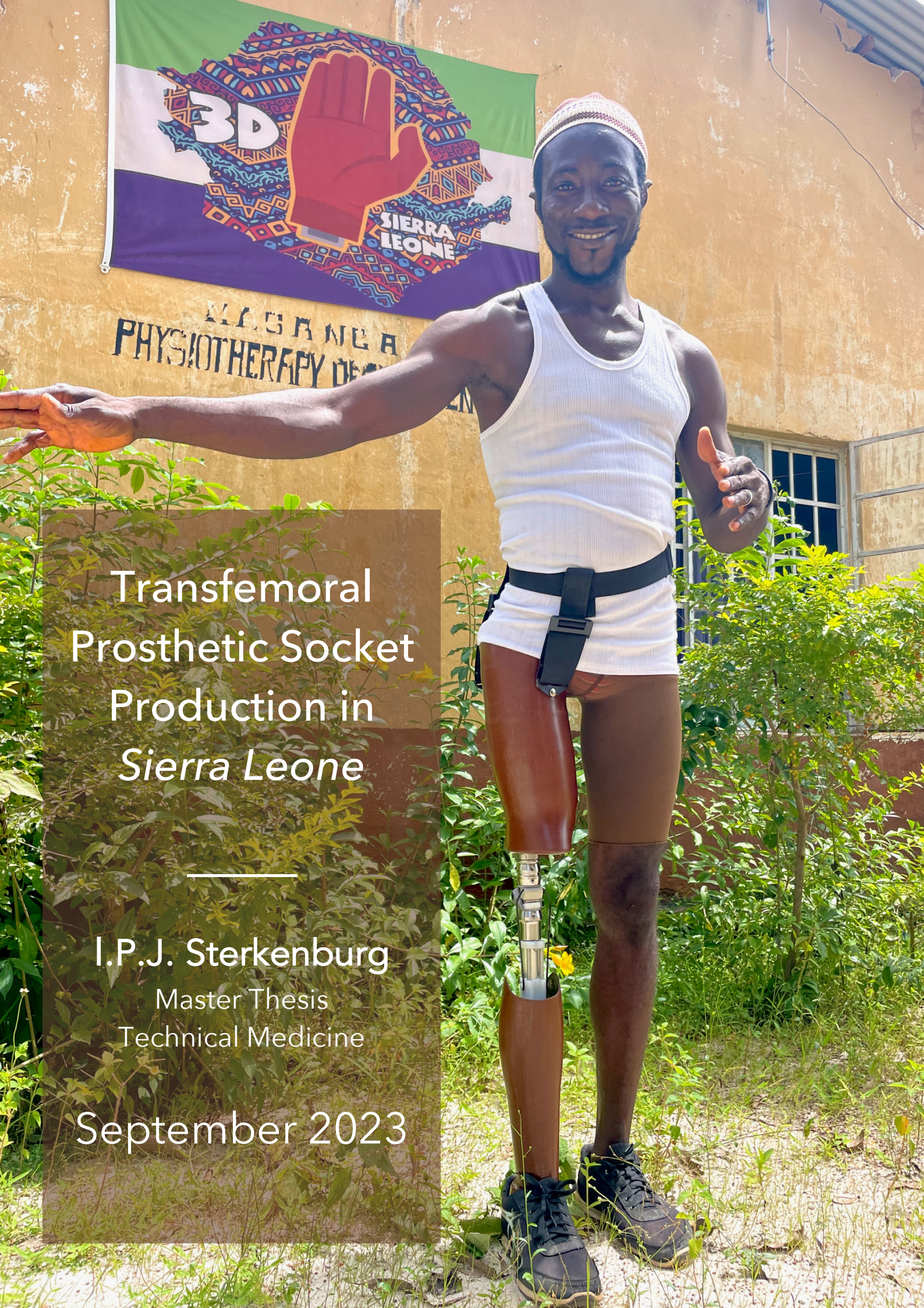




Transfemoral Prosthetic Socket Production in *Sierra Leone*

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List of Abbreviations

3D	Three Dimensional
AP	Anteroposterior
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
FFF	Fused Filament Fabrication
IC	Ischial Containment
ICRC	International Committee of the Red Cross
LMICs	Low- and Middle-Income Countries
ML	Mediolateral
PLA	Poly Lactic Acid
QOL	Quality of Life
Quad	Quadrilateral
Radboudumc	Radboud University Medical Center
STL	Stereolithography
TF	Transfemoral
WHO	World Health Organization

Chapter I

Introduction

Across the globe, amputations are an unfortunate reality, affecting over one million individuals annually, resulting in permanent disabilities [1]. The primary factors contributing to limb amputations exhibit regional variations. In high-income nations, peripheral vascular disease and diabetes stand out as the leading causes, while in low- and middle-income countries (LMICs), trauma emerges as the predominant factor documented [2]. Sierra Leone is classified as a low-income country, ranked 182 out of 189 countries on the United Nations (UN) human development index [3]. Out of a population of currently 8.8 million inhabitants [4], the prevalence of disability in 2015 was 1.3%, of which 8.9% was due to amputations [5]. However, the prevalence is probably under-representative as the World Health Organization (WHO) estimates the prevalence of disability is 18% in low-income countries [1].

Amputation, by definition, leads to an alteration in the body which can subsequently lead to disturbance in the perception of a person's body and appearance [6]. Individuals who have lost a limb frequently experience a sense of incompleteness and insecurity. This can result in reduced engagement in social activities, depression, diminished self-esteem, and a lower overall quality of life (QOL) [7-9]. To aid people with an amputation in improving their psychosocial well-being, a prosthetic device should be created to meet individuals' needs and goals. People with an amputation in Sierra Leone indicate that wearing a prosthesis for aesthetic purposes already gives them more self-confidence to increasingly participate in society [10]. Besides prostheses primarily fulfilling aesthetic needs, functionality in lower limb prosthetics is just as important. Transfemoral (TF) prosthetics aim to accomplish a gait close to normal with an acceptable burden level in energy expenditure [11]. A TF prosthesis is functionally made of the following components: the socket, suspension system, knee, and foot. The socket interface serves as the fundamental part of TF prostheses as it connects the stump with the prosthetic device. Main functions of the prosthetic socket are to provide prosthetic control to the user, stabilize the stump in sagittal and coronal planes, and bear weight comfortably [12, 13].

TF Socket Types

The general classification of socket constructions includes the traditional rigid socket design and a more advanced socket design such as flexible inner sockets, vacuum systems, or liner alternatives [11]. While rigid sockets are known for simplicity and durability, advanced designs offer enhanced comfort and performance but are costlier and require more clinical expertise [11, 14]. Current study focuses on TF rigid socket designs.

A socket comprises two main components: the proximal part, referred to as the brim, which determines the trimlines, and the distal part, which determines the volume of the socket. Socket design strategies vary in trimlines, design principles, and enclosed areas [15]. Traditionally, there have been two basic socket designs for a TF amputation: the 1950s quadrilateral (Quad) socket and the 1980s ischial containment (IC) socket [16]. A more recent development involves the sub-ischial (brimless) socket variation [11]. Figure 1 illustrates the fit of the different socket designs. The Quad has a lowered posterior brim and a wide seat on which the pelvic ischium rests (known as the ischial seat) [11]. While the ischium is held in place through anteroposterior (AP) socket compression, an increased mediolateral (ML) dimension is required to allow proximal soft tissue to enter the socket. These socket

dimensions negatively affect coronal stability, leading to gait deviations such as lateral trunk flexion [17]. Poor coronal stability also causes the remnant femur to be abducted inside the socket uncomfortably contacting the lateral wall [18, 19]. Overall, the disadvantages of the Quad socket design have led to the initiation of the IC socket design [20].

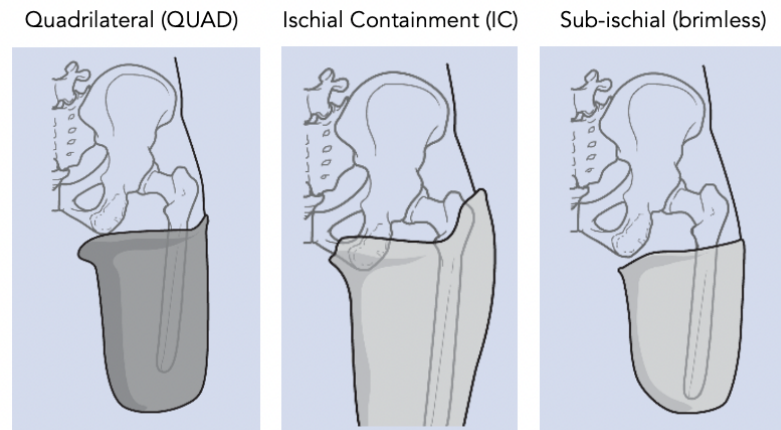


Figure 1: Different TF socket designs.

In current practice, the IC socket is most commonly used [11, 12, 15, 21]. The IC socket encloses the medial aspect of the pelvic ischial tuberosity and the ramus through a high medial brim and has a narrow ML dimension to ensure coronal stability [11]. To accommodate muscle contraction and allow proximal soft tissue to enter the socket, a relatively wide AP dimension is incorporated [22]. An important dimension for the manufacturing of IC sockets is the skeletal ML dimension, which determines the ML dimension of the brim that encapsulates the pelvis, also known as the “bony-lock” mechanism [23]. The skeletal ML dimension refers to the coronal plane distance between the medial aspect of the ischium and the lateral shaft of the femur just below the greater trochanter and includes the subcutaneous adipose tissue and skin [24]. Previous studies suggest the dimension to be related to sex, showing larger measurements for males [25–27]. Disadvantages of the IC socket include a limited range of motion and discomfort due to high proximal trim lines [15, 28].

In addition, a hybrid socket can be considered, combining the IC's narrower ML dimension with the lowered trimlines and slightly broader ischial seat from the Quad design. This hybrid brim configuration includes the bony lock mechanism and facilitates vertical support of the body weight as the ischial tuberosity rests on the ischial seat, which will be referred to as the “tuber support” [31, 32].

The development of the brimless sockets is an appealing way to address the difficulty of designing a socket that interacts with the pelvis [29]. In addition, since discomfort has been deemed the primary complaint among prosthetic users [30], socket designs with lower trimlines may improve the QOL of people with a TF amputation [29]. However, this socket type has the disadvantage that an expensive silicone liner for vacuum-assisted suspension is required.

Traditional TF socket Manufacturing Workflow

Following the traditional casting method to create TF sockets, the measurements of the stump and manufacturing of the socket are done manually using plaster casting. For this, prosthetists need adequate knowledge of socket design principles and appropriate manufacturing skills to sculpt the models to meet anatomical and functional prosthetic requirements [33, 34]. Figure 2 visualizes the workflow of the manufacturing process of a socket (in this case an IC socket). First, prosthetists apply wet plaster bandages on the stump to create a negative impression mould, which is squeezed with the prosthetists hands to indicate crucial parts (Figure 2a). Once the cast is cured and removed, it is filled with plaster to create a positive model of the stump (Figure 2b). The positive model is modified and shaped with rasps to create a final representation of the socket's shape and geometry. Thermoplastic material is heated (Figure 2c) and drawn over the positive mould. After curing the thermoplastic material, the plaster inside the socket is destroyed (Figure 2d). Post-processing of the socket consists of smoothing the proximal trim lines (Figure 2e).



Figure 2: The traditional workflow for manufacturing TF sockets, consisting of (a) making a negative plaster model of the stump (b) modifying the positive plaster model representing the stump shape inside the socket (c) heating the thermoplastic material to cover the positive plaster model and create the socket (d) removing the plaster inside the socket, and (e) post-processing of the socket.

Problem Statement and Previous Work

The provision of a proper prosthetic device is key to successful rehabilitation. However, in LMICs, the availability of assistive devices is severely limited, with estimates indicating that only 5-15% of individuals have access to these devices [35]. The provision of prostheses for individuals with a TF amputation poses challenges due to factors such as high costs, inadequate facilities, and the required high level of expertise to produce traditional TF sockets [35-39].

Computer- Aided Design/Computer-Aided Manufacturing (CAD/CAM) is of increasing interest for prosthetic socket design and manufacturing [40-42]. The utilization of digital three-dimensional (3D) techniques in the creation of prosthetic sockets holds the potential to automate part of the process and, thus, reduce the extent to which socket fitting relies on the prosthetists' expertise and skills [40, 41, 43-47].

Digitalization and standardization of the TF socket manufacturing process started in 1983, when Novicov et al. [48] introduced computer-aided socket design. This pioneering idea involved digital adjustment of a standardized socket shape based on anatomical stump measurements provided by the prosthetist. The primary aim was to objectify and speed up the manufacturing process. Subsequently, Torres-Moreno et al. [49] contributed to the field by developing a digital reference library of 27 socket shapes with variations based on skeletal structure, stump length, and tissue mass. In addition, the adjustable brim method was developed [50]. The method involved a prosthetist utilizing a set of brims, being scaled replicas, capable of accommodating a wide range of stump sizes, or circumferences. For individual patients, the prosthetist determined the appropriate brim circumference, which then formed the proximal part of the TF socket. Initially, a brim set was developed using the Quad brim shape. The utilization of such set introduced an element of standardization into the manufacturing process.

Nowadays, various TF computer-aided socket design software tools exist that use CAD/CAM methods [51–53]. Typically, these software tools offer an array of digital reference brim shapes, which can be complemented by a 3D-scan or numerous manual anatomical measurements of the stump. However, these tools are infeasible for implementation in LMICs due to their requirement of extensive understanding of stump anatomy and its behavior within sockets. Hence, there is a need for a simplified approach that demands less expertise, thereby enabling individuals with limited knowledge to execute it.

3D Sierra Leone

In 2018, the project “3D Sierra Leone” was set up in collaboration with the 3D-Lab at Radboud University Medical Centre (Radboudumc), Nijmegen, the Netherlands [54]. The project has established a 3D-Lab in the Masanga Hospital in rural Sierra Leone. This nation deals with a high amputation rate [55], resource limitations [56], and the inability for amputated people to afford a prosthesis [36], leading to exclusion and discrimination which causes a diminished QOL [57]. The project intends to improve local manufacturing facilities and provide people with affordable prosthetics. The project started with a feasibility study focusing on using 3D printing in resource-limited settings [10]. Medical aids and prosthetic devices for the upper limb were developed, and follow-up is being conducted to evaluate the quality and durability of the 3D-printed prostheses. Furthermore, an observational cohort study focused on transtibial prosthetics presented promising results in short-term follow-up [46]. To automate the development of transtibial prostheses, software is developed that enables local personnel to manufacture transtibial prostheses themselves.

In 2022, a previous study as part of the project (see Appendix A for its abstract) proved the feasibility of manufacturing low-cost (~150 USD) TF prosthesis using CAD/CAM methods in both the Netherlands and Sierra Leone. The study introduced an alternative workflow that replaces the manual stump measurement, socket design and manufacturing phases with 3D technologies. In addition, the previous study investigated two socket types: brimless and hybrid. The latter was deemed more feasible for LMIC implementation as it more effectively met the measuring and manufacturing criteria established for the Sierra Leone context. Figure 3 visualizes the established digital workflow of a hybrid socket. To form the hybrid socket, the adjustable brim method was copied, and a hybrid brim was fitted to the patient

to determine the correct size and a 3D-scan of the distal stump volume was made (Figure 3a). For this, an off-the-shelf hybrid brim set that covered diverse sizes was created by uniformly scaling a single model in all dimensions. Subsequently, the chosen brim size and the 3D-scan were digitally translated into a socket using CAD (Figure 3b). The digital model underwent 3D-printing (Figure 3c), followed by post-processing of the socket, involving the addition of foam to the tuber support and the application of pigmented coating (Figure 3d).

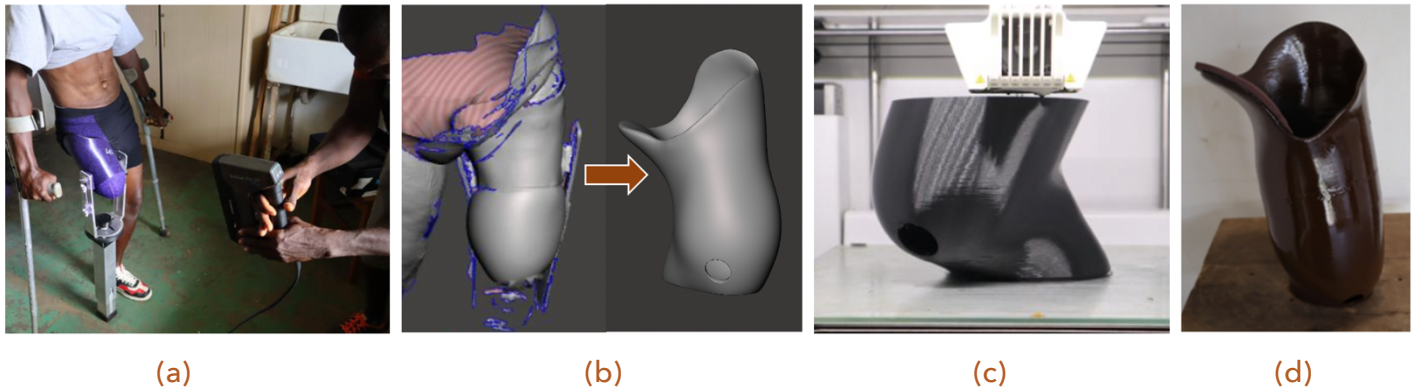


Figure 3: The digital workflow for manufacturing hybrid TF prosthetics developed in the previous study, consisting of (a) making a 3D scan of the stump after a suitable brim size was picked (b) digitally transform the 3D scan and the chosen brim size into a socket (c) 3D printing of the socket, and (d) post-processing of the socket.

The previous study served as a proof-of-concept, demonstrating the possibility of manufacturing TF prosthetics using CAD/CAM technologies. However, to achieve the 3D Sierra Leone project's goal of locally manufacturing personalized prosthetics, the next step should be standardization and simplification of the TF socket workflow to reduce the required level of specialized knowledge and to facilitate its integration into software.

Current Work

The current thesis aims to streamline the digital manufacturing workflow of TF sockets by addressing two main components that were identified as needing improvement in the previous study. The first component includes the improvement of the design of the set of hybrid brims that covers a wide range of stump sizes. To do this, data is collected of existing hybrid brims and analyzed on anatomical characteristics. Subsequently, based on the results of the analysis, a data-supported standardized brim set is developed. The second component addressed in this thesis is the method to determine the distal stump volume in the previous study. A simplified method is developed as alternative to 3D-scanning, as the previous study showed that the scanning process posed challenges for TF stumps. In addition, a method to digitally transform the measurements obtained through the proposed alternative method into a socket is established. Following the digital design, the socket is 3D-printed, which is in accordance with the methodology established in the previous study.

This thesis consists of two studies. While the first study focuses on streamlining the TF socket workflow, with a focus on the creation of a data-supported standardized brim set, the second study delves into the implementation of the developed workflow within the context

of Sierra Leone. The second study actualizes the concepts established in the first study by including those in need of a TF prosthesis in the Masanga Hospital. The streamlined workflow to manufacture TF sockets is conducted and the full rehabilitation process is followed, assessing the potential of the streamlined TF socket workflow that comprises a data-supported standardized brim set, and a simplified method to measure distal stump volume and to design the socket.

In essence, the cohesion between the two studies emerges from their shared mission: streamlining the TF socket manufacturing process for eventual implementation in software, with the ultimate goal of diminishing the dependence on specialized expertise. Altogether, this thesis represents a stride towards making TF prosthetic solutions more accessible in LMICs, enhancing the lives of those who have lost (part of) a lower limb.

Aim of the Study

The primary study aims are divided per study of this thesis and defined as follows:

Study 1: *To streamline the TF hybrid socket manufacturing workflow by developing (1) a data-supported hybrid brim set covering a wide range of stump sizes and (2) a simplified method to measure the distal stump volume and digitally design the distal socket part*

Study 2: *To implement the streamlined TF hybrid socket manufacturing workflow in Sierra Leone and assess socket fit by conducting the full rehabilitation process*

This thesis consists of four chapters, with the present introduction serving as the first chapter. The second chapter comprises the first study and focuses on the development of a streamlined TF socket workflow. The third chapter covers the second study of this thesis and describes the implementation of the streamlined workflow. Lastly, the thesis is concluded presenting a General Discussion and Final Conclusion (Chapter 4).

Chapter II

Developing a Streamlined
Transfemoral Hybrid Socket
Workflow: Empowering LMIC
Implementation

Abstract

Introduction: Prosthetic devices are life-improving for individuals with TF amputations, but their accessibility often relies on the expertise of prosthetists and is limited in LMICs. Current study addressed the need to reduce the operator dependency by streamlining the TF hybrid socket manufacturing workflow. This was achieved by developing a data-supported standardized hybrid brim set and a simplified method to measure the distal stump volume and digitally design the distal socket part.

Method: This developmental study consisted of three phases. In Phase 1, an analysis of existing hybrid brim dimensions was conducted, focusing on brim characteristics like the distance between the center of the tuber support and the lateral wall (approximated skeletal ML distance) in relation to its circumference. This analysis aimed to identify any correlations between the circumference of the brim and other important brim dimensions, to define a scaling procedure. Phase 2 covered the development of a data-supported brim set based on the scaling procedure of Phase 1, and Phase 3 focused on the establishment of a simplified method to measure distal stump volume used for digital socket design and was finalized with TF socket fitting.

Results: Phase 1 included 13 hybrid brims and revealed a correlation ($p=0.0003$, $R^2 = 0.717$) between the brim circumference and the approximated skeletal ML dimension which functioned as the foundation for the scaling procedure applied in Phase 2 to develop the data-supported brim set. Promising brim fitting results were yielded on 8 (5 males) participants with room for improvement on the medial and anterior trimlines. Phase 3 successfully developed a simplified method to measure distal stump volume, and digitally transform these into a distal socket design. Valuable insights were obtained regarding the shape of the socket design during the full TF socket fitting on 2 (1 male) participants.

Discussion: The TF socket workflow was streamlined with a data-supported brim set and a simplified method to measure distal stump volume that relies on just a few measurements, eliminating the need for locating specific anatomical landmarks. Limitations included a small brim dataset and limited generalizability to LMIC populations. Further research should involve diverse population and consider additional factors influencing socket effectiveness by going through the full rehabilitation process. In addition, the data-supported brim set can be further enhanced by analyzing more brim shapes in relation to user characteristics. The study's clinical relevance lies in its potential to implement the TF socket workflow in automated software, reducing operator dependency and increasing accessibility, especially in LMICs.

Keywords: 3D Technology, Data-supported hybrid brim set, Prosthetists' skills, Socket manufacturing workflow, TF prosthesis

Introduction

Worldwide, more than one million limbs are amputated each year, leading to permanent disability [1, 2]. In LMICs, the availability of assistive devices is severely limited, with estimates indicating that only 5-15% of individuals have access to these devices [35]. The provision of prostheses for individuals with a TF amputation poses challenges due to factors such as high costs, inadequate facilities, and the labor-intensive nature of producing traditional TF prosthetic sockets [35–39].

Following the traditional casting method to create TF prosthesis, the measurements of the stump and manufacturing of the prosthetic socket are done manually using plaster casting (Figure 2). For this, prosthetists need adequate knowledge of socket design principles and appropriate manufacturing skills to sculpt the models to meet anatomical and functional prosthetic requirements [33, 34]. CAD/CAM is of increasing interest for prosthetic socket design and manufacturing [40]. The utilization of CAD techniques in the creation of prosthetic sockets holds the potential to automate the entire process and, thus, reduce the extent to which socket fitting relies on the prosthetists' skills [40, 41, 43–47].

The previous study as part of the 3D Sierra Leone project (see Appendix A for its abstract) proved the feasibility of manufacturing low-cost (~150 USD) hybrid TF prosthesis using CAD/CAM methods. The study developed a digitalized method to produce TF sockets, thereby replacing the manual, operator dependent proceedings from the traditional manufacturing method. To develop a customized hybrid socket, the adjustable brim method was copied, and a hybrid brim was fitted to the patient to determine the correct size. In Figure 4, a hybrid brim with its important characteristics is visualized, including an approximated skeletal ML distance. To develop an off-the-shelf hybrid brim set with diverse hybrid brim circumferences required to accommodate various stump sizes, a single model was uniformly scaled in all dimensions. This simple method does not take the possible non-proportional changes in the anatomy of the stump into account. As a result, the fit of the brim may not have been optimal for individuals with different stump sizes. For the creation of a standardized hybrid brim set that accommodates the (non-proportional) anatomical changes in TF stumps, several brim characteristics are important. These characteristics are usually manually incorporated into the design of the brim during the first casting step of the traditional method and include factors such as the skeletal ML dimension and the size of the tuber support. Therefore, in current study, existing hybrid brims were digitalized and analyzed on the mentioned characteristics and compared to their size, or circumference, to seek correlations. The results from this analysis were translated into a scaling procedure to form an improved data-supported standardized brim set, characterized by various circumferences.

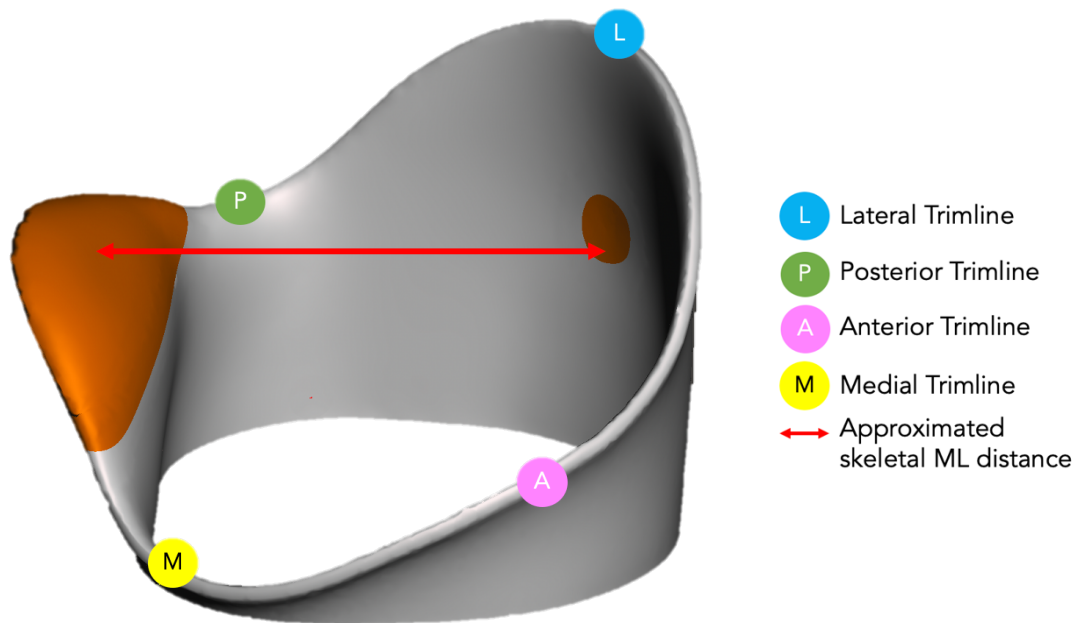


Figure 4: Top anterior-medial view of a TF hybrid brim. The tuber support is depicted in orange, and the assigned trimlines are shown, including the approximated skeletal ML distance, representing the horizontal distance between the center of the tuber support and the lateral wall.

To supply the brim and formulate the distal socket part, a 3D-scan of the distal stump volume was made during the previous study. However, while conducting the 3D scanning to measure the distal stump volume, challenges arose due to complexities in scanning the crotch area and the subsequent intricate digital post-processing steps required. In addition, in most cases, the distal stump had a similar conical shape, only differing in length and volume. Considering the various online TF stump measurement forms, it appears that the most common measurements are the length and circumferences. These measurements are critical in determining the volume of the stump. Therefore, a simplified method to obtain these measurements in a standardized manner was developed. In addition, the developed method eliminated the necessity to localize anatomical landmarks, a challenge that was encountered during the previous study. Furthermore, a method to digitally transform the measurements obtained through the stump measurement method, comprising the selection of a brim circumference and the distal stump volume measurements, into a complete TF socket was established.

In Figure 5, it is visualized how the streamlined method developed in current study differs from the digital method from the previous study, and the traditional method.

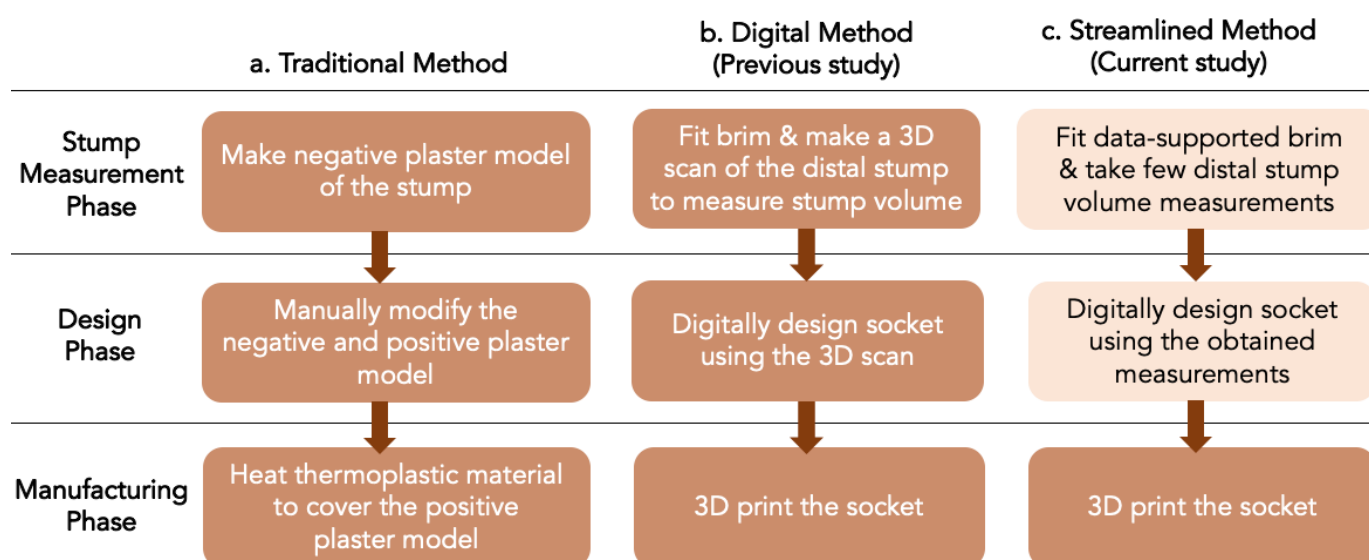


Figure 5: TF socket manufacturing workflows with a. Traditional Method b. Digital Method established in the previous study and c. the Streamlined Method established in this study, differing from the Digital Method within the stump measurement and design phase.

Current developmental study consists of three phases and aimed to streamline the TF socket manufacturing workflow to reduce operator dependency with the primary focus on developing a data-supported standardized brim set. The first phase involved the analysis of digital hybrid brim characteristics based on anatomical characteristics of the TF stump in relation to their circumference. The second phase build upon the findings from Phase 1 to develop and evaluate a data-supported standardized brim set. The third and final phase supplemented the stump measurement method by introducing a simplified method to measure the distal stump volume. Subsequently, the measurements from the stump measurement method were used to digitally design the complete TF socket. Finally, the socket was 3D-printed and evaluated for its fit.

Phase 1 – Analysis of Brims

The objective of Phase 1 was to evaluate characteristics of hybrid brims relative to their circumference. Prior to commencement, the research protocol (file number: 2022-16070) was reviewed by the medical ethics review committee East Holland and ethical approval was obtained on January 4, 2023.

Method

Participant Inclusion

Participants were selected through Papenburg Orthopedie (Ravenstein, The Netherlands), based on the inclusion criterion of using a TF prosthesis with a hybrid socket manufactured through the traditional plaster cast method. Informed consent was obtained from all participants before their inclusion.

Data Collection

During the participant's visit, demographic information and patient characteristics were collected as outlined in Appendix B. A flexible tape measure was used to obtain the relaxed thigh circumference of the stump at the groin level and a 3D-scan was acquired of the inside of the hybrid TF brim using a texture handheld 3D-scanner (EinScanner Pro Plus, Shining 3D Technology, Hangzhou, China).

Data Analysis

The 3D-scans were preprocessed in MeshMixer (Autodesk Inc., San Rafael, CA, USA) as stereolithography (STL) files. Excessive data was removed, and the brims were trimmed 1.25 cm below the lowest point on the medial trimline. Correlations were examined between the brim circumference (cm), and various characteristics of the hybrid brim (Figure 4). These characteristics included the approximated skeletal ML dimension (cm), the tuber support area (cm²), and the heights (cm) of the medial, anterior, lateral, and posterior trimlines. The approximated skeletal ML dimension was defined as the horizontal distance between the center of the tuber support (representing the ischial tuberosity's position) and most outward point on the lateral wall (representing the lateral shaft of the femur bone trochanter major) and determined in Matlab (The MathWorks, Natick, MA, USA). The tuber support area was defined as the area that was angled towards the horizontal plane relative to the remaining brim. The height of the trimlines was defined as the vertical distance from the center of the tuber support to the concerning trimline. Both the tuber support area and the heights of the trimlines were determined using 3DMedX software (3D-Lab Radboudumc, Nijmegen). Furthermore, an analysis was conducted to explore the relationship between the thigh circumference and the difference between the thigh and brim circumference. This offers insights into the level of reduction integrated into the brim and whether this reduction varies with variations in thigh circumferences.

Statistical Analysis

The normality of continuous participant, stump and brim data was assessed using the Shapiro-Wilk test to determine the distribution characteristics of the relevant variables. In cases of normal distribution (Probability of $W > 0.05$), means and standard deviations were computed. Alternatively, for non-normally distributed data, the median, 25th percentile (Q1), and 75th percentile (Q3) values were derived. Due to the limited sample size, simple linear regression models were used to determine any relationships between the brim circumference (independent variable) and the following dependent variables: the tuber support area, approximated skeletal ML dimension, and heights of the medial, anterior, lateral, and posterior trimlines. In addition, the thigh circumference was compared to the difference between the thigh and brim circumference through a simple regression model. If a statistically significant non-zero slope ($p < 0.05$) was observed, implying a correlation between the variables, the plot was shown, and the equation was provided.

Results

Table 1: Measured thigh and brim dimensions per participant. If the Prob<W was <0.05, the Median (Q1, Q3) are given.

Participant #	Sex (M/F)	Thigh circumference (cm)	Brim circumference (cm)	Appr. Skeletal ML (cm)	Area tuber support (cm ²)	Medial trimline height (cm)	Anterior trimline height (cm)	Lateral trimline height (cm)	Posterior trimline height (cm)
1	F	46.0	43.3	14.1	40.7	-4.2	0.1	6.5	1.2
2	F	55.0	48.1	16.1	44.6	-5.9	0.7	9.4	1.7
3	F	58.0	48.6	13.7	48.0	-2.0	0.4	5.5	-1.0
4	M	39.0	40.6	12.6	43.3	-6.0	-2.7	6.0	1.6
5	M	35.0	37.2	11.8	52.8	-5.8	0.9	5.9	-0.4
6	M	44.0	41.9	12.7	28.0	-7.0	-2.5	6.2	0.2
7	F	54.0	49.9	15.4	37.1	-6.3	-3.0	6.3	-2.0
8	M	42.0	43.6	14.2	17.0	-2.1	1.0	9.0	-0.4
9	M	48.0	50.1	16.1	37.2	-8.8	-2.3	7.2	-0.4
10	M	49.5	44.7	13.4	53.1	-3.4	-0.8	6.9	-0.9
11	M	50.0	45.9	13.6	48.7	-8.3	-2.3	5.2	-1.7
12	F	57.0	46.5	15.1	51.2	-6.7	-3.1	-0.4	-4.8
13	M	49.0	47.2	14.1	53.6	-6.4	-2.5	5.7	-1.0
Prob<W		0.873	0.712	0.736	0.074	0.322	<0.0001	0.007	0.245
Mean (SD) / Median (Q1; Q3)		48.2 (6.9)	45.2 (3.8)	14.1 (1.3)	42.7 (10.8)	-5.6 (2.1)	-0.8 (-3.1; 0.6)	6.2 (5.6; 7.1)	-0.9 (1.6)

Thirteen participants (8 male, 5 female) were included in Phase 1 of the study, hereafter referred to as group A, see Figure 6. Table 1 presents the measured brim dimensions for each participant.

In Figure 7, a plot of the brim circumference against the approximated skeletal ML dimension is shown, revealing a significant regression slope ($p=0.0003$, $R^2 = 0.717$) described by Equation 1:

$$\text{Approximated Skeletal ML (cm)} = 0.294 * \text{Brim Circumference (cm)} + 0.77$$

Additionally, Figure 8 illustrates a linear correlation of significance ($p < 0.0001$, $R^2 = 0.769$) between the thigh circumference and the difference between the thigh and brim circumference. This correlation is expressed by Equation 2:

$$\text{Thigh} - \text{Brim Circumference (cm)} = 0.536 * \text{Thigh Circumference (cm)} - 22.81$$

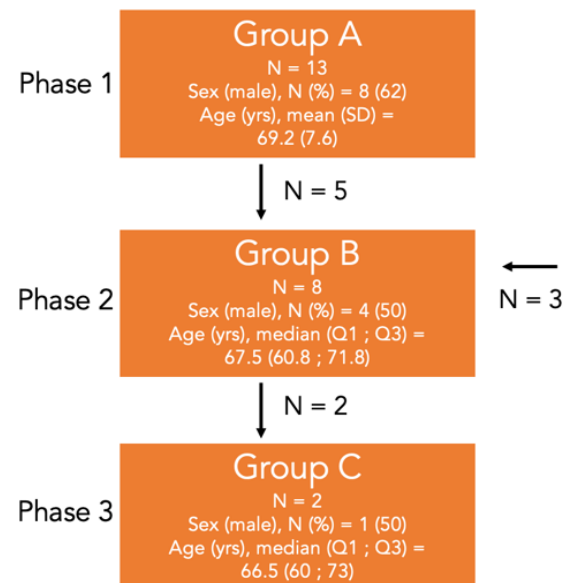


Figure 6: General included participant information per phase of the study.

No correlations were found between the brim circumference and the area of the tuber support ($R^2 = 0.001$, $p = 0.940$), as well as the height of the medial ($R^2 = 0.020$, $p = 0.643$), anterior ($R^2 = 0.160$, $p = 0.175$), lateral ($R^2 = 0.000$, $p = 0.997$), and posterior ($R^2 = 0.226$, $p = 0.101$) trimlines. Appendix C displays the plots for the non-significant variables that were tested.

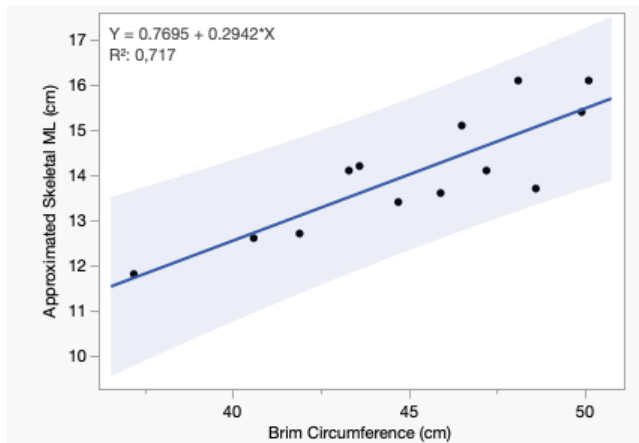


Figure 7: The approximated Skeletal ML dimension against its circumference.

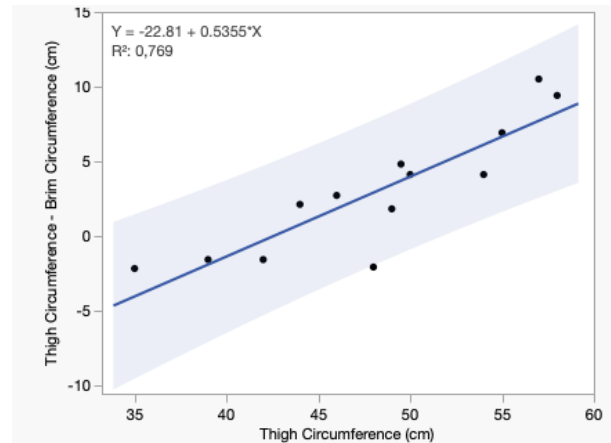


Figure 8: The difference in thigh and brim circumference compared to the thigh circumference.

Interpretation of Results

The findings indicated a correlation between larger brim circumferences and an increase in the approximated skeletal ML distance, whereby 72% of its variance can be explained by the brim circumference. The derived equation provided a useful formula for positioning the tuber support in relation to the brim circumference. However, it must be kept in mind 28% of the variability in skeletal ML dimension remains unexplained and is attributed to other factors.

The results indicate that for individuals with larger thigh circumferences, a larger reduction in brim circumference is present. This insight holds practical value for Phase 2b and 3 as it aids the prediction of the appropriate brim circumference based on a given proximal thigh circumference. However, it must be kept in mind that 23% of the variation of the difference between thigh and brim circumference cannot be explained by the thigh circumference, and other factors play a role.

No significant correlation was found between the brim circumference and the tuber support area. This suggests that the tuber support area can be maintained constant during scaling. Furthermore, no correlation was discovered between the brim circumference and the height of the trimlines. Therefore, it is not recommended to alter the height of the brim when developing different circumferences. The information obtained regarding the characteristics of the brim was integrated into a scaling procedure used to generate a brim set covering various circumferences and therefore stump sizes during Phase 2 of the study.

Phase 2 – Design & Evaluation of the Standardized Brim Set

The objective of Phase 2 was twofold: first, to design a data-supported standardized brim set and second, to evaluate its fitting.

Method

2a – Design of the Data-Supported Brim Set

To establish the brim set, the mean brim shape derived from the 13 digital brim STL files obtained in Phase 1 was used as the initial brim. To compute this mean brim shape, first, landmarks were assigned to the trimlines and tuber support using 3DMedX software. The MeshMonk algorithm [58] employed these landmarks as part of its process, applying non-rigid registration for 3D shapes, thereby establishing quasi-landmarks with equivalent vertex numbers across all brims (see Appendix D for the used Matlab code). To achieve these quasi-landmarks, a template – randomly chosen from the 13 shapes – served as the initial reference. Subsequently, the template was aligned to the remaining 12 brims, or target brims, and the vertex numbers of the template were projected onto these brims (Figure 9). For the first iteration, a random brim among the 13 shapes was chosen as the template. Then, the mean brim shape was derived by calculating the average value for each vertex across all brims. Moving on to the second and final iteration, the mean brim shape obtained from the first iteration was employed as the template. The MeshMonk algorithm was once again applied, resulting in the re-evaluation of the final mean brim shape used as the starting point for creating the data-supported brim set, along with its associated standard deviation. For the resulting mean brim, the area of the tuber support and the height of the medial, anterior, lateral, and posterior trimlines were determined in a similar way as in Phase 1.

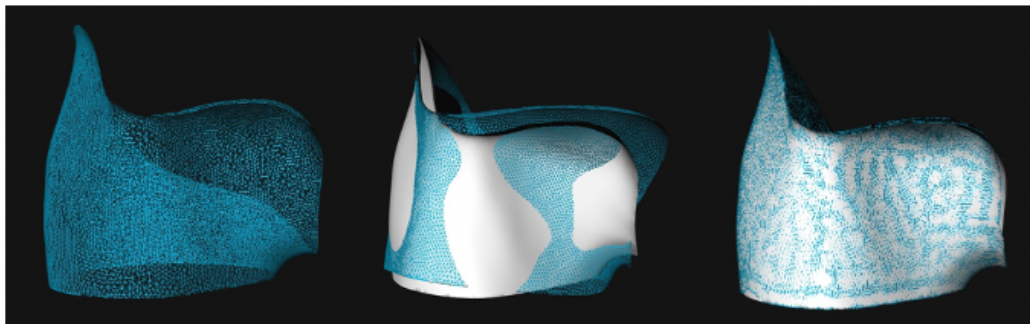


Figure 9: The non-rigid registration process performed by the MeshMonk algorithm with the template in blue and a target brim in white.

In Phase 1, no significant correlations were identified regarding the dimensions of the brim relative to its size, except between the brim circumference and the approximated skeletal ML dimension. Therefore, a simple scaling of the mean brim shape was carried out to obtain a brim set that contains various brim circumferences. The tuber support was isolated and remained constant for all brim sizes, while the remaining brim was scaled in the X- and Y- directions to achieve the desired circumference. Equation 1 presented in Phase 1 was used to position the tuber support. The scaled brim was finalized by reconnecting the tuber support to the remaining brim. This procedure was repeated to create a brim set comprising brims with circumferences ranging from 35 to 60 cm, with 1 cm increments. For a

comprehensive explanation including graphics on the scaling procedure of the mean brim performed in Matlab and MeshMixer, please refer to Appendix E.

2b – Evaluation of the Data-Supported Brim Set

Participant Inclusion

Initially, participants undergoing rehabilitation at the Radboudumc were selected to test the brims from the newly developed data-supported standardized brim set (referred to as group B). The aim was to evaluate the brims from the data-supported brim set in a different cohort than used for its design (group A). However, due to limited availability, participants from group A were also included in group B to increase the sample size (Figure 6). Inclusion criteria were having a TF prosthesis, the ability to stand on the sound leg with assistive devices and a thigh circumference ranging from 35 to 65 cm.

Study Procedure

Brim fittings and evaluations were conducted by a professional including a rehabilitation physiotherapist (R.L), an experienced prosthetist (M.P) or the researcher (I.S) and by the participant. The researcher, a Technical Medicine student, performed the evaluations after training by the experienced prosthetist (M.P). Participant's demographics and characteristics were obtained with an assessment form prior to the fitting (Appendix B).

Test Procedure

The digitally designed brims were 3D-printed (Ultimaker S5 3D printer, Ultimaker BV, Geldermalsen, the Netherlands) that makes use of Fused Filament Fabrication (FFF) using generic Poly Lactic Acid (PLA) material and a 0.8 mm print core, 100% infill, 0.2 mm layer thickness, and print speed of 45 mm/sec. The brims were connected to a custom-designed brim standard, allowing proper positioning and weight loading of the brim (Figure 10). The patient wore tights of 50 denier. The most suitable brim circumference was determined by first measuring the thigh circumference at the groin level and subsequently trying multiple adjacent smaller circumferences. When the proper circumference was chosen, the following brim sections were evaluated on a scale from 1 (poor), 2 (insufficient), 3 (moderate), 4 (good) to 5 (excellent): a) Tuber support, b) Medial trimline, c) Anterior trimline, d) Lateral trimline, and e) Posterior trimline. In case a medium to low score was given, the reason for that rating was obtained. See Appendix F for the used assessment form.



Figure 10: Set-up to evaluate the fitting of the brims using the custom-designed brim standard.

Data Analysis

Per participant, the achieved points for each brim section (ranging from 1 to 5) were summed. Subsequently, the total awarded points were divided by the maximum achievable points per evaluation to obtain the percentage of the achieved points. The evaluation was presented separately for the professional and the participant. Next to the analysis per evaluation from

the professional or the participant, the data was analyzed per brim section by calculating the total points and corresponding percentage from all included participants together. In addition, a similar analysis was performed as in Phase 1 for the thigh circumference compared to the difference between the thigh and chosen brim circumference from the data-supported brim set.

Results

2a – Design of the Data-Supported Brim Set

Figure 11 displays the mean brim shape that followed from the 13 brim shapes included in Phase 1 along with its corresponding standard deviation as gradient color. Figure 12 presents three different circumferences from the data-supported brim set. The area of the tuber support was 42.5 cm² from the mean brim shape. The height of the trimlines were -5.6, -0.5, 6.2, and -1.2 for the medial, anterior, lateral, and posterior trimlines respectively.

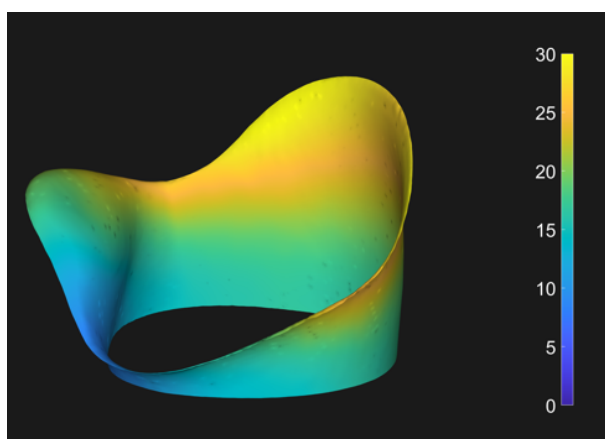


Figure 11: Top anterior-medial view of the mean brim shape including its standard deviation in mm.

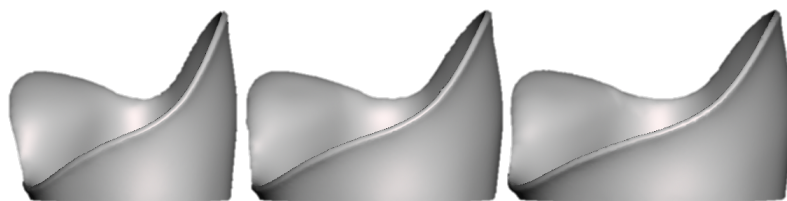


Figure 12: Anterior view of three different brim circumferences from the standardized set. From left to right, circumference: 40, 44 and 48 cm.

2b – Evaluation of the Data-Supported Brim Set

Group B included a total of 8 participants (Figure 6), with 5 participants from group A and 4 being males. The results of the brim fitting assessments are presented in Table 2. In Figure 13, the correlation between the thigh circumference and the difference between thigh and brim circumference shows a significant regression slope ($R^2 = 0.636$, $p = 0.018$) described by Equation 3:

$$\text{Thigh} - \text{Brim Circumference (cm)} = 0.271 * \text{Thigh Circumference (cm)} - 9.19$$

Table 2: Evaluation of brim sections with total scores and percentages per assessor and brim section.

Subject	Assessor	Brim Size (cm)	Tuber Support	Medial Trimline	Anterior Trimline	Lateral Trimline	Posterior Trimline	Total (X/%)
1	IS	44	4	4	4	4	4	20/80
1	P	44	4	4	4	4	4	20/80
2	MP	48	4	3	3*	4	4	18/72
2	P	48	4	4	3*	4	4	19/76
3	IS	50	4	3*	3*	4	4	18/72
3	P	50	4	3*	2*	4	4	17/68
4	IS	36	4	3*	2*	4	4	18/72
4	P	36	4	3*	3*	4	4	18/72
5	IS	35	4	4	4	4	4	20/80
5	P	35	5	4	4	5	4	22/88
14	IS	48	4	4	3*	4	4	19/76
14	P	48	4	4	3*	4	4	19/76
15	IS	46	4	2*	3*	4	4	17/68
15	P	46	4	2*	2*	4	4	19/64
16	RL	37	2**	4	4	4	4	18/72
16	P	37	3**	3*	3*	4	4	17/68
Total (X/%)			61/76	54/68	51/64	64/80	63/79	

Legend: IS: Technical Medicine student RL: Rehabilitation Physiotherapist

MP: Experienced Prosthetist P: Participant

* Indicates that the cut of the respective trimline was too high, resulting in discomfort. ** Indicates that the position of the tuber support was displaced relative to the ischial tuberosity.

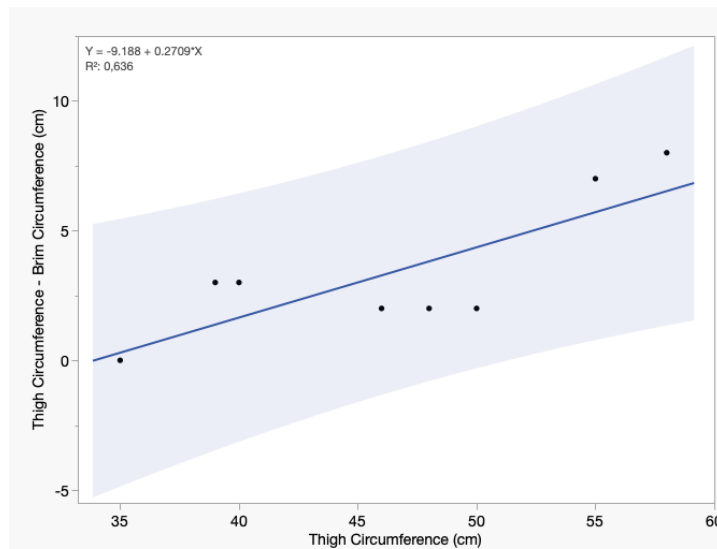


Figure 13: The correlation between the thigh circumference and difference between the thigh & brim circumference.

Interpretation of Results

The results concerning the correlation between the thigh circumference compared to the difference between thigh and brim circumference comply with the findings from Phase 1: showing a positive correlation thus implying that for individuals with larger thigh circumferences relatively smaller brim circumferences are suitable. However, in Phase 2b, a larger portion of the variance remains unexplained.

Despite concerns about the medial and anterior trimlines, all other brim sections' total scored above 75%, and the total individual assessments per participant exceeded 68% for 7 out of 8 participants. However, discomfort due to elevated medial and anterior trimline cuts was reported by 6 participants. In addition, participant 16 had a low score due to insufficient positioning of the tuber support relative to the ischial tuberosity. In Phase 3 of current study, the brim sections were re-evaluated in a complete TF hybrid socket.

Phase 3 – Measure, Design and Evaluate Complete Socket

The goal of this phase was to supplement the data-supported brim with a distal socket part, for which the distal stump volume was measured using a simplified method. The measurements from the stump measurement method were digitally translated into a total hybrid socket design that was subsequently evaluated for its fit.

Method

Participant Inclusion

A selection from group B was chosen for inclusion based on practical considerations related to participant and assessor availability.

Study Procedure

Stump Measurement Method

The selection of a suitable brim size and conducting the established method to measure the distal stump volume together form the stump measurement method (Figure 14). The established method relies on one length and, depending on this length, a few circumference measurements. First, in step 1, the proximal thigh circumference was measured and to determine the hip **flexion contracture**, the Thomas Test was used [59]. The most suitable brim circumference was chosen for the concerning participant in step 2, whereby a donning sleeve was used to facilitate easy donning and to pull down the soft tissue. Subsequently, during step 3, the distal stump volume was measured while the participant was fitted with the brim in a loaded situation using the self-designed brim standard. Stump **circumference measurements** were taken at 5 cm intervals starting 5 cm proximal to the bottom of the stump until the distal edge of the brim, using a flexible tape measure. Additionally, the **length of the distal stump**, measured as a vertical line from the distal lateral edge of the brim up to the end of the stump, was recorded. The stump measurement method was performed by the researcher (I.S).

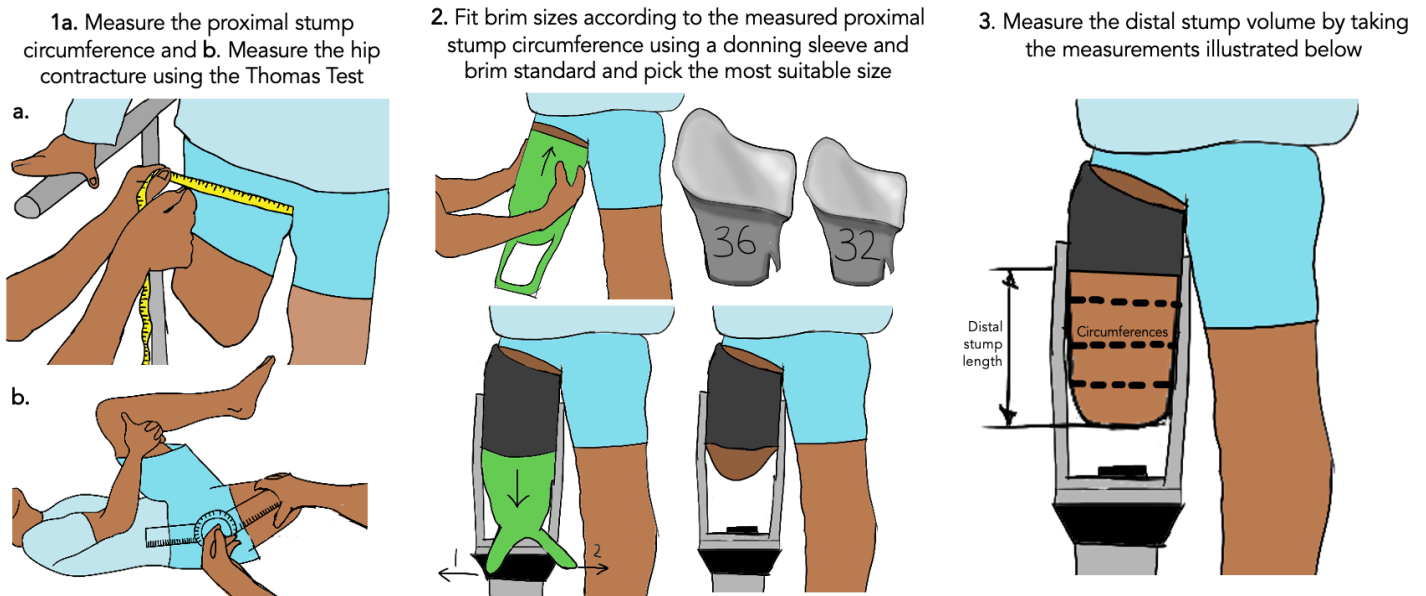


Figure 14: Steps taken during the stump measurement method developed in the current study.

Socket Design and Manufacturing

The obtained circumference and length measurements in combination with the selected brim circumference were used to digitally design the TF socket. The process, as depicted in Figure 15, involved several steps performed by the researcher in MeshMixer.

Step 1:

The chosen brim circumference was selected, and circular rings were scaled to match the measured distal **circumference measurements**. A reduction of 5-3-1% from proximal to distal was applied on the rings. To prevent friction with the distal stump, the socket's distal end was positioned at the measured **length of the distal stump** + 1.5 cm.

Step 2:

The rings and socket bottom were connected, and the distal part was rotated in a 6-degree adduction angle [60] and in a flexion angle of **<flexion contracture + 5 degrees>**. The brim was rotated in a 5 degrees flexion angle. The socket's total thickness was set at 4.8 mm, whereby the weight bearing area surrounding the tuber support was given an extra thickness.

Step 3:

An inserts plate, where the prosthetic knee was affixed, was aligned beneath the socket, ensuring that its position was situated behind the load line.

Step 4:

After connection of the brim to the distal part and the insert plate, a 3 cm diameter opening was incorporated on the distal anterior-medial part for removal of the donning sleeve.

Step 5:

Due to its dimensions surpassing the print building volume of 33x24x30 cm, the socket was divided into two segments, and a connection method was introduced to join the two parts.

Steps 2-5 were copied from the digital method established in the previous study (Figure 3 & 5) as part of the project.

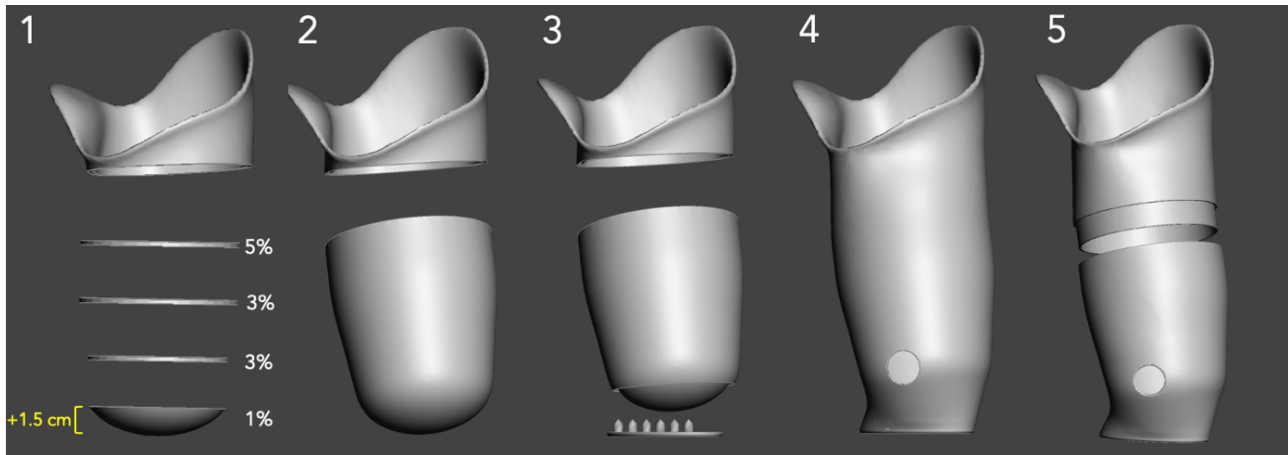


Figure 15: Steps taken in MeshMixer to design a hybrid TF socket, using a selected brim circumference. The socket's bottom was positioned at the stump length + 1.5 cm and a reduction of 5-3-1% was applied on the conical rings.

Evaluation of Socket

The fitting of the socket was evaluated by the rehabilitation physiotherapist (R.L), experienced prosthetist (M.P), and participant. Each assessor independently evaluated the fitting of the socket, and there was no interaction between them during the evaluation process. The participant was asked to rate each section of the brim and socket, which were pointed out by the researcher (I.S)

Test Procedure

The socket parts were 3D-printed in a similar manner as in Phase 2 for the brims. To be able to assess the socket fit, it was assembled with a low-cost prosthetic knee and foot (Shijiazhuang Wonderfu Rehabilitation Device Technology Co., Ltd, Luancheng District, Shijiazhuang City, Hebei, China). The prosthetic parts were attached to each other according to the Otto Bock guidelines for alignment of TF modular lower limb prostheses [61]. In addition, a suspension system was added based on the silesian belt style (Figure 16). See Appendix G for a manual to form the silesian belt using nylon and elastic straps. Both the selection of the prosthetic parts and the suspension system were copied from the previous study as part of the project.



Figure 16: Silesian belt from a lateral view in which the socket is attached to the belt through an anterior and posterior strap.

The fitting evaluation was divided into the brim, which was assessed in a similar manner as in Phase 2, and the distal part the of the socket. The assessment of the distal part focused on (F) the distal connection of the socket and (G) the shape of the socket. The distal connection of the socket should allow space between the distal stump and the socket to prevent friction. The rating and if applicable the reason were obtained in a similar manner as in Phase 2. See Appendix H for the used assessment form.

Data Analysis

Per participant, the points for each brim section and distal part elements were summed and percentages were calculated. In addition, the data was analyzed per brim section and distal part element by calculating the total points and corresponding percentage from all included participants together.

Results

Two participants (participants 3 and 16 from group B) were included (Figure 6), including 1 male. The results of the socket fitting assessments, along with the reasons for moderate (3) to insufficient (2) scores, are presented in Table 3.

Table 3: Evaluation of Brim sections and Socket elements per assessor.

Subject	Assessor	Brim Size (cm)	Brim					Socket		Total (X/%)
			A	B	C	D	E	F	G	
3	RL	36	4	2*	2*	4	4	3***	4	23/66
3	MP	36	3**	4	3*	4	4	3***	3****	24/69
3	P	36	4	3*	2*	4	4	3***	3****	23/66
16	RL	50	2**	2*	2*	4	4	4	4	22/62
16	MP	50	3**	2*	3*	4	4	4	4	24/69
16	P	50	3**	2*	3*	4	4	4	4	24/69
Total (X/%)			19/63	15/50	15/50	24/80	24/80	21/70	22/73	

Legend: A: Tuber support B: Medial trimline C: Anterior trimline D: Lateral trimline E: Posterior trimline F: Distal connection G: Socket Volume Shape. RL: Rehabilitation Physiotherapist MP: Experienced Prosthetist P: Participant
Note: * indicates that the cut of the trimline was too high, resulting in discomfort. ** indicates that the position of the tuber support was displaced relative to the ischial tuberosity. *** indicates that there was insufficient space left between the distal stump and socket. **** indicates there was a sudden decrease in socket volume at the distal end.

Interpretation of results

The results of the socket assessments in Phase 3 indicate positive outcomes, with 5 out of 6 total individual assessments scoring above 66%. However, it is worth noting that the medial (B) and anterior (C) trimlines received low scores, which aligns with the findings from Phase 2. Furthermore, participant 16 received an insufficient score for the tuber support section, consistent with the results of Phase 2.

Regarding the distal part of the socket, an observation was made for participant 3. There was insufficient space noted between the distal anterior portion of the socket and the stump. Conversely, an excess of space was identified in the distal medial and posterior sections of the socket. In addition, an abrupt reduction in socket contour had an impact on the aesthetics of the socket (Figure 17). As a result, both the distal connection (F) and the shape of the socket (G) elements were rated as moderate.

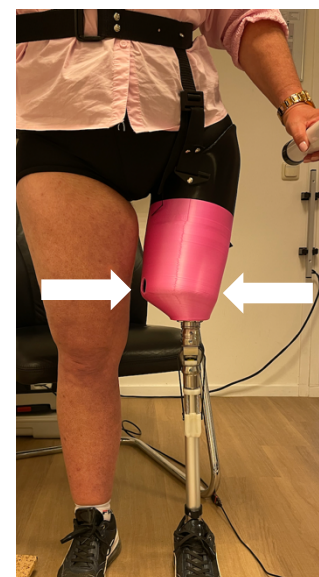


Figure 17: Participant 3 wearing the socket, with an arrow indicating the abrupt reduction in socket contour.

Discussion

The objective of this developmental study was to streamline the workflow to produce hybrid TF prosthetic sockets, aiming to reduce operator dependency and ultimately implement the workflow in automated software. The study built upon the previous study as part of the 3D Sierra Leone project, which proved the feasibility to produce TF prosthesis using CAD/CAM methods. Current study aimed to fulfill the requirement for an enhanced standardized data-supported brim set and a simplified method to measure distal stump volume. These components are part of the initial phase of the socket manufacturing workflow, covering the stump measurement method. In addition, during current study, a method to digitally combine the measurements obtained from the stump measurement method into a socket was developed.

The analysis of hybrid brim dimensions relative to their circumference in Phase 1 provided input for the design of a data-supported standardized brim set, which was then subjected to fitting assessments in Phase 2. Subsequently, a simplified method to measure the distal stump volume was developed in Phase 3 to facilitate the digital design, manufacturing, and evaluation of a total TF hybrid socket. Both the developed data-supported standardized brim set and the simplified method to measure distal stump volume enhanced the efficiency of the stump measurement method and overall streamlining of the TF socket workflow. In addition, the method to digitally transform the measurements from the stump measurement method into a 3D-printable TF socket has the potential to be implemented in automated software. The progress made in current study took one step closer to the future goal: enabling local personnel with limited expertise to execute the workflow.

Main Findings

The outcomes of Phase 1 showed a significant correlation between the brim circumference and the approximated skeletal ML, serving as the foundation for the scaling procedure applied in Phase 2. The positive results obtained during brim fitting assessment in Phase 2, with an average score of 74% per individual evaluation, indicated the data-supported brim set to fit a diverse range of TF stump circumferences. This promising outcome highlights the potential of the data-supported brim set to be a foundational component in the workflow of TF hybrid sockets. However, the cut of the medial and anterior trimlines were repeatedly judged as too high by both the assessor and the participant. The feedback garnered from socket fitting evaluations during Phase 3 aligned with Phase 2 regarding the fit of the brim and provided valuable insights regarding the design of the distal socket part.

In Phase 1 and 2, the thigh circumference was compared to the difference between the thigh & brim circumference. In both phases, the results revealed a positive correlation between larger thigh circumferences and the discrepancy between the thigh and brim circumference. The mean difference was smaller in the first phase (3.0 ± 4.2 cm) compared to the second phase (3.4 ± 2.7). However, the difference shows a smaller increase for larger thigh circumferences in Phase 2, as shown by the smaller slope of the regression line. Nevertheless, the findings of current study can be implemented in the streamlined TF socket workflow by providing guidance to select a specific brim circumference based on the thigh circumference. Consequently, individuals with larger thigh circumferences should opt for a recommended

brim circumference that is a few sizes smaller, while those with smaller thigh circumferences may consider a size that is proximate.

In Phase 2 and 3, it was observed that the medial and anterior trimline brim cuts were positioned too high, resulting in discomfort for the participants in the groin area. It was noted that the design of the brim set created in current study was derived from existing hybrid brims rather than being based on stump geometrics. This approach introduced an element of subjectivity, as the prosthetist manually designed the socket. However, this subjective aspect also provides flexibility in the design process, enabling the possibility to adjust certain sections of the socket, such as the medial and anterior trimlines. Nonetheless, more brim fittings will reveal if these trimlines require permanent and standardized adjustments.

Participant 16 experienced inadequate positioning of the tuber support in both Phase 2 and Phase 3. The tuber support was not properly positioned underneath the ischial tuberosity bone. This is considered problematic because the resting of the ischial tuberosity on the tuber support is important for providing support through the bony lock. Given the fact that the experienced prosthetist encountered a similar issue of inadequate positioning of the tuber support for this specific participant, there is a likelihood that the participant's anatomy deviates from the norm. Furthermore, during Phase 3, it became evident that the 1.5 cm elongation of the socket length was inadequate for participant 3. As a result, the distal stump tended to contact the socket, potentially giving rise to pressure or friction in later stages. A suitable design adjustment would be to elongate the socket with 2 cm. Additionally, the abrupt reduction in socket contour highlighted the necessity of revising the design approach. Currently, the circumference of the socket bottom aligned with the circumference measured 5 cm above the end of the stump. To achieve a better shape, a suitable adjustment would involve the socket's bottom to have a smaller circumference than the one measured above.

Comparison with Literature

In Phase 1 of current study, the average approximated skeletal ML dimension was determined to be 14.1 ± 1.3 cm, with a range of 11.8 – 16.1 cm. These measurements are comparable to the dimensions found in a previous study from Dillon et al. [62], which reported values of 13.8 ± 1.1 cm (range: 10.6-16.7 cm) for males and 12.0 ± 1.1 cm (range: 9.1-14.9 cm) for females. Their study aimed to identify variables contributing to the prediction of the skeletal ML. Notably, body mass had the highest positive correlation, accounting for 21% of the impact. This confirms the correlation between brims with a larger circumference and the increase in the approximated skeletal ML dimension, as demonstrated in the current study. However, the skeletal ML distances found in current study are approximated values, as they were indirectly derived from brim dimensions. Therefore, a direct comparison might not be valid. Besides, the skeletal ML was found to be bigger in females (14.9 ± 1.0 cm) compared to males (13.6 ± 1.3 cm) in current study. Nevertheless, it must be kept in mind that this finding is based on a small sample size of 8 and 5 males and females respectively. In addition, the deviating result compared to Dillon et al. [62] might be related to the bigger thigh circumference found for women in current study compared to men: 47.7 ± 2.3 versus 43.9 ± 3.8 cm, which is associated with a bigger skeletal ML.

Colombo et al. [52] developed a knowledge-based socket modelling assistant, whereby the orthopaedic technician's operations are emulated. This tool aims to reduce socket development time and costs by reducing the number of physical prototypes. However, this design tool is intended for prosthetists and still necessitates expertise for its effective utilization. Additionally, the tool requires a digital model of the stump by combining data from a laser scanner and images from computed tomography and magnetic resonant imaging. A study in India [63] attacked the following challenges associated with the large number of TF amputation patients and the traditional method to manufacture sockets: (1) requirement of trained technicians, (2), high possibility of manual errors leading to rework, (3) long production time, and (4) difficulty in scaling up for widespread application. In their study, they found an approach of 3D-printed sockets to be unsuitable for rapid and cost-effective socket manufacturing, thereby prioritizing challenges (3) and (4), while current study focused on addressing the challenges (1) and (2). Instead, they presented a method using CAD and numerically controlled machining to manufacture low-cost sockets based on 60 parameters derived from 23 measurements on the stump, requiring the localization of anatomical landmarks.

Given the different overarching objectives of the current study compared to the study that developed the socket modelling assistant [52], and the study in India [63], it is not feasible to make a valid comparison between the established workflows. Both other studies add up to the mentioned socket design software tools in the Introduction, which necessitate various anatomical measurements and multiple intricate digital design steps [51–53]. Unlike these tools, which are primarily designed for use by prosthetists due to the specialized knowledge they demand, the current study proposed a simplified stump measurement method. The operator's task involves selecting the appropriate brim circumference, which defines the proximal shape of the socket during the digital design process. Upon selecting the appropriate brim in a shared decision-making setting with the participant, the operator only needs to gather one distal stump length measurement and a few circumference measurements depending on the length of the distal stump, using a simple flexible measurement tape. For this simplified method to measure distal stump volume, there is no need to localize anatomical landmarks, making it easier to perform for people with limited expertise.

The current study's comparison with existing literature revealed a lack of focus in literature on both the use and evaluation of a (data-supported) brim set and a simplified method to measure distal stump volume, used in the initial phase of the workflow to manufacture TF prosthetic sockets. In a scoping review on '3D printing and amputation,' only one study focused on TF amputations [41], specifically evaluating a 3D-printed prosthetic knee. Another study [64] conducted a review on the utilization of additive manufacturing in prosthesis production and cited three studies that developed finite element analysis models to predict TF socket fitting [65–67]. This particular aspect was not within the scope of current study, which did not predict brim and socket fitting based on simulation. Furthermore, a systematic review on 3D-printed prostheses [68] highlighted the necessity for more published scientific research to address the limited availability of limb prostheses in LMICs and establish sustainable solutions.

Limitations & Recommendations

In Phase 1 of current study, a relatively small dataset of 13 brims was included, all manufactured by one single prosthetist. This introduced certain limitations. First, this resulted in a large reliance on the skills of the prosthetist, and in a possible homogenous shape across the brims, including the tuber support. Secondly, in Phase 2, an average brim shape was computed from the dataset of 13 brims and utilized as the foundational brim for the data-supported brim set. However, noteworthy variations were observed within this dataset, particularly evident in the standard deviation of the tuber support area. Additionally, significant variations were noted in the heights of the anterior and lateral trimlines. These fluctuations can be attributed to individual user preferences, as indicated by the experienced prosthetist, who mentioned adjusting these trimlines upon user requests. Considering the variations, it is important to recognize that the derived average brim shape may not provide an optimal fit for all types of TF stumps. Thirdly, the size of the available dataset did not permit an examination of potential distinctions in brim shape between male and female participants. Additionally, no assessment of the Ischial Ramus angle was performed, an angle between the pelvic ischial ramus and the horizontal plane that exhibits variances across genders [69]. To address these limitations, more hybrid brims created by multiple prosthetists should be analyzed. This would allow the brim dimensions to be further assessed on similar and other aspects, such as the differences between sexes and the Ischial Ramus angle, to gain a better understanding of its expressions regarding the shape of the brim.

In addition to exploring additional variables, utilizing a more extensive dataset allows the plotting of multiple linear regression models. This, in turn, can result in higher R^2 values, enabling an investigation into other factors besides the brim circumference that influence the shape of the pelvic brim. These analyses may lead to the identification or necessity of developing distinct brim phenotypes, potentially categorized by attributes like gender or BMI. Overall, by increasing the sample size and involving a wider range of expertise, the establishment of a standardized brim set gains greater validity and reliability.

The evaluation of brim and socket fitting was based on a relatively small sample size of Dutch participants, which limits the extent to which the findings can be generalized to other populations, particularly in LMICs where the implementation of the workflow is intended. To enhance the generalizability and applicability of the findings, further research should be conducted with a larger and more diverse sample of TF stumps, including individuals from different racial backgrounds. Gathering more comprehensive fitting data is recommended to investigate whether the improper tuber support position observed in participant 16 is an isolated occurrence or if it may be encountered more frequently. Together with analyzing more brim shapes using multiple regression models, more brim fittings might point out that one brim set is insufficient to fit all stumps adequately, and multiple phenotypes, for example divided by sex, or stump circumference ranges, are necessary.

In current study, the developed brims and sockets were only worn for a short period of time. To comprehensively assess their fitting, they should be worn for a longer period. This involves engaging in stabilizing and walking exercises as part of the rehabilitation program. In this way, potential friction, and pressure spots that determine the socket fitting can be further assessed. Future studies should therefore aim to incorporate the complete rehabilitation process and

conduct follow-up evaluations to assess user satisfaction, prosthetic use, and durability over an extended period.

In addition to the importance of a good socket fit, it is important to recognize that the effectiveness and functionality of a TF prosthesis are influenced by other factors. Importantly, part of these factors also in turn exert an impact on socket fit. Contributing factors encompass the suspension system, the prosthetic knee mechanism, and the alignment of the prosthetic components. In current study, the prostheses were bench aligned and worn for a short period of time. During rehabilitation, adjustments might be necessary for improved gait. Changes in the alignment can alter the socket comfort. Further research should be conducted to mitigate the impact of alignment on socket fitting.

The workflow developed in current study was tailored specifically for the hybrid socket type while excluding other variations. This choice was made because the rigid socket type offered a practical balance for implementation in LMICs. It is important to emphasize that while the workflow presented here utilizes the hybrid socket type effectively, it is not the exclusive approach to achieve a streamlined digital TF socket workflow. If, for instance, an IC-shaped socket turns out more appropriate during future research, the workflow can be adapted to accommodate that socket type. However, adapting the workflow to for example a brimless socket type would pose more challenges.

In current study the stump measurement method was executed by the researcher. However, to validate the feasibility of this method for operators with less clinical knowledge and to assess its independence from operator expertise and prosthetic knowledge, further research is needed. This future research should involve multiple operators performing the stump measurement method to evaluate inter- and intra-operator variability and determine the extent to which operator skills impact the workflow's outcomes. In addition, the digital design of the socket was performed by the researcher and required technical skills. It is the intention to further standardize this digital design process such that it can be implemented in automated software.

Clinical Relevance

The workflow from the International Committee of the Red Cross (ICRC) is considered the standard for LMICs, where TF prostheses are manually measured and produced, following the traditional casting method [70]. However, the manual adjustment of the positive mold in the process of manufacturing sockets introduces a high degree of dependency on the prosthetist's experience and skills, making quality assurance challenging. To address these limitations, current study developed a streamlined stump measurement method whereby no anatomical landmarks need to be localized and used CAD/CAM techniques for the design and manufacturing of the socket. By adopting these techniques, the entire digital design process of the prosthetic socket can be automated, reducing the reliance on individual prosthetists' skills and experience. This automation has the potential to increase the number of successful prostheses, especially in LMICs.

The long-term goal is to develop a software program that automates the socket design process, simplifying it to a few essential entries: amputation side, brim size, distal stump

volume measurements (circumference & length), and flexion contracture. In this way, local staff with limited knowledge can be empowered to manufacture TF prosthetic sockets. Nevertheless, before further standardizing and subsequently implementing the digital socket design process into software, it is essential to conduct further evaluations of the performance of the sockets, produced using the streamlined workflow developed in current study.

Conclusion

Overall, the data-supported brim set and simplified method to measure distal stump volume developed in current study have the potential to revolutionize the stump measurement phase as part of the workflow to manufacture TF prosthetic sockets, addressing the operator dependency present in the traditional manufacturing method. In addition, using the measurements from the stump measurement method, a digital socket design process was established that holds the potential to be standardized and implemented in automated software. Based on the results from the current study, additional research in Sierra Leone to evaluate the streamlined workflow is approved. More brim fitting information will offer valuable insights to the effectiveness of the data-supported brim set. In addition, taking into account the many factors that influence the effectiveness and functionality of a TF prosthesis, it is important to evaluate the fit of the socket during the full rehabilitation process.

Chapter III

Transfemoral Socket Production
in Rural Sierra Leone:
The Implementation of a
Streamlined Workflow

Abstract

Introduction: Current study aimed to implement the streamlined TF socket workflow developed to reduce operator dependency. The streamlined TF socket workflow can be divided into the stump measurement phase (included the fitting of a data-supported brim set and a simplified method to measure distal stump volume), the design phase (included digital socket design) and the manufacturing phase (included 3D printing). This workflow enabled local production of TF prostheses in Sierra Leone, whereby the full rehabilitation process was conducted to evaluate socket fitting.

Method: During a period of 3 months, participants with a TF amputation were recruited in the Masanga Hospital in Sierra Leone. Participants received a TF socket manufactured through the streamlined TF socket workflow. After receiving training, local personnel conducted the stump measurement method. The resulting measurements were digitally processed to design the TF socket. After 3D printing of the socket and assembling the full TF prosthesis, the fit of the socket was assessed prior to and during the rehabilitation process based on visual inspection and the occurrence of pressure spots.

Results: Four participants (3 males, and a mean age of 48.3 years) were included for who a TF prosthesis was made. For all male participants, the medial and anterior trimlines were positioned too high as measured during the stump measurement phase and therefore lowered during the design phase. Pressure spots were observed for two participants in the proximal medial area and the distal posterior portions of the socket, but adjustments to the concerning area in the socket's shape resolved them.

Discussion: The streamlined TF socket workflow was successfully implemented in Sierra Leone, whereby part of the workflow was performed by the local personnel. In addition, the socket fit was good with only minor necessary adjustments. However, it is important to (1) include a larger and more diverse sample size to further assess socket fit and (2) conduct follow-up evaluations to further assess socket performance. The study its potential to transform prosthetic production in LMICs by reducing reliance on skilled prosthetists and therefore increasing accessibility is significant and should be further explored.

Keywords: CAD/CAM, Operator dependency reduction, Prosthetic rehabilitation, Sierra Leone, Socket fit assessment, Streamlined TF socket workflow, Stump measurement phase

Introduction

Sierra Leone ranks low on the UN human development index (182 out of 189) [71], with amputations being a common occurrence due to infections, complex wounds, and accidents [55]. However, reliable data on the number of people in need of a prosthesis is scarce, as the number of amputees in the country may be much higher than officially reported [46].

People with a missing limb often feel incomplete and insecure, leading to reduced participation in society, depression, and lowered self-esteem and QOL [45, 57]. In Sierra Leone, people with disabilities feel excluded from society because they face severe discrimination due to traditional beliefs. To give people with an amputated limb more self-confidence and to allow them to participate in society again, rehabilitation using a prosthetic device is essential [7–9].

It cannot be assumed that people with an amputation in LMICs receive a prosthetic device and proper rehabilitation. The Community-Based Rehabilitation Guidelines Health component indicates that in many low-income countries, only 5% of the people who require assistive technology have access to it [72]. Especially in rural areas of Sierra Leone, access to prosthetic devices for people with an amputation is limited [73]. Low prosthetic availability is mainly due to a lack of resources and trained personnel, and prohibitive costs [35–38]. The average cost of a TF prosthesis in Sierra Leone is ~150 USD [45] which is beyond the reach of many due to the average income being only 490 USD per capita per year [74].

Furthermore, TF prosthetic device manufacturing requires the prosthetist to have an elevated level of clinical skills [75]. Following the traditional casting method, the measurements of the stump and fabrication of the prosthetic socket are done manually using plaster casting. For this, prosthetists need knowledge of socket design principles and manufacturing skills to sculpt the models to meet anatomical and functional requirements [33, 34]. Because of the reliability on the prosthetist's skills, quality assurance cannot be given and variability between prosthetic sockets arises. Hence, there is a need for a method that demands less expertise, thereby enabling individuals with limited knowledge to manufacture TF prosthetic sockets.

In collaboration with the 3D-Lab at the Radboudumc, a 3D-Lab was set up in the Masanga Hospital in Sierra Leone [46, 47, 76]. As part of this project, a feasibility study explored the use of CAD/CAM methods to manufacture low-cost TF prostheses in Sierra Leone in 2022, showing promising results (see Appendix A). This previous study established an alternative workflow whereby a TF hybrid socket was digitally measured, designed and 3D-printed.

Further research, described in Chapter 2 of this thesis, aimed to standardize, simplify, and overall streamline the established workflow from the previous study (Figure 5). Firstly, an enhanced data-supported standardized brim set based on the analysis of anatomical characteristics present in existing hybrid brims was developed (Figure 18). Secondly, a simplified method to measure distal stump volume, situated beneath the brim, was developed. This method can be conducted using a simple measuring tape, relies solely on one length measurement, a few circumference measurements and does not necessitate the identification of anatomical landmarks. Subsequently, a method to digitally translate the

measurements following from the stump measurement method and design a 3D-printable TF hybrid socket was developed.



Figure 18: Anterior view of three different brim sizes from the data-supported brim set. From left to right, circumference: 40, 44, and 48 cm.

The fit of the data-supported standardized brim set, and the complete TF socket were evaluated by 8 and 2 Dutch participants, respectively. This yielded positive outcomes, except for a single participant who experienced inadequate positioning of the tuber support relative to the ischial tuberosity bone. Additionally, 6 participants found the cut of the medial and/or anterior trimlines to be positioned too high, causing discomfort.

To further assess the fitting of the socket manufactured through the streamlined TF socket workflow, it is important to conduct further clinical research in the intended setting. Considering that elements beyond socket fit, such as proper suspension and alignment, have a substantial impact on the effectiveness and functionality of a TF prosthesis, and the fact that socket fit can change when worn for a longer period, it is important to include the entire rehabilitation process. Therefore, the objective of this feasibility study is to implement the streamlined TF socket manufacturing workflow, assess socket fitting during a period of a few weeks, to locally produce TF prostheses for people in Sierra Leone.

Method

Ethical considerations

This research was conducted in the Masanga Hospital in Sierra Leone. During a period of three months, from May 2023 until August 2023, participants received a TF prosthesis. Written informed consent was obtained from all participants for participation in the study and for publication of photos, videos, and data.

Participant Inclusion

For the current study, the following inclusion criteria were defined:

- Participants were 18 years of age or older
- Participants did not have any wounds or pain on the stump
- Participants had a proximal stump circumference ranging from 35 to 65 cm
- Participants had a stump length >15 cm
- Participants had a hip flexion contracture on the stump side <20 degrees
- Participants needed to be capable of walking independently with crutches
- Participants needed to be available in the Masanga Hospital for a minimum of three weeks, during which they would undergo 2-3 hours of rehabilitation on weekdays

During inclusion, intake questionnaires were used to capture information on the participant's demographic, health, and functional status (Appendix I).

Prosthesis Manufacturing

The complete TF prosthesis workflow is depicted in Figure 19, with an emphasis on the socket.

Stump Measurement Method

To obtain the necessary measurements to digitally design the TF socket, the stump measurement method, developed in Chapter 2, was performed (Figure 19, step 1). In Figure 20, the method is depicted in more detail. First, in step 1A, the proximal thigh circumference was measured and to determine the hip flexion contracture, the **Thomas Test** was used [59]. The most suitable brim circumference was chosen for the concerning participant in step 1B, whereby a locally made donning sleeve was used to facilitate easy donning and to pull down the soft tissue. Subsequently, during step 1C, the distal stump volume was measured while the participant was fitted with the brim in a loaded situation using the custom-designed brim standard. Stump circumference measurements



Figure 19: Flowchart showing the sequential steps taken to manufacture a hybrid TF prosthesis using a streamlined method for the socket.

were taken at 5 cm intervals starting 5 cm proximal to the bottom of the stump until the distal edge of the brim, using a flexible measuring tape. Additionally, the **length of the distal stump**, measured as a vertical line from the distal lateral edge of the brim up to the end of the stump, was recorded. Initially, the researcher performed the measurement method. After training the local personnel during the inclusion of the first participant, they carried out the measurement method for subsequent participants under supervision of the researcher.

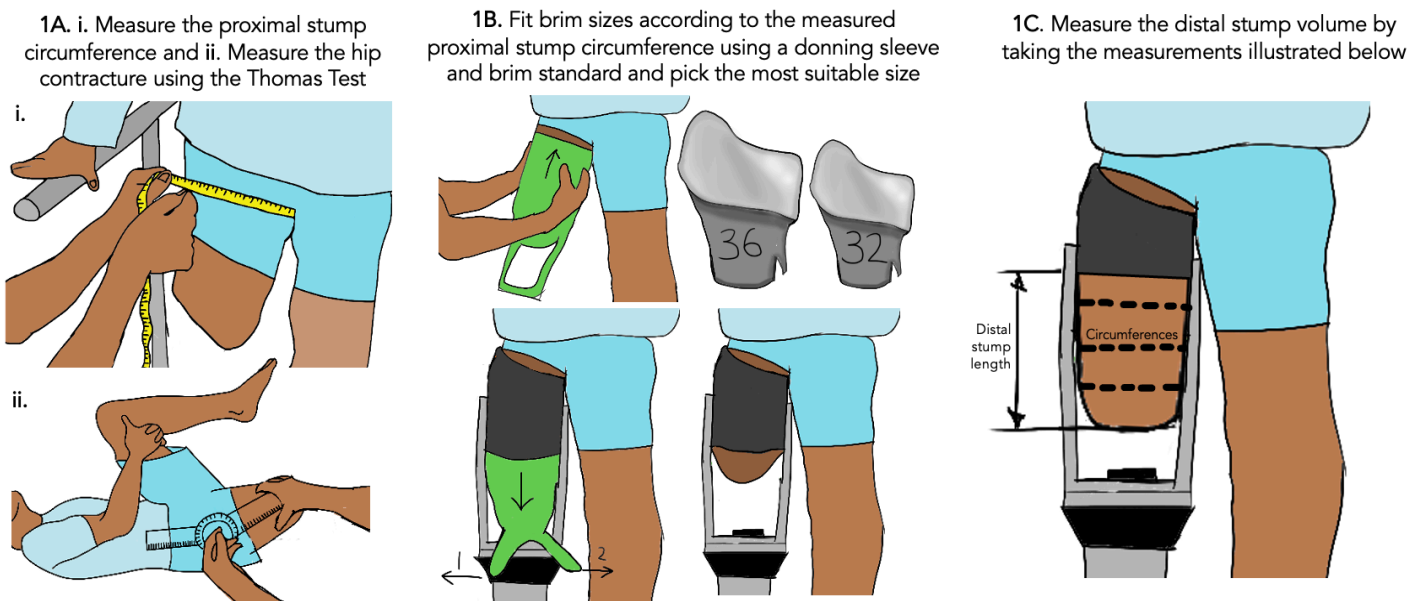


Figure 20: Steps taken during the established stump measurement method.

Digital Socket Design

The obtained measurements from the stump measurement method were used to digitally design the TF socket. The design process is described as step 2 in the complete TF socket workflow (Figure 19) and illustrated in more detail in Figure 21. The process was performed by the researcher in MeshMixer.

Step 1:

The chosen brim circumference was selected, and circular rings were scaled to match the measured distal **circumference measurements**. A reduction of 5-3-1% from proximal to distal was applied on the rings. To prevent friction with the distal stump, the socket's distal end was positioned at the measured **length of the distal stump** +2 cm.

Step 2:

The rings and socket bottom were connected, and the distal part was rotated in a 6-degree adduction angle [60] and in a flexion angle of **<flexion contracture + 5 degrees>**. The brim was rotated in a 5 degrees flexion angle. The socket's total thickness was set at 4.8 mm, whereby the weight bearing area surrounding the tuber support was given an extra thickness.

Step 3:

An inserts plate, where the prosthetic knee was affixed, was aligned beneath the socket, ensuring that its position was situated behind the load line.

Step 4:

After connection of the brim to the distal part and the insert plate, a 3 cm diameter opening was incorporated on the distal anterior-medial part for removal of the donning sleeve.

Step 5:

Due to its dimensions surpassing the print building volume of 33x24x30 cm, the socket was divided into two segments, and a connecting method was introduced to join the two parts.

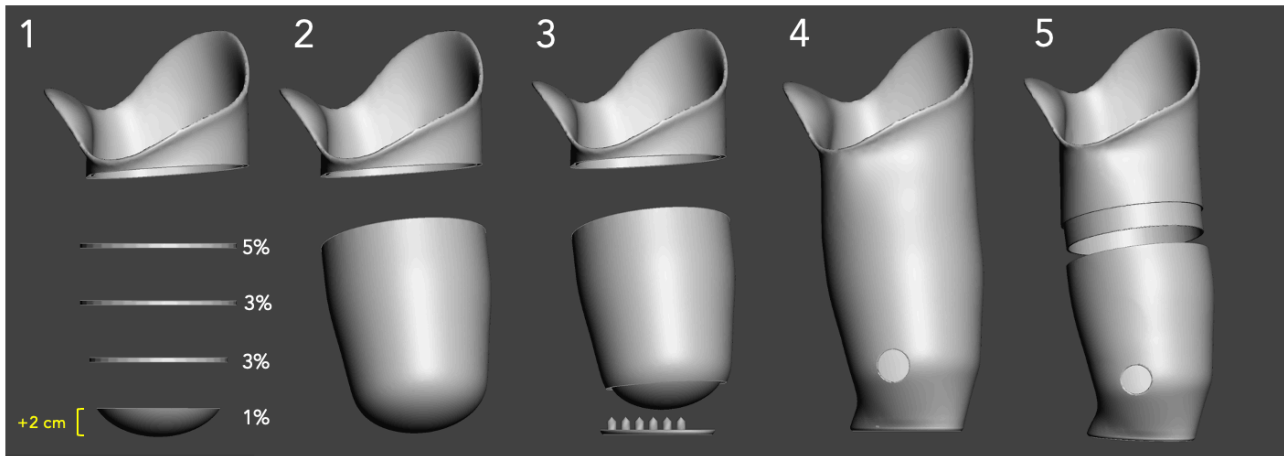


Figure 21: Steps taken to digitally transform the measurements from the stump measurement method and design the hybrid TF socket using MeshMixer.

Socket Manufacturing

Sockets were 3D-printed using an Ultimaker S5 printer located at the Masanga Hospital (step 3 in Figure 19). The FFF modeling technique was employed, and Tough PLA from Ultimaker BV was used as the print material [77]. Prior to printing, the virtual 3D-models were loaded into Cura (Ultimaker BV, Geldermalsen, the Netherlands), an open-source 3D-printer slicing application, to generate a printable file (g-code). For the printing process, a 0.8 mm print core was used with 100% infill, a 0.2 mm layer thickness, and a print speed of 45 mm/sec. The socket manufacturing was performed by the researcher.

Prosthetic Parts Assembly, Alignment & Comfort

A suspension system following the silesian belt style was created using nylon and elastic bands and attached to the socket (Appendix G). The TF prosthesis was assembled using components from Shijiazhuang Wonderfu Rehabilitation Device Technology Co., Ltd, Luancheng District, Shijiazhuang City, Hebei, China. The prosthetic single-axis knee with adjustable friction and Sach foot were connected through a rotatable socket adapter, tube, tube adapter, and foot adapter. The bench alignment of all prosthetic parts followed the Ottobock guidelines for TF modular lower limb prostheses [61] and was carried out using a simple laser (step 4 in Figure 19). Throughout the ongoing rehabilitation process, gait videos in the sagittal and frontal plane were recorded and analyzed remotely by an experienced Dutch physiotherapist and prosthetist. After assessment of the videos, they offered feedback on optimizing the alignment, thereby improving the participant's gait.

To ensure comfort and accommodate stump volume fluctuations, foam liners of 3- and 6-mm thickness were custom-made. The foam was shaped to match the socket's volume by heating it and then placing it inside the socket, applying pressure from the inside to achieve the desired fit. Moreover, 3-mm thick foam was shaped to match the tuber support's contour, and subsequently attached to it (step 5 in Figure 19).

Lamination & Prosthetic Cover

In the final stage of rehabilitation, the prosthesis was reinforced by laminating it with stockinettes. A mixture of Orthotoxyl Siegelharz & Orthocryl Laminierharz including a pigment paste (Ottobock B.V., Duderstadt, Germany) to match the participant's skin tone, was prepared and applied to harden the stockinettes. Additionally, an aesthetical cover was created to enhance the appearance of the distal part of the prosthesis. The cover was coated with Epoxy (XTC-3DTM, Smooth-on, Macungie, Pennsylvania, USA) and the same pigment paste. The final prosthesis is displayed in step 6 in Figure 19.

Rehabilitation Program

In the current study, a rehabilitation program similar to the one used at the Radboudumc was followed, but adapted to suit an African setting, see Table 4. Participants engaged 2-3 hours of physiotherapy on weekdays for approximately 3-4 weeks, depending on their progress in rehabilitation. If both the participant and healthcare worker were satisfied with the prosthesis, and the participant could walk independently or safely with crutches, they were permitted to take the prosthesis home. Local adjustments were carried out to ensure comfort and solve pressure spots that arose during the rehabilitation by slightly bending the thermoplastic with a 1500W heater.

Table 4: Participant rehabilitation program outline.

Learning to put on the prosthesis
Symmetrical posture training
Pelvic shift exercise
Active pelvic lift exercise
First phase of the step with the prosthetic foot
Spining phase exercise
Walking between parallel bars
Walking with 2 crutches in 3-point gait
Walking with 2 crutches in 2-point gait
Walking with 2 poles in 2-point gait
Walking with Nordic walking poles
Walking without a tool
Walking with different walking speeds
Walking on uneven terrain
Various walking shapes: sideways, backwards, stopping and turning
Walking up and down slope

Brim & Socket Fitting Assessment

While the participant was fitting the brim during the stump measurement method (Figure 20), it was evaluated whether the ischial tuberosity was positioned correctly on the tuber support, and whether the cut of the trimlines were positioned correctly and experienced as comfortable by the participant. This resulted in the following portions being evaluated individually: tuber support, medial trimline, anterior trimline, lateral trimline, and posterior trimline. If there were any dislocations or discomfort, the required adjustments to the brim were measured in centimeters and processed during the digital design process by adjusting the selected brim circumference from the data-supported brim set in MeshMixer.

When the full prosthesis was assembled and initially fitted on the participant, next to the re-evaluation of the brim on the same aspects, the distal socket part was evaluated. The distal socket part involved assessing (1) the distal connection of the socket to the stump and (2) the shape of the socket volume. Adequacy of the distal connection was determined by the presence of sufficient space between the distal stump and the socket, measured through the distal hole for the donning sleeve. The adequacy of the shape of the socket volume was assessed based on visual inspection of the researcher and whether the participant encountered any initial pressure points. During rehabilitation, arising pressure spots and other stump-related complications were noted as well as the adjustments made in the shape of the socket.

Results

Four participants were included, including three males. Table 5 provides an overview of their general and stump characteristics.

Table 5: Overview of general participant and stump characteristics.

Study ID	1	2	3	4
Age (years)	67	51	35	40
Gender (M/F)	M	M	M	F
Elapsed time after amputation (months)	14	15	17	12
Cause of amputation	Complication of underlying disease	Infection	Trauma	Infection
Education	High school	High school	Elementary school	None
Daily job/activity	Retirement	Farmer	Power saw operator	Housewife
Stump proximal circumference	46	56	45	63
Brim size	40	48	38	52
Flexion contracture	10	0	0	15

Brim and Socket fitting

The brim fitting assessments conducted during the stump measurement method showed good tuber support position. However, the medial and anterior trimlines were cut too high for participants 1, 2 and 3, including all males. Therefore, for these participants, the medial and anterior trimlines were lowered with a maximum reduction of 1.5 cm as shown in Figure 22. No further complications concerning the brim's shape were encountered.

For the distal socket part, the distal connection of the socket was found to be good for all participants, except for participant 2. For this participant, only a small space of 0.5-1 cm was left at the distal portion of the socket. However, this did not cause any complications during the rehabilitation program. For all participants, the socket did not cause friction and no pressure spots were present during the initial fitting.

Stump Complications during Rehabilitation

Participant 1 had a pressure spot on the distal posterior side of the stump on the surgical suture resulting in a blister after walking with the prosthesis for one week (Figure 23). Participant 4 experienced a pressure spot on the medial-anterior trimline after two days. Both pressure spots were resolved after extending the socket at the indicated spots. Additionally, participant 2 reported moderate pain in the muscles of the stump during the rehabilitation process, attributed to adjusting to the new socket and walking extensively.

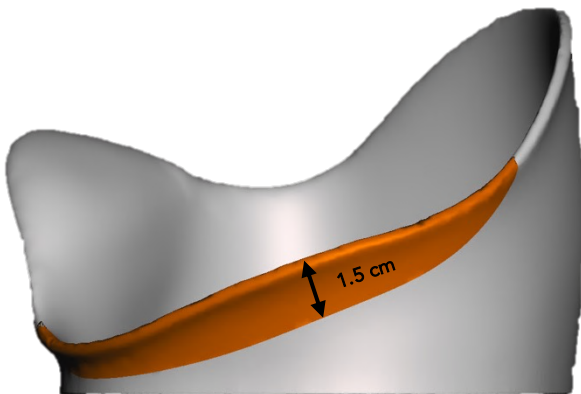


Figure 22: Anterior-medial view of brim whereby the indicated orange marked area was removed to lower the anterior and medial trimlines.



Figure 23: Participant 1 with a distal posterior blister on the surgical suture.

Rehabilitation Process and Participant Experience

Figure 24 shows the four participants with their TF prosthesis. All participants showed high motivation throughout the rehabilitation program by consistently attending rehabilitation sessions. Unfortunately, Participant 4 was unable to complete the program due to financial constraints preventing her from obtaining the prosthesis. At the end of the rehabilitation program, Participant 1 achieved the ability to walk on all surfaces with the support of just one

crutch. Participant 2 solely required a walking stick for stability on uneven terrain. Remarkably, participant 3 demonstrated impressive progress, walking on all terrains without the need for any assistance.

In their own words, the participants shared their experiences: "The project provided me with the opportunity to stand up again and actively participate in society," said one. Another expressed gratitude, saying, "Thanks to the dedicated team, I can now take care of myself and my children again." A third participant emotionally remarked, "You've given me my life back." The transformation of participant 3 extended beyond personal achievements; he was also reintegrated into his family and community, gained employment, and regained the ability to take care of his children, one week after he returned to his town.



Figure 24: Result after having received the TF prosthesis manufactured using the streamlined socket workflow.

Discussion

The current study aimed to implement the streamlined TF socket workflow, developed in Chapter 2 of this thesis, which involved using a data-supported set of brims and a simplified method to measure distal stump volume, for the local production of TF prostheses in a rural area of Sierra Leone. The study showed positive outcomes whereby the simplified method to measure distal stump volume was successfully performed by the local personnel. The measurements were, together with the chosen brim circumference, digitally translated using a simplified model for the distal socket part, into a 3D-printable socket. Four TF prostheses were manufactured which achieved good, personalized fit after making minor adjustments to the socket. However, no follow-up evaluations were conducted to assess the socket's performance and overall satisfaction with the TF prosthesis. These evaluations were scheduled 10-weeks post-delivery of the device and could therefore not be included in this thesis.

Current study addresses a literature gap in the use of a stump measurement method that includes a data-supported brim set, simplified method to measure distal stump volume, digital socket design and 3D-printing in the TF socket workflow. A scoping review about "3D printing and amputation" included only one study about TF amputations [41], evaluating a

3D-printed anatomically scalable prosthetic knee. A systematic review [68] highlighted the need for more research to provide sustainable solutions for limb prostheses in LMICs. While a study in India [63] presented an alternative approach using CAD and numerically controlled machining, their method involved multiple measurements and anatomical landmarks, making it potentially challenging for local personnel and prone to errors. This study adds up to the available TF socket design software tools, that require numerous anatomical dimensions to be entered [51–53]. Hence, these tools are not suitable for use in the current study, given its focus on LMICs where there is a shortage of adequately trained personnel. Current study successfully implemented a streamlined stump measurement method including a simplified method to measure distal stump volume. The method relies on a few length and circumference measurements that can be taken with a simple measuring tape. In addition, the method eliminated the necessity of identifying anatomical landmarks. The successful execution of the method by local personnel, along with the achievement of a well-fitting socket despite the minimal measurements and simplified digital model for the distal socket part, underscores its potential.

Brim and Socket Fittings

The brim fittings complied with the previous study (Chapter 2) and revealed that, for 3 out of 4 participants, the medial and anterior trimlines were cut too high. Notably, all three of these participants were males. Especially the medial trimline was observed to be positioned too high in the groin area. This observation aligns with anatomy, considering the lower positioning of male genitalia in his region. However, the remedy for this issue was straightforward — by simply lowering these trimlines during the digital design phase.

Two pressure spots were identified for two participants during rehabilitation — one in the distal posterior region and another on the medial-anterior trimline. The first pressure spot was located at the surgical suture, which is known to be a pressure sensitive area [78]. Another potential cause for the observed friction could be attributed to the relatively high built-in flexion angle, causing the distal posterior area to come into contact with the socket. It is remarkable that the second pressure spot occurred in the case of the only participant for whom the medial-anterior trimline was not lowered. However, this occurrence goes along with the participant possessing the largest thigh circumference and having the largest amount of adipose tissue on the medial aspect of the stump. It indicates that possibly for TF stumps possessing more loose tissue, the medial-anterior section of the brim should have a different shape such that compression is prevented. However, both pressure spots were eliminated after widening the socket at the compressing area.

Due to the small sample size ($n=4$), the statistical power of current study does not allow drawing hard conclusions regarding the fit of the data-supported brims. Therefore, subsequent research whereby the fit of the brims is further assessed on a larger and diverse sample size is recommended and will reveal whether multiple brim phenotypes, such as for men and women, or for smaller and bigger thigh circumferences, are necessary.

Distal Socket Part

More research into the method to measure distal stump volume and the corresponding digitally designed shape of the distal socket part are recommended. In the first study of this thesis (Chapter 2), the simplified method that relied solely on a few manual measurements was developed. This approach was established in response to challenges with 3D-scanning of TF stumps observed during a previous study, and under the assumption that TF stumps have a conical shape differing mainly in length and volume. Although no major issues were encountered in the current study regarding the use of a simple round conical shape for the distal socket part, additional investigation into this aspect is recommended. Specifically, it would be beneficial to compare distal 3D-stump volume shapes with the corresponding shape of the interior of the socket. This comparison would allow the exploration of two key aspects: (1) the presence and characteristics of typical distal stump shapes, if they exist, and (2) how these stump shapes are reflected in the design of the socket. Using this information, the optimal shape of the distal socket part can be further investigated and substantiated.

Visual Inspection

In current study, the evaluation of brim and socket fitting were both reliant on visual inspection and thus subjective judgements. These assessments relied on the perspective and expertise of the operators and the input of participants who lacked experience in wearing a prosthesis. It is recommended to develop an objective way to quantify socket fit in the future. For example, pressure sensors can be placed inside the socket to identify higher and lower loaded areas [79].

Participant Size and Stump Diversity

The included study population in current study consisted of four participants. In this early stage of the fabrication of TF prosthesis in a low-income country using an alternative streamlined method, this number was deemed feasible whereby at the same time enough valuable information could be obtained that can be used for further research. In addition, given the pioneering nature of TF prosthetic production and rehabilitation programs for the local personnel, it was more beneficial to intensively study a small number of cases. This approach enabled the dedication of the necessary time to perform the workflow and the education of the local personnel. However, because of the small sample size, it is challenging to generalize the findings to a broader population of individuals with TF amputations. For example, the inclusion criteria of a minimum stump length of 15 cm may limit the applicability of the prostheses to individuals with amputations at higher levels, who may face different challenges in using prosthetic devices. Therefore, future studies should include a larger and more diverse sample size, encompassing individuals with different stump dimensions.

Prosthetic Knee Selection and Cover

During the previous study as part of the project, the single-axis constant friction knee joint emerged as the most suitable choice for several reasons. Firstly, it allows for easy adjustment of the friction according to the user's preferences. Additionally, it offers low costs and weight when compared to a four-axis knee. However, a significant limitation of the single-axis constant friction knee joint is the user's requirement to adequately respond to changing

conditions on uneven surfaces to avoid abrupt collapse [80]. Such sudden collapsing of the knee can be discouraging and may reduce the user's confidence in the device, which is undesirable. By providing clear guidance on how to prevent a collapse and how to handle it if it does occur, participants maintained their confidence while using the prosthesis and a positive user experience was ensured. Nonetheless, the situation remains challenging as most roads and surfaces in Sierra Leone are uneven. Consequently, with regards to participant 1, the knee's friction was raised to resist bending during the swing phase. This adjustment eliminated sudden collapses and improved stability. One drawback is that when the user wants to sit down, manually bending of the knee is required, which may cost some effort. It is recommended to further explore the options for prosthetic knees that are cost-effective and are possibly more suitable for walking on uneven surfaces.

In addition, recognizing the significance of aesthetics for participants, future research should be devoted to designing a suitable cover for TF prostheses. This cover should provide a realistic appearance while ensuring unrestricted movement of the knee.

Adjustable Socket Fitting

It is worth noting that advanced socket technologies with adjustable features, dynamic muscle movement allowance, inner socket shape alteration, and flexible inner sockets have advantages in terms of comfort and adaptability to volume fluctuations [11, 37]. However, they come with drawbacks such as higher costs due to the used materials, extended manufacturing timelines, and the need for advanced clinical skills. On the other hand, an adjustable socket allows for reduced costs, as it can be used for an extended period [81]. For LMIC implementation, the design process should prioritize material strength, ease of use for the patient, and simplicity for local staff to ensure practicality and effectiveness.

Automated Software for Socket Manufacturing

The 3D Sierra Leone project's overarching goal is to facilitate local manufacturing of personalized prosthetics, reducing the dependency on operator expertise. Therefore, automated socket design software is currently under development for transtibial prosthetic sockets, with similar intentions for TF sockets. However, the current process for digital socket design was performed by the researcher as it required technical skills. To transform this process into a software-ready one, further standardizations are necessary.

Challenges arose concerning the alignment and attachment of the insert plate to the socket, responsible for the connection to the prosthetic knee. The process of creating a seamless transition for the insert plate varied for each individual socket, demanding distinct digital adjustments. It is advisable to explore the potential for automating the plate's positioning and achieving a smooth transition, allowing for implementation within socket design software. Additionally, the introduction of a connection method that divides the socket into two printable parts hindered the automatization of the socket design process in two ways. Firstly, the complexity lies in determining a suitable location along the socket's length where the connection can be established (approximately 2.5 cm), given the requirement for a continuous shape within this range. Secondly, the creation of the actual connection method involved

multiple manual steps within MeshMixer. Consequently, an investigation into adapting this process for integration into automated software is warranted.

Once the socket design process is standardized, automated, and incorporated into software, additional research should investigate whether personnel with limited expertise can execute the socket design process, assessing both intra- and inter-operator variability.

Transforming Prosthetic Production in LMICs

The prosthetics manufactured by the ICRC are considered the standard for LMICs, following the traditional plaster cast method [70]. The manual adjustment of the positive mold in the process of manufacturing TF sockets creates a high dependency on the experience and skills of the prosthetist, making quality assurance challenging [34].

Current study proposed a streamlined method to manufacture TF sockets using CAD/CAM techniques. The local staff successfully executed the stump measurement method finding it feasible for implementation. Furthermore, there is potential to automate the design process of the prosthetic socket. This automation would reduce the reliance on individual prosthetists' skills and experience.

To assess the potential advantages of digitally designed produced sockets, a direct comparison using the future-developed automated designing program with the traditional manual manufactured sockets should be conducted. This comparison will provide valuable insights into the effectiveness, functionality, durability, and efficiency of sockets produced using a simplified digital workflow compared to the traditional method.

Conclusion

In summary, this feasibility study successfully implemented the streamlined TF socket workflow, whereby the local personnel performed the stump measurement method. Positive results were achieved, producing personalized TF prostheses for four participants, requiring minor adjustments on the medial and anterior trimlines and pressure spots. However, the study lacks information on the follow-up of the socket and overall prosthetic performance. To enhance the implemented workflow, future research should include more brim fittings, distal socket shape investigations, and explore objective fit assessment methods. Furthermore, there is a need to investigate the transformation of the current digital socket design process into a software-ready format, enabling automation and making it accessible for local personnel with limited expertise to conduct the digital socket design process.

Chapter IV

General Discussion and
Final Conclusion

The first study (Chapter 2) of this thesis started addressing the aim of streamlining the workflow for manufacturing TF prosthetic sockets to reduce dependency on prosthetists' skills. This multifaceted study unfolded in three phases. Phase 1 provided insights into the relationship in-between brim dimensions and with thigh circumferences, forming the foundation for the subsequent phases. The data-supported brim set containing various circumference sizes, developed in Phase 2 showed potential, fitting a diverse range of TF limb circumferences. Phase 3 simplified the method to measure and design the distal socket part, extending the streamlined TF socket workflow.

The observations regarding the inadequate positioning of medial and anterior trimlines provided valuable insights regarding the fit of the developed brim set. In the case of one participant, experiencing inadequate tuber support positioning, it became evident that individual anatomical variations might deviate from the norm. This highlights the fact that the development of one standardized brim set might not be sufficient to meet all stump sizes. Furthermore, the inadequate socket length and shape for another participant underlined the need for further socket design refinements processed in the second study (Chapter 3).

The first study had its limitations. A relatively small dataset from one single prosthetist to develop the data-supported brim set limited its scope, highlighting the importance of analyzing more hybrid brims created by multiple prosthetists to enhance the brim set's design, that possibly needs multiple phenotypes to adequately fit all types of TF stumps. To investigate whether multiple phenotypes are necessary, further research is needed to determine which variables influence the design of the brim that increase the coefficient of determination (R^2) through multiple linear regression models. Moreover, the small Dutch sample size on which the brim and total TF socket was fitted for a short period of time emphasized the need for further clinical research in the intended setting on a broader population. Further research should comprise the full rehabilitation process to consider various factors influencing socket fit.

Hence, in the second study (Chapter 3) of this thesis, the developed streamlined TF socket workflow was implemented in the Masanga Hospital in Sierra Leone. The successful production of four TF prostheses with personalized fits after minor adjustments marked a meaningful achievement. The positive outcomes demonstrated the feasibility of the streamlined workflow, which was partially conducted by the local personnel not specialized in prosthetics. Extended follow-up evaluations should be conducted to provide comprehensive evaluations on socket and overall prosthetic performance.

Brim fittings in Sierra Leone resembled the findings in the Netherlands, highlighting the need to lower medial and anterior trimlines, particularly for male participants. Pressure spots in the distal posterior region and proximal medial area called for further investigations into the TF socket design. Future research into the method to measure distal stump volume and its correlation with distal socket design presents potential areas for improvement. In addition, it would be of added value to investigate objective socket fit assessment methods, considering both studies of this thesis relied on visual inspection and thus subjective judgements. Yet, it should be kept in mind that besides socket fit, other factors such as the alignment and prosthetic knee are important to form an effective and functional TF prosthesis.

In current study, the suitability of the chosen methodologies for both the first and second study were carefully considered. The method to divide the first developmental in multiple consecutive phases, allowed the ability to develop and test the streamlined workflow step by step. In this way, a big difference encompassing multiple aspects from the previous workflow was prevented, and it allowed the evaluation of different components separately. Diving deeper into the applied methods per phase of the study, the established methods to analyze brim and distal socket fitting using scoring models were innovative and not used before in literature. The employed methods included the analysis of the fit of the brim divided per section. This method was chosen because it provides more guidance to the assessment process and makes it possible to subsequently make more targeted adjustments to specific sections of the brim. However, the method remains subjective and dependent on who performs the assessment. Therefore, the assessment form used in the first study of this thesis to evaluate socket fitting was not used in Sierra Leone. In addition, the included participants were not familiar with a TF prosthesis and therefore did not know when a socket has a good fitting. Instead, the full rehabilitation process was conducted, which allows the tracking of stump complications related to the socket fitting.

Investigating the feasibility to include the digital TF socket workflow in automated software could enhance the TF prosthetic care. By developing a fully automated workflow that eliminates the reliance on operator skills, and still delivers adequate socket performance, increased accessibility is achieved as more individuals can execute the workflow.

By introducing a data-supported standardized brim set and simplified method to measure and digitally design the distal socket part into the TF socket workflow, current study aimed to streamline the TF socket workflow in low-income countries, thereby reducing reliance on expert prosthetists. While the results are promising, ongoing research to refine and adapt current methods is necessary, to ultimately implement the workflow in automated software. The automated software strives to revolutionize TF prosthetic production, aiming to improve the QOL of many individuals worldwide.

Chapter V

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Chapter VI

Appendices

Appendix A – Abstract of feasibility study to produce transfemoral prosthesis using CAD/CAM methods

Introduction – Amputation is one of the major causes of permanent disability. Whereas peripheral vascular disease and diabetes are identified as leading causes in high-income countries, trauma has been documented as the leading cause in many low- and middle-income countries. Sierra Leone is a low-income country with a disproportionate number of limb amputations, while a prosthetic device is beyond reach for most people. Especially in rural areas of Sierra Leone, access to prosthetic services has been demonstrated to be very limited. It is estimated that only 5% of the people who require assistive technology have access to them. The 3D Sierra Leone project aims to improve people's lives by providing affordable prostheses and making the prosthetic manufacturing process sustainable by involving local staff. The current study evaluated whether it is feasible to use computer-aided design and computer-aided manufacturing in the manufacturing workflow of low-cost prosthetic devices for people with a unilateral transfemoral amputation in Sierra Leone. Research objectives included the establishment of a computer-aided workflow and comparing the brimless and narrow mediolateral (NML) socket.

Methodology – A novel approach for measuring the geometry of the residual limb and digitally designing and additive manufacturing the transfemoral prosthetic socket was evolved. Through 3D scanning, a digital model of the residual limb was made from which the prosthetic sockets were designed in Meshmixer and 3D-printed using the Ultimaker S5 3D printer. Conceptual designs of the transfemoral prosthetics, including different types of prosthetic socket shapes, suspension systems and knee joints, were generated and evaluated through clinical assessments in the Netherlands. Dutch experienced prosthetic users were asked to participate in the study and to assess the prostheses through exercises, questionnaires, and open interviews. After applying the concept selection methodology Pugh matrix and evaluating the findings of the clinical assessment, selected concepts of the transfemoral prosthesis were defined. These selected concepts were locally manufactured at Masanga Hospital in Sierra Leone and evaluated following a crossover study design. Sierra Leonean participants were assigned to a sequence of rehabilitation sessions varying in prosthetic socket type. User satisfaction was measured through questionnaires, including the Socket Comfort Score (SCS), Comprehensive Lower-limb Amputee Socket Survey, and a self-made set of open questions. The prosthetic performance was measured through the 2-min Walk Test (2MWT), Timed Up and Go (TUG) test, 5-Times Sit-to-Stand Test (FTSST), 10-m Walk Test (10MWT), and gait analysis. Follow-up questionnaires were administered four weeks after study completion.

Results – The selected concepts of the transfemoral prosthesis consisted of a brimless and NML socket, a custom-made Silesian belt-type suspension system, and the single-axis knee joint. Two participants were included in the clinical assessment in Sierra Leone, only one of whom performed the walking tests. Both participants rated a higher SCS score for the NML socket related to the brimless socket (10 versus 3) and gave the NML socket a higher satisfaction score while standing and walking. However, the brimless socket was considered more satisfying while sitting than the NML socket. Slightly better outcomes of the 2MWT, TUG and FTSST were measured with the NML socket (76.2m, 14.9sec, 15.5sec respectively) compared to the brimless socket (75.0m, 16.4sec, 20.7sec respectively). Furthermore, the degree of asymmetry was recorded lower in the NML socket indicating the gait variability was more symmetrical than when using the brimless socket (-0.02 versus -0.09). Participants were generally satisfied with their prosthesis, and health-related quality of life was increased at follow-up.

Conclusion – The study served as a proof-of-concept, demonstrating the possibility of manufacturing transfemoral prosthetics using 3D scanning and 3D printing, and the NML socket and Silesian belt to be the most promising assessed on technical feasibility, user satisfaction, and prosthetic performance.

Copied from: Toering, T. (n.d.). *Manufacturing 3D-printed Transfemoral Prosthetics for people in Sierra Leone*. University of Twente.

Appendix B – Questionnaires used to obtain general and demographic participant information

Datum: _____

Studienummer: _____

Geslacht:

☐
☐

Man

Vrouw

Leeftijd: _____ (Jaar)

Lichaamsgewicht: _____ (Kg)

Lichaamslengte: _____ (cm)

Welke zijde is geamputeerd:

☐
☐

Linkerzijde

Rechterzijde

Reden van amputatie:

☐
☐
☐
☐

Trauma

Diabetes

Perifere vaatziekte

Anders: _____

Tijd tussen amputatie en inclusie: _____ (Jaren/maanden)

Hoe lang loopt u al met een prothese? _____ (Jaren/maanden)

Appendix C – Plots of non-significant regression models describing brim characteristics

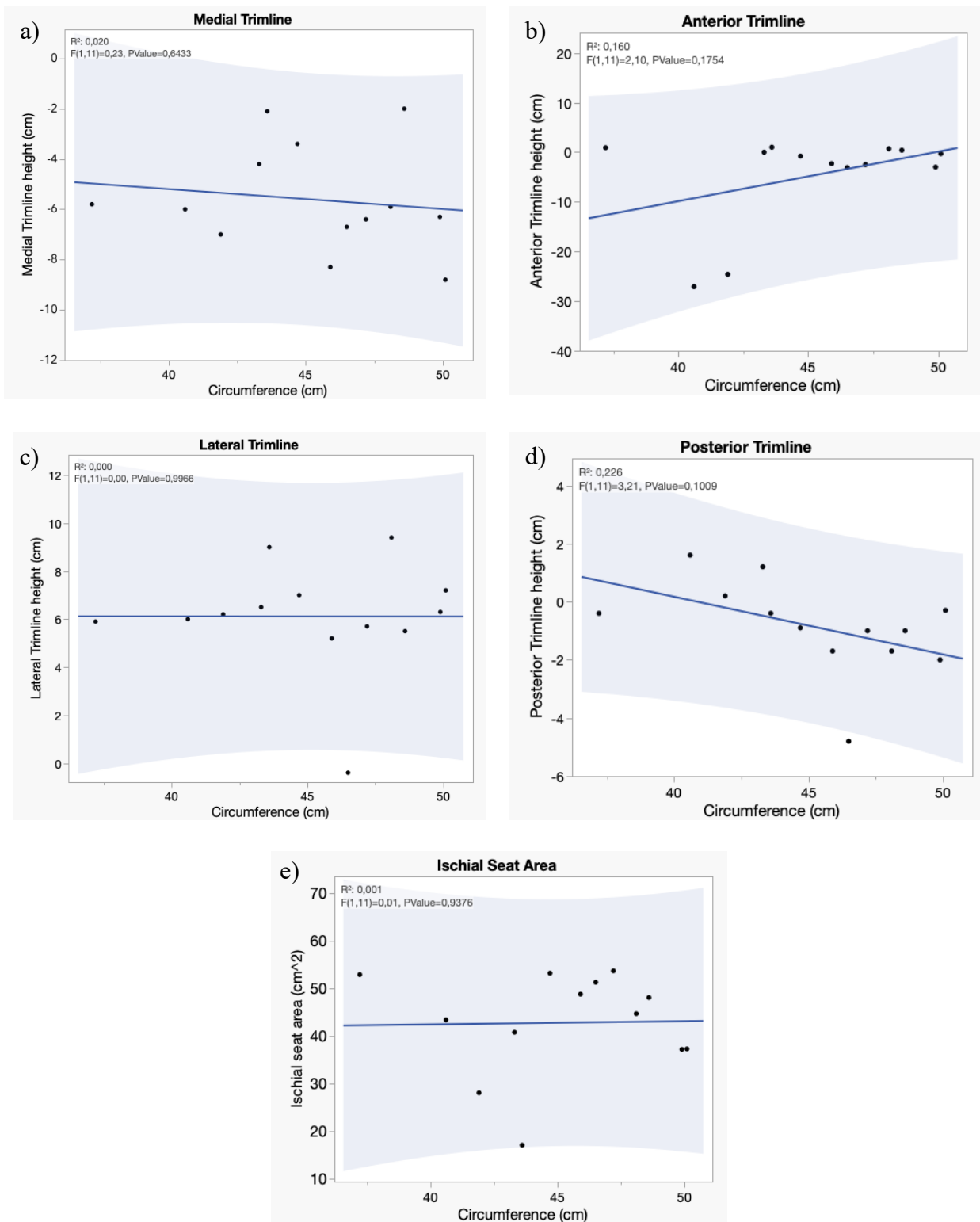


Figure E1: Regression plots from the brim circumference in relation to the a) medial trimline b) anterior trimline c) lateral trimline d) posterior trimline and e) ischial seat area (also known as the tuber support area). All simple regression slopes were non-significant, indicating no correlations between the variables.

Appendix D – MeshMonk algorithm used in Matlab

```
%% This tutorial focuses on the practicalities of processing many files with
Meshmonk
% before you begin you want each image in .obj format in a single folder. These are
called your 'Targets'. You also want to have a few landmarks roughly indicated onto
each target.
% Each file in 'Targets' must have a Corresponding '.csv' file containing
% the co-ordinates of the landmarks. These should be in a separate folder
% called 'Landmarks'. You can indicate landmarks and export
% them using many software including the GeoMorph R package or MeshLab.
% The landmarks in all files must be IN THE SAME ORDER.
% If any mapping goes awry the landmarks are ALWAYS the first thing you should
check.
% at present MeshMonk incorporates three steps:
% 1. initialisation based on landmarks
% 2. Rigid ICP
% 3. NonRigid ICP
% The purpose of the first two steps are to provide a good starting point
% for the third step.

%% Set up paths
% ensure meshmonk is on your MATLAB path
clear all; close all;
addpath(genpath('C:\Users\Iris\Documents\GitHub\meshmonk\matlab')) % change this to
the correct path on your computer
projectPath = 'C:\Users\Iris\Documents\GitHub\meshmonk\BatchProcessing';
path2objs = 'C:\Users\Iris\Documents\GitHub\meshmonk\BatchProcessing\Data\Targets';
% check always that the path ends with a separator chara
path2landmarks =
'C:\Users\Iris\Documents\GitHub\meshmonk\BatchProcessing\Data\Landmarks';
path2results = strcat(projectPath,filesep,'MappedResults');
% get structs containing information for each file
%check if path2results exists and create it if not
if ~exist(path2results,'dir')
mkdir(path2results)
end
objs = dir(strcat(path2objs,'*.obj'));
landmarks = dir(strcat(path2landmarks,'*.csv'));
if numel(objs)~=numel(landmarks)
error('Check each landmark file has an equivalent obj file and vice versa')
end

%% Set up shape mappers
% The ShapeMappers handle the mapping according to the given transformation
% type. We define one for the rigid step and one for the non-rigid step
% for this demo we use the default settings we have found optimal for faces
% where the meshes are regular
% see supplementary material of White et al (2019):
https://doi.org/10.1038%2Fs41598-019-42533-y
% Set up Rigid ICP step using ShapeMapper with 'rigid' transformation type
% in general this works fine and the settings don't need that much thinking
% about
RM= ShapeMapper;
RM.NumIterations = 30;
RM.TransformationType = 'rigid';
RM.UseScaling = true;
% settings for determining the correspondences
RM.CorrespondencesNumNeighbours = 3; % number of neighbours to use to estimate
correspondences
RM.CorrespondencesFlagThreshold = 0.9;
RM.CorrespondencesSymmetric = true; % if true correspondences are estimated from
the template to target and target to template and combined -
% this can help with mapping structures
% such as long bones and allows the
```

```

% target to 'pull' the template
RM.CorrespondencesEqualizePushPull = false;
% settings that determine which points are 'outliers' not used to estimate the
% transformation. This is based on 1. whether the point is an outlier in the
% distribution of differences between floating and target and 2. Whether
% the points corresponds to a point that has been 'flagged'.
RM.InlierKappa = 3;
RM.InlierUseOrientation = true; % use surface normal direction to determine of
point is inlier/outlier
% ignore points that correspond to the edges of the mesh – only applicable
% to 'open' surfaces like the face
RM.FlagFloatingBoundary = true; % ignore points that correspondences to the edge of
Floating surface – only applicable if using SymmetricCorrespondences
RM.FlagTargetBoundary = true;% ignore points that correspondences to the edge of
Target surface
RM.FlagTargetBadlySizedTriangles = true; % ignore points that match to regions of
abnormally sized triangles
RM.TriangleSizeZscore = 6; % threshold to determine which triangles are abnormally
sized
RM.UpSampleTarget = false; % will upsample the target mesh. if meshes are irregular
it can help to set this to true

% Set up non rigid ICP with ShapeMapper with 'nonrigid' transformation type
NRM = ShapeMapper;
NRM.TransformationType = 'nonrigid';
NRM.NumIterations = 200;
NRM.CorrespondencesSymmetric = true;
NRM.CorrespondencesNumNeighbours = 3;
NRM.CorrespondencesFlagThreshold = 0.9;
NRM.CorrespondencesUseOrientation = true;
NRM.CorrespondencesEqualizePushPull = false;
NRM.InlierKappa = 12; % basically you want this really high, so that the outlier
detection is effectively turned off. in future you will be able to actually turn
this off.
NRM.InlierUseOrientation = true;
NRM.FlagFloatingBoundary = true;
NRM.FlagTargetBoundary = true;
NRM.FlagTargetBadlySizedTriangles = true;
NRM.TriangleSizeZscore = 6;
NRM.UpSampleTarget = false;
% parameters specific to non-rigid step. In general, if computing time is not a
factor
% set the NumIterations and the TransformNumViscousIterationsStart and
% TransformNumElasticIterationsStart as high as possible. This will ensure
% a slow, gradual deformation of the template to target.
% please see the tutorial 'UnderstandingNonRigidMappingWithMeshmonk' for
% some more details on how this all works.
% TransformNumViscousIterationsEnd, TransformNumElasticIterationsEnd should
% always be around 1. If they are higher than the floating shape may not
% actually match the shape of the target at the end of the algorithm. They
% can be 0 but this is only advisable with very high quality meshes
NRM.TransformSigma = 3;
NRM.TransformNumViscousIterationsStart = 200;
NRM.TransformNumViscousIterationsEnd = 1;
NRM.TransformNumElasticIterationsStart = 200;
NRM.TransformNumElasticIterationsEnd = 1;
NRM.TransformNumNeighbors = 80;

%% Batch process files
% load Template floating face
Floating = shape3D;
Floating.importWavefront('Template.obj',strcat(projectPath, filesep,'Data/'));
% load landmarks on template
FloatingLandmarks =
readTextLandmarkFile(strcat(projectPath,filesep,'Data/Template.csv'),'');
for f = 1:numel(objs)

```

```

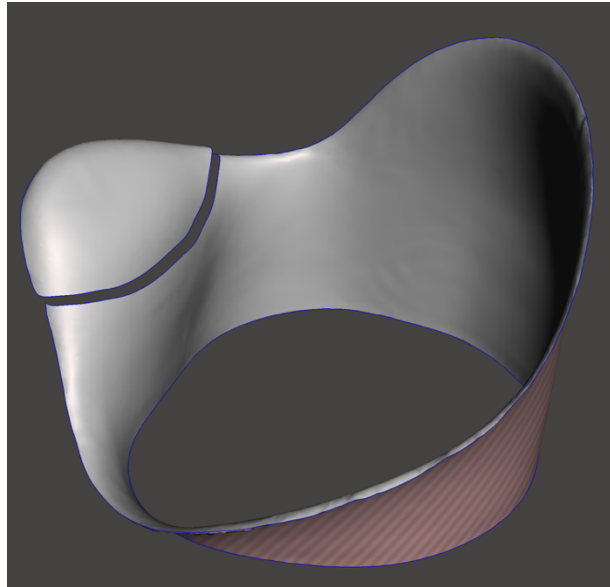
% For every target...
f % print which skull is currently being mapped
tic % Measure the time
% load Target obj and landmarks
targetName = objs(f).name;
Target = shape3D;
Target.importWavefront(targetName, path2objs);
TargetLandmarks = readTextLandmarkFile(strcat(path2landmarks,targetName(1:end-
4),'.csv'),'');
%%% Initialisation from landmarks
% calculate rigid transformation from FloatingLandmarks to
% TargetLandmarks
T = computeTransform(FloatingLandmarks,TargetLandmarks,true);
% apply rigid transform to Floating
forFloating = applyTransform(Floating,T);
%check normals of floating and target consistently point inward or
%outward. If they are inconsistent the normals will be flipped.
% The only way to exactly check this is to plot
% each shape with their normals
% e.g v = viewer(Shape)
% plotVectorField(Shape.Vertices,Shape.VertexNormals,v)
if ~normalsConsistent(Target, forFloating)
Target.FlipNormals = true;
end
% Execute Rigid Mapping
forRM = clone(RM);
forRM.FloatingShape = clone(forFloating);
forRM.TargetShape = clone(Target);
forRM.map();
% Execute Non-Rigid Mapping
forNRM = clone(NRM);
forNRM.FloatingShape = forRM.FloatingShape; % floating shape is now the floating
shape after Rigid Mapping
forNRM.TargetShape = Target;
forNRM.map()
%save result
forNRM.FloatingShape.exportWavefront(targetName,path2results);
end

```

Appendix E – Scaling procedure used to create the standardized brim set

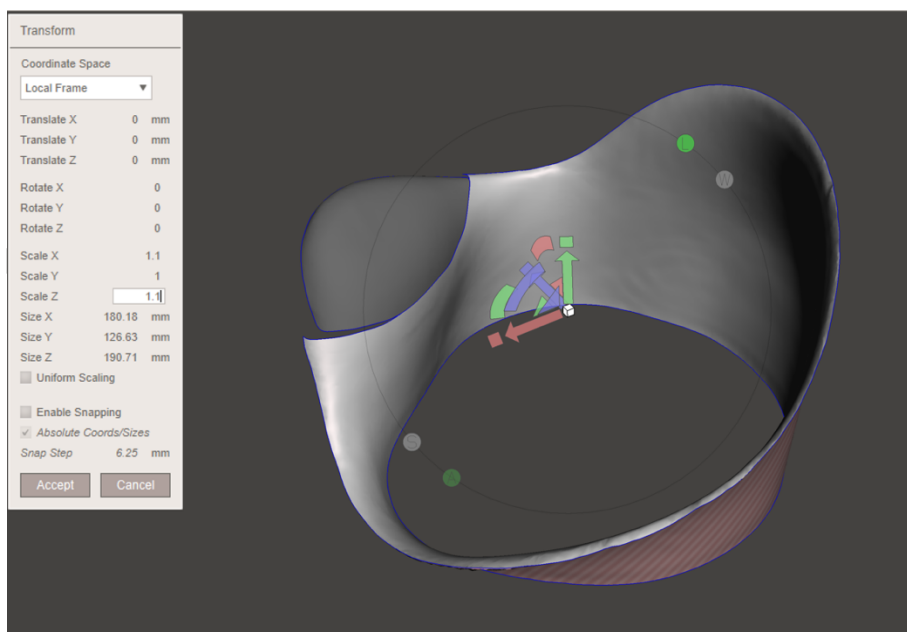
The following steps show the scaling procedure for an example case. This procedure was repeated to obtain brims with circumferences ranging from 35 to 60 cm.

Step 1 – Isolate the tuber support from the calculated mean brim model.



Remarks: The tuber support was manually selected and the outwarded angle that the tuber support makes with the vertical oriented brim walls was used as a reference for the separation line.

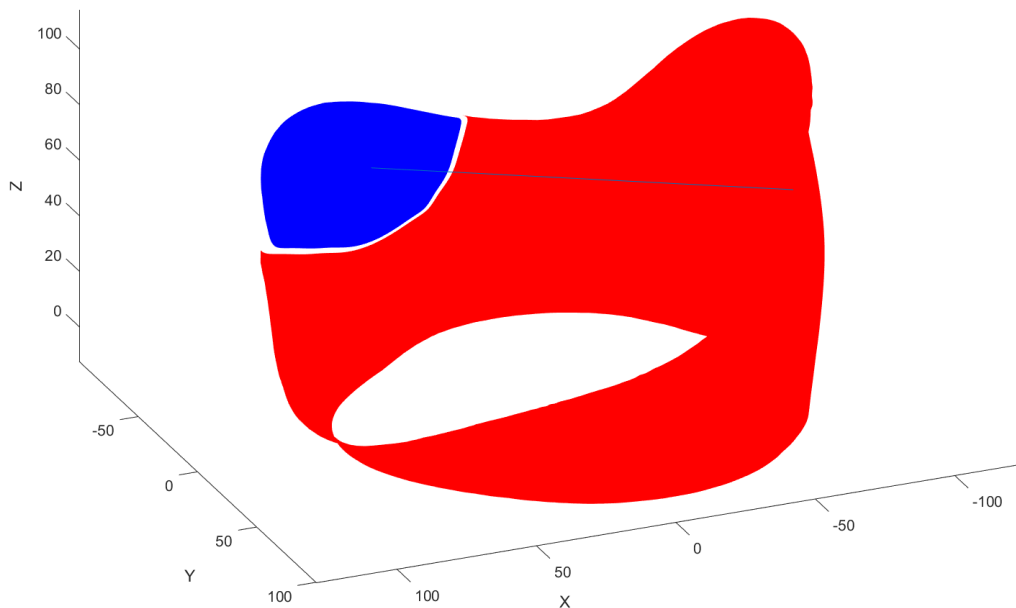
Step 2 – Scale the remaining brim to the desired circumference size in x- and y-directions.



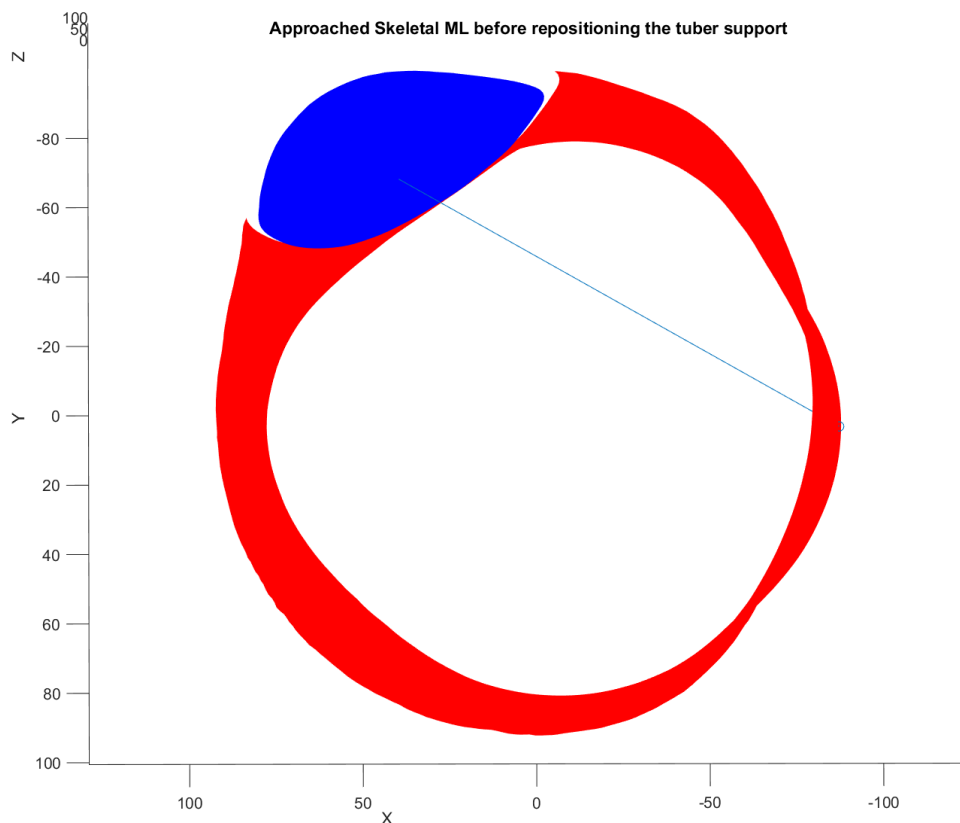
Remarks: In this example case, the circumference was scaled with 1.1. For the developed brim set, the mean brim was scaled to circumferences from 35 to 60 cm, with 1 cm increments.

Step 3 – Determine the horizontal distance from the not-moved tuber support's center to the lateral wall of the brim (approximated skeletal ML).

Approached Skeletal ML before repositioning the tuber support



Approached Skeletal ML before repositioning the tuber support



Remarks: Matlab code:

CALCULATE DISTANCE

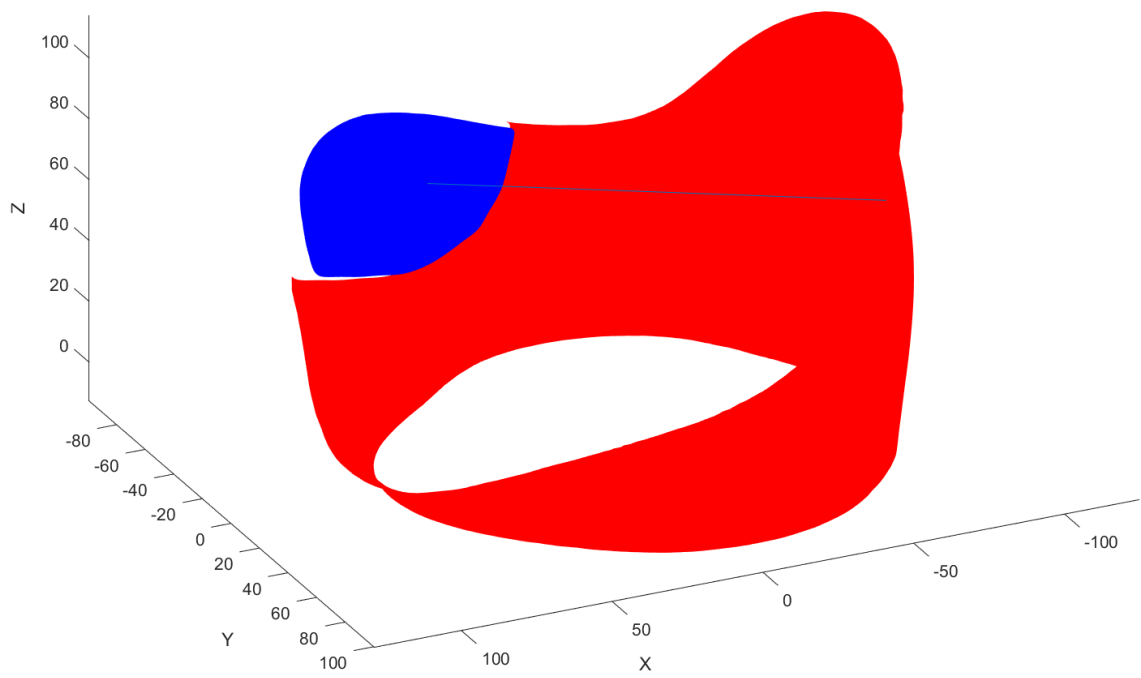
```
%% Find the center point of the tuber support
mesh1 = stlread('isolated_tuber.stl');
center = mean(mesh1.Points);
figure
h1 = patch('Faces',mesh1.ConnectivityList,'Vertices',mesh1.Points,'FaceColor','yellow');
axis equal
hold on
scatter3(center(1),center(2), center(3), "+", "MarkerFaceColor",'g','LineWidth',0.8)
hold off
% Calculate distance between center point of tuber support and lateral wall
mesh2 = stlread('remaining_brim.stl');
% Extract the vertices of the mesh that have a z-coordinate in the at the
% same height as the center of the tuber support
zVertices = mesh2.Points(mesh2.Points(:,3) >= center(3) -2 & mesh2.Points(:,3) <= center(3) +2,:);
% Find the vertex with the smallest x-coordinate (representing the most lateral point on the remaining brim)
[~, minXIndex] = min(zVertices(:,1));
minXVertex = zVertices(minXIndex,:);
% Calculate the distance between the mean point of the tuber and the vertex with the smallest x-coordinate
distance = pdist2(center, minXVertex);
% Plot the distance as a line in a figure
figure;
% Plot the mesh
h = patch('Faces',mesh2.ConnectivityList,'Vertices',mesh2.Points,'FaceColor','yellow');
axis equal
hold on;
plot3([meanPoint(1), minXVertex(1)], [meanPoint(2), minXVertex(2)], [meanPoint(3), minXVertex(3)], '-o');
hold off
xlabel('X');
ylabel('Y');
zlabel('Z');
title(['Distance between the mean point and most lateral point on the brim wall']);
```

Step 4 – Calculate the desired approximated skeletal ML distance based on the brim circumference the remaining brim was scaled to in step 2 using the following formula:

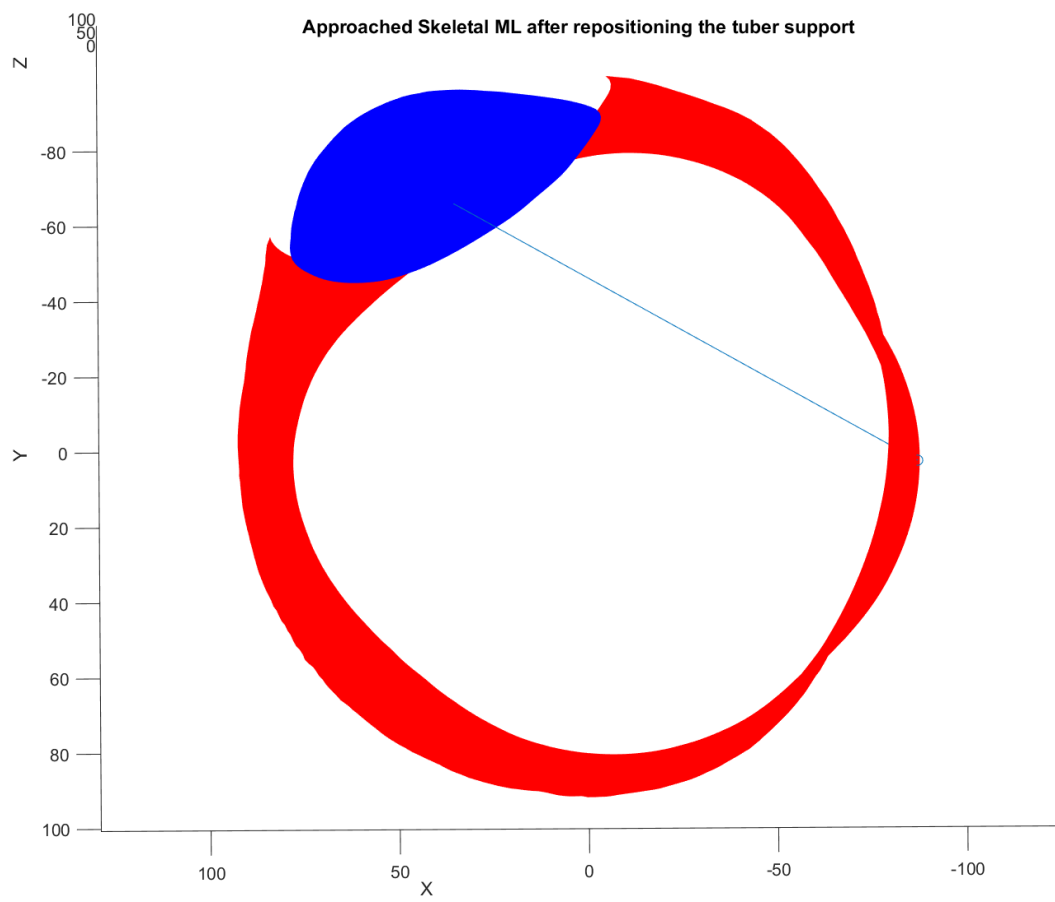
$$\text{Desired distance/ approximated Skeletal ML (cm)} = 0.294 * \text{Brim Circumference (cm)} + 0.77$$

According to the difference between the calculated distance in step 3 and the desired distance, reposition the tuber support by moving it out- or inwards (depending on whether the difference has a negative or positive value) on the slope of the calculated distance in step 3 such that it meets the desired distance.

Approached Skeletal ML after repositioning the tuber support



Approached Skeletal ML after repositioning the tuber support

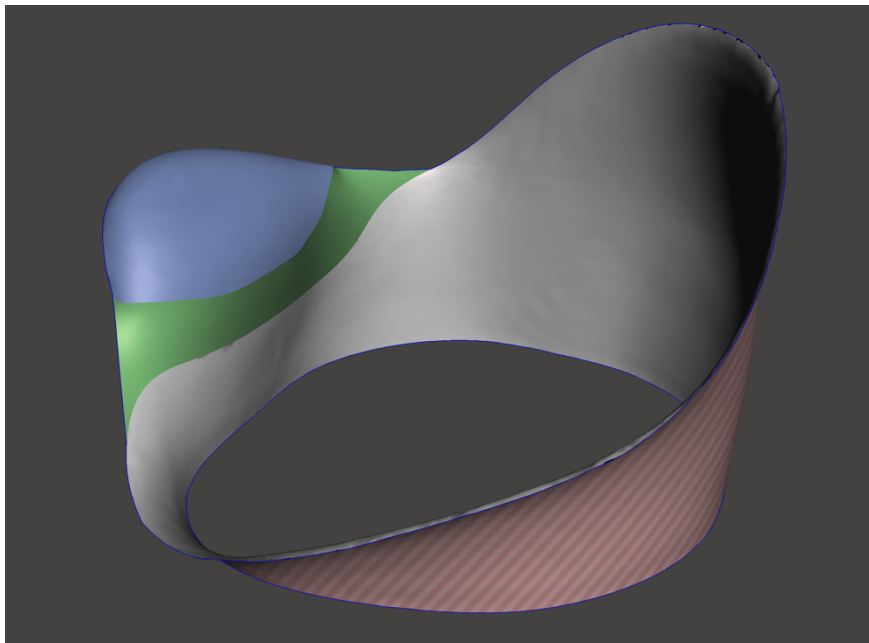


Remarks: Matlab code:

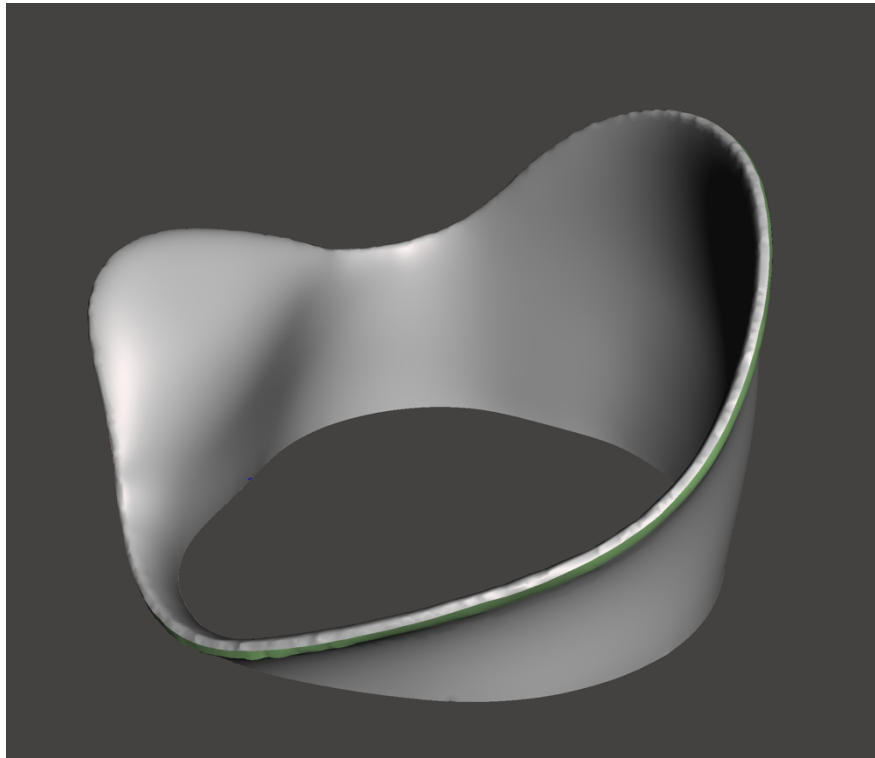
RECALCULATE DISTANCE AND REPOSITION TUBER SUPPORT

```
%% the distance should be
Desired_approached_skeletalML_distance = 0.294 * Brim_Circumference (mm) + 7.7;
%difference in distances
difference_distance = original_distance - desired_distance;
scaling_distance_difference = desired_distance / recalculated_distance;
% Calculate the slope of the line
m2 = (center_tuber_support(2)- point_lateral_wall(2))/(center_tuber_support(1)-point_lateral_wall(1));
angle = atand(m2)
angle1 = (angle / 180) * pi;
y_desired_distance = sin(angle1) * desired_distance
x_desired_distance = cos(angle1) * desired_distance
y_distance = sin(angle1) * recalculated_distance
x_distance = cos(angle1) * recalculated_distance
y_distance_difference = y_distance - y_desired_distance
x_distance_difference = x_distance - x_desired_distance
%move tuber support
moved_tuber(:, 1) = tuber(:, 1) - x_distance_difference;
moved_tuber(:, 2) = tuber(:, 2) - y_distance_difference;
moved_tuber(:, 3) = tuber(:,3);
```

Step 5 – Reconnect the tuber support to the remaining brim to form a smooth connection.



Step 6 – Give the brim a thickness of 4.8 mm.



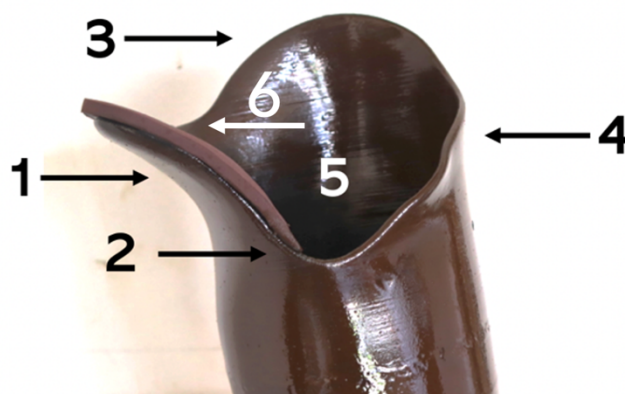
Appendix F - Assessment form used to evaluate the Brim fitting (Dutch)

Datum: _____

Naam instrumentmaker/fysiotherapeut: _____

Studienummer patiënt: _____

Toelichting: eerst wordt de aanmeetstandaard ingesteld aan de hand van de flexiecontractuur van de deelnemer. De deelnemer past verschillende brim modellen in de (niet-veranderende) aanmeetstandaard. Uiteindelijk wordt de brim met de meeste potentie uitgekozen. De vorm van het brim model mag niet worden aangepast. Onderstaande vragen worden op basis van de gekozen brim ingevuld. De brim dient hierbij op de juiste manier te zijn uitgelijnd in de brimstandaard. Per onderdeel van Figuur 1 zal gevraagd worden om de pasvorm te beoordelen.



Figuur G1: Brim hybride transfemorale koker

Vragen over de brim

1. Welke brim-maat heeft volgens u de meeste potentie voor deze deelnemer?

2. A. Hoe beoordeelt u de pasvorm van onderdeel 1: de tubersteun?

Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

3. A. Hoe beoordeelt u de pasvorm van onderdeel 2: de mediale trimlijnen?

Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

4. A. Hoe beoordeelt u de pasvorm van onderdeel 3: de laterale trimlijnen

Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

5. A. Hoe beoordeelt u de pasvorm van onderdeel 4: anterieure trimlijnen?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

6. A. Hoe beoordeelt u de pasvorm van onderdeel 5: de transversale aansluiting/omvng van de brim ten opzichte van de stomp?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

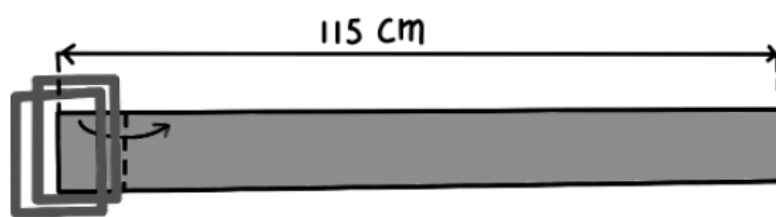
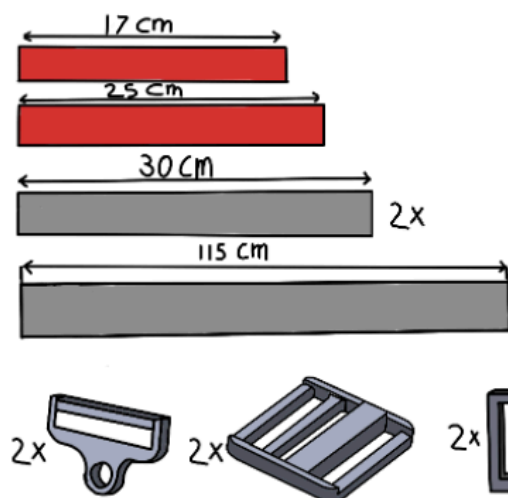
7. A. Hoe beoordeelt u de pasvorm van onderdeel 6: de posterieure trimlijnen?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

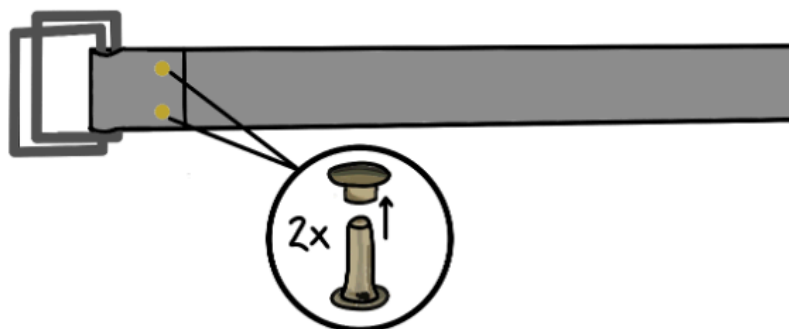
8. Heeft u suggesties voor het verbeteren van het ontwerp van de brim?

9. Heeft u nog op- of aanmerkingen m.b.t. de brim?

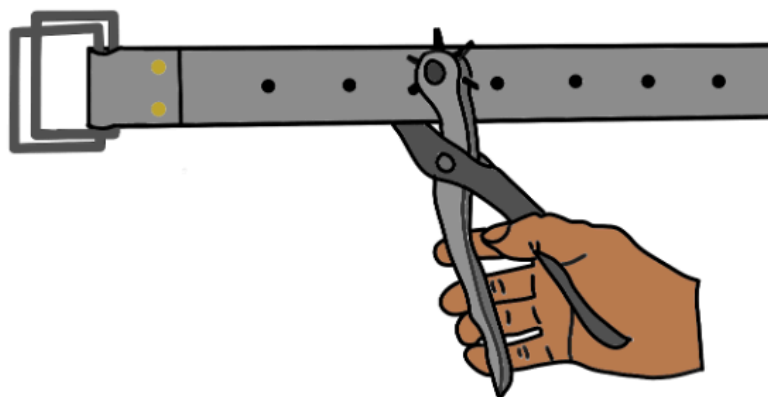
Appendix G – Manual to create the Silesian belt



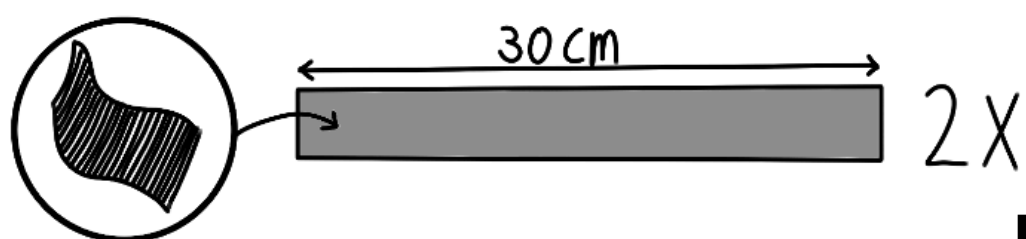
1



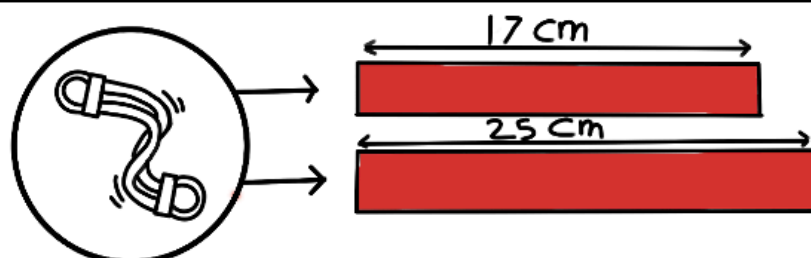
2



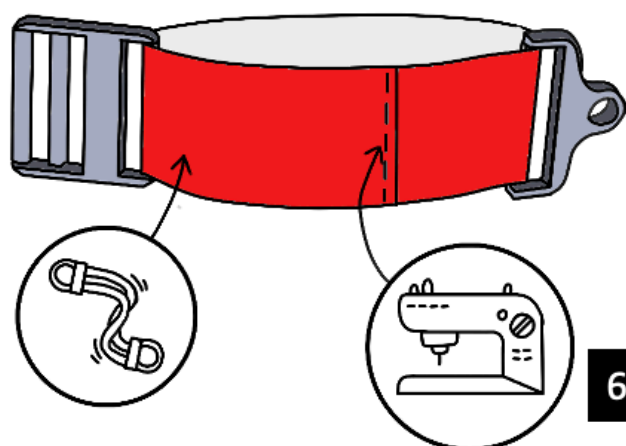
3



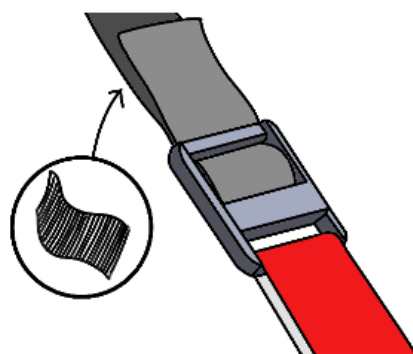
4



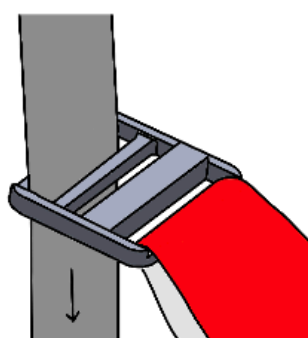
5



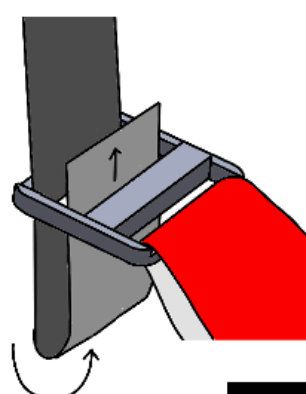
6



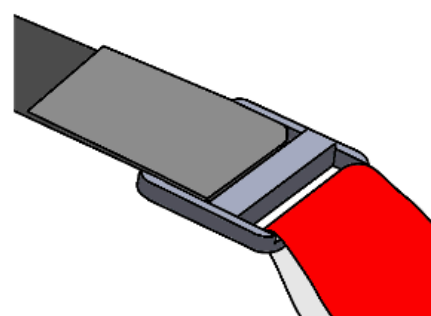
7



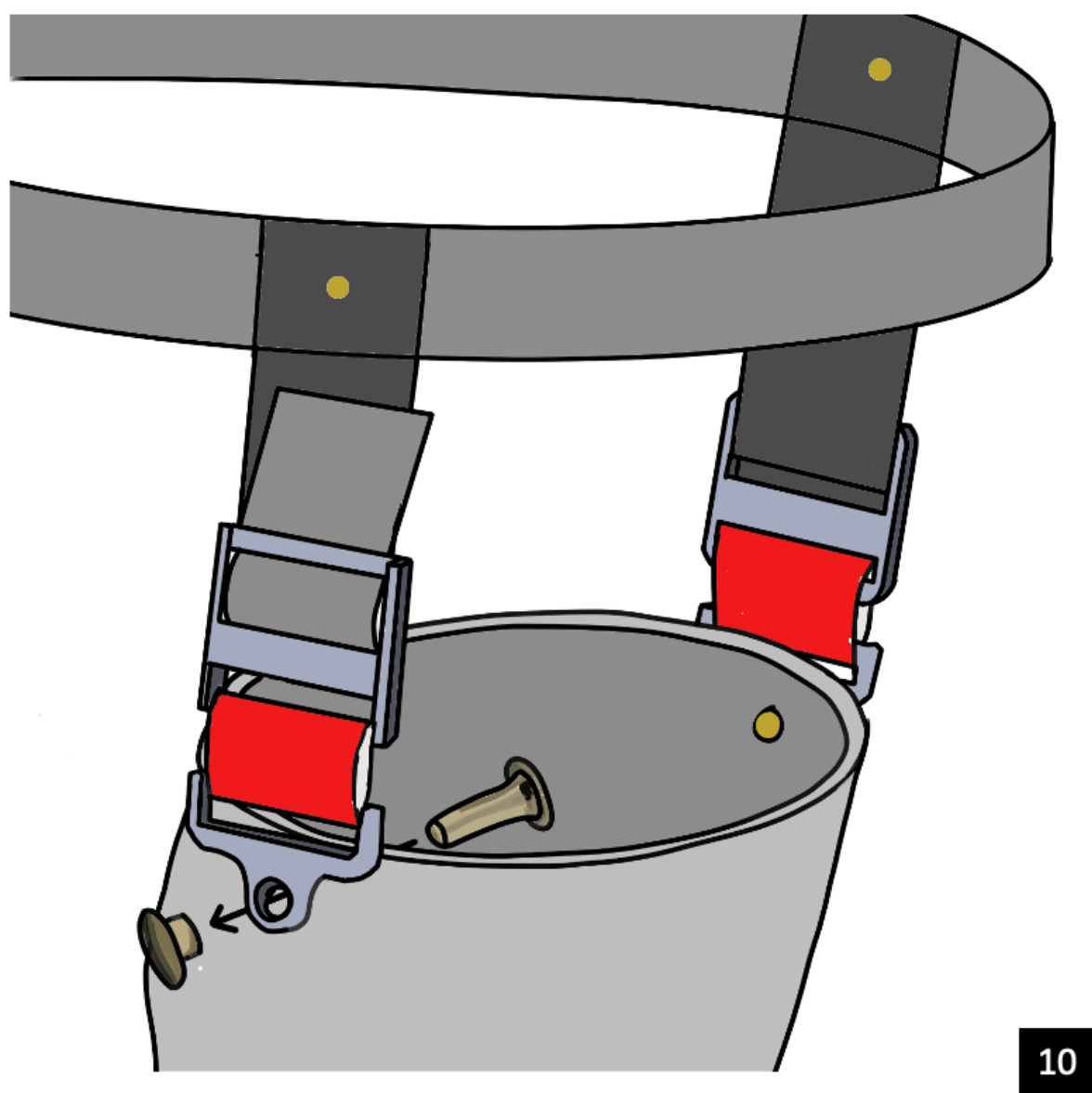
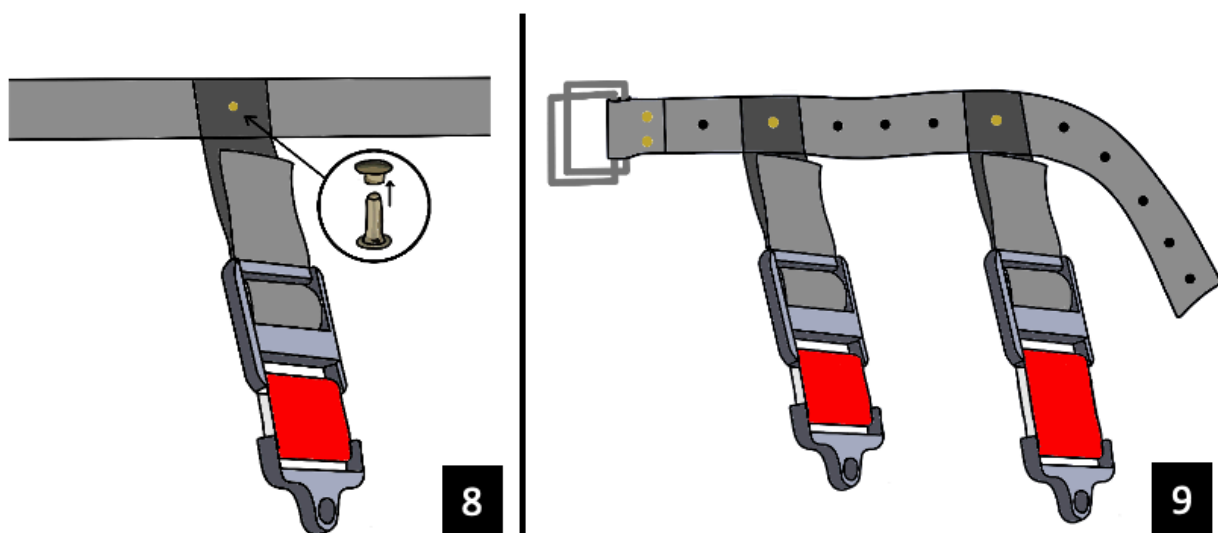
7A



7B



7C



Appendix H - Assessment form used to evaluate the Socket fitting (Dutch)

Datum: _____

Naam instrumentmaker/fysiotherapeut: _____

Studienummer patiënt: _____

Brim

1. A. Hoe beoordeelt u de pasvorm van onderdeel 1: de tubersteun?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

2. A. Hoe beoordeelt u de pasvorm van onderdeel 2: de mediale trimlijnen?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

3. A. Hoe beoordeelt u de pasvorm van onderdeel 3: de laterale trimlijnen
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

4. A. Hoe beoordeelt u de pasvorm van onderdeel 4: anterieure trimlijnen?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

5. A. Hoe beoordeelt u de pasvorm van onderdeel 5: de transversale aansluiting/ omvang van de brim ten opzichte van de stomp?
Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

6. Heeft u suggesties voor het verbeteren van het ontwerp van de brim?

7. Heeft u nog op- of aanmerkingen m.b.t. de brim?

Kokervolume

1. A. Hoe beoordeelt u de distale aansluiting van het kokervolume op de stomp, beoordeeld via de distale opening van de koker?

Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

2. A. Hoe beoordeelt u de vorm van het kokervolume?

Slecht: Onvoldoende: Redelijk: Goed: Uitstekend:
☐ ☐ ☐ ☐ ☐

B. Licht uw keuze toe:

3. Heeft u suggesties voor het verbeteren van het kokervolume?

4. Heeft u nog op- of aanmerkingen m.b.t. het kokervolume?

Appendix I – Intake Questionnaires Sierra Leone

General intake survey (Intake questionnaire: Lower and upper limb)

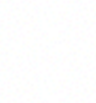
Name of investigator: Current date:/...../..... (month/day/year)

General patient information:

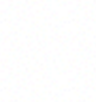
Client ID:	Name client:
Age: (years)	Gender: Man / Female
Address:	Phone number(s):
Daily activity/job:	Average monthly income:(Leones)
Highest schooling level achieved: Elementary school / Middle school / High school / University & College / No school	
Literate (can read or write): Yes / No	Language(s) spoken:
Affected limb(s): Right / Left / Both	
Amputation level left leg: none / transfemoral / transtibial / Knee-ex / foot / transhumeral / transradial	
Amputation level right leg: none / transfemoral / transtibial / Knee-ex / foot / transhumeral / transradial	
Amputation date:	
Operation technique, scar at: Bottom side / Front side / from front to back	
Number of stump operations:	
Hospital of amputation:	
Reason for amputation:	
☐ Present from birth ☐ Trauma. Due to?..... ☐ Diabetic ☐ Infection ☐ Vascular ☐ Sequel to/complication of an underlying disease. Name of disease if known:	
Was traditional healing a contributory factor: Yes / No	

Questions about pain

Do you have stump pain? Yes/No
 If yes. What kind of pain do you have? Stump pain/phantom pain
 How much stump pain do you have on a 0 -10 scale?

0	1	2	3	4	5	6	7	8	9	10
										

How much phantom pain do you have on a 0 -10 scale?

0	1	2	3	4	5	6	7	8	9	10
										

Can you specify the location of the pain?.....

Questions about device

Reason not having a (proper) prosthesis: (Multiple options possible)

- ☐ Patient cannot afford the prosthetic cost
- ☐ Patient cannot afford the travel cost
- ☐ Patient is not aware of available facilities
- ☐ Other:

Does the patient have a prosthesis?

- ☐ No, the patient is not having a prosthesis
- ☐ Yes, a prosthesis made in a different clinic, but the patient cannot use it anymore
- ☐ Yes, a prosthesis made in this clinic, but the patient cannot use it anymore
- ☐ Yes, the patient is still using the prosthesis that has been made in a different clinic, but has problems with it
- ☐ Yes, the patient is still using the prosthesis that has been made in this clinic, but has problems with it

Questions in case of existing device: If answer to previous question was 'Yes':

Why is the patient returning to the clinic? (Multiple options possible)

- ☐ Skin problems
- ☐ Stump pain
- ☐ Problems with socket size
- ☐ Prosthesis is broken. If yes, what broke:
- ☐ Other:

What is the condition of the existing prosthesis? Please mark what applies: (Multiple options possible)

- ☐ No damage to the prosthesis
- ☐ Prosthetic socket broke
- ☐ Prosthetic hand/foot broke
- ☐ Prosthetic metal parts broke
- ☐ Suspension broke (for example, the straps)
- ☐ Cover broke
- ☐ Other:

In case of damaged prosthesis:

- After how much time:..... (Years/months)
- How did it happen:.....

How many socks is the patient wearing when using the prosthesis:

Personal Goal

Should the new prosthesis look like a realistic body part?

- ☐ Yes
- ☐ No

What kind of activity would the patient want to be able to do with the new prosthesis:

What is the functional level that the patient wants to achieve?

- ☐ K-Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance quality of life or mobility.
- ☐ K-Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.
- ☐ K-Level 2: Has the ability or potential for ambulation with the ability to transverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
- ☐ K-Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion.
- ☐ K-Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

How many minutes does the patient want to be able to walk without a break with the prosthesis?.....(min)

Using what kind of assistive device?

Walking frame / Two crutches or two sticks / One crutch or one stick / Guidance of a person / None

Version May 2023

Modified OPUS: Health Quality of Life Index
(Lower limb intake questionnaire)

Note: for the questions below, the term “physical condition” refers to the reason you use an orthotic or prosthetic device	Not at all	A little	A great deal	Excessively
1. To what extent do you feel embarrassed by peoples’ reactions to the missing body part or your need for a device?	☐	☐	☐	☐
2. To what extent do you find that peoples’ attitudes toward your physical condition are insulting?	☐	☐	☐	☐
3. To what extent are you prevented from doing what you want to do?	☐	☐	☐	☐
4. How much does pain interfere with your activities (including both work outside the home and household duties)?	☐	☐	☐	☐
5. To what extent do you do less than you would like because of your physical condition?	☐	☐	☐	☐
6. To what extent do you do less than you would like because of emotional problems?	☐	☐	☐	☐
7. How much does your physical condition restrict your ability to go to the market?	☐	☐	☐	☐
8. How much does your physical condition restrict your ability to things that make you happy?	☐	☐	☐	☐
9. How much does your physical condition restrict your ability to do routine tasks (for example: cleaning, cooking, dressing up)?	☐	☐	☐	☐
10. How much does your physical condition restrict your ability to do paid work?	☐	☐	☐	☐
11. To what extent are you doing less on work or other activities because of your physical condition?	☐	☐	☐	☐
12. To what extent are you doing less on work or other activities because of emotional problems?	☐	☐	☐	☐

EQ5D-3L: Health Quality of Life Index (Lower limb intake questionnaire)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- ☐ I have no problems in walking about
- ☐ I have some problems in walking about
- ☐ I am confined to bed

SELF-CARE

- ☐ I have no problems with self-care
- ☐ I have some problems washing or dressing myself
- ☐ I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- ☐ I have no problems with performing my usual activities
- ☐ I have some problems with performing my usual activities
- ☐ I am unable to perform my usual activities

PAIN / DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have extreme pain or discomfort

ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am extremely anxious or depressed

We would like to know how good or bad your health is TODAY

- This scale is numbered from 0 to 10.
- 10 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.

**The worst health
you can imagine**

0 1 2 3 4 5 6 7 8 9 10



**The best health
you can imagine**