Variable Stiffness Prosthetic Foot

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Faculty of Industrial Engineering, Mechanical Engineering and Computer Science
University of Iceland
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Dissertation submitted to the Faculty of Industrial Engineering, Mechanical Engineering and Computer Science, University of Iceland, in partial fulfillment of a Philosophiae Doctor degree in Mechanical Engineering

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Abstract

Prosthetic devices are intended to replace missing limbs. Although this statement is simple, the design, testing, and validation of these devices are considerably complex. A number of energy-storing-and-returning prosthetic feet are commercially available, and the recently developed bionic prosthesis aims to increase ankle push-off power or ankle joint compliance. The motivation for this thesis is to propose an alternative device design for a variable sagittal stiffness prosthetic foot. The device must retain the benefits of existing energy-storing-and-returning devices with the addition of stiffness modulation possibilities but with limited additional mass. The second objective of this thesis is to propose an advanced machine testing procedure capturing data that are usually collected during user trials in a gait lab. The data collection can reduce the necessity for user testing in the early phases of the design process.

Four different concepts in which stiffness modulation is mechanically tested are explored in this work. Non-Newtonian foam was used in the first prototype device; however, the concept was abandoned due to the intrinsic limitations in the stiffness change of the material relative to impact and speed. A discrete stiffness mechanism was then modeled, allowing a considerable change in the foot response with a quick user action. Finally, a cantilever beam with a movable support was preferred, leading to the design of two different devices. A final prosthetic foot design that enables wireless sagittal ankle stiffness modulation by the user or prosthetist is proposed. The variable stiffness ankle foot prosthesis was evaluated mechanically and on transtibial amputees. The device was subjected to advanced machine testing to contrast the results with those of biomechanical testing. The developed input curves for simulated incline and decline walking on the machine are promising. The machine and biomechanical ankle test results were compared.

This work is anticipated to encourage the development of devices prioritizing simple yet clinically relevant functions as well as support biomechanical and mechanical engineers with a test method that can further advance the communication between these two engineering fields.

Útdráttur

Gervifótum er ætlað að koma í stað útlima sem vantar. Þrátt fyrir að þessi fullyrðing sé einföld þá er hönnun, prófun og staðfesting á réttri virkni fótanna flókin. Nokkrar tegundir gervifóta sem geyma og skila orku eru á markaði. Nýlega hafa komið fram gervifætur stýrðir af lífmerki og miða að því að auka kraft frá ökkla. Markmið þessa verkefnis var að hanna nýjan gervifót með breytilegri stífni. Föturinn varð að hafa eiginleika núverandi fóta sem geyma og skila orku, ásamt möguleikum á breytilegri stífni án þess að auka massa fótarins umtalsvert. Annað markmið þessa verkefnis var að leggja til vélaræna prófunaraðferð sem fangar gögn, sem venjulega er safnað við göngugreiningu notenda á rannsóknarstofu. Vélræn prófun getur dregið úr þörf á notendaprófum á fyrstu stigum hönnunarferlisins.

Í þessu verkefni voru fjórar útfærslur stífnibreytinga prófaðar vélrænt. Svampur með ólínulega stífni var notaður í fyrstu útfærslu. Fallið var frá henni vegna eðlislægra takmarkana á stífleika efnisins við högg og hratt álag. Næst var hönnun þar sem notandi gat breytt stífni ökklans umtalsvert á fljótlegan hátt, prófuð í tölvu. Þá var valin hönnun sem byggði á bita með hreyfanlegum undirstöðum sem leiddi til tveggja mismunandi útfærslna á ökkla. Loka hönnunin er gervifótur sem býður upp á þráðlausa stillingu stífleika ökkla. Gervifóturinn var prófaður og metinn vélrænt og á notendum í göngugreiningu sem höfðu misst fót fyrir neðan hné**.** Niðurstöðurnar fyrir göngu upp og niður brekku voru bornar saman og reyndust sambærilegar.

Gera má ráð fyrir að þetta verkefni hvetji til þróunar tækja sem forgangsraða mikilvægum eiginleikum fóta ásamt því að koma fram með prófunaraðferð sem aðstoðar verkfræðinga og hönnuði stoðtækja við frekari þróun og prófanir.

I dedicate this work to my wife and soulmate Heiða, for her endless support,

and to our two children, Emily, and Leo, whom I wish to inspire to follow their ambitions.

I also dedicate this work in memory of my parents Paule and Claude.

« Je passe mon temps à faire ce que je ne sais pas faire, pour apprendre à le faire. »
- Pablo Picasso

Preface

This dissertation has been prepared in partial fulfilment of the requirements for a doctorate degree in Engineering at the University of Iceland. The research was conducted at the Department of Mechanical and Industrial Engineering, University of Iceland, and at Össur, a medical device company.

This work is part of a research project focusing on variable stiffness prosthetic feet considering multiple aspects of lower limb prosthetics in a multidisciplinary approach. The study was conducted in collaboration with the mechanical and physical therapy departments of the University of Iceland. Although this research presents variable stiffness design concepts and advanced mechanical testing, the clinical benefits, user perspective, and usage of smart material is integrated in the project group research.

Despite the years of developing and bringing lower limb prosthetics to the market, the author desires to improve his understanding and work methods. Moreover, hopefully, through this effort, valuable new knowledge can be offered to engineers and researchers in this field. In addition to sweat management and powered prosthetics, a variable stiffness prosthetic foot is one of the "holy grails" in prosthetics. The interaction with prosthetic users inspired the variable stiffness foot project idea, and its realization was made possible by discussions with professors at the University of Iceland.

This work was funded by the Technology Development Fund of the Icelandic Center for Research (Grant no. 163805-0612). The materials and test machine for measurements were provided by Össur Inc. where Christophe Lecomte is an employee.

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Abbreviations

CAD	Computer-aided Design
CFRP	Carbon Fiber-reinforced Plastics
DoF	Degree of Freedom
EMG	Electromyography
ESAR	Energy Storage and Return
FEM	Finite Element Model
FJC	Functional joint center
RoM	Range of Motion
SACH	Solid Ankle Cushioned Heel
SM	Smart Materials
STF	Shear Thickening Fluid
VSA	Variable Stiffness Ankle foot prosthesis

Acknowledgements

I have been extremely fortunate to collaborate with individuals and organizations. Without them, this thesis would not have been completed.

I wish to profoundly thank my advisors, Professors Kristin Briem and Sigurður Brynjólfsson. The thesis concept started as a discussion and turned to be five years of collaboration. I wish to express my gratitude for your mentorship, guidance, and critical review of my work. I learned so much, professionally and personally. Thank you.

I would like to thank my colleagues in the project group, Anna Lára Ármannsdóttir, Heimir Tryggvason, and Felix Starker. The time we worked together is one of the highlights of my career. We went through difficult assignments together but always kept the work enjoyable.

I wish to thank the Össur Company and Kristleifur Kristjánsson for allowing me to engage in this research and providing the equipment necessary to conduct the study while continuing my engineering work.

I would like to thank Rannis, the Technology Development Fund of the Icelandic Center for Research, for supporting this project.

My most special thanks go to my wife, Heiða, for her extraordinary support, and to our two children, Emily and Leo, who I am so proud of. I love you guys! Every day you remind me of the most important things in life.

Declaration of contribution

I declare that I have composed this thesis by myself. I confirm that the work submitted is my own, except for included work that has been formed as part of jointly authored publications. My contribution and those of the other authors to this work have been explicitly indicated.

1 Introduction

The purpose of a prosthetic foot is to replace a missing limb, identifying a clear objective for researchers and designers. However, to achieve this, considerable design complexity is involved. Amputation is a life-transforming experience and working with amputees is a great motivation to provide them with an improved prosthetic device. This research focuses on the physical parameters of prosthetic feet (e.g., sagittal stiffness) but does not undermine the long-term impact of wearing a prosthesis in terms of physical and psychological aspects. The common thread of this work is the evaluation of possible designs and relevant testing elements that could be useful for researchers and engineers.

The work presented does not intend to solely demonstrate a single novel prosthetic foot. Rather, the aim is to highlight an important element that is missing today in commercially available prosthetic feet. It further seeks to improve the current state-of-the-art in terms of linking the mechanical and biomechanical testing of prosthetic feet. This thesis is a narrative on variable stiffness in the design of prosthetic feet as well as the biomechanical and mechanical evaluations of these prosthetics.

1.1 Background

The evolution of prosthetics may seem to have rapidly developed from the perspective of outsiders in this field of research. The first prosthetic devices discovered are dated from 2600 B.C. in Egypt. Subsequently, technological advancement in materials, design, and testing have aided in improving these devices [1]. This research focuses on lower limb prosthetics, specifically prosthetic feet, with the goal of adding prosthetic ankle compliance, adjustability, and in due course, improved comfort for users as they undertake various daily activities. Unfortunately, the field remains distant from the "ideal solution," and users experience various problems with their prosthetic devices in ordinary activities of daily living, such as walking on uneven terrains, slopes, or stairs [2].

The human foot has a specialized anatomy developed through bare-foot bipedalism and has important biomechanical implications for stability and propulsion [3]. The foot bones account for a quarter of the human skeleton, indicating that the foot is a complex mechanical structure and the challenge involved in the design of prosthetic devices [4]. Prosthetic feet are simpler and less adaptive, and after lower limb amputation, individuals lose functions that are important in gait. The calf muscles contribute to both shock absorption and forward propulsion during walking, and lower limb amputees suffer functional impairments for power generation and shank forward progression [5]. After the toe-off during the early swing phase, the ankle dorsiflexors quickly reverse the ankle motion from plantarflexion to dorsiflexion for subsequent foot clearance. Moreover, dorsiflexors are necessary during the first phase of the gait cycle because they eccentrically lower the foot after the heel strike during weight acceptance. Plantar flexors perform an important function during other phases of gait. In mid-stance, they eccentrically control of the ankle as it moves into dorsiflexion, reducing the rate of tibia advancement to half of its former speed [6]. During push-off, the plantar flexors are the predominant source of positive muscle work as they concentrically contract [7]. Consequently, transtibial amputees commonly experience asymmetrical gait patterns [8].

1.2 Research objectives

This research has two objectives.

Objective I: Model, design, and prototype a variable stiffness prosthetic foot that can adjust its sagittal plane stiffness in dorsiflexion and plantarflexion.

The working hypothesis is that a passive mechanical design adapting to user preference and activity is beneficial for lower limb amputees. The specific aims of this objective are:

a) Model, evaluate, and test different solutions of the variable ankle stiffness adjustment

b) Prototype a final design concept for mechanical and biomechanical analyses

Objective II: Compare a prosthetic foot ankle stiffness using biomechanical and mechanical test methods.

Mechanical and biomechanical tests are both used for the evaluation of prosthetic foot stiffness. The specific aims of the second objective are as follows.

a) Propose a test method where mechanical and biomechanical results are comparable.

b) Compare stiffness results for both methods on a variable stiffness prosthetic ankle.

The importance of this research is that it seeks to assist lower limb amputees with a system that enables them to engage in various activities without compromised function.

The originality of this work is demonstrated by the different design approach implemented in contrast with the current state-of-the-art research. A different paradigm was followed to combine the design of sagittal stiffness adjustability with the intrinsic benefits of currently available prosthetic feet. The mechanical testing method and comparison with biomechanical evaluation are also novel in the research field.

The thesis research objectives and hypothesis are depicted in Figure 1-1.

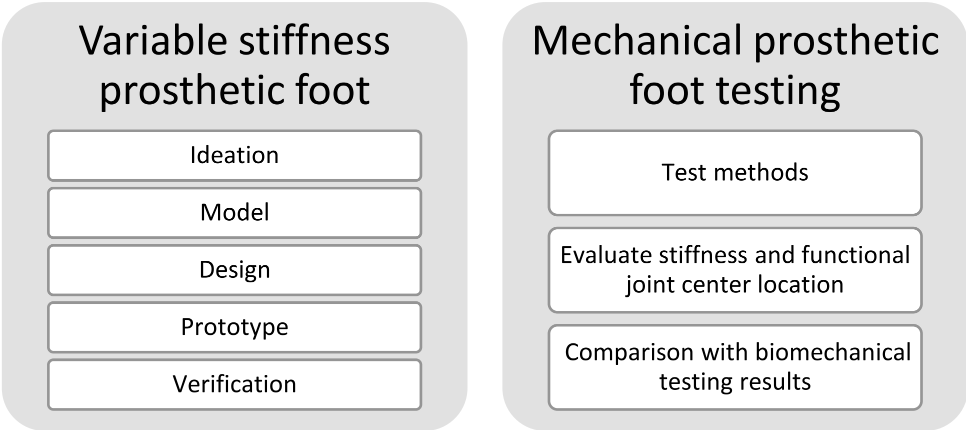


Figure 1-1. Thesis research objectives and hypothesis.

1.3 Research motivation

Energy-storing and energy-returning (ESAR) feet have been used for decades in prosthetics. Innovative bionic foot designs that provide ankle adjustment and power are also available in the market. The principal goals of these designs are to reduce metabolic cost and increase user comfort and safety. The field of rehabilitation and engineering research strives to improve lower limb prosthetics. Moreover, innovative research devices have been developed to advance existing bionic feet and power-assisting devices, such as AMP-Foot (ankle mimicking prosthetic foot) 2.0 [9]. These devices enable running similar to that described by Grimmer et al., who modeled a series of elastic actuators to reduce peak power requirements compared with a direct drive [10]. The idea of such novel devices, allowing users to engage in multiple activities, is one of the motivation for this research.

However, the aforementioned devices are expensive to manufacture and are typically heavier than conventional passive components due to the actuator technology utilized to provide push-off power. The mass and manufacturing cost of powered systems are limiting factors, reducing a wider acceptance in the prosthetic field. Therefore, the intention of this research was to propose a design responding to a clinical need while keeping the device mass and cost acceptable when compared to conventional prescribed prosthetic devices. The approach of this study was to investigate ankle stiffness and the provisions for adjusting it when necessary. The adjustment of the ankle joint stiffness can provide a means to satisfy the requirements of an amputee and the amputee’s prosthetist.

1.4 User perspectives

Prosthetic users desire to engage in a wide range of activities, from walking to running, and not to be limited by their handicap. Amputees walk “out in the world” on different terrains, such as level ground, inclines, declines, and stairs with current prosthetic technologies. Their activity level, impact level, or body mass can vary with time during and after rehabilitation.

In developed countries, a prosthetist prescribes a prosthetic foot for daily use that can typically be replaced every two to three years. Users may have access to a specific sport prosthesis; however, unfortunately, this access is often limited due to reimbursement rules or device cost. The prosthetic foot for daily use has a fixed ankle stiffness, which is generally intended to be adequate for all the user's typical daily life activities. However, the fixed stiffness limits mobility in different terrains and/or activities.

The working hypothesis was that an ankle with varying stiffness is beneficial when walking or running on different terrains. Moreover, increased ankle's range of motion, which can be achieved by lowering ankle stiffness, is beneficial when walking uphill by reducing energy expenditure [11].

The second working hypothesis was focused on ankle stiffness and locomotion speed. At higher speeds, increased ankle stiffness could be advantageous. A practical example is the concept of "catching a bus" where the user has to increase his walking speed. This requires higher keel stiffness to counteract the increased moment generated by the greater ground reaction forces.

Following a user-centered approach, the work presented in this thesis emphasizes that common daily tasks are not fully reported in conventional biomechanical data collection. The advantage of using a variable stiffness prosthetic foot can aid an amputee when the load temporarily increases (e.g., when carrying grocery bags or a child). This form of loading situation was evaluated by Koehler-McNicholas et al. on service members wearing a 22-kg vest [12]. The evaluation demonstrated that the sagittal stiffness of prosthetic feet had an effect on the late-stance energy return.

As for sport prosthetics, variable or adjustable stiffness could be necessary. As an example, for a 100-m run, athletes use a fixed-stiffness composite blade with no heel component. During the race, a range of loads is applied to the blade depending on the impact and speed of the athlete [13]. Many athletes describe having a stiff blade at the start of the race where energy return is difficult to generate. However, between 50 and 60 m, when the maximum speed is attained, blade deformation increases due to higher loads. Maintaining the maximum speed is challenging for the amputees due to the fixed stiffness of the running blade.

1.5 Prosthetist perspectives

Certified prosthetists/orthotists (CPOs) aim to provide prosthesis users with a suitable prosthetic foot, which can be selected from a wide range of manufacturers and products. However, they also have to choose the appropriate foot stiffness for the person. Manufacturers supply information guidelines for foot selection according to the user weight and activity. In a few cases, CPOs order several prosthetic feet of different stiffnesses or categories at initial fitting, allowing the users to try, feel, and select the best stiffness suitable to their walking style. Prosthetic fitting is a dialogue between the amputee and CPO. The CPO can adjust the prosthetic foot alignment to fine-tune the roll-over or the prosthetic foot response depending on the user reaction. A prosthetic foot with stiffness adjustability may prove beneficial for CPOs at the initial fitting or even during follow-up visits. The adjustability feature can provide them with "another screw to turn" to achieve successful outcomes for prosthesis users.

1.6 Scientific contribution

1.6.1 Journal articles

The scientific contribution included in the research work presented in this thesis is reflected by the three first-author publications in peer-reviewed international journals.

The journal papers and publications directly contributing to this dissertation are as follows.

1. **Paper I -** C. Lecomte, F. Starker, E.Þ. Guðnadóttir, S. Rafnsdóttir, K. Guðmundsson, K. Briem, S. Brynjolfsson, "Functional joint center of prosthetic feet during level ground and incline walking". Med. Eng. Phys. 81 pp. 13-21, 2020. https://doi.org/10.1016/j.medengphy.2020.04.011

Compared with the human ankle, ESAR prosthetic feet do not provide a defined articulation joint. Three prosthetic feet were evaluated on a roll-over test machine. The same prosthetic feet were fitted on two transtibial amputees. Kinematic data were collected during level-ground walking and walking up and down a 7.5° slope. For each test method, the functional joint center (FJC) was calculated, allowing the comparison between the two methods. Differences in the FJC location were observed between the tested devices and gait conditions. This analysis provides an assessment method using the mechanical test machine. Moreover, for the level-ground test, the analysis proves the correlation of the FJC location between the machine and biomechanical testing.

Author contributions:
C.L conceptualized the study; E.G, S.R, K.G, and K.B performed the gait analysis and data processing; C.L, F.S, and K.B analyzed and organized the data; and C.L prepared the original article. All authors provided inputs for review and editing; K.B and S.B supervised and acquired funding.

2. **Paper II -** C. Lecomte, A. L. Armannsdóttir, F. Starker, H. Tryggvason, K. Briem, S. Brynjolfsson, "Variable Stiffness Foot Design and Validation", Journal of Biomechanics, 122, 2021. https://doi.org/10.1016/j.jbiomech.2021.110440

A variable stiffness prosthetic foot, the variable stiffness ankle foot prosthesis (VSA) unit, which is capable of modulating its stiffness in the sagittal plane, was presented. The stiffness change was realized by moving the support points on a glass fiber leaf spring. The adjustment is performed using a wirelessly controlled lightweight servo motor. The device was evaluated mechanically and assessed by one transtibial user. The novel test method, which uses a six-degree-of-freedom (6-DoF) load cell and motion capture, allowed to contrast results between the mechanical and biomechanical tests. This study is a continuation of the test method comparison and introduction of a novel variable stiffness prosthetic foot.

Author contributions:
C.L conceptualized the study; C.L, F.S, and H.T conceived the VSA idea; C.L designed and prototyped the VSA foot; A.A performed the gait analysis; F.S performed the mechanical testing; C.L, A.A, and F.S analyzed and organized the data; and C.L prepared the original

article. All authors provided input for review and editing; K.B and S.B supervised and acquired funding.

3. **Paper III -** C. Lecomte, A. L. Armannsdóttir, F. Starker, K. Briem, S. Brynjolfsson, "Comparison of mechanical and biomechanical test on prosthetic foot stiffness", Applied Sciences, 11, 5318, 2021. https://doi.org/10.3390/app11125318

The VSA prosthetic foot was refined for multiple gait trials. Biomechanical data were collected from five transtibial amputees walking on level ground and walking up and down a 7.5° slope. The same device was tested on the roll-over test bench. The sagittal ankle moment, angle, and FJC were compared for the two test methods. A strong correlation was found for level-ground walking. This paper proposed machine inputs to evaluate the prosthetic feet for walking up and down a slope on a roll-over test machine. This paper contributes to this research by providing an improved mechanical test method and further advancing the variable stiffness prosthetic foot presented in published papers I and II.

Author contributions:
C.L conceptualized the study and designed and prototyped the second version of the VSA foot; A.A performed the gait analysis; F.S conducted the mechanical testing; C.L, A.A, and F.S analyzed and organized the data; and C.L prepared the original article. All authors provided inputs for review and editing; K.B and S.B supervised and acquired funding.

In addition, the candidate contributed to the following published work:

4. H. Tryggvason, F. Starker, C. Lecomte, F. Jónsdóttir, "Variable stiffness prosthetic foot based on rheology properties of shear thickening fluid". Smart Mater. Struct., 2020. https://doi.org/10.1088/1361-665X/ab9547

The rheological properties of shear thickening fluids were used in a prosthetic foot to introduce damping and force-coupling effects. The variable stiffness research group referred to this paper, which described another method to achieve stiffness modulation in a prosthetic foot. C. Lecomte analyzed the design, provided the prototype resources, and reviewed the first draft.

5. H. Tryggvason, F. Starker, C. Lecomte, F. Jónsdóttir, "Use of Dynamic FEA for Design Modification and Energy Analysis of a Variable Stiffness Prosthetic Foot". Appl. Sci., 10(2), 650, 2020. https://doi.org/10.3390/app10020650

Dynamic finite element analysis was implemented on a prosthetic foot by simulating the ISO16955 test method. The damping properties were adjusted in the model, resulting in the change in rotational stiffness. This work, which was referred to by the variable stiffness project group, provided a link between the finite element model (FEM) and roll-over testing. C. Lecomte analyzed the design and reviewed the first draft.

6. H. Tryggvason, F. Starker, A.L. Ármannsdóttir, C. Lecomte, F. Jónsdóttir, "Speed Adaptable Prosthetic Foot: Concept Description, Prototyping and Initial User

Testing". IEEE Transactions on Neural Systems and Rehabilitation Engineering, vol. 28, 12, 2978-2986, Dec. 2020. https://doi.org/10.1109/TNSRE.2020.3036329

This paper presents the final concept of the speed-adaptable prosthetic foot using shear thickening fluids. This research was utilized by the variable stiffness project group. C. Lecomte analyzed the design, provided the prototype resources, and reviewed the first draft.

7. L. Ármannsdóttir, C. Lecomte, S. Brynjólfsson, K. Briem, "Task dependent changes in mechanical and biomechanical measures result from manipulating stiffness settings in a prosthetic foot". Clinical Biomechanics. Clinical Biomechanics, 89, 2021. https://doi.org/10.1016/j.clinbiomech.2021.105476

This research paper presents the mechanical and biomechanical measurements of the variable stiffness prosthetic foot developed in the current study (i.e., VSA foot). This research was utilized by the variable stiffness project group. C. Lecomte provided the test device, supported the data collection, analyzed the results, and reviewed the first draft.

8. M.K. Shepherd, S. Member, D. Gunz, C. Lecomte, E.J. Rouse, "Methods for Describing and Characterizing the Mechanical Behavior of Running-Specific Prosthetic Feet". IEEE Int Conf Rehabil Robot., Jun 2019. doi: 10.1109/ICORR.2019.8779557.

The mechanical behavior of running-specific prosthetic feet was evaluated. The deformation and rotation of the composite blade were characterized. The work was inspired by the observed mechanical behavior of conventional walking feet with a FJC. This work is a collaboration with the University of Michigan. C. Lecomte reviewed the study design, provided the prototype resources, and reviewed the first draft.

9. DA. Türk, H. Einarsson, C. Lecomte, M. Meboldt, "Design and manufacturing of high-performance prostheses with additive manufacturing and fiber-reinforced polymers". Prod. Eng. Res. Devel. 12, 203–213, 2018. https://doi.org/10.1007/s11740-018-0799-y

The mechanical strength and mass of a prosthetic knee were optimized using hybrid additive manufacturing and composite-reinforced plastic structures. This work supported the composite modeling and additive manufacturing knowledge required in the current study. The research is a collaboration with ETH Zurich. C. Lecomte reviewed the prototype design, supported the prototype resources, and reviewed the first draft.

1.6.2 Conferences

During the conduct of this research, parts of the scientific work were presented in two oral presentations and one poster presentation.

Oral presentations:

1. Presentation at OT World on "effect of torsional stiffness on various terrains"; May 2018, Leipzig, Germany.

Presentation during orthotic and prosthetic conference in Leipzig. The study showed the rotational stiffness of two different prosthetic feet. A portable load cell system was used to enable user measurements outside the gait laboratory. The presentation highlighted the torsional stiffness properties of prosthetic feet on uneven terrain.

2. Comparison of three-dimensional (3D) biomechanical analysis of amputee gait and mechanical test bench simulation; Biomedical and Health Science Conference, May 2021, Reykjavik, Iceland.

The results of state-of-the-art biomechanical analysis of the gait of an amputee considering three terrains were compared with those of a mechanical test bench by simulating each task. The output measurements provided a satisfactory comparison between the two methods. Dynamic testing allowed the researchers and prosthetic foot designers to evaluate the device properties on a testing machine.

Poster presentation:

3. Poster presentation at "Nýsköpun á Heilbrigðisvísindasviði"; 2016, Reykjavik, Iceland.

The poster presented the results of a biomechanical study on a functional ankle joint center. The study showed that prosthetic feet have different FJCs. More importantly, it indicated that the position of the ankle joint center varies among different terrains.

1.6.3 Patents

The research work contributed to four utility patents.

1. "Prosthetic Foot with Variable Stiffness Ankle," US63/071,604 (filing number, not yet published) filed in 2020; inventor: C. Lecomte.

The utility patent describes the design of VSA foot, configuration of blades, and stiffness adjustment.

2. "Variable Stiffness Prosthetic Foot," US10,034,782; US10,624,765; and US20200281746 published in 2018; inventor: D. Sandahl.

The utility patent describes the discrete stiffness adjustment using a connection knob and flexible members.

3. "Variable Stiffness Mechanisms," US16/131,769 (filing number, not yet published) filed in 2017; inventors: C. Lecomte, F. Starker.

The utility patent describes the prosthetic foot construction with non-Newtonian material.

4. "Variable Stiffness Mechanism and Limb Support Device Incorporating the same," US16/132,004 (filing number, not yet published) filed in 2018; inventors: H. Tryggvason, F. Starker, C. Lecomte.

The utility patent describes the design of a variable stiffness damper using shear thickening fluid.

1.6.4 Award

1. Vísinda-og nýsköpunarverðlaun Háskóla Íslands 2021

The research project received the University of Iceland’s Science and Innovation Award in a competition of innovative ideas that may contribute to social or commercial benefits in the health and wellness category.

Project Team: Christophe Lecomte, Sigurður Brynjólfsson, Kristín Briem, Fjóla Jonsdottir, Felix Starker, Anna Lára Ármannsdóttir, and Heimir Tryggvason.

1.7 Thesis outline

The thesis is divided into the following chapters.

Chapter 2—State-of-the-art prosthetic feet, science, and industry. This presents an overview of the prosthetic research focusing on variable stiffness and an impression of the market state-of-the-art prosthetic feet.

Chapter 3—Evaluation of prosthetic feet. This outlines the methods commonly used in the industry and the research on prosthetic foot evaluation. This chapter includes a summary of high-level gait analysis and mechanical test methods.

Chapter 4—Variable stiffness foot design. This provides a narrative of the variable prosthetic foot designs evaluated during the research. The design concepts are presented and summarized.

Chapter 5—VSA Prosthetic Foot. This highlights the final device developed in this research. Biomechanical and mechanical testing results are presented. Future work is suggested for improvement and control.

Chapter 6—Discussion. This explains the relationship observed between mechanical and biomechanical testing conducted in this work. The evaluated variable stiffness design concepts are discussed.

Chapter 7—Overview of research structure and results. This summarizes the research questions, specific aims, and key findings of this research.

Chapter 8—Conclusions. This presents closing comments.

2 State-of-the-art prosthetic feet

The prosthetic foot design has continued to evolve with the aim of improving user benefits and foot functionality. In the 1980s, carbon fiber technology was utilized to store and release energy, and was considered a breakthrough. The ESAR feet became the most advanced ankle–foot system. In contrast, previous designs only used wood, foam, or thermoplastics. The ESAR feet are predominantly fitted on lower limb amputees, and their design continues to improve. Feet with a microprocessor were introduced in 2006 with the Proprio Foot (Össur). Figure 2-1 illustrates various prosthetic feet, showing the evolution in material selection and technology.

Figure 2-1. Evolution of prosthetic feet: (from left to right) 1) 1G6 SACH (Ottobock), 2) Vari-Flex (Össur), 3) Pro-Flex Pivot (Össur), 4) Elan Foot (Blatchford), 5) Proprio foot (Össur) and 6) Empower (Ottobock).

Research institutes, universities, and manufacturers are continuously developing new systems using novel technologies or adapting advanced materials for lower limb prosthetics. This chapter provides a summary of the state of the art of science and industry.

2.1 State of the art—Science

This section summarizes the state of science concerning stiffness and its clinical relevance. Then, a review of prosthetic foot stiffness and research on variable stiffness are presented.

2.1.1 Prosthetic foot stiffness—Clinical relevance

Although prosthetic devices are seemingly advanced and functioning well, falls are a common risk among lower limb amputees. Based on a survey of 164 prosthetic foot users, 58% of those with unilateral amputations reported at least one fall within a year [14]. Among the common reasons for outdoor falls are missed steps and uneven surfaces. Consequently, fear of falling can limit the daily life activities of amputees [15], with amputees reporting that they tend to avoid uneven terrains and steep slopes. However, the terrains in the real world are not always flat. The variability of human gait can be constrained by contextual tasks [16]. People constantly adapt their gait depending on the information from the outside world and their own body. For example, different gait strategies are used for stair ascent depending on multiple factors, such as stair height, number of stair steps, and individual strength. Allowing a change in the stiffness of the prosthetic ankle based on user preference, could improve prosthetic satisfaction.

To support this idea, a focus group study in 2016 explained the subject "What People Want in a Prosthetic Foot [2]." The critical points were directly obtained from the responses of prosthetic users; unfortunately, such points reported are typically not resolved in the literature. Obstacles, such as sidewalks, which are encountered daily, remain difficult to surmount. Different terrains, such as downhill walking, are also challenging.

2.1.2 Prosthetic foot stiffness—Biomechanics

Shortly after their introduction to the market, ESAR feet were improved over previous designs in terms of the ankle range of motion and the center of mass motion [17]. Several studies explored the sagittal ankle stiffness in prosthetic feet. The evaluation of roll-over shapes conducted by Klodd showed that modifying the forefoot stiffness affected the effective foot length [18]. The general consensus is that decreasing foot stiffness can increase the ankle range of motion [19], increased ankle push-off and range of motion can also lower the sound side loading, as observed by Heitzmann [5]. Static measurement was developed to determine the energy loss and displacement of prosthetic feet [20,21].

Quasi-stiffness and propulsion work can be estimated using Shamaei's method [22]. The relationship between ankle moment and angle can be determined from the heel contact to terminal phase, as shown in Figure 2-2a. The graph in Figure 2-2b depicts the nonlinear mechanical properties of the human ankle corresponding to different walking speeds.

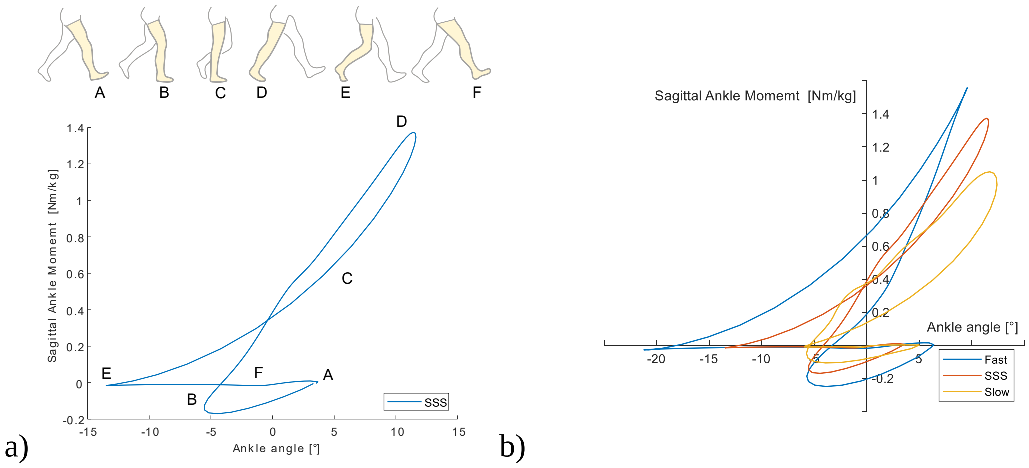


Figure 2-2. a) Able-body ankle moment versus ankle angle for self-selected walking speed. b) Able-body ankle moment versus ankle angle for fast, self-selected, and slow walking speeds (Gait analysis data from able side of a unilateral amputee; data extracted from work of Anna Lara Ármannsdóttir [23]*).*

Prosthetic feet are designed to mimic the moment and angles presented in Figure 2-2. The schematic shown directly above the figure highlights the different phases of the gait cycle: heel contact (A), onset of dorsiflexion (B), onset of dual-flexion (C), onset of plantarflexion (D), terminal stance (E), and swing (F). The dual-flexion term is used to define the phase where the ankle demonstrates dorsi-flexion motion at slow and plantar-flexion motion at fast gait speeds. Rouse thoroughly defined the difference between ankle stiffness and quasi-stiffness with an inversed pendulum example [24]. In 2014, he extended his work with the estimation of human ankle impedance during the stance phase [25]. His findings have an implication on the design development of the current project.

The slope of the moment and angle curve represent quasi-stiffness. Figure 2-2b presents the ankle stiffnesses of an able-bodied subject at fast, self-selected, and slow walking speeds. In this example, a larger quasi-stiffness is required for faster walking speeds. The prosthetic ankle rotational stiffness affects balance, and adequate quasi-stiffness may enhance gait safety for transtibial amputees [26]. Adamczyk evaluated the heel and forefoot stiffness properties by testing different stiffnesses on six active amputees [27]. The investigational device allowed the change in the properties of the ankle; biomechanical data were collected. He suggested that stiffness must be adapted to the amputation and activity levels to reduce gait deviations.

Hydraulic systems can be added to a standard ESAR foot. De Asha indicated that hydraulic systems can change damping and are most effective at the speed set up during fitting [28]. This finding is also one of the drivers of this research where the "adaptability" of the prosthetic foot to different walking speeds is beneficial for amputees. Adaptable ankle systems have shown some positive effects while walking on slopes [29,30]. The previous studies observed biomechanical variations and compared specific prosthetic foot models with a limited number of users. Typically, ESAR feet are simplified as spring elements; however, damping occurs during walking. Hysteresis is apparent in the clockwise curve of the ankle–moment curve at low speeds, whereas the counterclockwise curve indicates the input power (Figure 2-2b).

The instantaneous stiffness of prosthetic feet was evaluated by Webber [31], and the conclusion relevant to this thesis is the argument concerning mechanical testing as a reproducible method for evaluating and comparing dynamic prosthetic foot performance. One objective of this thesis is the application of mechanical testing to assess the prosthetic feet. Womac provided a report on the prosthetic foot stiffness, energy storage, and return characteristics. The force–displacement data of seven different devices at various orientations were collected [32,33], but only a few stiffness categories from each model were tested. Difficulty in interpretating the results is encountered in foot characterization when a quasi-static method is exclusively used. The assumption is that the dynamic testing of a simulated roll-over motion can be more relevant and closer to the “real world”. Frossard proposed a stiffness evaluation method where a 12-step process is recommended for the automated characterization of stiffness profile [34]. A portable kinetic system (IPECS, US), attached below the distal attachment of the limb, measured the forces and moments; a digital camera recorded the foot motion. The measurements were performed on amputees with osseointegrated prostheses. Frossard’s method inspired the development of the mechanical testing and stiffness evaluation in this research; consequently, this approach was implemented on a testing machine. Although this thesis focuses on sagittal stiffness, the work of Klute on coronal plane stiffness adjustment for prosthetics [35–37] encouraged the development of the vision to explore prosthetic foot stiffness adjustability.

2.1.3 Biomechanical results on specific devices

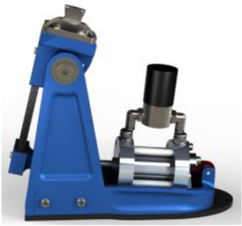
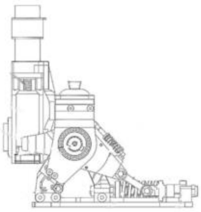
Prosthetic ankle stiffness has been thoroughly studied, and many research paths have been proposed to improve the ankle torque and prosthetic ankle range of motion. The following reviews some interesting projects that influenced this work.

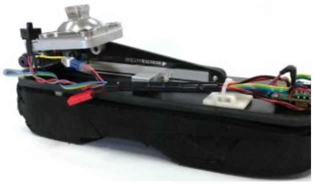
One of these projects pertains to bio-inspired design—an efficient lockable spring ankle [38]. The adjustable parallel spring system in the ankle is promising, and stiffness is adjustable using a control system via a series of elastic actuators. The concept of “reinjecting power” to the gait cycle using a lightweight device is interesting. A quasi-passive ankle–foot device was designed and characterized by Rouse et al. [39]. The system used a pneumatic piston, bending spring, and solenoid valve. The idea of an adjustable prosthetic foot is not novel and has also been attempted for ankle–foot orthoses, such as the adjustable robotic tendon using a spring in the work of Herring et al. [40]. In this research, similar to the others cited in this chapter, a device is developed using a novel mechanism. However, the benefits gained by amputees are not always statistically relevant compared with those derived from state-of-the-art prosthetic feet. Vrije Universiteit Brussel has been exploring Ankle Mimicking Prosthetic feet in the evolution of AMP-Foot [41–43]. Unfortunately, the intensity of effort required by AMP-Foot 4.0 during walking is higher than current passive prosthesis.

Regarding the prosthetic foot designs tested on users, Nickel proposed a prosthetic foot with an automatic adaptive ankle when walking on a slope [44]. More recently, Shepherd presented a prosthetic foot design with a glass fiber spring mounted along the foot length with a slider that modulates stiffness [45]. The improvement afforded by the design had been tested [46–48], and amputees perceived an 8% change in prosthetic foot stiffness. A similar mechanical principle has been used by Glanzer to develop a device based on a cantilever beam [49]. Moreover, Klute proposed to solve the nonlinear behavior of an ankle based on cam design [50]. One research group started to evaluate the use of a viscoelastic material unit in a prosthetic foot [51]. This initial work provides a positive impression on how this technology can be applied to the field of prosthetics. Some devices are not limited to sagittal motion stiffness adjustment or power input. The ankle–foot prosthesis proposed by Rogers et al. for rock climbing augmentation is a prosthetic foot with 2-DoF, thus allowing inversion–eversion motion [52].

Table 2-1 lists devices considered during this thesis.

Table 2-1.Research devices considered during this thesis

Prosthetic foot	**Figure**	**Considerations**
Efficient Lockable Spring Ankle (ELSA) prosthesis [38]		This low build-height prosthetic foot utilized lockable parallel spring, nylon rope and a mechanical release mechanism. A simpler design approach was preferred for this thesis to focus on a stiffness modulation without power input at push-off. However, this approach is effective for increasing peak torque.
Biologically Inspired Quasi- Passive Prosthetic Ankle-Foot [39]		The piston requirements are challenging for prosthetic foot variable stiffness, durability, and weight. Secondly, no foreseeable solution was found to keep roll-over characteristics of an ESAR foot when using pneumatic system during this thesis.
Ankle Mimicking Prosthetic (AMP-) Foot [41–43]		A low power actuator was storing energy in springs which was then released at push-off. A lockable or energy storing mechanism seemed interesting for a variable stiffness modulation, however the weight and complexity of the possible mechanism were deemed to outweigh the benefits for this thesis.

Passive prosthetic ankle-foot mechanism for automatic adaptation to sloped surfaces [44]		This system was self-adjustable to lock the ankle depending on the shank angle. This concept helped considering means to adjust stiffness depending on the user activity such as gait velocity. The idea was further developed with non-Newtonian materials in this thesis. The user can´t however change his preferences on the foot behavior.
The VSPA Foot: A Quasi-Passive Ankle-Foot Prosthesis with Continuously Variable Stiffness [46–48]		The semi-active device was noteworthy for this thesis. The cantilever beam approach was deemed to be answering some of the objectives. However, the roll-over sole surface could be further improved by introducing benefits of existing ESAR feet. The cam design can be replaced with other composites blades arrangement to adjust ankle torque-angle relationship.
Semi-Active Variable Stiffness Foot Prosthesis [49]		The lightweight (650g) and low build height device used overhung beam with adjustable support for stiffness modulation. The prosthetic foot is relevant to this thesis and fulfills the variable stiffness objective. However, the aim was to modulate stiffness in both plantar and dorsiflexion. A new design approach was required.
Nonlinear Passive Cam-Based Springs for Powered Ankle Prostheses [50]		A cam-based design was designed to achieve a non-linear ankle response. The stiffness constrains were answered with a compression spring in the ankle housing. A different composite leaf springs arrangements was preferred to achieve non-linearity and the cam-based approach

		considered to be challenging to fulfill durability requirement.
Viscoelastic ankle-foot prosthesis [51]		Spring-damper mechanism were developed to replicate the moment-angle loop in normal walking. The prototype unit was deemed too voluminous to further explore in this thesis. However, properties of viscoelastic materials were considered.
Ankle-Foot Prosthesis for Rock Climbing Augmentation [52]		Despite the device being presented for a specific activity as rock climbing, it brought interesting thoughts on the benefits of two degree-of-freedom movement in the ankle joint. One of the thesis prototypes was briefly tested for inversion-eversion stiffness adjustability. The EMG controls described for the rock-climbing foot are relevant for possible further control scheme of a variable stiffness ankle.

The following devices that have been investigated, are considered the most relevant for this work.

The semi-active variable stiffness foot prosthesis by Glanzer and Adamczyk is a low build height device allowing a stiffness range of 10–32 N/mm (Figure 2-3). The variable stiffness keel uses an overhanging beam with an adjustable support to enable stiffness change [49].

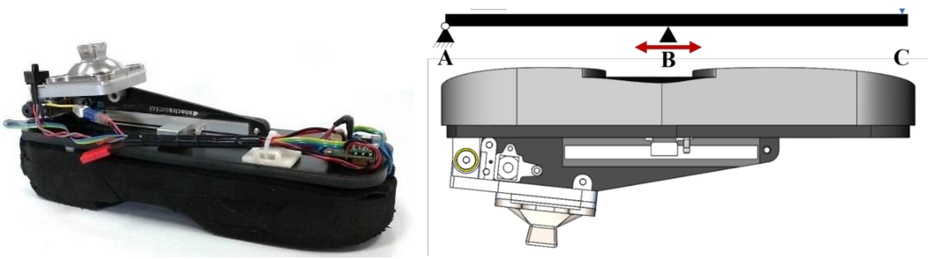


Figure 2-3. Semi-Active Variable Stiffness Foot by E. Glanzer and P. Adamczyk (reproduced from [49]*).*

The quasi-passive ankle–foot prosthesis with variable stiffness by Shepherd and Rouse uses the principle of an overhanging beam for stiffness change (Figure 2-4).

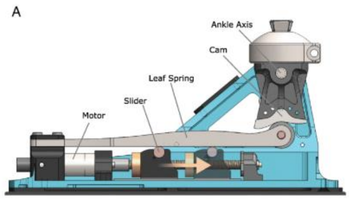


Figure 2-4. Quasi-passive ankle–foot prosthesis with biomimetic variable stiffness by M. Shepherd and E. Rouse (reproduced from [47]*).*

This novel design approach introduces a cam-based transmission to mimic the nonlinear ankle torque–angle curve [53][45]. The possible stiffness modulation is in the range 0.17–2.8 kN/mm.

2.2 State of the art—Industry

This section describes the state-of-the-art ankle–foot prosthesis and design concepts relevant to the thesis.

Prosthetic feet are usually categorized according to user activity (i.e., from low to high activity). User assessments can vary and are performed by the CPO [54]. In few countries, like the United States of America, this assessment is then used to “fit in” a specific reimbursement grade. Predicting user mobility level is difficult, and the selection between two activity levels can be vague, as demonstrated by Dillon [55]. Studies have shown that better-performing devices, which are typically prescribed to medium active users, can improve the gait symmetry of low active users [56,57]. Unfortunately, the access to advanced prosthetic system is limited by their cost.

Prosthetic feet can be categorized into three main styles: solid ankle cushioned heel (SACH), ESAR, and powered prosthetic feet. Mechanical feet, including SACH and ESAR, are the most prescribed prosthetic feet. More than a hundred ESAR feet are available in the market, and all have distinct designs or claims [58,59].

The ESAR feet, manufactured from carbon-reinforced plastic (CRFP) (Figure 2-5), are prescribed for the majority. Some mechanical components, such as shock absorber, alignment device, and vacuum systems, can be mounted on top of the CRFP foot.

Figure 2-5. Triton Foot by Otto-Bock (left) and Vari-Flex Foot by Össur (right).

In 2006, microprocessor feet became commercially available with the introduction of Proprio foot (Figure 2-6-1). This was the first prosthetic ankle with sensors and an actuator. The mechatronic ankle is mounted on a low-profile ESAR foot. The bionic device provides ankle angle adaptation in different terrains, toe lift during swing, and heel height adjustability.

Figure 2-6. (1) Proprio foot by Össur, (2) Biom foot from I-walk manufactured by Otto-Bock, (3) Air-Flex from Flex-Foot, and (4) Ceterus Foot from Flex Foot by Össur.

In 2010, MIT and iWalk introduced a powered ankle with the BiOM foot, providing a stance phase adaptation, generating active plantarflexion (Figure 2-6-2). The ball screw actuator at the rear of the unit is linked to a composite front spring. The unit is fixed to a low-profile ESAR foot. This is the first commercialized prosthetic foot that provides a powered push-off.

Older mechanical designs have already attempted to introduce a variable stiffness element. For example, Vari-Flex from Flex-Foot was introduced in the mid-1980s. The current product differs from the original design intent; an additional blade is mounted on the foot pylon to fine-tune the prosthetic foot stiffness, leading to the name “Vari-Flex.” This design was discontinued a few years thereafter due to its complexity and field failures. With Flex-Foot, the investigation of variable stiffness concept was continued and developed Air-Flex. This prosthetic foot used a design based on Vari-Flex with an additional air bladder sandwiched between two composites blades. The bladder pressure was tuned by adjusting the amount of air (Figure 2-6-3). This design was also discontinued due to air pressure loss in the system. An air pump similar to a small bicycle pump was also necessary to inflate the bladder.

Ceterus was introduced in 2001 (Figure 2-6-4). This high-profile ESAR foot had a rotational and vertical shock damper. The shock absorber is a combination of air pressure and a polyurethane rod. The air pressure in the system was tunable using a small air valve. To reach the appropriate compression, users could inflate or deflate the shock absorber. This design was discontinued in 2009 due to complaints of air pressure loss during use. Few users brought the pump with them to adjust the stiffness when necessary.

Figure 2-7. Prosthetic feet with hydraulic damping unit, (1) Elan by Blatchford, (2) Meridium from Ottobock, and (3) Triton smart ankle from Ottobock.

To overcome stiffness limitation, hydraulic prosthetic feet have been developed with adjustable dorsi- and plantarflexion by varying the system´s damping (Figure 2-7).

3 Evaluation of prosthetic feet

This chapter focuses on the sagittal plane of prosthetic feet. The stiffness values of prosthetic feet are not unified across devices and manufacturers. Research papers frequently compare one style or model of a prosthetic foot against another. The feet are compared and discussed in terms of stiffness values, range of motion, or energy return. Mechanical testing is commonly used to evaluate prosthetic feet, and each prosthetic foot type has its own stiffness category selection chart. Figure 3-1 shows an example for the Pro-Flex Pivot by Össur and the Taleo Vertical Shock by Ottobock.

CATEGORY SELECTION CHART

Weight lbs	99-115	116-130	131-150	151-170	171-194	195-221	222-256	257-287	288-324	325-365
Weight kg	45-52	53-59	60-68	69-77	78-88	89-100	101-116	117-130	131-147	148-166
Low Impact Level	1	1	2	3	4	5	6	7	8	9
Moderate Impact Level	1	2	3	4	5	6	7	8	9	N/A
High Impact Level	2	3	4	5	6	7	8	9	N/A	N/A

Spring stiffness relative to body weight and activity level		
Body weight [kg]	**Normal activity level**	**High activity level**
up to 51	1	2
52 to 58	2	3
59 to 67	3	4
68 to 77	4	5
78 to 88	5	6
89 to 100	6	7
101 to 115	7	8
116 to 130	8	9

Figure 3-1. Category selection chart example (*Pro-Flex Pivot by Össur and 1C51 Taleo Vertical Shock by Ottobock*).

Mechanical testing allows the comparison and characterization of prosthetic foot stiffness and provides a reproduceable test method.

3.1 Machine testing

This section describes two types of mechanical testing for evaluating the ESAR prosthetic foot stiffness.

3.1.1 Quasi-static testing

Heel and keel prosthetic foot stiffness values are commonly measured on a single-axis load compression test bench described in a setup derived from ISO10328 [60]. The heel and keel are loaded at 15° and 20°, respectively (Figure 3-2). The American Orthotic and Prosthetic Association published similar standard test guidelines to improve the consistency in reimbursement codes in the US [21]. Vertical force is applied, and the resulting displacement is recorded.

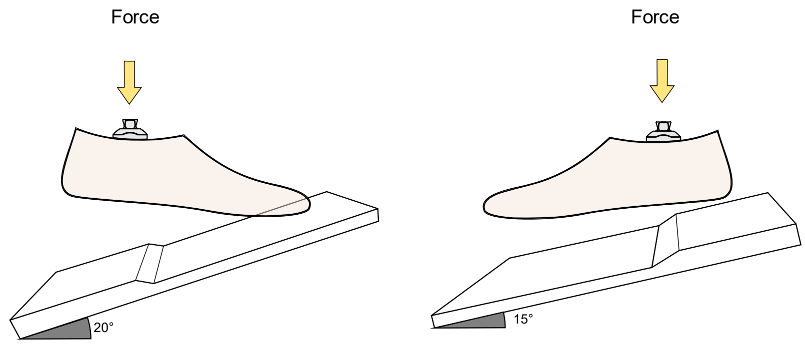


Figure 3-2. Schematic of heel and keel quasi-stiffness test based on ISO10328.

The quasi-static test yields a force–displacement curve. The setup and machinery used are simple, enabling results to be quickly obtained.

A quasi-static test was performed on three devices of the same size (27) and category (cat 5) to illustrate the different stiffness properties among the prosthetic feet using this test method. The heel and keel stiffness curves for Pro-Flex Pivot, Vari-Flex XC, and Pro-Flex XC (Össur) are depicted in Figure 3-3.

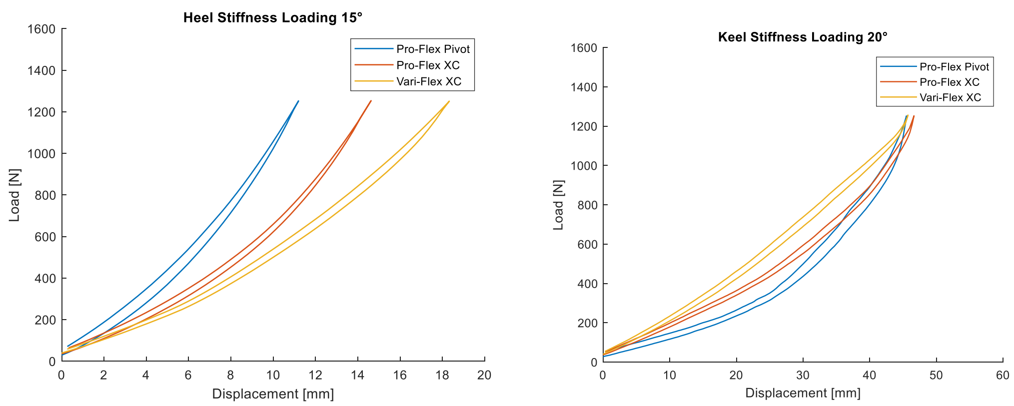


Figure 3-3. Heel and keel stiffness curves for category 5 size 27 of Pro-Flex Pivot, Pro-Flex XC, and Vari-Flex XC by Össur with 1250-N load.

The results well illustrate the variations in the quasi-stiffness of different feet models of the same category. The prosthetic feet are intended for similar user activity and body mass; however, the measured stiffness values of the heel and keel considerably differ. The heel results point to different displacement values measured for the same load, indicating a stiff heel or compliant heel. The keel data show the same total deformation for all devices; however, they characterize the difference in the stiffness curve from being progressive (for Pro-Flex Pivot) to virtually linear (for Vari-Flex XC).

Quasi-static testing can also be performed to contrast the same prosthetic foot across different stiffness categories or sizes. The stiffness progression across categories can differ per foot model but typically follows a linear progression between the categories and loads when same displacement is applied. The keel and heel trends are depicted in Figure 3-4 for Pro-Flex Pivot (size 27).

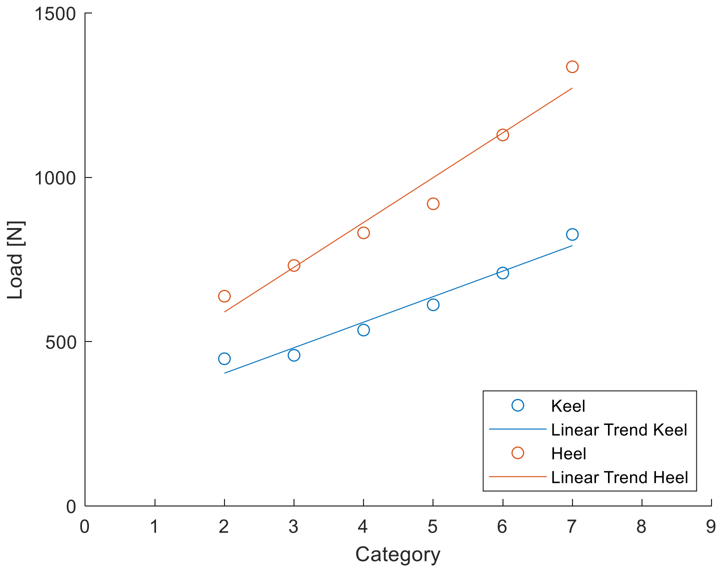


Figure 3-4. Quasi-static test results of stiffness (categories 2–7) for heel and keel of Pro-Flex Pivot size 27 by Össur (fixed deformation).

In this example, the stiffness change per category is 16% on average for the heel and 13% for the keel.

3.1.2 Roll-over testing

More complex test methods have been developed to create realistic loading in the assessment of prosthetic feet. A roll-over test for evaluating prosthetic foot durability is ISO22675 [61]. The test equipment can be used to quantify the physical parameters of prosthetic feet, and ISO/DIS 16955 describes the quantitative methods for evaluating the key performance indicators of prosthetic ankle–foot devices that are correlated to measurable prosthesis user benefit [62].

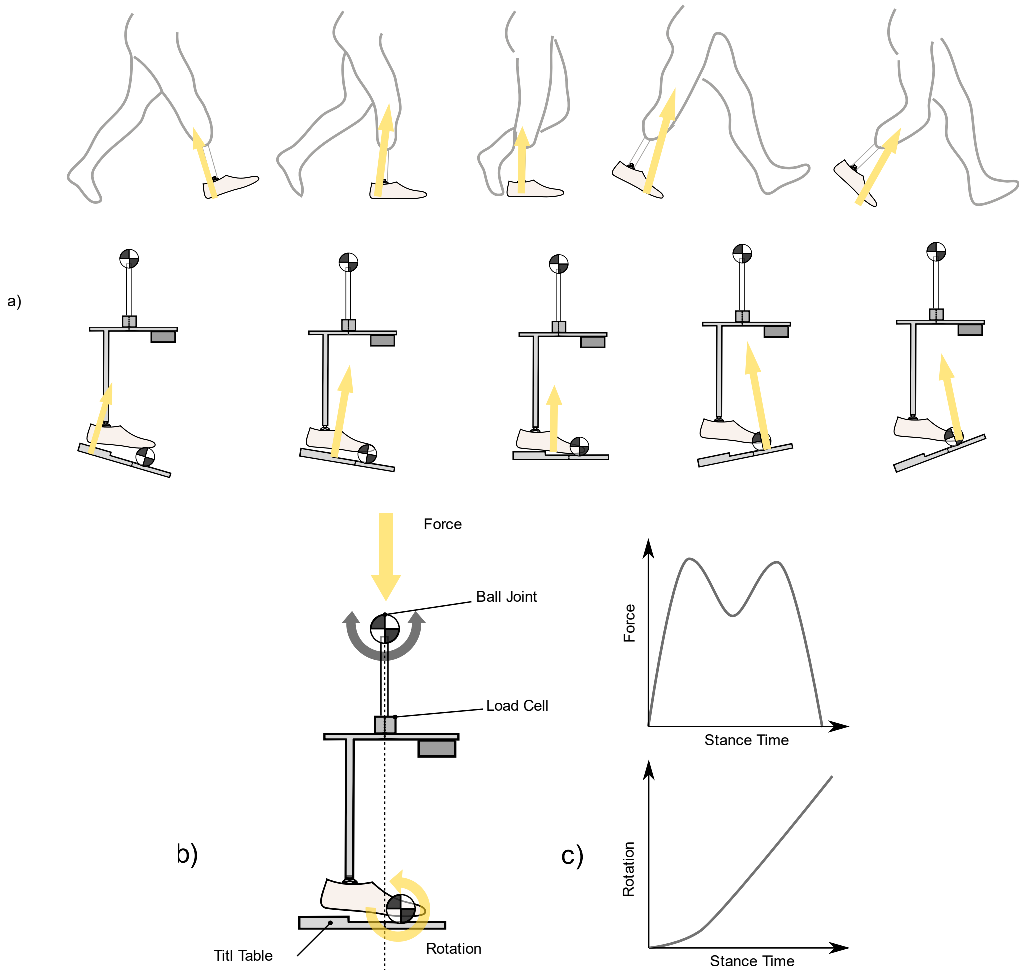


Figure 3-5. Schematic of mechanical test setup according to ISO16955; a) schematic contrasting gait cycle and roll-over cycle on test machine; b) mechanical test setup (yellow arrows indicate force and rotation; c) vertical force on ball joint and rotation of tilt table as functions of stance phase time (b and c are adapted from work of F. Starker).

The test is intended to simulate a heel-to-toe roll-over walking cycle. The test sample is subjected to an M-shaped force and a rotating plate synchronized with the vertical force profile. The plate angle starts at −20° for heel strike and ends at +40° for push-off. The machine setup is described in Figure 3-5.

The dynamic motion and test bench configuration allows the adjustment of input for the load and tilt plate angle. The 6-DoF load cell allows the forces and moments in the three planes to be recorded. The results of this test method are comparable with biomechanical measurements. The resulting forces and moments can be transferred mathematically from the load cell to a virtual ankle joint center.

3.2 Biomechanical testing

Gait analysis is the study of human locomotion. Since Aristotle’s De Motu Animalium, technology has enhanced the possibility and accuracy of collecting gait movements and forces. The analysis in three planes of motion on the prosthetic and sound sides reveals essential information on foot performance [63]. Prosthetic foot evaluation using state-of-the-art biomechanical analysis can be strenuous for users. The studies are typically performed in a controlled environment, such as a gait laboratory. Reflective markers are placed on the prosthesis and user to record motion with infrared cameras. Ground reaction forces are collected using force plates, and inverse dynamics method is employed to compute forces and moments based on the kinematics of every joint, inertial properties, and external forces.

The motion analysis data can be overwhelming to process and analyze. The typical focus points of biomechanists in prosthetic feet investigation are the ankle range of motion, ground reaction forces, quasi-stiffness values, center of mass progression, and ankle power. Roll-over performance is a critical element for prosthetic foot acceptance, which is insufficiently emphasized in the most recently published literature. The effects of prosthetic foot roll-over shape and effective rocker have been well described in the literature [64–69]. For the author, Hansen’s work is a key element in prosthetic foot user acceptance [69,70]. With regard to driving changes in prosthetic alignment or feedback on foot function, the prosthetic foot roll-over shape is the main focus in the CPO–user interaction.

An interesting yet challenging task for biomechanical engineers is to comprehend the effect of the prosthetic device on the user gait. Clearly understanding the interaction between the user and device can be complicated, and reaching a conclusion can be difficult if assumptions are solely based on examining the biomechanical data analysis results. The effect of prosthetic foot stiffness is difficult to capture in the laboratory environment, and the perceived prosthetic foot stiffness can be unreliable across users after the accommodation time [71]. Capturing the sensitivity to comfort is challenging when testing prosthetic devices. The users adapt to their prescribed devices and frequently use their daily prosthetic experience as a neutral point when testing new devices, consequently influencing their feedback on test devices unintentionally.

3.3 Functional joint center

To emulate the ankle motion, ESAR prosthetic feet rely on the deformations of the composite flexible members; no joints or articulations are clearly defined. The deformation rate or stiffness of each composite spring present in the prosthetic foot affects the prosthetic foot response when the prosthesis is loaded. The first article of this thesis presents the FJC evaluation for different prosthetic feet on different terrains (**Paper I**).

A single stiffness value is insufficient to describe prosthetic foot properties. ESAR prosthetic feet are often described as a spring element. A common misunderstanding in the field is the association of the prosthesis with a linear spring system. However, prosthetic feet exhibit vertical, horizontal, and angular deflections under load. The target deformations are reached depending on the prosthetic foot design. The flexible elements geometry, the laminate tapering along its length, and the contact surface among elements are some of the factors affecting the prosthetic foot deformation along the three planes.

Biomechanical gait analysis uses the motion of a defined body segment. A common approach to define the ankle joint location on a lower limb amputee is to assume this position as the anatomical joint on the contralateral side [72]. Research performed on running-specific prosthesis demonstrated that its composite blade exhibit vertical and horizontal components when loaded [73]. The research aim was to explore stiffness adjustment and measure changes in the spring constant. The unified deformable segment model can be used to disregard the ankle joint definition and is valuable for direct comparison between anatomical and different prosthetic feet [74]. Nevertheless, another direction component on the measured prosthetic foot function is required to answer the following questions: 1) What is stiffness change? 2) How does the prosthetic foot deform?

Further study of foot deformations was performed. The roll-over test setup was used to simulate dynamic walking with additional data recorded. Landmark markers were placed on the prosthetic foot, as shown in Figure 3-6; the marker positions were recorded by a two-dimensional (2D) camera. The markers were then tracked using motion analysis software (Tema, Image Systems, Sweden), and the coordinates were exported for further data processing in MATLAB.

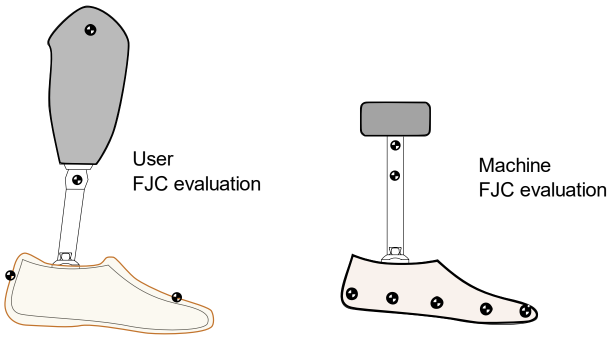


Figure 3-6. Schematic of marker positions used for FJC location calculation in biomechanical tests (left) and machine test (right).

Additional data were obtained for comparing the foot deformation between the mechanical test and biomechanical tests performed on users in the gait laboratory. The FJC is then calculated and compared, as depicted in Figure 3-7.

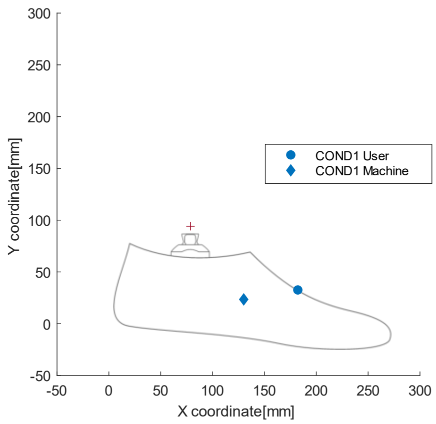


Figure 3-7. FJC location by machine and biomechanical tests of Vari-Flex XC (Össur).

The FJC location is dependent on the foot design, stiffness, and terrain. The rigid-body assumption among markers was used for the calculation. The center of zero velocity was calculated in the stance phase using a MATLAB custom script. To the author’s opinion, the FJC is not a parameter to be evaluated individually; it must be considered as an additional indicator in the comparison of prosthetic feet. The author suggests that using an FJC location close to the anatomical joint location is advantageous and is well accepted by users (**Paper I**).

4 Variable stiffness prosthetic foot design

This chapter describes the variable stiffness prosthetic foot designs evaluated in this research. The designs were formulated considering three distinct mechanical approaches: 1) the utilization of variable stiffness material, 2) the activation of composite blades, and 3) the support arm modulation on a cantilever beam composite spring.

The first research objective was to model, design, and prototype a variable stiffness foot. The design criteria included a stiffness change of 15% and a minimum mass addition compared with a standard ESAR foot. The common thread in the design approach was preventing the reduction in the advantages of original ESAR feet, specifically the roll-over performance.

“Having a vision for what you want is not enough. Vision without execution is hallucination.” (Thomas A. Edison)

Although the variable stiffness prosthetic foot idea is not novel, the execution of the concept is challenging. The ideation presented in this thesis didn´t follow a linear process, from a concept to a final device. The research started by focusing on the clinical and user requisites for a variable stiffness prosthetic foot. Two brainstorm sessions were completed with design and clinical experts from the research and development group at Össur and professors at the University of Iceland. All ideas were categorized and graded based on the technology, foreseeable stiffness modulation outcome, and novelty for the field. The research objectives and conceptualized mechanical models indicated that some ideas had to be adjusted or simply cancelled due to their poor feasibility for a prosthetic foot. For example, they may be inadequate due to mass or volume constraints. No single design emerged as a predictably successful concept for stiffness modulation; hence, this research considered three possible approaches and then finally selected one model for further verification and analysis.

4.1 Non-Newtonian polymers

Non-Newtonian polymers are used for human body protection [75,76]. The concept was to use an intermediate layer between composite blades to achieve variable stiffness depending on the deformation rate of the prosthetic foot. An off-the-shelf foam sheet was used for the experiment (i.e., 3DO) [77]. The rate-sensitive foam has the capacity to absorb and dissipate impact energy. Figure 4-1 shows the schematized concept for a running-specific blade (Flex-Run, Össur).

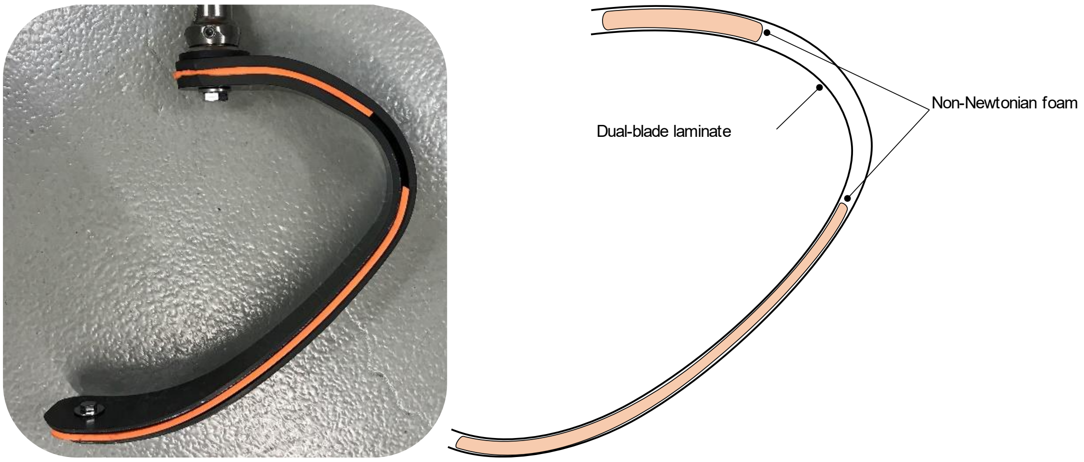


Figure 4-1. Running prosthetic foot concept using non-Newtonian intermediate layer.

A second prototype was built by adding a foam layer between the two C-shape blades of a commercially available size 27 prosthetic foot (Pro-Flex XC, Össur), (Figure 4-2).

Figure 4-2. Prosthetic foot with non-Newtonian foam intermediate layer.

The concept was evaluated on a mechanical testing machine for loading rates ranging from 0.5 to 3 Hz. The loading frequency was arbitrarily selected to span a wide speed range to possibly detect the effects of the foam material on foot deformations. A 1.0-Hz loading rate approximates a 3-km/h walking speed [78].

The keel stiffness was measured using the quasi-static method with a 20° plate angle at a maximum load of 850 N. The stiffness curves are shown in Figure 4-3.

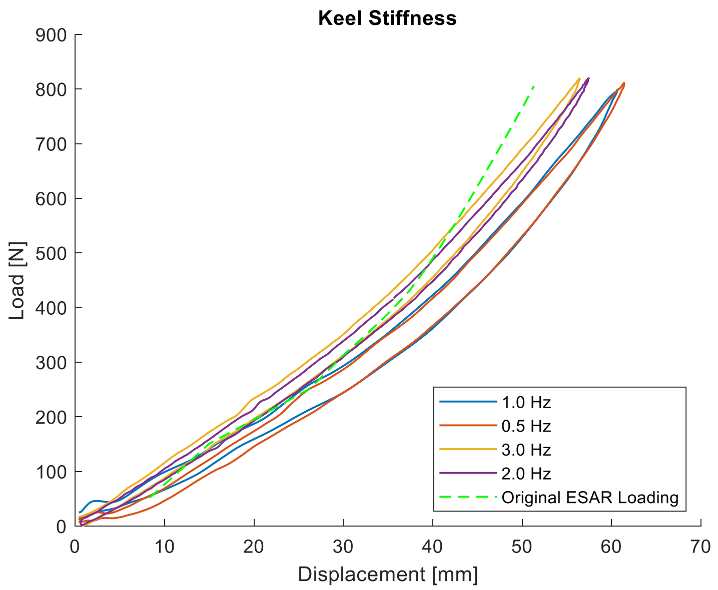


Figure 4-3. Non-Newtonian intermediate layer on size 27 C-shape prosthetic foot; Keel stiffness test results for varying loading speed (0.5, 1, 2, and 3 Hz) and original ESAR with 850-N load.

Table 4-1. Keel energy return and maximum displacement for different loading rates (0.5, 1, 2, and 3 Hz) for concept integrating non-Newtonian intermediate layer on size 27 C-shape prosthetic foot.

Loading rate (Hz)	**Energy return (%)**	**Maximum Displacement (mm)**	**Quasi-stiffness (N/mm) evaluated between 30-mm and 55-mm displacements**
3	90.1	56.4	18.0
2	88.9	57.5	17.9
1	87.3	60.7	17.1
0.5	88.6	61.5	16.4

The stiffness change is measurable with the changes in the loading speed and damping properties based on the energy return calculation (Table 4-1). The measured decrease in maximum displacement is 5.1 mm or 8.3% between loading rates 0.5 and 3 Hz. The quasi-stiffness change is 1.6N/mm (9.8%) from 0.5 to 3Hz.

A case study was performed on one transtibial amputee (activity level: K3; age: 48 years; size: 27; mass: 92 kg). The user was asked to walk at different speeds from slow to fast and then identify the perceived stiffness of the prosthetic foot. Only a “minor” perceptible change was acknowledged.

The advantage of this design concept is the ability of the device to adjust its stiffness automatically at higher compression velocities. No user interaction is required. The concept has limited additional mass compared with an existing device. On the C-shape prosthetic foot, the additional mass of the material used was only 80 g. However, due to its many shortcomings, this concept was abandoned. The stiffness change is extremely limited and speed-dependent. These deficiencies in the design concept have been identified because the user cannot adjust the stiffness for specific activities or preference. Finally, environmental temperature can also have an undesirable perceivable effect on the non-Newtonian foam stiffness; cold or warm environmental conditions can influence the material stiffness. This idea has been patented, US16/131,769 (filing number, not yet published).

4.2 Blade activation—Switch Blades

The utilization of different composite beams using a support engaging or releasing a second flexible element is the second concept evaluated in this research. The prosthetic foot stiffness increases when the support beam is connected. The concept is shown in Figure 4-5, where a commercial prosthetic foot (Pro-Flex XC, Össur) is modified to accommodate the blade activation concept and a control knob.

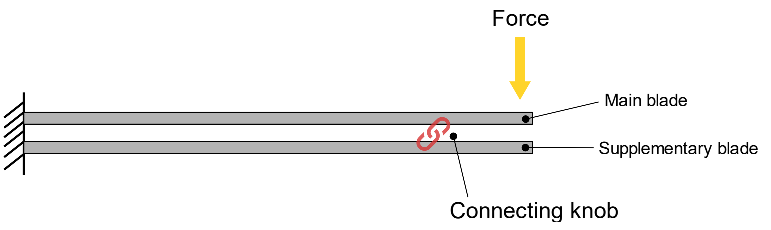


Figure 4-4. Schematic of blade activation concept with connecting knob.

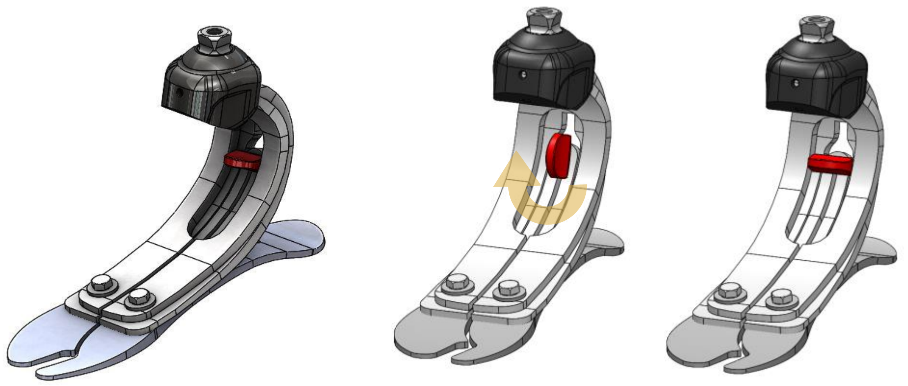


Figure 4-5. Schematic of blade activation concept applied to prosthetic foot (Pro-Flex XC, Össur).

The control knob (shown in red in Figure 4-5) can be manually rotated to engage a secondary spring, which is part of the lower C-shape blade. The stiffness change can be described as a discrete “ON or OFF” approach where the stiffness is increased by rotating the knob. The heel and keel stiffnesses are measured using the quasi-static method. Results are shown in Figure 4-6. With plate angles of 15° for the heel and 20° for the keel, a maximum load of 850 N was applied.

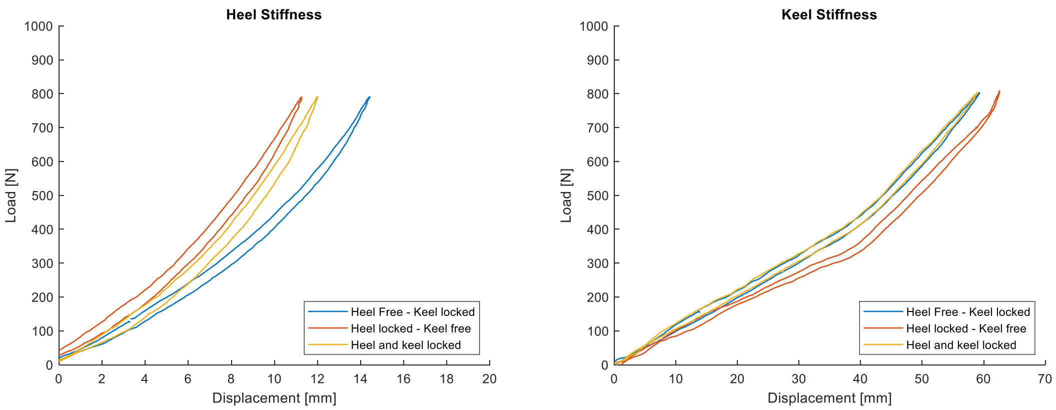


Figure 4-6. Quasi-stiffness test results for heel and keel of blade activation prototype (size: 27; knob positions: "Heel Free and Keel Locked," "Heel Locked and Keel Free," "Heel and Keel Locked"; load: 850 N).

Table 4-2. Energy return and maximum displacement under different stiffness conditions of blade activation concept (size 27; soft heel and soft toe locked).

	Keel			**Heel**		
Condition	Energy return (%)	Maximum displacement (mm)	Quasi-stiffness (N/mm) evaluated between 20-mm and 50-mm displacements	Energy return (%)	Maximum displacement (mm)	Quasi-stiffness (N/mm) evaluated between 2-mm and 10-mm displacements
Heel Free and Keel Locked	92.6	59.3	13.6	90.0	14.4	45.0
Heel Locked and Keel Free	91.1	62.6	12.3	87.8	11.3	68.0
Heel and Keel Locked	91.8	58.9	11.8	87.7	12.0	65.6

The energy return and maximum displacement results for the heel and keel are summarized in Table 4-2. The keel displacement change is 6% (3.7 mm) between the locked setting and soft toe and 20% (3.1 mm) for the heel displacement between the locked setting and soft heel. The measured changes in the quasi-stiffness values are approximately 15% (1.8 N/mm) and 45% (20 N/mm) for the keel and heel, respectively.

The simple design approach is advantageous to achieve adequate stiffness modulation. The additional mass compared with the original ESAR model is limited to 50 g. The stiffness variability can be further explored by modifying the inertial ratio of the main blade to the supplementary blade. The main blade's functionality is to withstand conventional loads, whereas the supplementary blade can be defined as an additional spring component. Moreover, because the CRFP blades of the prosthetic foot are subjected to tension and compression during the gait cycle, the control knob can be adjusted to control the heel and keel stiffnesses separately. The coupling location is fixed in the concept presented; however, a mechanism can be introduced to adjust the coupling location. The knob can be translated in an oblong slot machined in the blades. The position change will create change of lever arm when the blades are connected with the knob. In the current concept, the knob was positioned as distal as feasible on the existing prosthetic foot, to ease user accessibility.

The simplicity of this concept can be a benefit or a drawback depending on the type of stiffness modulation envisioned. The adjustability has a single discrete effect, shifting from a compliant to a stiffer system. This idea has been patented in US10,034,782; US10,624,765; and US20200281746.

4.3 Cantilever Beam Design

4.3.1 Concept

The cantilever beam design is another approach to vary the stiffness change in prosthetic feet. The basic principle is to move the load support point to one of the flexible members, as schematized in Figure 4-7.

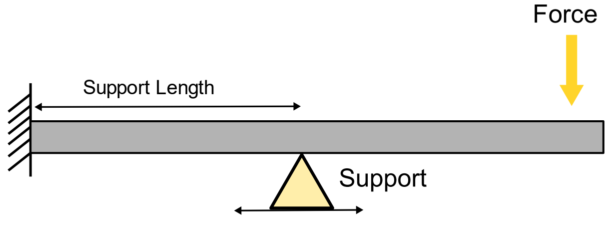


Figure 4-7. Schematic of cantilever beam with adjustable support.

The formula for the deflection of a cantilever beam with a single load is applied to evaluate the maximum deformation of the beam:

$$\partial = \frac{FL^3}{3EI},$$

where ∂ is the beam deformation; F is the applied force; L is the length to the support; E is the flexural modulus; and I is the second moment of inertia.

The first concept evaluated is a C-shape design using an adjustable inner spring, as schematized in Figure 4-8.

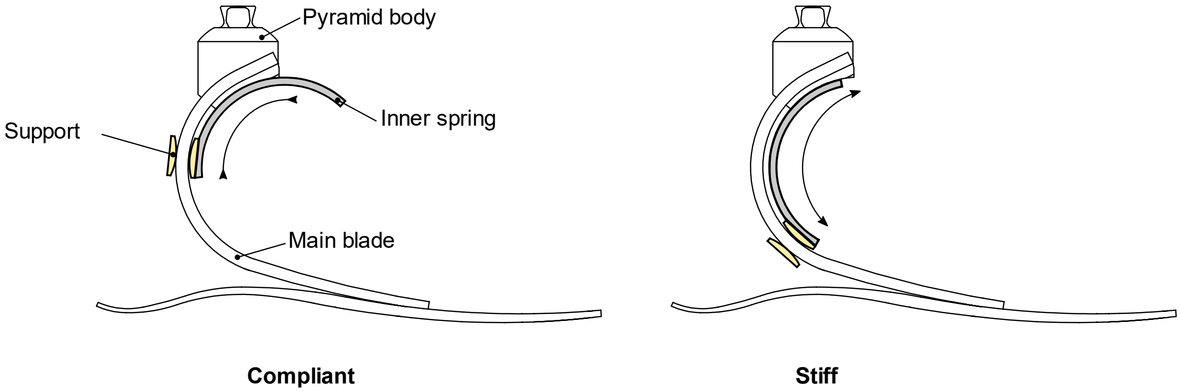


Figure 4-8. Schematic of C-shape concept with movable inner spring support: (left) compliant position; (right) stiffest position.

To adjust the support lever arm distance relative to the main blade, the inner spring can be rotated and fixed to the pyramid body at different positions. The proof of concept is prototyped for a size 27 prosthetic foot and evaluated in a quasi-static stiffness test, as shown in Figure 4-9.

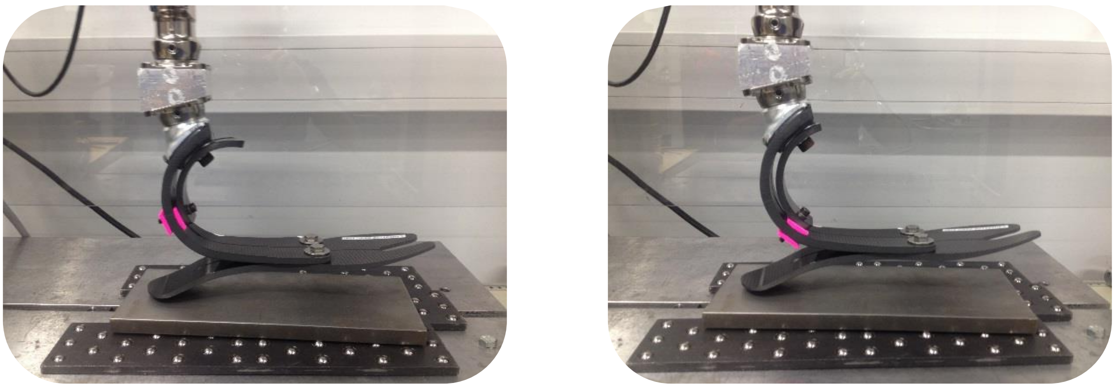


Figure 4-9. Heel quasi-stiffness test of size 27 C-Shape design concept prototype: (left) medium stiffness; (right) stiffest position of support.

The stiffness curves for the heel and keel are depicted in Figure 4-10. A 1250-N load was applied with plate angles of 15° and 20° for the heel and keel, respectively.

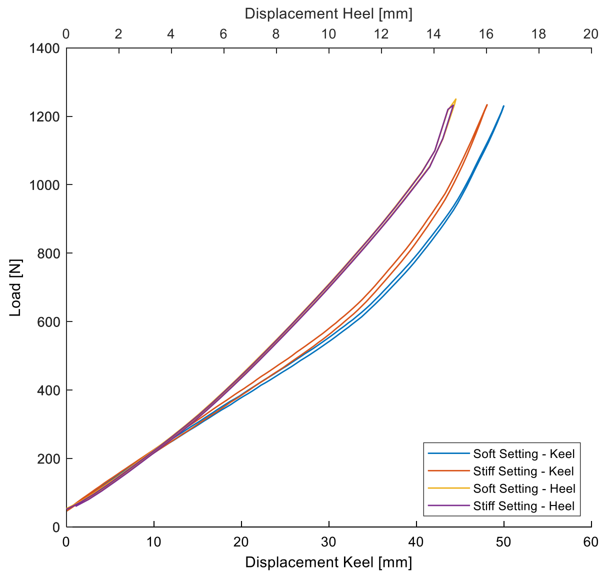


Figure 4-10. Heel and keel quasi-static test stiffness curves of C-Shape design with 1250-N load.

The energy return and maximum displacement results for the heel and keel are summarized in Table 4-3. The keel displacement change is 4%. The keel stiffness change was limited. Moreover, due to the C-shape design, the plantarflexion was not affected by the second inner spring position.

Table 4-3. Energy return and maximum displacement corresponding to different softest and stiffest positions of support on C-shape blade.

Condition	**Keel energy return (%)**	**Maximum keel displacement (mm)**	**Heel energy return (%)**	**Maximum heel displacement (mm)**
Soft	98.5	50.0	99.1	14.8
Stiff	97.7	48.0	99.2	14.7

The prosthetic foot concept must be adjustable for dorsiflexion and plantarflexion. The second iteration explored for stiffness change is an ankle unit with two parallel blades that allow different stiffnesses for plantarflexion and dorsiflexion.

The adjustable support point can be set at different positions, changing the lever arm support on the two blades. The mechanical principle is schematized in Figure 4-11.

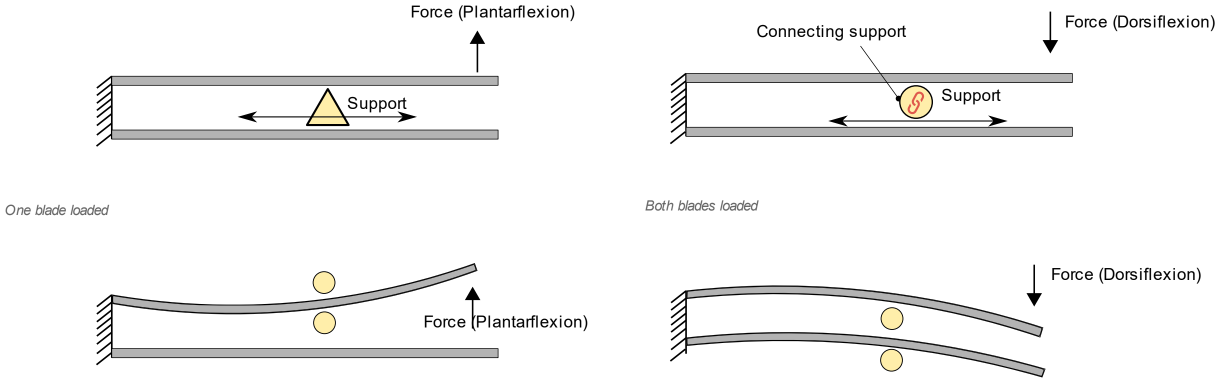


Figure 4-11. Schematic of dual-blade concept with adjustable support.

4.3.2 Stiffness Model

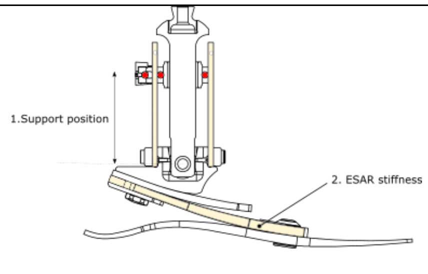
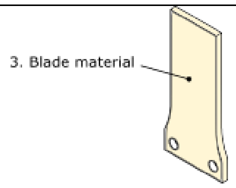
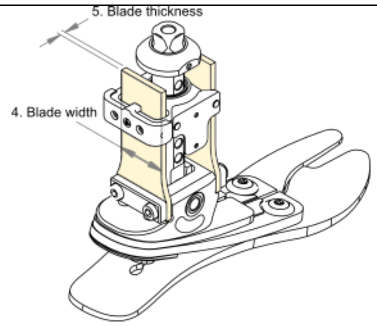
The double-blade cantilever concept allows the mechanical design freedom to adjust the prosthetic foot performance and the range of stiffness modulation. A vertical blade arrangement was estimated to fit well in a human calf. A low-profile commercially available prosthetic foot was selected as a base foot (Pro-Flex LP, Össur). The variable stiffness unit was mounted on top of the foot. This design path allows the retention of some of the base foot roll-over properties; hence, focus can be set on the VSA unit.

The double-blade unit provides the system's adjustable spring constant. The equivalent spring constant of the double-blade prosthetic foot can be calculated as

$$\frac{1}{k_{eq}} = \frac{1}{k_{ESAR}} + \frac{1}{k_{double\ blade}},$$

where k_{eq} is the equivalent spring constant; k_{ESAR} is the ESAR spring constant; and $k_{double\ blade}$ is the double-blade spring constant. A custom MATLAB script was created to evaluate the overall prosthetic foot stiffness change with the design parameters of the VSA unit summarized in Table 4-4. The model was built to create a unit for a 90-kg user with a stiffness modulation capability (15% softer to 15% stiffer) for the equivalent system (ESAR foot + VSA unit).

Table 4-4. VSA unit design parameters and model outputs.

Parameter	**Values**	**Illustrations**
	Known Parameters	
1. Heel and keel support positions	Fixed range: 65–85 mm (limited by the maximum build height allowed for the prosthetic foot)	
2. ESAR model stiffness	Range: 72–90 N/mm (limited by the stiffness category available for the ESAR foot)	
	Material selection	
3. Blade flexural modulus	a) E-glass pre-impregnated fibers: 35 MPa b) S-glass pre-impregnated fibers: 50 MPa c) Carbon pre-impregnated fibers: 95 MPa	
	Dimensioning	
4. Blade width	Range: 25–45 mm	
5. Blade thickness	Range: 2–6 mm	
	Output - Results	
Equivalent stiffness of unit (ESAR + VSA) Material: S-glass Blade width: 49 mm Blade thickness: 6.2 mm		

The model was used to 1) dimension the flexible elements of the VSA unit and 2) estimate the stiffness change. A force input of 1250 N was applied to calculate the spring stiffness for the heel and keel. An iterative approach was used in the script to test design options for the material, and an incremental loop supported the iteration of blade parameters for inertia calculations.

An S-glass prepreg with a flexural modulus of 50 GPa in the fiber direction was used to model the blades of the variable stiffness unit (Mitsubishi composites, USA). This model was further developed to rearrange the blade configuration and support points of the variable stiffness unit.

4.3.3 Realization

The unit was manufactured using MATLAB model guidance. Figure 4-12 depicts the variable stiffness unit and the assembly mounted on the ESAR prosthetic foot.

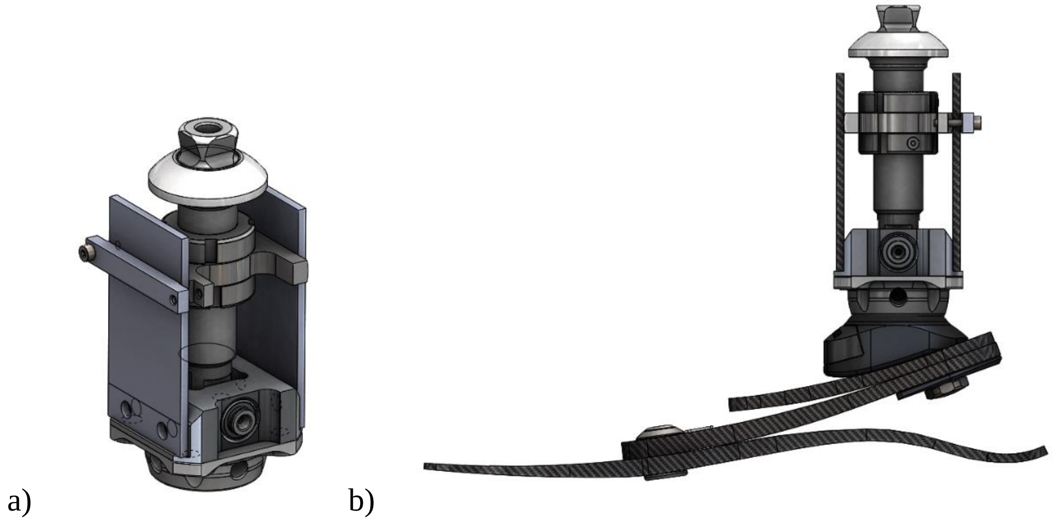


Figure 4-12. a) Isometric view of dual-blade unit; b) Dual-blade unit installed on commercial ESAR prosthetic foot (Pro-Flex LP, Össur).

The assembly and variable stiffness unit with the ESAR foot were evaluated by a quasi-static stiffness test. Results are shown in Figure 4-13. A 1250-N load was applied with a 20° plate angle for the keel.

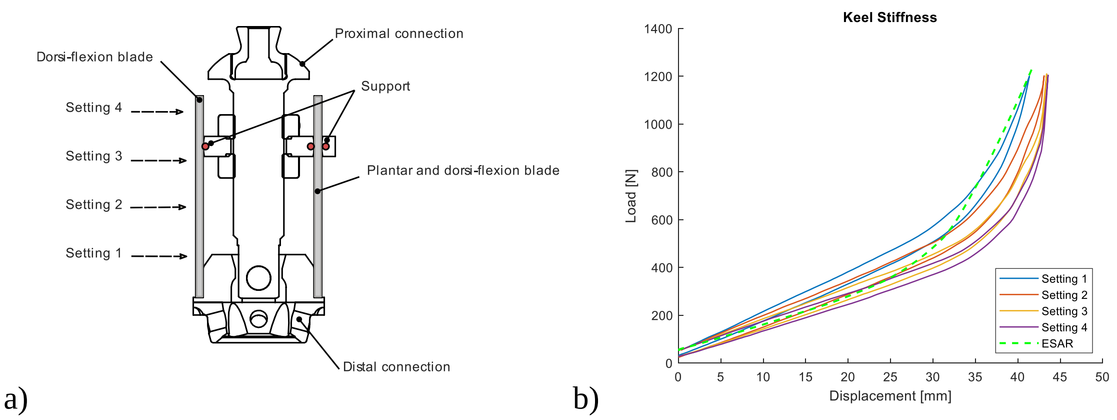


Figure 4-13. a) Cantilever double-blade concept; b) Keel stiffness results of cantilever double-blade concept when assembled on ESAR foot and original ESAR (load: 1250 N).

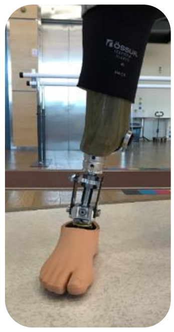
Table 4-5. Energy return, maximum displacement, and load of cantilever double-blade concept at 30-mm displacement and quasi-stiffness for different positions of support (settings 1– 4).

Condition	**Keel energy return (%)**	**Keel maximum displacement (mm)**	**Load at 30-mm displacement (N)**	**Quasi-stiffness (N/mm) evaluated between 5-mm and 30-mm displacements**
Setting 1	88.6	41.4	570.7	17.2
Setting 2	85.7	43.1	508.4	15.0
Setting 3	87.0	43.4	453.8	13.2
Setting 4	87.6	43.6	422.2	11.9

For the keel data collected, the energy return, maximum displacement, resulting load, and quasi-stiffness between 5-mm and 30-mm displacements were calculated, as summarized in Table 4-5. The quasi-stiffness was calculated between the two displacement points to focus on the keel ankle stiffness modulation and not when the top blade of the ESAR foot starts to engage. The change in the stiffness modulus from the lowest to the highest position of the slider is 69% (5.3 N/mm).

The benefits from the cantilever double-blade concept emanate from the multiple mechanical design options that the scheme offers. The separate ankle unit design approach allows the concept focus to be set on the variable stiffness performance while endeavoring to maintain the original roll-over performance of the ESAR prosthetic foot. The dorsiflexion and plantarflexions stiffnesses of the CRFP blade on the unit can be separately adjusted to achieve the desired stiffness modulation.

Although this research focuses on the sagittal plane stiffness, the concept shows prospects for further exploring the user requisites for frontal plane stiffness, as shown in Figure 4-14. The inversion and eversion movement capabilities of the ankle unit are interesting to explore further.

a) 

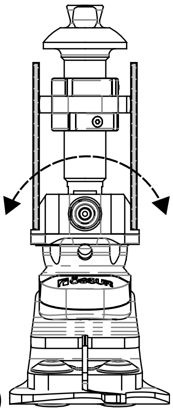
b) 

Figure 4-14. a) Frontal plane configuration of variable stiffness unit on 5° incline; b) Schematic of variable stiffness unit configured for frontal plane motion.

The main deficiency of this approach is the activation of one flexible member at the heel contact for plantarflexion stiffness that starts to load both blades from flat foot to push-off during dorsiflexion. Consequently, contact noises can be generated over time when the second flexible member is loaded.

5 VSA prosthetic foot

This chapter completes the report on the design and testing activities for a variable stiffness prosthetic foot. It includes additional discussion and information from the published article.

5.1 Design and Mechanics

The second paper considered in this research focused on the VSA prosthetic foot verification (**Paper II**).

Various possible concepts were investigated in this research. The aim of the design work was to refine previous achievements. The design path preferred for the VSA prosthetic foot is both justified by 1) a vision for future development, 2) a previous work in the research field, and 3) an exploration of sagittal stiffness.

1) This research was driven by the author’s motivation to improve functionality in prosthetic feet and enable lower limb prosthetic users to adjust the stiffness according to their walking tasks or preference. The design path for the VSA prosthetic foot has to be manufacturable and durable; further, it must use affordable technologies.
2) Robotic and prosthetic research has driven development in the field of stiffness adjustment. An approach similar to Rouse and Adamczyk [53][49] using an adjustable support on a flexible beam is appealing.
3) The author intends to explore user preference. A finely tunable system was preferred over a discrete “on–off” activation. The second research objective focused on mechanical testing was achievable with the cantilever beam approach, allowing the evaluation of various stiffness settings. A pivot connection that approximates the location of the anatomical ankle joint was preferred to further explore the FJC depending on foot stiffness.

Several iterations were modeled in a computer-aided design system (Figure 5-1). The variable stiffness unit was integrated in the ESAR foot adapter from design iterations 1 and 2. Version 3 permitted the attachment refinement and clamping of flexible composite blades to the unit. These concepts still used a manual knob to adjust the position of the support on the pylon. From iteration 4, a single-blade design and an actuator were introduced. Version 5 depicts the final tested version with the lowest mass and build height from all previous iterations. From version 4, another model of an “off-the-shelf” actuator for increased travel was used to allow greater stiffness modulation.

Static FEMs were generated to optimize the unit mass, build height, and stiffness range as well as ensure structural integrity.

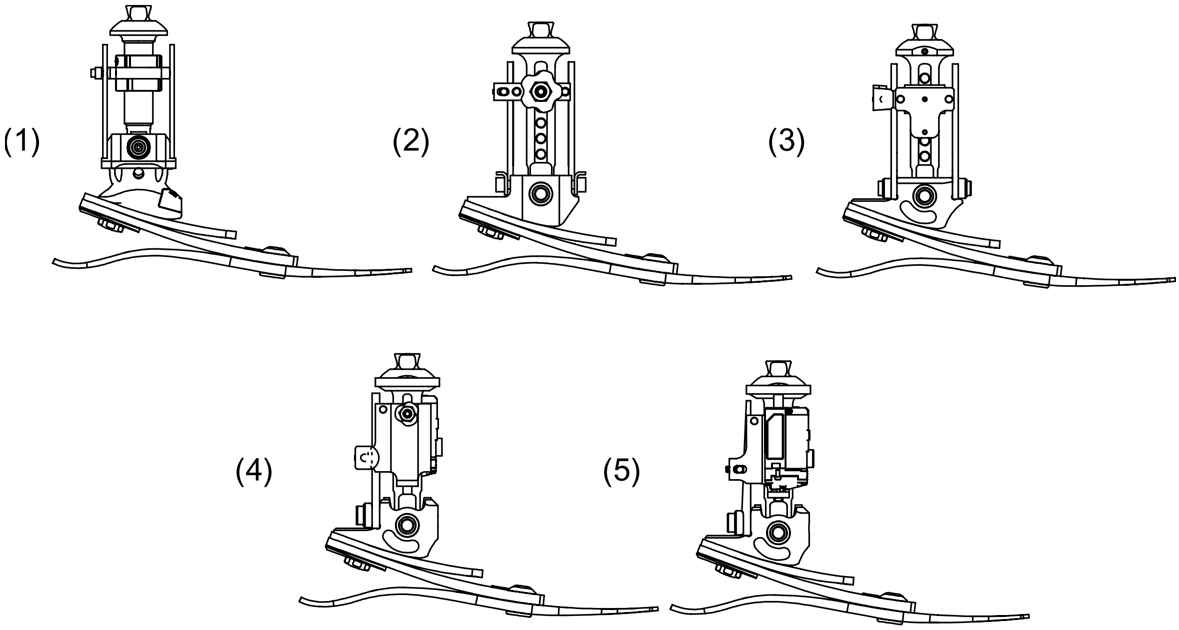


Figure 5-1. VSA concept and design iterations, (1) dual blade - locking nut, (2) dual blade – locking pin, (3) dual blade – spring loaded pin, (4) single blade – locking pin and (5) single blade with actuator.

The stiffness modulation script in the MATLAB model was refined, and a second set of finite element analysis was set up for the composite flexible blades only.

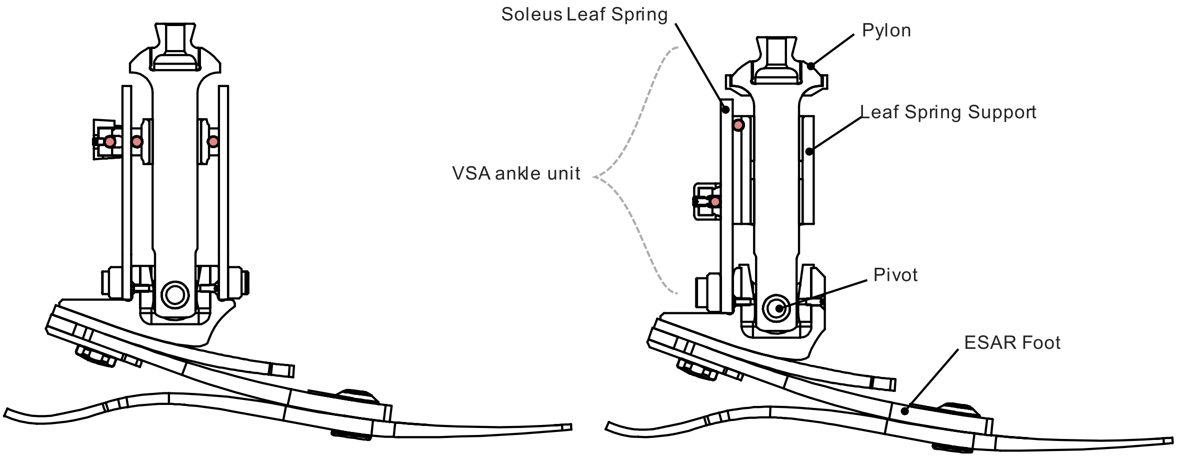


Figure 5-2. Single-blade and double-blade designs.

After design optimization, the ankle unit was simplified to use a single CRFP blade different from the use of two blades in the previous concepts. The driving factors for this decision were to lower the volume on the prosthetic foot around the ankle area and limit the possible generation of frictional noise from heel strike to mid-stance. The soleus leaf spring was manufactured with a thermoplastic protective sheet to reduce frictional noise from the support pins. Tight tolerances and additional spring elements were used to lower “clicking” sound. To overcome the difference in stiffness modulation between the heel and keel, a two-point support was integrated to the adjustable unit (Figure 5-2). With this choice, several design opportunities were withdrawn using a single blade, and some limitations on the heel and keel stiffness ratio were introduced.

The model allows the soleus blade re-dimensioning and stiffness change estimation depending on the support position (Figure 5-3).

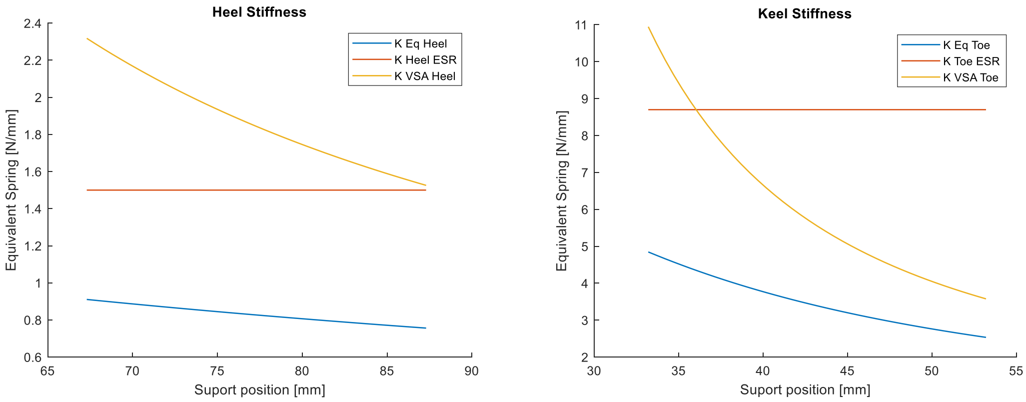


Figure 5-3. Equivalent stiffness model of VSA foot depending on support position.

The model allows the quasi-stiffness prediction the VSA ankle unit, and the equivalent stiffness of the variable adjustable unit mounted on the ESAR prosthetic foot. The modeling was further refined using flexible elements FEM simulation of the foot (carbon blades from ESAR and glass blade from the VSA ankle). The model was verified by experimental measurements. In the quasi-static tests, a video camera and 6-DoF load cell were used to the track the ankle motion for the heel and keel tests, allowing the collection of ankle moment and angle data. The quasi-static test results and rotational stiffness are shown in Figure 5-4. This test method appears to provide satisfactory insight without using a roll-over test machine to contrast dorsi- and plantarflexion stiffness change.

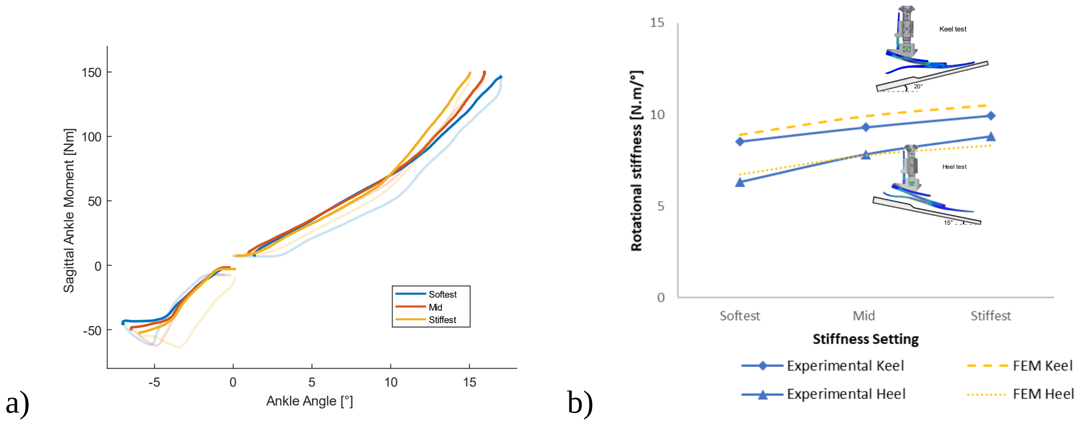


Figure 5-4. a) VSA prosthetic foot ankle moment versus ankle angle stiffness test results for softest, mid-stiffness, and stiffest settings at 1250 N; b) Angular stiffness of keel and heel in sagittal plane for softest, mid-stiffness, and stiffest settings (FEM and experimental measurements).

The VSA prosthetic foot stiffness modulation results are summarized in Table 5-1.

Table 5-1. Plantarflexion and dorsiflexion stiffness values for FEM, mechanical testing, and biomechanical results (five steps average) with calculated stiffness change for softest, mid-stiffness, and stiffest settings.

	Plantarflexion (Nm/°)						Dorsiflexion (Nm/°)					
	FEM		Experimental		Biomechanical		FEM		Experimental		Biomechanical	
VSA Prosthetic foot (softest)	6.7	100%	6.3	100%	3.6	100%	8.9	100%	8.5	100%	6.2	100%
VSA Prosthetic foot (mid-stiffness)	7.8	116%	7.8	124%	3.7	103%	9.9	112%	9.3	109%	6.6	106%
VSA Prosthetic foot (stiffest)	8.3	124%	8.8	139%	3.9	108%	10.5	118%	9.9	116%	6.9	112%

5.2 Mechatronics

In the early trials, the support position was manually adjusted and locked into position with a knob fixing the leaf spring support to the pylon. Although this action is relatively simple for the user or the CPO, it requires manual interaction with the prosthetic foot. In the first trials, the users were observed to "loosen" the stiffness settings, attempting to move the support back and forth to retrieve their preferred stiffness. An actuated system was added to the VSA prosthetic foot, allowing position repeatability during the trials. The leaf spring support position was adjusted using one linear servo motor (MightyZap, Irrobot, South Korea). A control unit including an Arduino mega-microcontroller board, a Bluetooth board, and a lithium–polymer battery was interfaced with the servo motor (Figure 5-5). The support position was controlled via a smartphone application and allowed the retrieval of the servo motor position after adjustment.

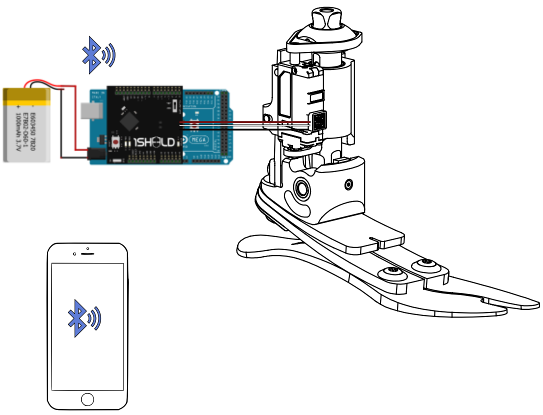


Figure 5-5. VSA control unit.

The servo motor was powered only during the stiffness adjustment and required no additional power during walking due to its self-locking design. A stroke of 25 mm was required to move the leaf spring support from the softest to stiffest position. The position adjustment required limited force when the foot was unloaded, and the maximum motor force of 75 N was sufficient to move the support on the prototype prosthetic foot. However, due to the VSA foot design using a single blade for dorsiflexion and plantarflexion adjustment, the micro servo actuator could not be used for stiffness adjustment during stance phase. The soleus blade deforms between the two supports under load in stance phase, thus requiring a greater force for the actuator to move. The actuator position was displayed on the smart phone and mapped from 0% to 100% (100% being the stiffest setting). The position control was successful during the machine and user trials. However, the system should be further simplified for commercialized products. The author believes that a smart phone should not be required to interact with the device. The current device operates with an Arduino microcontroller, which allows the movement control of the actuator with several pins of the microcontroller utilized for the Bluetooth connection and digital display. A simplified user interaction should be used, such as a keypad on the unit or a simple key-chain remote to move the support position along the soleus spring and adjust the sagittal ankle stiffness.

5.3 Link between mechanical and biomechanical tests

The third article considered in this research focuses on the link between mechanical and biomechanical tests (Paper III).

Development of a lower limb prosthesis can be long and expensive. Medical device development requires extensive processes to verify and validate a product. For designers and engineers, the goal of developing improved products is challenging. Durability is a primary requirement that can be easily checked on a test bench. For prosthetic feet, the device must withstand ultimate static loading and 2 000 000 cyclic loadings [60]. The applied loads are adapted depending on the weight and activity of the intended user. However, user benefits are more challenging to evaluate on a test bench. The field predominantly uses two types of testing methods: biomechanical testing on amputees and mechanical testing on dedicated test machines. For a lower limb prosthetic designer, engineer, and researcher, the link between these two testing methods is typically blurry, leading to the following questions. 1) Based on a machine test, is it possible to draw conclusion on the user acceptance of the device? 2) Based on the user testing feedback, is it possible to interpret the mechanical testing results?

This research focuses on the contrasting results of biomechanical and machine tests. However, user feedback and preference were not considered in this research; instead, these were included in the project group research [23].

The third paper showed promising perspectives on adequately linking biomechanical and machine evaluations. The VSA prosthetic foot was used is this study. Five male prosthetic foot users (age: 57 ± 11 years; mass: 97.5 ± 8.7 kg) participated in and completed the study. The users walked at 0.8 m/s during level-ground and ramp ascent/descent data collection. All gait trials were performed on an instrumented dual-belt treadmill (Bertec, Columbus, USA), and an eight-camera-based 3D motion capture system (Qualisys AB, Gothenburg, Sweden) was used to track the markers of defined body segments (400 Hz). Machine testing was performed using the test method, combining the collection of force and moment data using a 6-DoF load cell and the 2D sagittal motion capture. Machine inputs, vertical force, and tilting plate angle were evaluated to simulate ramp ascent and descent. Three stiffness conditions of the VSA prosthetic foot were evaluated on the machine and on users: condition 1 (softest), condition 2 (medium stiffness), and condition 3 (stiffest). The ankle moments versus ankle angles are contrasted in Figure 5-6, showing the five user's average.

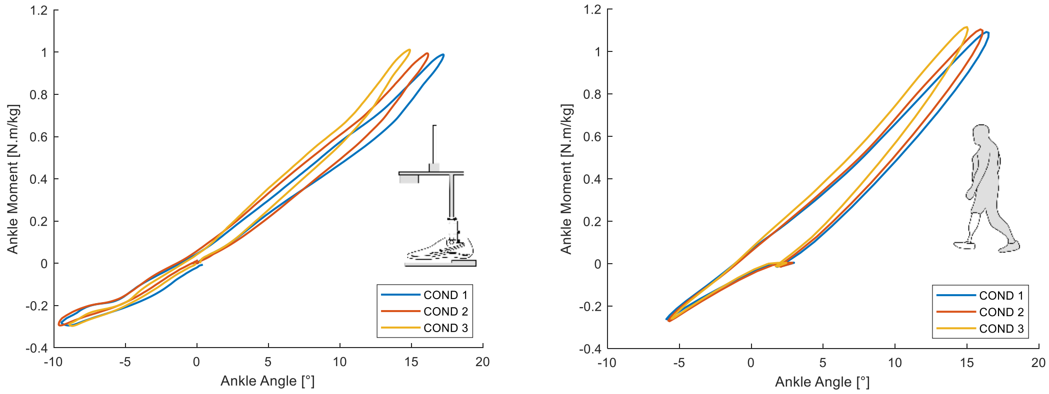


Figure 5-6. Ankle moment versus ankle angle during level-ground walking for three stiffness settings (condition 1 (softest), condition 2 (mid-stiffness), and condition 3 (stiffest)): (a) test machine results and (b) biomechanical test results (average of five users).

In addition to the published results, comparison between the test bench and biomechanical results can be further explored in later research. The butterfly or Pedotti diagram can be plotted to represent the force vector moving forward with each arrow representing the ground reaction force at the center of pressure (CoP) [79]. Biomechanical data were collected on a treadmill; unfortunately, the CoP position was difficult to accurately estimate. To further compare the two test methods, the anterior–posterior force and vertical ground reaction force can be graphed as a vector plot, as shown in Figure 5-7.

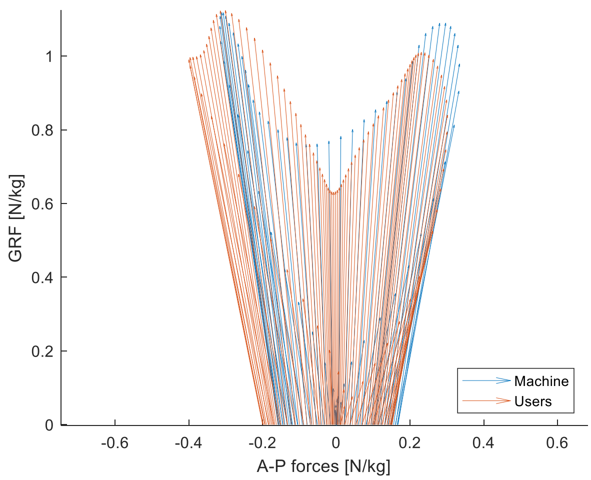


Figure 5-7. Ground reaction force versus anterior–posterior force for roll-over comparison between machine and biomechanical tests at self-selected speed.

The above graph is yet another example of how biomechanical and machine data can be used as a comparison tool to estimate the roll-over characteristics of prosthetic feet.

5.4 Future evolution of VSA

5.4.1 Controls

The VSA prosthetic foot is controlled using a wireless remote control via a mobile phone application. An exact stiffness setting can be selected with this type of position control. It allowed the investigator to adjust the stiffness without interfering with the prosthetic foot and alignment as well as select a stiffness setting for the biomechanical trials. However, to apply a variable stiffness prosthetic foot outside the laboratory environment, usability must be improved. This can avoid requiring the user to stop walking to adjust the stiffness via the app before changing tasks. One possible evolution direction is to incorporate an intent control approach to the VSA prosthetic foot. The muscle signals collected via the surface of or implanted electromyography on the residual limb could be interpreted to adjust the device. The volitional electromyographic-driven control via a user–prosthetic electronic interface can allow users to set and alter regional stiffness properties and aid them to adapt the prosthetic foot to various tasks or situations. The contextual inquiry on lower limb prosthetic users and experts reported by Valgeirsdóttir et al. emphasizes the potential improvements in mobility and quality of life when the user has the ability to control and adjust the prosthetic device [80]. The problems reported by users regarding imbalance when walking on gravel due to increased ankle motion or the necessity for improved dorsiflexion when squatting could be resolved with a variable stiffness prosthetic foot. The recent research of Leestma et al. proposes a novel control method to adjust the variable stiffness foot developed by Glanzer and Adamczyk [81]. The dynamic mean ankle moment arm (DMAMA) may be a suitable biomechanical metric to adjust semi-active devices. However, the DMAMA requires a 6-DoF load cell, which could add to the build height and mass of the prosthesis. A future research path for controlling the VSA foot can be the use of accelerometers to detect surface angles, and a hall-effect angle sensor at the pivot joint of the ankle unit can be employed to measure the torque–angle depending on the surface angle. Preset stiffness values could then be adapted depending on the gait speed and terrain detection without introducing considerable complexity and weight to the current design.

5.4.2 Mechanical design evolution

The VSA prosthetic foot design can be refined further. During the mechanical and biomechanical testing that showed the limitations of the prosthetic foot, some ideas for improvement were conceived. To further reduce the mass of the device and increase the stiffness modulation, the soleus blade can be designed as a part of the ESAR base foot, as schematized in Figure 5-8. The soleus blade length could be increased by moving the bolt connection more posterior and keeping a correct fit in the cosmetic cover. The middle blade of the Pro-Flex LP and the soleus could also be manufactured as a single composite piece.

Figure 5-8. Schematic of future design evolution of VSA prosthetic foot.

The newly designed decoupled ESAR by Quraishi et al. suggests an interesting concept of harvesting energy during the start of the stance phase and then reinjecting it to the system for increased push-off power [82]. However, this concept may be difficult to integrate into the VSA prosthetic foot.

6 Discussion

This thesis reports on sagittal plane stiffness evaluation of prosthetic feet. The quasi-static method used in previous research provides data on foot deformation in one load vector orientation [83,84]. Although this type of stiffness information can be useful to categorize the same prosthetic foot model across categories and sizes or for energy return calculation, the results are difficult to interpret during normal use in terms of dynamic roll-over motion. Roll-over testing provides a more realistic loading condition. Results show that the machine input can be adjusted to simulate different walking speeds or terrains. Data processing is relatively straightforward to reach curves comparable to those commonly used in prosthetic foot gait analysis. However, this test method is considerably more complex than the quasi-static method and requires dedicated equipment. The ESAR prosthetic foot functionality can be more accurately described using the roll-over test method than the quasi-static method. Reaction forces and moments are quantified during dynamic motion in the machine. The ankle moment and angle data were compared with biomechanical testing results. Moreover, the data collected using the machine represent rates that are close to the biomechanical data derived from different gait tasks. Hence, these can aid to the communication between design and biomechanical engineers.

The FJC calculation was shown to be possible using dynamic testing. For the author, this is an important factor for interpreting the prosthetic foot function on a user. Stiffness provides information on the rate of deformation, and the FJC provides insight on the location of the ankle joint center. Since the introduction of ESAR prosthetic feet in the 1980s, the field has been focused on characterizing the energy return of the composite material used in the devices. Unfortunately, energy return is only one data point; to the author's view, it is certainly not the most important measure to evaluate the functionality of a prosthetic foot.

During the research, several concepts of variable stiffness were modeled, prototyped, and tested. First, a self-adjusting foot using "smart materials" seemed appropriate. However, design limitations and usability required another ideation route for this work. The clinical relevance of adapting stiffness that solely depended on walking speed did not appear to be pertinent to the research. New concepts using this type of approach must be considered according to the stiffness requirement for the design. The concept provided a measured 1.6N/mm (9.8%) quasi-stiffness change for varying loading rates. This change was not significant enough for the stiffness modulation objective.

Second, a discrete "on–off" stiffness change approach was assessed, and the concept was demonstrated to be viable. The introduction of an additional spring component to modify stiffness is a simple method for increasing foot rigidity. In this thesis, the adjustment is accomplished using a manual knob. However, automatic adjustment, using a small actuator to the detriment of a device mass increase, is possible. An additional increase of approximately 250 g is estimated if a small servo motor, lithium–polymer battery, and control unit are used. Multiple prosthesis functionality may be relevant for prosthetic users. For example, the user could benefit from increased foot rigidity when engaging in high-impact activities, such as fast walking, load carrying, or sports activities. The stiffness change rates achieved using the concept in this research are 15% and 45% for the keel and heel, respectively. Due to the design, a larger stiffness change can be easily achieved.

Finally, the use of a cantilever beam with an adjustable support location was selected as the preferred approach. This method is advantageous for gradually changing stiffness. The stiffness incremented by moving the contact point on the CRFP beam. This method did not require powerful motors and kept the variable stiffness prosthetic foot mass low. The VSA prosthetic foot adjustment was automated using control units and an actuator. Multiple benefits can be listed for this concept. First, the CPO can adjust the prosthetic foot response during initial fitting or follow-up visits. During the first adjustment, the CPO can conduct evaluations and converse with the user on a preferred stiffness depending on the clinical assessment. Throughout the follow-up visits, the prosthetic foot stiffness can be further adjusted if the user activity increased or decreased. The stiffness modulation in the presented VSA foot is unique compared with any other type of adjustment present on commercial devices. The heel wedges are used in numerous ESAR feet to adjust the heel stiffness; however, they have a limited effect on the entire stiffness adjustment during roll-over and must be manually assembled on the device. The user can "dial in" his preferred foot stiffness for daily use and modify it when necessary. The prosthesis use cases enable adjustment during long walks or steep inclines. Stiffness adjustment is ideal if it can be implemented automatically, or only limited interaction is required from the user to enhance usability. The experimental tests demonstrated a plantarflexion stiffness change of 39% and a dorsiflexion modulation of 16%.

This study demonstrated that novel mechanical test methods can be used and are comparable to biomechanical testing. This observation is useful for researchers and allows the comparison of prosthetic feet across different models by performing the same controlled procedure. Mechanical testing input curves can be further fine-tuned to represent different walking activities and gait patterns. The method is beneficial for evaluating and optimizing a prosthetic foot before user testing. The intent is not to collect all prosthetic foot characteristics but to support the collection of multiple datasets, such as moments and forces, combined with the deformations of the flexible elements of the ESAR foot. Clinical testing is a challenging validation activity. The preparation side of this activity involves ethical approval, protocol preparation, and the recruitment of users. The execution of trials is typically performed for several days depending on the availability of the user and CPO. Biomechanical collection and post-processing are also time-consuming. Advanced mechanical testing may not fully replace user testing. However, it enables trials to start with a "proven" device and allows the focus to be set on important biomechanical factors. The devices can be tested in a controlled environment at different walking speeds and on various terrains over a shorter period instead of testing them on users. The roll-over test method could be further used as a tool to correlate user feedback to measurable parameters, such as the roll-over characteristics shown in the butterfly diagram, FJC, or angle–moment curves.

User perception is not presented in this thesis; however, it is one of the main motivations for exploring the variable stiffness approach and prosthetic foot concepts. For the author, the design and study of lower limb prosthetics are extremely rewarding; occasionally, it can also be discouraging. The efforts devoted to modeling, designing, and testing a device can be overrun by user comments and preference. The drive of this study was to go "back to the basics" and review new tools and models to evaluate and increase the understanding of user feedbacks and comments on prosthetic devices. During the redaction of this thesis, Clites et al. published a recent work on a variable stiffness prosthetic foot and understanding user preference [85]. This comprehensive work demonstrates the challenge of clinically proving the “correct stiffness for a user.” In their study, the preferred stiffness maximized the kinematic symmetry between the prosthetic and unaffected joints. Higher ankle stiffness values were not preferred for heavier users, implying that the category selection charts commonly used for prescription may not be appropriate or another selection tool was necessary. The VSA prosthetic foot or any user-adjustable devices could start an evolution in the prosthetic field where the device can be controlled and adjusted according to the requisite of the user. A user-centered approach to design medical devices can support variable stiffness prosthetic foot development [86].

7 Overview of research structure and results

An overview of the research problem and the contribution of each publication are summarized in Table 7-1.

Table 7-1. Overview of research design and how individual papers contribute to the resolution of the research problem.

Research objectives 1. Model, design, and prototype a variable stiffness prosthetic foot 2. Compare biomechanical and mechanical test results of the stiffness of a prosthetic foot ankle			
Specific aims 1-a. Model, evaluate, and test different solutions of a variable stiffness prosthetic foot 1-b. Prototype a final design concept for mechanical and biomechanical analyses 2-a. Propose a test method where mechanical and biomechanical results are comparable 2-b. Compare stiffness results for both methods on a variable stiffness prosthetic ankle			
Title	**Purpose**	**Contribution to research question**	**Key findings**
Paper I FJC of prosthetic feet during level-ground and incline walking	The primary aim of this study was to calculate FJC position in three prosthetic feet of varying stiffnesses, contrasting the positions found during level-ground, uphill, and downhill walking.	2-a	The calculated FJC reflects the different properties of the three prosthetic feet and reveals the response of the prostheses to different demands of three walking tasks.
Paper II Variable Stiffness Foot	The objectives of this paper were to present a variable stiffness prosthetic foot allowing a modulation	1-a 2-a	A variable stiffness prosthetic has been successfully modeled, designed, and prototyped. A quasi-

Design and Validation	of 20% change in the sagittal plane and propose a mechanical stiffness test.		static method is proposed to evaluate prosthetic feet using a 6-DoF load cell.
Paper III Comparison of mechanical and biomechanical tests on prosthetic foot stiffness	The objective was to assess two methods of data collection on the same prosthetic foot. The results of the state-of-the-art biomechanical analysis of the gait of an amputee for level-ground walking and ascending/descending a ramp were compared with those of a mechanical testing machine simulating each gait task.	1-b 2-b	A final concept has been evaluated mechanically on a roll-over test machine and on five transtibial amputees in a gait laboratory. The results from the mechanical and biomechanical tests are contrasted for level-ground walking and ramp ascent and descent.
Conclusions			
A novel prosthetic foot design was successfully designed, prototyped, and tested mechanically by roll-over test and motion laboratory analysis performed on users. The VSA prosthetic foot retains the benefits of conventional ESAR feet with sagittal stiffness modulation ability. An advanced mechanical roll-over test is possible to enable comparison with biomechanical testing for level-ground walking. Further work is necessary to explore machine inputs for different user gaits and ramp ascent and descent.			

8 Conclusions

The purpose of this work was to propose a novel design approach for sagittal variable stiffness for prosthetic feet. First, different concepts were explored and prototyped, and stiffness change was measured on a testing machine. The drawbacks and benefits of the concepts were presented. A final design was selected and further developed following a design paradigm including limited additional mass and satisfactory stiffness modulation characteristic. The VSA concept was selected. A composite cantilever beam with an adjustable support was used; its stiffness change was controlled wirelessly. The device was modeled, designed, prototyped and then mechanically verified. The VSA foot has been clinically evaluated on five transtibial users in a gait laboratory at three speeds on level-ground walking and self-selected speed for ramp ascent and descent. The mechanical and biomechanical trials indicated a sagittal stiffness change in the prosthetic foot. The key to these achievements is the advantage of designing a VSA mounted on a proven ESAR foot. The device introduces a novel approach where the benefits of the existing ESAR are maintained, and the variable stiffness unit is set up as an additional benefit for the CPO and user.

The second objective of this work was to propose and execute a more realistic test method for evaluating prosthetic feet on a testing machine. The proposed method allowed the evaluation of devices for level-ground and ramp ascent and descent. The VSA foot was evaluated on the testing machine, and results were compared with those of the biomechanical tests. Some adjustments were necessary for the input forces and tilt-plate angle of the machine for simulating ascent and descent; the level-ground results could be replicated to a considerable extent. Machine testing allowed the comparison of ankle moment and angle curves with those collected during the biomechanical trials. The key to these findings is to use a motion-tracking model of the prosthetic foot while performing the machine tests. This novel approach can be valuable for researchers and prosthetic foot designers in comparing prosthetic feet or evaluating functionality before performing time-consuming clinical trials with users.

This research has highlighted that the design of a variable stiffness foot is feasible. It has also demonstrated that an advanced machine testing method can be useful for the evaluation of lower limb prosthetics at different stages of the design process.

This research has identified several areas for further study that have a potential for improving the understanding of variable stiffness prosthetic feet and the characterization of their mechanical testing. The “correct” prosthetic foot stiffness appears to be a difficult goal for prosthetic foot design. The current approach of foot category selection based on user body mass or activity might provide a satisfactory median for the CPO. However, a user-specific selection or adjustment could improve their satisfaction with the prosthetic device. Further clinical studies combined with questionnaire and biomechanical measurements to correlate the user-preferred stiffness for different walking tasks are necessary.

The proposed mechanical testing approach and prosthetic foot design are promising; however, they require refinements. Nevertheless, both research goals have been satisfied. The research results hopefully provide information and encourage future prosthetic development, thereby enabling users to interact with their devices via a simple approach and not be restricted to the use of a prescribed prosthetic foot with fixed stiffness. A simple design and testing approach will significantly benefit users, researchers, and developers.

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9 Paper I

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