

Application of 3D Printing Technology in the Development and Prototyping of an Above-Knee Prosthesis

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Abstract

This paper describes the process of creating a new type 3D model of an above-knee prosthesis and its subsequent 3D printing using modern technology. The introduction provides a brief history of prosthetics, kinematics of new prosthesis mechanism, highlighting the advantages of contemporary solutions over earlier models. Following this, the components of the above-knee prosthesis are described in detail, along with the CAD technology used to create the 3D model, as well as an analysis of the issues with previous prosthetic prototypes and the necessary design modifications. A 3D model of the hydraulic cylinder was developed using SolidWorks, after which the remaining parts of the prosthesis were designed with the required adjustments. A static analysis was performed to verify that the prosthesis could support a weight of 120 kilograms. The paper also discusses additive manufacturing and the preparation for 3D printing of the parts. Finally, after 3D printing, the parts were assembled into the final above-knee prosthesis structure.

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1 Introduction

In recent decades, the remarkable and almost exponential progress in 3D additive manufacturing has completely changed the approach to production in many fields. One is medicine, particularly in the production of medical aids, such as various prostheses. Prostheses, which serve as artificial replacements for body parts, aim to enhance the quality of life for individuals with physical impairments [1, 2]. Additive manufacturing enables the personalization and customization of products to meet the specific needs of users, which is crucial in orthopedics. Integrating 3D additive manufacturing into the production process of above-knee prostheses offers the potential for faster, more flexible, and cost-effective manufacturing.

This paper describes the creation of an above-knee prosthesis designed for individuals with amputations. A relatively new production method,

additive manufacturing, which is still in its early stages of development, will be used.

While conventional manufacturing of individual components often requires significantly more time and cost [3, 4], additive technology enables faster production and testing of separate parts. This paper will examine the processes involved in creating 3D and 3D printed parts, as well as conducting static analysis to ensure the reliability of the production process [5].

Finally, the paper will provide an overview of potential challenges and solutions in the manufacturing process, as well as an analysis of possible improvements in the design of the above-knee prosthesis.

2 Components of an Above-Knee Prosthesis

An above-knee prosthesis can be constructed using various materials and components [6, 7].

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Transfemoral prostheses typically consist of five main components [8, 9]: socket, knee unit, lower leg and ankle joint with foot, as shown in Figure 1.

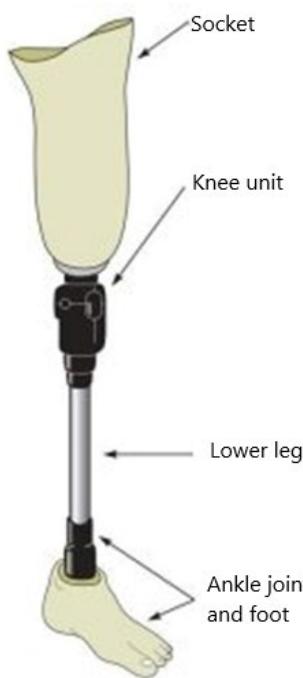


Figure 1 Main components of an above-knee prosthesis [2]

2.1 Foot-ankle assembly

Prosthetic feet serve a range of functions, including mimicking the shape of the natural foot, providing stability when standing, allowing the foot to bend during the early stance phase, enabling toe flexion, and many others [10]. They also help maintain a neutral position of the ankle joint during the swing phase.

2.2 Artificial lower leg - pylon

The primary role of the artificial lower leg is to connect the knee unit and the ankle joint, thereby enabling the transfer of vertical loads caused by the user's weight to the foot and further to the ground. Modern lower legs incorporate various advanced materials and technologies, enabling a lighter construction and enhanced functionality. Some lower legs may include a shock absorption unit, which can be beneficial during fast walking or running, reducing impact on the joints and increasing the user's comfort.

2.3 Knee unit

Among all prosthetic components, the knee unit is considered the most complex as it must provide stable support while standing and allow controlled movements during walking.

2.4 Socket

The transfemoral socket connects the residual limb, the user, and the rest of the prosthesis. It must be fitted appropriately to ensure adequate load transfer, stability, and control. The quadrilateral and ischial containment designs are the two most common designs for load transfer. The quadrilateral design distributes the load to the ischial tuberosity and gluteal muscles, relying on the posterior part of the socket. In contrast, the ischial containment design evenly distributes the load across the entire surface of the residual limb.

2.5 Extension mechanism

The extension mechanism connects the residual limb to the socket and the rest of the prosthesis. This connection is crucial for the overall prosthesis design—the better the quality of this link, the greater the energy transfer, comfort, and control over the prosthesis. There are several ways to achieve this connection, with vacuum suspension being the most popular method, which involves removing air from the socket using a pump.

3 Modified prosthesis

The primary objective of modifying an above-knee prosthesis is to enable individuals with transfemoral amputations to climb stairs naturally. For this activity, the following modifications are required:

- Integration of a linear actuator into the knee joint;
- Redesign of the ankle joint and installation of a linear actuator in the ankle joint.

The appearance of the modified Endolite prosthesis with built-in linear actuators in the knee and ankle joints is shown in Figure 2.

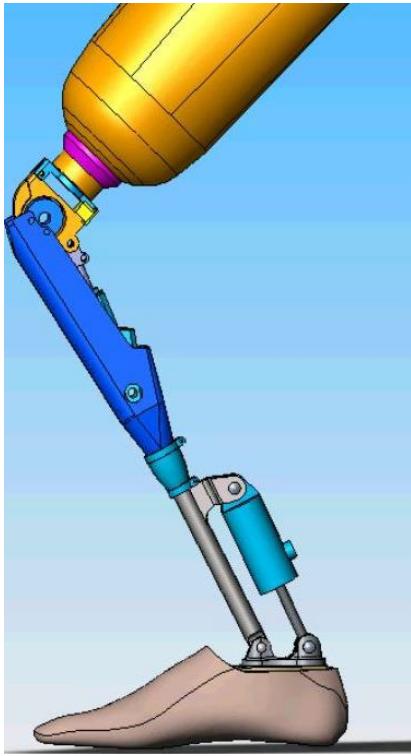


Figure 2 Modified prosthesis

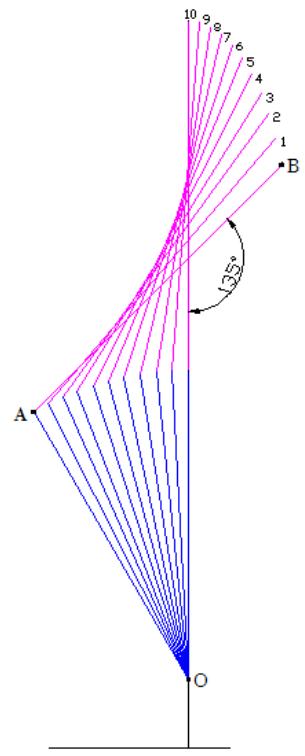


Figure 3 Trajectory diagram during stair-climbing simulation

3.1 Kinematics of the Above-Knee Prosthesis Mechanism

Kinematic analysis of mechanisms examines methods for determining individual mechanism components' trajectories, velocities, and accelerations. Graphical and analytical methods are used for kinematic analysis [11]. In the graphic analysis of the kinematics of the transfemoral prosthesis, the basic mechanism is determined so that the foot is supported on the ground, the joints are points O and A, and the link \overline{OA} represents the lower leg part of the prosthesis, while link \overline{AB} represents the thigh part (Figure 3).

a. Graphical Determination of Trajectories

Modifying the transfemoral prosthesis with two mechanisms for stair climbing enables the movement of both the prosthesis's lower leg and thigh parts [12].

b. Graphical Determination of Velocities

To determine the velocities of the moving components of a mechanism using the graphical method, it is necessary to draw the mechanism to

scale in its desired position and know the angular velocity of the driving member.

Given that the angular velocity ω_1 of the driving member one is known, the velocity of point A is:

$$v_A = \omega_1 \cdot \overline{OA} \quad \text{Eq (1)}$$

The instantaneous center of velocity is arbitrarily chosen, and from this point, the absolute velocity, which is perpendicular to the link \overline{OA} , is plotted to scale. The member 2 has a complex motion, consisting of both translation and rotation:

$$\vec{v}_B = \vec{v}_A + \vec{v}_B^A \quad \text{Eq (2)}$$

The relative velocity is perpendicular to the link \overline{AB} , and using ω_2 , it is calculated and plotted at the tip of the velocity vector \vec{v}_A . The point P_v is then connected to the tip of the velocity vector \vec{v}_B^A , which results in the absolute velocity vector \vec{v}_B (Figure 4).

c. Graphical determination of acceleration

To determine the accelerations of the mechanism components using the graphical method, it is necessary to draw the mechanism to scale in the

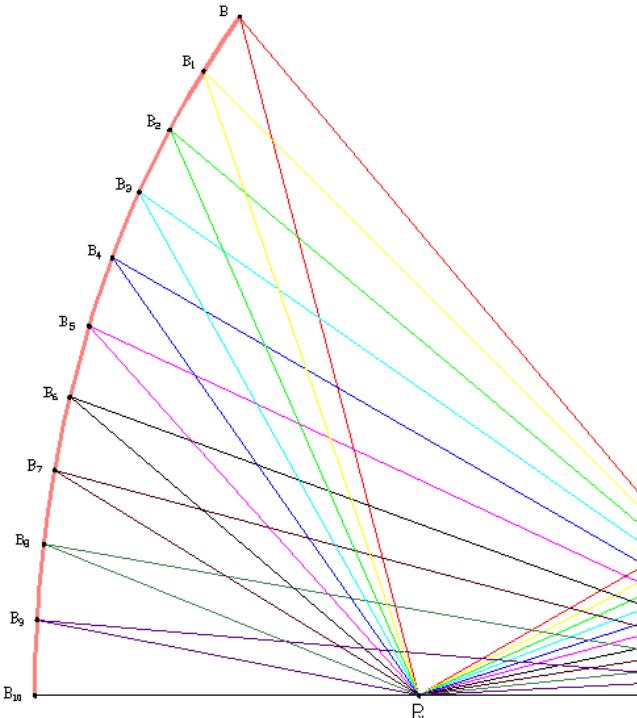


Figure 4 Speed diagram while climbing stairs

desired position, draw the velocity diagram, and calculate all the absolute and relative velocities.

It is assumed that the angular velocity of the driving component is constant. The acceleration of point A can be expressed in vector form as:

$$\vec{a}_A = \vec{a}_{AN} + \vec{a}_{AT} \quad \text{Eq (3)}$$

The perpendicular component of acceleration can be calculated from the expression:

$$a_{AN} = \frac{v_A^2}{OA} \quad \text{Eq (4)}$$

The tangential component of acceleration is equal to zero because the angular velocity of the driving element is constant.

The instantaneous center of acceleration is established, and from it, the vector of the perpendicular acceleration component is drawn to scale in the direction of the rod \overline{OA} .

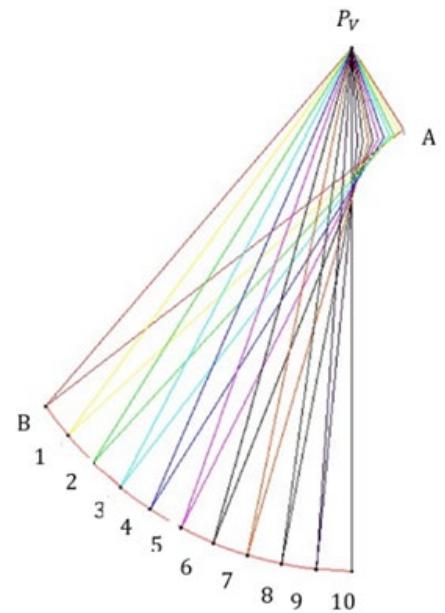


Figure 5 Acceleration diagram when climbing stairs

The acceleration of point B can be expressed in vector form as:

$$\vec{a}_B = \vec{a}_A + (\vec{a}_B^A)_N + (\vec{a}_B^A)_T \quad \text{Eq (5)}$$

The perpendicular component of acceleration can be calculated from the expression:

$$(\vec{a}_B^A)_N = \frac{(\vec{v}_B^A)^2}{AB} \quad \text{Eq (6)}$$

From the tip of the vector, the perpendicular component of acceleration is drawn in the direction of the rod \overline{AB} . By connecting this point with the center, the vector of the absolute acceleration of point B is obtained (Figure 5).

4 Experimental testing of the modified prosthesis

After installing linear actuators in the standard above-knee prosthesis, experiments were conducted to verify the functionality and kinematics of the modified prosthesis [13].

a. Laboratory testing

For the experimental testing of the prosthesis kinematics, POLARIS measurement equipment was used (Figure 6).

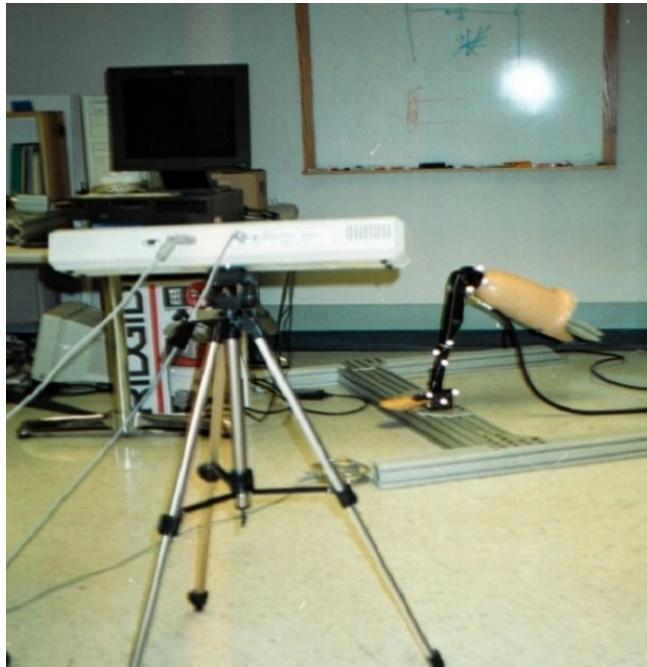


Figure 6 Prosthesis testing in a lab condition

b. Testing on the patient

The results of the experimental testing of the prosthesis movement are shown in Figure 7. The prosthesis testing on the patient was conducted in the orthopedic workshop (Figure 8).

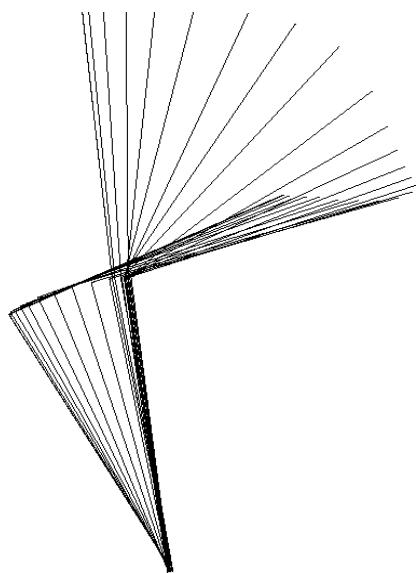


Figure 7 Experimental testing of the prosthesis



Figure 8 Prosthesis testing on a patient

5 Modeling of the Above-Knee Prosthesis

The above-knee prosthesis will feature a single-axis knee with hydraulic components, while the foot-ankle assembly will utilize a SACH (Solid Ankle Cushion Heel) foot with hydraulic features. Since prototypes of the above-knee prosthesis already exist, as shown below, a redesign is necessary to adapt the components to hydraulic cylinders [14]. Additionally, specific changes are required to address aesthetic and ergonomic concerns. The redesign will be carried out using the SolidWorks software package. Components will be modeled separately and assembled into a single unit (Figure 9). A numerical analysis will also be conducted using the SolidWorks Simulation module, where stress simulations will be performed using the finite element method.

5.1 Overview of Previously Made Above-Knee Prostheses Prototypes

The first above-knee prosthesis prototype was made of wood and consisted of three parts: the femur, the lower leg, and a metal foot that connected them. The

longer cylinder is connected to the femur, allowing for knee rotation, while the shorter cylinder is connected to the foot, ensuring the tilt of the prosthesis.

The next step was to apply the new knowledge to create a new prosthesis using additive manufacturing technology (Figure 9). A new feature of the next model was the use of standardized adapters from manufacturers like Ottobock, along with the disassembly of the lower leg into an upper and lower part that would be connected with these new adapters, resulting in a new, square-shaped lower leg.

Inside the lower leg is a cavity that houses the hydraulic cylinders. The shorter cylinder is connected to the foot and the lower part of the lower leg, similar to the wooden prosthesis, while the longer cylinder is connected to the knee and the upper part of the lower leg. The innovation of this design lies in the fact that the knee acts as a separate component, unlike the previous wooden model. The femur, made by orthopedic specialists, will be attached to the knee. Additionally, the pump and motor holder have been redesigned.

5.2 Hydraulic installation

The hydraulic installation of the above-knee prosthesis comprises a minimal number of hydraulic components designed to maximize the weight



Figure 9 The first attempt at applying additive technology in the creation of a transfemoral prosthesis

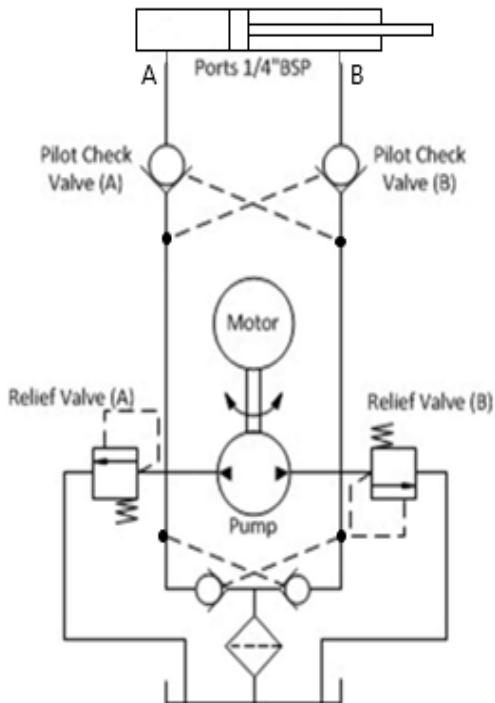


Figure 10 Hydraulic installation diagram for control

reduction of the hydraulic system. The schematic of the hydraulic system is shown in Figure 10.

The actuating component is a double-acting hydraulic cylinder powered by a dual-flow gear pump [15]. The pump is driven by an electric motor supplied by a 12V battery.

5.3 Hydraulic Cylinders

The foundation of the prosthesis, from which the modeling will begin, consists of hydraulic cylinders. The shorter cylinder, which connects the lower part of the lower leg to the foot mount, should allow for a forward tilt of the prosthesis by 30° when the piston extends. In addition to the shorter cylinder, the longer cylinder connects the prosthetic knee to the upper part of the lower leg. Its goal is to allow approximately 90° knee rotation [16, 17].

5.4 Modeling of the Hydraulic Cylinder

Since the cylinders consist of multiple components, they are divided into five parts, each modeled separately in the Part module before being assembled in the Assembly module.

After modeling the individual components, they are assembled into the final unit within the assembly module, as shown in Figure 11. The elements are

positioned and aligned using appropriate mates, ensuring correct placement and orientation, essential for the hydraulic cylinder's proper operation.

Additionally, during modeling, the option to create a groove on the piston for installing an O-ring was considered. The O-ring serves as a crucial sealing element between the piston and the cylinder's interior, preventing hydraulic fluid leakage between chambers.

5.5 Modeling of the Parts of the Transfemoral Prosthesis

In the new design of the thigh prosthesis, the primary goal is to reduce its overall length for use by individuals of average height, with the degree of reduction depending on the hydraulic cylinders. The modeling process starts with the lower part of the tibia, which will be slightly shorter and broader due to the dimensions of the new cylinders. This modification ensures the prosthesis retains functionality while accommodating the updated hydraulic components.

Compared to previous designs, several changes have been made, including adjustments to the spacing of holes at the top of the tibia section, vertical screw hole spacing, and the widening of the tibia. Additionally, side holes have been added for hydraulic oil connections, replacing the outward-facing connections from older models.

Aesthetically, the tibia's appearance has been significantly altered to more closely resemble a natural human leg. An adjustable "plate" has been introduced at the top of the lower tibia, allowing

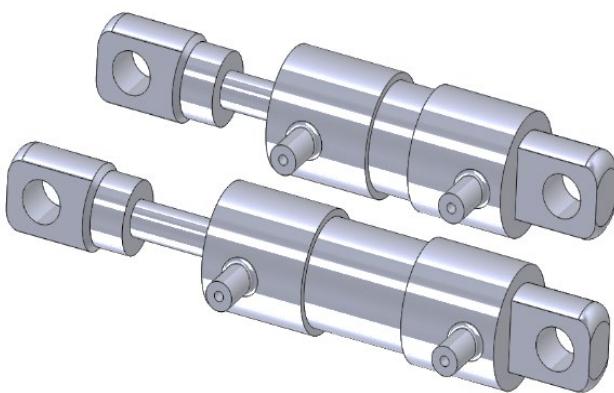


Figure 11 3D Assembly of a double-acting hydraulic cylinder



Figure 12 Assembly of the lower part of the tibia

height adjustments. Plates of varying heights can be produced using 3D printing, ensuring optimal customization for the user, with a plate thickness of 10 mm.

For the foot lever redesign, the length and width of the opening for the hydraulic cylinder have been adjusted for proper installation. The lower prosthesis requires two adapters, and the foot must be modeled. The male adapter will connect to the foot, while the female adapter will link it to the foot lever. These parts are standardized and will not be subject to design changes. After assembling the lower tibia, it is necessary to model the male and female adapters that connect the upper and lower parts of the tibia (Figure 12).

The upper part of the tibia has undergone several changes, such as the distance between the holes, the creation of two side holes for hydraulic cylinder oil connections, and the longer cylinder will be fully contained within the upper tibia, unlike the shorter cylinder, which will be partially outside due to the connection with the foot lever. Additionally, eight holes have been made through which the pump bracket will be attached using screws. Compared to

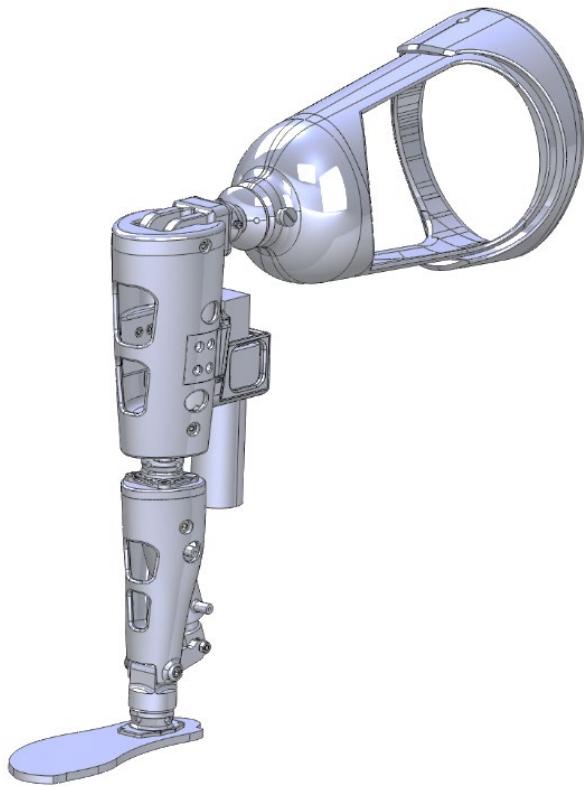


Figure 13 The final shape of the above-knee prosthesis

the previous prototype, the design has undergone a complete overhaul (Figure 13).

The knee has also been redesigned due to the width of the new cylinders, with changes reflected in the angles and the width of the piston rod's top.

6 Analysis of parts

After designing and analyzing the components in SolidWorks, a numerical analysis will be conducted using the Finite Element Method (FEM). This approach simplifies complex problems by dividing the analyzed object into minor, more discrete elements, thereby facilitating detailed assessments of stress and deformation[18]. The analysis will focus on the foot lever and the upper part of the lower leg because, according to [9], the upper part is 20% more loaded than the lower part (Figure 14).

To perform a component analysis, open the Simulation module in SolidWorks. Once opened, define boundary conditions, apply material properties, set loads, and create a finite element mesh. After selecting the material and determining

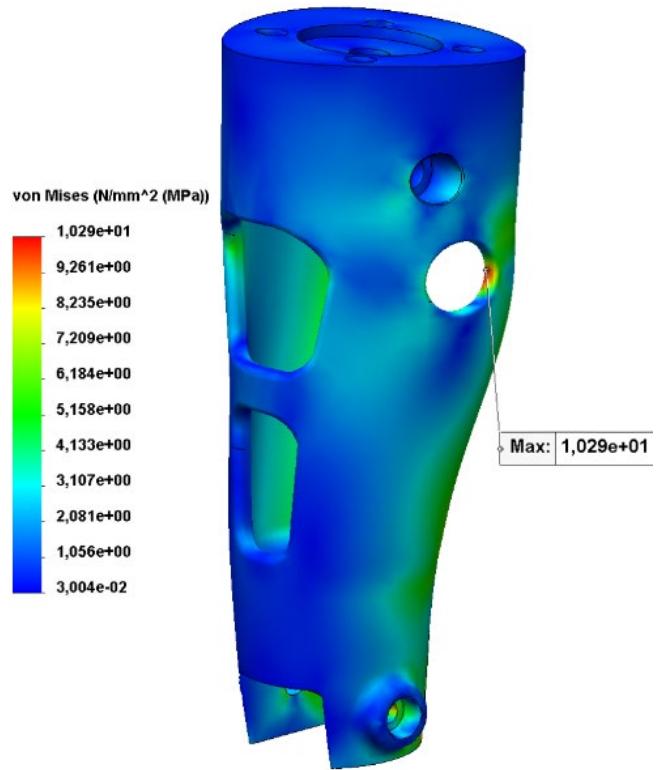


Figure 14 Results obtained from the analysis of the lower leg component

the boundary conditions, a load is applied to assess whether the component can withstand it. A force of 2000 N, acting on the connection of the foot lever and the hydraulic cylinder, is applied as the maximum load with a safety factor of 1.6, after which the analysis begins.

7 Manufacturing Prostheses Components Using 3D Printing Technology

After the parts have been designed and analyzed in the SolidWorks software suite, their realization as physical objects must be achieved through additive manufacturing, specifically 3D printing. Additive manufacturing is an innovation enabled by the advancement of computers, particularly the technological development of various computer-aided design, computer-aided manufacturing, and computer-aided engineering (CAD, CAM, and CAE) technologies.

7.1 Additive Manufacturing

Additive manufacturing (AM) is a process of creating parts by adding material layer by layer, enabling the

production of complex three-dimensional objects based on predefined digital models. The model is converted into a series of thin horizontal cross-sections derived from CAD data, where each layer's thickness determines the final part's precision—thinner layers result in a more accurate approximation of the original 3D model [19].

Unlike conventional manufacturing methods, such as machining (where parts are shaped by material removal) or casting (where liquid material is poured into molds), additive manufacturing enables the creation of customized designs with minimal material waste. While the term "3D printing" is often used as a synonym for additive manufacturing, it refers explicitly to one of the many techniques within the broader additive manufacturing (AM) spectrum [20].

Several key steps must be followed to obtain a final product from a 3D model. The additive manufacturing process typically comprises eight stages [21]: CAD modeling, conversion to STL format, transfer and preparation, machine setup, printing process, part removal, post-processing, and application, including proper method selection [22, 23].

8 3D Printing and Assembly of Parts

After designing and analyzing the parts in SolidWorks, they must be saved in STL format, which defines the surface geometry for 3D printing. Before saving, it is essential to adjust the resolution settings to ensure smooth geometry. Lower resolutions may result in faceted rather than soft, cylindrical surfaces.

The Prusa i3 MK3S 3D printer will feature a working volume of 250×210×210 mm. If the model exceeds these dimensions, it will be scaled down or split into parts for reassembly. The material chosen for the prosthesis is ABS due to its superior mechanical properties, including abrasion and heat resistance, and better ductility compared to PLA. Despite requiring higher printing temperatures and a heated bed, ABS is ideal for producing functional and durable parts, such as prostheses.

The lower tibia part fits within the printer's volume, and its orientation is critical for strength and material usage as it affects the component's durability and the costs of the support material. The optimal layer

height is set to 0.3mm, balancing price, time, and strength. For most areas, 50% infill is selected, while 100% infill is used for high-stress zones. Support is enabled everywhere for stability, increasing material use and print time, with a 0.3 mm layer taking 844 minutes to print.

ABS material was chosen with a nozzle temperature of 260°C and bed temperature set to 110°C. The G-code is then exported and transferred to an SD card. G-code is a programming language that links digital designs to 3D printing, controlling the printer's movements and material extrusion. It directs the printer on where to move, speed, height, and extrusion parameters, ensuring precise component formation. Before printing, cleaning the print bed, applying adhesive for better layer adhesion, and checking all settings are crucial. After the printer reaches the required temperature, the G-code is loaded from the SD card, and printing begins after a brief calibration.

After the printing process is completed, excess material, mainly support structures, must be removed. These supports ensure the stability of the printed part (Figure 15). The parts are printed similarly, except for the upper part of the tibia, which has dimensions too large for the 3D printer to handle. Therefore, it must be divided into two parts: a joint with a slot and pin must be created, each part printed separately, and then they are joined using glue. The

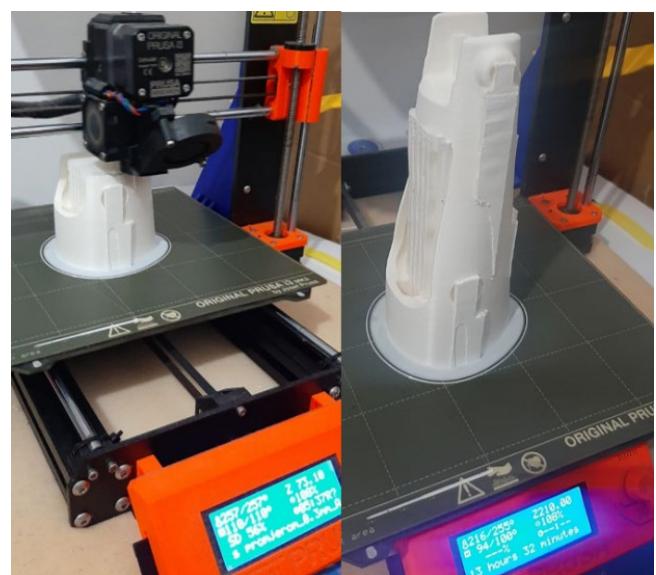


Figure 15 Display of the process of creating the lower part of the tibia at 56% and 100%

image below shows the connected upper part of the tibia.

To assemble the parts of the prosthesis, screws, nuts, and threaded inserts are needed. The threaded inserts are pressed into the holes to connect the adapters to the other parts (Figure 16). Threaded inserts have already been pushed into the lower part of the tibia, and the same procedure will be applied to the knee and upper part of the tibia. Additionally, the Ottobock 4R51 adapter will be tested to check if the holes for the screws are correctly made. To connect the male and female adapters, DIN 913 M6 screws are needed, with a total of eight, four for connecting a male and female adapter and the others connecting the foot to the footstep and the upper and lower parts of the tibia. The final step is to assemble the sub-assemblies into the thigh prosthesis using six DIN 912 screws.

The final step is to connect the unit holder to the upper part of the tibia using eight DIN 7991 M5x12 mm or M5x16 mm screws. Once all the parts are assembled, the final shape of the prosthesis is achieved. Based on the final results, a forward tilt of the prosthesis of 30° was completed when extending



Figure 16 The final assembly of the above-knee prosthesis

the shorter cylinder by 25 mm. The knee rotation angle is 90°, which is satisfactory but not fully optimal due to the thickness of the piston head.

In total, the prosthesis has been shortened by 83 mm compared to the previous prototype.

In addition to the prosthesis, the patient's healthy foot was scanned, a 3D printed personalized artificial foot, which was then connected to the above-knee prosthesis.

This prosthesis will be used for experimental tests in the laboratory to verify the kinematics and functionality of the above-knee prosthesis.

If the results are as expected, it is possible to conduct basic experiments with a patient in an orthopedic workshop.

After that, a functional carbon fiber prosthesis would be 3D printed.

9 Conclusion

The development of a prototype of an above-knee prosthesis with active drive actuators in the knee and ankle joints made by 3D printing represents a significant step forward in the development of personalized medical devices.

By scanning a healthy foot and 3D printing an artificial foot, a new quality is obtained. The third step should be to scan and 3D print a lower leg mask according to the healthy lower leg of the patient.

The use of additive technology achieves high precision, design flexibility and rapid adaptation to user needs, significantly shortening production time compared to conventional methods. Materials such as ABS, chosen for this project, allow the creation of strong and functional parts that can withstand mechanical loads.

This approach opens up opportunities for further research and development of prosthetics, making them more accessible, personalized and sustainable for users in the long term.

Conflicts of Interest: The author(s) report there are no competing interests to declare.

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