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# Custom Humeral Joint Prostheses Using Additive Manufacturing and Biocompatible Smart Materials

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***Abstract:*** *Personalizing prosthetic components based on individual anatomical landmarks can increase implant lifespan and it can reduce the postoperative complications due to prosthesis geometry that does not mold on the patient's anatomy. This article aims to present a method of optimizing shoulder prostheses by conducting both medical and technological studies, based on which a personalized prototype was obtained, designed according to the patient's landmarks. Thus, a computer-assisted methodology has been developed that targets the preoperative planning of shoulder arthroplasty starting from the traditional planning used by orthopedic surgeons, as well as the principles of determining the relevant humeral parameters. Initially, a set of DICOM CT (Digital Imaging and Communications in Medicine) patient scans with a presumed fracture at the glenohumeral joint requiring a shoulder arthroplasty was used. The acquired data were transferred to a medical image processing software, where was performed the bone segmentation, specifying the image processing algorithms used to reconstruct the geometry of the patient's shoulder. The 3D model of the humerus obtained during this stage was imported into a CAD (Computer Aided Design) software application where the humeral anatomical landmarks were established and used to design a suitable prosthesis according to patient's needs, which was manufactured through additive manufacturing using a biocompatible material.*

***Keywords:*** *custom humeral prostheses, additive manufacturing, biocompatible materials*

## 1. Introduction

In comparison to the considerable number of hip arthroplasties performed over time, there haven't been as many reported surgical interventions at the shoulder level. However, in the past two decades, this type of arthroplasty has gained interest in the orthopedic field and is undergoing continuous development, aiming to personalize humeral prostheses to closely replicate the anatomy of each individual patient. Studies on this subject, highlight several key aspects, such as increasing the implants lifespan and reducing the number and severity of postoperative complications. Therefore, this paper serves as a support in optimizing shoulder prostheses by conducting medical and technological studies, which resulted in a personalized prototype designed based on the patient's specific anatomical landmarks.

Therefore, the theoretical part presented in this study emphasizes its necessity for the subsequent practical stages. Information with a medical focus, including the anatomy and morphology of the humeral joint and shoulder biomechanics. It then proceeds with classifying humeral arthroplasty techniques, presenting some available commercially prosthetic solutions and materials, as well as additive manufacturing technologies and 3D printing of biocompatible materials by using FDM (Fused Deposition Modeling) of ABS (Acrylonitrile Butadiene Styrene) SmartFil Medical, a biocompatible material that can enter in contact with the human tissue for a limited period of time.

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# 2. Materials and methods

## 2.1. Three-dimensional virtual preoperative planning

Three-dimensional (3D) preoperative planning of surgical interventions represents the future trend in shoulder arthroplasty. It began with technological progress and is currently undergoing continuous development. The discovery of this preoperative approach is important due to the significant increase of shoulder replacement surgeries number in recent years (25,000 shoulder arthroplasties were performed in 2019) [1]. The trend towards computer–assisted preoperative planning has had a major impact in the orthopedic field [2-4], especially in shoulder arthroplasty. It allows the design of personalized prosthetic components that accurately replicates the morpho–anatomical landmarks of each patient's humerus, resulting in improved osseointegration at the interface between the implant and bone, finally leading to successful surgical outcomes [1, 5].

A set of 162 CT images of a shoulder joint in DICOM format was obtained for testing purposes, provided by the InVesalius software. Subsequently, the DICOM set was verified using the MicroDicom software. Regarding clinical data, the subject is an 18-year-old male born on 15/08/1988. It was assumed that, due to an accident, the patient suffered a severe injury to the right shoulder, thus generating a proximal humerus fracture. Since the right arm is vital for the young individual's daily activities, the option of prosthetic replacement was necessary as a treatment choice, as any other method would have been ineffective in restoring mobility and range of motion in the glenohumeral joint. Among the shoulder arthroplasty techniques, the procedure of hemiarthroplasty was chosen, as it yields the best results for resolving this pathology at the shoulder joint level.

## 2.2. Bone segmentation process

To reconstruct the geometric structure of the bone and subsequently obtain the CAD model of the humerus, the bone segmentation process was performed using Simpleware ScanIP, a software program designed for medical image processing. The Simpleware software provides the user with a range of complex processing algorithms that can be applied to CT scans to obtain solid 3D models of the region of interest [6-8], thus accelerating and optimizing the preoperative planning methodology. Furthermore, it plays a crucial role in conducting virtual analyses and preparing the model for additive manufacturing. The following algorithms and tools were used to extract the regions of interest in Simpleware ScanIP to later design the humeral endoprosthesis:

a. *Threshold algorithm* (enables the extraction of a specific bone tissue as shown in Figure 1*a*);

b. *Region Growing algorithm* (the result obtained in the previous stage, which highlights the 3D model of both the bone structures of the glenohumeral joint and the patient's characteristic thoracic cage, underwent another processing step called Region Growing - Figure 1*b*);

c. *Paint with threshold* (using this tool, voxels can be manually selected, those not identified by the previously applied algorithms to fully fill the bone tissue region - Figure 1*c*);

d. *Island removal algorithm* (to eliminate residual particles that affect the segmented bone surface, Simpleware ScanIP provides the Island Removal tool, in this case, a voxel size value of 40 was used – Figure 1*d*);

e. *Morphlogical-Close algorithm* (close small gaps that may appear in the mask from the manual segmentation process, to better define the surface);

f. *Recursive Gaussian* (to refine the 3D geometric models represented by the thoracic cage and shoulder bones, the Recursive Gaussian tool was used, which acts as a filter - Figure 1*e*);

g. *Crop Tool* (as the name suggests, the Crop option allows the user to remove unwanted surfaces while keeping the region of interest in the foreground - Figure 1*f*);

h. *Split Regions Tool* (to facilitate the segmentation process by quickly and easily separating neighboring bone segments that "*touch*" each other, Simpleware software provides the Split Regions tool - Figure 1*g*).

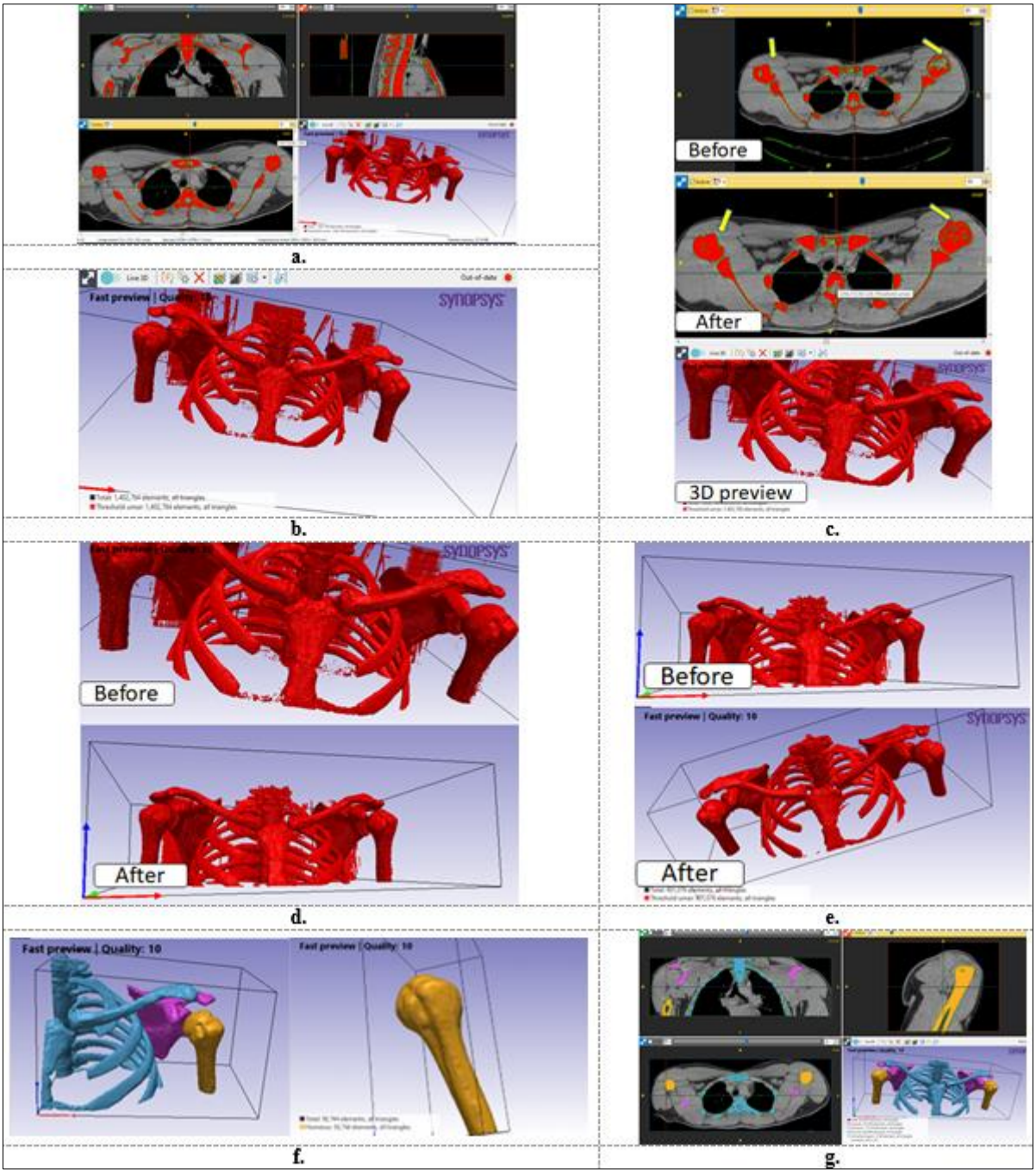



**Figure 1.** Bone segmentation process. **a.** Threshold algorithm; **b.** Region Growing algorithm; **c.** Paint With Threshold tool and the generated result; **d.** Before and after applying Island Removal tool; **e.** Before and after applying the Recursive Gaussian filter; **f.** Final results obtained using the Spilt Regions tool; **g.** Split Region tool

## 2.3. Mesh adjustment

This data processing was performed using an open–source software called MeshLab. To simplify the mesh, the *Quadric Edge Collapse Decimation* filter was applied. The original model had 6,032 faces and 3,020 vertices, and it was simplified (re-meshed) to a model characterized by 5,000 faces and 2,504 vertices. As for the anatomical surface of the right humerus, which initially had 5,776 faces and 2,892 vertices, it underwent the same steps of adjusting the number of elements. In this case, after applying the settings, the complexity of the humeral surface was simplified, resulting in a model with 4,500 faces

and 2,254 vertices. The results obtained were exported as *STL* files. These files can be imported in a subsequent stage into CAD software, such as Inventor Professional.

### 2.4. Methodology for identification and measurement of patient–specific humeral landmarks

Considering that hemiarthroplasty is the appropriate treatment option for addressing the patient's condition, the focus of the complete 3D preoperative planning will be on the following humeral parameters explained below [9-12, 18, 19].

*Humerus diaphysis axis*: the humerus can be approximated by a cylinder, where the height corresponds to the humerus diaphysis axis. However, there can be alternative approaches to estimating this humeral landmark. For example, the diaphysis axis can be approximated by contouring elliptical shapes in different arbitrarily selected areas along the humerus, and the diaphysis axis or humeral channel axis can be determined by connecting their centers (Figure 2*a*).

*Humerus length*: this parameter is determined by accurately tracing the intramedullary central axis of the humerus diaphysis and is useful for selecting the size of the humeral stem. In this case, the anatomical axis of the humerus has a total length of 131,17 mm.

*Center of rotation (COR) of the humeral head*: known as the joint rotation center, the COR determines the range of natural movement of the upper limbs and is a significant landmark that needs to be restored. Since the anatomical surface of the humeral head is irregular, one method to approximate this landmark involves tracing a tangent sphere to the humeral surface (Figure 2*b*).

*Humeral head inclination angle or neck-shaft angle (NSA or CCD)*: represents the angle formed at the intersection between the intramedullary central axis of the humerus diaphysis and the humeral head axis drawn perpendicular to the anatomical neck axis characteristic of the humerus and passing through the center of the humeral head (Figure 2*e*). In most cases, the average value of the inclination angle is 135° (a standard angle for a normal patient), but this humeral landmark can exhibit significant individual variations within the range of 125°–150°. Furthermore, knowing the value of this landmark can determine the patient's osteotomy. An angle of ~120° indicates a varus case, while an angle of ~150° is associated with a pathological valgus humerus [13].

*The anatomical neck axis of the humerus*: to identify this humeral landmark with high accuracy, two points of interest located in the concave and convex areas (near the greater tubercle) representative of the humeral neck are identified. In 2D preoperative planning, the axis connecting these two points represents the anatomical neck axis of the humerus, and its size reflects the value of the diameter at the humeral head base seen in the frontal plane (humeral neck diameter).

*Humeral head axis*: the humeral head axis is defined as the line passing through the center of the humeral head and perpendicular to the anatomical plane of the humeral neck (Figure 2*c*). This reference has a major implication in determining the thickness of the articular surface of the humeral head (Figure 2*d*).

*Height of the articular surface of the humeral head*: this reference defines the thickness of the humeral head and represents the distance between the axis of the anatomical neck and the ridge of the articular surface determined by a line drawn tangent to the articular surface and parallel to the neck axis. To measure this parameter, the extreme point on the convex area of the humeral head needs to be identified, specifically at the level of the articular cartilage.

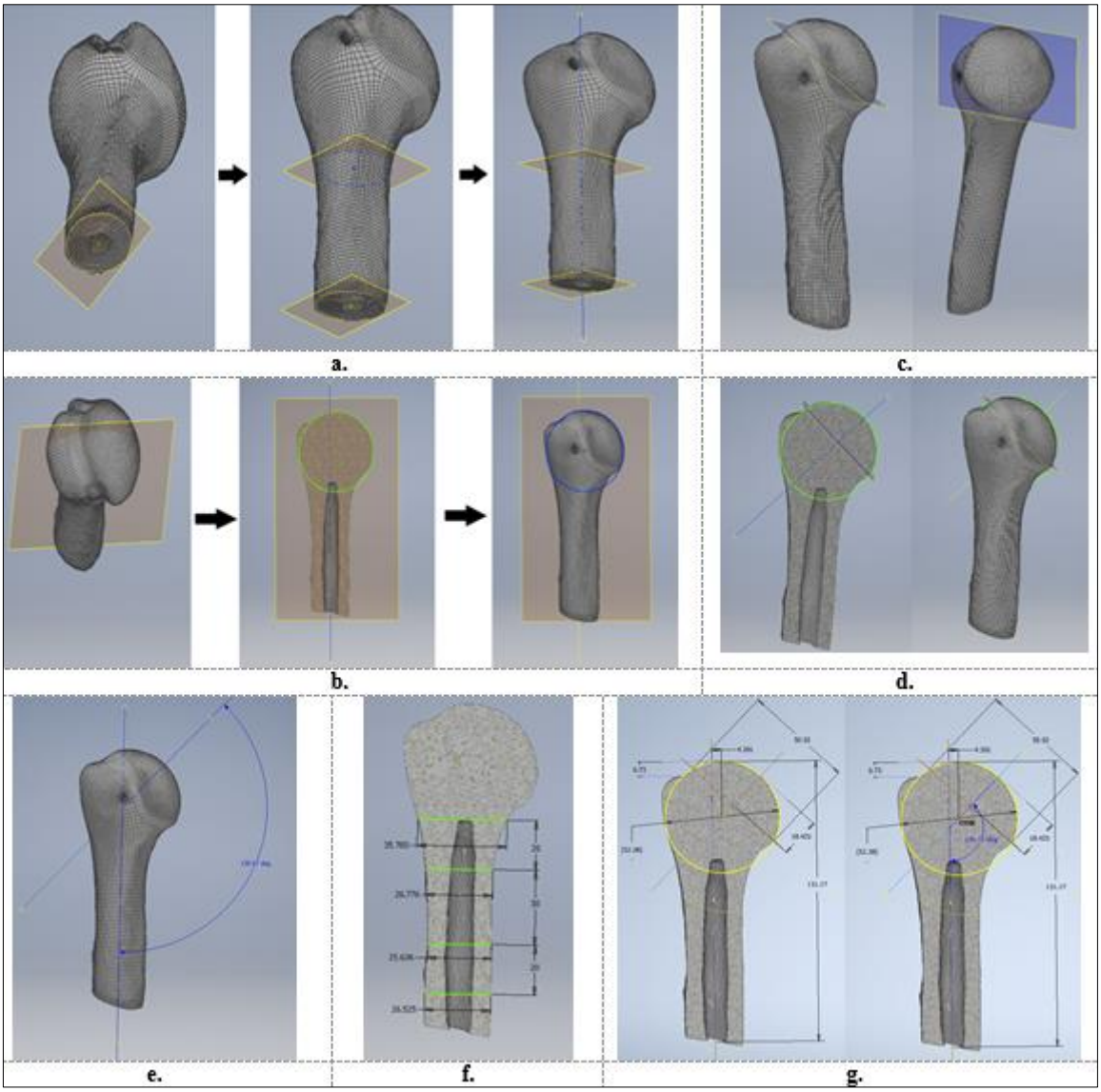



**Figure 2.** Measuring patient's anatomical landmarks. **a.** Methodology for determining the patient's humeral diaphyseal axis; **b.** Methodology for determining the patient-specific humeral joint rotation center; **c.** Determining the plane of the anatomical humeral neck; **d.** Determination of the patient's humeral head axis (sectioned and unsectioned humerus); **e.** Determination of the patient's CCD angle; **f.** Determination of the patient's humeral channel width; **g.** The specific measurements of the humeral landmarks of interest

*Medial offset/deviation of the humeral head*: represents the distance measured from the center of the humeral head to the intramedullary axis of the humeral diaphysis.

*Distance from the greater tuberosity to the humeral head*: this reference reflects the height of the humeral head in relation to the greater tuberosity. It is defined as the distance between the highest point on the articular surface of the humeral head (the most proximal point of the humeral head) and the critical point identified in the upper region of the greater tuberosity, specifically in the convex area near the humeral neck. To approximate this landmark, two parallel construction lines will be drawn starting from the previously fixed points.

*The width of the humeral channel at the surgical neck of the humerus:* is important to identify this reference because of the role played by the axis drawn at the surgical neck. By measuring the generated axis, the width of the humeral channel in the middle can be determined (Figure 2*f*).

*The width of the humeral channel below the surgical neck of the humerus I*: an assisting criterion in determining this is mentioned in the study conducted by J. G. Skedros et al. [14], which consists in creating a construction axis at 20 mm below the representative axis of the surgical neck. In this way, by measuring the axis, the value of the width of the humeral channel characteristic to this section will be calculated/deduced (Figure 2*f*).

*The width of the humeral channel below the surgical neck of the humerus II*: taking into consideration the same identification methodology as mentioned in the previous study, to identify this point of interest, a construction line is drawn at 30 mm from the previously drawn one, and by measuring this axis, the value of the humeral channel width in the proximal section will be determined. For a more accurate estimation of the humeral width, a new construction axis can be drawn, this time at 20 mm below the previous one (Figure 2*f*).

**Table 1.** Identification and determination of the patient's humeral landmarks (Figure 2*g*)

| N° | HUMERAL LANDMARK | | DIMENSIONS |
|---|---|---|---|
| 1 | The humerus length | | ~ 131,17 mm |
| 2 | The humeral head diameter | | ~ 52,28 mm |
| 3 | The humeral head height of the articular surfaces | | ~ 18,425 mm |
| 4 | The diameter of the anatomical humeral neck | | ~ 50,02 mm |
| 5 | Cervico–Diaphyseal Angle | | ~ 136.67° |
| 6 | Tuberosity–humeral head distance | | ~ 6,73 mm |
| 7 | The medial gab | | ~ 4,301 mm |
| 8 | The width of the humeral channels | At the level of the surgical neck | ~35,703 mm |
| | | 20 mm below the surgical neck | ~26,776 mm |
| | | 50 mm below the surgical neck | ~25,626 mm |

## 2.5. Custom humeral prosthesis design

One of the essential parameters to consider in the design is the humeral length of the endoprosthesis [15]. Considering the shape and dimensions of the humeral channel, as well as the patient's age, it has been decided to create a short humeral stem with a length of approximately 96.87 mm (Figure 3*a*). Specific attention must be given to the humeral prosthesis length choice, as an inappropriate length can lead to severe complications. To improve outcomes and reduce unwanted postoperative complications such as fractures at the humerus level, bone loss, osseointegration failure, etc., one solution is to shorten the humeral stem. Thus, designing a prosthesis with a short humeral stem preserves the bone loss, allows for better and more stable fixation, and is recommended for use in younger patients [16, 17]. The cervico–diaphyseal angle has particular importance in the prosthesis design. In this studied case, the humeral stem is inclined in relation to the patient's CCD angle, which measures 136,67° (Figure 3*b*). To achieve this inclination of the stem model, two axes were drawn, and the angle between them corresponds to the patient's CCD angle. In the humeral stem design template, this landmark is used as a reference but can be adjusted on a case-by-case basis, according to the patient's landmarks.

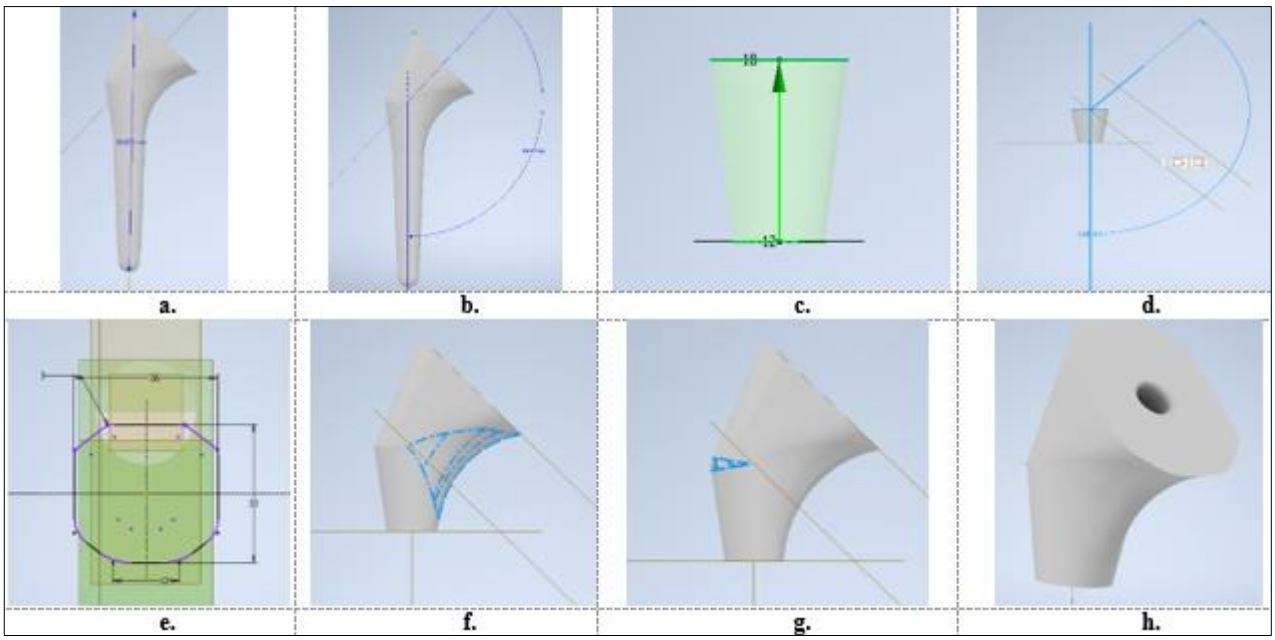
Another important humeral landmark considered in the prosthesis design, which significantly influences shoulder arthroplasty, is the width of the humeral channel. Considering the values determined in the previous stage, the humeral stem was designed to have a width of 12 mm in the proximal area, followed by 10,5 mm, 9,5 mm, and 8 mm at the base. The following steps describe the process of creating the prototype of the personalized humeral stem. Initially, using the XZ plane in Inventor as a reference, a sketch of a circle with a diameter of 12 mm was created. Starting from the front plane, a new parallel plane (Offset from Plane) was created, where a circle with a diameter of 18 mm was sketched. Using the Loft command, a solid (Figure 3*c*) was created based on these two sketches. Subsequently, two reference axes were drawn at an angle of 136,67°, as shown in Figure 3*d*. Between the previously obtained solid and a newly created sketch (Figure 3*e*), the Loft command was applied, resulting in the body illustrated in Figure 3*f*. To achieve the rounded shape of the stem inclination in both the concave area (Figure 3*f*) and the convex area (Figure 3*g*), two fillets were created between the first solid and the second Loft. To create the hole where the humeral component will be inserted, the *Extrude* command was applied,

selecting the profile of a circle with a diameter of 6 mm, shown in Figure 3*h*. The *Chamfer* command was used to create a chamfer along the contour of the hole, which will ensure a proper assembly of the stem with the humeral component. Figure 3*h* exemplifies the result obtained after applying these commands.

Using the XZ plane as a reference plane, three parallel planes were generated at distances of 20 mm, 35 mm, and 47 mm from it, which facilitated the protocol for obtaining the complete design of the stem and the distal part. The first plane was used to sketch a circle with a diameter of 10.5 mm, and by applying the Loft command, the transition from a diameter of 12 mm to the lower diameter of 10.5 mm was achieved. The result of this operation is illustrated in Figure *i, j, k.* Similarly, the process was repeated using the sketches created in the other two generated planes. Thus, the Loft command was successively applied to transition from a diameter of 10.5 mm to 9.5 mm, and from 9.5 mm to 8 mm. The design stage of the humeral stem was completed with the creation of the curved end at its base (Figure 3*l*). This construction was generated by applying the Revolve command, selecting both the profile of the circular arc and the central axis that coincides with the axis of the humeral stem. The radius of the circular arc was chosen to be 4 mm, and in the Revolve settings, a full rotation of the profile with an angle of 360° was specified. The 3D model of the obtained stem is highlighted in the left lateral view and in the frontal view in Figures 3*p.*

In designing the humeral component, two landmarks were considered, namely the diameter and height of the humeral head. Thus, based on the previously identified humeral landmarks, the dimensions of this component were set to 50.02 mm (diameter) and 18.43 mm (height). The humeral component is press–fit into the stem through a cylindrical connecting element, with a height of 13 mm and a base diameter of 6 mm. Additionally, this prosthetic component features a circular cutout, designed to have a diameter of 25 mm and a height of 3 mm. The sketch created for the humeral component design is shown in Figure 3*m, n, o.*

Following the individual design of the two prosthetic components, the assembly of the humeral prosthesis was subsequently achieved using assembly constraints (using the Constraint mode). In this case, an insertion constraint was applied by selecting two concentric circular edges of the humeral component and the 3D model of the stem, positioning their faces in opposite directions (Figure 3*q*). As a result, the humeral component will be inserted into the stem through a press–fit procedure, and the fixed geometry of the prosthetic system was designed in a way that does not allow variation with an inclination angle of ±15°. The constraints defined for the selection of the relevant edges are highlighted in Figure 3*q* and the final obtained assembly is shown in the same figure.



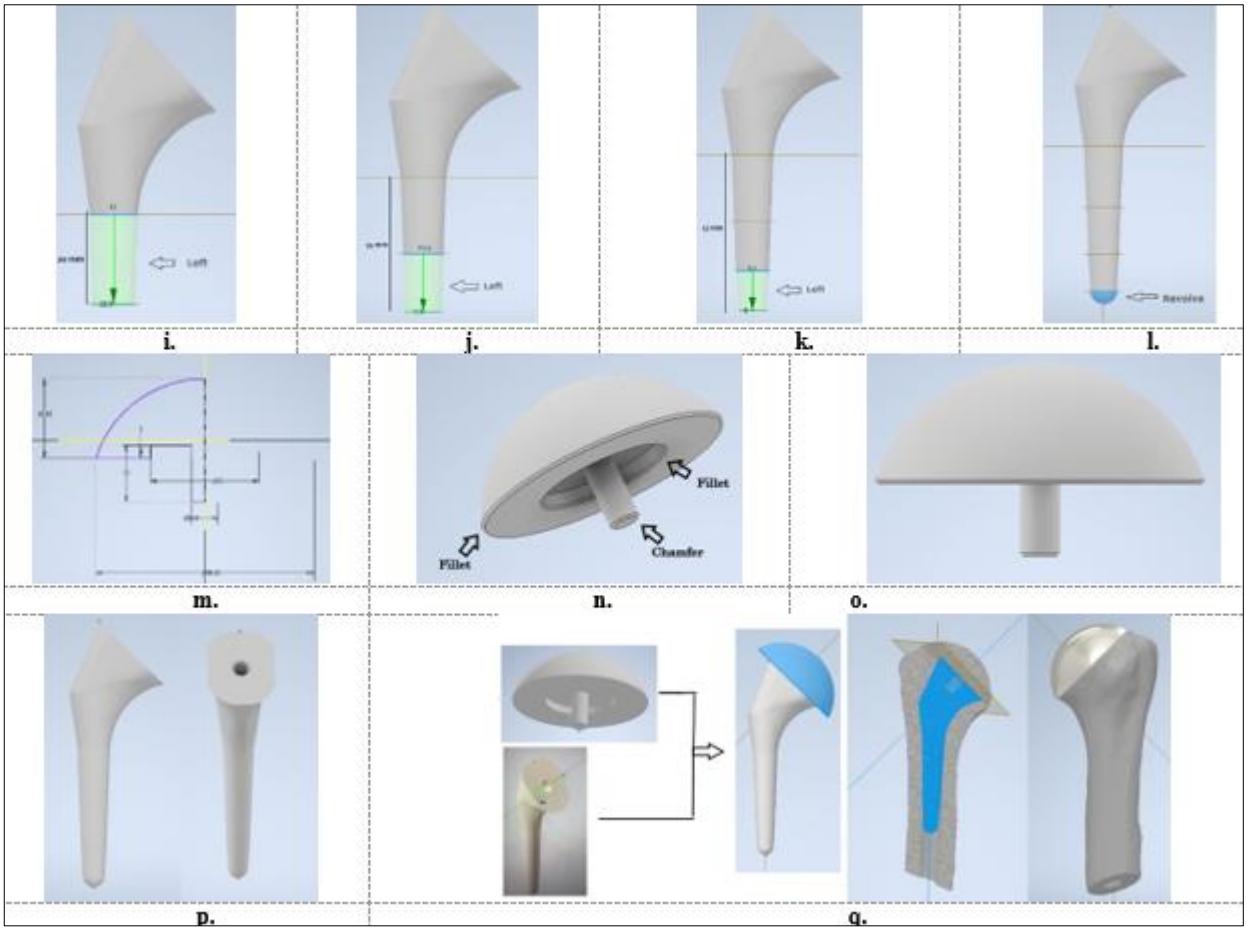



**Figure 3.** Custom humeral prosthesis design. a. Prototype length; b. The tilt angle; c. First *extrude*; d. Tilt angle construction; e. Sketch generation; f. Inner prosthesis curvature; g. External prosthesis curvature; h. Cup insertion hole; i. Prosthesis length (first *extrude*); j. Prosthesis length (second *extrude*); k. Prosthesis length (third *extrude*); l. Stem insertion end; m. Prosthetic cup sketch; n. Cup retouching; o. Final prosthetic cup geometric model; p. Final humeral stem geometric model; q. Assembling the humeral prosthesis

## 3. Results

To obtain the prototype of the custom humeral endoprosthesis, additive manufacturing technology was used, based on the previously designed 3D model. For this purpose, the prototype was 3D printed using FDM technology, using the Flashforge CREATOR PRO 3D printer. The software used in this case was FlashPrint.

The biomaterial used in this process is Smartfil Medical 3D, a natural and high-quality ABS filament. This material is specifically designed for use in the additive manufacturing of medical devices due to its biocompatibility with the human body. Moreover, the quality of this filament allows the user to create complex parts with fine details without significant deformations in their model. The choice of using this natural filament for rapid prototyping of the endoprosthesis was based on its physical, thermal, and mechanical properties, as well as its 3D printing technical characteristics.

To initiate the manufacturing process, it was necessary to export the 3D model of the humeral prosthetic stem from Inventor as an STL file. Subsequently, it was imported into the FlashPrint software, which is designed for generating printing files. Then, the initial position of the imported model was rotated by an angle of 270° around the X–axis to ensure that it was parallel to the printing platform (Figure 4*a*).

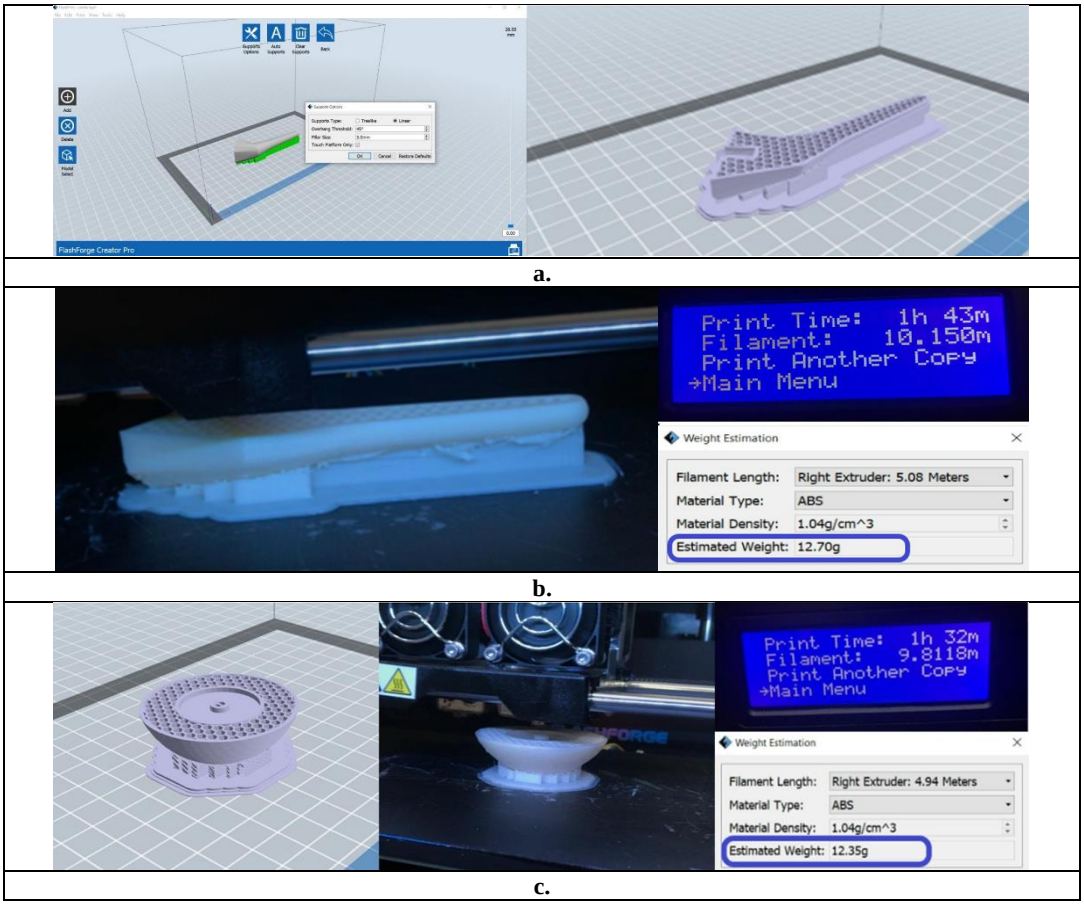
The model centering on the platform was chosen and the positioning at 3 mm above it were performed to avoid the risk of material sticking to the printing platform, which could have occurred due

to the irregular design of the model and would have affected the printing process. The filament can be printed under optimal conditions with the appropriate settings. The first setting involved adjusting the support structure. A layer height of 0.12 mm and a support structure height of 20 mm were chosen. Four solid, lower and upper layers and three perimeter shells were selected for the shell settings.

Another parameter of the process is the fill density. In this case, the infill density value was set to 30%. The fill structure of the model was chosen to be hexagonal, as shown in Figure 4*a*. The default settings for printing speed and travel speed were 50 mm/s and 70 mm/s. Regarding the temperature used in the process, the extruder temperature reached 240°C, while the printing platform temperature was set at 90°C.

The entire additive manufacturing process for the humeral stem prototype took approximately 1 hour and 43 min, using approximately 10,15m of SmartFil Medical filament. As for the weight of this component, it was estimated that the humeral stem prototype would weigh around 12.7g. This information, displayed on the 3D printer screen, is highlighted in Figure 4*b*.

Similarly, to obtain the prototype of the humeral component, the same settings as mentioned earlier were configured to prepare the 3D printer for the additive manufacturing process. According to Figure 4*c*, the internal structural fill pattern of the component, which is hexagonal with a specified fill density, is highlighted. For the 3D printing of the prototype component was estimated a weight of 12.35 g, approximately 9.81 m of ABS material was used, and the entire process took 1 hour and 32 min. Upon completion of the 3D printing process, the characteristic prototype of the humeral component was obtained, as highlighted in Figure 4*e*. Once the two individual components that make up the shoulder prosthesis were obtained, a final step was performed, which consisted of assembling the two components by pressing them together. As can be seen in Figure 4*d and f*, the result obtained after completing the 3D printing process highlights a clearly defined prototype of a customized shoulder prosthesis.




**a.**

**b.**

**c.**

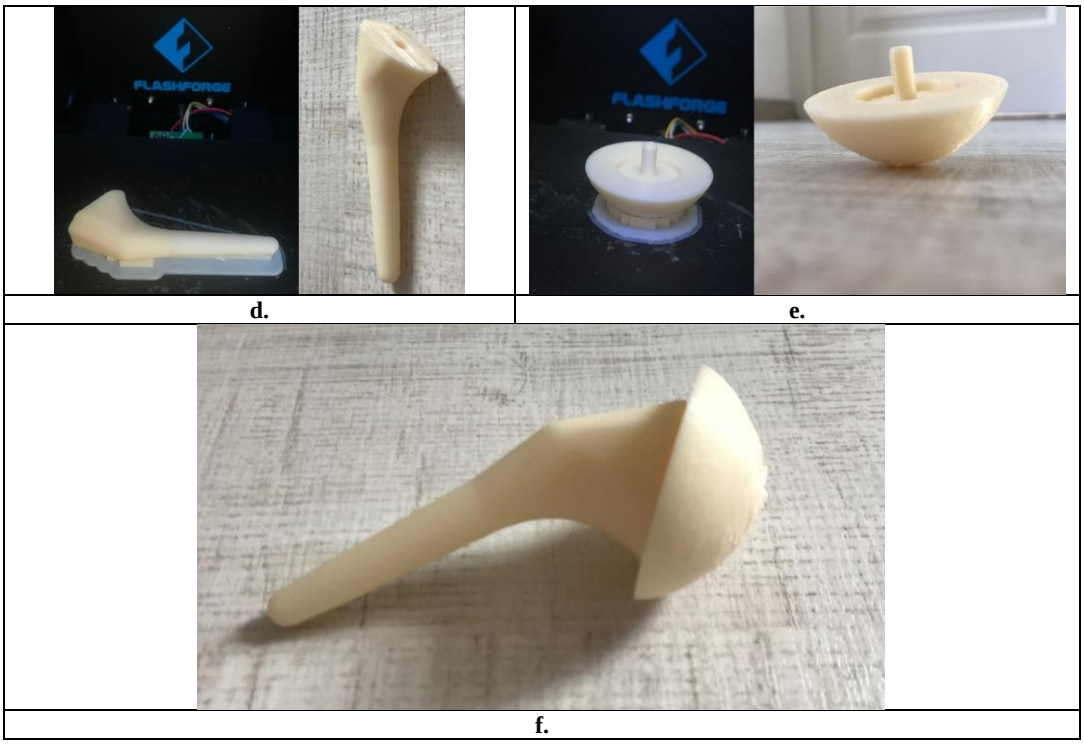



**Figure 4.** Custom humeral prosthesis additive manufacturing using ABS SmartFil Medical.
**a.** Preparing the humeral stem in Flash Print; **b.** The FDM manufacturing process of the humeral prosthetic stem; **c.** The prosthetic cup manufacturing process;
**e.** Final humeral stem prototype; **f.** Final prosthetic cup prototype

## 4. Conclusions

Summarizing, this work involved detailed studies on the anatomical structure of the glenohumeral joint, analyzing both the causes and pathologies that lead to shoulder prosthetics, as well as the degrees of freedom associated with the targeted joint. The goal was to demonstrate the beneficial impact that medical engineering can have on improving the quality of life for patients. Furthermore, the study emphasizes the idea of uniqueness in relation to each human body, highlighting the need for personalizing prosthetic components based on the specific humeral anatomical parameters of each individual patient. The aim is to increase the longevity of the implant to reduce revision surgeries, particularly among younger patients with severe shoulder conditions. Moreover, building upon existing commercial solutions, this work opted for developing a prosthetic system characterized by simplified geometry using CAD software. The humeral component has the ability to vary in inclination by ±15°, as seen in more advanced humeral prostheses. However, its fully anatomical design is intended to provide adequate joint biomechanics, ensure implant stability, and enhance the range of motion for patients. In future research, is desired to adjust the simplistic design of the humeral prosthesis prototype to obtain a complex 3D model with variable geometry for better precision in restoring humeral joint mobility. This approach promotes joint stability and increased range of motion without compromising the fixation of the implant. In the components manufacturing process, 3D printing technology was used with an FDM 3D printer and biocompatible ABS material called SmartFil Medical, scientifically certified for short-term contact with the human body.

The future trends in this field aim to optimize the morphology and functionality of the humeral endoprosthesis, closely mimicking the anatomy and biomechanics of the glenohumeral joint. This includes improving bone segmentation and virtual prototyping through the development of specialized medical software for preoperative planning of shoulder arthroplasty, using the VTK library in Python programming language. Future perspectives also involve conducting virtual finite element analysis simulations to simulate the mechanical behavior of the customized humeral endoprosthesis and

conducting a comparative study with a standardized prosthesis to identify weak areas and further improve the prototype. The impact of these additional research efforts is valuable in avoiding errors in the reconstruction of the normal shoulder joint by designing a highly accurate 3D model, aiming to achieve a personalized shoulder prosthesis that closely mimics the patient's anatomical structure and morphology.

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