

# Design and Manufacture of a Customized Prosthetic Foot

Inês Jorge Ferreira  
ines.j.ferreira@tecnico.ulisboa.pt

Instituto Superior Técnico, Lisboa, Portugal

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## Abstract

Congenital limb deformity is the most common cause of amputation in young ages, in developed countries. Amputee's inability to perform basic activities, e.g. walking, compromise social and personal fulfillment. For children, lower limb prosthetic fitting is recommended when they grow from crawling to standing, which happens between the ages of 9 and 16 months. When designing any equipment for children, emotional and aesthetic needs are very important. Additionally, foot influences gait biomechanics by its shape and stiffness. Small dimensions, the constant need for adaptation, scarce available options of aesthetics and mechanical characteristics are currently the main concerns in prosthetic feet for children.

Available technologies of tridimensional scanning (3D scan) and additive manufacturing (AM) offer the possibility of achieving a customized solution with reduced production costs and manufacturing time. The aim of this work is to develop a methodology to design low-cost, short production-time prosthetic feet, with a natural-aesthetic, using 3D scan technology, CAD modeling and AM technology, able to improve the amputee's gait cycle. Both modeling and production of the prosthetic foot include two components: a rigid material (PLA) for impact absorption and pylon connection (internal); and a flexible material (Filaflex) for energy dissipation and better aesthetics (external). The structural integrity of the overall structure is addressed using FEA.

The implementation of the methodology was performed with the consent of the ethics community of Instituto Superior Técnico. A 5-year-old bilateral amputee girl was the clinical case study. A database was built with feet geometries, height, and weight from 20 non-impaired children with ages ranging from 2 to 5 years old with the purpose of having geometries to use for the external component when needed. The proposed methodology took into consideration the amputee's weight and height. A Matlab® tool was developed to extract a matching foot geometry from the database. The feet were developed, printed and tested with the amputee child in a controlled setting, with the presence of her mother, physician, physiotherapist and prosthetist.

This work proved 3D-printable prosthetic feet can be manufactured using AM with PLA and Filaflex filaments, evidencing a great potential for a low-cost, low-weight and customized solution for low-to-moderate activity level amputee children. It is hypothesized heavier children, with more than 10Kg, may require an integration with a metallic pyramid adapter. Lighter children can use completely 3D-printed prosthetic feet. Future work includes larger customization with more foot geometries, improve its durability with physical tests from specialized machinery and testing with more patients.

**Keywords:** Amputee children, Prosthetic foot, 3D Scanning, Additive manufacturing, PLA, Filaflex, Precision medicine

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The medical community is becoming more and more aware of the importance of improving the quality of life in patient healthcare in the early stages of human development [41].

The human body requires the existence of feet in order to provide stability and balance when standing or moving [5] [1] [31]. Amputation of a lower limb reduces significantly amputees' ability to per-

form basic activities such as walking. The ability of walk without depending on someone else and with few or no limitations is a major factor in people's quality of life considering that mobility is nearly indispensable to most human activities [20] [32]. Walking is not only a tool for movement but also a key feature in social and personal fulfillment [4] [21].

Focusing on young amputees, in developed countries, congenital limb deformity seems to be the most common cause of amputation [3]. Studies regarding congenital limb deformity in the US and European countries reported rates falling within 2 to 7 per 10,000 live births every year suffering from this condition [23] [14].

Children have smaller foot dimensions and are in constant growth. There is a need to develop personalized prosthetic feet for children of young ages that meet their needs. Personalized prosthetic foot requires several customization steps [44] [11], which makes these solutions commercially unappealing, expensive and scarce. Commercially available technologies of 3D scan and AM start to offer the possibility of achieving personalized solutions with reduced production costs, time and intermediary steps [15] [30] [24]. These technologies also allow digital storage of anatomical geometries, promoting their further use in other areas and applications [25].

The aim of this work is to design a methodology to produce a customized prosthetic foot, that can be adapted to any children and at any stage of their development improving their gait cycle. In this work, prosthetic feet were developed to fit a 5 years old bi-lateral amputee girl. To proceed with this work, the first step was to acquire the anatomical geometries of 20 healthy children from 2 to 5 years-old and build a database considering their foot geometries, weight and height. With the help of a developed Matlab® tool, a matching foot geometry from the database was extracted.

The customized prosthetic foot was computationally tested prior to testing with the bi-lateral amputee test subject.

The final prosthetic foot has two components, manufactured with two different materials: the cosmetic component, a flexible part to ensure the natural-aesthetic of the prosthetic foot (made of FilaFlex 3D filament); and the support component, rigid to be capable of supporting the forces and deformations during daily activities, while allowing the pylon connection (made of PLA 3D filament).

This work was approved by the Ethics Committee of Instituto Superior Técnico, Lisboa, Portugal.

## 1. Background

### 1.1. Amputation

Amputation is a surgical procedure consisting on the removal of a limb or other part of the human body [29]. Since limb loss often has profound economic, social and psychological effects on the patient and their family, this procedure is considered the last resort, only chosen when limb salvage is impossible, the limb is dead or dying, and compromis-

ing the normal functioning or the life of the patient [6] [26] [20] [42].

Congenital limb deformity is when a limb does not develop normally during gestation and is the most common cause of amputation in young ages in developed countries [3]. This condition is identified on a fetus mostly during the first trimester, which is the most critical pregnancy phase for limb formation [43]. The exact causes of congenital limb deformity are still unknown. However, studies indicate that genetic factors or environmental factors such as alcohol, drug abuse, medication, dangerous chemicals, radiation exposure and abdomen trauma during pregnancy are related, in some cases, with the development of such deformities to the unborn child [38] [19] [18] [10].

For young children amputees, it is recommended to start lower limb fitting when they go from crawling to standing, which occurs between the ages of 9 and 16 months. It is important to begin this procedure at this stage of life to allow them to have a good base of support while starting to stand, maintain their orthostatism and begin walking [37]. Introducing the prosthesis early on the development of the child also improves the acceptability of more complex prosthetic devices in their future [16].

Rehabilitating children with lower limb amputation is a true challenge. However, with well-fitted prostheses and adequate rehabilitation at a suitable age, many children can learn functional skills and may find the opportunity of living and interact with their peers without having to feel completely dependent or limited by their amputation.

### 1.2. Level of amputation

In general terms, it is easier to fit, use and adopt a prosthesis for the amputee when the remaining limb is longer and more joints are kept intact.

The more prevalent levels of amputation are Transfemoral (above the knee) and Transtibial (below knee). The prosthetic feet were developed for a transfemoral bi-lateral amputee girl.

### 1.3. Prosthetic systems

Transfemoral prostheses are more complex than transtibial ones considering that the first requires an additional mechanism to replace the knee. However, most of the terminology used for transtibial prosthesis also applies to transfemoral prostheses.

The three main components of a prosthesis are: the socket, which interfaces with residual limb, the foot, and the pylon connecting the foot to the socket. For the integration between the prosthetic foot and the pylon, a pyramid adapter is used. In addition to the fitting of the custom-made socket, the alignment between the foot and the socket must be adjusted by the prosthetist to ensure the best

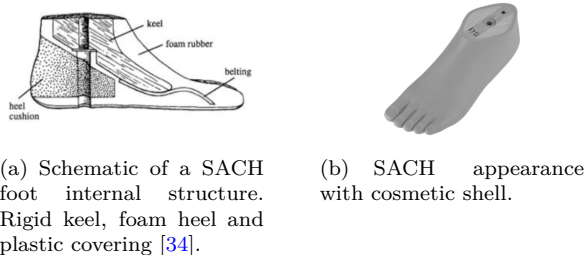


Figure 1: SACH foot.

performance and comfort of the entire system [17].

### 1.3.1 Prosthetic feet used by children

The solid ankle cushioned heel (SACH) foot, figure 1(a) and 1(b), is the most common prosthetic foot device among children because it is inexpensive (costs less than 100€), light, and robust [33] [36]. However, it limits the movements and actions of the amputee as these rigid designs have limited shock attenuation and do not store nor return energy during gait, which would be expected under natural loading in a human foot [2] [9]. SACH users are typically restricted to indoor walking or very limited outdoor activity.

### 1.4. Clinical procedures

After surgery, the residual limb must heal before a temporary (preparatory) prosthesis can be worn. This preparatory prosthesis is easy-to-use and lightweight, being used until the swelling is resolved in order to allow the amputee to learn how to use and interact with a prosthesis.

Training is usually a continuous process. The physiotherapist develops a program of gait training including exercises to improve strength, flexibility and cardiovascular fitness. During those trains, the skills needed to perform daily activities, as lower body hygiene and dressing, use of stairs, walk up and down hills, and walk on uneven surfaces are taught ensuring a sufficient amount of independence [22].

For child amputees, the prosthesis needs to be constantly adapted in accordance to their development and growth, so their gait is correctly assisted and modeled to be as close as possible to a normal gait at an important stage of their growth when the gait itself is being developed [6]. This is one big concern with child amputees, as opposed to adult amputees.

Table 1: List of target specifications from the identified requirements.

Needs	Target Specification	Metric of the Specification
	To weight	Yes / No
Adaptability	Compatible with global prosthesis having a standard pyramid adapter geometry	Yes / No
	To form (can be used with universal shoes)	Yes / No
Support and stability	When stand up	1 to 5 (Interviews)
Comfort	During its use	1 to 5 (Interviews)
Lightweight	Less than SACH weight (0.800 Kg)	Weight [Kg]
Cheap	Cost similar to SACH foot (less than 100€)	Cost [€]
Simple	Less than 1 week to have the prosthetic foot	Time [days]
Energy restitution	Material/format that can accumulate energy	1 to 5 (Interviews)
Gait development	More-physiological gait events	1 to 5 (Interviews)
Aesthetic	Good appearance	1 to 5 (Interviews)

## 2. Product Development

### 2.1. Identification of amputee needs

To develop a meaningful product that can have an impact on people’s lives and respond to real patient needs, it was followed a human-centered design approach during the product development process. Interviews with important stakeholders were conducted to gather and discuss the amputee’s needs and other aspects of using a prosthesis, such as comfort, limitations, and design.

A total of 13 people were interviewed: a 5-year-old and a 6-year-old amputee children, who’s reason of amputation was congenital limb deformity; two mothers of those amputee children; one physician specialized in physical medicine and rehabilitation; a physiotherapist that has daily contact with amputee children; four prosthetists; and three amputee adults. Each interview provided with a very detailed understanding of the amputee’s day-to-day life, their struggles and concerns, problems and limitations faced by their family, a medical perspective of what is fundamental for the development of an amputee child, a physiotherapy perspective on amputees learn how to walk properly and have a daily routine without constantly depend on their parents, a prosthetist perspective on prostheses development and integration, and how the impairment can be faced in the adult life.

### 2.2. Establishing the target specifications

Patient needs are generally expressed in the “language of the patient” or in the “language of the professional” and leave too much margin for subjective interpretation. For this reason, a set of specifications were set, which spell out in precise, measurable detail the product requirements. Those specifications are presented in table 1 and described below.

- **Adaptability** - The foot geometry chosen for an amputee child should take into consideration the amputee’s height and weight. The de-

veloped prosthetic foot should also allow the integration with the rest of the prosthesis and enable the child to use regular shoes. To accomplish these goals, a database of different 3D digital models from children from 2 to 5 years old was built. By choosing the most similar foot geometry from the database it can be further scaled before printing to fit, becoming even more adapted to the individual;

- **Support and stability** - The prostheses should provide a good base of support to allow the amputee to stand without the fear of falling. To satisfy this specification, the developed internal structure of the prosthetic foot should have good stability;
- **Comfort** - For the amputee to feel safe and confident while walking and performing daily activities, the prosthetic foot should allow different movements and facilitate them. Therefore, the internal structure of the prosthetic foot should be responsive and adaptable to the most common movements;
- **Lightweight** - The lighter the prosthetic foot, the more comfortable is the prosthesis. If the prosthesis, with all the components, is too heavy, wounds on the stump start to appear which is painful for the amputee. By manufacturing the prosthetic foot with 3D printing, not only the materials are lightweight but also the weight can be further controlled by the printing specifications;
- **Cost** - Customized products are known to be extremely expensive, however, by using additive manufacturing, the costs can be reduced since there is no need for using expensive tools or materials to manufacture the product;
- **Simple** - The window of time spent between the order of the prosthetic foot and its delivery should be as small as possible since children are constantly growing and the prosthetic foot is an important component of the prosthesis to allow the amputee to walk and perform their daily tasks;
- **Energy absorption and return** - During heel-strike, the energy of the impact should be absorbed to avoid the force propagation causing injuries on the stump or at the amputee's spine level. Along with the shock absorption, the energy should return on a later stage of the gait cycle, which is important to facilitate the gait cycle until the toes-off phase;
- **Gait development** - Stiffness is an actual problem with the SACH foot because it does

not allow the toes to bend and promote the activation of the mechanical prosthetic knee. By using a soft material for the cosmetic component of the prosthetic foot, FilaFlex, this feature can be improved;

- **Aesthetic** - The aesthetic of the prosthetic foot improves the confidence of the amputee as it plays an important role on the child's well-being and self-esteem. Using anatomic real models to design the prosthetic foot is essential on this process. The option of using different colors for the manufacturing of the product matching the skin color is an important consideration.

### 2.3. Concept generation

The product was broken into simpler subproblems, or components: cosmetic and support. The cosmetic component is the external part of the prosthetic foot that aims to answer the needs of customization and natural-aesthetic appearance, using a 3D scan and the developed Matlab® tool. The support component is the internal part which aims to satisfy the needs of stability and energy restitution, to help the patient during the gait cycle. In the latter, the integration of the prosthetic foot with the pylon is made. Using FDM 3D printing technology, the low-cost, lightweight and short production-time requirements are satisfied.

#### 2.3.1 Cosmetic component

The cosmetic component of the prosthetic foot is responsible for absorbing the impact during heel-strike and also for enabling a smooth toes-off. Therefore, this component requires a soft, foldable material, to reduce stiffness and allow better impact absorption and the activation of the mechanical prosthetic knee.

#### Precision Prosthetic Foot

To produce a customizable prosthetic foot, adjusted to the amputee child necessities, it is essential to have a real foot geometry from a non-impaired child with similar anthropometric characteristics. A natural-aesthetic look, with reasonable foot-proportions, weight, and form to allow the use of regular shoes improves the child's confidence, well-being, and self-esteem. To accomplish this, a database with foot geometries, weight, and height from 20 healthy children with ages ranging from 2 to 5 years old was built in collaboration with Técnico Lisboa's nursery.

The real foot geometries were acquired using a 3D scan, Shinning3D EinScan Pro®, using foot support with a wood structure and a 3mm glass inter-

face, to ensure stability and right positioning of the foot when scanning.

Each of the acquired foot geometries was simplified using Meshlab® software and later imported to Siemens NX® software to close up existing holes on the mesh, remove unwanted parts and correct mesh imperfections. Finally, the big toe was separated from the rest of the toes, to allow the possibility of using different shoes, such as flip-flops, a need stated by multiple interviewees. To complete the cosmetic component of the prosthetic foot, the ankle was cut transversally. In figure 2 the geometries of the 20 acquired feet are presented.

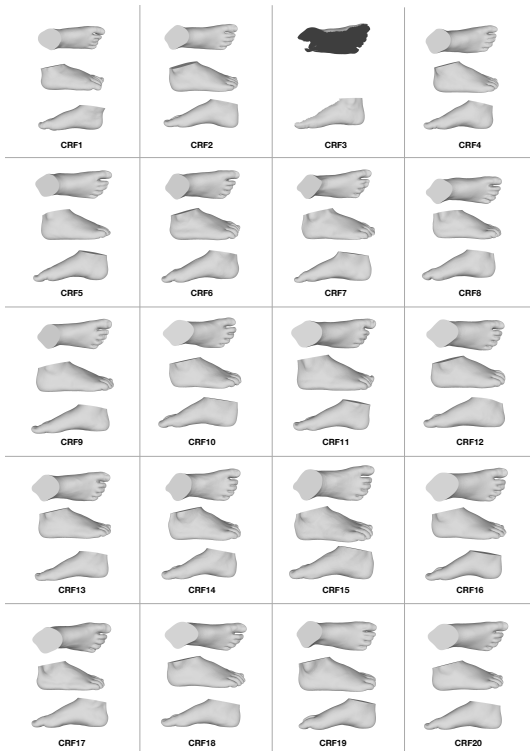


Figure 2: Database of foot geometries. CRF3 was a restless child who complicated the scanning process.

### Foot Measures

Measurements were performed using Meshlab® software environment to extract the anatomical proportions of a child’s foot dimensions. The most common measurement is the foot length (FL), which is the distance between the back point of the heel and the foremost point of the longest toe. The anatomical ball width (ABW) is the distance between MTH1-Metatarsal Head 1 and MTH5-Metatarsal Head 5, and the technical ball width (TBW) is the orthogonal distance between the most medial and lateral point at 61.8% of foot length. Technical Heel width (THW) is the orthogonal distance between the most medial and lateral points of the heel. Lastly, the instep high (IH), also

Table 2: Relations in children’s foot dimensions.

	$\frac{TBW}{FL}$	$\frac{THW}{FL}$	$\frac{IH}{FL}$
$\mu_{N=20}$	38.24%	24.70%	31.12%
$\sigma_{N=20}$	1.79%	1.06%	1.19%

Table 3: Relations in adult’s foot dimensions.

	$\frac{TBW}{FL}$	$\frac{THW}{FL}$	$\frac{IH}{FL}$
$\mu$	40.54%	26.50%	45.19%
$\sigma$	1.78%	0.61%	1.42%

known as the height of the foot, is commonly measured at 50% of the foot length.

Major relations between feet measurements among children are presented in table 2.

Studies with children foot dimensions are scarce. Therefore, for comparison, data from studies with European adult and elderly populations were analyzed [13] [39] and were summarized in table 3. Since the foot proportions between adult and child feet are not similar, one cannot scale an adult’s foot into a child’s. This way, a database with real child foot geometries is of extreme importance to develop an adapted prosthetic foot.

Using Matlab® software, the relation between the children’s height, weight and the acquired foot length was determined using a linear regression model. The relation follows the equation 1. Note this Matlab® function does not take into consideration the gender of the individual, since the differences in the foot geometry only become significant around the age of twelve [8], and the acquired foot geometries were from children ranging 2 to 5 years old. There is a notorious relation between weight and foot length. The heavier a child is, the bigger is his/her foot across all ages, which is hypothesized due to larger stress between bones that results in bone growth stimulation.

$$FL = 7.9351 + 0.016896 \times height + 0.33983 \times weight \quad (1)$$

A matching foot geometry for the test subject was found with the help of a developed Matlab® tool, which took into consideration the acquired feet geometries and linear regression model from 1. The tool receives as input the height and the weight of the amputee child and returns the desired foot length for the prosthetic foot and a scaling factor to be used if the matching foot geometry is significantly different in proportion.

For the test subject, with a height of 110 cm and weight of 17.7 Kg, the linear regression model output was subject CRF8, with a scale factor of 1.05% (difference of 0.08 cm), which is not signif-

icant enough to undergo the scaling procedure. It was decided the scaling procedure would take place if the difference between the required foot length and the most similar is larger than 1 centimeter.

After having the right foot geometry matching amputee’s characteristics, it can be used as a reference for the support component design.

### 2.3.2 Support component

The support component is responsible for supporting the body weight while standing, while also absorbing elastic energy during heel-strike, which in turn helps the child’s gait.

The concept generation for rigid component began with the external search for currently available solutions and patents. Additionally, meetings with all stakeholders, such as amputee children, their parents, prosthetists and specialized physicians in rehabilitation were carried out. Those meetings brought great insight into the recurrent adaptations to improve the child’s gait cycle. For example, when a 1S30 SACH foot is chosen, the prosthetist is requested to sand the foot with the aim of reducing its overall dimensions and acquiring an appearance similar to the sole of the shape-up sneaker, figure 3, since it enables the child to do a proper roll-over of the prosthetic foot during the gait cycle. When it is not possible to sand the SACH foot, as in most cases, figure 1(a), the physician asks parents to buy sneakers with a sole similar to shape-up sneakers model.



Figure 3: 1S30 SACH foot for children by Ottobock® available with 12 and 13 cm (left). Shape-up sneakers from Sneakers® (right).

During the internal search phase, a sketch concept ideation was undertaken to craft a solution that incorporated the main principles of ESAR feet, in which the deformation upon heel-strike stores energy that is transferred through the prosthesis and released during the midstance and toes-off phases of gait, one of the target specifications. After drawing a total of 8 concept ideas, a set of 4 different CAD concepts were designed on Siemens NX® software. All those 4 concepts were 3D printed and carefully observed in order to better understand their advantages and disadvantages when a force is applied, figure 4.

Evaluating the concepts with respect to the needs of the stakeholders, evaluating their rela-



Figure 4: Four different concept ideas for the support component.

tive strengths and weaknesses, the design was improved and the process converged on one concept to develop and test. The chosen internal geometry, depicted in figure 5, considers the metatarsophalangeal joint of the foot which, during toes-off, will enable the external component to bend. The sole of the rigid component was carefully designed as a curve that takes into consideration the physician adaptations that facilitate the roll-over of the foot during the gait cycle. The heel design allows the exterior component to absorb the majority of the impact energy during heel-strike.



Figure 5: Final CAD model to prototype.

### 2.4. Concept testing and prototyping

After combining the support and cosmetic components on Siemens NX® software, Finite Element Analysis (FEA) was applied considering the FDM filament materials used, in order to understand if some adjustments are required before the additive manufacture process. A 3D printer with dual extrusion technology was used to fabricate the prototype. To represent muscle and skin, the cosmetic component was printed with FilaFlex, a flexible material [35], while to represent bone in the support component, PLA, a rigid material, was used. Lastly, the prosthetic feet were applied to the amputee child and feedback was gathered from the test subject, her mother, prosthetist, and physician.

#### FEA to understand if the prototype can support the applied forces

For Finite Element Analysis, foot components were meshed with tetrahedral elements with 2 mm, since convergence studies proved convergence. The numerical foot model was analyzed for three phases of foot support during the gait cycle, corresponding to heel-strike, midstance and toes-off with loading forces corresponding to the girl’s weight, with a safety factor of 3. Since the safety factor is a product of different contributors, both static forces, contributing with a factor of safety of 1.5, and dynamic forces, contributing with a factor of safety of 2, were considered, contributing to a *safety factor* =  $1.5 \times 2 = 3$ . Therefore, *Applied force* =

$mass\ of\ the\ child \times gravitational\ acceleration \times 3 = 17.7 \times 10 \times 3 = 531\ N$ .

PLA filament has typically  $1.24\ g/cm^3$ , with 3120 MPa of Tensile Modulus and 52 MPa of flexural strength (also known as modulus of rupture). The manufacturing procedure, layer-by-layer, provides the printed model with different properties in all the directions, conditioning it to experience anisotropic properties. In fact, Poissenot’s study [27] with PLA 3D printed models proved that it could be considered orthotropic. Taking this study into consideration, since it was not possible to determine all the specifications required to simulate the model as orthotropic and considering that the differences between the properties along X and Y axes were of 2%, the analysis was approximated as transversely isotropic. This approximation was conducted by averaging the Poissenot study’s data acquired on XX and YY axes and using the same characteristics along the ZZ axis [27].

FilaFlex filament has  $1.14\ g/cm^3$ , with 42 MPa tensile strength and 54 MPa ultimate tensile strength, according to its technical sheet. Its tensile storage modulus is 48 MPa and the specified elongation at break is 665%. Similar to previous studies [28], this study was also assumed a Young modulus of 48 MPa. FilaFlex is a thermoplastic polyurethane and Qi and Boyce [28] stated that for polyurethane (TPU) “it is reasonable to assume the Poisson’s ratio ranges from 0.48 to 0.5”. According to Tsukinovsky [40] and Elleuch [7] studies, an average of 0.48 should be used for the Poisson’s ratio. Due to the lack of studies with this filament, it was considered isotropic for FEA simulations.

The numerical loads for the three load cases were applied over a moving plane, performed during a contact simulation. For heel-strike simulation, the moving plane was placed at an angle of  $20^\circ$ , whereas for the toes-off phase the angle was of  $40^\circ$ , similarly to what is used in physical ISO tests, figure 6.

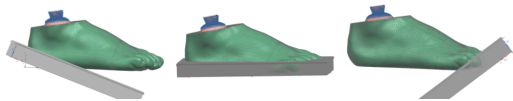


Figure 6: Simulation conditions. Pyramid adapter was fixed. The applied moving plane had different inclinations: Heel-strike, on the left,  $20^\circ$ . Midstance, in the center,  $0^\circ$ . Toes-off, on the right,  $40^\circ$ .

## 2.5. Prototype development

The final prototype was manufactured in BCN3D Sigma® 3D printing machine with a 20% infill for the cosmetic component and 85% for the support component. The pyramid adapter geometry was

printed with an infill of 100%. Each manufactured prosthetic foot used 135 g of PLA and 59 g of FilaFlex. Although the material cost is dependent on the supplier, it is estimated 7,43€ per 3D printed foot. The manufacturing process takes roughly 28 hours.

## 3. Results and discussion

### 3.1. Prosthetic foot test

The testing phase was divided into two parts: 1) computational modeling in Simens NX® and 2) physical test with the patient, in which different stakeholders were involved.

#### 3.1.1 Computational test

A contact simulation between a moving plane and a computational model of the developed prosthetic foot was performed.

The support component was modeled as transversely isotropic, which is more realistic than isotropic, even though differences between Young Modulus along XY and Z directions were less than 7%. Additionally, since only one value of Yield Stress was known and Filaflex was characterized as isotropic, results were analyzed considering Von Mises stress for both components, due to its simplicity and well correlation with experimental results [12].

For all three simulations, Von Mises stresses were higher on the support component, exactly on the border of the fixed constraint region, located on the universal pyramid adapter geometry. For heel strike simulation, a maximum Von Mises stress was 32.90 MPa, for midstance 20.14 MPa and for toes-off 30.38 MPa. All of those Von Mises stress estimations were lower than the yield stress of PLA, 52 MPa, even using the safety coefficient of 3.

#### 3.1.2 Physical test with amputee child

Two meetings took place at Hospital Dona Estefânia to gather relevant insights from the test subject, physician, physiotherapist, prosthetist, and her mother regarding the satisfaction of the target specifications, listed in table 1. During those meetings, a physical therapy session with both SACH and the developed prosthetic feet were performed in a controlled setting, with the aim of comparing the biomechanical behavior of each and observe the interaction between the amputee child and the prototype.

Table 4 reflects how well the requirements were rated according to each specification’s metrics. A scale from 1 to 5 was used on subjective characteristics.

Table 4: Summary of how the target specifications were met. 1 = No attempt to solve this was performed; 2 = Attempts to solve this were performed but a good result was not obtained; 3 = Acceptable result; 4 = Good result; 5 = Excellent result.

Needs	Target Specification	Metric of the Specification
Adaptability	To weight	Yes
	Compatible with global prosthesis having a standard pyramid adapter geometry	Yes
	To form (can be used with universal shoes)	Yes
Support and stability	When stand up	3
Comfort	During its use	5
Lightweight	Less than SACH weight (0.800 Kg)	0.139 Kg
Cheap	Cost similar with SACH foot (less than 100€)	Difficult to estimate
Simple	Less than 1 week to have the prosthetic foot	4 days
Energy restitution	Material/format that can accumulate energy	5
Gait development	More-physiological gait events	5
Aesthetic	Good appearance	5

- Regarding the **adaptation** requirement, all the specifications were rated with “yes” since the matching foot geometry from the database took into consideration both the weight and height of the test subject. The geometry of the rigid component of the prosthetic foot includes the geometry of the universal pyramid adapter for the integration with the pylon and the rest of the prosthesis. Moreover, since the foot geometry was from a real child, the form of the prosthetic foot is completely anatomical and can be used with universal shoes.
- **Support and stability** were rated with only 3 due to the fact that the girl tilted her body when standing up, not having a perfectly vertical position. However, during her gait, her confidence while walking showed extreme improvements and she even started to dance and perform several ballerina positions which, according to the mother and physiotherapist, she had never been able to do with the SACH foot.
- The **comfort** of the prosthetic foot was rated with 5. The amputee child mentioned the foot was soft and lightweight, motivating her to raise her leg and exhibit the foot, as well as doing the dance movements with her leg in the air. The happiness of the child when performing all these movements was noticeable.
- The test subject felt how **lightweight** the prototype was, and this was also noticed by the physician, prosthetist, physiotherapist, and mother while holding it in hand. The difference of weight between her SACH foot and prototype foot is 42 g, equivalent to a considerable 24% decrease in weight.
- On what concerns the **cost** of the developed prosthetic foot, this was hard to estimate, because it depends on multiple factors. The ma-

terial cost was estimated at 7,43€ per foot. The 3D printing time was 28 hours, while for foot geometry acquisition was 15 minutes, depending on the ability of the acquisition subject to remain still during the scan, and for the CAD design process, the time estimated was 2 to 3 days.

- The **total estimated time** to develop the prosthetic foot is 4 days.
- The **energy restitution** was classified with 5 since the gait cycle appeared to absorb energy during the heel-strike and return in toes-off phase. The training was performed with and without the shoes covering the prosthetic foot. The girl showed interest in observing the foot behavior when without shoes, particularly the toes behavior, as they were bended during toes-off similarly to a healthy foot and as opposed to the SACH foot.
- The **gait performance** was classified with 5, because there were considerable improvements in the gait. The walking base got lower and more physiological, allowing better development. Because the prosthetic toes started to bend during the gait cycle, it became easier for the test subject to use her the mechanical knee.
- The **aesthetics** of the developed prosthetic feet was classified with 5 because of the extremely well acceptance from the test subject. It was observed the amputee child would stare at her feet whenever she could, mentioning it was beautiful and she wanted to use the prototype outside the clinical setting. Both her mother and prosthetist mentioned the more-anatomical appearance geometry and behavior. The color of the prosthetic foot, previously underestimated by the girl and mother, was at this point noticed to be an important improvement over the caucasian-colored SACH option.



Figure 7: Child’s gait test with the new prosthetic feet.

Even though static computational tests were performed, physical tests are also needed to validate the product. With the extremely well acceptance of

the prototype, the physician and the test subject's mother signed an informed consent which allowed the child to experiment the prosthetic foot for the rest of the day and during school.



Figure 8: Adaptation with the metallic pyramid adapter.

After a day of usage, the right prosthetic foot broke on the pylon integration, a consideration that should be included in the next iteration of the product development. It is hypothesized children heavier than 10Kg may require a metallic pyramid adapter, as represented in figure 8, since PLA material seems to not have enough resistance to support continuous loads.

#### 4. Conclusions and Future work

The purpose of this work was to design a low-cost, lightweight, patient-specific and natural-aesthetic prosthetic foot for children, with a short production-time able to improve the gait cycle of the amputee. Product development methodologies were implemented that encompass 3D scanning, CAD design, FEA, and 3D printing techniques.

The present work proposed a methodology that followed a human-centered design approach. Interviews with important stakeholders were conducted to gather and discuss needs and other aspects, such as comfort, limitations, and design. A list of precise, measurable product requirements was set. Since a 5-year-old bi-lateral amputee girl was the clinical case study, a database was built with feet geometries, height, and weight from 20 healthy children with ages ranging from 2 to 5 years old. A Matlab tool was developed to extract a matching foot geometry from the database, based on the test subject's anthropometric data. The prototype, which was divided into cosmetic (external) and support (internal) components, was manufactured using a 3D printer with dual extrusion technology, evidencing the potential for a low-cost, lightweight and customized solution. The external component, printed with a flexible material, proved to answer the needs of customization and natural-aesthetic appearance, whereas the internal component, printed with a rigid material, satisfied the needs of stability and energy restitution, which helped the test subject during the gait cycle. Before testing with the patient, a computational model of the prototype underwent FEA, which did not exceed the imposed limit. The prototype was tested by a 5-year-old bi-

lateral amputee girl in a controlled setting, with the presence of her mother, physician, physiotherapist and prosthetist. The new prosthesis was extremely well accepted by the child and the remaining stakeholders. Apart from the child's happiness and almost immediate affection with the prosthetic feet developed, the test subject decreased the base of walking, which was a problematic characteristic of her gait, and showed more confidence using her mechanical knee.

Given the advantages of the developed prosthetic foot, future studies should focus on enriching the created database with more foot geometries from healthy children from 1 to 7-year-old. A wider range of possible geometries will result in higher customization since a great variability of geometries makes it easier to find similarities between the patients and the individuals from the database. On what concerns FEA, studying the orthotropic mechanical characteristics of Filaflex and PLA, in similar conditions as the ones used in the present study, would enable more accurate FEA results. A more realistic simulation of the interaction between the pylon and the prosthetic feet may provide more realistic results. Additionally, the simulation of the three phases during the gait cycle can take into consideration the experienced forces during a gait cycle, recorded in a biomechanics laboratory using force plates, instead of only body weight. Lastly, physical tests with specialized machinery are required to ensure the safety of the prosthetic foot and allow to improve its resistance and durability.

Despite all the abovementioned steps that can be done to improve the developed work, this work has proven 3D-printable prosthetic feet can be manufactured using AM with dual materials, evidencing the ability to improve the quality of life of a 5-year-old bilateral amputee girl.

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