Univerza v Mariboru

Fakulteta za strojništvo

DEVELOPMENT AND MANUFACTURING OF AN ARTIFICIAL RESIDUAL LIMB FOR STRUCTURAL TESTING OF 3D PRINTED PROSTHESES COMPONENTS

Master's thesis

Student:	Rubén Quevedo Martínez
Study program:	Master's degree
Specialty:	Design engineering
Mentors:	Dr. Gregor Harih, Ph.D. Dr. Vasja Plesec, Ph.D.

Maribor, February of 2024

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Table of contents

Table of figures

Index of tables

List of abbreviations

3D	Three-dimensional
ABS	Acrylonitrile butadiene styrene
AM	Additive manufacturing
CF	Carbon fiber
CAD	Computer assisted design
DLP	Digital light processing
FDM	Fused deposition modeling
ISO	International Organization for Standardization
MJF	Multi jet fusion
PETG	Polyethylene terephthalate glycol
PLA	Polylactic acid
PTB	Patellar tendon–bearing
PVA	Polyvinyl alcohol
SLA	Stereolithography
SLS	Selective laser sintering
TPU	Thermoplastic polyurethane
TSB	Total surface–bearing
UV	Ultraviolet

Development and manufacturing of an artificial residual limb for structural testing of 3D printed prostheses components

Keywords

3D printing, manufacturing, prosthetics, testing, artificial residual limb, silicone.

Abstract

The aim of this master's thesis was to design and implement a below-the-knee artificial residual limb capable of replicating the characteristics of an intact human leg. These characteristics include not only similar shape and size but also the material properties of the limb's surface and soft tissues. Consequently, we developed a lower limb suitable for attaching various prosthetic devices to a robotic arm, facilitating the execution of all necessary performance tests. Additionally, we aimed to take advantage of the extensive customization capabilities offered by fused deposition modeling (FDM), enabling the creation of highly customizable parts in terms of both shape and material. Taking advantage of the possibility of using and combining rigid and flexible printing filaments, along with silicon, our goal was to create an accurate model of a residual limb. FDM was employed not only for crafting components for the model but also for constructing jigs to aid in the manufacturing process.

1. Introduction

The development of FDM 3D printing has led to a new era of innovation in the fields of rapid prototyping and manufacturing. This technology reaches different fields in the health sector, including surgery, implants or prosthetics [1, 2, 3]. In the latter case, we can see how it is now possible to create affordable prosthetic systems that can reach a wider range of people. However, it is important to point out that producing prostheses using this technology still has some limitations that need to be sorted out.

When a prosthesis is designed, it is essential to ensure its reliability and endurance, a principle that applies equally when employing FDM printing technology. The material chosen and the printing settings can lead to huge differences in terms of endurance and toughness, which must be appropriate for prosthetic applications, which would otherwise lead to premature breaks [4]. This also applies to the chosen orientation for printing parts; changing it will also change the layers' orientation. Consequently, parts with the same shape, material and printing settings will have different failure loads when printed in different positions [5]. Delamination is more likely to occur when forces are applied perpendicularly to the layers. Other parameters like the infill pattern and its density, the layer height, the number of perimeters or the nozzle diameter also influence the mechanical properties as well as the printing time [6, 7].

As we can see, 3D printing offers vast potential that demands exploration to fully leverage its capabilities. Its significant advantage over traditional manufacturing methods, aside from cost-effectiveness, lies on its high level of customizability, even during advanced stages of the design process [8]. Additionally, the ability to rapidly produce complex shapes is among the primary advantages, particularly in the realm of prosthetics. This capability of customization is something we can also take advantage of for creating accurate systems for testing such devices.

The motivation for considering additive manufacturing (AM) in the creation of testing systems lies on the inadequacy of the existing standard (ISO 10328:2016) for testing prosthetic systems to meet our specific needs. We found that this standard was not meant to test sockets in the first place and, when it comes to 3D printing, it is not adapted to these new manufacturing methods and the challenges they present [9, 10]. To ensure that the required characteristics of a prosthetic system are met, it is necessary to develop a new testing system specifically designed for evaluating printed prototypes. Some existing systems for testing prostheses consist of a mandrel covered with soft material that applies cyclic tests on the socket as stipulated in the ISO standard [11]. If we aim to create a more faithful simulation, our system will have to emulate the characteristics of human extremities as accurately as possible.

In reviewing the literature, we find that models of residual limbs have been created as a tool for the molding process of the socket. They are used to help obtain the geometry for their interior, thereby enabling an optimal shape to suit the user's needs. As a result, we find that creating an artificial limb for other purposes, like testing of the prostheses, is something others have approached before and it turns out to be a very effective way to emulate the behavior of the socket during gait [12, 13, 14].

Considering the above, the objective of this thesis was to manufacture an artificial residual limb replicating human limb characteristics, allowing performance tests to be carried out to ensure the durability of prosthetic models. A key focus of the thesis was to develop a method for building the artificial limb to closely resemble an intact leg structurally while maintaining ease of replication, despite its complexity. This also demanded the use of suitable materials for several components (including soft tissue, bones and supporting jigs for the manufacturing process) capable of meeting the required characteristics. Additionally, since the limb needed to be attached to a testing machine capable of simulating human gait for conducting all tests, developing a method for attaching the limb to the machine was also essential.

2. Overview of research field

2.1 Background and previous stages of the master's thesis

This master's thesis originated as a follow-up to prior research, which involved the manufacturing of fully 3D printed sockets for prostheses [15]. In order to analyze the loads and stresses these sockets would hold, a finite elements model of the residual limb was developed to perform the required analysis and extract data to be able to know where and how the modifications should be applied.

As the objective of this thesis was to develop an artificial residual limb for mechanical testing purposes, the geometry established in the previous research was foundational. All subsequent models used in this thesis were derived from this initial geometry.

2.2 Lower limb prostheses

When we talk about major lower limb amputations, we find two main types. The difference between them is given by the place where the amputation has been performed, whether it is above the knee (transfemoral) or below it (transtibial). As this master's thesis centers on the last type, we will only deepen into it.

2.2.1 Socket rectification

Every person's limb is specific, and it is possible to find variations in the geometry and material properties. This fact leads to the need to have a customized socket with a unique shape for every person depending on the characteristics of their residual limb and their needs. Traditionally, the process of the socket rectification has been done by taking measurements of the limb and creating a negative cast out of it that is then transformed into a positive mold. This mold is then modified to improve the socket fit. Nowadays, CAD is also used for the modeling of sockets. This shaping process is what we call rectification [16, 17].

Modifications performed during rectification are done following three primary designs mainly for distributing the loads properly inside the socket:

1) **Patellar tendon–bearing (PTB)**. Traditional approach based on the principle that certain areas of the residual limb can withstand increased pressure, such as the patellar tendon region. The design involves carving out areas capable of increased load and relieving areas intolerant to pressure. It is beneficial without gel liners but may lack rotational stability. Other drawbacks include high localized pressure causing adverse limb changes like calluses and skin breakdown.
2) **Total surface–bearing (TSB)**. Unlike traditional designs, this approach applies uniform pressure across the residual limb. The positive model is adjusted globally based on the limb's tissue density, with bony areas requiring greater reduction. The main idea of TSB socket designs is to ensure consistent pressure, often combined with a gel liner, to conform the socket to the limb's anatomy.
3) **Hybrid**. Combining features from both PTB and TSB sockets, bringing together their respective advantages. While TSB designs help in reducing pressure differences, they may struggle to effectively relieve localized loads on specific areas of the residual limb. To address this limitation, prosthetic concepts from both designs have been used to create sockets that blend global reductions with localized reductions and buildups in load-tolerant and load-intolerant regions, respectively.

2.2.2 Suspension methods

Prostheses should be able to be attached to the residual limb in order to be functional. This attachment to the limb is called suspension, and can be achieved by various methods. Four of the main ones are listed below [16, 18]:

1) **Supracondylar suspension**. Prosthesis is secured by extending the medial and lateral trim lines over the femoral condyles.
2) **Patellar tendon–bearing strap**. Suspension is gained using a strap that is attached to the hard socket and tightened over the femoral condyles.

3) **Distal pin suspension**. The liner has a peg attached to the bottom of it that is used for locking into the socket.
4) **Vacuum suspension with expulsion valve**. Suspension is obtained creating an airtight seal on the skin and the socket. Vacuum can be created using a hermetic sleeve that creates an airtight seal on the skin and the hard socket. These sockets use an expulsion valve to be able to empty the air inside the socket. Apart from the hermetic sleeve mentioned before, vacuum can be obtained using an external pump.

2.3 Limb anatomy

When shaping a residual limb model, several aspects of its anatomy must be considered to achieve accurate geometry, as happens in the model mentioned in section 2.1. Figure 1 illustrates the main bone structures in a residual lower limb. Building upon that, these bones can be scaled using anthropometric databases. The same happens with the soft tissue, where the circumferences described in Figure 2 can be used as parameters to give it scale and shape. Both figures were extracted from Plesec's dissertation, where the mentioned modeling process is discussed in depth [15].

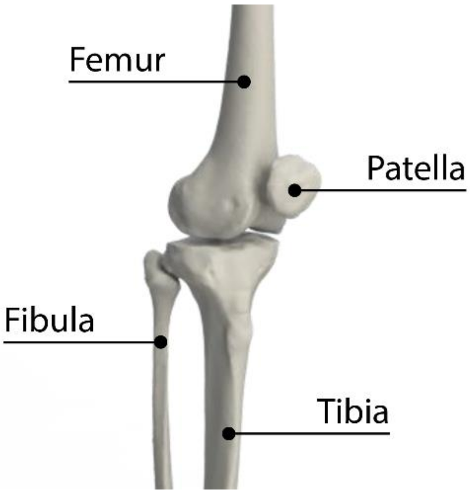

Figure 1. Main bone structures in the knee of a lower limb

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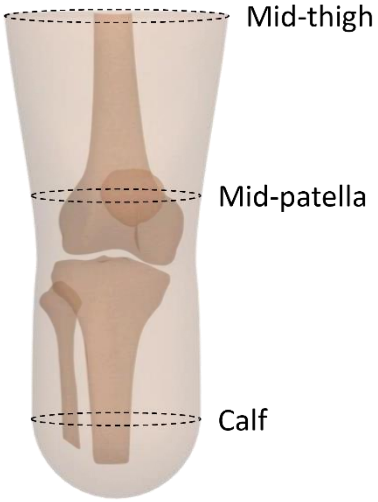


Figure 2. Transparent anterior view of soft tissue with depicted circumferences

2.4 3D printing technologies

Numerous AM technologies exist, each with distinct advantages and limitations. Understanding their capabilities and resource requirements is necessary for selecting the most suitable method for each specific application. The predominant 3D printing technologies used in the production of prostheses typically involve extrusion, powder solidification (sintering), and liquid solidification (polymerization) [19]. AM technologies rely on the layer-by-layer construction of components, a process that can be executed through various methods depending on the specific technology. Below, we provide brief descriptions of some of the most commonly utilized 3D printing methods.

2.4.1 Powder bed fusion

This field of AM includes several technologies, of which we will focus on SLS and MJF, as they are very commonly used. In SLS (selective laser sintering) printing technology, a specific volume of powder is compressed to a designated density, constituting one layer. Subsequently, a laser beam fuses the powder particles together through a process known as sintering. Following this, another layer of powder is added and compressed again, replicating the described process for each layer of the component. This printing technology is capable of building large volumes [20].

Figure 3. SLS printer (3D Systems' *SLS 380*)

Figure 4. SLS printed socket [21]

MJF (multi jet fusion) is another AM technology that bears a significant resemblance to the previously described SLS. However, unlike SLS, MJF does not use a laser beam to heat the powder and melt the material together. Instead, a fusing agent is selectively applied to the powder bed with added heat using an infrared lamp, resulting in the formation of solid parts [22, 23].

Figure 5. MJF printer (HP Jet Fusion 5200 Series)

Figure 6. MJF printed prosthetic foot [24]

2.4.2 Vat photopolymerization

In this section, we focus on SLA (stereolithography) and DLP (digital light processing), as they are two very commonly used vat photopolymerization methods. Both methods are closely related and rely on the polymerization of liquid resins. In DLP, a vat containing liquid resin is illuminated with a UV light projection shaped according to the current layer. As a result, the section exposed to light solidifies. Each time a layer is printed, the object is incrementally raised (printing occurs in an inverted position). The object continuously ascends out of the resin container to replenish the resin between the object and the screen. Once the entire object has been printed, it undergoes a curing process to harden its structure.

However, in SLA (stereolithography), objects are formed through localized photopolymerization of liquid resin, achieved by a UV laser beam that solidifies each layer. This characteristic makes the process slower compared to DLP, yet it also results in higher quality output [25].

Figure 7. SLA printer (3D Systems' *SLA 750)*

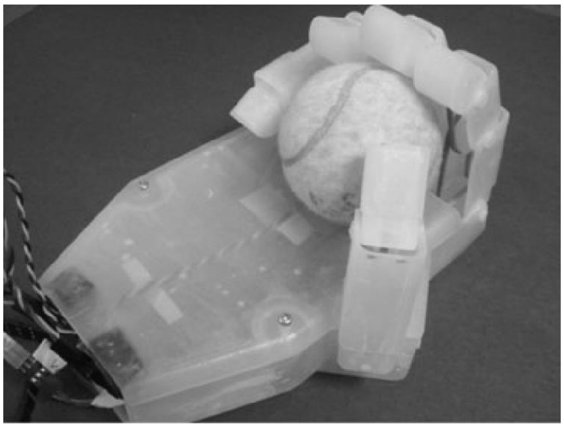


Figure 8. SLA printed prosthetic hand [26].

Figure 9. DLP printer (Anycubic's *Photon D2*)

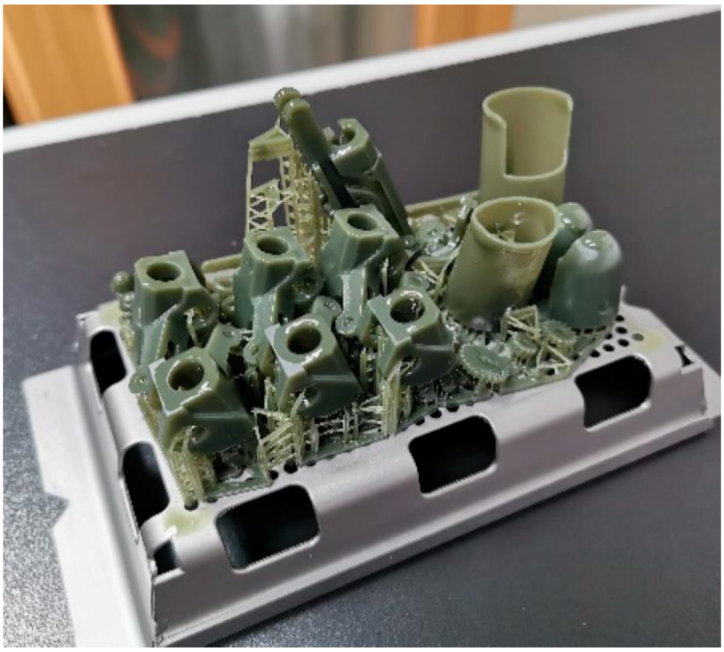


Figure 10. DLP printed parts for upper limb prosthesis [27].

2.4.3 FDM

The most commonly employed 3D printing technology is FDM, primarily due to its user-friendly nature and cost-effectiveness [28]. This is evident in both the affordability of the printing machines and the printing materials compared to other AM technologies. In FDM, the printing material, typically referred to as filament, is fed into the extruder where it is heated until it reaches its melting point. Subsequently, it is extruded through a nozzle and allowed to cool, forming the layers of the print. The initial layer is deposited onto a printing platform, which may be heated to ensure adhesion of the component as needed, depending on the filament used [29]. Figure 11 illustrates the described process. Additionally, FDM offers the versatility to print a diverse range of materials, as elaborated in the following section.

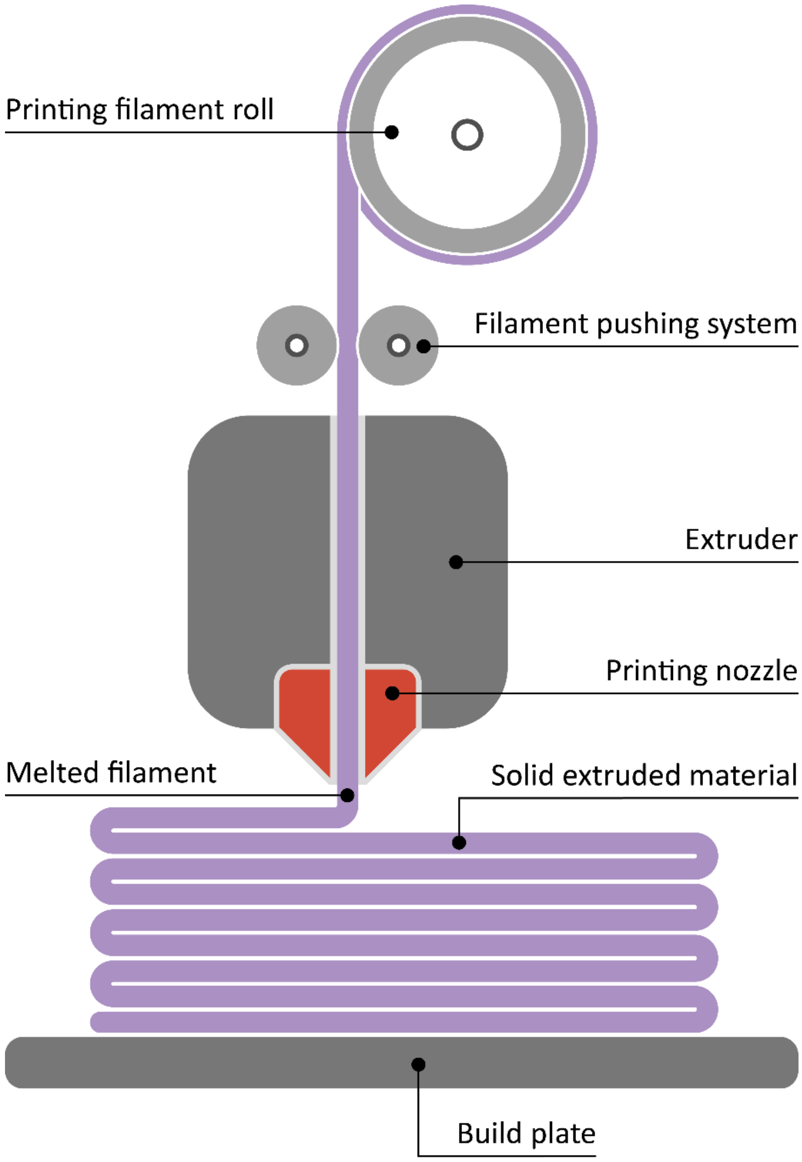


Figure 11. Diagram of the operation of an FDM printer

While the mentioned AM technologies have been utilized for manufacturing prosthetic components, FDM is notably more common [30]. This can be attributed to the advantages it offers over other technologies mentioned earlier.

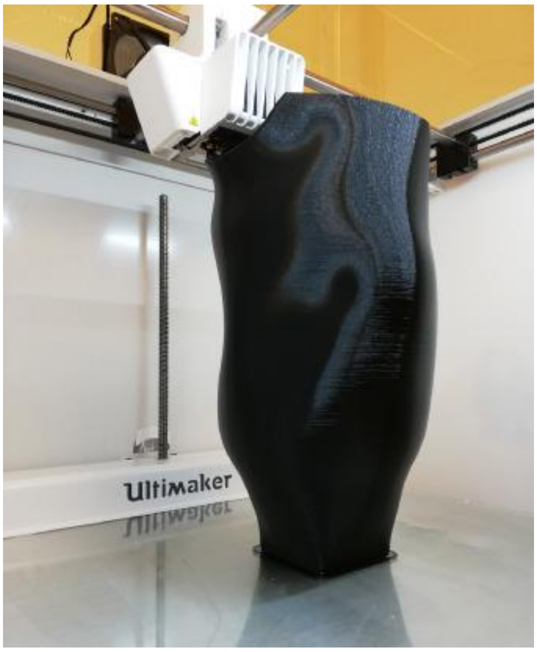


Figure 12. FDM printed lower-limb prosthesis socket [31].

2.5 Materials and available filaments

As mentioned above, FDM printing provides us with the possibility of printing with a big number of materials. For this reason, in Table 1 we have a comparison of different polymers with pros and cons extracted from *Polymers used in 3D printing* [32]. With the information in this table we can get an idea of what their main characteristics are so we can discern when to use one filament or another. The selected polymers have been chosen because they are either very commonly used, or they may have interesting characteristics for the aim of our master’s thesis.

Polymer	Pros	Cons
PLA	• Biodegradable. • Low cost. • Low processing temperature. • Less likely to warp, compared to other materials. • Does not emit any unpleasant fumes during the printing process. • Stiff and good strength. • Good dimensional accuracy. • Good shelf life.	• Low heat resistance. • Can ooze and may need cooling fans. • Filament can get brittle and break. • Not suitable for outdoors (sunlight exposure). • Prints degrade over time.

ABS	• Quite low cost. • Good impact and wear resistance (high endurance to heat pressure and stress). • Less oozing and stringing (smoother finish). • Water resistance. • Easily treated to obtain great finish.	• Heavy curling and warping. • Shrinking (dimensional inaccuracy) • Odor while printing. • Susceptible to sunlight, UV radiation e not suitable for outdoor use.
PETG	• Very strong. • Flexible. • Lower risk of warping. • Low shrinkage. • Glossy and smooth surface finish.	• Quite high printing temperature and bed temperature. • Sticky and stringing problems. • Poor bridging characteristics. • Clarity will make any imperfections within the internal layers visible. • Less resistant to scratches than ABS.
CF-PLA	• Increased strength and stiffness. • Used for quality parts. • Very good dimensional stability. • No heated bed needed. • Little warping and shrinkage during the cooling process.	• Material contains abrasive strands. • Increased oozing while printing. • Increased brittleness of filament. • Higher tendency to clog. • Excessive wear on printer nozzles, especially brass. • Regular users need to invest in harder metals for print nozzles.
PVA	• Good for building supports. • Easily adheres to other polymers. • Water soluble. • Biodegradable and nontoxic. • Easy to print.	• Partially hydrolyzes (breakdowns) at a temperature of 180 °C. • Moisture sensitive. • It can release some vapor if overheated. • Expensive.
TPU	• Rubberlike elasticity • Good load-bearing capacity • It can bend easily without any effect on the design, strength, and durability • High resilience, good compression set • Resistance to impact, tear, abrasion, scratches, weather • Ability to perform at low temperature.	• Short shelf life • Drying is required before processing • Not as cost-effective as other alternatives • Narrower hardness range • Narrow temperature range for processing • Difficult to print • Poor bridging characteristics • Possibility of blobs and stringing

Table 1. Pros and cons of different printing filaments

For the same reasons mentioned above, information in Table 2 has been gathered. This table collects some mechanical properties that are very useful when choosing a filament for printing a specific component. The data have been extracted from *Polymers used in 3D printing* [32].

Polymer	**PLA**	**ABS**	**PETG**	***CF-PLA***	**PVA**	**TPU**
Density (g/cm3)	1.24	1.08	1.27	1.17	1.23-1.31	1.22
Tensile strength: yield (MPa)	49.5	39	50			8.6
Tensile strength: break (MPa)	45.6	33.9	28	63	78	39
Tensile elongation: yield (%)	3.3	3.5				55
Tensile elongation: break (%)	5.2	4.8	100	3	9.9	580

Table 2. Mechanical properties of different polymer filaments of interest for the current project

3. Materials and methods

The criteria followed in developing the artificial residual limb focused on creating a model that closely resembles anatomical structures to achieve the most realistic biomechanical responses possible while also minimizing production costs using available resources. The pursuit of affordable prosthetic designs is a driving factor behind choosing AM over other technologies the reason why it is so important to keep the production costs as low as possible. Additionally, optimizing available resources enhances the design process.

3.1 Approaching the limb's development

Since we were unable to determine the success of the procedure for building the limb until it was manufactured and the results were observed, we devised three different options for developing the testing residual limb. These options served as alternatives if the others did not behave as expected. All of them featured 3D printed bones on the inside, made of rigid materials like PLA. The differences they had were mainly in how we recreated the leg's muscles and other soft tissues.

- **Option A**. The inside would be made of silicone. This silicone would be poured inside the mold, which would also become a part of the model, acting as outer skin. This skin would be made of 3D printed flexible material TPU [Figure 13 (a)].
- **Option B**. This one would use a 3D printed skin made of flexible material, with an organic-shaped infill on the inside. Inside of, we would introduce silicone that would fill the void left in the interior [Figure 13 (b)].
- **Option** C. It would consist of building a mold for creating the soft tissue that surrounds the bones and filling it with silicone. After that, this mold would be removed [Figure 13 (c)].

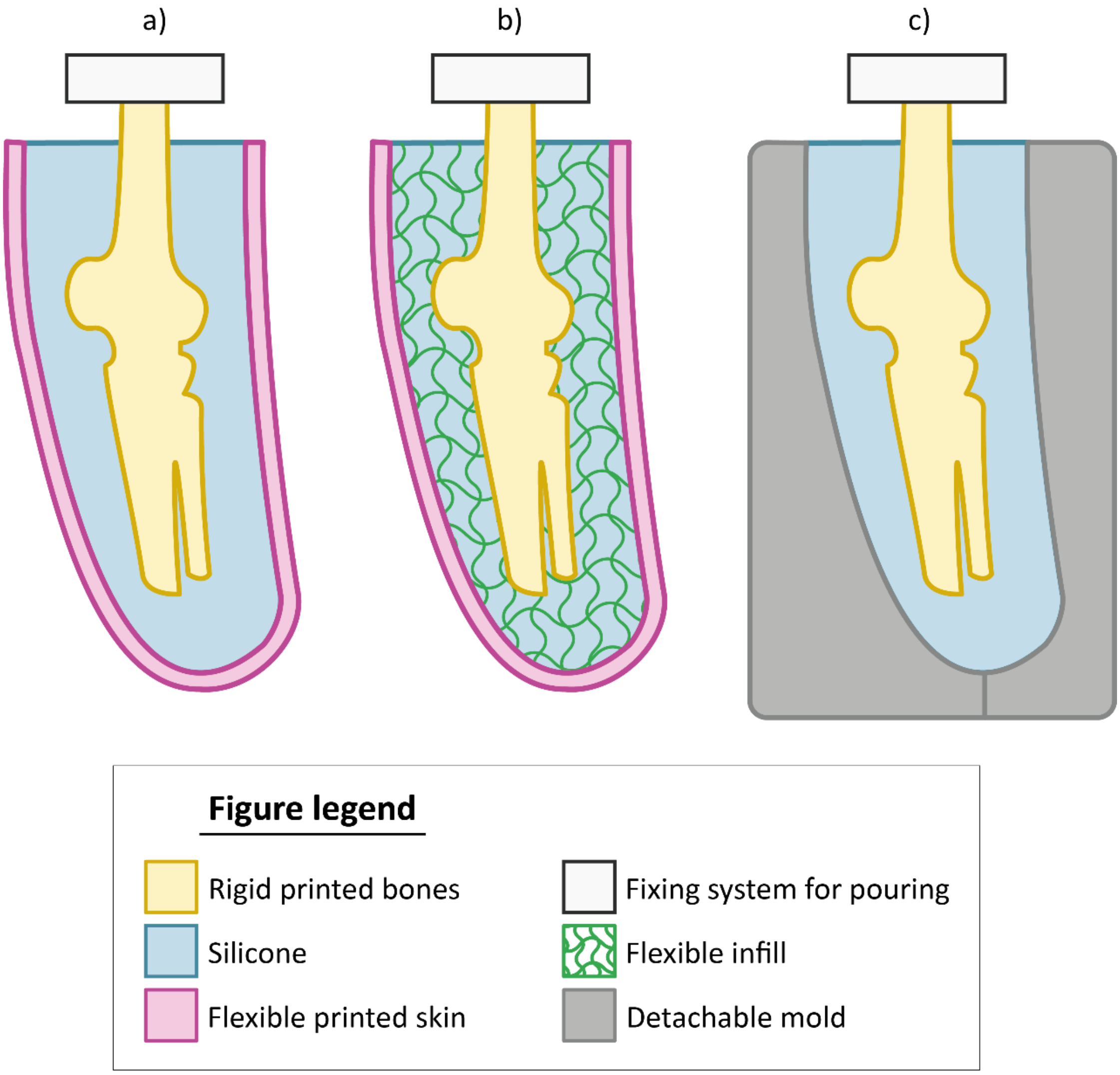


Figure 13. Schematic sketch of options A, B and C for developing the artificial residual limb

All options have their respective advantages and drawbacks, as shown in Table 3. Our objective was to design the artificial limb in the simplest manner possible while ensuring it possessed the necessary anatomical and mechanical properties. With option A, the outer skin would serve as both natural skin and a container for the silicone inside. In option B, this principle is preserved, but with the addition of the infill serving as support to hold the silicone inside, resulting in a more robust limb without significant changes to the mechanical properties. However, option C would require a mold, leading to additional material waste and exposing the silicone to loads during testing without protection. For these reasons, we would proceed with the first option one. If it did not work as expected, we would try the others following the above-described order.

Option	**Pros**	**Cons**
A	Simple structure. Resembles the structure of a natural leg to some extent.	Printing skin may present difficulties. Potential for silicone leakage if skin not printed properly.
B	The connection between components is more robust. Skin printing made easier with infill.	Complex structure. Filling every cavity inside with silicone can be difficult. Printing the skin with infill and getting the bones inside would be challenging.
C	Simple structure. Simpler manufacturing process (than the others).	Soft parts are very uniform, unlike human soft tissue. Less innovative, as similar approaches have been previously explored.

Table 3. Pros and cons of the different presented options for manufacturing the residual limb

3.2 FDM printer

The 3D printing technology we used was FDM, whose characteristics are described in section 2.4.3. The decision to opt for FDM over other AM technologies was driven by several factors. These include its ability to print a wide variety of materials, including PLA and TPU, which were specifically desired for this project. Additionally, FDM allows for the printing of relatively larger volumes compared to SLA or DLP, and with greater ease and lower costs than SLS or MJF technology.

The specific printer model used was FlashForge Creator 4 [33]. This printer is equipped with two different extruders, enabling the printing of multi-material parts. With a printing volume of 400 × 350 × 500 mm, it can produce large parts in a single print without the need to divide components due to lack of space. Its chamber provides isolation from the external environment and enables users to control the internal ambient temperature conditions to suit specific printing requirements. In addition, the integrated camera, connected to the network, allows users to remotely monitor and control the printing process, with the ability to pause or stop it if necessary. The printing platform is easily replaceable, which is convenient when working with different filament types that may require a bed with different characteristics [Figure 14].

Figure 14. FlashForge Creator 4 FDM printer

3.3 3D models and their dimensions

As mentioned in section 2.1, the modeling of the various elements was derived from that of a previous work, which was subsequently modified when needed. Below, we describe the design and manufacturing processes of the different elements.

When dimensioning the above-mentioned CAD model of the bones, a 50th percentile of European male using the AnyBody Repository was used [15, 34]. Considering that the testing limb would be used with a robot that would apply less force compared to an adult's leg and, given the uncertainty regarding the successful completion of the manufacturing process, we decided to manufacture the residual limb using a scaled-down version of the model. For this reason, every component derived from the previous CAD model was scaled to approximate the size of a 3-year-old kid [35]. The scale factor applied to obtain these measures was 0.587.

3.4 Modeling and printing of the bones

The 3D models used for printing the bones were obtained using the previously designed bones displayed in Figure 15 (left), which were created for the simulations using SolidWorks [15]. Taking into account that these models were not meant to be printed, some changes had to be made so that printing was possible and, to create a stiffer structure to hold the strengths. In addition, given that bones are an organic object that is not bound to concrete geometric parameters changes in geometry were applied using digital sculpting with Blender [Figure 16], modifying the 3D meshes instead of the parametric CAD design. This way, the patella part was extended to merge the bones next to it and several pillars were added to make the fibula join the tibia, making all the bones form a single piece [Figure 15 (right)].

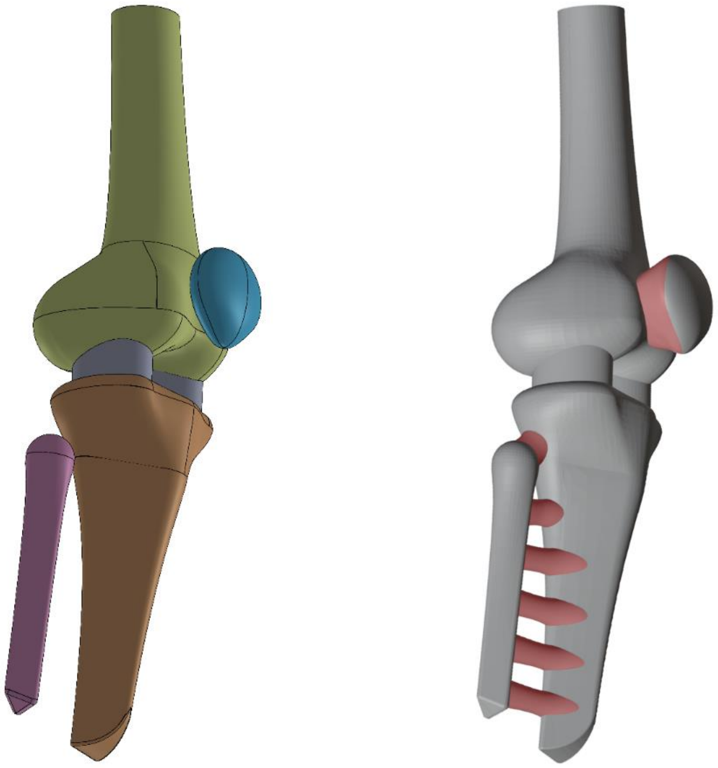
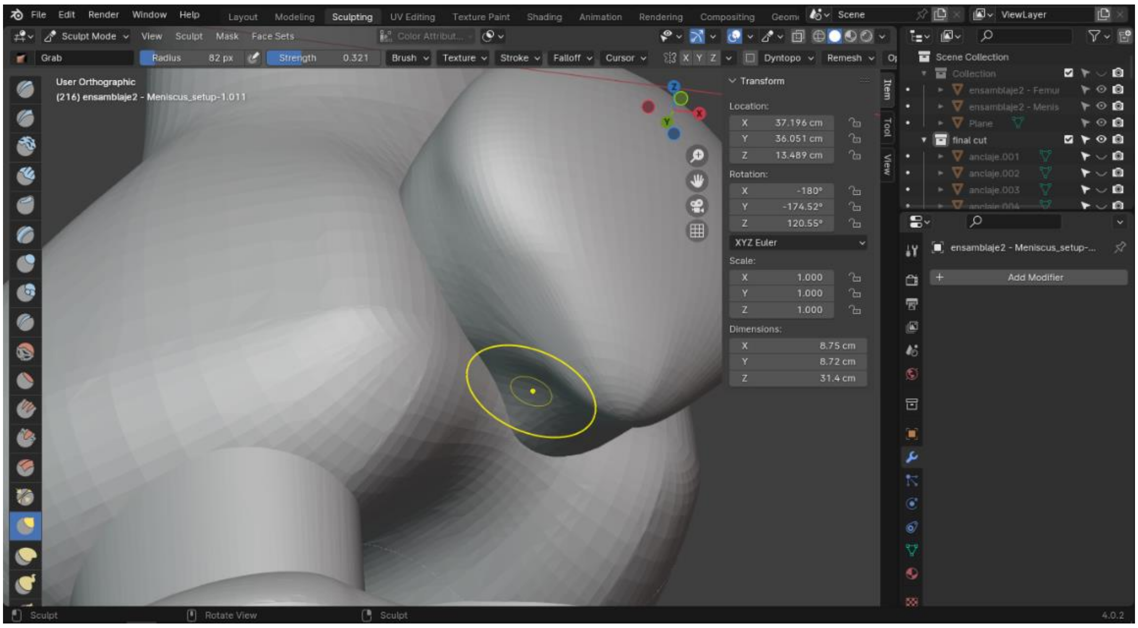


Figure 15. CAD model of the bones for simulation (left) and bones model after combining all the bones into one single part adding new geometry [highlighted in red] (right).



Grab
Radius 82 px
Strength 0.321

User Orthographic
(216) ensamblaje2 - Meniscus_setup-1.011

Transform
Location:
X 37.196 cm
Y 36.051 cm
Z 13.489 cm
Rotation:
X -180°
Y -174.52°
Z 120.55°
XYZ Euler
Scale:
X 1.000
Y 1.000
Z 1.000
Dimensions:
X 8.75 cm
Y 8.72 cm
Z 31.4 cm

ensamblaje2 - Meniscus_setup-...

Figure 16 Screenshot of Blender workspace while modeling changes to the bones

Figure 17. Bones with modified end for attaching to the testing robot

At this stage, it is necessary to mount the bones of the limb onto the robot (KUKA KRC4 KR16-2) so the tests can be performed. To achieve this, we modelled a part that fits the robot and added it to the proximal end of the femur as shown in Figure 17.

There were mainly two options for printing the bones using FDM printing. The first one was splitting the bone into two separate parts, which would not require supports for printing. The two parts would be glued together after being positioned in their correct place using small holes all over the flat surface, which would have small 3D printed cylinders inside. The second option was printing the bones as a single component, but it would have implied using supports, which led us to discard it.

A draft version of the bones was printed to test that the definitive bones were printed with the correct dimensions and that all of the pins and holes fitted correctly, as well as the attachment to the robotic arm [Figure 18]. Given the successful fit, we could proceed with printing the final bones.

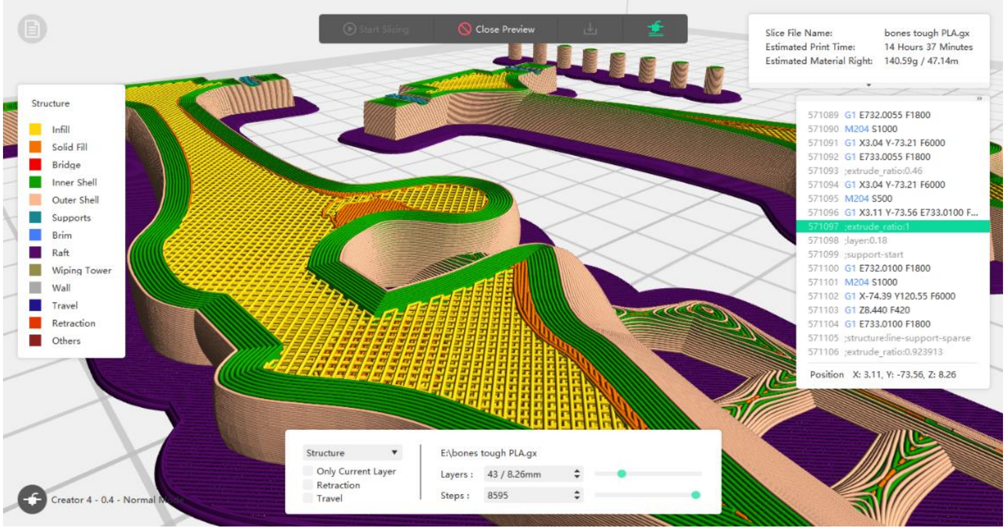
Figure 18. Draft version of the printed bones attached to the robotic arm

As discussed in the Introduction, printing parameters can be critical when we intend to obtain strong and robust 3D printed components. In our case, the printing parameters we could use were defined by the slicer we were using. This FDM printer had its own specific slicing software (FlashPrint 5), which is advisable to use in order to be able to use all of the printer's features.

Choosing different parameters would result in different mechanical properties, the reason why it was important to choose them carefully to get the highest performance with as little amount of material and printing time as possible. When it comes to making strong parts while keeping the quality of the model, the two most important parameters are the number of exterior layers (including shell, bottom and top layers) and the pattern of the infill, also taking into account its density [36]. Of these two, the one that really makes a very big difference is the thickness of the shell, as it improves the strength of the print with every new layer that is added.

However, filling everything inside with the outside layers is not favorable, as it can lead to some printing problems (there can be some over extrusions that can spoil the final result). Also, this approach requires a significant amount of time and material. Similarly, it would not be beneficial to fill the inside space with a 100% infill. This is why it was necessary to decide how much density and what shape the pattern would have.

FlashPrint slicer provided us with five different patterns: rectilinear (or linear), grid, honeycomb (or hexagon), triangle and 3D infill. When reviewing the literature, we found studies regarding the strength of patterns for mainly all of them, except for the 3D infill one, which creates organic-looking shapes [37]. We find that, although the honeycomb pattern presents high performance it uses more material and spends more time for printing than the others. Although the honeycomb pattern presented high performance, it consumed more material and time for printing compared to the others. However, the rectilinear pattern stood out for having a high elastic modulus, tensile strength, and impact resistance. It was also the most material-efficient while requiring less time to print.



Slice File Name: bones tough PLA.gx
Estimated Print Time: 14 Hours 37 Minutes
Estimated Material Right: 140.59g / 47.14m

```
G1 E732.0055 F1800
M204 S1000
G1 X3.04 Y-73.21 F6000
G1 E733.0055 F1800
;extrude_ratio:0.46
G1 X3.04 Y-73.21 F6000
M204 S500
G1 X3.11 Y-73.56 E733.0100 F...
;extrude_ratio:1
;layer:0.18
;support-start
G1 E732.0100 F1800
M204 S1000
G1 X-74.39 Y120.55 F6000
G1 Z8.440 F420
G1 E733.0100 F1800
;structure:line-support-sparse
;extrude_ratio:0.923913
```

Position X: 3.11, Y: -73.56, Z: 8.26

E:\bones tough PLA.gx
Layers : 43 / 8.26mm
Steps : 8595

Figure 19. Slicer's preview of the bones print

With this in mind, the chosen parameters for printing the bones with PLA are 9 layers thickness for the shell, 4 top solid layers and 3 in the bottom. The infill pattern is linear with a density of 40% [Figure 19]. The result is shown in Figure 20.

Figure 20. Both separate parts of the printed bones with their pins

With both sides of the bones and the pins printed, it was now time to glue them together. The glue chosen was a two-component epoxy, which can hold them strongly enough while delivering a little flexibility on the contact surface helping to avoid cracks. After sanding the flat surface as well as the pins to let the glue adhere better, the glue was spread all over this surface, the holes for the pins and the pins themselves as seen in Figure 21 (left). Then, some force was applied using two clamps [Figure 21 (right)] which were removed once it had dried completely [Figure 22].

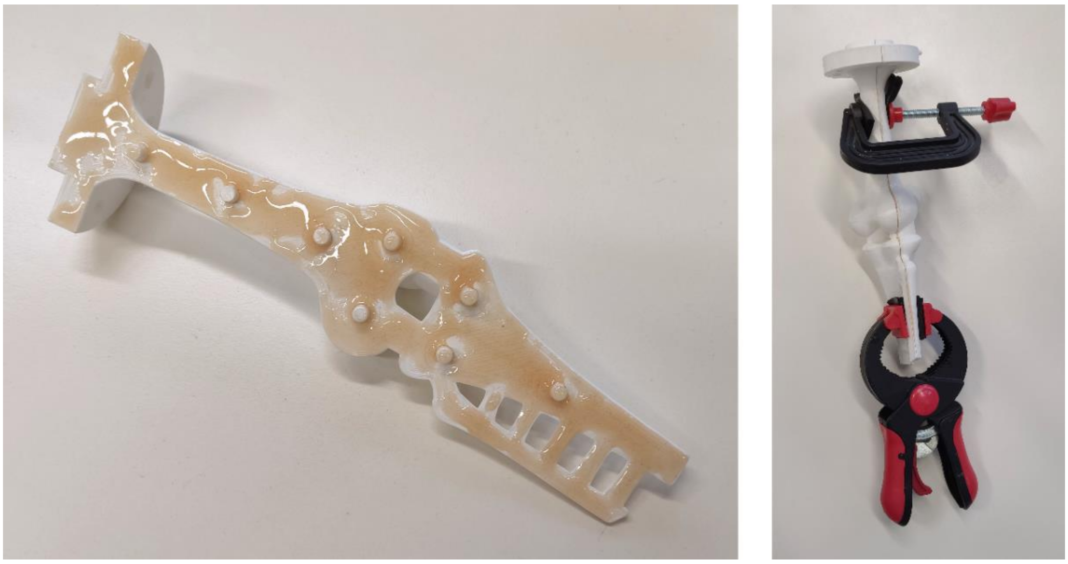


Figure 21. One of the parts of the bone with the glue applied right before fixing it to the other part (left) and both parts with clams while the glue is drying (right)

Figure 22. Bones assembled together

3.5 Bone and skin positioning support for pouring

To have every part of the model in accordance to the limb’s anatomy and in a proper position when pouring the silicone in, it was necessary to have a positioning device that made sure that every part of the residual limb was fixed. To do this, a support made of three different parts was designed for being 3D printed [Figure 23 (left)]. The part that held the attachment of the bones was divided into two to be able to place the bones inside.

It also included a small gap that accommodated a protrusion in the bone's attachment, functioning similarly to a cotter pin [Figure 23 (right)], which would prevent rotation.

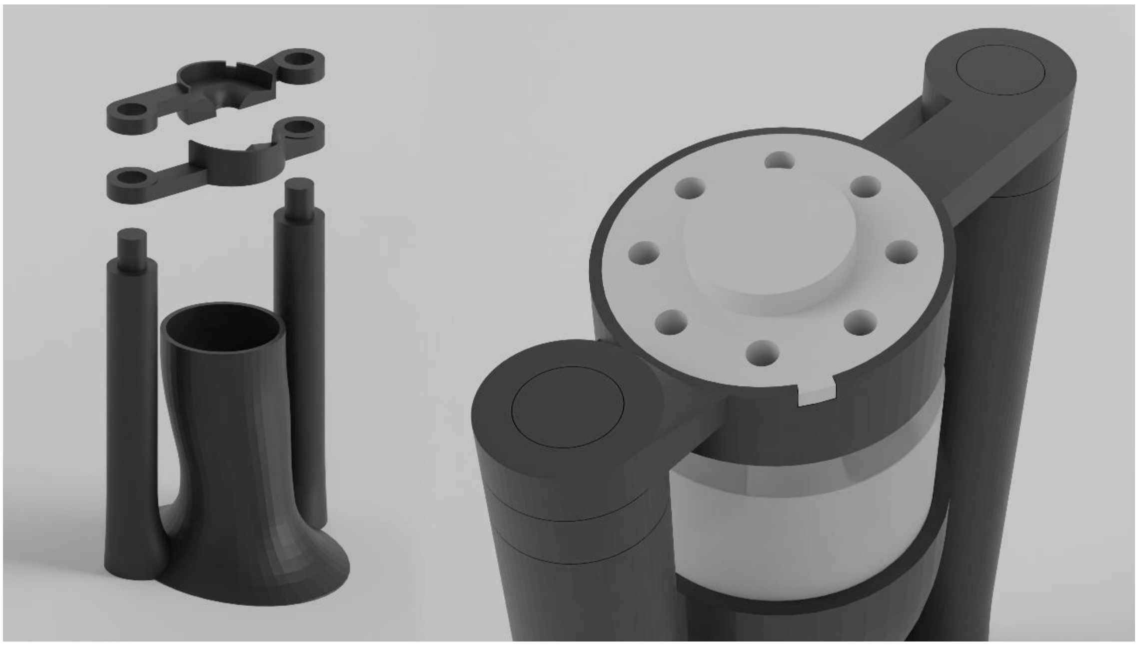


Figure 23. Exploded view of the component parts of the support for positioning (left) and detail view of how the bone and the liner fit inside the support for pouring the silicone (right)

3.6 Skin

The outer skin of the residual limb was also 3D printed with FDM using flexible TPU 85A material. The geometry was also taken from the previous CAD model and was made to have a thickness of two layers, equivalent to 80 µm width. Keeping in mind that epidermis in the thigh region has a thickness of 60 ± 3.2 µm, the thickness of our printed skin is not very far from the biological one [38]. It also has a brim in the interior of the ring that, not only prevents the liner from detaching from the bed while printing but also creates a surface that prevents the silicone from coming out of the liner when poured and, more importantly, after it has already cured [Figure 24].

Figure 24. Printed flexible skin

3.7 Choosing a silicone

The two main factors taken into account when choosing a silicone that would emulate the soft tissue of the residual limb were the following. Finding a product that resembles the material properties of the soft tissue well enough and a material that is affordable, since these kinds of silicones can be very expensive.

After market research to explore available products, the options displayed on Table 4 were selected. All of them seemed to bring the required physical properties together but the ones produced by Smooth-on (*Dragon Skin* and *EcoFlex*) were more cost-effective. Their prices and selling quantities can be seen in Table 5, indicating their availability for purchase as of November 8th, 2023.

Company	Product name	Uses and interest data
Smooth-on	*EcoFlex 00-30*	Mainly used for creating skin effects and other movie special effects. Also, for suture training.
Smooth-on	*Dragon Skin 20*	Mainly used for creating skin effects and other movie special effects. Also, medical prosthetics and cushioning applications.
Polytek	*PlatSil Gel-25*	Most often used to make prosthetic appliances, life casting and mold making.
BJB Materials	*Specialty Gels and Skins*	For medical training models. There is also a softener to obtain the desired hardness (46.69€).

Table 4. Review of the selected silicones after first market research

Country	Price (€)	Selling quantity (kg)	Silicone	Online store
Croatia	47.46	Only 0.9	*EcoFlex*	PAP promet
	68.51	Only 0.9	*Dragon Skin*	PAP promet
Italy	43.92	0.9	*EcoFlex*	Ferba
	317.2	7.26		
	43.92	0.9	*Dragon Skin*	Ferba
	317.2	7.26		
Spain	27.61	0.9	*EcoFlex*	FormX
	229.85	7.26		
	32.53	0.9	*Dragon Skin*	FormX
	225.94	7.26		
USA *(does not ship outside US)*	29.12	0.9	*EcoFlex*	Reynolds AM
	179.92	7.26		
	31.9	0.9	*Dragon Skin*	Reynolds AM
	199.37	7.26		

Table 5. Review of the prices in different stores of *Dragon Skin* and *EcoFlex*

The chosen silicone was *EcoFlex 00-30* because it seemed to have similar properties to *Dragon Skin 20*. Besides, given that costs were not so different between these two specific silicones, the decision to purchase both was taken to have a second option in case the first one did not work as expected.

3.8 Pouring silicone

With all the previously described components prepared, we began assembling the different parts of the artificial residual limb. The first step was placing the bones and the skin together with the support for pouring, as seen in Figure 25.

Figure 25. Components of the artificial residual limb assembled in the pouring support before adding the silicone

Next, we could start working with the silicone. We required 434.32 $cm^3$of silicone, extracted from the .stl file using Blender. With the density of the silicone being 1070 kg/m^3, we were able to calculate the required mass of silicone: 0.463 kg [39]. The quantity of each component of silicone we used was 0.231 kg. Another aspect to consider is that the pot life of this silicone was 45 minutes, indicating that it was the maximum time available. After that, it would no longer be possible to work with the silicone. We mixed the two components of the silicone, weighing them beforehand to ensure we obtained the required amount and maintained the 1:1 ratio they were supposed to have.

Figure 26. Mixing of both components of the silicone

After preparing the support with all the components and ensuring the silicone was ready for pouring, we filled the skin up to the brim with the required amount of silicone, as shown in Figure 27. Once this step was completed, the silicone was left to cure for at least 4 hours at a room temperature of approximately 23 °C. When the curing process was complete, we were able to remove the finished artificial residual limb from the pouring support, as illustrated in Figure 28.

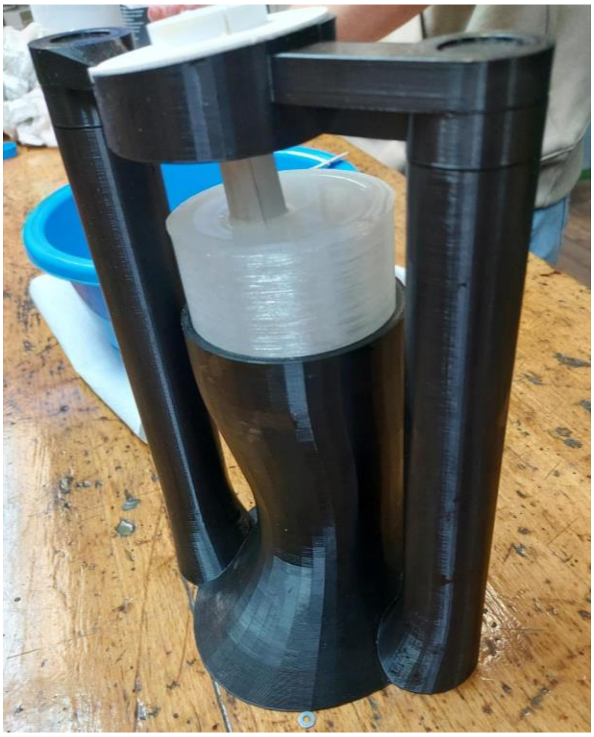


Figure 27. Residual limb with the silicone right after it had been poured

Figure 28. Side view of the final artificial limb

3.9 Modeling of pylon, foot and socket for testing

To test test the artificial residual limb, a PTB rectified socket was printed, serving as an element to start working on the programming of the robotic arm. Additionally, we designed and printed a functional TPU flexible foot and a PLA cylinder that acted as a pylon to attach all these elements together.

We elaborated every model based on the previous CAD models we already had, applying the same scale factor that was used for the bones, as described in section 3.3 of this document.

3.9.1 Pylon

The pylon had a simple geometry, consisting of a cylinder printed lying down on the printing platform to obtain a stronger pylon than if it was printed standing up. This cylinder had six holes on each end [Figure 29]. These holes would require threads to allow elements to be screwed inside. This would be achieved by introducing threaded metal inserts (Ruthex RX – M3 × 5) using a soldering iron to heat them, melting the surrounding plastic and allowing them to be fixed inside as seen in Figure 29 (right). The reason for adding six holes was that were not sure if these inserts would be able to withstand the applied strength.

Figure 29. CAD model of the pylon (left) and the printed pylon with three of the six inserts positioned already (right)

3.9.2 Modeling of the foot

To create the 3D model of the foot, a preliminary model obtained from a cosmetic foot was used. This initial model was generated by scanning the foot using 3DMakerPro Mole. However, its geometry was unsuitable for printing purposes, as it was not a closed volume and lacked a flat surface on the base. Below, we elaborate on why this last factor could be a problem. Hence, some remeshing and reshaping was performed using both ZBrush (for its capability to execute high-quality remeshing and the possibility to perform organic cutting of meshes with ease) [Figure 30] and Blender (for refining the topology); closing the hole in the ankle and adding three cuts in the bridge of the foot to allow to bend [Figure 31].

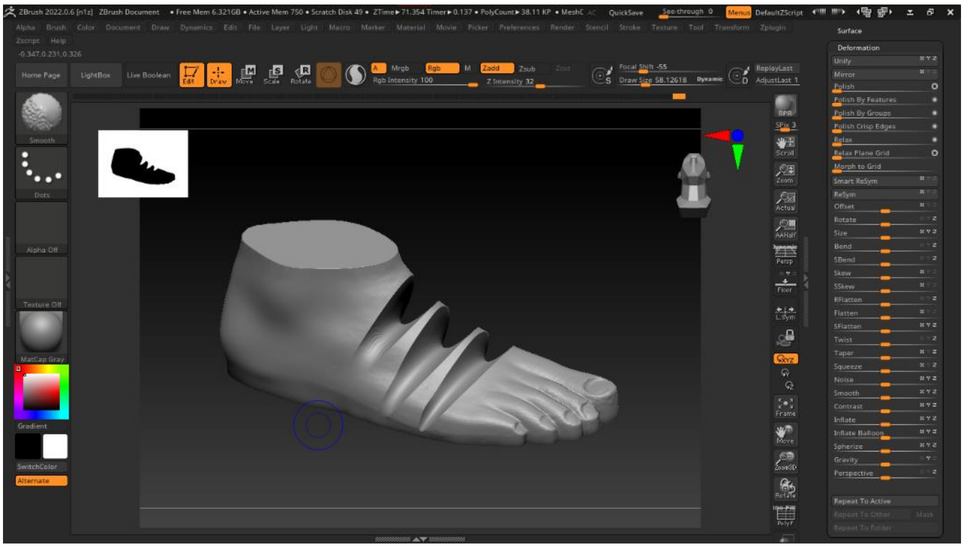


Figure 30. ZBrush workspace while working with the foot model

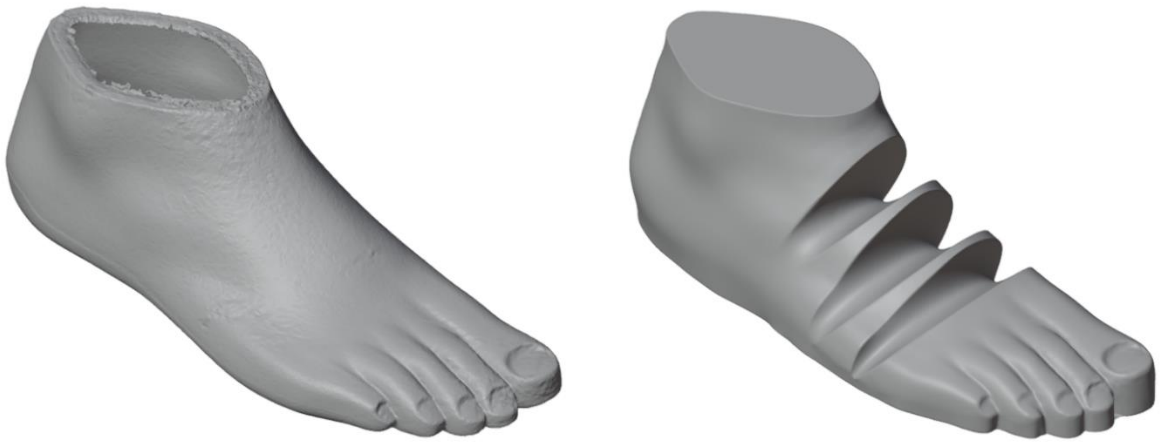


Figure 31. Mesh of the scanned foot (left) and the remeshed foot after cuts were applied in its bridge

The bottom surface of a foot is not flat, which requires supports when printing. Since the foot is meant to be printed with flexible material and supports, this means a much poorer result when using such materials, the base of the foot was flattened [Figure 32]. With the foot finally reshaped, a hole was added along with six more holes inside [Figure 33] to accommodate the screws (hexalobular socket pan head screws ISO 14583 – M3 × 25) that will make the attachment to the pylon possible as seen in Figure 34.

However, although supports were avoided, they were necessary for building the holes for the attachment of the pylon. Some of the supports' printing default settings were changed to be able to remove them with more ease. This meant increasing the vertical distance to model, increasing the amount of sop solid layers and decreasing the solid density of these top layers. This is applicable to every other TPU printed part involving supports.

Figure 32. Profile view of the foot before (left) and after the remeshing and reshaping (right)

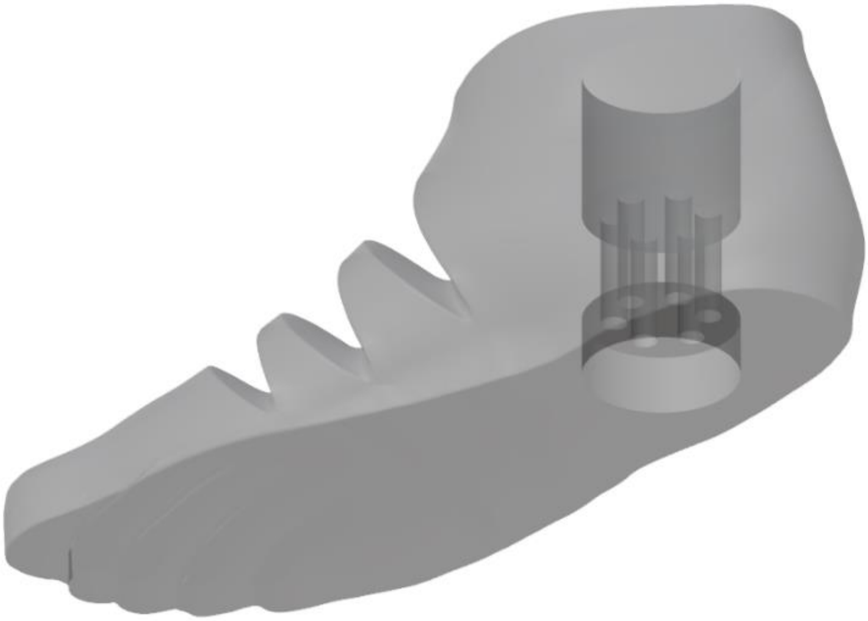


Figure 33. Foot with the holes for fitting the pylon and its screws

Figure 34. Screws fixing the foot to the pylon

To be able to have a solid attachment between the foot (made of flexible material) and pylon, we modelled a washer that would fit the 6 screws. This washer was intended to be 3D printed [Figure 35]. We can see it assembled in Figure 34.

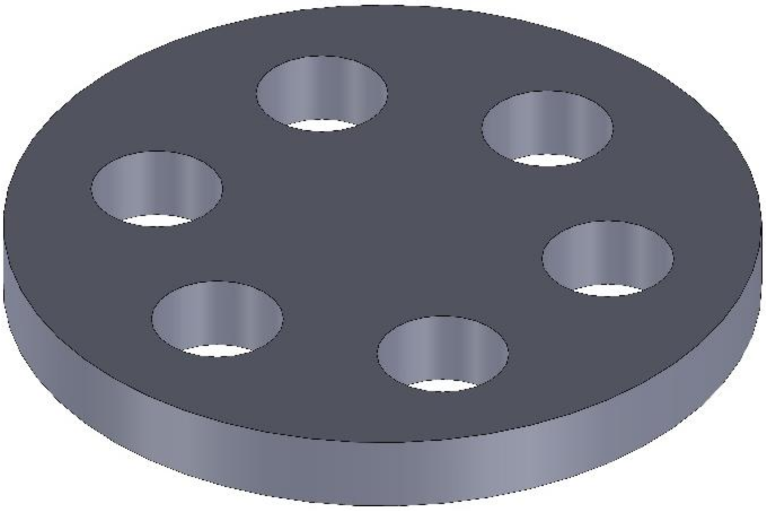


Figure 35. CAD model of the washer

3.9.3 Modification to the socket

To be able to attach the pylon, the bottom part of the socket was extended [Figure 36] to create a hole that accommodates the pylon. Additionally, six smaller holes were added in a circular pattern [Figure 37] allowing the hexalobular socket pan head screws ISO 14583 – M3 × 25 (the same screws used to secure the foot to the pylon, as described in section 3.9.2) to pass through and be positioned to attach the pylon as shown in Figure 38.

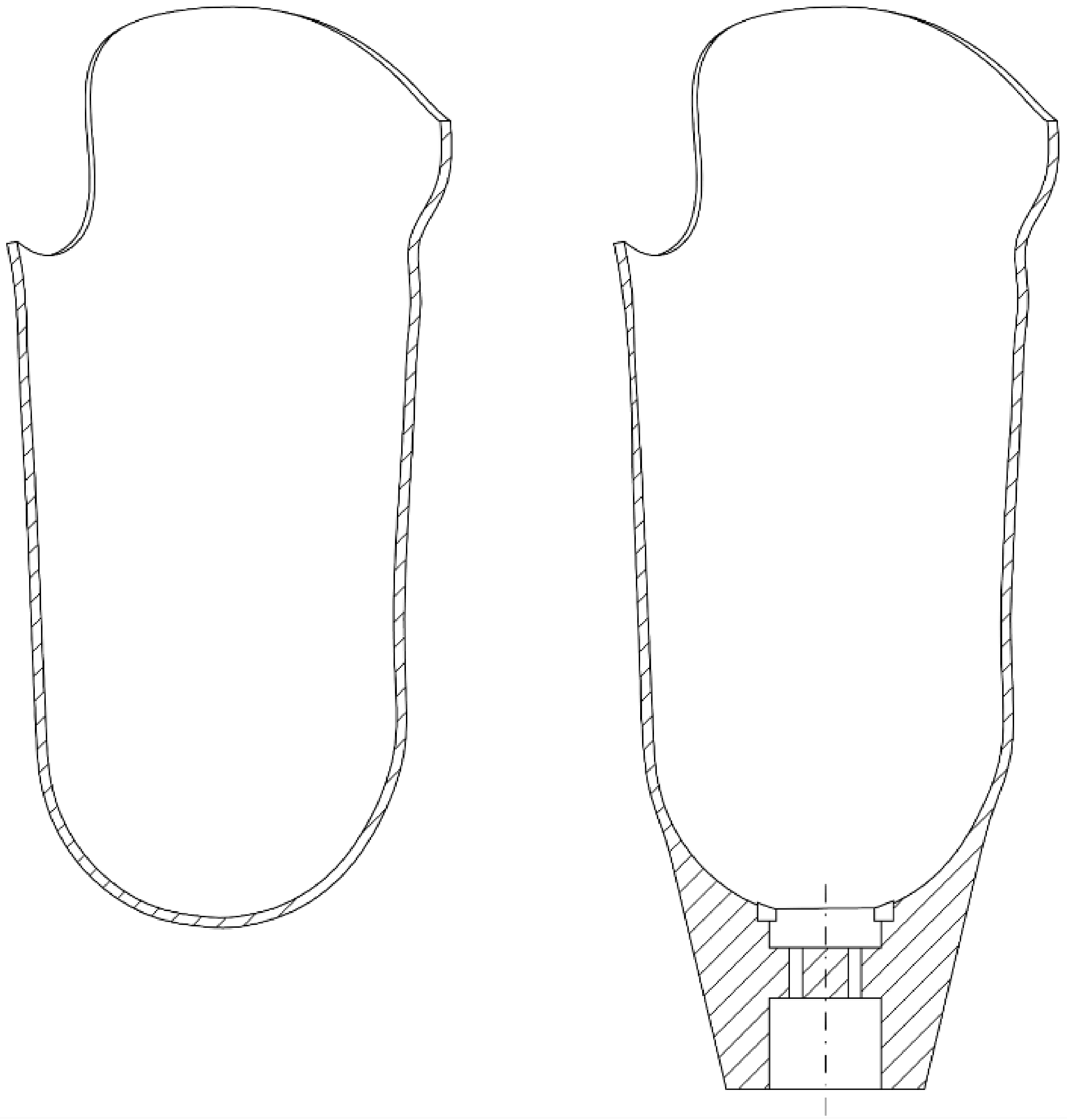


Figure 36. Cut view of the socket before the modification (left) and after (right)

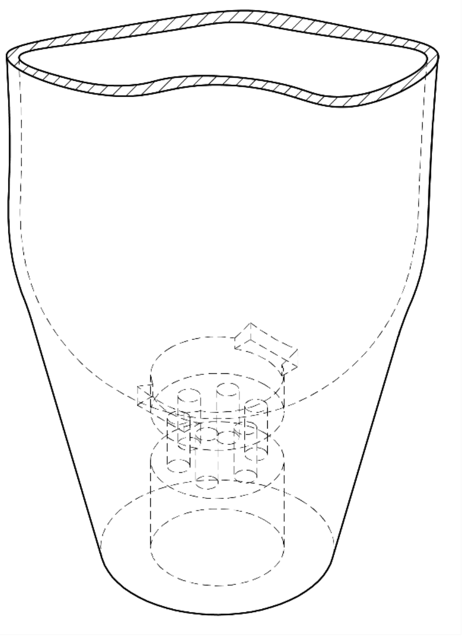


Figure 37. Perspective view of the holes inside the socket

Figure 38. Screws already positioned in the socket to fix the pylon to it

3.9.4 Liner

To have the full assembly of a functional prosthetic leg, we still needed a liner for positioning the residual limb into the socket. The geometry for printing was obtained simply taking the CAD model of the socket and extruding by 3 mm the interior surface (the full-size size was 6 mm) while applying the same scale mentioned in section 3.3 of this document. The result can be seen in Figure 39 (right).

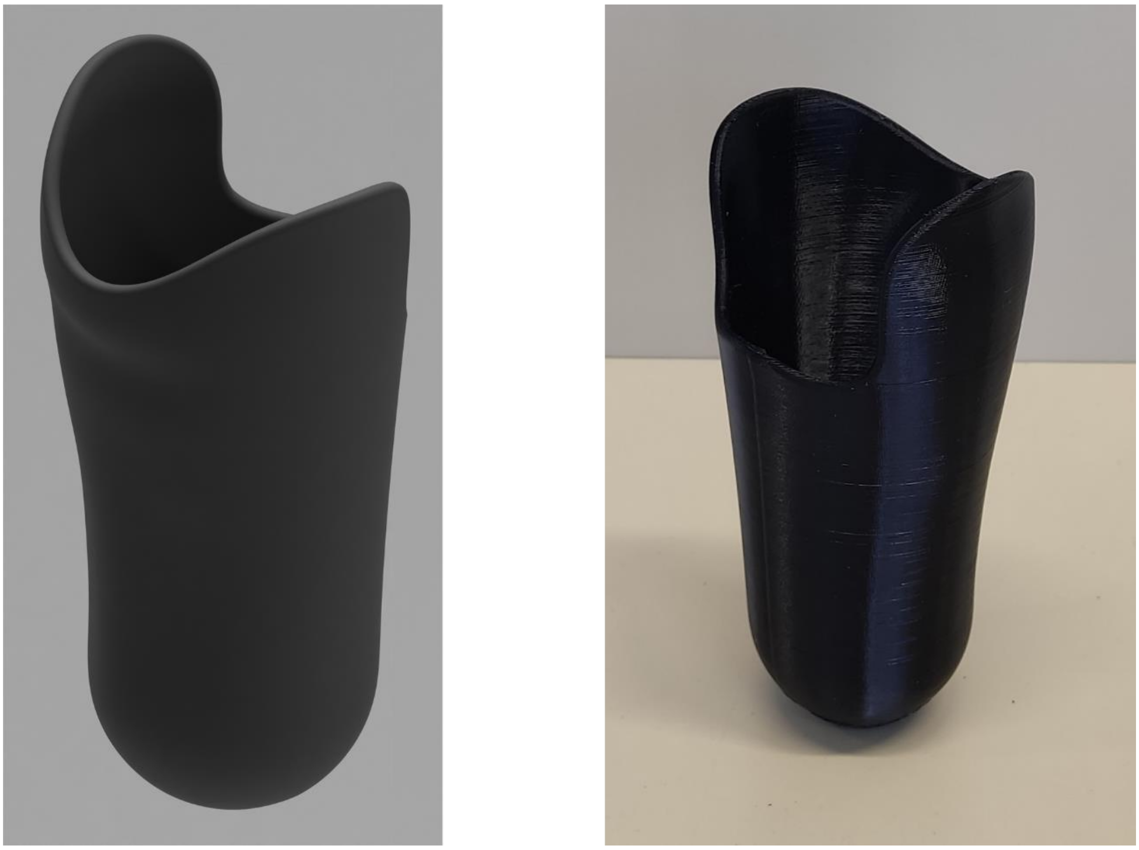


Figure 39. CAD model of the liner (left) and the printed result (right)

3.9.5 Assembling everything together

Then, with all the previously described parts ready, it was time to put them all together, introducing the pylon inside the foot and screwing them together after positioning the washer. Next, the other end of the pylon was screwed to the socket. Finally, the liner was introduced inside of the socket. The provisional prosthesis for testing was finished.

4. Results

In the previous section we described the methods employed to manufacture the artificial residual limb and the transtibial prosthetic leg. We will now discuss the result of these two elements independently and how they fit each other.

4.1 Artificial residual limb

The integration of silicone and TPU successfully recreated the soft tissue. Moreover, the seamless fusion of these distinct components was successfully achieved, with the skin merging with the silicone, as well as the silicone integrating with the bones.

Figure 40. View of the skin filled with the cured silicone

4.2 Assembled prosthesis

The different components of the transtibial prosthesis fitted together as expected as seen in Figure 41, resulting in a functional assembly that would work as a testing device. Until an adult-size model for testing was developed, this scaled-down model would serve the purpose of emulating the behavior of a fully refined prosthesis. This will help when doing the programming of the robotic arm to replicate the movement of human gait. It is also important to point out that by manufacturing this scaled version, we ensured that fabrication at a larger scale is feasible.

Figure 41. Transtibial prosthetic leg for testing with liner

4.3 Artificial limb and prosthetic leg assembly

Both the artificial residual limb and the prosthesis fit together, as shown in Figure 42. During assembly, the adjustment between them was tight enough, ensuring that both parts remained together, similar to a TSB socket as described in section 2.2.1.

Figure 42. Assembly of the transtibial prosthetic leg and the artificial residual limb

5. Discussion

In this section we will look more in detail at the challenges, implications and findings of the present work.

5.1 Modeling software

We chose SolidWorks CAD software for modeling the socket, pylon, liner, skin, and because of the tools this kind of program has, that allow to execute such tasks in a quick and efficient way. These tools include circular patterns for radial drills, beveling tools for smoothing sharp angles, shaft tools for creating revolution geometries, the shell tool for hollowing out parts, and the ability to extrude given surfaces.

However, Blender was used to model the final shape of the bones and the foot for printing. Although ZBrush was also employed for the foot, Blender was chosen primarily for its ability to create more organic shapes with less investment of time compared to other CAD programs such as SolidWorks or Catia, thanks to its digital sculpting capabilities.

Even though the stated reasons are true, it must also be noted that working with meshes, as opposed to parametric design, can lead to slower workflows when certain operations such as drills, circular patterns or calculating objects' volumes (in the last case, only if working with overlapping meshes or meshes with topology issues such as self-intersecting or not fully closed volume) need to be performed. To address this issue, it is also possible to combine both types of software, as it was done for modeling the bones, where the attachment of the robot was designed in SolidWorks and then integrated with the Blender model of the bones. However, this remains an alternative worth considering in some cases. This integration should be done at the end of the design process, since it is easy to export a mesh from SolidWorks to Blender and edit it there, but not as easy (or at least it will take more time) to edit a mesh from Blender in SolidWorks.

5.2 Geometry of the parts

As mentioned earlier, the models were obtained modifying existing geometry to meet the requirements of each component required. For instance, in the case of the bones, adjustments were made to integrate certain components such as the patella with the main body. This involved extending the mesh face between the patella and femur and creating a shape that could be printed without requiring supports. Additionally, the fibula, being a long part separated from other bones, required additional support and structural reinforcement. Therefore, columns were added between the fibula and tibia to ensure stability.

Regarding the soft tissues of the model, we opted to use both 3D printed flexible skin and silicone to mimic the mechanical properties of human soft tissue. This approach allows us to differentiate between various types of soft tissues (each with its own mechanical behavior) in our model: skin (TPU) and muscles (silicone) [40].

When we decided to make a flexible foot able to bend, besides printing it with flexible material, we saw it was necessary to modify its shape. For this reason, three cuts were added in the bridge of the foot. The decision to make these cuts was taken while creating other more complex structure patterns mainly because the modeling process was simpler, left a smoother result and the printing time was reduced.

With regards to the attachment of the pylon to the socket and foot, metal threaded inserts were used, although it was not the only option available. Another possibility considered was designing a specific geometry that could accommodate additional printed parts for fixation. However, the chosen approach was simpler to design and implement, and we opted to test its effectiveness, which turned out to be successful.

5.3 FDM printing

Although the final result of bones with two parts glued together is structurally stiff and hence functional for testing purposes, it would also be worth exploring to print the all the parts of the bone as a single component, adding supports. Supports lead to bigger imperfections which affect the surface finishes which make the finish product less aesthetically pleasing. However, as we are more interested in the optimal performance of the bones it would be worth attempting to print the bones without splitting them into two parts and gluing them together.

This approach would simplify the process and, although supports for printing would be required, we must to bear in mind that bones are printed using PLA, which does not cause as big problems as other filaments do when removing supports, like TPU does. Furthermore, even with the cuts the bones have, it is not possible to get rid of the supports completely when printing, as the drills for the screws of the attachment for the robotic arm have some hanging surfaces that make it impossible.

If the filament used for the rigid parts had failed, it would be worth exploring carbon fiber (CF) based filaments, such as CF-PLA (described in section 2.5), given their superior mechanical properties. In case this was done, CF-PLA could be a potential alternative to enhance the strength of the printed rigid parts.

Regarding the printed flexible foot, the way it behaves, how it bends or how it can be attached to the pylon of the prosthesis, the manufactured foot would allow the tests of the prosthesis to be conducted. However, it is not stiff enough if we compare it to the stiffness of the bottom of a traditional prosthetic leg. This excessive flexibility would result in a huge bending of the foot when lifting the leg while walking.

This problem could be addressed by switching from the TPU filament we used to a less flexible one. However, the most effective solution would be to use different printing parameters. Adding more shell layers as well as top and bottom solid layers would provide more stiffness in the printed components. Additionally, increasing the infill density would also provide more stiffness. The way these parameters affect the print are described in section 3.4. After implementing these modifications, a way to measure if the foot is stiff enough could be to measure the required strength to bend the foot to a given angle and then compare to the strength needed to perform such operation with a traditional transtibial prosthesis.

As mentioned before, removing supports from TPU-printed parts can be quite challenging. The supports tend to adhere to the surface, often pulling off some layers of material when removed. This results in a compromised surface finish and needs careful cutting, which can also damage the result and requires more time. An alternative approach is to print these flexible components using SLS technology, which enables printing without supports. However, it's important to consider that SLS technology typically comes with higher costs.

Another possibility would be, to take advantage of the fact that the printer we used had two different extruders. To try printing these components using the second extruder for building the supports with another material, such as PLA (or even PVA). This might make removing supports from TPU easier, although it would have to be tested out.

However, the mentioned approach may introduce other challenges. Using different materials with varying coefficients of thermal expansion can result in different contraction behaviors during printing, potentially leading to undesirable outcomes. Additionally, the printing platform temperatures for these materials differ; PLA typically requires a temperature of about 55 °C, while TPU is printed at room temperature. This difference means that they cannot be printed on the same surface. However, this issue can be addressed by including a PLA raft in the slicing process. This would ensure that the contact surface with the hot plate is entirely PLA, facilitating printing for both materials..

5.4 Pouring of the silicone

Even though we were able to pour the silicone into the mold which, in this case, was the limb's flexible skin, the methodology used could be improved to make the procedure more comfortable for the person carrying it out. It could be also more material-efficient, since some of it was spilled over the pouring process and some was lost when changing containers for working with the silicone during different stages of the process.

One option could be changing the shape of the support for pouring so that its geometry leaves more empty space over the superior hole of the skin. Another alternative, which unfortunately we did not consider until after pouring the silicone, could be pouring the silicone without positioning the bones, adding just the required amount we need, which is specified in section 3.8 and, once this has been done, placing the bones in their position and leaving it for curing.

6. Conclusion

Overall, this thesis successfully achieved its initial objectives by producing an artificial limb suitable for conducting tests on the prosthetic socket. That said, there is always plenty of room for improvement and changes can be applied to bring advancements, as mentioned in Discussion section. For instance, modifying the manufacturing process could lead to greater efficiency and the printing could be improved by trying new parameters or exploring new filament materials to obtain stronger parts.

During the development of the residual limb, the final shape remained undetermined as certain aspects had yet to be finalized, such as the attachment to the pylon. In addition, the method for achieving suspension was not resolved; there was no air valve for vacuum creation, as seen in TSB sockets, nor any PTB system for attaching the socket. It would be beneficial for the next step in the design process to specify the suspension method, enabling a more accurate simulation of the prosthetic system.

Another approach improve in the artificial residual limb could involve testing different types of silicone, such as *Dragon Skin 20*, which we did not test, to determine whether the result has a better resemblance to a human leg. Since we did not explore this option and are unsure whether it would enhance or degrade the result, conducting mechanical tests in future work to the silicone to observe its behavior as compared to human soft tissue could determine which product is more suitable for the manufacturing process.

As said in the Discussion, if printing the bones in a single print it would also be worth observing if the result has improved since the last one; as well as the mentioned issues with the foot's flexibility and the printing of TPU's supports.

Regarding the modeling software, as a consequence of what was said in section 5.1, if a similar work had to be done after this one, it would be advisable to use a 3D modeling software such as Blender or ZBrush only if some remeshing of a previous mesh is required (as in the case of the modeling of the foot) or if an extensive organic modeling was required. Before starting the modeling, it is crucial to make an attentive reflection on the nature of the objects to be modeled. Failure to do so can result in misjudgments, as was the case with modeling the bones, Blender was used and it turned out to be a mistake. Using a CAD program instead of digital sculpting would have saved time, mainly because many of the performed modifications were not organic.

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