Design and Manufacture of a Customized Prosthetic Foot

Inês Jorge Ferreira

Thesis to obtain the Master of Science Degree in

Biomedical Engineering

Supervisors: Prof. Miguel Pedro Tavares da Silva
Dr. Maria José Martins Costa da Silva

Examination Committee

Chairperson: Prof. João Orlando Marques Gameiro Folgado
Supervisor: Prof. Miguel Pedro Tavares da Silva
Member of the Committee: Prof. Jorge Manuel Materus Martins
Dr. Manuel Cassiano Neves

May 2019
I declare that this document is an original work of my own authorship and that it fulfills all the requirements of the Code of Conduct and Good Practices of the Universidade de Lisboa.
Preface

The work presented in this thesis was performed at the Biomechanics of Movement Research Group of Instituto Superior Técnico (Lisbon, Portugal) in collaboration with Hospital Dona Estefânia, during the period September 2018 - May 2019, under the supervision of Professor Miguel Tavares da Silva and Professor Marco Leite. Co-supervised by Dr. Maria José Costa of Hospital Dona Estefânia.
Acknowledgments

Biomedical Engineering was my first choice since I discovered its content and multidisciplinarity in high school. Developing this project for my Master’s thesis was one of the most rewarding experiences I ever had. There are a few people in particular who were instrumental in supporting me through this dissertation.

First and foremost, I would like to express my heartfelt gratitude to my supervisor and adviser Professor Miguel Tavares da Silva, for his immense support and help during my Master thesis, for his encouragement and for always believing in my capabilities. I would also like to thank my supervisor Professor Marco de Oliveira Leite for all the shared knowledge, motivation and guidance essential during the first steps of the project. To my co-supervisor, Dr. Maria José Costa da Silva, along with the physiotherapist Paula Agulheiro, were fundamental on the elaboration of this thesis and I really appreciate all the time both dedicated to this project, clarifying both basic and difficult questions I had. I would have never been able to test this prototype with a child without your help. The constant motivation and enthusiasm from you all was pivotal to the success of this thesis. I will always be grateful for having you aboard this project!

I would like to thank Manuela Alves from Instituto Superior Técnico’s nursery for all the help on building the database with children foot geometries. Without all the children volunteers, this work would have never been possible.

I would also like to thank Professor João Folgado for his availability to give me suggestions and to clarify every doubt I had regarding finite elements.

For all the orthopedic stores that opened their doors for me, a huge thank you, in special to Ortopedia Moderna and their prosthetist Sérgio Jorge for helping me kick-start the implementation of the developed prosthetic foot.

I would also like to express a warmful thank you to my friend Frederico Alves for always being present to help me during my Siemens NX stressing moments (there were not few!), and for always being available to help. He was an encouraging and very talented teacher!

For both LBL Lab and Product Development Lab teams, I deep thank you, specially Luis Quinto for all the encouraging words before any presentation and Sérgio Gonçalves for his inputs and help during the 3D scan acquisitions.

From the bottom of my heart, I would like to express a huge thank you to my parents, Ana Paula Jorge Ferreira and Agostinho Ferreira, who never gave up on me all the way through and were always available to try to find a solution to my problems. To all my cousins and uncles and little cousins, I am thankful for your support, admiration and funny moments. A special thank you to my cousin Bruno Ferreira and his little daugher for helping me with the first 3D acquisition of a child’s foot, which ended up being my first proof of concept!

All of the my friends, especially Carina Barreto, Inês Mataloto, Rita Oliveira, Mariana Fernandes, Ricardo Honório, Mariana Lamas and Rita Barreiros, I do not know what I would do without you. Thank
you for bringing me chocolate candies at the most random times, but also when I needed the most. I really enjoyed our relaxing coffee breaks and boardgame nights. Rita Barreiros, a special and huge thank you for always be my partner in adventures (even if that means going to Aveiro to a music festival!). I now know what is like to just be on the grass, feel the sun and hear the birds. Thank you for never letting me forget my accomplishments and how amazing I can be. Your help reviewing this thesis deserves more walks on the beach at 6:00.

TEDxULisboa team, I am grateful to be part of such dream team! Each one of you taught me the power of having a strong, cohesive team, and I love what we were capable of doing together. On May 4th we made history by organizing the biggest TEDx university event at Aula Magna, Universidade de Lisboa, for more than 1500 attendees. Thank you for trusting my leadership skills and I am certain we will do many more things together. We rock!

I also want to share an enormous gratitude for my friend, partner and lover, João Apura. Thank you for reminding me of my capabilities, my internal motivations and also the impact a good run has on me. I am grateful for the courage of picking me up after my big falls and moments of shaken confidence. Thank you for not letting me forget to trust and believe and push through at the very end.

I could not end this section without thanking to my dearest grandmother, Avó Maria! Unfortunately, it is not possible to have you physically with me here. However, you are still my confident. Thank you for your good energy and for always believing in me. I will never forget our laughs, talks and weird moments. You are still the grandmother of 18 borrowed grandchildren and the godmother of 10 borrowed children, a powerful and loving woman! Wherever you are, we all love you.
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, 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 a 3D scan technology, CAD modeling, and AM technology, 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 Tecnico. A 5-year-old bilateral 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 with the purpose of having geometries to use for the cosmetic component when needed. The proposed methodology takes 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 thesis has 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 adaptor. 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
Resumo

A malformação congénita é a causa mais comum de amputação de crianças em países desenvolvidos. A incapacidade dos amputados para realizar atividades básicas como caminhar compromete a sua realização pessoal e social. Para as crianças, recomenda-se a implementação de próteses nos membros inferiores entre os 9 e 16 meses. Ao desenvolver qualquer equipamento para crianças, as necessidades emocionais e estéticas são muito importantes. Além disso, o pé influencia a biomecânica da marcha pela sua forma e rigidez. As pequenas dimensões, a necessidade constante de adaptação, e a escassez de opções disponíveis de características estéticas e mecânicas são atualmente as principais preocupações.

As tecnologias disponíveis de digitalização tridimensional (3D scan) e manufatura aditiva (AM) oferecem a possibilidade de obter uma solução personalizada com custos de produção e tempo de fabricação reduzidos. O objetivo deste trabalho é desenvolver uma metodologia para desenvolver pés prostéticos de baixo custo e rápida produção, com uma aparência natural, recorrendo à tecnologia de 3D scan, modelação CAD e tecnologia AM, capaz melhorar o ciclo da marcha do amputado. Tanto a modelação quanto a produção do pé prostético incluem dois componentes: um material rígido, PLA, para absorção do impacto e conexão com o resto da prótese (interno); e um material flexível, FilaFlex, para dissipação de energia e melhor estética (externa). A integridade estrutural da estrutura geral é testada recorrendo à análise de elementos finitos (FEA).

A implementação da metodologia foi realizada com o consentimento da comissão de ética do Instituto Superior Técnio. Uma menina biamputada de cinco anos foi o caso de estudo clínico. Foi construída uma base de dados com geometrias de pés, altura e peso de 20 crianças saudáveis, com idades entre 2 e 5 anos com o propósito de ter geometrias de pés disponíveis em caso de necessidade. A metodologia proposta tem em consideração o peso e a altura do amputado. Assim, foi desenvolvida uma ferramenta em matlab® para extrair a geometria do pé da base de dados que melhor corresponde às características do amputado. Os pés foram desenvolvidos, impressos e testados com a criança de 5 anos bi-amputada num ambiente controlado, com a presença da sua mãe, médica, fisioterapeuta e ortoprostético.

Este trabalho comprovou que os pés prostéticos podem ser fabricados com recurso a AM utilizando filamentos de PLA e FilaFlex, evidenciando grande potencial para uma solução customizada, de baixo custo e baixo peso para crianças amputadas de nível de atividade baixo a moderado. É importante ter em consideração que, para crianças com mais de 10Kg, é necessário efectuar a integração com um pyramid adaptor metálico. Em crianças mais leves é possível utilizar o pé prostético desenvolvido recorrendo apenas a AM. Trabalhos futuros devem incidir sobre a maior customização aumentando a base de dados de geometrias de pés; melhorar a durabilidade e testar com testes físicos recorrendo a máquinas especializadas e efectuar testes com mais pacientes.

Palavras-chave: Crianças amputadas - Pé prostético - Digitalização 3D - Manufatura aditiva - PLA - FilaFlex - Medicina de precisão
# Table of Contents

Acknowledgments .................................................. v
Abstract ............................................................... vii
Resumo ................................................................. ix
Table of Contents ..................................................... xiii
List of Figures ......................................................... xvii
List of Tables ........................................................ xix
List of Abbreviations ............................................... xxi

## 1 Introduction

1-1 Motivation ......................................................... 1
1-2 Prostheses state of the art ..................................... 2
1-3 Objectives ......................................................... 5
1-4 Main contributions ............................................... 6
1-5 Structure and Organization ..................................... 6

## 2 Lower Limb Amputation

2-1 The amputation ................................................... 9
  2-1-1 Level of amputation ....................................... 10
  2-1-2 Clinical procedures ....................................... 11
2-2 Gait cycle .......................................................... 12
  2-2-1 Step and stride ............................................. 13
  2-2-2 Cadence and speed ....................................... 13
  2-2-3 Gait cycle and its events ................................ 13
  2-2-4 Ankle motion .............................................. 14
  2-2-5 Ground reaction forces ................................... 15
  2-2-6 Amputee’s gait ............................................ 16
2-3 Foot development ............................................... 17
  2-3-1 Foot dimensions and foot types ......................... 17
  2-3-2 Foot types in different age groups ..................... 18
  2-3-3 Influence of gender on foot types ...................... 19
  2-3-4 Influence of body composition on foot types ........ 19
2-4 Prostheses ......................................................... 19
  2-4-1 Prostheses development .................................. 20
  2-4-2 Prosthetic systems ....................................... 21
# 2-4-3 Prosthetic foot options

## 3 Product Planning

- **3-1 Opportunity identification** ........................................... 33
- **3-2 Available technologies** ............................................... 35
  - 3-2-1 3D Scanning ................................................. 35
  - 3-2-2 Additive manufacturing ....................................... 35
- **3-3 Product development** .................................................. 39
  - 3-3-1 Identification of patient’s needs ............................... 40
  - 3-3-2 Establishing the target specifications ......................... 40

## 4 Product Development and Prototype Generation

- **4-1 Concept generation** .................................................... 43
- **4-2 Cosmetic component** .................................................. 44
  - 4-2-1 Design methodology behind the cosmetic component ..... 44
- **4-3 Support component** .................................................... 45
  - 4-3-1 Concept generation and concept selection of the support component ........................................ 45
  - 4-3-2 Concept selection ..................................................... 47
  - 4-3-3 Design methodology behind the support component of the prosthetic foot ........................................ 49
- **4-4 Concept testing and prototyping** .................................. 49
  - 4-4-1 Finite Element Analysis to understand if the model can support the applied forces .................................... 50
  - 4-4-2 Stakeholders perspective ........................................... 52
- **4-5 Prototype development** ................................................. 53
  - 4-5-1 Printing highlights .................................................... 54

## 5 Precision Prosthetic Foot

- **5-1 Prosthetic foot** .......................................................... 57
- **5-2 Database building with acquired foot geometries of sound children** ............................................. 58
  - 5-2-1 Procedure to acquire foot geometries and anthropometric data ...................................................... 58
  - 5-2-2 Foot Measures .......................................................... 61
  - 5-2-3 How to choose a foot geometry from the database after meeting a bi-lateral amputee child .................... 62

## 6 Clinical Case

- **6-1 The amputee child** ...................................................... 65
  - 6-1-1 Choose the right foot geometry matching amputee’s characteristics .................................................. 66
  - 6-1-2 Prosthetic foot development ........................................ 66
- **6-2 Prosthetic foot test** ...................................................... 69
  - 6-2-1 Computational test ..................................................... 69
  - 6-2-2 Amputee child test ..................................................... 71

## 7 Conclusions and Future Work

- **7-1 Conclusions** ............................................................. 75
- **7-2 Future work** ............................................................. 76

## References

- **References** ................................................................. 79
List of Figures

2-1 Main amputation levels. .......................................................... 11
2-2 Step and stride (126). ............................................................ 13
2-3 Normal gait cycle and nomenclature of each phase. ................... 14
2-4 Reference axes and anatomical terms of location for the foot-ankle system. ......................................................... 15
2-5 Example of the vertical ground reaction force recorded during the stance phase of a normal gait cycle (10). .................. 16
2-6 Common foot width measurements. ABW - Anatomical Ball Width, the width between Metatarsal Head 1 (MTH1) and Metatarsal Head 5 (MTH5); TBW - Technical Ball Width; AHW - Anatomical Heel Width; and THW - Technical Heel Width. Adapted from (30). .................. 18
2-7 Common foot height measurement. IH - Instep Height. Adapted from (30). .................................................. 18
2-8 Distribution of foot types within different age groups (30). ........ 19
2-9 Endoskeletal transtibial prosthetic systems (left) and Exoskeletal transtibial prosthetic systems (right). Three of the four components are shown: a socket, pylon and prosthetic foot (99). .......... 21
2-10 Different types of pyramid adapters available, with the same geometry for the integration with the pylon of the prosthesis. (a) SACH foot adapter, Tiger paw by Bulldog® made of titanium; (b) SACH foot adapter by Ossur® made of aluminum; (c) MightyMite® SACH Foot Pyramid by Fillauer® made of titanium; (d) Foot Pyramid by Medex® with two models. One made of Stainless Steel and other made of Titanium; (e) Foot pyramid adapter by Trulife® made of Aluminum. Provide a safe and cost-effective alternative to titanium; (f) Bulldog prosthetic foot leg standard pyramid adapter with 4 pyramid holes and a center hole, made of titanium. ...................... 22
2-11 Schematic of a SACH foot internal structure, with a rigid keel, foam heel and plastic covering (99). ..................... 24
2-12 SACH appearance with cosmetic shell. .................................... 24
2-13 Schematic of a single-axis prosthetic foot (left) and a single axis foot from College Park (right). ......................... 24
2-14 Schematic of a multi-axis prosthetic foot. .................................. 25
2-16 ESAR prostheses: (a) Ossur Flex-foot Modular III, (b) Ossur Flex-foot Variflex, (c) Otto Bock Springlite Foot, (d) Ossur Flex-foot Talux (32). ........................................... 26
2-17 CESS foot (19). ................................................................. 27
2-18 Jaipur foot. .................................................................. 27
2-19 Niagara prosthetic foot (103). ........................................... 28
2-20 Shape & Roll prosthetic foot (92). ........................................ 28
2-21 Jonathan Yap and Gianni Renda prosthetic foot (131). .......................... 28
2-22 Most used SACH feet: (a) J1k30 Ottobock® SACH foot for children. (b) 1S30 Ottobock® SACH foot for children. .......................... 29
2-23 Regular cosmetic cover for prosthetic feet (left). Realistic cosmetic cover (right). .......... 29
2-24 Child’s Play Energy from Trulife®, USA, ESAR prosthetic foot. ....................... 29
2-25 RUSH Kid prosthetic foot from RUSH®, USA, ESAR prosthetic foot. ................. 30
2-26 Tuper foot by College Park®, USA, single-axis prosthetic foot. ...................... 30
2-27 Flex Foot (left) and Vari Flex (right), by Ossur®, are ESAR prosthetic feet. .......... 30
2-28 Pediatric SACH foot (left) and Pediatric Impulse foot (right) by Willow Wood®, USA, ESAR prosthetic feet. ........................................ 31
2-29 MightyMite feet by Fillauer®, USA (left) and Kingsley Juvenile SACH by Kingsley®, USA (right). ......................................................... 31

3-1 Shinning3D EinScan Pro® ................................................................. 36
3-2 Fused deposition modeling (FDM). ....................................................... 36
3-3 Product development activities, adapted from (113). ..................................... 40

4-1 2 year-old test subject. ........................................................................ 44
4-2 External 3D geometry before ((a) and (b)) and after ((c) and (d)) processing with Meshlab® and Siemens NX® softwares. ............................... 45
4-3 1S30 SACH foot for children by Ottobock®, available with 12 and 13 cm (left). Shape-up sneakers from Sneakers® (right). ................................. 46
4-4 1K30 SACH foot for children by Ottobock®, available with 14 and 21 cm. .......... 46
4-5 Most relevant patents: (a) Patent number 5,062,859 published on November 5th 1991; (b) Patent number 5,037,444 published on August 6th of 1991; (c) Patent number patent 6,099,572 published on August 8th of 2000; (d) Patent number 6,197,066 published on March 6th of 2011. ................................................... 47
4-6 External foot geometry, a reference for the design of the internal component. .... 47
4-7 Four different concept ideas for the support component. ............................. 48
4-8 FDM 3D printed concepts to analyse. ......................................................... 48
4-9 Final support model FDM 3D printed. ......................................................... 48
4-10 Final support model. .............................................................................. 48
4-11 Most commonly used pyramid adapter. ................................................... 49
4-12 Computational model of the final prototype. .............................................. 49
4-13 Simulation conditions. Pyramid adapter is fixed. The applied forces are represented with arrows. Toes-off with a geometric distribution of the applied force with 40° (left). Midstance (center). Heel-strike simulation (right) with a geometric distribution of the applied force with 20°. ................. 50
4-14 Mesh representation and the selected nodes (1 and 2) for the convergence analysis. ......................................................................................... 50
4-15 Convergence study on node 1 during all three simulations. ......................... 51
4-16 Convergence study on node 2 during all three simulations. ......................... 51
4-17 Siemens NX® results. ............................................................................. 52
4-18 Acquired foot geometry with eversion. ....................................................... 53
4-19 3D printed prosthetic foot, evidencing the possibility of using different infill percentages. ................................................................. 54
4-20 Failed print due to moisture. ..................................................................... 55
4-21 FilaFlex in the oven (left). Storage vacuum bag (right). ........................................... 55
5-1 Child’s posture during 3D scan procedure. ................................................................. 59
5-2 Children's diploma after the scan. ............................................................................ 59
5-3 Geometries on database. CRF3 was a restless child difficulting the acquisition process. .. 60
5-4 Measures taken on the CRF8 child foot. ................................................................. 61
5-5 Foot length (cm) vs. Weigh (Kg). ............................................................................. 62
5-6 Foot length (cm) vs. Heigth (cm). ............................................................................. 62
5-7 Matlab® function’s graph. ....................................................................................... 63
5-8 Matlab® result for the data: 20Kg and 112cm. ......................................................... 64
6-1 Bi-lateral amputee test subject (left) and her prosthesis (right). ......................... 66
6-2 Matlab® tool output for the test subject, with 110 cm height and 17.7 Kg weight. .... 66
6-3 CAD design to prototype, from Siemens NX®. ....................................................... 67
6-4 Mesh representation and the selected nodes (1 and 2) for the convergence analysis. . 67
6-5 Convergence study on node 1 of simulations with the 3 gait phases in study. ........ 67
6-6 Convergence study on node 2 of simulations with the 3 gait phases in study. ........ 68
6-7 Left: Heel-strike simulation using a moving plane with an inclination of 20°. The plane had to move 2.15mm to have a total reaction force of 531N; Middle: Midstance simulation using a moving plane, in which the plane moved 0.6mm for a total reaction force of 531N; Right: Toes-off simulation using a moving plane with an inclination of 40°. The plane moved 6.4mm for a total reaction force of 531N. 68
6-8 Heel-strike Siemens NX® results. .......................................................................... 69
6-9 Midstance Siemens NX® results. .......................................................................... 70
6-10 Toes-off Siemens NX® results. ............................................................................ 70
6-11 CAD design for the first simulations (a) side view and (b) top view. New model with improved resistance (c) side view and (d) top view, which was used for prototyping. .......................... 70
6-12 3D printed prosthetic feet. ..................................................................................... 71
6-13 First interaction of the test subject with the prototype (top left). Prosthetic foot comparation (bottom left). The implementation procedure with the help of the prosthetist (right). ....................... 71
6-14 Child’s gait test with the new prosthetic feet. ....................................................... 72
6-15 Location of the rupture in the prototype. ............................................................. 74
6-16 Original prototype (left). Prototype with a metallic pyramid adapter integration (right). ........................... 74
A-1 3D printed Layer settings in ideaMaker® software. ................................................... 87
A-2 3D printed Extruder settings in ideaMaker® software. ............................................ 88
A-3 3D printed Extruder settings in ideaMaker® software. ............................................ 88
A-4 3D printed Cooling settings in ideaMaker® software. .......................................... 89
A-5 3D printed Ooze settings in ideaMaker® software. ............................................... 89
C-1 Relation between foot length and TBW. ............................................................... 93
C-2 Relation between foot length and THW. ............................................................. 94
C-3 Relation between foot length and IH. ................................................................. 94
List of Tables

3-1 Foot dimensions considering age, from https://www.blitzresults.com/gb/kids-shoe-size-chart/, last accessed on January 2019 .............................................. 34

3-2 Selection matrix of interviewees. Five transfemoral amputees (3 adults and 2 child), one physician, four prosthetists, two mothers of amputee children and one physiotherapist. The interviews were conducted in person. .............................................. 40

3-3 Interviewee data, with sample customer statements and interpreted user requirements. .............. 41

3-4 List of target specifications based on the identified requirements. .............................................. 41

4-1 Convergence for Von Mises stress: node 1. ................................................................. 51

4-2 Convergence for Von Mises stress: node 2. ................................................................. 51

5-1 Demographic information of the children in the database. ........................................ ...... 58

5-2 Relations between dimensions of adult feet. ........................................................................ 61

5-3 Relations between dimensions of children feet. ................................................................. 61

5-4 Relations between dimensions of SACH’s foot. ................................................................. 62

6-1 Convergence of Von Mises stress on node 1. ................................................................. 68

6-2 Convergence of Von Mises stress on node 2. ................................................................. 68

6-3 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. ...................................................... 72
List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3D scan</td>
<td>Tridimensional scanning</td>
</tr>
<tr>
<td>ABS</td>
<td>Acrylonitrile Butadiene Styrene</td>
</tr>
<tr>
<td>ABW</td>
<td>Anatomical Ball Width</td>
</tr>
<tr>
<td>AHW</td>
<td>Anatomical Heel Width</td>
</tr>
<tr>
<td>AM</td>
<td>Additive Manufacturing</td>
</tr>
<tr>
<td>CAD</td>
<td>Computer-Aided Design</td>
</tr>
<tr>
<td>CESR</td>
<td>Controlled Energy Storing and Returning foot</td>
</tr>
<tr>
<td>ESAR</td>
<td>Energy Storage And Return</td>
</tr>
<tr>
<td>FDM</td>
<td>Fused Deposition Modeling</td>
</tr>
<tr>
<td>FEA</td>
<td>Finite Element Analysis</td>
</tr>
<tr>
<td>FF</td>
<td>Foot flat</td>
</tr>
<tr>
<td>GRF</td>
<td>Ground reaction force</td>
</tr>
<tr>
<td>HS</td>
<td>Heel strike</td>
</tr>
<tr>
<td>IH</td>
<td>Instep Height</td>
</tr>
<tr>
<td>MTH1</td>
<td>Metatarsal Head 1</td>
</tr>
<tr>
<td>MTH5</td>
<td>Metatarsal Head 5</td>
</tr>
<tr>
<td>PLA</td>
<td>Polylactic Acid</td>
</tr>
<tr>
<td>SACH</td>
<td>Solid Ankle Cushioned Heel</td>
</tr>
<tr>
<td>SLS</td>
<td>Selective Laser Sintering</td>
</tr>
<tr>
<td>STL</td>
<td>Stereolithography</td>
</tr>
<tr>
<td>TBW</td>
<td>Technical Ball Width</td>
</tr>
<tr>
<td>THW</td>
<td>Technical Heel Width</td>
</tr>
<tr>
<td>TPU</td>
<td>Polyurethane</td>
</tr>
</tbody>
</table>
CHAPTER 1

Introduction

1-1 Motivation

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 (114).

The human body requires the existence of feet in order to provide stability and balance when standing or moving (23) (3) (89). Amputation of a foot significantly reduces amputees' ability to perform basic activities such as walking. The ability to walk, from one place to another, without depending on someone else to do it 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 (70) (97). Walking is not only a tool for movement but also a key feature in social and personal fulfilment (22) (71).

Limb amputation practice is one of the most ancient surgical procedures. It has been practiced for numerous reasons, from punishment to therapeutic reasons. Due to the profound implications of amputating a limb, for the patient and their family, the actual amputation is considered a last resort, used when the patient's life is endangered, or when the limb's salvage is impossible (80). The incidences of different pathologies leading to limb amputation have been reported to vary among countries and age of the individuals, as it will be further discussed in chapter 2. In the particular case of Portugal, information of incidence and prevalence is very scarce, however, several comparisons have been made between European countries and the US, and found to be similar, with the majority of the rates falling between 2 to 7 per 10,000 live births who suffer from congenital limb deformity (77) (55) (116) (86) (76).

Accordingly with the relevance of the ability to walk, artificial legs of one kind or another have been made and used since ancient times (26). The basic goal of an artificial limb (prosthesis) is to restore normal functions of a missing body part. Lower limb prosthetic fitting is recommended to begin when children go from crawling to standing, which happens between the ages of 9 and 16 months. The reason for this is to match as well as possible functional goals such as standing and the beginning of walking during the growth of the child (104) (83). Starting this procedure at this stage of the children's life is
1. Introduction

important to improve the acceptability of more complex prosthetic devices in the future (58).

When deciding on a general medical device, the cost of the device, a person's functional need, and the availability of a particular device should be considered (42). Recent studies indicate that emotional needs, together with body image, are essential determinants of an individual's willingness to accept the use of an assistive device, this being general all over the world, regardless of the wealth, age, or social status of the individual (44). Considering that in children self-image is still developing and that a series of ever-larger assistive devices will be needed as they grow, the emotional and aesthetic needs are even more important when designing any equipment to be used by them (44). As the foot prosthesis provides contact to the ground, it also has to provide shock absorption and stability during stance. Additionally, the foot influences the gait biomechanics by its shape and stiffness. The main concerns in current prosthetic feet for children are the dimensions and the constant need to acquire new matching sizes as they grow, the available aesthetics options, and the prosthetics capacity of helping a child learning to walk.

Considering the above-mentioned information, there is a need to develop personalized prosthetic feet for children of young ages. Personalized prosthetic foot construction requires several customization steps (131) (47), which makes these solutions commerically unappealing, expensive and scarce. Available technologies of tridimensional scanning (3D scan) and additive manufacturing (AM) started to offer the possibility of achieving personalized solutions with reduced production costs, time and intermediary steps (56) (87) (78). These technologies also allow digital storage of anatomical geometries, promoting their further use in other areas and applications (79).

1-2 Prostheses state of the art

Throughout history, mankind has always been subjected to accidents, injuries, diseases leading to amputations and birth malformations. Artificial limbs are a necessity not only to maintain subject’s autonomy but also for the psychological balance of the individual. There is evidence of the use of prostheses from as early as the XV century BC in an egyptian mummy (54). Prostheses started to be developed for function, aesthetics, and to provide a psychological sense of wholeness (27). Throughout history, major advances in technology and health care have occurred during wartime, for tactical reasons and for the care of the soldiers. It was specially after WWII, when many soldiers returned amputated, that people became more aware of the everyday issues faced by these men when attempting to lead a normal lifestyle (54) (27). The escalated number of amputees and increased awareness of people, forced the development of prosthetics to grow.

From heavy, immovable limbs to lighter and more functional limbs, prosthetics has come a long way (54). Today, modern materials such as plastics, carbon fiber, and strong but lightweight metals like titanium and aluminum are used, being water resistant and better able to withstand harsh environments when compared with their ancestors. All these materials are now widely used along with advanced designs, allowing the patient to expend less energy, have better stability, improved comfort and generally better performance (54). Technology development has increased the diversity of prosthetic components and fabrication techniques (107) (20) used in assisting people with limb loss (54).
All ages, genders and classes in our society are exposed to factors contributing to amputation. The child amputee, as a segment of the population and an important member at the incoming generation, should be totally rehabilitated (106). Superficially, amputations among children appear to be no different from those in adults. However, a child is a growing human with a progressively developing skeleton (57) (31) (27). When dealing with an amputated child it is necessary to be aware of, and plan in accordance with, the possibility that a lot of surgeries have to be made due to bone growth. Moreover, new prostheses have to be introduced with a relatively short period of time in between due to the fast growth of children, which also generates additional economic concerns (22) (44) (57) (27).

Amputation of a lower limb significantly reduces the ability to perform basic activities as standing and walking. People with lower-limb loss may need a prosthetic leg system with a knee, if they are above-knee amputees, or not, if they are below-knee amputees. Most use silicone liners for limb/prosthesis interface, and many also use sleeves to add comfort and improve performance of their leg system, but every lower-limb amputee needs a foot. The prosthetic foot not only provides contact to the ground but is also the base of support while standing, performing many daily life activities, including walking, indubitably influencing gait biomechanics. Lower limb fitting is recommended right from the early stages of growth, as mentioned above, so that children have an adequate base of support allowing them to stand, maintain orthostatism and allowing them to begin walking (104) (83). Early fitting also improves the acceptability of more complex prosthetic devices in the future (58).

Adult amputees have several available designs of prosthetic feet with a variety of materials, shapes, and functions, each device aimed at raising the 3C-level (control, comfort and cosmetics). However, an ideal design able to improve all three requirements was never fully obtained due to the inability of any design to single-handedly perform all the functions of sound limbs (107).

Prosthetic feet can be classified in three categories: bionic feet, passive feet and energy storage and return (ESAR) feet (117). The bionic foot is a contemporary, state of the art, prosthetic foot in which a powered ankle-foot prosthetic generates the required torques for the propulsion of the amputee (7). The ESAR foot devices are energetically efficient but do not provide the extra power needed for propulsion during walking (107) (128). In the passive prosthetic feet, the most commercially available feet, it is the remaining musculature of a patient that has to compensate for the absence of the propulsive ankle torques. This category excels in terms of its low weight, as the low weight of a prosthetic foot is crucial for reducing the burden on the remaining musculature of a patient (66). The main two methods to achieve a low weight of the prosthetic feet are structural optimization and selection of lightweight materials. The most used materials in prostheses are carbon and glass fiber reinforced composites, metal and plastic (92) (40) (107). The first two materials are able to store and return back energy to provide propulsion. However, they make the prostheses expensive. The performance of prosthetic feet differs with material properties such as density and elastic modulus (107). The most affordable prosthetic foot is the Solid Ankle Cushioned Heel (SACH) designed for patients with low activity level, like older people and young children. Nonetheless, it has minimal shock absorption and fails to return the required energy. Moreover, the stability that the SACH foot provides could be improved (131).

Children do not have as many options as adults do when it comes to prosthetic feet. Children’s feet
1. Introduction

are not solely miniatures of the feet of adults. The foot growth is not linear and simply scaling the foot of an adult will result in inaccurate feet proportions, unsuitable for children. With children, as with adults, aspects such as support, comfort, appearance and physiological needs should be weighed (53) (44).

Additive Manufacturing, also known as 3D printing, has been used in the manufacturing of prostheses and it has proved to be an alternative choice for moderate activity level amputees (107) (131). Additive Manufacturing and rapid prototyping are emerging techniques with a variety of medical applications such as surgical planning and training, implant design, biomedical research and medical education (88). In spite of its grow, rapid prototyping is not yet used in everyday clinical practice. However, in the fields of medical devices, particularly implants and prosthesis, it has great potential (88). The progress in three-dimensional-scanning technologies and computer-aided-design (CAD) programs offers the possibility of designing, printing and fitting low-cost customized prosthetics, with short production time (56) (108) (107) (88).

The most used additive manufacturing technologies are Fused Deposition Modeling (FDM) and Selective Laser Sintering (SLS). Although SLS is a professional and industrial 3D printing process, able to produce thousands of high-quality prints per week on uninterrupted production, it is expensive [1]. FDM 3D printers are the most affordable and are mostly oriented towards a moderate printing frequency. The concept behind FDM is very simple: a plastic filament is melted and positioned in a structured way, layer by layer. This made FDM the most popular 3D printing technology and flooded the market with inexpensive and relatively easy-to-use desktop 3D printers, able to create objects in a short lead time.

Producing prostheses with FDM technology brings several benefits. The geometric freedom of addictive technology makes it possible to maximize strength and minimize weight. These parameters are also controlled by the infill pattern and, with the right infill, energy storage can be improved (2) (109). The geometric freedom provided by 3D printing enables a large degree of customization, and makes it easier to meet the varying needs of the patients. Through this method one can create an optimal geometry for low-volume production or for individual customized prostheses (109).

Recently, Yap and Renda (131), Rochlitz and Pammer (90) and Tao et all (107) explored the potential of using 3D-print technology on the manufacture of passive prosthetic feet.

Yap and Renda, in 2015, designed and manufactured a 3D-printable foot prosthesis using PLA filament (131). Their research aimed to minimize the costs, so that the product can be printed and donated to patients of low-income countries. Later, Rochlitz and Pammer (90) found these results appealing. However, they considered that the low heat resistance of PLA might cause excessive deformation, hence it was not the most adequate material. In 2017, they presented an alternative foot using ABS for moderate activity level amputees. Also in 2017, Tao et all (107) considered that even though there were prosthetic feet made of PLA, as presented by Yap and Renda (131), they did not focus on the weight reduction. For this reason, they developed, 3D-printed and tested a low-cost ESAR foot with novel geometry using PLA plastic. Their design exploration and testing demonstrates how a low-cost 3D-printed prosthetic foot has a comparable, if not better, performance level as a SACH foot.

Although some progress is being made to design more affordable and customized prosthetic feet,

the focus has been in reducing their cost or weight, and not on the required adaptation to the children’s needs. Moreover, all the efforts are being directed to the design of the rigid internal part of the prosthetic foot and not to the external cosmetic component. Hence, patients are limited to the already existing covers that will be dovetailed to the rigid component or will have to pay for a hand-sculptured one, similar to the sound foot, which is extremely expensive.

There is a need to fill in the mentioned gaps. The purpose of this work is to design a personalized prosthetic foot for children of a young age. Not only the rigid part, but also the cosmetic component using a 3D scan, a CAD software and 3D print both components in only one print. The intention is not only to reduce the cost and time expended but also to provide children with customized options to satisfy their needs.

1-3 Objectives

The aim of this work is to present a novel methodology to design and develop a personalized prosthetic foot for 2-to-5-year-old lower limb amputee children, in order to improve the gait cycle of the amputee. To achieve this goal with reduced production costs, time and intermediary steps, technologies as 3D scan, CAD and AM are to be used.

The main ambition 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. The final prosthetic foot has two components: the cosmetic component, a flexible part to ensure the natural-aesthetic of the prosthetic foot; and the support component, which is rigid to be capable of supporting the forces and deformations during the daily activities of children, while allowing the pylon connection.

To proceed with this project, the first step of the developed methodology is to acquire the anatomical geometries of the patient, or amputee child, with a 3D scan. After geometry acquisition, the acquired mesh has to be simplified using Meshlab® and, with a CAD program - Siemens NX® - the mesh is manipulated in order to correct some 3D scan imperfections derived from the acquisition process. The design of the cosmetic component is complete at the end of this stage. In the case of a bilateral amputee child, a database of feet geometries had to be built in order to choose the right foot for each child using the help of the developed matlab® tool.

Once the cosmetic component is complete, it is possible to design the support component within the available space of the first one. This rigid component is modeled with NX® inside the cosmetic part, having in mind that it has to support the body weight of the child to allow for stability and that it has to help the gait cycle by absorbing energy from the heel-strike and stimulate the gait progression until push-off phase, facilitating the use of the mechanical knee.

Once the designs of both components are completed, the cosmetic and rigid component of the prosthetic foot, the next step is to manufacture the prosthesis using 3D printing technology with dual extruder to allow the use of two different materials. The chosen material for the cosmetic part is flexible and high-strength (FilaFlex) and the support part was produced with a rigid material (PLA).

To complete the project before it can be tested by an amputee child, a finite element analysis of
1. Introduction

the most relevant gait events (heel-strike, midstance, toes-off) is carried out to allow the identification of modifications needed on the CAD design. Finally, the physical test takes place with the child in the presence of the parents, physician, physiotherapist and prosthetist that provides important feedback to perform additional improvements.

1-4 Main contributions

This thesis was developed in Tecnico Lisboa, University of Lisbon in collaboration with Hospital Dona Estefânia.

The main contributes of this thesis are:

• Development of a methodology for the development of customized prosthetic feet for children with ages between 2 and 5 years-old;

• Development of a 3D scanning methodology to acquire children's feet geometries;

• Development of a CAD manipulation process to obtain a customized prosthetic foot;

• Construction of a database with 20 foot geometries of healthy children with ages between 2 and 5 years-old;

• Development of a Matlab® tool used to match the amputee child’s weight and height with the desired foot length suggesting a foot geometry from the database. The numerical tool also presents the scaling factor that has on be used to the chosen foot geometry to have a perfect match of foot dimensions;

• Design and manufacture of a customized prosthetic foot for a 5 year-old child able to improve her gait cycle events;

• Achieving of a 3D printed prosthetic foot solution for children with 3D printing technology using PLA and FilaFlex filaments.

Some of the contents of this thesis were presented in 8th National Congress of Biomechanics and in VII ABC AEICBAS Biomedical Congress, where it was awarded 3rd in the Scientific Competition Award Prize.

1-5 Structure and Organization


Chapter 1 begins with the motivation of the project, continues with the state of the art of prostheses, the concrete goals and contributions of this thesis, and ends with a summary of the work developed in this thesis.
Chapter 2 begins by covering the incidence, prevalence and causes of amputation in adults and children, from both developed and developing countries, as well as the general clinical procedure. This chapter is focused on the already existing prosthetic feet and their characteristics. It is also where the gait cycle and the foot anatomy are detailed.

In Chapter 3, product planning starts with the identification of an opportunity. Product development is also focused at the end of this chapter, starting with the identification of patients’ needs. This chapter ends by establishing the target specifications to be addressed in the following chapters.

Chapter 4 is focused on product development. It covers the manufacturing process of the prosthetic foot, from the chosen materials, to a step-by-step description of the process, including the reasons behind each choice involved.

In Chapter 5 a precision medicine approach is considered to the prosthetic foot development.

On Chapter 6 the proposed methodology is put in practice with a 5-years-old bi-lateral lower limb amputee girl.

Finally, in Chapter 7 conclusions of the developed work are presented. Future research developments in this field of study are suggested.
This chapter is designed to provide the reader with the essential background information needed to understand the discussions and explanations in the following chapters.

2-1 The amputation

Amputation is a surgical procedure consisting of the removal of a limb or other part of the human body (86). It is one of the most ancient surgical procedures, dating back for more than 2500 years. Since then until nowadays, amputations have been practiced for punitive, ritual and therapeutic reasons. Therapeutic reasons include trauma, peripheral vascular disease, tumor, diabetes, infection and congenital anomalies (62). Limb loss often has profound economic, social and psychological effects on the patient and their family, therefore, despite existing a list of reasons for an amputation, to actually amputate the limb is considered the last resort, used only when limb salvage is impossible, the limb is dead or dying, and compromising the normal functioning or the life of the patient (27) (80) (70) (116).

The incidences of different pathologies leading to limb amputation have been reported to vary across countries and across ages. In developed countries, peripheral vascular disease and diabetes are the first causes for amputation, the majority of amputee patients being more than 60 years-old. Whereas in developing countries, the amputee patients are younger and the common causes of amputation are trauma, uncontrolled diabetes mellitus and malignancies (63) (91). Young amputees in developed countries seem to have congenital limb deformity as the most common cause of amputation (16) (91). Post-burn contractures, iatrogenic and congenital limb deformity, on other hand, were the most common indications in children aged 10 years and below in developing countries (16).

Information about incidence or prevalence of lower limb amputation in the Portuguese population, as well as causes and age of amputation, is scarce or absent (116) (86) (76). However, Ephraim et al. examined rates from 1964 to 1993 regarding congenital limb deformity in US and European countries reported by different investigators, and found similarities on the rates of these countries. The majority of the reported rates fall within 2 to 7 per 10,000 live births. Not enough data is available for European
2. Lower Limb Amputation

countries in recent years. Although, as reference, in the United States, the Centers for Disease Control and Prevention estimate that there are approximately 2 per 10,000 live births every year affected with congenital lower limb deficiencies (77) (55).

A congenital limb deformity is when an arm or a leg does not develop normally during the gestation. This impairment is identified on a fetus mostly during the first trimester, which is the most critical pregnancy phase for limb formation (123). The exact causes of this malformations 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 (105) (67) (65) (34).

Regarding lower limb amputee children, the main focus of this thesis, it is recommended to start 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 the life of the children to allow them to have a good base of support while starting to stand, maintain their orthostatism and begin walking (104). Introducing the prosthesis early on the development of the child also improves the acceptability of more complex prosthetic devices in their future (58).

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 interacting with their peers without having to feel completely dependent or limited by their amputation.

2-1-1 Level of amputation

Prosthesis users are often differentiated by their level of amputation. In general terms, the longer the remaining limb and the more joints that are kept intact, the easier it is to fit and use a prosthesis for the amputee and the easier it is for them to adapt.

Elements such as the age, sex and general condition of the patient, available cosmetic fitting region, extensiveness and degree of damaged tissues, and the vascular supply of the limb are taken into account before surgery while deciding the level of amputation. However, it is not always possible to make the final decision before surgery as it may not be possible to determine all these factors prior to surgery.

Considering the level of amputation, the major categories of lower limb amputations are [1], as depicted in figure 2-1:

• **Foot Amputations** - Amputation of any part of the foot, where all the portions of the leg are saved, being beneficial if the problem is among the toes;

• **Transtibial Amputations** - Amputation occurs at any level from the knee to the ankle. It is a below knee amputation;

• **Knee Disarticulation** - Amputation occurs at the level of the knee joint;

2-1 The amputation

- **Transfemoral Amputations** - Amputation occurs at any level from the hip to knee joint. It is an above knee amputation;

- **Hip Disarticulation** - Amputation is at the hip joint with the entire thigh and lower portion of the leg being removed.

The more prevalent levels of amputation are Transfemoral and Transtibial (49).

![Figure 2-1: Main amputation levels.](image)

2-1-2 Clinical procedures

It is essential to have a proper surgical technique in order to, ultimately, reach a proper prosthetic fitting (78). Before surgery, a surgeon, a prosthetist, a physician specialized in physical medicine and rehabilitation and a physiotherapist should discuss the plans and goals with the children's parents. It is important that the parents and family are aware of what happens during and after surgery.

To increase muscle strength and flexibility, in order to allow the patient to learn how to perform more activities with and without prosthesis, some exercises are taught before and after the amputation. These exercises are also needed to help reduce the swelling and to prevent tissues in the residual limb to shorten, called contracture. The contracture stiffens the tissues and thus limits the range of motion of the surrounding joint, being, as a result, more difficult to use a prosthesis (121).

After surgery, the residual limb must heal before a prosthesis can be worn, and swelling of the limb must be reduced before a prosthesis can be fitted for long-term use. To reduce swelling, an elastic sock or bandage is applied over the residual limb, which also helps its shaping and prevents irregularities that can make fitting the interface difficult. The application of this elastic sock or bandage also increases circulation and makes pain less likely. How long it is worn varies from case to case (121).

Until the swelling is resolved, a temporary (preparatory) prosthesis can be used. This preparatory prosthesis is lightweight and easy-to-use. Therefore, some experts believe it helps people to learn how to use and interact with a prosthesis. Later, the long-term prosthesis, with higher-quality components is introduced. However, this approach is not common in Portugal nor among children, as it forces them to learn how to use two different prosthesis. An alternative approach is to use a prosthesis with permanent components (as the knee, or the foot) but with a temporary socket and frame. As some parts remain the same, this approach may enable the amputee to get used to the final prosthesis more quickly. In either
2. Lower Limb Amputation

case, since the residual limb changes in shape and size, the first socket and frame almost always need to be replaced within 4 to 6 months after the amputation.

Just like for the surgery, for the procedure of introducing a prosthesis, a multidisciplinary team composed by a wide range of experts must be included. These experts may include a rehabilitation physician, an orthopedic surgeon, a prosthetist and a physiotherapist, to help to achieve better results. Not every patient will need to contact with every member of the team. In order to take full advantage of the prosthesis, besides a good fitting in terms of the socket and a good alignment, it is also important to have a skilled training (1).

Training is usually continued and performed by the mentioned multidisciplinary team. A physiotherapist provides a program of gait training including exercises to improve strength, flexibility and cardiovascular fitness (74). It is also the physiotherapist that provides sufficient amount of independence by teaching the skills needed to perform daily activities, such as lower body hygiene and dressing, the use of stairs, walk up, down and on uneven surfaces (74). Then, the rehabilitation consists of specific exercises designed to strengthen the muscles and maintain their flexibility in the residual limb, as well as teaching the patient how to use the prosthesis for daily activities. The basics of using prosthesis, taught from the beginning of the entire procedure, are: how to put the prosthesis on; how to take it off; how to walk and stand with it; how to care for the skin of the residual limb and the prosthesis. This process is slower and more limited in people with above-knee amputation, older people and people with weak or low motivation to progress (124).

Due to the development of children, it is also important to consider bone growth, which can cause pain and injuries on the stump. For this reason, along the child's amputee life, several surgeries may have to be performed. Another preoccupation with child amputees, which does not concern adult amputees, is that the prosthesis has to be constantly adapted in accordance to their development and growth, so that their gait is correctly assisted and approximated to a normal gait as close as possible, without being constrained by having non-adequate prostheses during a specific stage of their growth, specially a stage where the gait itself is being developed (27).

2-2 Gait cycle

Human gait is the cyclic walking pattern of human locomotion. It is a result of various complex movements occurring in synchronization, beginning with the placement of one foot in front of the other, allowing the propulsion of the body forward, and ending when that same foot returns to the ground after being lifted during the stages of gait. Walking is thus a repetition of the gait cycle.

Humans begin walking from a very early age, when they develop the neural connections to activate specific groups of the leg muscles that aid in walking (28). It is necessary to understand a normal gait before analyzing pathological gait. Before further discussion, several terms and parameters related to human gait must be defined.
2-2-1 Step and stride

There are two important terms used to describe distances in relation to human gait: step and stride. The stride length is defined as the distance between two consecutive ground contacts of one of the feet. The step is the distance between two consecutive ground contacts of one foot and the other, as depicted in figure 2-2. This means that the stride is the sum of the left step and the right step, and in an ideal gait pattern these two are the same, although in reality they are never exactly the same. Determination of these distances is necessary in order to afterwards define walking speeds (126).

Figure 2-2: Step and stride (126).

2-2-2 Cadence and speed

As it exists for distance, there are a few important terms used to describe time events and speed in relation to the human gait. The cadence is the number of steps a person takes during a certain amount of time. A peculiarity of this variable is that since the common unit is steps per minute, it measures half cycles per unit of time, which is not considered to be scientifically acceptable. Another reason for not being scientifically acceptable is that for people with a normal gait, as mentioned above, but specially for people with a pathological gait, the left step and right step are not necessarily equal in distance. A better variable to use is the cycle time or stride time, which is the time it takes a person to move two steps, or one stride. Its relation with the cadence is:

$$ \text{cycle time (s)} = \frac{120}{\text{cadence (steps/minute)}} $$

(2-1)

The walking speed can be computed dividing the length of one stride by the cycle time:

$$ \text{speed (m/s)} = \frac{\text{stride length (m)}}{\text{cycle time (s)}} $$

(2-2)

2-2-3 Gait cycle and its events

As mentioned above, gait refers to a periodic motion that people exhibit to support and propel themselves. The gait cycle can be defined as a complete sequence, starting at the moment when one of the
2. Lower Limb Amputation

heels makes contact with the ground right until it makes contact with the ground again.

There is a simple way to divide the gait cycle, considering two periods for each leg: the stance and the swing period. The stance period is defined by the contact between the leg and the ground. This period begins when the heel strikes the ground and ends when the toe of the same foot leaves the ground. During the swing period, the foot is not in contact with the ground. When one foot is in swing phase, the other is at stance phase (127). The stance is about 60% of the total cycle and the swing phase is about 40% of the gait cycle. This indicates that there is an overlap between the stance periods of the 2 legs, and during 20% of the gait, both legs have ground contact which is called double limb support, as opposed to single limb support (125), as depicted in figure 2-3 adapted from [2].

![Figure 2-3: Normal gait cycle and nomenclature of each phase.](image.png)

The gait cycle can be further divided in 8 key phases, as represented in figure 2-3, 5 during stance phase and 3 during swing. During stance: the heel-strike, foot flat, midstance, heel-off and toes-off. During swing: acceleration, midswing and deceleration. A more detailed explanation of each phase can be found on Whittle’s book (126).

2-2-4 Ankle motion

Reference axes and anatomical terms of location for foot-ankle system are shown in figure 2-4. There are different terms to describe ankle rotations in the different planes. In the sagittal plane, the rotation which causes the toes to move upwards, closer to the leg, is called Dorsiflexion. The rotation in the other direction, downward towards the toes, is called Plantarflexion. The rotations in these planes are the most frequently used or referred to, since most of the kinematics is studied in this plane. A rotation in the frontal plane is called Inversion when the foot rotates towards the other foot, and Eversion when it rotates away from it. For rotations in the transverse plane the used terms are Adduction, when there is a rotation towards the other foot, and Abduction for the opposite rotation. The ankle joint does 93% of its work in the sagittal plane, during flat ground walking (129). The ability to move in the transverse and frontal planes through inversion/eversion, or abduction/adduction is a way to comply with uneven ground and enables a vast diversity of walking and standing strategies.

[2]https://www.researchgate.net/publication/316056514/figure/fig1/AS:482409037733892@1492026685832/Human-gait-cycle.png consulted in september, 2018
It is during stance phase, the phase of support, that the behaviour of prosthesis will matter the most. During stance phase, at the initial contact with the floor (heel-strike) the ankle is in neutral position. After this short period (2% of the gait cycle), the ankle is in plantarflexion in order to preserve the momentum generated by the body weight falling onto the stance limb. During single support, the tibia moves forward, forcing the foot to be in dorsiflexion and the heel and forefoot are in contact with the floor in a stable foot-flat posture. During double support, when the heel raises, only the forefoot is in contact with the floor. The ankle quickly moves from dorsiflexion to plantarflexion (11).

During the swing phase, at the beginning, the ankle is in plantarflexion and the tibia is behind the body (initial swing, 60% to 75% of the gait cycle). The midswing (75% to 87% of the gait cycle) is where, in the gait cycle, the ankle is in dorsiflexion to enable foot clearance while the terminal swing (87% to 100% of the gait cycle) enables the ankle to move in neutral position to prepare the initial contact with the floor (heel-strike) (11).

### 2-2-5 Ground reaction forces

The ground reaction force (GRF) is an important force in the gait cycle. The point of application of this force is underneath the contacting foot and it opposes body weight. Thus, the GRF influences the movement of the entire body during gait (11). During the stance phase of a normal gait, the GRF has a pattern with a double bump corresponding to two maxima, surpassing body weight with an intermediate minimum inferior at the body weight. The generation of the ground reaction forces occurs when the foot contacts the ground at heel-strike. At this instant, the body weight is quickly transferred to one leg and the foot and the leg act together as a shock absorber (11). Consequently, the impact force is followed by a loading response. During this period, the whole foot is in contact with the ground and the vertical GRF increases. This is when the first maximum, or peak, of the force is reached (F1 in figure 2-5). After this peak, the vertical force diminishes, which corresponds to the midstance phase (F2 in the figure 2-5). During midstance, the opposite foot is in the midswing phase, therefore the whole body weight is supported by the stance limb. At this phase, the foot and the leg provide a stable platform to enable the movement of the body. When the heel lifts away from the ground, the GRF starts to increase, ascending
2. Lower Limb Amputation

to the second peak (F3 in the figure 2-5), which corresponds to the beginning of the double support. Finally, the GRF patterns start to descend to zero with the pre-swing phase and drops to zero when the foot leaves the ground (11).

![Figure 2-5: Example of the vertical ground reaction force recorded during the stance phase of a normal gait cycle (10).](image)

2-2-6 Amputee’s gait

Studies showed that both unilateral transfemoral and transtibial amputees fitted with a prosthesis have asymmetry between the prosthetic and sound limb on their stance and swing phases of the gait cycle (46) (35). This asymmetry results in a discrepancy between the loading of the sound and amputated limb. Amputees experience a greater weight acceptance peak on their sound limb. Furthermore, the peak forces are higher than in normal gait. As walking speed increases, the peak force is also higher due to the increase in acceleration. Amputees often walk slower than regular individuals (35). The aforementioned asymmetry is present regardless of the speed of walking. Amputees tend to compensate with their stride length rather than step rate (46). This means that the amputee spends more time on their sound leg than on the leg that has the prosthesis (41). It has been suggested that the prolonged swing phase of the prosthesis forces a slower cadence and, therefore, a slower walking speed (95). Since children rely on a fast cadence to obtain an adequate walking speed, a prolonged swing phase can be a major obstacle to a comfortable and efficient normal-speed walking.

Unilateral transfemoral amputees expend more energy than unilateral transtibial amputees or healthy subjects (43) (12). This shows that there is a correlation between the energy expenditure and the number of joints that were lost. This functional loss is due to the missing joints, or degrees of freedom, in the amputated leg. To equalize the functional losses, the body has to work harder. In this case, it is the intact leg that experiences an increase in joint force moments and has to expend more energy (73). There are also residual stresses that are experienced in the stump, resulting in discomfort while walking (94). The stresses in the residual stump are a bi-product of asymmetric reaction forces and moments (94).
2-3 Foot development

A child’s foot changes its shape and proportions during growth so that it adapts to function (30). Age, gender and body mass index (BMI) affect the maturation of a child’s foot.

The growth process is based on bone changes. Bone maturation includes changes of form as well as hardening processes (30) (38) (39). The child’s foot is constantly growing and solidifying its structure and form. The complete ossification of the feet occurs throughout the first ten years of life and the closure occurs at the end of the growth of a person, between the ages of 15 to 21 years (24).

The foot grows most rapidly between the second and third year, up to 1.8 cm in girls and 1.6 cm in boys. The foot achieves two thirds of its final length at the end of this period (119). From 3 to 6 years old, the foot grows approximately 1 cm per year, and the slowest growth occurs in girls between the sixth and seventh year (120). In the period between five to twelve years old, the increasing length comprises about 0.8 to 1 cm per year (4) (18). During this period, differences in foot length according to sex are already visible, where boy's feet are on average 2 mm longer than the feet of girls (30). After the age of twelve, the gender differences become more obvious. The ratio between foot length and body height is about 16% in boys and 15.7% in girls (30).

The arch of the foot enables it to adapt to the ground surface in different positions and to absorb shock during walking and standing. Its development is conditioned by internal factors such as genetic disposition and gender, as well as external factors such as body weight, physical activity and footwear (52) (64). For instance, Mickie et al. (69) found that boys have statistically significant thicker fat pads than girls (68) (69). The authors also found that the fat pad is still present at the age of five. Therefore, flat feet are considered as a physiological transitional phase in pediatric development, and their prevalence diminishes with increasing age (9) (81).

2-3-1 Foot dimensions and foot types

There are different ways to characterize the type of foot. One way is to consider the shapes of the forefoot, toe length and the relative proportion among the toes: Egyptian, Square and Greek. In the Egyptian type, the great toe is the largest, followed by each of the lesser toes. The great toe is shorter than the second toe in the Greek foot shape, while in the square foot shape all toes are practically in line. This terminology is mostly used within adults (31) while, in children, the foot dimensions are determined considering the dimensions described below, in figure 2-6. Nonetheless, in children, the Egyptian foot type is the most common, followed by the Greek type, and very rarely the square type.

The most common measurement of foot is the foot length. Different width measurements are presented in figure 2-6.

There are other types of measurements that provide information about the volume of the foot. Among them is the instep height, which is commonly measured at 50% of the foot length, as represented in figure 2-7. During foot development, the longitudinal arch also suffers alterations.

Among children, studies made in Germany have identified five types of feet: flat, robust, slender, short and long feet (60) (30).
2. Lower Limb Amputation

Figure 2-6: Common foot width measurements. ABW - Anatomical Ball Width, the width between Metatarsal Head 1 (MTH1) and Metatarsal Head 5 (MTH5); TBW - Technical Ball Width; AHW - Anatomical Heel Width; and THW - Technical Heel Width. Adapted from (30).

Figure 2-7: Common foot height measurement. IH - Instep Height. Adapted from (30).

Flat feet: This foot type is mainly characterized by its flattened medial longitudinal arch, or small arch angle; the volume and length proportions show medium characteristics;

Slender feet: Feet in this cluster are characterized by their very small volume, which means they have narrow ball and heel widths and a low dorsal arch height. In addition, they display long toes and a relatively high arch;

Robust feet: In contrast to slender feet, this foot type has a fairly large volume and rather short toes with an average arch;

Short feet: This cluster represents a foot type with a short hind foot proportion and a long forefoot. Compared to other clusters, it displays a relatively high arch and a rather high volume;

Long: The feet in this cluster are characterized by a long hind foot proportion and short toes. Regarding volume and arch, these feet present medium characteristics.

2-3-2 Foot types in different age groups

Fritz (30) studied the distribution of the five feet types in different age groups, as depicted in figure 2-8, so to understand the development of the foot of children. A large percentage of two-year-old children show Flat Feet. It is shown that the proportion of children with Flat Feet decreases with age. At the same time there are more Robust Feet in young children, while Slender Feet are increasingly found in
older children. There are hardly any Long Feet until the age of five, but a noticeable increase of this foot type occurs from the ages seven to thirteen.

![Distribution of foot types within different age groups](image.png)

**Figure 2-8**: Distribution of foot types within different age groups (30).

### 2-3-3 Influence of gender on foot types

Kouchi (52) reported that, in general, foot dimensions of boys may change until the ages of 18 to 21 years, while girls have their feet unchanged from around the age of 13 years.

Other studies examined the development of the longitudinal arch of children’s feet, and observed that the arch height increases with increasing age - in girls more than in boys. In Fritz study (30), it was stated that, in fact, a higher proportion of flat and robust feet is observed in boys. Girls show a higher proportion of slender feet, particularly starting around the age of six years. However, the differences between boys and girls are only more evidenced after the age of twelve years-old.

### 2-3-4 Influence of body composition on foot types

Several studies show that obese children have a flatter feet characteristic as well as an increased mechanical loading in plantar pressures (68). In addition, larger foot dimensions were found to be a result of increased body mass in terms of broader, taller and thicker feet, when compared to normal-weight counterparts.

### 2-4 Prostheses

According to Black's Medical Dictionary (115), a prosthesis is an artificial replacement of a missing or malfunctioning body part. Prosthetics have been mentioned throughout history. The Egyptians were early pioneers of the idea. As early as the fifteenth century BC, it was found a wooden foot toe on a
2. Lower Limb Amputation

body from the New Kingdom[3].

In the 15th century, there were not many prosthetic alternatives available to the amputee besides basic peg legs and hand hooks. However, even those where only afforded by rich people (75) (14).

From 1600 to the late part of the eighteenth century, great improvements of the prosthetic and surgical principles happened. The invention of the tourniquet, anesthesia, and disease fighting drugs brought medicine to the modern era, but also made amputation an accepted curative measure rather than a last ditch effort to save life (54). With the emergence of anesthesia, the surgeon gained time to make residual limbs more functional, and therefore allowed the prosthetist to make better prostheses (75). The chosen materials to manufacture prostheses during the Renaissance period (1400 to 1800) were iron, steel, cooper and wood. Only in the late part of the nineteenth century was suggested aluminum, instead of steel, in order to obtain a lighter and more functional device.

Artificial limbs started to be mass-produced in response to the enormous number of casualties in World War One, so as to allow amputees to return to work and live a regular life after the war. By this time, these functional prostheses were still by no means comfortable to wear, but the user was much more mobile and independent with the use of such a device (75) (14). Prosthetics has come a long way since those first heavy and almost immovable artificial limbs, to the lighter and more functional artificial limbs of today. With the development of prostheses, the materials used also evolved. Today, the most used materials to produce prostheses are plastic, carbon fiber, and strong but lightweight metals such as titanium and aluminum (75).

Lower-extremity prostheses have undergone progressive development and large numbers of prostheses have been invented over the course of history in an attempt to overcome loss of support, energy, sensibility, and cosmetic value (75).

2.4.1 Prostheses development

The peg leg is known to be the first lower limb prosthesis to be implemented (75). However, the peg leg user was unable to walk properly. On one hand, if the prosthesis was long enough to match the uninjured leg (and shoe), the wearer had troubles with clearing the ground during the swing phase. This would be accomplished either by vaulting (by excessive plantarflexion of the sound foot), or by swinging the peg to the side in a clumsy circumduction gait (75). On the other hand, if the prosthetics were short enough to permit swing-through in the line of progression, a limp in the prosthetic stance phase was the result (75) (14). In order to correct these existing problems, an “L”-shaped rigid extension, simulating a foot, was added. The addition not only increased the base of support during standing but also provided support against buckling the knee during the middle and latter parts of the stance phase.

There are, however, some implications on the gait cycle that result from adding a rigid foot to a prosthesis for above-knee amputation. Firstly, the foot blocks the possibility of dorsiflexion, causing the heel to rise and the floor reaction to shift forward to the ball of the foot in the middle stance, usefully prolonging knee stability. Secondly, the absence of dorsiflexion requires considerable knee flexion (or circumduction or hip elevation) to give toe clearance early in swing phase. Thirdly, at heel contact, lack

[3] https://science.howstuffworks.com/prosthetic-limb1.htm consulted in September, 2018
of plantar flexion or equivalent may cause the knee to buckle. Lastly, plantarflexion immediately after heel contact allows the knee to remain stable.

To overcome the remaining problems, the prosthetic foot needed to be re-invented, so that the amputee can roll over the foot during the gait cycle, restoring basic walking and occupational tasks (75) (14) (117). An early example of a flexible foot-ankle unit is the solid rubber foot, where rubber is molded over a wood core. Due to the flexibility of rubber, this foot is useful where water, sand or dust are encountered. However, curving up the barefoot and toes during the forward shift of the weight, comparable to dorsiflexion action, may be an excessive movement for the prosthesis, failing to provide adequate support for push-off. Still, the resistance to plantarflexion is too high unless a hollow space in the heel is introduced to provide a soft air cushion, or unless the solid rubber heel is replaced by a wedge of sponge rubber. Another important fact to consider is that the solid rubber foot tends to be rather heavy.

2-4-2 Prosthetic systems

Transfemoral prostheses are more complex than transtibial ones considering that the first require an additional mechanism to replace the knee. However, most of the terminology for transtibial prosthesis also applies to transfemoral prostheses, as they both have to include a prosthetic foot. 80% of the lower limb amputees are transtibial amputees (100). There are two general classifications of prosthetic systems, endoskeletal and exoskeletal, as shown in figure 2-9. The three main components of a prosthesis are: the socket, which interfaces with the residual limb, the foot and the shank connecting the foot to the socket (pylon for an endoskeletal shank or an enclosure for an exoskeletal shank). In addition to the fitting of the custom-made socket, the alignment between the foot and the socket must be adjusted to ensure the best performance and comfort of the entire system (59). The sockets have to be tight around the residual stump to avoid slipping, which causes additional discomfort to the amputee due to sweat and friction, and can result in skin sores and other dermatological complications (25). The comfort of the prosthesis is mainly influenced by the socket fit while the biomechanical functions are ensured by the foot design and the used knee, if it is a transfemoral prosthesis (59).

Figure 2-9: Endoskeletal transtibial prosthetic systems (left) and Exoskeletal transtibial prosthetic systems (right). Three of the four components are shown: a socket, pylon and prosthetic foot (99).

Lower limb amputees have reduced muscle function, neural response and bone structure, resulting in altered gait patterns and requiring, naturally, more effort to walk (122). Ideally, the prosthetic foot should compensate for the musculature and bone structure loss and enable the person to engage in daily activities with little effort.
2. Lower Limb Amputation

2-4-2-1 Foot and pylon integration

For the integration between the prosthetic foot and the pylon, a pyramid adapter is used. There are different designs for the interaction of this component with the foot. However, all of them have the same structure of interaction with the pylon using a pyramid shape interface. The most used materials are aluminum, titanium and stainless steel. Most of these adapters are made for SACH prosthetic feet since modern prosthetic feet have an already integrated pyramid adapter. Some examples of this type of adapter are presented in figure 2-10.

![Figure 2-10: Different types of pyramid adapters available, with the same geometry for the integration with the pylon of the prosthesis. (a) SACH foot adapter, Tiger paw by Bulldog® made of titanium; (b) SACH foot adapter by Ossur® made of aluminum; (c) MightyMite® SACH Foot Pyramid by Fillauer® made of titanium; (d) Foot Pyramid by Medex® with two models. One made of Stainless Steel and other made of Titan; (e) Foot pyramid adapter by Trulife® made of Aluminum. Provide a safe and cost-effective alternative to titanium; (f) Bulldog prosthetic foot leg standard pyramid adapter with 4 pyramid holes and a center hole, made of titanium.]

2-4-3 Prosthetic foot options

Designing prosthetic foot systems is challenging. To end up with a correctly made functional foot, a very careful quality control during manufacture is essential, otherwise the durability of the foot may be compromised, which can culminate in a foot that lasts only a few cycles of utilization (75). It is very difficult to reproduce the complex function of the human foot and ankle. Ideally, the foot will be light because its weight is added to the rest of the leg prosthesis. A good prosthetic foot should also be strong, as it will be loaded with large forces and torques while the amputee walks and runs (90). The rigid component of the foot must also be small enough to fit within a foot shell, a cosmetic covering of the prosthetic foot, thus fitting within a shoe (89). Being light, strong, and small, and yet functional and durable is the challenge.

Two different approaches (passive and active) have been used to design prostheses. Most of the commercially available prostheses are passive devices. Passive devices use the energy provided by the amputee himself to mimic the behavior of a sound foot and are less costly and easier to use. However it is possible to insert energy into the system through an external source. Prostheses that use that external source are named active prosthesis and use motors (pneumatic or electric) to generate the torque required for the propulsion and ankle motion. Studies have shown that these prostheses improve gait performance and enable users to walk at a lower metabolic cost when compared to passive feet (6)
However, these prostheses require daily battery charging, are much heavier, less robust, fragile, not waterproof, extremely complex to fabricate and maintain and are very expensive, compared to passive devices. They can cost tens of thousands of dollars (7). Passive devices are more affordable and can be purchased for several thousand dollars in the developed world and tens of dollars in the developing world (61). Passive prosthetic feet are usually composed of passive components such as springs, dampers, or compliant structures of various forms.

Since this work focuses on children and inexpensive solutions, passive prosthetic feet options were analyzed. Passive prosthetic feet can generally be placed into one of the three following categories: conventional feet, single and multi-axis feet, and ESAR feet (36). There are single unit designs, where the keel is incorporated into the rest of the foot, and other designs, where the cover is a separate component into which the keel is inserted; this allows for the cover to be replaced when needed, while using the same keel (99).

2-4-3-1 Convencional prosthetic feet

The most common conventional prosthetic foot is the solid ankle cushioned heel (SACH) foot which, for years, has been the industry’s standard (32). The first SACH foot was designed in California in the 1950’s. SACH foot, figure 2-11, consists of a central rigid keel bolted to the shank and extends from the ankle region through the instep to the ball of the foot. A wedge of layers of relatively soft sponge rubber, installed in the heel region provides adequate stiffness for balance in standing but at heel contact allows compression simulating plantarflexion after the initial contact to provide shock absorption. Lamination of the sponge rubber permits control of the stiffness. The Solid Ankle refers to the fact that the ankle joint does not rotate, and the core of the prosthesis is a rigid wooden keel. The rigid wooden keel provides midstance stability but little lateral movement (75) (98) (102) being designed to provide base stability and rigidity. The cushioned rubber heel absorbs shock at impact and the belting allows for bending of the foot to mimic human ankle deflection. The density of the heel is an important design property. Belting is usually made of metal or plastic and it determines the resistance of dorsiflexion by its length extended from the ankle. SACH foot has the described interior surrounded by a plastic cosmetic shell that protects the keel from the environment and gives the prosthesis an appearance similar to a human foot as represented in figure 2-12.

SACH foot simulates plantarflexion at heel-strike by compression of the cushioned heel and provides dorsiflexion by the flexible belting. The SACH foot has a very simple construction with no moving parts, which makes it easy to replace and maintain (96).

SACH is the simplest type of non-articulated foot. Despite being a non-articulated foot, the SACH foot remains a popular prosthetic device especially among individuals with lower activity level, and in low income countries because it is inexpensive, light and robust due to the lack of rotating mechanical parts (98) (102). However, it limits the movements and actions of the amputee (it provides no lateral movement) as these rigid designs have limited shock attenuation, do not store and return energy during gait, thereby increasing the effort required by the user to walk, nor do they deform under normal loading, as a human foot does (5) (33). Users are typically restricted to indoor walking or very limited outdoor
2. Lower Limb Amputation

activity. The price of the SACH foot usually goes from ten to a hundred dollars (61).

![Schematic of a SACH foot internal structure](image)

**Figure 2-11:** Schematic of a SACH foot internal structure, with a rigid keel, foam heel and plastic covering (99).

![SACH appearance with cosmetic shell](image)

**Figure 2-12:** SACH appearance with cosmetic shell.

2-4-3-2 Single and Multi-Axis feet

The single-axis foot is the second most popular prosthetic foot (33) and is represented in figure 2-13. This prosthesis has a single rotating mechanical component in the ankle with two bumpers at both sides of the joint, allowing the foot to flex up or down and limit its rotation. This prosthesis is heavier than the SACH foot, and due to the rotating mechanical components, it needs maintenance more often. However, due to the presence of the two bumpers, this type of prosthesis is more suitable for uneven terrain and provides more stability (117) (33). Studies show that, when the temporal distribution of the stride for both prostheses is compared, the time between HS and FF is bigger when using the SACH foot, which provides a roll-over, which is more comfortable (5) (33). Like the SACH foot, the single-axis foot does not store and return energy during gait, thus requiring some additional effort by the user to walk.

![Schematic of a single-axis prosthetic foot](image)

**Figure 2-13:** Schematic of a single-axis prosthetic foot (left) and a single axis foot from College Park (right).

The multi-axis foot, represented in figure 2-14, although similar to the single-axis foot in terms of weight, durability and cost, performs better on uneven surfaces. In addition to the up and down mobility of the single-axis foot, a multi-axis foot can also move from side to side. Since the added ankle motion absorbs some of the stresses of walking, both the skin and the prosthesis are protected from wear.
2-4-3-3 Energy Storage and Return Feet

Driven by the higher demands and needs of amputees, as jumping, running, practicing sports, varying the walking speed, quickly changing directions or walking long distances, among several others, the prosthetic feet have been improved over time. Energy storage and return (ESAR) feet store energy during stance, like a spring, and return it as propulsion in late stance (117). The energy is absorbed in the keel during the “roll-over” phase and then springed back to provide a subjective sense of toes-off for the wearer. Because the toes-off is improved, moving forward is made easier for the amputee (117). Some (ESAR) feet feature a split-toe design that increases further the stability, by mimicking the inversion/eversion movements of the human ankle and foot. People with an active lifestyle prefer these lightweight feet since they provide a more dynamic response (51). Generally, ESAR feet consist of a carbon fiber leaf spring, requiring less maintenance but lacking stability and costing several thousands of dollars (61). The Seattle foot (5) (36) was developed in Washington in 1981 and was the first foot of this type to be designed. The Seattle foot incorporates a flexible keel inside a shell of polyurethane, as represented in figure 2-15 A. The flexible keel replaces the typically used elastic springs to return part of the stored energy later in the gait. There are many prosthetic feet with different designs following a similar strategy. Each model utilized some variation of a compressible heel. Some examples are shown in figure 2-15.

![Figure 2-15](image)

Figure 2-15: Early ESAR prostheses: A. Seattle foot B. Dynamic foot C. STEN foot D. SAFE foot E. Carbon Copy foot.

As mentioned, the first ESAR, or Seattle foot, returns a portion of the input work provided by the weight of the body by loading the "spring" into compression and returning the energy back to the system on a later gait phase. However, the energy lost in the system as a result of friction remains high, being dissipated in the form of heat and sound.

Better knowledge and understanding of the human gait and biomechanics, combined with the development of new (composite) materials, such as carbon fiber composites, and the evolution of Computer Aided Design (CAD), led to the development of new types of ESAR prostheses.
2. Lower Limb Amputation

In 1987, the Flex-foot, represented in figure 2-15, a totally different type of ESAR foot, was designed. This prosthetic foot is made of a flexible carbon-fiber composite material and has better biomechanical properties than the early ESAR-feet. This new concept differs from others as it allows the entire prosthesis, rather than solely the foot part, to flex, store and return energy (37). The use of carbon fiber composites reduces both the energy losses and the weight of the prostheses, which gives Flex-foot a significant advantage (78). All the models, represented on figure 2-16, offer significant advantages when compared to the conventional SACH prosthetic foot. The heel spring of the Flex-Foot system acts like a compressible foam, providing a good energy storage and return. It is compressed and stores energy in the early stance and slowly releases the stored energy as the foot moves forward. As the heel stiffness increases, the duration of the shock absorption decreases and less energy is wasted. Some latest designs of Flex-Foot add additional springs or dampers along the shank, which allows multi-axis movement and superb shock absorption. A more comfortable and responsive feel to the user is provided with this design (96).

![Figure 2-16: ESAR prostheses: (a) Ossur Flex-foot Modular III, (b) Ossur Flex-foot Variflex, (c) Otto Bock Springlite Foot, (d) Ossur Flex-foot Talux (32).](image)

Rather than storing energy during stance and then releasing it in late stance, it is also possible to use the weight of the body on initial contact to store energy and release it later in the stance to provide a better push-off. The Controlled Energy Storing and Returning foot (CESR foot), represented in figure 2-17, was developed at the university of Delft and is based on this principle. This prosthetic foot has a rotating joint in the middle of the foot which locks after heel-strike. During heel-strike, a spring in the heel is compressed and the energy in this spring is released during toes-off when the rotating joint unlocks (19).

Although current passive prostheses try to mimic the energy storage and return observed in human ankles, still none of the commercially available prostheses can provide an adequate amount of energy needed for the forward propulsion during push-off. Below-knee amputees with prosthetic devices still need to expend 20% to 30% more energy than people without any movement constraint to walk at the same speed (8). However, active prostheses are being developed to address this problem.
2-4 Prostheses

2-4-3-4 Solutions developed for low-income countries

Low-income countries, such as India, imported the SACH foot from America and Germany and, although it was the cheapest foot available, it did not fit the needs of the Indian population (84) (98). The foot, due to its rigid internal structure, did not adjust to the common Indian, who would walk barefoot, sit cross-legged, squat and work on uneven land. As an answer to these constraints, the Jaipur foot is a prosthetic foot, invented in 1968 in Jaipur in India, and is now a world leader in low cost foot prosthesis. The prosthetic foot that was created specifically to Indians found a place in many low-income countries of the world and is known for helping people in underprivileged and downtrodden countries ravaged by war, terrorism and disease (20) (72). The Jaipur foot represented in figure 2-18 is more flexible, it has a wooden ankle and a combination of two different types of rubber. This foot costs around $8 to fabricate and the entire fitting process costs $30, and can be fabricated in less than 3 hours (13). Its biomechanical characteristics can be compared with SACH and Seattle feet (5).

Even though improvements to Jaipur foot are being made and some kids are fond of some activities that it allows, its characteristics are not appropriate for the reality we are in as a developed country (72) (78).

The Niagara foot, represented in figure 2-19 was developed for low-income countries in 2002 and is a very simple, inexpensive, practical and sturdy foot, made from a single piece of Delrin plastic molded to the shape of a normal human foot. The shape of this foot was designed to provide energy return. However, although weight and energy expenditure are not an issue, the cosmetic appeal of the foot, the non-ability to wear shoes and the lack of stability during gait due to irregular motion, made this foot not
2. Lower Limb Amputation

very popular (103). Years after, a plan for a low-cost artificial leg, designed by Sébastien Dubois, was featured at the 2007 international Design Exhibition and award show in Copenhagen, Denmark, where it won an award. It would be able to create an energy-return prosthetic leg and being composed primarily of fiberglass. In 2014, the ‘Shape & Roll’ prosthetic foot (patent pending), represented in figure 2-20, was designed. This low-cost prosthetic foot intends to be simple to fabricate, is light and highly functional for walking, in terms of mimicking sound roll-over characteristics (92). With the introduction of 3D printing technology, in 2015, Yap and Renda (131), hoping to reduce production costs and send feet prosthesis to low-income countries, presented a foot prosthesis using PLA filament on the Design4Health congress in Australia, figure 2-21. In 2017, Rochlitz and Pammer (90) proposed the use of ABS plastic on a similar geometry and, also in 2017, Tao et al (107) designed a prosthetic foot with a novel geometry using PLA plastic. Their studies revealed good comparisons between those 3D printed prosthetic feet and SACH feet, which is a motivating starting point for the present work.

![Figure 2-19: Niagara prosthetic foot (103).](image1)

![Figure 2-20: Shape & Roll prosthetic foot (92).](image2)

![Figure 2-21: Jonathan Yap and Gianni Renda prosthetic foot (131).](image3)

2-4-3-5 Prosthetic feet for children

The currently available prosthetic feet for children are presented below. As there are few studies focused on children, only the known facts about the prosthetic feet are described.
The most used foot for amputee children is the SACH foot, figure 2.22(a), which is available from 14 to 21 centimeters. For younger children, the most important feature of the prosthetic foot is the stability. For them, the 1S30 SACH foot, represented in figure 2.22(b), is available with 12 and 13 centimeters. However, this foot does not have a good cosmetic appearance. The SACH foot is one of the most popular prosthe...
2. Lower Limb Amputation

Figure 2-25: RUSH Kid prosthetic foot from RUSH®, USA, ESAR prosthetic foot.

Figure 2-26: Tuper foot by College Park®, USA, single-axis prosthetic foot.

centimeters and are ESAR prosthetic feet. The carbon heel of these prosthetic feet absorbs shock loads and stores energy returning it later on the gait.

Figure 2-27: Flex Foot (left) and Vari Flex (right), by Ossur®, are ESAR prosthetic feet.

Willow Wood® is another American company with two prosthetic feet, Pediatric SACH foot and Pediatric Impulse foot, both represented in figure 2-28, being both ESAR prosthetic feet. Pediatric SACH foot is available from 9 to 22 centimeters and Pediatric impulse foot is available from 13 to 22 centimeters.

Fillauer® and Kingsley® are two USA companies with prosthetic feet for children. Fillauer® has the MightyMite available from 14 to 21 centimeters. Kingsley® has Kingsley Juvenile SACH foot available from 10 to 22 centimeters. Both feet are SACH feet and are represented in figure 2-29.

In Portugal however, and in most European countries, the most commonly used solution for children is the SACH foot. The reasons behind the choice of SACH foot are its accessibility and its low cost, stability and availability. In Europe, the most used brands are Ossur® and Ottobock®, since they are based in Europe. There are less options in the European context than in North America. American brands are usually avoided when choosing a prosthetic foot since the time and money wasted in the expedition adds to the actual price of the prosthetic foot.

As previously mentioned, information about incidence or prevalence of lower limb amputation among children in the Portuguese, or other European countries, population is scarce or absent (116) (76). However, previous studies indicate that US and European rates of congenital limb deformity, the major cause of amputation among children in developing countries, were similar (55). Recent data from the USA, coming from the Centers for Disease Control and Prevention, estimates that there are approximately 2
per 10,000 live births each year affected with congenital lower limb deficiencies \[5\].

There is very little information published about pediatric prosthetic orthotic care and solutions. This is an area that needs to be more adequately addressed as children are an important segment of the population (21).
2. Lower Limb Amputation
This chapter is focused on product planning. For a proper product development, it is essential to begin with the product planning process to identify an opportunity and to take into consideration the available technologies and resources. It is on top of this product planning that the product development effectively begins.

3-1 Opportunity identification

In the context of product development, an opportunity is an idea for a new product. A new product can rise to fulfill a new need, it can rise due to the discovery of a new technology or a rough match between a need and a possible solution (113).

It was during a conversation with Dr. Maria José, a physician specialized in physical medicine and rehabilitation in Dona Estefânia Hospital, Lisbon, that an opportunity was identified. Doctor Maria José enlightened us about the fact that younger and smaller children have fewer choices in prosthetic components, since they do not weigh as much and are not as strong as amputee adults. In fact, nowadays, the cheapest and most-used prosthetic foot among children in Europe with the smallest dimensions is SACH 1K30 foot, from Ottobock®️, which is 14 centimeters long. It is essential for the development of children that they are fitted with a prosthesis and begin physical therapy in the early stages of their development, especially when they go from crawling to standing, in order to facilitate their habituation and adaptation. Nevertheless, children go from crawling to standing from 9 to 16 months old which, as seen in table 3-1, corresponds to a foot length of 11 centimeters, less than the 14 centimeters prosthetic foot offered by Ottobock®️. Hence, limb impaired children are currently confined to using a foot prosthesis that is bigger than their physiologically proportional foot during these early stages of their development. This makes walking harder as it will be more difficult to maintain balance during the 60% of the gait cycle that corresponds to stance phase. Moreover, the prosthetic SACH foot is too stiff to help the child to properly learn how to walk.

Several interviews with the physician, physiotherapist and prosthetists, among other stakeholders
were made, as well as some research, in order to better understand the logistics behind the implementation process of a prosthesis, and to empathize with real cases that catalyze creativity in order to find a solution for these young children.

In Portugal's public health care system, the state covers the majority or all the costs related with the implementation of a prosthesis, previously chosen through a national bid. In this bid, several prosthetic stores compete among themselves to present a prosthesis to be set as the one that the state covers. This process, which includes the prescription from a doctor, the bid and the choice of the prosthesis to be covered by the state can take up to one year. The cheapest prosthetic solution proposed by orthopedic stores is usually the chosen one. If any modification is wanted by the children or parents, it has to be all paid by them without the help of the state.

When prescribing prosthetic components, a number of factors related to the needs and abilities of the individual are involved. These factors include: the level of amputation, the condition of the remaining limb, age, the activity level and specific goals and needs. In fact, prosthesis function can vary from purely aesthetic to a functional necessity for a patient to retrieve independence in performing daily life activities and, in the case of children, physiological development (117). For example, for a child, a soft prosthetic foot is important or else a lot of forces are experienced in the stub. Active children get too tired from using the SACH foot, since it is too stiff and it does not have energy restitution during gait. Combining all these characteristics presents an engineering challenge since there is not one (apparent) design that adequately fulfills all needs to their fullest. For the prosthetist to know the specifications to order the prosthesis, it is important to collect the weight of the amputee, their foot size, psycho-socially acceptance, acceptable price and durability needs or even how quick turns, fast movements and varying terrain exist on their day-to-day life (44) (20) (93).

Amputee children have to attend regular appointments with a physiotherapist who is specialized in the developmental stages of children. It is recommended that an amputee child is evaluated by their physician every three to six months. If the prosthesis is not adjusted to accommodate the child’s growth,
causing rubbing, sores or pain, a new socket or other prosthetic modifications may be necessary. Due to the fast-paced growth of children, until they turn eighteen, prosthetic components need to be renewed at least once a year.

3-2 Available technologies

The identified need for the creation of a new, cheap and more functional prosthetic foot to be integrated in lower limb prosthesis in the children category indicates that technologies such as 3D scan and AM may be used to help achieving that purpose.

On one hand, modern 3D surface scanning systems allows obtaining repeatable digital representations of the foot shape with high precision, accuracy and robustness, being successfully used in medical, ergonomic and footwear development applications (108) (56). For the development of this thesis, access to a 3D scan system, Shining3D EinScan Pro®, was provided.

On the other hand, the foot prosthetic industry has been dominated by steady, small improvements in performance, comfort, and marketability due to the expenses involved with metal molds, which have a high cost due to the metal processing, unless it is a large scale process, which interferes with customization purposes. With additive manufacture, it is possible to generate a single product without the need of expensive tools and molds, which can drastically reduce the costs. Access to 3D printing machines (Raise Pro2® and BCN3D Sigma®) was provided for the development of this thesis.

3-2-1 3D Scanning

3D surface scanning has the potential to play an important role in the development of customized products, since several devices and apparel can be designed for the individual using precise anthropometric measurements (45) (133). Indeed, some research has been made to apply this technique to orthotics and footwear (108). 3D scanning technology also provides a mean to store geometry data, which will be explored in chapter 5. Until recently, the anthropometric databases used by designers and manufacturers to guide the ergonomic form of products have primarily been based on 1D and 2D measurements, resulting in approximations (108). 3D foot scanning may also have a positive impact in the development of a prosthetic foot for children. Besides, as mentioned above, this technology allows high precision, high-speed, robust and accurate measurements (108) (56) which makes it an appropriate tool to be used when acquiring anthropometric data from children.

The available system for 3D scanning was the Shining3D EinScan Pro®, represented in figure 3-1. This system uses non-nocive visible light and supports different scanning modes where the 3D scanner can be handled or fixed during the process. It is also portable and ergonomic with a low mass of 0.800 Kg.

3-2-2 Additive manufacturing

Additive manufacturing (AM), commonly referred to as 3D printing, is an emerging manufacturing technology with many applications such as rapid prototyping, biomedical engineering and industrial de-
sign. This technology is often used to develop complex optimized shapes with low production volumes (130). The most used additive manufacturing technology is Fused Deposition Modeling (FDM) since FDM 3D printers are affordable and the concept behind it is very simple. The manufacturing process consists on melting a thin filament of plastic, which is selectively deposited in a predefined path, layer-by-layer, using a series of cross-sectional slices (87). Figure 3-2 illustrates the basics of fused deposition modeling. This technology belongs to the material extrusion family and can only be used with thermoplastic polymers, shaped in the form of a filament.

The process behind additive manufacturing follows the 7 steps presented hereafter:

1. The manufacturer creates a digital model of the object to be produced, normally by using a computer-aided design (CAD) program and employing some form of 3D scan;

2. The CAD model is converted into an appropriate file format, such as stereolithography (STL);

3. The STL file is then imported into a slicing software to be horizontally sliced into thin layers with two-dimensional contours information. Meanwhile, support structures are auto-detected and generated in the models according to the overhang angle. This slicing software converts the STL file into G-code for the 3D printer to read and manufacture the object (a process similar to transferring a file to a standard printer when printing a document);

4. The 3D printer is loaded with the appropriate printing materials;

5. The printer builds the object, layer by layer. During this manufacturing process, the feedstock filament is extruded into a heated nozzle at semi-liquid state and deposited as a thin solidified layer onto the previous layer of the built model on the platform in the form of the X-Y plane according
to the slide information. As the environmental temperature is lower than the melting point of the materials, the deposited material quickly solidifies and bonds with the adjacent layer. After the deposition of one layer, the built-in platform moves downward along the Z axis by the height of one layer thickness and the next layer starts to be printed, as shown in figure 3-2. This process can take hours, or even days, depending on the size and complexity of the object and the materials used to create it;

6. Once the 3D printer has completed the building process, the object is removed from the machine;

7. The object may require some post-manufacturing actions, such as brushing and polishing, as well as removing building supports.

The main advantage of this process is that no chemical post-processing is required, no resins to cure are needed, which reduces the total cost since there is no need for expensive tools, molds, or punches, resulting in a more cost-effective process. This way, 3D printing allows to economically build custom products in small quantities. Additionally, the speed and ease of designing, modifying products, the ease of share and outsource manufacturing, are other advantages of 3D printing over other manufacturing technologies. By designing and modifying products to 3D print, there is a geometric freedom inherent to this technology that makes it possible to maximize strength and minimize weight. These parameters are also controlled by infill pattern which can be designed to improve energy storage and release (2) (109).

The aforementioned characteristics make FDM 3D printing an adequate technology to design and produce customized products and build test prototypes, with the potential to improve amputee rehabilitation. The inherent geometric freedom allows the customization of the prostheses in order to better meet the varying needs of patients. Through this method one can create an optimal geometry for low-volume production or for individual custom prostheses (90).

However, there are limitations in FDM 3D printing technology. Firstly, the resolution on the Z axis is low compared to other additive manufacturing processes such as Selective laser sintering (SLS). Moreover, although there is no need for high-cost post-processing methods, a finishing process is necessary if a smooth surface is required. In addition, sometimes the process is slow since it can take days to build large complex parts. To save time, 3D printing machines permit two modes: a fully dense mode, slower, and a sparse mode, faster but at the detriment of the mechanical properties of the printed object. There is also a reduced choice for materials, colors and surface finishes. Lastly, there is still low precision when printing in 3D, relatively to other technologies, and a limited strength, resistance to heat and color stability.

3-2-2-1 Dual-Extrusion 3D Printing

Two-materials 3D printing is becoming popular. This process involves dual extrusion fused deposition modeling. It is inexpensive and accessible (101) and it allows manufacturing products with the same material but different colors or even with different materials. Therefore, by having access to a double-extruder 3D printing machine, for the presented project, a focus was placed on two-material printing, involving filaments with different mechanical properties. The end product, the foot prosthesis,
was made with the combination of Polylactic Acid (PLA) and an polyurethane thermoplastic elastomer (FilaFlex). The reason behind this choice is related to the unique soft elastic and adhesive properties of FilaFlex combined with the hardness and ease of printability of PLA. Although the combination of PLA and FilaFlex materials for 3D printing is not novel (101), and FilaFlex has been applied to creating a neonatal rib cage and aortic arch, this is the first description of this particular dual material application to prosthetic feet.

Soft compressive filaments are difficult to print due to their predilection for blocking the printing channels and not having enough force to pull the filament to melt and extrude it. However, the Raise pro2® design proved to be fairly effective for FilaFlex. This 3D printing machine is a fused-deposition (FDM) printer that retails at a price of $3,999.00. Each extruder of Raise pro2® has a nozzle with 0.4 mm diameter. The printer has a build volume of \(300 \times 305 \times 305 = 27,907,500 \text{mm}^3\) (approximately 28 L) and can print with a wide range of filaments of 1.75 mm diameter. Both PLA and FilaFlex, are from Recreus Industries S.L.®, Elda, Alicante, Spain. The cost of the materials used for the prosthetic foot was approximately 19.90€ for 1000 grams of PLA and 40.21€ for 500 grams of FilaFlex.

Before printing, as mentioned when describing the steps of 3D printing, a G-code has to be generated considering the model to print with specific parameters, which will be further presented in annex A. All 3D printers use a 3D software that measures the cross-sections of each product at thousands of instances to determine exactly how each layer is to be constructed. In the presented study, for the process of slicing the FDM files into machine readable G.code, the ideaMaker® software was used.

3-2-2-2 3D Printing filaments

The most common used materials for 3D printing are Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA). PLA is becoming popular since it is easy and safe to print. Compared to ABS, PLA is less prone to warping due to its low thermal expansion coefficient. Also, in terms of applications, PLA is preferred for components operating in tension and compression. However, ABS is more suitable if the components are operating in flexion and torsion (82).

As previously mentioned, the used (FDM) filaments were PLA and polyurethane thermoplastic (FilaFlex) from Recreus®. PLA is a biodegradable, thermoplastic, aliphatic polyester derived from renewable resources such as cornstarch or sugarcanes. Using this material has several benefits including low weight, environmental protection and ease to FDM 3D print (107). PLA is a good rigid polymer for FDM printing with high quality. Studies focused on PLA's mechanical characteristics show that this material is appropriate for prosthetic applications for low-to-moderate activity level amputees (107).

FilaFlex is a thermoplastic polyurethane, an elastomer material that has a maximum elongation to break of almost 700%, which means it can stretch up to 700% of its size before breaking. This material allows easy bend without any effect on the design, strength and durability. This way, FilaFlex has different characteristics from PLA such as resistance to abrasion, elasticity, and mechanical properties along with rubber-like elasticity, being the most flexible and softest material available to FDM 3D printing. As all flexible filament, it is hard to find the right parameters to print with quality (101). As stated by Yarwindran (132), FilaFlex is compatible with PLA and useful in mimicking muscles, tendons and ligaments. Con-
Considering also the fact that a simple mild soap \(^{[1]}\) can be used for its cleaning, this material has interesting characteristics for its usage as an external shell of the prosthetic foot.

PLA filament, from its technical sheet, has a density of \(1.24 \text{ g/cm}^3\), with 3120 MPa of Tensile Modulus, and 52 MPa of flexural strength (also known as modulus of rupture, or bend strength). PLA’s Poisson ratio is estimated to be of 0.36 in Zhen Tao et al. tests after FDM 3D Printing \((107)\).

From FilaFlex technical sheet, the flexible material has a density of \(1.14 \text{ g/cm}^3\), with 42 MPa tensile strength and 54 MPa ultimate tensile strength, 48 MPa tensile storage modulus and 665% elongation at break. Previous studies have used 48 MPa as the value of Young modulus. As previously mentioned, FilaFlex is a thermoplastic polyurethane. Past studies, such as Qi and Boyce \((85)\), Tsukinovsky, D. et al. \((111)\) and Elleuch et al. \((29)\), have studied a Poisson’s ratio in the range of 0.48 to 0.5 for TPU, therefore in this study it was considered 0.48 for FilaFlex’s Poisson ratio.

Note that these values are related to specimens printed with 100% infill in a different 3D printer, and that the environmental conditions of these results are unknown. The maximum force and maximum stress depend on the infill. In Yarwindran’s \((132)\) study it is stated that “the pattern and percentage of infill pattern affects tensile strength, hardness and flexure towards a specimen produced by 3D printing machine technology FDM”.

The manufacturing procedure, layer-by-layer, makes it so that the finished product has anisotropic properties even though the base materials are isotropic. It can be considered orthotropic, however, as mentioned in Poissenot’s study of 3D printed models with PLA \((82)\). Taking this study into consideration and since it was not possible to simulate the model as being orthotropic, the model was approximated as transversely isotropic by averaging the data acquired for the XX and YY axis, the isotropic plane. Characteristics of the material along the ZZ axis were obtained from previous studies \((82)\) and were used for the transversely isotropic material simulation. The elastic modulus in the transverse plane and in principal axis were calculated as 2340 MPa and 2510 MPa, respectively, and the Poisson’s ratio 0.26 and 0.33, respectively. Equation 3-1 was used to determine the shear modulus \((G)\) along in an isotropic plane, where \(E\) is the young modulus and \(\nu\) is the Poisson ratio. The shear modulus on the transverse plane and in the principal axes were of 929 MPa and 944 MPa, respectively.

\[
G = \frac{E}{2 \times (1 + \nu)} \tag{3-1}
\]

### 3-3 Product development

In order to provide clear guidance for the product development, represented in figure 3-3, it is important to formulate a more detailed definition of the product to be developed, which is captured in a mission statement. Thus, the mission statement of this project is:

Create a prosthetic foot in the children prosthetics category that can meet the patient’s own characteristics with natural-aesthetics while also being low-cost, low-weight with short production-time, able to improve the amputee’s gait cycle.

\(^{[1]}\)https://gizmodorks.com/blog/all-about-tpu-filament/ consulted in november, 2018
3. Product Planning

![Figure 3-3: Product development activities, adapted from (113).](image)

| Table 3-2: Selection matrix of interviewees. Five transfemoral amputees (3 adults and 2 child), one physician, four prosthetists, two mothers of amputee children and one physiotherapist. The interviews were conducted in person. |
|---|---|---|
| Lead users | Users | Service centers and important interventiens |
| 2 | 3 | 8 |

3-3-1 Identification of patient’s needs

The process of identifying patient needs is a fundamental part of the larger product development process, represented in figure 3-3. 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, as specified in table 3-2: 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 prothetist perspective on protheses development and integration, and how the impairment can be faced in the adult life.

All the interviews helped to identify latent or hidden needs as well as explicit patient’s needs, which provides a fact base for justifying the product specifications (113). The most relevant statements are resumed on table 3-3.

3-3-2 Establishing the target specifications

Patient needs are generally expressed in the “language of the patient” or in the “language of the professional”, in the case of doctors and prosthetists, and leave too much margin for subjective interpretation. For this reason, it is necessary to establish a set of specifications, which spell out in precise, measurable values of what the product has to do or needs to have. Those specifications are presented in table 3-4 and are described bellow.
Table 3-3: Interviewee data, with sample customer statements and interpreted user requirements.

<table>
<thead>
<tr>
<th>Question</th>
<th>Interviews</th>
<th>Interpreted need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislikes from current solutions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Children self-esteem is being developed and amputee children are afraid that is too obvious for their friends that they have a prosthesis.”</td>
<td>5 (38%)</td>
<td>Foot adaptation to shoes &amp; Aesthetics / Customizable</td>
</tr>
<tr>
<td>“All the components are expensive with limited options for kids.”</td>
<td>12 (92%)</td>
<td>Cost &amp; Adaptability / Customizable &amp; Production Time</td>
</tr>
<tr>
<td>“Adults have to renew all the prosthetic components in every 2 years while children usually have to replace their components every 6 months.”</td>
<td>11 (85%)</td>
<td></td>
</tr>
<tr>
<td>“Children have to renovate their prosthesis more often and the cheapest solutions are the ones used.”</td>
<td>6 (46%)</td>
<td></td>
</tr>
<tr>
<td>“Amputee children have never learned how to walk and they should have a foot that helps them learn in a proper way. Not a rigid one.”</td>
<td>4 (31%)</td>
<td>Good support &amp; Energy restitution</td>
</tr>
<tr>
<td>“Patients have to wait almost 1 year since the prescription to have authorization to buy the prosthesis”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Some patients have to pay themselves to have the prosthesis.”</td>
<td>6 (46%)</td>
<td>Cost &amp; Preparation Spread</td>
</tr>
<tr>
<td>“There is no freedom. The prosthetist does as doctor writes.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suggested Improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Cheap production as children have to replace their prosthetic foot every year.”</td>
<td>13 (92%)</td>
<td>Cost</td>
</tr>
<tr>
<td>“Children have to be stable and be used to their orthostatism.”</td>
<td>4 (31%)</td>
<td>Support</td>
</tr>
<tr>
<td>“A prosthetic foot should have the common foot dimensions since it must fit on a shoe.”</td>
<td>13 (100%)</td>
<td>Adaptability / Customizable</td>
</tr>
<tr>
<td>“Feet adapted in height and weight as it happens with adult solutions.”</td>
<td>11 (85%)</td>
<td>Adaptability / Customizable</td>
</tr>
<tr>
<td>“Feet that can reuse the energy from the first contact of the foot in the floor.”</td>
<td>9 (69%)</td>
<td>Energy restitution</td>
</tr>
<tr>
<td>“In Portugal cosmetic is important and both children and parents complain about the similarity of the feet.”</td>
<td>3 (23%)</td>
<td>Aesthetic</td>
</tr>
<tr>
<td>“The foot should not add a lot of weigh to the prosthesis. Light weight increases comfort and decreases energy required for walking.”</td>
<td>7 (54%)</td>
<td>Low weight</td>
</tr>
</tbody>
</table>

Table 3-4: List of target specifications based on the identified requirements.

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

- **Adaptability** - The foot geometry chosen for an amputee child should take into consideration the amputee’s height and weight and the developed 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 better 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 the weight can also 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 of using expensive tools or materials to manufacture the product;

- **Simple** - The time spent between the order of the prosthetic foot and its delivery should be as small as possible, since they are constantly growing, hence changing their anatomical features, 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.
This chapter is focused on both product development and prototype generation. Product development was already approached in chapter 3, where identification of patient needs and setting of the product specifications were performed. This chapter begins with concept generation, followed by concept selection and product test. While the product is being developed, the methodology of building the prototype is applied.

4-1 Concept generation

The process of concept generation begins with the clarification of the problem by reviewing the customer needs and target specifications. The concept generation phase results in a set of different product concepts from which the final selection, or the final concept, will be made (113). The starting specifications are, as follows: being customizable; having a natural-aesthetic appearance; allowing energy restitution and good support; being low-cost and low-weight; having short-production-time.

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.

By dividing the problem in a cosmetic and a support component, solution concepts can be identified for the sub-problems by external and internal search procedures. External search consists on identifying the available solutions, which was started in chapter 2 and continues in the present chapter, and
was complemented by searching already-existing patents. Internal search consists on the individual
generation of concept ideas based on the specific needs and features to satisfy.

4-2 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, deformable
and elastic material, to reduce stiffness and allow better impact absorption and the activation of the
mechanical prosthetic knee.

With the available 3D scan technologies and mentioned characteristics, this component becomes
simpler to design. The following sections describe the chosen methodology, using the 2 year-old subject
presented in figure 4-1 as an example.

![Figure 4-1: 2 year-old test subject.](image)

4-2-1 Design methodology behind the cosmetic component

The first step in designing a patient-specific prosthetic foot is to make a 3D scan of the existing sound
foot in order to acquire the foot geometry of the patient, and mirror it to manufacture a prosthetic foot
for the amputated side. If the patient is a bi-lateral lower limb amputee, it is essential to have the foot
geometry of a non-impaired child with similar characteristics as the amputee, such as height and weight,
which reflect on the anatomical features of the foot. This will be discussed on Chapter 5.

Once the sound foot geometry is acquired, the raw data, presented in a form of a point cloud in figure
4-2, needs to be processed and modified. This technology allows the scanning in three dimensions by
collecting information about the position of the object in space. It only captures skin surface and it has
limitations, namely the inability to capture surfaces between toes. After acquisition of the geometry,
the first task is to position the acquired data in a coordinate system that facilitates posterior modeling
operations (namely the design of the rigid component); this is accomplished using Meshlab® to facilitate
posterior modeling. The resulting mesh is then simplified to reduce its size and speed up modeling
further ahead in the process, without loss of quality or information from the original scan. This process
also reduces noise generated during the scanning phase, thus smoothing the surface and contributing
to the natural-aesthetic look intended. This geometry is then imported into Siemens NX® in a STL file
and further processed using the program's reverse-engineering tools in order to correct any remaining defects, open a slit between the big toe and other toes, and prepare the geometry for the modeling of the support component. A $10^\circ$ cut is made at the ankle to match that of the SACH prosthetic foot since this model will use the standard stump. After the cosmetic component is processed, one can move on to the creation of the support component.

![Figure 4-2: External 3D geometry before ((a) and (b)) and after ((c) and (d)) processing with Meshlab® and Siemens NX® softwares.](image)

### 4-3 Support component

The support component is responsible for withstanding the body weight of the patient while standing, to absorb energy during heel strike and to release it later during the gait cycle, helping with the child’s gait. The cosmetic component serves as a reference for the design of the support component since the former must fit inside the latter, follow its shape and retain the necessary characteristics of energy storage and release enunciated above.

### 4-3-1 Concept generation and concept selection of the support component

As suggested by Ulrich (113), the concept generation is a process with 4 steps:

1. Search externally to gather information from lead users, experts, patents, published literature and related products.
2. Search internally using individual methods to adapt the knowledge.
3. Explore systematically the generated concepts to organize the thinking and to synthesize solution fragments.
4. Reflect on the solutions and the process identifying opportunities for improvement in subsequent iterations.

Concept selection is the stage just after concept generation which is the process of evaluating concepts with respect to customer needs, comparing the relative strengths and weaknesses of the concepts...
and selecting and combining concept ideas for testing and development (113). While the concept gen-
eration stage of the development process benefits from unbounded creativity and divergent thinking,
concept selection is the process of narrowing the set of concept alternatives under consideration (113).

4-3-1-1 Search externally

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 medicine and rehabilitation were carried out. Those
meetings brought great insight on both the actual problems and positive characteristics of each available
solution, insights later used to identify the patient needs on Chapter 3, and the recurrent adaptations to
improve the child’s gait cycle.

In fact, the most used prosthetic foot for amputee children is, as mentioned in previous chapters,
the 1K30 SACH. It is sometimes possible to use the 1S30 SACH foot from Ottobock® (12 and 13
centimeters long), depending on the height, weight and level of activity of the child. When a 1S30 SACH
foot is chosen, the prosthetist may be 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 4-3, since it
enables the child to do a proper roll-over of the prosthetic foot during gait cycle. When it is not possible
to sand the SACH foot, as in most cases, figure 2-11, the physician asks parents to buy sneakers with a
sole similar to shape-up sneakers model.

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{1S30_SACH_foot_Ottobock.png}
\caption{1S30 SACH foot for children by Ottobock®, available with 12 and 13 cm \textit{(left)}. Shape-up
sneakers from Sneakers® \textit{(right)}.}
\end{figure}

In the case of children other than 2 years old, the cheapest available prosthetic, a 1K30 SACH foot
(according to table 3-1 and illustrated in 4-4) cannot be sanded. In this case, the physician asks the
parents to buy sneakers with a sole similar to shape-up sneakers model to, again, help the child to learn
and develop a healthy gait cycle.

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{1K30_SACH_foot_Ottobock.png}
\caption{1K30 SACH foot for children by Ottobock®, available with 14 and 21 cm.}
\end{figure}
Some patents were also analyzed in order to better understand the characteristics that were considered for prosthesis development over the years. Patent numbers 5,062,859 published on November 5th 1991, 5,037,444 published on August 6th of 1991, 6,099,572 published on August 8th of 2000 and 6,197,066 published on March 6th of 2011 were the most relevant patents analyzed.

The published literature, presented on Chapter 1, was used to gain a better understanding of the development of prosthetics using 3D printed materials.

**Figure 4-5:** Most relevant patents: (a) Patent number 5,062,859 published on November 5th 1991; (b) Patent number 5,037,444 published on August 6th of 1991; (c) Patent number 6,099,572 published on August 8th of 2000; (d) Patent number 6,197,066 published on March 6th of 2011.

### 4-3-1-2 Search internally

As mentioned in (113), "internal search is the use of personal knowledge and creativity to generate solution concepts", often called brainstorming.

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. It also allows the learning of how to roll over the foot during gait, as suggested by the physician.

### 4-3-2 Concept selection

After drawing a total of 8 concept ideas, by combining different ideas and considering the available space on the foot geometry, as depicted in figure 4-6, 4 different CAD design concepts were developed on Siemens NX® software, figure 4-7.

**Figure 4-6:** External foot geometry, a reference for the design of the internal component.
4. Product Development and Prototype Generation

Every one of the 4 concepts were 3D printed and carefully observed, as represented in figure 4-8, in order to better understand their strengths and weaknesses when a force is applied.

Evaluating the concepts with respect of the needs of the stakeholders, evaluating their relative strengths and weaknesses, the design was improved and the process converged on one concept to develop and test, presented in figure 4-9.

Some adaptations were made in order to have a better and more-natural performance with a good integration of the pylon, and the final interior component design was established, as depicted in figure 4-10.

With this solution, the standard pyramid adapter, which connects the prosthetic foot and the pylon, and consequently, makes the integration with the rest of the prosthesis, was considered. The chosen internal geometry, depicted in figure 4-11, 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 gait cycle. The heel design allows the exterior component to absorb the majority of the impact energy during heel-strike, figure 4-12.
4-3-3 Design methodology behind the support component of the prosthetic foot

The design of the support component of the prototype was carried out using Siemens NX®’s surfacing tools in order to account for the space available inside the geometry obtained from the 3D scan. It is important to notice that, due to the organic geometry of the foot, each designed shape was susceptible to adaptations. The pyramid adapter, used to make the connection to the pylon of the prosthesis, was added in last place after the shape of the support component was finalized. Both geometries (the cosmetic one and the support one) were then combined in order to make a production-ready model which would also be used to conduct Finite Element Analysis using the same software. The materials used for such analyses were the same ones used on the FDM 3D printing process - FilaFlex for the cosmetic component and PLA for the support component - with the goal of iterating on the design without needing to print numerous prototypes. Feedback from the stakeholders was gathered after the final prototype was manufactured and the finishing applied.

4-4 Concept testing and prototyping

The concept testing phase is closely related to concept selection in that both activities aim to further narrow the set of concepts under consideration based on the analysis of their potential (113). However, concept testing is distinct in that it is based on data which is gathered directly from stakeholders. Concept testing is also closely related to prototyping, because concept testing involves some kind of representation of the product concept, often a prototype.

The methodology of product development is an iterative process. For this reason, all phases are prone to gather new data and information to improve the developed product to better meet the customer needs.

The purpose of the concept test is to both understand if the designed model can support the applied forces of a healthy 2-year-old child and understand the perspective of stakeholders.
4-4-1 Finite Element Analysis to understand if the model can support the applied forces

For Finite Element Analysis (FEA), the prototype model was meshed on Siemens NX® software, using second-order tetrahedra and it was analyzed for three phases of foot support during the gait cycle corresponding to heel-strike, midstance and toes-off with loading forces related to the child test subject’s weight, with a factor of safety of 3 and the material properties as described on Chapter 3. Since the factor of safety is the product of all the different contributors, it has to be considered the static forces, contributing with a factor of safety of 1.5, and the dynamic forces, contributing with a factor of safety of 2, thus, safety factor = 1.5 × 2 = 3. Therefore, Applied force = mass of the child × gravitational acceleration × 3 = 11.5 × 10 × 3 = 345 N.

The numerical loads for the three load cases were applied over an approximated region, having the forces applied with an angle of 20° for heel-strike and 40° for the toes-off phase, as used in physical ISO tests, as represented in figure 4-13.

Figure 4-13: Simulation conditions. Pyramid adapter is fixed. The applied forces are represented with arrows. Toes-off with a geometric distribution of the applied force with 40° (left). Midstance (center). Hell-strike simulation (right) with a geometric distribution of the applied force with 20°.

Figure 4-14: Mesh representation and the selected nodes (1 and 2) for the convergence analysis.

The points chosen for the mesh convergence analysis are illustrated in figure 4-14. Both chosen points are located on the support component since it is where it is possible to observe a tension gradient to study. On the following graphics, presented in figures 4-15 and 4-16, it is possible to visualize the convergence of Von Mises Stress for all the three tested phases. The support component was modeled as transverse 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 analysed considering Von Mises stress for both components, due to its simplicity and well correlation with experimental results (48).
The convergence of the error is calculated using the expression 4-1, where $\sigma$ is the Von Mises stress. If the difference is lower or equal to 5%, one can assume that the analysis converged. This way, a mesh with 3 mm as the dimension of the elements is already a good approximation for all the performed simulations, as it can be observed from the results presentes in tables 4-1 and 4-2.

$$\left| \frac{\sigma_{i+1} - \sigma_i}{\sigma_i} \right| \times 100$$  \hspace{1cm} (4-1)

**Table 4-1:** Convergence for Von Mises stress: node 1.

<table>
<thead>
<tr>
<th>Element dimension</th>
<th>Number of elements</th>
<th>Heel-strike</th>
<th>Toes-off</th>
<th>Mid stance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm</td>
<td>23229</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>3 mm</td>
<td>20843</td>
<td>0.84%</td>
<td>2.44%</td>
<td>1.30%</td>
</tr>
<tr>
<td>5 mm</td>
<td>19524</td>
<td>29.69%</td>
<td>12.46%</td>
<td>3.69%</td>
</tr>
<tr>
<td>7 mm</td>
<td>18805</td>
<td>16.03%</td>
<td>35.05%</td>
<td>6.25%</td>
</tr>
<tr>
<td>9 mm</td>
<td>18372</td>
<td>12.36%</td>
<td>32.66%</td>
<td>23.38%</td>
</tr>
</tbody>
</table>

**Table 4-2:** Convergence for Von Mises stress: node 2.

<table>
<thead>
<tr>
<th>Element dimension</th>
<th>Number of elements</th>
<th>Heel-strike</th>
<th>Toes-off</th>
<th>Mid stance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm</td>
<td>23229</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>3 mm</td>
<td>20843</td>
<td>4.10%</td>
<td>3.49%</td>
<td>5.95%</td>
</tr>
<tr>
<td>5 mm</td>
<td>19524</td>
<td>21.39%</td>
<td>10.82%</td>
<td>34.47%</td>
</tr>
<tr>
<td>7 mm</td>
<td>18805</td>
<td>61.59%</td>
<td>47.04%</td>
<td>18.15%</td>
</tr>
<tr>
<td>9 mm</td>
<td>18372</td>
<td>46.03%</td>
<td>61.33%</td>
<td>56.16%</td>
</tr>
</tbody>
</table>
4. Product Development and Prototype Generation

From FEA, Von Mises stress distributions were obtained for the three mentioned gait cycle phases, as represented in figure 4-17. The maximum stress is experienced on the pyramid adapter geometry, where the fixed constraint is located, seen in figures 4.17(a), 4.17(b), 4.17(c). The yield stress of PLA material is of 52 MPa. For heavy children, it could be problematic to ensure the resistance and integrity of the prosthesis in this area. The simulation considered a safety coefficient of 3, which means that the forces applied were three times higher than the forces experienced when only considering the weight of the child. The value of the applied forces were equal during the simulation of all the three different phases. Moreover, during the gait cycle, the different support phases do not experience all the body weight of the child at once, as used during the simulation. The interaction between the pyramid adapter and the prosthetic foot is a fixed constraint in all the area of interaction which can be better modeled if the simulation takes into consideration the pylon and the screws used to make the integration.

Figure 4-17: Siemens NX® results.

4-4-2 Stakeholders perspective

The chosen format for this phase of concept testing was a face-to-face interaction with a physician specialized in Physical Medicine and Rehabilitation and a physiotherapist from the pediatric hospital, Hospital Dona Estefânia, in Lisbon. The concept was presented through a verbal description, to summarize the product concept, and a complete working prototype. The experts demonstrated their satisfaction with the prototype. Some improvements were suggested concerning the external foot geometry and was in eversion, depicted in figure 4-18, because it can impair the gait learning. The reason behind this imperfection had to do with the geometry acquisition. In the end of the meeting, a suggestion was
made to build two prosthetic feet for a bi-lateral lower limb amputee child that is being followed on Dona Estefânia Hospital. Since the child is 5 years old, the external foot geometry of a healthy child is much easier to obtain. The process behind the child’s feet development is thoroughly described on chapter 6.

![Figure 4-18: Acquired foot geometry with eversion.](image)

There are different possible methods to evaluate the developed prosthetic foot, from which subjective information related with the satisfaction of the prosthesis user, as well as the perceived performance of the foot are included. These measures are then used to provide insight into the satisfaction over the performance of the prosthetic foot, which will be put in practice on chapter 6, with the development of a prosthetic feet for bi-lateral amputee child.

### 4-5 Prototype development

The first built prototype for a 2-year-old child has as general dimensions: 135 mm long, height of 63 mm and width of 52 mm. For the manufacturing of the prototype, FDM 3D printing was performed by Raise pro 2® with a double extruder. The chosen materials were PLA, for the interior, and FilaFlex, for the exterior component, as previously mentioned. The left extruder of the printer was the one printing with FilaFlex, while the right extruder was the one printing with PLA.

In the manufacturing process, the designed prosthetic foot was placed with the medial face on the plate of the 3D printer in order to increase the flexibility of the 3D printed layers during heel-strike and toes-off, avoiding increased rigidity and fragility during those phases of the gait cycle. This orientation of printing was also considered during FEA. The first complete prototype was printed with a setting of 15% grid infill pattern. The process took 23 hours and 53 minutes to complete and consumed 81.4 g of PLA and 36.6 g of FilaFlex including the raft and support material made of PLA, which is equivalent to 4.56 € at wholesale material prices. After prototype finishing was complete by removing the raft and support material, the prosthetic foot weighed 118 g; 55 g lighter than the smallest SACH foot.

The infill of 15% was chosen in order to use less material and for the manufacturing process to be faster, since the primary goal of this first prototype was to observe the result and iterate. Since it appeared to be too flexible, prosthetic feet with different infill densities were manufactured, using only half the foot to observe the infill and conclude which is the ideal percentage, as represented in figure 4-19. Observing that after repeated experiences with the pylon integrated on the pyramid adapter, this geometry started to have some cracks, the final structure had an infill of 100%.
4. Product Development and Prototype Generation

Figure 4-19: 3D printed prosthetic foot, evidencing the possibility of using different infill percentages.

4-5-1 Printing highlights

FDM is a complex process with a large number of parameters that influence product quality and material properties. The combination of these parameters is often difficult to understand (15). There are several main parameters which must be changed depending on the choice of the material: printing temperature and velocity, infill density, retraction value, etc (15). Other printing parameters, such as layer thickness, raster angle, raster width, air gap, infill density and pattern, and feed rate, among others, have a substantial effect on the quality and performance of FDM printed parts (15).

Flexible filaments are inherently harder to print than rigid filaments, mainly because the mechanical setup of FDM 3D printers is designed for the latter. As an example, flexible filaments cannot retract as well as rigid ones. A key parameter to adjust when printing with a flexible filament is the printing speed, which should be reduced. While printing speed is an issue with flexible filaments, build plate adhesion generally is not. They adhere very well to the platform, even without a heated bed or any other change on the surface. Since flexible filaments should be printed with low velocity and with almost no retraction, residues of the filament drop inside the model and at the surface of the model during 3D printing process. The most important parameters used for the FDM manufacture are presented on the appendix A.

During the manufacturing process, some problems emerged to which solutions were obtained. Firstly, with flexible materials, extrusion problems can occur in diverse ways and these can have several reasons. Typical problems in extrusion of FilaFlex are bubbles formation, excessive blocking and excessive retraction. By reducing the nozzle temperature, retraction and the moisture in the filament these problems can be bypassed. The result of a failed print, using filament with high moisture content, is presented in figure 4-20.

Among all the attempts to manufacture the model, the biggest problem was the moisture on the FilaFlex filament. This material is sensitive to moisture and the failed attempts to manufacture the model happened mostly during winter, where the levels of humidity are high. After various tests with the FilaFlex filament, a combination of placing the filament in an oven at 40°C for 6 to 12 hours, figure 4-21, and then storing it in a vacuum bag, figure 4-21, would allow for one print to be made, without problems since it took almost 24 hours to print the entire prototype. The oven was set to 40°C since that is lower than the
glass temperature of FilaFlex ($T_g = 66^\circ$C) and would thus not compromise the filament's structure while also getting rid of most of the moisture present.

Figure 4-20: Failed print due to moisture.

Figure 4-21: FilaFlex in the oven (left). Storage vacuum bag (right).
4. Product Development and Prototype Generation
CHAPTER 5

Precision Prosthetic Foot

Precision medicine is a medical term that suggests the customization of healthcare, with medical decisions, treatments, practices, or products being tailored to the individual patient. For device manufacturers, precision medicine provides an opportunity to develop products that are targeted to patient groups for whom the traditional solutions on health systems have failed (118). The successful practice of precision medicine requires changes in practice patterns and management strategies since the focus is shifted from mass manufacturing to producing customized products.

This chapter is focused on applying precision medicine on prosthetic foot development.

5-1 Prosthetic foot

As mentioned during interviews, it is of extreme importance 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. Considering the previously mentioned available technologies, the use of a 3D scanning system allows the design of a patient-specific prosthetic foot.

For a single-leg amputee child, a 3D scan can be performed on the sound foot of the amputee to acquire its own external foot geometry and anthropometric data. Additionally, a single-leg amputee child may prefer to use a different foot geometry than his own. For a bi-lateral amputee case, there is no sound foot to acquire the geometry or anthropometric data from. On those situations, a database with collected foot geometries and anthropometric data of non-impaired children is needed. Once there is a database, it is then possible to use the geometric information for a bi-lateral amputee child from a child with similar characteristics, or for a single-leg amputee child if they wish to use a different foot geometry than their own. This dataset is possible to build using a 3D scanner that can quickly acquire accurate geometric data with high precision and robustness, which is the case of Shinning3D EinScan Pro®.
5. Precision Prosthetic Foot

Table 5-1: Demographic information of the children in the database.

<table>
<thead>
<tr>
<th>Years-old</th>
<th>Gender</th>
<th>Subject's code</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1 Female</td>
<td>CRF1</td>
</tr>
<tr>
<td></td>
<td>2 Female; 3 Male</td>
<td>CRF16; CRF17; CRF18; CRF19; CRF20</td>
</tr>
<tr>
<td>4</td>
<td>1 Female; 4 Male</td>
<td>CRF3; CRF4; CRF5; CRF6; CRF11</td>
</tr>
<tr>
<td>5</td>
<td>3 Female; 6 Male</td>
<td>CRF2; CRF7; CRF8; CRF9; CRF10; CRF12; CRF13; CRF14; CRF15</td>
</tr>
</tbody>
</table>

Total number of foot geometries acquired: 20

5-2 Database building with acquired foot geometries of sound children

Considering the development of such a database, the collaboration of Técnico Lisboa’s nursery was fundamental. After this study was approved by the Ethics Committee of the Técnico Lisboa Faculty and after collecting the signed informed consent of the children’s parents, the process of building the database was pursued.

During one month, foot 3D scans of 20 children were acquired. Each participant provided a verbally informed consent even after the authorization of their parents. The participants were all healthy children from 2 to 5 years-old with their BMI values within the normal parameters. With the collaboration of each child, by being still, the 3D scan procedure took less than 15 minutes per child. Demographic information about the participant is provided in table 5-1. Performing 3D scans of children who were younger than 3 years was a difficult task since they were constantly moving and did not like to be near strange equipment nor in strange environments.

5-2-1 Procedure to acquire foot geometries and anthropometric data

After the feedback from the physician specialized in physical medicine and rehabilitation, and a physiotherapist from Hospital Dona Estefânia, a strategy to correct the initial prototype, which was produced with the foot in eversion, was developed. A support for the foot was conceptualized. This support was made of wood and glass was and allowed some adjustments to the inclination of the foot for a better positioning during the 3D scan. To acquire the foot geometry, the first step is to place the foot of the child on the set up with the help of one adult. The foot should be placed on the glass surface, in this
case a glass with 3 mm of thickness, that prevents light refraction when acquiring the scan and allows an easy and fast cleaning between procedures, and supported by the built wooden structure to prevent the eversion of the foot, as represented in figure 5-1.

![Figure 5-1: Child’s posture during 3D scan procedure.](image1)

To stimulate the participation of the children and thank them for the help in this project, they were offered a diploma of good behavior and a bag of dehydrated food, given after the acquisitions, as shown in figure 5-2.

![Figure 5-2: Children’s diploma after the scan.](image2)

After having the external foot geometry, mesh treatments took place as mentioned on Chapter 4.

Once the mesh of the external foot geometry was complete, it was possible to measure each mesh in the Meshlab® software environment. The chosen measurements were in accordance with the ones mentioned by Fritz (30). In figure 5-3, the geometries of the 20 acquired feet are briefly presented.
Figure 5-3: Geometries on database. CRF3 was a restless child dificulting the acquisition process.
5-2 Database building with acquired foot geometries of sound children

5-2-2 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 and MTH5, 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 known as the height of the foot, is commonly measured at 50% of the foot length, as represented in figure 5-4.

![Figure 5-4: Measures taken on the CRF8 child foot.](image)

Studies with children foot dimensions are scarce. Therefore, for comparison, data from studies with European adult and elderly populations were analyzed (52) (110) and were summarized in table 5-2. On table 5-3 major feet measurements for children, obtained through the 3D scan, are presented. Since the foot proportions between adult and child feet are not similar, one cannot scale a adult’s foot into a child’s.

**Table 5-2:** Relations between dimensions of adult feet.

<table>
<thead>
<tr>
<th>Ball Width (TBW)</th>
<th>(\frac{TBW}{FL})</th>
<th>Heel Width (THW)</th>
<th>(\frac{THW}{FL})</th>
<th>Instep high (IH)</th>
<th>(\frac{IH}{FL})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult's average</td>
<td>40.54%</td>
<td>Adult's average</td>
<td>26.50%</td>
<td>Adult's average</td>
<td>45.19%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>1.78%</td>
<td>Standard deviation</td>
<td>0.61%</td>
<td>Standard deviation</td>
<td>1.42%</td>
</tr>
</tbody>
</table>

**Table 5-3:** Relations between dimensions of children feet.

<table>
<thead>
<tr>
<th>Ball Width (TBW)</th>
<th>(\frac{TBW}{FL})</th>
<th>Heel Width (THW)</th>
<th>(\frac{THW}{FL})</th>
<th>Instep high (IH)</th>
<th>(\frac{IH}{FL})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children's average</td>
<td>38.24%</td>
<td>Children's average</td>
<td>24.70%</td>
<td>Children's average</td>
<td>31.12%</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>1.79%</td>
<td>Standard deviation</td>
<td>1.06%</td>
<td>Standard deviation</td>
<td>1.19%</td>
</tr>
</tbody>
</table>

Nevertheless, to understand if the dimensions and proportions of the SACH prosthetic foot are the same of children, the same measurements were performed to the prosthetic foot, as represented in table 5-4. Comparing that data with the data from table 5-3 shows that the dimensions of the SACH prosthetic foot do not take into consideration the natural dimensions of a foot, with the biggest differences happening on the toes.
5. Precision Prosthetic Foot

### Table 5-4: Relations between dimensions of SACH’s foot.

<table>
<thead>
<tr>
<th>Years-old</th>
<th>Foot length</th>
<th>Ball Width (TBW)</th>
<th>Instep high (IH)</th>
<th>Heel Width (THW)</th>
<th>Instep high (IH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SACH</td>
<td>5</td>
<td>16 cm</td>
<td>6 cm</td>
<td>3 cm</td>
<td>6 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>37.50%</td>
<td>3 cm</td>
<td>18.75%</td>
<td>6 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>37.50%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5-2-3  **How to choose a foot geometry from the database after meeting a bilateral amputee child**

The dimensions of the foot have been used for the determination of sex, age and stature of an individual. Foot length displays a biological correlation with height (50) and its geometry varies when considering different ethnic groups (52) (17). Thus, it should only be taken into account European geometries when comparing dimensions of European subjects.

In adults, all the foot measurement values are bigger in males than in females and these sex differences are statistically significant, proving that gender has an impact on the relation between each measurement and stature (112). However, no significant gender differences between children younger than twelve years old have been found (30).

To explore the children’s height and weight relation with foot length, the acquired data during the 3D scanning session was used. Graphics depicted in figures 5-5 and 5-6 show such relations.

![Figure 5-5: Foot length (cm) vs. Weight (Kg).](image)

![Figure 5-6: Foot length (cm) vs. Height (cm).](image)
There is a strong relation between weight and foot length. The heavier a child is, the larger his/her foot is across all ages, which is hypothesized due to a larger stress between bones that results on bone growth stimulation. For what concerns the relation between foot length and height, there is not a notorious relation from graphic in figure 5-6. From all the measurements and displayed graphics, it is evident that children are in constant growth and each child has his own growth rate resulting in relations depending on weight and height and no relevant differences between different ages. Other relations between foot length and individual’s characteristics are presented in annex C.

Using Matlab® software, it was developed a tool to automatically choose a matching foot geometry for the prosthesis, based on the amputee’s anthropometric characteristics. The tool should receive as input the height and the weight of the amputee child, and should return 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 more details, the reader is referred to the contents of annex B.

To better understand the best equation to approximate the relationship between weight, height and foot length, two regression models, linear and quadratic, were analyze. Considering the lower the p-value is, the better the approximation will be, it was decided to use a linear approximation, with a p-value of 0.0017 and a stronger dependence with weight, as previously observed. The quadratic approximation showed a p-value of 0.3773. This way, linear equation 5-1 was taken into account, represented graphically in figure 5-7. Note this Matlab® tool 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 (30), and the acquired foot geometries were from children ranging 2 to 5 years old.

\[
FL = 7.9351 + 0.016896 \times \text{height} + 0.33983 \times \text{weight} \tag{5-1}
\]

As an example, testing the tool with a child with 20 Kg and 112 cm outputs the result represented in figure 5-8. The scale means how much the foot should be scaled from the foot of the database. In this case, the foot of the subject CRF15 should be scaled by 1.0075 to obtain the best prosthesis dimensions for the child of the input characteristics. However, a scale of 1.0075 is not relevant enough.
5. Precision Prosthetic Foot

to be considered. It is only worth to scale the foot geometry if the difference between the required foot length and the most similar is of more than 1 centimeter. If the scaling procedure is required, it should be the same in all three main directions (xx, yy and zz).

Foot length = 16.62 cm. The most similar child is CRF15.
Scale = 1.0075.

Figure 5-8: Matlab® result for the data: 20Kg and 112cm.
Chapter 6

Clinical Case

The end goal of this project is to design a customized prosthetic foot that can be used by amputee children. The following step to test this concept is having the designed prosthetic foot tested by a real subject. The test of the prosthetic foot with an amputee child will be the focus of this chapter.

6-1 The amputee child

To test this real application of the developed work, a 5 years-old bi-lateral lower limb amputee girl, who has been followed in the pediatric hospital in Lisbon, Hospital Dona Estefânia, was the clinical case test subject. The test subject is from San Tomé and arrived in Portugal with her mother in 2014. They went to the first medical appointment in August 2014, when the little girl was 15 months old. At that time, she presented a little tail, malformations on her fingers and multiple malformations on her legs that did not allow her to do as little as standing up. It was only on September 2016, when she was 3 years old, that the surgery was performed to amputate the legs and the little tail. The amputation of both legs was transfemoral, as can be observed in figure 6-1. The congenital malformation of the girl, polymalformative syndrome, was not detected on the ultrasound scan performed in San Tomé during the gestational period. It was only during a suffering birth that the malformations were detected. After the advice of a physician from San Tomé, the decision to come to Portugal, in search of better conditions, was taken since it was not possible to perform the amputation and implement the prosthetics at her home country. Being 3 years old and never being able to experience orthostatism, the acceptance of the prosthesis was neither immediate nor easy. A lot of training was needed after the stump healing. The training started as 2 to 3 times per week of stretching and muscle strengthening exercises, and the use of pneumatic prostheses to allow her to get used to orthostatism before the application of the final prosthesis. Nowadays, 2 years later, the training sessions with the physiotherapist are focused on muscle strengthening, stretching, equilibrium and gait cycle. The girl, and her mother, are happy and thankful for having the possibility to lead a better live, with less dependency between them. The child loves to play with others kids and is always trying to make everything on her own. In figure 6-1
photographs of the child and of the prosthesis used are presented.

Figure 6-1: Bi-lateral amputee test subject (left) and her prosthesis (right).

Despite the care from her mother, motivating the child to train some movements at home whenever possible, there are still difficulties and imperfections on her gait cycle that should be corrected for a better growth: the walking base and the use of the mechanical knee. From the physician and physiotherapist’s perspective, the foot plays an important role on those needed improvements, which may be achieved with some modifications of the prosthesis, such as having a softer and lighter prosthetic foot. An interesting fact mentioned by the mother of the child was the child’s desire to use ballerina shoes.

6-1-1 Choose the right foot geometry matching amputee’s characteristics

For the test subject, with height of 110 cm and weight of 17.7 Kg, the linear regression model output was subject CRF8, figure 6-2.

\[
\text{Foot length} = 15.81 \text{ cm. The most similar child is CRF8.} \quad \text{Scale} = 1.0006.
\]

Figure 6-2: Matlab® tool output for the test subject, with 110 cm height and 17.7 Kg weight.

As mentioned in the previous chapter, the development of the foot among young children is similar between boys and girls. Differences in foot geometry are only noticed around the age of twelve (30). Hence, the Matlab® function does not take into account the gender of the child. The scale between the predicted foot length and the closest foot length from the dataset is of 1.0006, which is not significant to perform a scale of the second.

6-1-2 Prosthetic foot development

Using the suggested foot geometry from the database, the CAD design for the rigid component of the prosthetic foot was performed and the result is presented on figure 6-3.
FEA was performed on Siemens NX® considering the girl’s weight and a safety factor of 3. This way, \( \text{Applied force} = \text{mass of the child} \times \text{gravitational acceleration} \times 3 = 17.7 \times 10 \times 3 = 531 \, \text{N} \). The points chosen for the mesh convergence analysis are illustrated in figure 6-4 and are situated in the zones of the rigid part where the stress gradients are higher.

\[
|\frac{\sigma_{i+1} - \sigma_i}{\sigma_i}| \times 100
\]  

(6-1)
6. Clinical Case

Figure 6-6: Convergence study on node 2 of simulations with the 3 gait phases in study.

<table>
<thead>
<tr>
<th>Element dimension</th>
<th>Number of elements</th>
<th>Heel-strike</th>
<th>Toes-off</th>
<th>Midstance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm</td>
<td>56820</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>3 mm</td>
<td>54803</td>
<td>1.41%</td>
<td>1.90%</td>
<td>4.49%</td>
</tr>
<tr>
<td>5 mm</td>
<td>51676</td>
<td>5.83%</td>
<td>2.87%</td>
<td>13.16%</td>
</tr>
<tr>
<td>7 mm</td>
<td>49819</td>
<td>23.29%</td>
<td>13.52%</td>
<td>15.05%</td>
</tr>
<tr>
<td>9 mm</td>
<td>48811</td>
<td>12.08%</td>
<td>13.93%</td>
<td>20.32%</td>
</tr>
</tbody>
</table>

Table 6-1: Convergence of Von Mises stress on node 1.

<table>
<thead>
<tr>
<th>Element dimension</th>
<th>Number of elements</th>
<th>Heel-strike</th>
<th>Toes-off</th>
<th>Midstance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm</td>
<td>56820</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
<tr>
<td>3 mm</td>
<td>54803</td>
<td>2.67%</td>
<td>0.61%</td>
<td>3.61%</td>
</tr>
<tr>
<td>5 mm</td>
<td>51676</td>
<td>5.78%</td>
<td>5.75%</td>
<td>12.52%</td>
</tr>
<tr>
<td>7 mm</td>
<td>49819</td>
<td>15.37%</td>
<td>13.20%</td>
<td>7.92%</td>
</tr>
<tr>
<td>9 mm</td>
<td>48811</td>
<td>39.43%</td>
<td>37.01%</td>
<td>41.00%</td>
</tr>
</tbody>
</table>

Table 6-2: Convergence of Von Mises stress on node 2.

For a more realistic approach, simulations considering a moving plane towards the foot were also performed. The simulation results of this simulation and the one mentioned on Chapter 4 were similar.

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 place was placed at an angle of 20° with the sole of the foot, whereas for the toes-off phase the angle was of 40°, similarly to what is used in physical ISO 22675 tests, as represented in figure 6-7.

Figure 6-7: Left: Heel-strike simulation using a moving plane with an inclination of 20°. The plane had to move 2.15mm to have a total reaction force of 531N; Middle: Midstance simulation using a moving plane, in which the plane moved 0.6mm for a total reaction force of 531N; Right: Toes-off simulation using a moving plane with an inclination of 40°. The plane moved 6.4mm for a total reaction force of 531N.
6-2 Prosthetic foot test

The testing phase can be divided in two components. Firstly, the computational test has to be performed considering the characteristics of the amputee child, such as their weight. Secondly, it is essential to gather information from different stakeholders, such as the physician specialized in physical medicine and rehabilitation, the physiotherapist, the prosthetist, the mother and the amputee child itself.

6-2-1 Computational test

On what concerns the computational test, a contact simulation between a moving plane and the developed prosthetic foot was performed. Figures from 6.8(a) to 6.10(a) show the results of these simulations. Because product design and development are iterative processes, the simulations are also a mean to acquire more information about the behavior of the developed product and perform some improvements if needed.

Results from the heel-strike simulation are shown in figure 6.8(a). On this figure, the displacement is presented, per node, in the plane’s normal direction and the Von Mises stress is also shown. The experienced Von Mises stress is higher on the rigid component, exactly on the border of the fixed constraint region on the universal pyramid adapter geometry. The simulation did not exceed the theoretical Yield stress of PLA, 52 MPa, even using the safety coefficient of 3.

(a) Heel-strike displacement along the ZZ axis (normal to the moving plane) with a maximum of 1.978 mm.

(b) Heel-strike Von Mises stress with a maximum of 32.90 MPa.

Figure 6-8: Heel-strike Siemens NX® results.

On what concerns midstance simulation, figure 6.9(a) shows the obtained results. It presents the displacement per node on the plane’s normal direction and the Von Mises stress. The experienced Von Mises stress is also higher on the PLA component exactly on the border of the fixed constraint region on the universal pyramid adapter geometry. Once more, the simulation did not exceed the theoretical Yield stress of PLA under the same conditions as before.

Lastly, the results from the toes-off simulation are shown on figures in 6.10(a) that shows the displacement per node on the plane’s normal direction. It also presents the Von Mises stress. The experienced Von Mises stress is higher on the PLA component exactly on the border of the fixed constraint region on the universal piramid adapter geometry. Like before, the simulation did not exceed the theoretical Yield stress of PLA, 52 MPa, even using the safety coefficient of 3.
6. Clinical Case

(a) Midstance displacement along the ZZ direction (normal to the moving plane) with a maximum of 0.876mm.

(b) Midstance Von Mises stress with a maximum of 20.14 MPa.

Figure 6-9: Midstance Siemens NX® results.

(a) Toes-off displacement along the ZZ axis (normal to the moving plane) with a maximum of 6.400mm.

(b) Toes-off Von Mises stress with a maximum of 30.38 MPa.

Figure 6-10: Toes-off Siemens NX® results.

The integration between the rigid component and the pyramid adapter geometry was re-designed to improve its performance and resistance, as represented in figure 6-11, by removing sharp edges that might compromise the integrity of the rest of the product during its use. Results showed promising improvements for Von Mises stress, which were lower when compared with the previous geometry. A maximum Von Mises stress reduction of 15% was observed during the three phases of the gait cycle being studied.

Figure 6-11: CAD design for the first simulations (a) side view and (b) top view. New model with improved resistance (c) side view and (d) top view, which was used for prototyping.
The developed prosthetic feet were manufactured in BCN3D Sigma 3D printer with 20% infill for the cosmetic component (FilaFlex) and 85% for the support component (PLA). The pyramid geometry adapter was manufactured with 100% infill to improve resistance and strength. The remaining printing specifications introduced on Chapter 4 were kept. The printed prototype is depicted in figure 6-12.

![Figure 6-12: 3D printed prosthetic feet.](image)

### 6-2-2 Amputee child test

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 on table 3-4. 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.

The interaction between the amputee child and the developed prosthetic foot showed a positive contribution on her satisfaction with the prosthesis. In figures 6-13 and 6-14 is possible to observe the first interaction of the bi-lateral amputee child with the prosthetic foot, the integration and its test.

![Figure 6-13: First interaction of the test subject with the prototype (top left). Prosthetic foot comparation (bottom left). The implementation procedure with the help of the prosthetist (right).](image)
6. Clinical Case

![Child's gait test with the new prosthetic feet.](image)

**Figure 6-14:** Child’s gait test with the new prosthetic feet.

**Table 6-3:** 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.

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

Table 6-3 reflects how well the requirements have been rated according to the metric of the specification. A scale from 1 to 5 was used on more-subjective characteristics of the developed prosthetic foot.

- Regarding the **adaptation** requirement, all the specifications were rated with “yes” since the matching foot geometry from the database took into consideration both weight and height of the test subject. The geometry of the rigid component of the prosthetic foot includes the geometry of the universal piramid 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 perfect vertical position. However, during her gait, her confidence while walking showed extreme improvements and she even started to dance and perform several balle-
rina 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 rise 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 material cost was estimated 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 behaviour when without shoes, particularly the toes behavior, as they 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 a 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 extremelly 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 prothetist mentioned the more-anatomical appearance geometry and behaviour. 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.

Even though static computational tests were performed, physical tests are also needed to validate the product. With the extremelly 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.
6. Clinical Case

After a day of usage, the right prosthetic foot broke on the pylon integration, as can be seen in figure 6-15, a consideration that should be included in the next iterations of the product development. It is hypothesized children heavier than 10Kg may require metallic pyramid adapter, since PLA seem to not have enough resistance to support continuous loads when used in 3D printing. For those cases, an integration with a metallic pyramid adapter was already prototyped as represented in figure 6-16.

Figure 6-15: Location of the rupture in the prototype.

Figure 6-16: Original prototype (left). Prototype with a metallic pyramid adapter integration (right).
Chapter 7

Conclusions and Future Work

7-1 Conclusions

The motivation of this work was to design a low-cost, lightweight, customized and natural-aesthetic prosthetic foot for children, with a short production-time able to improve the gait cycle of the amputee.

After identifying the opportunity that motivates this project, it was essential to take into consideration the available technologies and materials for its development. Product development methodologies were implemented that encompass 3D scanning, CAD design, FEA and 3D printing techniques. The proposed methodology begins with a meeting with the patient and pediatric physician specialized in physical medicine and rehabilitation, where anthropometric measurements (height and weight) and activity level information were acquired, as well as personal information, such as age and gender. The first step into designing a patient-specific prosthetic foot is if the patient is single or bi-lateral amputee. For the single-leg amputee, this step consists on performing a 3D scan of the amputee’s sound foot in order to acquire their specific foot geometry. Once the geometry is obtained, it is processed with Meshlab® for data simplification and, with the aid of Siemens NX® software, mesh corrections and separation of the toes of the foot are performed. To finish the design of the cosmetic component of the prosthetic foot, a cut on the ankle level with an inclination of 10 degrees is performed to follow SACH foot characteristics. For the bi-lateral amputee, no sound foot exists for foot scanning. In this case, the cosmetic component needs to be chosen from a database of sound feet of children that was created in this work with similar characteristics and scaled to the desired dimensions. This process was automated by developing a Matlab® tool that allows for a precise foot selection and scaling. The following stage is the design of the support component that also allows the integration with the rest of the prosthesis and absorbs the impact of the foot when it hits the floor, and posteriorly for energy return. The design of this component was also performed on Siemens NX® taking into consideration the available space in the cosmetic component and patient features, such as weight. Subsequently, the support component is combined with the cosmetic component and a FEA is performed on the combined design. Improvements
7. Conclusions and Future Work

to the structure or manufacturing can arise from such an analysis. The manufacturing of the prosthetic foot is made using a 3D printer with dual extrusion technology. The cosmetic component is printed with a flexible material, Filaflex, to simulate the skin and other soft tissues and the rigid component is printed with a rigid material, PLA, to simulate the bones, providing a supporting structure. Lastly, after prosthetic prototyping, a physical test with the amputee is performed and feedback from the patient, her mother, prosthetist, physician and physiotherapist is gathered.

The foot geometries acquired from the 20 healthy children from Técnico Lisboa’s nursery allowed for establishing relations between foot length, weight and height. A tool was developed using Matlab® to find the correct foot size based on an amputee child’s height and weight. These results represent a big step forward in the development of customized prosthetic feet for both single and bi-lateral amputated children, since it provides real data for prosthetic foot development. For every amputee child from 2 to 5 years old it is possible to choose which foot geometry should be used, and a scaling factor if needed using only easily obtainable data: their weight and height.

FDM technology, using a double extruder to print simultaneously flexible and rigid materials proved to be a reliable manufacturing method with potential to make more customized, cheaper and quickly-produced prostheses. The developed methodology was applied to a 5 years-old bi-lateral amputee child, who accepted the prototype extremely well. The developed prosthetic foot proved to nail all the target specifications and check all the important characteristics required for a natural gait development. The geometry of the rigid component provided comfort and smoothened the gait cycle by allowing shock absorption during heel-strike, facilitating the transference of the weight to toes-off phase; the geometry of the rigid component near the toes allowed the cosmetic component, made of Filaflex, to bend, facilitating the use of the mechanical knee. Apart from the happiness of the child and almost immediate affection with the developed prosthetic foot, the girl decreased the base of walking, which was a problematic characteristic of her gait, and showed more confidence using her mechanical knee. The test subject performed new movements while using this prosthetic foot that had never been performed when using SACH foot, due to the comfortable and elastic feeling of the new prosthetic foot. A physical test of the prosthetic foot, originally planned to be of 2 hours, was extended after the enthusiasm of the physician, physiotherapist and prosthetist, who incentivised a longer test, allowing the girl to use the developed prosthetic foot at school. After a day of excessive and unplanned usage, the right prosthetic foot broke on the pyramid geometry, the most fragile region, that lead to the adaptation of a metallic pyramid adapter to the prosthetic feet.

7-2 Future work

The initial and biggest goal of the project, to develop a customized prosthetic foot able to improve the amputee’s gait cycle, has been achieved. However, there are some improvements to be made in prosthetic foot development for children.

For a richer database, more foot geometries from healthy children from 1 to 7 years old would be a good addition to allow establishing more consistent relations and identify outliers. With a wider range
of possible geometries, more personalized medical solutions can be achieved, since a great variability of geometries and characteristics makes it easier to find similarities between the patients and the individuals from the database, resulting in a higher efficiency and accuracy when choosing the best foot geometry to use. Such is not just useful for bi-lateral amputee children, single-leg amputee children can also benefit from it, since they can choose to use a foot geometry from this database instead of having to perform the 3D geometry acquisition of their sound foot. However, when acquiring the foot geometry of children younger than 3 years old, the methodology should be rethought due to the difficulty faced when trying to keep them still during a 3D scan, a requirement for obtaining good results.

On what concerns FEA, studying the orthotropic mechanical characteristics of FilaFlex and PLA, FDM 3D printed in similar conditions and with the same infill percentage as in the final product, would enable more approximate FEA results. Also, having a more realistic simulation of the interaction between the pylon and the prosthetic feet may provide more realistic results. Lastly, the simulation of the three phases during gait cycle could take into consideration the experienced forces during a gait cycle, recorded in a biomechanics laboratory using force plates, instead of only considering the body weight and the safety coefficient.

More computational tests should be performed in order to take into consideration different aspects such as shear stresses, dynamic analysis and take close attention to the rigid-flexible interface inside the developed prosthetic foot. Physical tests should also be performed to test material’s resistance to wear and fatigue.

This project, which contemplated the initial part of the development of a prosthetic foot, did not focus on its durability. However, to be able to commercialize the prosthetic foot, it has to pass ISO 22675, which ensures the possibility of using the prosthetic foot for 3 years. Although for children it is not expected them to use it over one year due to their fast-development, this is a mandatory requirement of the standard. However, in developing countries, it is possible the apply ISO 10328, a simplified version of the first, and commercialize it.

In order to have better results to rely on the potential of the developed prosthetic foot, a comparison between the gait analysis using SACH foot and the developed prosthetic foot would be necessary as well as more insights from more amputee children, after testing the prosthetic foot.

The fragility of the developed prosthetic foot is concentrated on the pyramid adapter, where the integration with the pylon is performed. In fact, the test performed by the bi-lateral amputee girl proved that this region should be carefully designed, and the use a metallic pyramid adapter has to be considered for heavier children for better results. Even though the developed prosthetic foot appears to have a better performance when comparing with the SACH foot, it is clear that SACH is stiffer and therefore more resistant. In fact, SACH foot passes ISO 22675 proving to be able to last 3 years of use. Nevertheless, the SACH foot is breakable, and its durability depends on the level of activity of the child.

Designing other prosthetic components, such as the leg shell, could be a direction to take in future works.

Another relevant feedback to take into consideration for future developments is to adapt the infill density according to the weight of the child to allow a easier bending of the toes of the prosthetic foot.
Despite these suggestions for future work, the developed prosthetic feet proved to improve the quality of life of a 5-year-old bilateral amputee girl.
References


References


[31]: Bettina Fritz and Marlene Mauch. Book: Handbook of footwear design and materials.

[32]: Joost Geeroms. Study and design of an actuated below-knee prosthesis, 2011.


References


[74]: Kenyail Chosette Norris. Rehabilitation process of lower extremity amputees.


[87]: Lucien Reclaru and Dan Grecu. 3d printing yesterday, today, and tomorrow in orthopedic field.
References


References


References


APPENDIX A

ideaMaker 3D printing settings

Here are presented the used settings for the 3D printing of the developed prosthetic foot.

![3D printed Layer settings in ideaMaker® software.](image)

**Figure A-1:** 3D printed Layer settings in ideaMaker® software.
A. ideaMaker 3D printing settings

**Figure A-2:** 3D printed Extruder settings in ideaMaker® software.

**Figure A-3:** 3D printed Extruder settings in ideaMaker® software.
Figure A-4: 3D printed Cooling settings in ideaMaker® software.

Figure A-5: 3D printed Ooze settings in ideaMaker® software.
A. ideaMaker 3D printing settings
Matlab function to predict the desired prosthetic foot length

In order to predict the best prosthetic foot length to introduce in each amputee’s prosthesis, it is importante to build a database with sound foot geometries and develop a Matlab® function able to select the best foot geometry to use from this database. The function has to take into consideration amputee child’s height and weight and, based on the function that relates these characteristics with the foot length from healthy children, estimate the desired foot length.

The function developed in Matlab® 2015b is named estimaFootDimension. Matlab® code from estimaFootDimension.m:

```matlab
function [pe, mdl] = estimaFootDimension(h, w)

% Load da Tabela
load('criancas_pes.mat')

% Load lista de nomes
[~, ~, listaNomesAnonimo] = xlsread('/Users/inesferreira/Documents/MATLAB/listaNomesAnonimo.xlsx','Folha1');
listaNomesAnonimo(cellfun(@(x) ~isempty(x) && isnumeric(x) && isnan(x), listaNomesAnonimo)) = {''};

% Separa a tabela em colunas
age = criancas(:,1);
height = criancas(:,2);
weight = criancas(:,3);
f1 = criancas(:,4);

% Calcula a equação b0 + b1*height + b2*weight
X=[ones(size(age)) height weight];
```
B. Matlab function to predict the desired prosthetic foot length

```matlab
mdl = fitlm(X,fl,'linear');
% linear, quadratic, .. e analisar p-value (que queremos que seja pequeno)
% e R-squared queremos elevado (próximo de 1)
% Em Estimate aparece os valores de b

% Faz plot do resultado com a regressão
scatter3(height,weight,fl,'filled')
hold on
x1fit = min(height):0.5:max(height);
x2fit = min(weight):0.5:max(weight);
[X1FIT,X2FIT] = meshgrid(x1fit,x2fit);
YFIT = feval(mdl,X1FIT,X2FIT);
mesh(X1FIT,X2FIT,YFIT);
xlabel('weight')
ylabel('height')
zlabel('foot length')
hold off

% Para o caso da Ariela
pe = predict(mdl,[h w]);
%b = mdl.Coefficients.Estimate; pe = b(1) + b(2)*h + b(3)*w; % APENAS LINEAR

% criança com maior semelhança ao p?
 [~,pos]=min(abs(fl-pe));
nome = listaNomesAnonimo{pos};

% FLsimilar = fl(pos);
% fprintf('
Foot length similar = %.2f cm. %s.
', FLsimilar);
porpocao = ((pe-fl(pos))/fl(pos))*100;
fprintf('%nFoot length = %.2f cm. The most similar child is %s. Scale = %.2f percent. 
', pe, nome, porpocao);
end
```
APPENDIX C

Relations between foot dimensions

The foot measurements taken from the 20 children from Técnico Lisboa’s nursery allowed establishing relations between different parameters of foot geometry, compiled in the graphics below.

Figure C-1: Relation between foot length and TBW.
C. Relations between foot dimensions

Figure C-2: Relation between foot length and THW.

Figure C-3: Relation between foot length and IH.