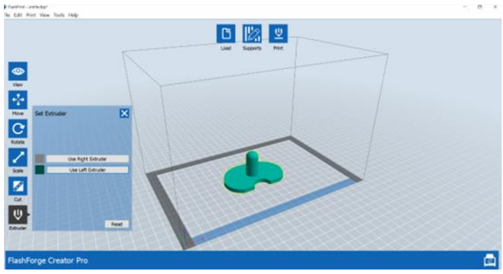

Fig. 10 Importing the 3D model of the tibial component into Flash Forge 3D printer software

The material used for printing customized knee prostheses for the tibial component, spacer and femoral component is ABS Medical Smartfil.

The ABS (acrylonitrile-butadiene-styrene) is an oil-based plastic with a high surface hardness and resistance on impact, with a density of 1.24 g/cm^3. ABS is recyclable, but remains an unsustainable option due to its petroleum-based origin, yet it exhibits excellent stiffness and dimensional stability at a low production cost [7].

ABS Medical Smartfil instead is a certified biocompatible material that can come into contact with the human body for a certain type of period, although is not a good option due to the short life of the prosthesis and the predisposition to wear, creating residual particles that can spread in the soft tissues, remains an example of manufacturing emphasizing the possibilities made available by additive manufacturing.

Table 1. ABS printing properties

Properties	Values
First layer height	0.20 mm
Layer height	0.12 mm
Filling density	30%
Filling pattern	Hexagonal
Print speed	50 mm/s
Printing temperature	240°C
Platform temperature	90°C

The manufacturing method can be replaced by other technologies that can print biocompatible metal powders such as titanium alloys, resulting in personalized prostheses [8, 9] that follow the anatomical curve-line of the patient, which leads to the reduction of post-operative complications that occur due to the mismatch of the standardized prosthesis.

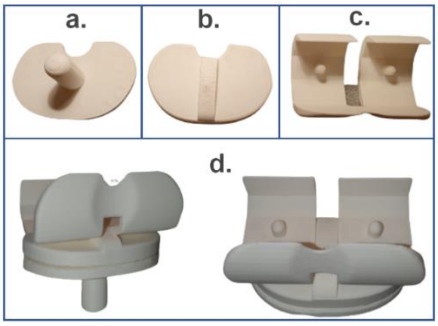

Fig. 11 Custom printed prosthesis. a. Tibial component; b. Prosthesis spacer; c. Femoral component; d. Total Knee Prosthesis Assembly

For 3D printing, the FlashPrint software was used, in which the components were imported one by one. The tibial component and the spacer were printed using the left extruder of the 3D printer, and the femoral component using the right extruder. The 3D printer used was CREATOR PRO Flash Forge. The prosthesis parts resulting from 3D printing are shown in Fig.11.

4 CONCLUSIONS

The main objective of this article was fulfilled by designing a total knee joint prosthesis using morpho-anatomical parameters with the help of virtual preoperative planning that can reduce postoperative complications caused by the geometry of the prosthesis and the components orientation.

The prototyping process of a customized knee prosthesis according to the morpho-anatomical parameters of the patient is a long one compared to the choice of using a prosthesis that comes from a range of prostheses with different sizes.

Although the prototyping of a total knee prosthesis may seem difficult due to the need of different software and implicitly an engineer qualified in this field, most of these processes can be automated or semi-automated by developing medical imaging processing software where the anatomical parameters of the patient can be automatically measured which later they can be transformed into an editable geometric model depending on the desired parameters.

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