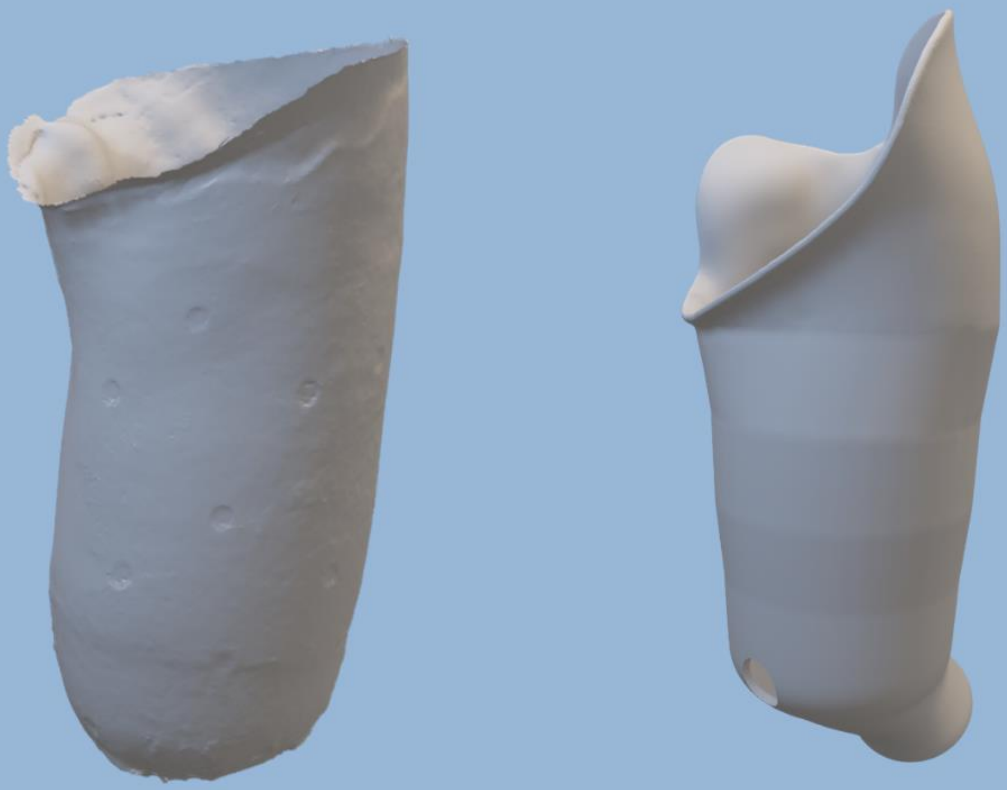
Exploring improvements to the manufacturing process of the transfemoral socket volume



Pim de la Fuente | Master Thesis Technical Medicine

Exploring improvements to the manufacturing process of the transfemoral socket volume

P.A. de la Fuente

s1806637

Thesis submitted to the University of Twente
for the degree of Master of Science in Technical Medicine

September 2024

University of Twente
Faculty of Science and Technology
Technical Medicine, Medical Imaging & Interventions

Radboud University Medical Center
Radboud 3D Medical Lab

Graduation committee

Chair	prof. dr. ir. G.J.M. Tuijthof
Medical Supervisor	R. Leijendekkers, PhD
Technical Supervisor	ir. E.E.G. Hekman
Process Supervisor	drs. A.G. Lovink
Daily Supervisor	M. van der Stelt, MSc.
External Supervisor	dr. A.T.M. Bellos-Grob

UNIVERSITY OF TWENTE.

3DLab Radboudumc

Abstract

Introduction – Provision of a prosthetic device is essential for successful rehabilitation after an amputation, but only realised for 5 – 15% of the patients in low- and middle-income countries (LMICs). The 3D Sierra Leone project aims to improve prosthetic accessibility and decrease operator dependency in LMICs, by streamlining the manufacturing process. This thesis builds further on a previous framework for the transfemoral (TF) hybrid socket, focussing on the socket volume. It explores possibilities to further standardize the measurement and design method to close the knowledge gap regarding socket manufacturing and improve measurement reproducibility.

Methodology – The explorative work presented in the thesis consisted of three studies. The first study mapped different measurement and design methods for the TF prosthetic socket, utilized by Dutch prosthetists, with an interview, observations and a questionnaire. Subsequently an experimental study was used to research the effect of wearing a prosthetic liner during residual limb measurement on measurement reproducibility as well as on shape and volume of the residual limb. At last, it was evaluated if the measurements obtained while wearing the liner could be translated into a socket design that is applied in a LMIC setting.

Results – The first study confirmed the variety in methodologies among prosthetists, highlighting the dominance of manual techniques in TF socket manufacturing and the absence of a broad accepted guideline. While different residual limb and patient characteristics were found to influence socket design, the quantitative relationship between them remains unclear. The second study showed that wearing a prosthetic liner improved measurement reproducibility, though no consistent effect on residual limb shape and volume was found. However, due to the small sample size and the high risk of measurement errors from the manual plaster casting process, the study cannot provide a definitive conclusion on the added value of a prosthetic liner in the measurement process. In the last study, both participant and prosthetist assessments showed the best results for the socket with the liner and narrowest ML dimension, reporting improved fit and comfort. Yet, these findings are based on a single participant and may be influenced by its individual characteristics.

Conclusion – The exploratory research presented in this thesis has provided important insights about the complexity of transfemoral socket manufacture process and taught valuable lessons regarding the direction of future research to the effect of the prosthetic liner.

Keywords – Low- and Middle-income countries, M*easurement- and design, Prosthetics, Socket volume, Transfemoral amputation*

List of Abbreviations

3D	Three Dimensional
AP	Anteroposterior
BMI	Body Mass Index
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
CT	Computed Tomography
FFF	Fused Filament Fabrication
IC	Ischial Containment
ICRC	International Committee of the Red Cross
LMIC	Low- and Middle-Income Countries
ML	Mediolateral
Magnetic Resonance Imaging	MRI
PLA	Poly Lactic Acid
QOL	Quality of Life
Quad	Quadrilateral
Radboudumc	Radboud University Medical Centre
SCS	Socket Comfort Score
SI	Sub Ischial
TF	Transfemoral
WHO	World Health Organisation

Table of Contents

Chapter I General Introduction

Epidemiology

The World Health Organisation (WHO) reports that more than one million limb amputations are performed each year, making it one of the leading causes of disability worldwide [1]. The cause of limb amputation varies between regions. Where vascular disease is the leading cause of amputation in high-income countries, trauma is the main cause in low- and middle-income countries (LMICs) [2]. Sierra Leone is reported as a low-income country, ranked 184 out of 193 countries and territories on the UN development index [3]. Out of a population of over 7 million people, the prevalence of disability was 1.3%, with 8.9% caused by amputations [4]. However, the prevalence is likely underestimated as the WHO reports that prevalence of disability is approximately 18% in low-income countries, and the prevalence of people in need of a prosthetic or orthotic device is estimated as 0.5% of the population [1]. It is difficult to find out exactly what the proportion of people with lower limb amputation is, but a small study (n = 37) conducted in 2020 by Allen et al. reported that 35% of the lower extremity amputations in Sierra Leone was transfemoral [5].

Impact of an amputation

An amputation is a life-transforming event that impacts mobility, quality of life, and engagement in daily activities [6]. People who have lost a limb often experience feelings of incompleteness and insecurity, which can lead to reduced social participation, depression, decreased self-esteem, and a lower overall quality of life (QOL) [7–10]. To enhance the psychosocial well-being of individuals with an amputation, it is essential to provide a prosthetic device tailored to their specific needs and goals, as this is key to successful rehabilitation. People with an amputation in Sierra Leone describe that wearing a prosthesis for aesthetic purposes alone already gives them more self-confidence to increasingly participate in society [11]. In addition to the fulfilment of aesthetic needs of the patient, lower limb prosthetics aim to meet functional needs by restoring gait of the patient.

Transfemoral prosthesis

A Transfemoral (TF) prosthesis aims to restore gait with an acceptable energy expenditure for individuals with a lower limb amputation above the knee [12]. A TF prosthesis consists of four main parts which are connected with tubes (Figure 1): the foot, the knee, the socket and the suspension system. Where foot, knee and tubes form the replacement of the missing limb, the suspension system prevents detachment of the prosthesis from the body, while the main loadbearing connection between the body and the residual limb is the socket. In this thesis, the focus will be on the design of the socket.

***Figure 1**: Transfemoral prosthesis, consisting of a foot (1), knee (2), socket (3), and suspension system (4).*

Patients show variation in characteristics such as anatomy of the residual limb, rehabilitation goals, and aesthetic preferences. Therefore, it is essential that the TF prosthesis achieves a balance between functionality, comfort and appearance, both in dynamic and static conditions [12]. The socket is a crucial component of the prosthesis, as it protects the residual limb and

transmits forces from the limb to the prosthesis [13–16]. A sufficient transmission of forces is achieved with good socket fit. This involves a correct distribution of the interface loads between the residual limb and the socket, where stress is reduced in sensitive areas and applied in stress-tolerant areas of the residual limb [17]. In poor socket fit, loads and stresses are incorrect distributed, resulting in decreased socket comfort caused by skin abrasion, pain. Compensation strategies of the patient to an uncomfortable socket can cause gait deviations, which can lead to long-term musculoskeletal degenerations [16, 18, 19]. To achieve optimal socket fit and comfort, the prosthetist customizes the socket design for each individual patient.

The socket design consists of two main parts: the brim, which is the proximal section defined by the trimlines, and the socket volume, which is formed by the volume distal of the lowest trimline. Over time, three principal socket designs have emerged, distinguished by variations in the shape of the brim and socket volume: the quadrilateral- (1950s), ischial containment- (1980s), and sub ischial (2010s) socket [12, 20–22] (Figure 2). The quadrilateral(quad) socket achieves weight bearing by the ischial tuberosity resting on the posteromedial aspect of the brim, which is known as the ischial seat [23]. The socket is held in place by anteroposterior (AP) compression created by a decreased AP dimension and increased mediolateral (ML) dimension of the socket volume relative to the shape of the residual limb. In contrast to the quad socket, the ischial containment (IC) socket encases the medial aspect of the ischial tuberosity by increased medial and posterior trimlines. The socket volume provides ML stability by narrowing of this dimension instead of the AP dimension. Weight bearing is provided by hydrostatic pressure between the socket and residual limb, instead of resting of the ischial tuberosity on the ischial seat. The design of the sub ischial (SI) socket has lowered trimlines compared to the IC socket and comes without an ischial seat. Weight bearing is provided by the pressure between the narrow socket volume and the residual limb [20]. In addition to the three described socket types, a hybrid socket type can be considered, that combines the narrow ML dimension of the IC and lowered trimlines as well as an adjusted version of the ischial seat of the Quad design.

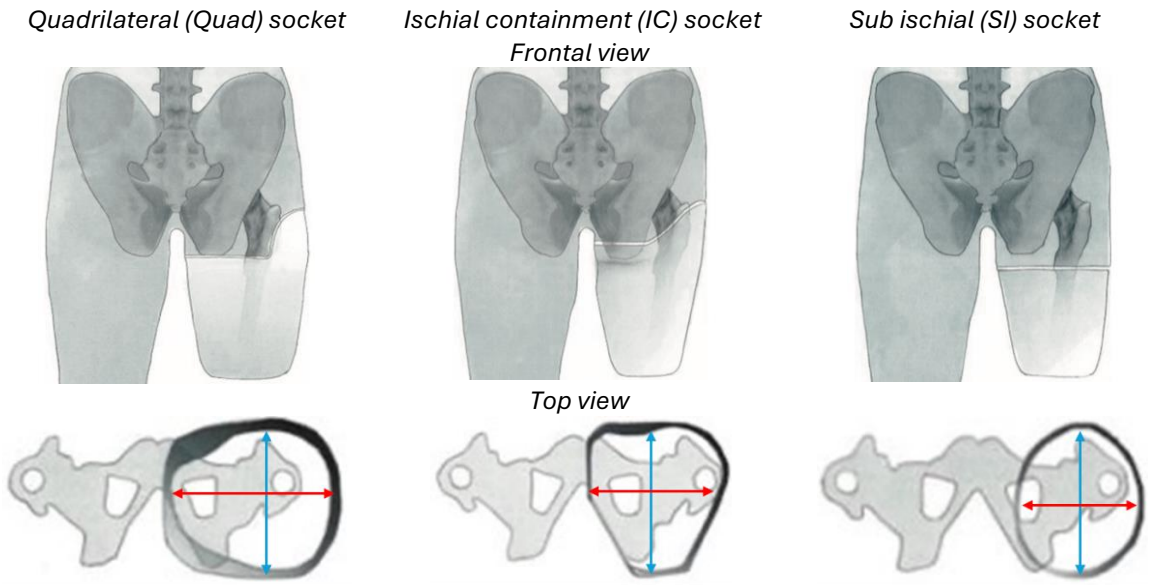


Figure 2: Designs of different transfemoral socket types [23]. The sockets vary in height and shape of the trimlines as well as the size and proportion of the AP (blue arrow) and ML (red arrow) dimensions.

During the swing phase of the gait cycle, when the prosthesis is off-loaded, a suspension system is needed to prevent displacement of the socket relative to the residual limb [12]. Different types of suspension systems exist ranging from belt-type suspension that uses a strapping system to provides a force that pulls the socket upwards, to vacuum type that uses negative pressure to maintain contact between socket and residual limb interface. The suspension comes frequently with a prosthetic liner, a roll-on sleeve at which parts of the suspension system are attached or that substitutes the residual limb interface to create the vacuum. In addition to its utility for suspension, liners reduce shear forces and manage residual limb volume, offering superior comfort and cushioning compared to traditional materials [24]. Prior to the manufacturing process of the socket, a prosthetist chooses a socket type and suspension system that best matches the characteristics of the patients.

Prosthetic socket manufacturing process

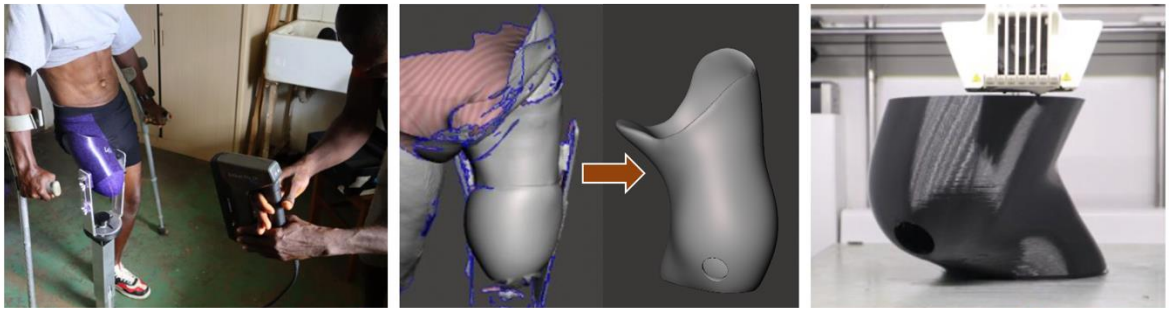
The manufacturing process of the socket consists of three phases: residual limb measurement, socket shape design and socket production. During this process, the prosthetist uses residual limb measurements and patient characteristics such as gender, age, activity level, and soft tissue to modify the shape of the selected socket type in the design phase [13]. In the production phase, the shape of the socket is realised. The scientific literature describes different manual as well as digital methods that can be utilized in the socket manufacturing process (Chapter 2 further elaborates these methods). The conventional method to manufacture the TF socket is a manual process that utilizes plaster casting. This method highly depends on the amount of knowledge and experience of the prosthetist, due to the large sequence of manual operations that is needed [13, 25, 26]. Digital methods emerged to decrease dependency of the skills of the prosthetists.

Local prosthetists in LMICs are currently utilizing the conventional method, according to the guidelines of the International Committee of the Red Cross (ICRC), to manufacture prosthetic devices, meaning that residual limb measurement, socket shape design and production are done manually using plaster casting [27]. The quality of the designs produced with the conventional methods varies significantly, as the process is influenced by the availability of materials and the knowledge and experience of the prosthetist. These factors make it difficult to standardize the manufacturing process of the prosthetic socket. Additionally, the limited resources, lack of trained staff and high prohibitive cost are contributing to a limited accessibility to prosthetic devices for patients in LMICs [28]. The WHO estimated that in low-income countries like Sierra Leone, only 5-15% of the people who require prosthetics have access to them [29].

3D Sierra Leone

To overcome the labour intensiveness and the high amount of required knowledge for the design of TF prostheses more interest has come in computer-aided design/computer-aided manufacturing (CAD/CAM) methods. These methods allow for digitally designing and manufacturing of prostheses in a more standardised and automated manner compared to the conventional method [11, 30–32]. 3D printing is an example of a CAM method that allows for fast, customizable, and low-cost production of prostheses and has the potential for standardisation of the manufacturing process. This decreases required education of local staff and thereby increasing prosthetic availability.

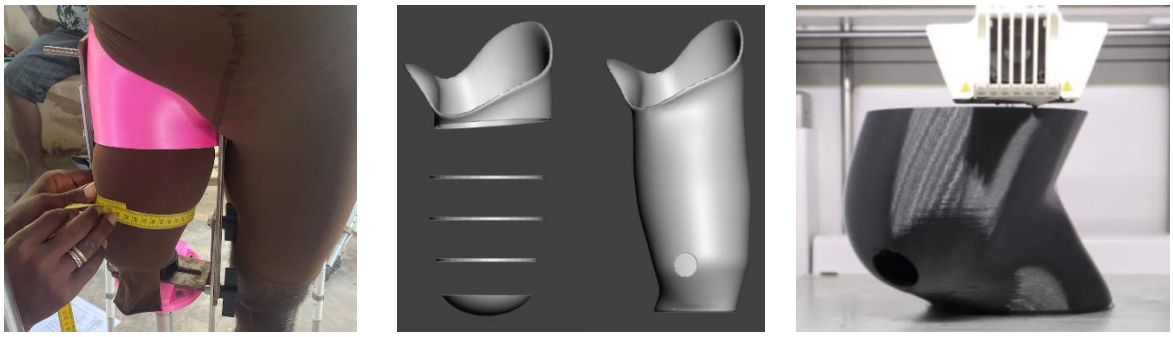
In 2018, the "3D Sierra Leone" project was launched in collaboration with the 3D-Lab at Radboud University Medical Centre (Radboudumc) in Nijmegen, the Netherlands [33]. The project set up a 3D laboratory at Masanga Hospital in rural Sierra Leone, aiming to enhance local manufacturing capabilities and offer affordable prosthetics to the community. In 2022, a proof-of-concept study was conducted within the 3D Sierra Leone project, demonstrating the feasibility of a CAD/CAM manufacturing workflow of the TF socket [34]. In the resulting workflow, conventional manual measurement, design and production techniques were replaced with 3D technologies (Figure 3).



a b c

***Figure 3**: Overview of the production workflow of TF prosthetic socket with CAD/CAM technologies* [34]. *a) Optical 3D scanning of the residual limb to obtain a 3D model, b) CAD of the socket, and c) 3D printing of the digital socket.*

As part of the 3D Sierra Leone project, a subsequent study aimed to further standardise the workflow and to overcome emerging difficulties regarding the 3D scanning of the distal residual limb volume [35]. The research focused on the development of an improved brim design and replaced the 3D scanning with a simplified method for residual limb volume measurement, followed by a method that digitally integrates the measurements into the socket design process. The simplified residual limb measurement method consisted of manual length- and circumference measurements obtained with measurement tape. Together with the brim, these measurements are transformed into a digital socket that is 3D printed (Figure 4).



a b c

***Figure 4**: Overview of the production workflow with the improved brim and simplified residual limb measurement method* [34]. *a) residual limb measurement, b) CAD of the socket, and c) 3D printing of the digital socket.*

Problem statement

Despite promising results during clinical testing of the TF socket manufacturing workflow in Sierra Leone, limitations and recommendations emerged regarding the measurement and design of the socket volume. Firstly, the simple round conical shape used in the previous study's socket design was based solely on the experience of one prosthetist and lacks substantiation by scientific research. Literature suggests that socket shapes are usually modified to relieve pressure on

sensitive areas and apply force to stress-tolerant regions, which may not be achieved with a round conical design. Furthermore, variations in socket design methods among prosthetists, due to differing education and experience, suggest that incorporating insights from multiple prosthetists could provide improvements for existing manufacturing process. However, no guidelines exist in the literature on how to translate residual limb measurements into an optimal socket shape, creating a gap that could be addressed through direct input from prosthetists. Secondly, it is uncertain if the current utilised measurement method is reproducible in capturing the shape of the residual limb. Various amount of force can be applied by the executor during circumference measurement and positioning of the measurement tape can deviate, which makes the manual circumference- and length measurements prone to variation. This creates the possibility that low reproducibility of the method could subsequently cause variation in socket design.

Thesis outline

This thesis aims to map measurement and design methods for the transfemoral socket volume, used by prosthetists and to translate these insights into recommendations that can be evaluated for adaptation in the current transfemoral socket manufacturing workflow applied in a LMIC setting. The primary research aim of this thesis is as follows:

Exploration of possibilities to further standardize the measurement and design method of the transfemoral socket volume, with the goal of enhancing their application in low- and middle-income country settings.

The outline of this thesis contains of three chapters contributing to the primary research aim, followed by a general discussion. In chapter two of this thesis an explorative study is presented that aimed to map measurement and design methods for the socket volume of the TF prosthetic socket utilized by Dutch prosthetists. The outcome of the study is a set of recommendations for adaptations to the measurement and design method of the socket volume, which will be applied and evaluated in the next two chapters. Chapter three consists of an experimental study that investigates how wearing a prosthetic liner during residual limb measurement influences 1) the reproducibility of residual limb measurements, and 2) the shape as well as the volume of the residual limb. Chapter four evaluates socket fit and comfort of multiple socket designs that differ in measurement method and cross-sections of the socket volume. Chapter five discusses the findings of chapter two, three and four and draws a final conclusion regarding the potential to further streamline the TF prosthetic socket production workflow in a LMIC setting.

Chapter II - Exploring the socket volume manufacturing process

Introduction

As previously described in chapter I the production workflow of the TF prosthetic socket consists of three main phases: 1) residual limb measurement, 2) socket design, 3) socket production. In this thesis, improvements to the measurement and design process of the socket volume were explored. Therefore, no attention was put on the production process of the socket.

During residual limb measurement, the prosthetist captures the shape of the residual limb. Measurement methods of the TF residual limb can be divided in manual and digital methods. Manual methods are the traditional plaster casting method and anthropometric measurements. Different prosthetic companies have standardised the taking of anthropometric measurements by implementation of a measurement form [36–38]. In these measurement forms, both dimensions of the residual limb (such as circumference and length) and patient characteristics (such as age, gender, and Body Mass Index (BMI)) are captured. Digital measurement methods are frequently described in recent years and used in computer-aided design (CAD) workflows of the TF socket. Examples of these methods include optical 3D scanning, computed tomography (CT) and magnetic resonance imaging (MRI) [19]. These technologies capture the three-dimensional shape of the residual limb, where CT and MRI can also identify orientation of anatomical structures of the residual limb such as the femur.

In the socket shape design phase, Aadjustments are made to the captured shape of the residual limb. These adjustments can be divided into two main actions: circumferential reduction and specific addition or removal of material. Circumferential reduction compresses the socket volume in the transversal plane with a specific reduction percentage, which creates a tighter fit of the socket. The tight fit allows for better transmission of forces between the interfaces of the socket and residual limb, which improves weight bearing and control of the prosthesis. The reduction percentage follows a decreasing profile from proximal to distal over the socket volume. The specific adjustments ensure increased loading of pressure tolerant parts and off-loading of pressure sensitive parts of the residual limb. Scar tissue, femur tip and inguinal canal are examples of off-loading areas, ischial tuberosity and soft tissue are examples of loading areas.

Prosthetists use patient and residual limb characteristics such as tonicity, gender, age, amount of soft tissue, which are collected during residual limb measurement, to decide which reduction profile and specific adjustments are applied in the design process [18]. For the development of a streamlined workflow, it is important to understand the effect of these characteristics on the design of the socket. This provides insight into which measurements are needed and how these measurements influence the choices made in the design process. In recent studies, CAD-CAM workflows were developed to (semi) automate the design process and standardize TF socket production (Appendix A) [25, 39–41]. However, the proposed workflows did not provide insight into the relationship between patient and residual limb characteristics and socket design. In addition, the workflows used either a large number of anthropometric measurements or expensive imaging such as MRI as input, and they still consisted of manual design steps which implicates that knowledge and experience of the operator is still required.

As the scientific literature does not provide insight into the relationships between characteristics and socket design, information could be gathered by different prosthetic facilities to map the experience of prosthetists that forms the foundation of the design choices. Therefore, an explorative study was conducted to map measurement and design methods of Dutch prosthetists. The study will research which individual patient, residual limb and prosthetic characteristics are collected during the measurement phase and how these characteristics influence the design of the TF prosthetic socket. The following research question and sub question are draw:

Which fitting and design methodologies, with their advantages and disadvantages, of the distal part of the transfemoral prosthetic socket, are used by; Dutch prosthetists?

- *To what extent is the design of the socket influences by specific patient-, residual limb- and prosthetic characteristics?*

Method

Study design

Mapping of different measurement and design methodologies used by prosthetists in the Netherlands falls within the domain of exploratory research as it involves gathering in-depth knowledge on a complex topic [42, 43]. A semi-structured interview was chosen as one of the data collection methods due to its flexibility in combining open- and closed-ended questions, as well as its ability to include probing questions. This approach is more suitable than a structured interview for researching the field of prosthetics, where professionals may hold diverse opinions on the same topic. With many manual methods existing to produce TF sockets, an on-site visit is most suitable for the study. This allows for combining the interview with observation of the workflow used by the prosthetist, making the study a qualitative observational study. However, supplementary to the qualitative data collection methods, a questionnaire was used to quantify relationships between a set of characteristics and parts of the manufacturing process of the TF prosthetic socket. This ensures that the design is not purely qualitative, but rather an explorative qualitative research with a generic approach that integrates both qualitative and quantitative methods.

Participants

A sample of Dutch prosthetists was selected by purposive non-probability sampling, using the network of a physiotherapist of Radboudumc. Inclusion criteria for the prosthetists were experience with the manufacturing process of transfemoral prosthetic sockets and current treatment of patients with a transfemoral amputation. It was aimed to select a sample that represented different facilities spread out across the country. Furthermore, it was considered that patients of all activity levels were treated at least by one of the facilities.

Data collection

During the on-site visit, different data collection methods were used to explore two domains regarding the previous described research questions: different measurement- and design methods used by each prosthetist, and the influence of different characteristics on these

methods. Three data collection methods were used during the visit: 1) semi-structured interview to collect in depth information about the used methods, 2) observations of the facility and the used methods, and 3) a questionnaire to quantify the influence of each characteristic on the utilized methods.

1. For the semi-structured interview an interview guide was created. The guide consisted of predefined questions that were categorised for each domain that was explored. An overview of the domains and categories is listed below, the interview guide can be found in appendix B. After permission of the prosthetist, the interview was recorded and transcribed with Microsoft Teams. Additionally, to Microsoft teams, notes were taken to overcome inaccurate transcription of the software.
2. The observations were elaborated with notations made during the visit and supported with pictures taken with a smartphone.
3. The questionnaire was formatted in a table which can be found in appendix C. In each row, the influence of the parts of the manufacturing process for a specific characteristic were scored with a 6-point Likert scale of 0-5 [44]. A score of 0 indicated no influence and 5 indicatesd a very large influence. Inclusion of characteristics was based on scientific literature, experience of the prosthetist affiliated with Radboud UMC, and measurement forms available online. The questionnaire was completed by each prosthetist for each socket type made at the facility, to allow for comparison between socket types.

Procedure

After confirmation of the prosthetist to participate in the study, the option was given for an online meeting as introduction to the study and the researchers. Afterwards an appointment was planned for a visit on site to conduct the interview and, if possible, observe the residual limb measurement of one TF amputee.

The visit of the prosthetic facility was commenced with an observation of the residual limb measurement. During this observation, questions pertaining to the methodology domain of the interview guide were posed. Subsequent to the observation of the residual limb measurement, further observations were conducted during a tour of the facility. Additionally, during this phase of the visit, also questions were posed using the interview guide. After the observations, the semi-structured interview was conducted with the remaining categories of the first domain and the second domain of the interview guide. If multiple socket types were produced by the prosthetic facility, the methodologies and processes were elaborated for each socket type separately. At last, the questionnaire was completed by the prosthetist for each socket type made at the facility. If questions were unanswered because of time limitation, or if some answers needed extra clarification, an online meeting was scheduled afterwards.

Data analysis

A framework analysis was conducted on the qualitative data collected during the interviews. The process began with familiarization of the data by listening to the transcripts and further elaboration of the notes taken during the visit. Following familiarization, main and sub-themes were identified. The categories of the two domains of the interview guide served as the conceptual framework for these themes, but additional themes emerging from the data were also incorporated. Once the themes were established, the answers of all prosthetists were

categorized according to the corresponding themes, allowing for a structured organization of information. This categorized data was then summarized to capture the essence of each theme. Finally, the summarized data was interpreted by identifying relationships between the themes and providing them of detailed descriptions.

The outcomes of the questionnaires are grouped per socket type and, for each characteristic scored against a part of the manufacturing process, the scores of the prosthetists are added together. For example, the scores of the influence of muscle tonicity on the shape of the socket volume is added up for every questionnaire completed for the IC socket. The accumulated scores were plotted in a bar chart as a percentage against the maximum possible scores. In the bar chart only the characteristics with a score of 50% or higher were plotted and compared between socket types. The summary obtained with the framework analysis was complemented with the quantitative data of the questionnaire by comparing the highest scoring characteristics with the answers of the prosthetists.

Results

Participants

Six prosthetists from six different prosthetic facilities across the Netherlands were included in the study (Table 1). The conducted observations differed between facilities, as it was not always possible to observe residual limb measurement process of a patient with a TF amputation.

***Table 1**: Overview of the participants of the study and the possible observations.*

Participant	Name facility	Observations
1	Heckert & van Lierop (Eindhoven)	Guided tour + TF residual limb measurement process
2	Livit Ottobock Care (Den Haag)	Guided tour
3	Militair Revailidatie Centrum (MRC) Aardenburg (Doorn)	Guided tour + TF residual limb measurement process
4	OIM Orthopedie (Nijmegen)	Guided tour
5	Papenburg Orthopedie (Ravenstein)	Guided tour + TF residual limb measurement process
6	ProReva (Hilversum)	Guided tour

Socket types, liner usage and suspension

Each interviewed prosthetist produced multiple socket types at their facility. Four main socket types were found, with no single TF socket type emerging as the most common among the six prosthetists (Table 2). This is caused by a difference in preference and experience between the prosthetists as well as policy of the prosthetic facility. An important difference in opinion lied in the consideration whether an SI socket is suitable for patients of all K-levels. Some of the prosthetists mentioned that the design is only applicable for low activity patients because the absence of a brim increased socket comfort while sitting. Other prosthetists mentioned that the absence of the brim asks for more muscle activity, making the design unsuited for low activity patients. However, prosthetists 1 and 6 apply the SI design for all activity levels, because of their positive experience with the use of the design. Besides activity classes, other factors were reported to influence the choice of socket type. Short residual limb length rules out the use of a SI design, as the socket volume would be too small to provide sufficient loading. Patient preferences for socket comfort and fit were a major factor of influence, with the IC socket

described as the design that provides less comfort and tighter fit compared to the other designs. Low finite load capacity of the residual limb was a factor ruling out designs that contain load bearing from the socket volume, which was the case for the IC as well as the SI socket. At last, the complexity of the production process could also contribute to the selection of a socket type. The Quad and hybrid socket were less complex to manufacture comparted to the IC Design.

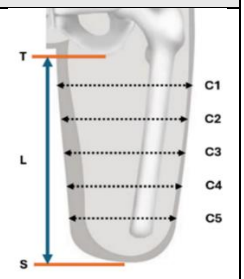
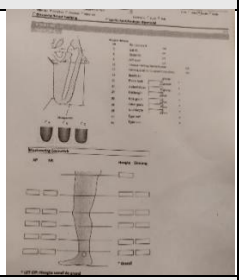
***Table 2**: Socket types produced, preference of a liner and suspension type, and K-level treated by the prosthetist. Dark blue indicates the preferred socket type, and light blue other types made at the facility.*

Prosthetist	**Socket type**				**Liner usage**	**Suspen-sion type**	**K-level treated**
	Sub ischial	Hybrid	Ischial containment	Quadrilateral			
1					Yes	Vacuum	K1-K4
2					Yes	Vacuum	K1-K4
3					No	Vacuum	K3-K4
4					Yes	Vacuum	K1-K4
5					Yes	Vacuum	K1-K4
6					Yes	Vacuum	K1-K4

All prosthetists preferred the use of a prosthetic liner during residual limb measurement except for the facility of prosthetist 3, where fitting and usage of the socket direct over the skin was preferred, as this resulted in more control over the prosthesis. The experience of the prosthetists was that a liner improves consistency of residual limb measurements. Employment of the liner during prosthetic usage was associated with a decrease of skin problems and increased socket comfort. All prosthetists preferred vacuum suspension because of increased control over the prosthesis compared to other suspension methods. Five out of six prosthetists treated patients of all activity levels, with K1 and K2 being the most common. At the facility of prosthetist 3 only high active patients were treated, as this was a military rehabilitation centre.

Measurement methods

Three manual methods for residual limb measurement were identified, with no digital imaging techniques in use (Figure 5).

Basic anthropometric measurements	
Basic anthropometric measuremens contain the length of the residual limb (L), starting from the ischial tuberosity (T) to the distal end (S), and transversal circumference measurements (C1-C5), taken over an interval of 3 or 5 cm along the length of the residual limb. Measurement tape is used as a tool to obtain the length and circumferences. By varying the amount of pressure applied with the measurement tape, both tight and loose measures can be taken by the prosthetists. The difference between these measures is used as indication of the amount of soft tissue of the residual limb.	
Extensive anthropometric measurements	
This measurement method obtains more information about the shape and anatomical landmarks of the residual limb, compared to basic anthropometric measurements. Extra measurements are taken that consider the ML and AP dimensions, amount of soft tissue and anatomical orientation of the bones in the residual limb. The data is collected in a measurement form, which is created by the manufacturer/prosthetic company.	
Plaster casting	

Use of plaster bandages to capture the shape of the residual limb in a negative plaster cast. During the casting, the shape is influenced by manual application of pressure by the prosthetist aiming to preshape the plaster to the desired socket type. The method of application of pressure differs between prosthetic facilities and socket types.	

***Figure 5**: Overview of the residual limb measurement methods utilized by the prosthetists.*

Shape design methods

The socket shape design methods were divided into three categories, adjusting a positive plaster model, a digital library model, or outsourcing of the design process (Figure 6).

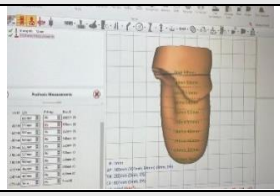
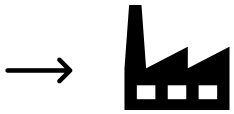
Positive plaster model	
Modification of a positive plaster model of the residual limb, obtained by filling the negative cast with plaster. The desired socket shape is obtained by removal and addition of plaster along the circumference as well as at specific areas of the model.	
Digital library model	
A digital library model is a virtual model of the residual limb, which can be edited in specific software. The same operations as with the positive plaster model can be performed. Important differences are that modification are reversible, concept designs can be saved during the process, and additional modifications are possible, such as uniform scaling of the model.	
Outsourcing	
Some facilities outsource the design process to an external manufacturer. Data from the residual limb measurement is sent to the external party in a specific measurement form, which is used to digitally design the socket shape. The design process used in this method is unknown, as the manufacturers use their private methodologies.	

***Figure 6**: Summary of the mapped design methods by the interviews and observations.*

Design considerations

The shape of the socket volume varied depending on the type of socket (Table 3). Both the IC and hybrid sockets featured an oval cross section with a narrowed ML dimension, while the Quad socket also had an oval cross section but with a reduced AP dimension. Circumferential reductions and specific adjustments in the design process differed across socket types and were further influenced by the individual approaches of prosthetists.

***Table 3**: Common features in design of the socket volume, and reduction profiles used by the prosthetists.*

	Quad	***Hybrid***	***IC***	***SI***
Socket volume Reduction profiles	Reduction of AP dimension 4-0%	Reduction of ML dimension 3-1%, 4-0%, 5-2%, 6-3%	Reduction of ML dimension 3-0%, 4-0%, 5-1%, 8-1%	Reduction lateral or lateral posterior 3%, 3-1% 4-0%, 4-2%, 5-3%, 6-4%

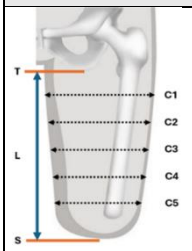
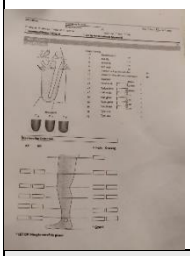
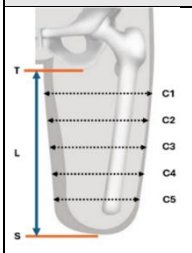
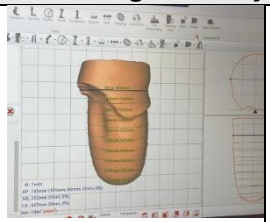
Characteristics affecting shape design

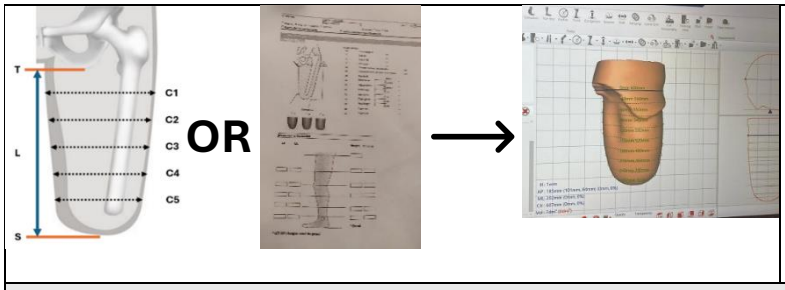
Additionally, to socket type, other factors influenced socket shape. The type of suspension system affected the cross section and reduction of the design. A vacuum suspension required a

rounder cross section of the socket combined with a higher reduction profile compared to other systems, because total contact between the socket and the residual limb was essential for maintaining the vacuum. According to the prosthetists, the utilization of a liner greatly influenced the design process. First, it was experienced that the compression of the liner resulted in a decrease in the reduction profile compared to reduction applied in a design process without involvement of a prosthetic liner. Furthermore, thicker liners necessitated greater reductions in the design compared to thinner liners. Additionally, the use of a liner facilitated the design process by smoothing the contour of the residual limb, thereby minimizing the adjustments required to tailor the socket to the patient's unique anatomical features. Soft tissue and bone orientation played varying roles in socket design. Most prosthetists agreed on the experience that the amount of soft tissue influenced the applied reduction. The importance of accommodating bony protuberances in the design to prevent loading on sensitive areas, thereby reducing the risk of skin damage and pain, was reported by a majority. However, both impact of soft tissue and bone orientation were downplayed by the experience of some of the prosthetists.

Manufacturing workflows

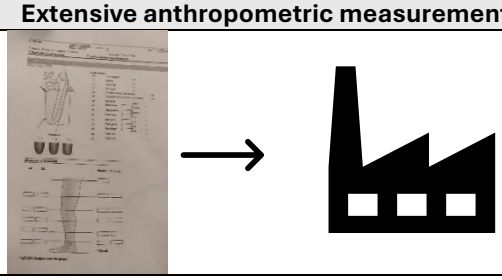
Figure 7 gives an overview of the mapped manufacturing workflows.

Residual limb measurement	Socket shape design	Description
Traditional workflow		
   		Traditional workflow using a negative plaster cast and anthropometric measurements to capture the shape and volume of the residual limb. Depending on socket type or prosthetic facility either basic or extensive anthropometric measurements are used. In the design, a positive plaster model is edited. Used by all prosthetists. For manufacturing of all four socket types.
Traditional workflow + digital library model		
 		Traditional residual limb measurement with plaster casting, but digital design with a library model. Solely used by prosthetist 2 for the SI socket.
Anthropometric measurements + digital library model		



Anthropometric measurements used to find the best matching library model, which is edited manually to obtain the desired socket design.
Used by prosthetist 2 for the Quad and IC, and by prosthetist 4 for the hybrid socket.

Extensive anthropometric measurements + outsourcing



Extensive measurement collected in a specific order form, which is sent to an external manufacturer that designs and produces the socket.
Used by prosthetist 2 and 4 for the IC socket.

***Figure 7**: Four manufacturing workflows used by the interviewed prosthetists for residual limb measurement and socket design.*

Influence characteristics – questionnaire

Data was obtained with the questionnaire about the IC, SI and hybrid socket. The Quad socket was not scored, because it was seldom made by the interviewed prosthetists. The questionnaire was filled in four times for the IC, three times for the SI and once for the hybrid socket. Residual limb characteristics such as shape, length, bone orientation, circumference, were reported as most influencing socket design. Figure 8 shows characteristics that received the highest scores regarding their influence on socket shape. An overview of the characteristics influencing circumferential reduction and specific adjustments of the socket volume can be found in Appendix D.

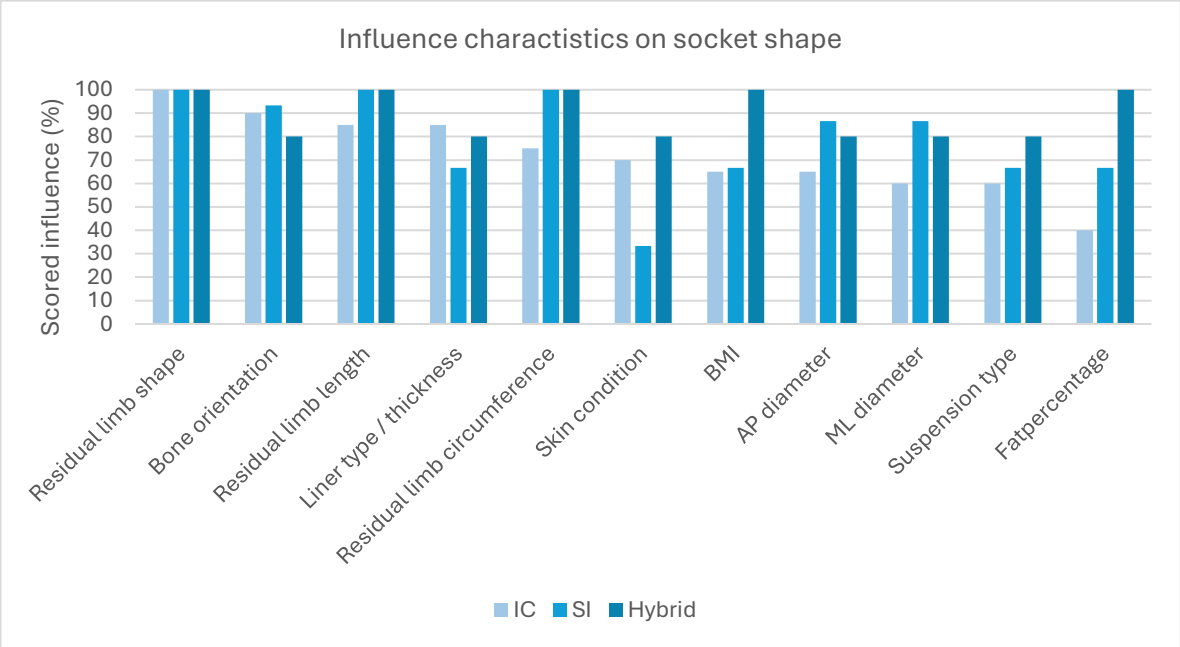


***Figure 8**: Scored influence of different characteristic on socket shape expressed in percentage relative to the maximum possible score.*

Discussion

The explorative study presented in this chapter aimed to map measurement and design methods of the TF socket volume, utilized by Dutch prosthetists, to close the knowledge gap regarding the manufacturing process of the TF socket. Qualitative data was collected during visits at six different prosthetic facilities across the Netherlands with both an interview and observations. A supplementary questionnaire was used to identify and quantify possible relationships between socket design and specific patient- and residual limb characteristics. The visits resulted in the identification of three distinct measurement and design methods, which were integrated into four manufacturing workflows. A comprehensive overview of these workflows was developed. Additionally, the quantified influence of various characteristics was visualized across three key aspects of the design process.

Main findings

The results of the interview and questionnaire confirmed the statement in the literature that variability exists in socket manufacturing methods between prosthetists. This was expressed in differences in utilized manufacturing workflows, selection of socket type, and applied modifications during socket shape design. These differences depended largely on the chosen socket type, but also on the prosthetic facility as multiple workflows were used to develop the same socket type. The prosthetists used personal experience to substantiate choices of socket type, which relied on a trade-off between advantages and disadvantages related to the design.

Although different manufacturing workflows were found, all of them could be considered as manual workflows. The adjustment of the digital library model consisted of the same manual steps as the traditional plaster method but performed with software on a computer. Digital residual limb measurement methods as described in the introduction or other CAD-CAM methods were not applied in the manufacture process of the TF prosthetic socket. Optical 3D scanning was deemed unsuitable for transfemoral residual limb measurements, as it could not accurately map key anatomical structures like bony protuberances. Other imaging techniques such as MRI and CT were not available at the prosthetic facilities. Therefore, the traditional workflow resulted as the most used method and emerged applicable for all four socket types.

The skill of plaster casting was reported by the prosthetists as something that needs to be maintained by applying it on a regular basis. Reason for this was the amount of knowledge and experience required to adequately execute the manual operations of the method. It could therefore be considered as the most complex residual limb measurement method. The basic anthropometric measurements were reported as the less difficult to implement, as limited anatomical knowledge was required, and measurements were relatively easy to perform. In the additional measurements of the extensive anthropometric measurements, anatomical structures were considered that were difficult to measure if the executor is inexperienced.

In addition to socket type selection, liner usage was a key factor influencing the manufacturing process of the socket. The prosthetists described that using a liner during residual limb measurement could reduce measurement variability and simplified the design process. These findings emphasised the potential of improved standardisation of the manufacturing workflow of the TF prosthetic socket, when a liner is used during residual limb measurement. However, the

extent of the influence of the prosthetic liner was not clear as the prosthetists could not substantiate their statements quantitatively.

Regarding the influence of different characteristics on the design process, agreement was found between the answers obtained with the interview and the questionnaire. Residual limb characteristics such as circumference, length, and shape were the highest scoring characteristics in the questionnaire and emerged from the interview as important measurements that influenced the socket design. Furthermore, bone orientation, liner type and thickness, BMI and suspension type were reported as characteristics of high influence by both methods. However, variation was found between the scores of different prosthetists showing that no clear broadly accepted guideline was utilised for the manufacturing of TF prosthetic sockets. Because of the absence of a guideline and lack of data collection during the design process, the quantitative effect of each characteristic on the socket design remained unclear.

Comparison with literature

In an exploratory study of Colombo et al, parameters were identified which were required for design and configuration of the prosthesis [45]. It was found that most of the decisions taken by the prosthetists are guided by patient characteristics that could be divided into three categories: patient evaluation, stump evaluation, and anthropometric measurements. The shape of the socket was influenced by the shape of the residual limb and the presence of bony protuberances. Circumferential reduction was influenced by stump and patient characteristics such as tonicity, weight, and lifestyle. Both findings corresponded with the characteristics that received the highest scores of the prosthetists in this study. Furthermore, the study developed a decision algorithm to select the reduction profile of the socket design based on the found characteristics. The used method could be a potential for standardised translation of characteristics obtained during residual limb measurement to the socket design. However, the study was based on only one prosthetic facility and socket testing for one participant.

The findings of the design of the sub ischial socket could be compared with the clinical algorithm of the NuFlex socket developed by Fatone et al [20]. Reduction profiles variating from 4-2% to 6-4% corresponded with the patterns used by the prosthetists. The areas where reduction was applied also corresponded because both the participants and the study described lateral and posterior reduction zones. Considerations for the reduction pattern were mainly based on soft tissue properties of the residual limb. The areas of reduction were chosen based on the symmetrical or asymmetrical shape of the residual limb. This corresponded with the finding that, according to the prosthetists, residual limb shape, which defines symmetry of the residual limb, influenced the reduction and specific adjustments.

The study of Li et al developed a compensation algorithm for the TF socket design based on interviews with ten prosthetists [46]. The influence of different features of the residual limb on three compensation types was obtained: increasing or decreasing the circumference, indenting or protruding specific areas, and lengthening or shortening of the socket. Findings of the study corresponded with the findings that compensation strategies differ between prosthetists, that soft tissue thickness had a positive relation with circumferential reduction, and bony protuberances ask for specific compensation of the socket. Other parameters, such as the amount of blood circulation, were studied that were not considered in this research. The

quantitative approach of the study enabled quantitative expression of the relationships between the researched parameters and the socket design. This could better facilitate the transition to a streamlined workflow compared to the qualitive approach of current research. However, it was not specified if a single socket type or multiple socket types were studied. This leaves a lack of clarity if the compensation method can be applied on a single or multiple socket types.

Limitations & recommendations

Interviewed prosthetists 2 and 4 mentioned that differences exist between TF socket manufacturing methods of prosthetists of the same prosthetic company. This research did not include prosthetists from different facilities from the same company and was therefore unable to examine differences existing within prosthetic companies.

Although the prior intention was to combine an interview with observation of a patient's fitting process every visit, this did not always happen. At some facilities, few or no patients with TF amputations were fitted at short notice, which made it difficult to schedule a visit. When the visit could not yet be planned, because of the absence of a patient that could be observed, it was decided to omit the observation of the fitting process. Instead, the fitting process was explained step by step by the prosthetist with the associated measuring instruments.

During some visits, less time was available than planned, causing that not all interview questions were asked, or the questionnaire could not be conducted. Missing questions were later addressed via email or online meetings, limiting the opportunity for probing and detailed responses. Questionnaires completed afterwards differed from those filled in during visits, possibly due to interpretation bias from the lack of explanation. For instance, one prosthetist used only 0 or 5 on the 6-point Likert scale instead of rating each characteristic properly

If repeated, the interview should be more structured and specific in eliciting choices made in the design process to decrease the risk in interpretation bias. Instead of a semi-structured interview, a structured interview could be used to map design choices more specifically. This should be conducted for every socket type separately.

The questionnaire aimed to quantify the influence of different characteristics on socket design, but with the used format only the extent of influence on the process was obtained. The method was unable to specifically determine how each considered characteristic modifies the shape, circumferential reduction or specific adjustments applied to the socket. For a specific quantification of the relationship between the characteristics and the design of the sockets, collection of quantitative data regarding the residual limb and the socket volume is necessary. When a large and diverse dataset of 3D volumes is gathered, patterns between socket design and the characteristics can be analysed. However, this data is currently unavailable at the visited prosthetic facilities, and gathering data for further research of this thesis is not feasible. It therefore remains a recommendation for future work that is not considered in this thesis.

Clinical relevance & future directions

The relevance of the findings of this study could be interpreted with respect to the aim of the 3D Sierra Leone project, the development of a streamlined workflow for the production of the transfemoral socket in LMICs. From the results of the study, four suggestions for further research emerged. First, based on the mapped measurement methods, the anthropometric from the

previous study could be further standardised by implementing the basic anthropometric measurement method found in this study. Instead of taking the circumference measurements starting from the distal tip of the residual limb, the method of using the ischial tuberosity as starting point could be used. The length of the residual limb was measured from this point to the distal end of the residual limb, instead from the distal end to the distal edge of the fitted brim. With this method only the ischial tuberosity needs to be palpated to perform the measurements, which does not require extensive anatomical knowledge. Secondly, the experience that prosthetic liners reduce measurement variation was a trigger to research the effect of introducing a liner in the residual limb measurement process. According to the prosthetists, the prosthetic liner preshapes the residual limb and applies surface tension, which could reduce variation of the anthropometric measurements. In a LMIC setting the use of liners could only be used as a reusable tool for residual limb measurement and not for daily usage with the prosthesis, as this makes the prosthesis too cost intensive. Therefore, it needs to be evaluated if measurements with liner still result in an applicable socket design for a LMIC setting. In addition to measurement reproducibility, the effect of the liner on residual limb shape and volume needs to be researched as this indicates whether adjustments to the design of the socket needs to be made. Thirdly, the findings of the study encouraged that the use of a hybrid socket in the workflow for LMICs was the best applicable socket type. Its broad applicability to all activity levels and limited number of measurements necessary for the design are the main reasons for this. Lastly, a narrowed ML dimension of the socket volume and different reduction profiles were described by the prosthetists, regarding the design of the hybrid socket. Since the specific amount of narrowing of the ML dimension and the best applicable reduction profile are unclear, these are important things to investigate for the socket design.

Conclusion

This study provided a comprehensive overview of the measurement and design methods used by six Dutch prosthetists in the fabrication of transfemoral (TF) prosthetic sockets. The variation in design choices among the prosthetists suggested that socket production was heavily influenced by the individual experience and expertise of the prosthetist. Furthermore, the study was limited in its ability to quantify the relationship between socket design and specific patient or residual limb characteristics. Consequently, the findings led to suggestions for future research to standardize the manufacturing workflow for implementation in LMIC settings.

Chapter III - Residual limb measurement: evaluating the effect of a prosthetic liner

Introduction

The production of the TF prosthetic socket consists of three main phases, 1) residual limb measurement, 2) socket design, 3) socket production. The socket is considered as both the most important and most patient specific part of the prosthesis, because the socket design needs to transfer loads and forces from the residual limb to the prosthesis sufficiently [13–17]. Accurate measurement of the residual limb is from great importance to obtain the desired design of the socket and is therefore contributing to socket fit and prosthetic functionality.

In part I of this thesis, it was found that prosthetists experienced that the use of a prosthetic liner during the residual limb measurement decreased variability in measurement outcomes between and within operators. However, this was not investigated this in a structured or quantitative manner. In the measurement method of the previous study that was applied in a LMIC setting, no liner was used during residual limb measurement. Compared to the commonly used methods in the Netherlands that include a liner, the outcomes could be more operator dependent. For the development of a streamlined production workflow for TF prosthetic sockets, it was aimed to reduce operator dependency as much as possible. Addition of a prosthetic liner to the existing measurement method in a LMIC setting could therefore improve reproducibility. However, before liners are purchased and implemented in the workflow, the effect of the liner on measurement reproducibility first needs to be evaluated to prove the added value to the process.

The shape and volume of the residual limb are influenced by the elastic forces transmitted by the prosthetic liner. According to the prosthetists from part I and the scientific literature, the prosthetic liner pre-shapes the residual limb in a more compressed and uniformly cylindrical shape. This influences the design process of the socket, because a lower reduction profile is needed to obtain the desired compression of the socket. For the design process it is important to find out what the effect of the liner is on the shape and volume of the residual limb. This could indicate whether adjustments to the socket design are necessary when measurements are taken with liner, but when the liner cannot be worn during actual prosthesis use. Hence, this study will try to answer the following research questions:

- How does wearing a liner during transfemoral prosthetic socket fitting, in patients with transfemoral amputation, affect the reproducibility of anthropometric residual limb volume measurements compared to not wearing a liner?
- To what extent does wearing a liner during transfemoral prosthetic socket fitting, influence the residual limb shape and volume of patients with transfemoral prostheses compared to not wearing a liner?

Because of the pressure distribution of the liner on the residual limb, it is expected that the shape of the residual limb varies less between individuals compared to the situation where no liner is worn. In addition, the displacement of tissue during manual measurements is expected to be less, because the interaction between liner and residual limb creates a more solid shape.

Therefore, capturing the shape of the residual limb will be easier and will be paired with less variation/measurement bias.

Soft tissue mainly consists of water, which is almost incompressible [47]. Therefore, the assumption is made that soft tissue is also incompressible [48]. When elastic forces of the liner are applied on the residual limb it is expected that the shape could change, but the total volume of the residual limb will not change.

Method

Prior to commencement, the research protocol (file: 2024-17283) was reviewed by the medical ethics review committee Oost-Nederland and ethical approval was obtained on May 13, 2024.

Study design

The reproducibility of the anthropometric residual limb measurements and possible changes in residual limb shape and volume are studied in two conditions: 1) while a prosthetic liner is worn over the residual limb and 2) while no prosthetic liner is worn over the residual limb. Both conditions are applied on all participants, making the study design an experimental study with a within-subject design [49].

Participants

The participants approached for this study are patients with a transfemoral amputation affiliated with Papenburg Orthopedie (Ravenstein, the Netherlands) and Radboudumc (Nijmegen, the Netherlands). Inclusion criteria are being familiar with the use of a TF prosthesis, above 18 years of age, weighing less than 100 kg and more than 50 kg. Exclusion criteria for the study are complaints of the residual limb, a flexion contracture of more than 20 degrees and a stump length of less than 15 centimetre.

Data collection

Demographic information and patient characteristics were collected with a general questionnaire which can be found in Appendix E.

The anthropometric measurements consisted of the length and circumference of the residual limb and were conducted by two executors per participant (Figure 9A). Because of limited availability of the executors, a pool of three possible executors was created, consisting of two prosthetists and one researcher from Radboud UMC. The two prosthetists were the preferred executors during the study, but if one is not available, the researcher functioned as stand-in. Measurement data was collected with a measurement form which can be found in Appendix F.

Possible shape and volume changes caused by the wearing of a prosthetic liner over the residual limb, were observed by collecting volumetric data of the residual limb with an optical 3D scan of plaster casts. The reason why the plaster cast was scanned instead of the residual limb, was that the previous study showed challenges in scanning the inguinal area. With plaster casting, this anatomical region could be captured and scanned indirectly. For each participant the plaster casting was performed twice, once while wearing the liner and without wearing the liner over the residual limb. The following materials were used to conduct the study:

- Prosthetic liner currently used by the participant
- Walking bridge
- Measurement tape
- Tape
- Aniline pencil
- 2 lasers on tripods
- Materials for plaster casting
- Einscan H2 optical 3D scanner (Shining 3D, Hangzhou, China)

Procedure

The procedure consisted of three main steps before data analysis was applied. First the manual length- and circumference measurements were taken, and the plaster cast was applied subsequently. Second, the current socket and the plaster casts were scanned with an optical 3D scanner. Third, the 3D scans of the plaster casts were pre-processed with the software of Meshmixer prior to data analysis.

Manual measurements and plaster casting

The preparation of the measurements involved the participant standing upright in the walkway, supporting themselves with the hands on the horizontal bars, with the residual limb hanging down relaxed. Two laser lines checked the position and orientation of the residual limb. The position of the laser lines was fixed for the other measurements (Figure 9B). Lateral and medial across the residual limb from proximal to distal painter's tape was taped parallel to the laterally positioned laser.

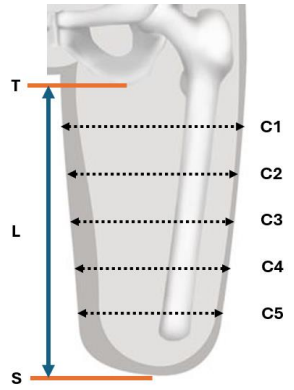


***Figure 9A**: Measurements taken from the residual limb. Length measurement (L) from the ischial tuberosity (T) to the distal end (S) and circumference measurements (C1/C5) each five centimetres distally from T.*

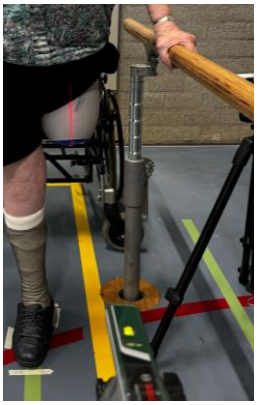


***Figure 9B**: Positioning of the participant in the walking bridge with two laser lines on tripods from the frontal and lateral side.*

***Figure 9C**: Marking of the positions for the circumference measurements according to the position of the ischial tuberosity.*

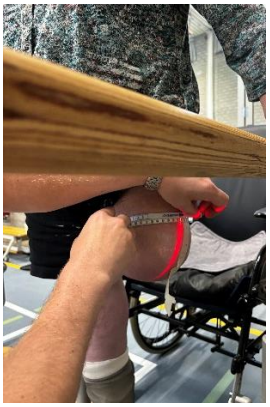


***Figure 9D**: Circumference measurement of the residual limb.*

The length of the residual limb was measured with the measurement tape from the ischial tuberosity to the distal end (figure 9C). After palpation of the ischial tuberosity, the position of the ischial tuberosity was marked at the painter´s tape on the lateral side. The height of the circumference measurements was indicated by marking every five centimetres below the height of the tuber on the painter´s tape. The residual limb circumferences were measured at the level

of each marking, except for the one marking the position of the tuber, with flexible measurement tape by the prosthetist (figure 9D). Both prosthetists performed the measurements separately and recorded the findings in the custom-designed measurement form (Appendix F).

During plaster casting, the participant remained in the walking bridge in the same position as during the previous steps. The prosthetist applied wet plaster bandages to the residual limb and exerted pressure with his hand to mark the location of the ischial tuberosity. The plaster cast dried for five minutes before removal. After removal, the location of the ischial tuberosity was marked at the inside of the plaster cast with a pencil. After making the plaster cast, the length- and circumference measurements were repeated by both implementers. Before the liner is doffed and the measurements were repeated, the participant rested for ten minutes.

Scanning of the current socket and plaster casts

The current socket was scanned with the optical 3D scanner for the design of the sockets used in part III of this thesis. From all obtained plaster casts, the inner surface was scanned with the optical 3D scanner. The resulting scan may contain small holes with missing data, but it suffices if the majority of the inner surface of the plaster cast was mapped.

Pre-processing steps in Meshmixer

Before analysis of the 3D volumes, the 3D scans of the plaster casts were pre-processed with the software of Meshmixer (Autodesk Inc., San Rafael, CA, USA) (Figure 10). After preprocessing, the volumes of the two casts of each participant were aligned. First the marked position of the ischial tuberosity and the lateral markings were used to align both casts. The first lateral marking and the marking of the ischial tuberosity were aligned with the y=0 plane. The lateral markings were aligned with the y-axis, with the distal end pointing towards the negative direction. Both volumes were translated so that the origin of the coordinate system lied in the midline of the scanned plaster cast. At last, the volumes were rotated so that the marking of the ischial tuberosity and first lateral marking are aligned with the x/z axis.

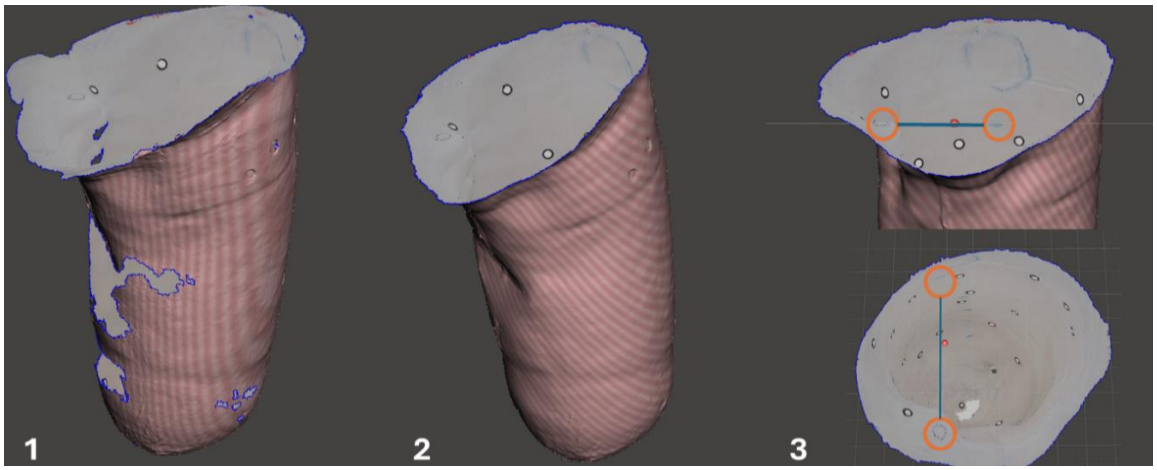


***Figure 10**: Pre-processing of the 3D scan of the plaster cast. The initial file (1) contained missing surface data, which was filled (2). At last, the cast was aligned with the two highlighted markers (3).*

Data analysis

Anthropometric measurements

The anthropometric measurements collected with the measurement form were entered in Excel. The residual limb length and circumferences of each participant were measured four times (two observers, 2 measurements per observer) both while wearing the liner and without wearing the liner. This resulted in 4 measurements of each length- and circumference measure with the liner and 4 without the liner. Due to different scales of the measures taken, the proximal circumferences were likely to be larger than the distal circumferences, absolute differences do not give comparable results about the variation. Therefore, the relative difference was calculated (Formula 1) to provide insight in the proportional variation of the measurements [50].

$$Formula\ 1: Relative\ Difference\ (\%) = \frac{|A - B|}{\frac{A + B}{2}} \times 100$$

The reproducibility of the measurements with and without liner was compared with two agreement constructs: the intra-rater and inter-rater agreement. These constructs were calculated by using the relative differences between measurements:

- Intra-rater agreement was expressed by the relative difference between the two measurements of each measurement pair of the observer. The relative difference was calculated for each observer specifically, so for each length- and circumference measure both the relative differences are calculated for observer 1 (measurement 1.1 and 1.2) and 2 (measurement (2.1 and 2.2) separately. After calculation, the spread as well as the mean of the differences of the circumferences were visualised in a scatterplot, and the difference of the length measure of each participant in a bar chart.

$$Rel\ Diff\ obs\ 1\ (\%) = \frac{|1.1 - 1.2|}{\frac{1.1 + 1.2}{2}} \times 100, \quad Rel\ Diff\ obs\ 2\ (\%) = \frac{|2.1 - 2.2|}{\frac{2.1 + 2.2}{2}} \times 100$$

- Inter-rater agreement was expressed by the relative difference between the first measurement the measurement pairs of the observers. The relative difference was calculated for each length- and circumference measure of the participant, with the differences of the circumference measurements visualised in a scatterplot and the lengths in a bar chart.

$$Rel\ Diff\ measure\ 1\ (\%) = \frac{|1.1 - 2.1|}{\frac{1.1 + 2.1}{2}} \times 100$$

Besides comparison of method reproducibility, the circumference measurements with and without liner were compared to evaluate possible volume differences caused by the liner. Therefore, the difference between the mean of the four measurements with- and without the liner was calculated (Formula 2). The result was expressed as a positive or negative percentage, grouped per participant and visualised in a bar chart.

$$Formula\ 2:\ Reduction(\%) = 100 \times \left(1 - \frac{mean\ without\ liner}{mean\ with\ liner}\right)$$

Plaster casts

After the alignment of the plaster cast volumes, MATLAB (MathWorks, Natick, MA, USA) was used to determine their length, circumference, volume and shape (see Appendix G, for the full script).

1. The plaster cast was aligned in such a manner that, when plotted, the length runs parallel to the y-axis (Figure 11A). The length was obtained between the marking of the ischial tuberosity, positioned at y=0, and the y-value of the most distal vertex of the plaster cast.
2. The circumference of the plaster cast was estimated over the length of the plaster cast (y-axis) with a step size of 1 mm. At each y-value a slice with a thickness of 1 mm finds all the vertices of the 3D model that are between y-value – 0.5mm and y-value + 0.5mm (Figure 11B). These vertices were projected on the xz-plane to create a 2D plot (Figure 11C). By calculating the convex hull of all plotted vertices, the circumference at the selected y-value was estimated. This circumferences at every 50th mm distal from the ischial tuberosity were used for comparison with the manual residual limb measurement, as these heights correspond with the positions of the circumference. The volume of the plaster cast was calculated in mm^3 by adding up the circumferences, as the volume of each slice equalled 1mm * circumference. The volume was calculated for the previously calculated length, starting at the ischial tuberosity until the distal tip of the cast. The volume of the plaster cast made while wearing the liner was compensated for the liner volume, which was estimated with the specifications of the liner.
3. Comparison of the shape of the plaster casts was done by plotting the outlines of the plaster casts for both the frontal and lateral view.

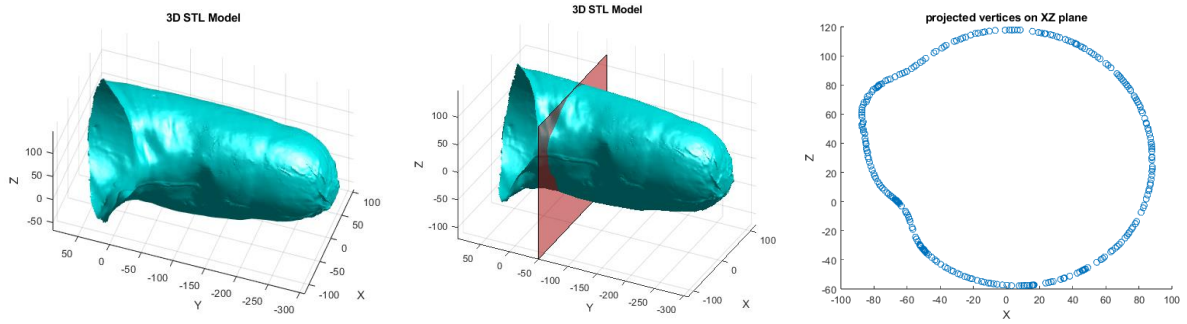


***Figure 11**: Calculation of the circumference of the plaster cast at y=-50. A) loading of the 3D model, B) selecting the vertices that lie within the 1 mm slice, C) projection of the vertices at the XZ-plane for calculation of the length of its convex hull, which is the estimated circumference.*

Results

Four patients with a transfemoral amputation were included in the study. Table 4 gives an overview of the collected demographic data and characteristics.

***Table 4**: Demographic data, residual limb and prosthetic characteristics of the four participants.*

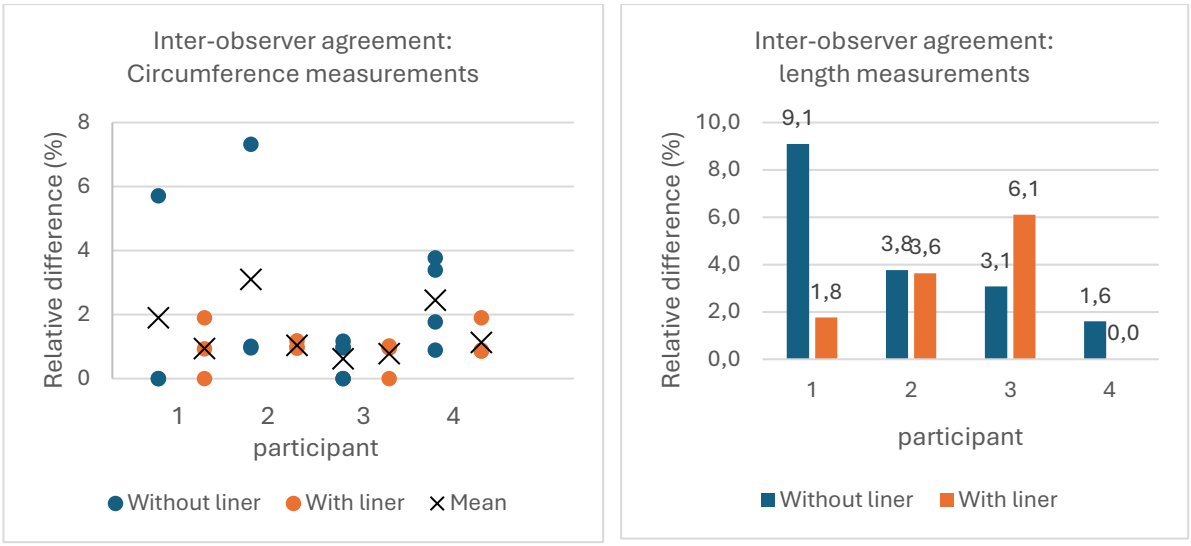
	Participant 1	***Participant 2***	***Participant 3***	***Participant 4***
		Demographic data		
Gender	W	M	W	M
Age	86 years	67 years	79 years	72 years
Weight	66 Kg	87 Kg	70 Kg	84 Kg
Length	165 cm	189 cm	170 cm	180 cm
Amputation side	Left	Left	Left	Left
Reason of amputation	Oncological	Oncological	Oncological	Infection
Time since amputation	4 months	11 years	5 years	1,5 months
Time since prosthesis	2 months	11 years	4 years, 10 months	2 weeks
		Prosthetic (socket) characteristics		
Flexion angle	15 degrees	10 degrees	10 degrees	20
Adduction angle	7 degrees	5 degrees	15 degrees	5 degrees
Liner	Lite Silkon SkinTex TF	Willowood Hybrid Alpha AK	Ottobock Proseal	Ottobock Proseal
Liner thickness	Non-uniform 3.5 - 13.4 mm	Non-uniform 2.5 - 9 mm	Uniform 3 mm	Uniform 3 mm
Type	Quad/Hybrid	HiFi socket	Hybrid	Hybrid
Suspension	Lanyard	Pin locking	Vacuum	Vacuum

Reproducibility of anthropometric measurements

Due to variation in residual limb length, differing amount of circumference measurements were taken of the participants: 3 measures for participant 1&2, 4 for participant 4 and 5 for participant 3. Figure 12 shows the relative differences of the length- and circumference measurements between observers. The mean relative difference of the circumference measurements decreased for all participants and the spread for participants 1-3. Relative differences increased for the length measurements between the observers for all participants except participant 4.

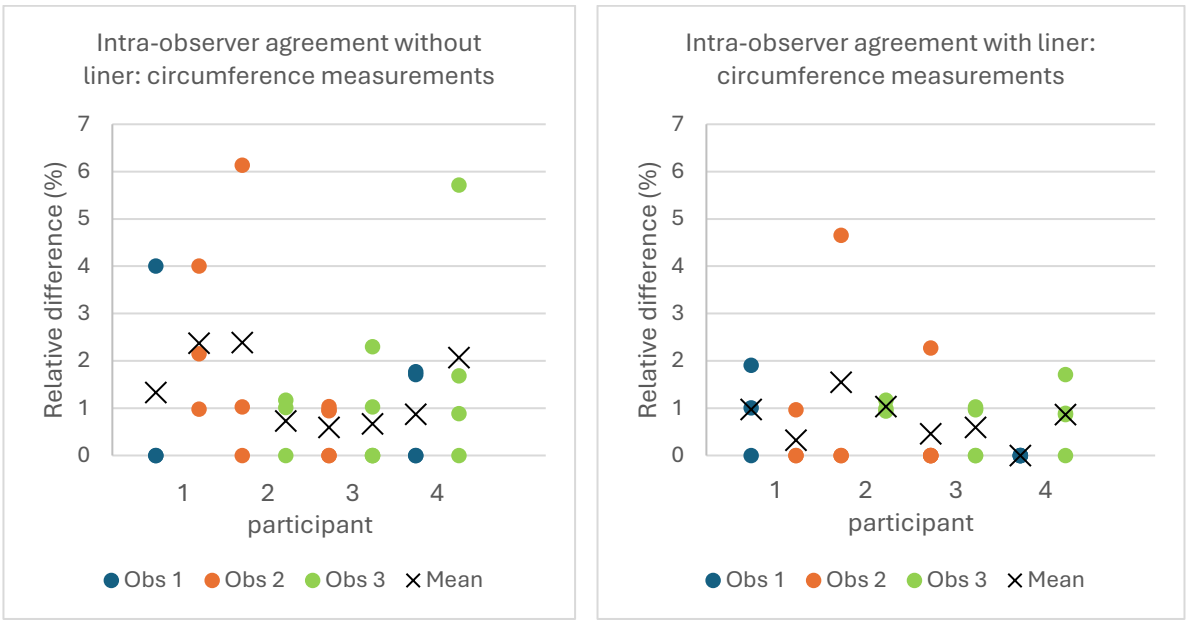
Figure 13 shows the spread of the relative differences between each measurement pair of each observer. The majority of the differences plotted in figure 13A lies under 3%, but the data shown in figure 13B remains under 2%, except for two measurement pairs of observer 2. The means of the measurements of each observer have decreased for almost sets of relative differences in the situation with liner.

Figure 14 shows the relative differences for the paired length measurements of each observer for the four participants. When the data of figures 12A and B were compared, no pattern of increase or decrease can be observed between the measurements with- and without liner.



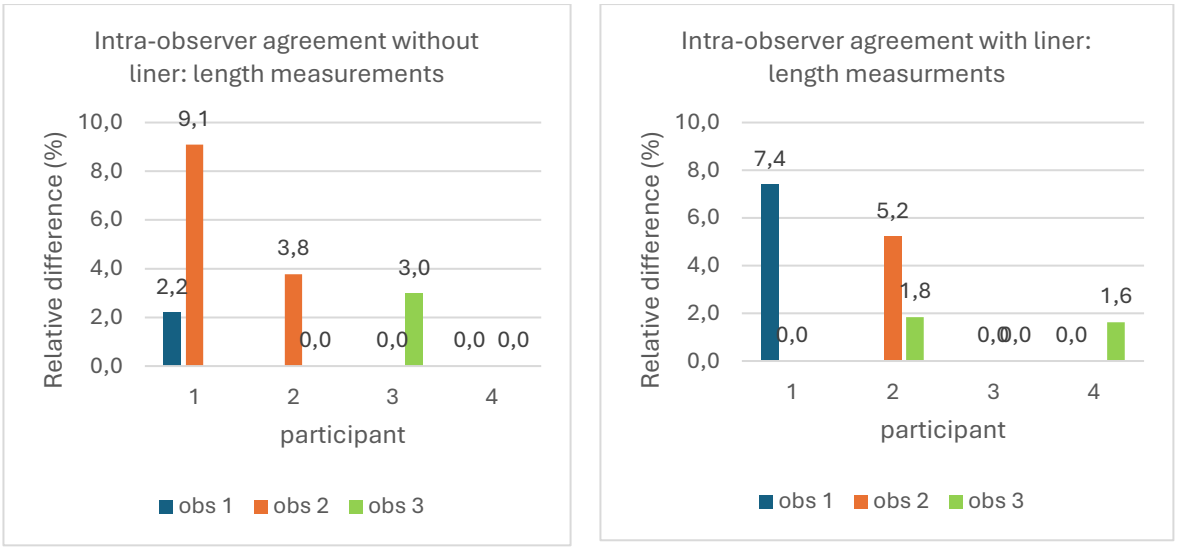
A B

***Figure 12**: Comparison of the inter-rater agreement between the situation with- and without liner by the spread of the relative differences for the circumference (A) and length (B) measurements.*



A B

***Figure 13**: Spread and mean of the relative difference of each observer for each participant, plotted for the situation without- (A) and with (B) liner. Observers 1 & 2 are prosthetists and observer 3 is a researcher of Radboudumc.*



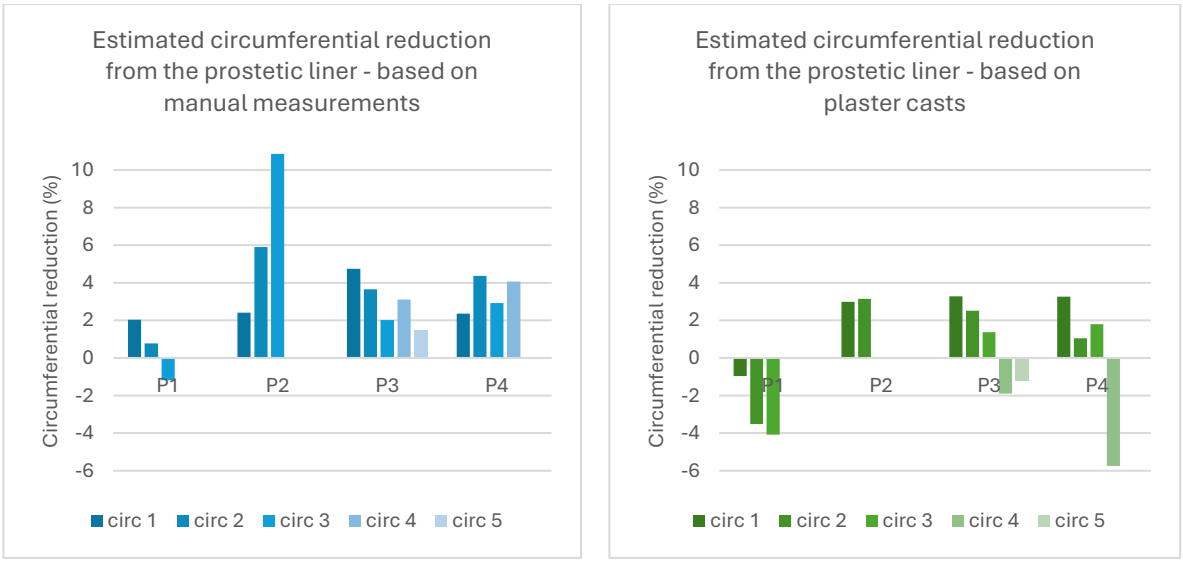
A *B*

***Figure 14**: Relative differences of the length measurements of each observer for each participant, plotted for the situation without- (A) and with (B) liner. Observers 1 & 2 are prosthetists and observer 3 is a researcher of Radboudumc.*

Comparison of residual limb volume and shape

Figures 15 and 16 provide an overview of the estimated changes in residual limb volume due to the application of the prosthetic liner. Figure 15 presents the change measured at each circumference, comparing two conditions: (A) the difference between the mean measurements taken by the prosthetists and (B) the difference between measurements obtained from the plaster casts. The y-axis in Figure 15 represents the magnitude of change, where a positive outcome indicates a reduced circumference with the liner, and a negative outcome an increased circumference with the liner. The results of the manual measurements show a reduction in the circumferences for all participants, except at the most distal point of participant 1's residual limb. The pattern of reduction differed among participants, with the largest contrast observed between the decreasing and increasing pattern of participants 1 and 2 respectively. The analysis of the plaster casts, conducted using MATLAB, showed that for participant 1, all circumferences increased when the liner was worn. Similarly, the distal circumferences of participants 3 and 4 also exhibited an increase under these conditions.

Figure 16 shows the volume difference between the two plaster casts of each participant. A negative difference implies that the volume of the plaster cast of the residual limb with liner is larger than the one without liner. The outcomes for participants 1 and 4 were negative, indicating an increased residual limb volume after application of the liner. For participants 2 and 3 a decreased residual limb volume was observed. The volume differences ranged between approximately 4 and -15%.



A *B*

***Figure 15**: Bar charts with the estimated circumferential reduction of the residual limb due to the application of the liner. A) estimation based on the difference between the manual measurements, B) estimation based on the difference between the plaster casts.*

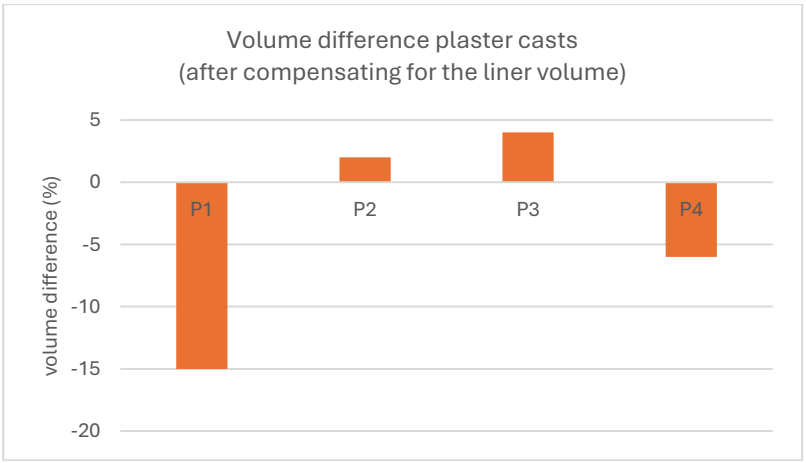


***Figure: 16**: Bar chart of the volume difference between the plaster casts of the residual limb without liner and residual limb with liner, compensated for the liner volume. A negative difference implies a larger volume of the plaster cast of the residual limb with liner, compensated for the liner.*

Figure 17 shows overlays of the outline of both plaster casts of each participant for the lateral and frontal view. The outlines of the plaster casts made while wearing the liner follow a more smoothed coarse as less unevenness is present in the shape. For participants 1, 2, and 4, noticeable differences in both volume and length are observed. However, for participant 3, the changes in volume and length are minimal. Additionally, the shape of the distal end of the plaster casts shows variability across participants.

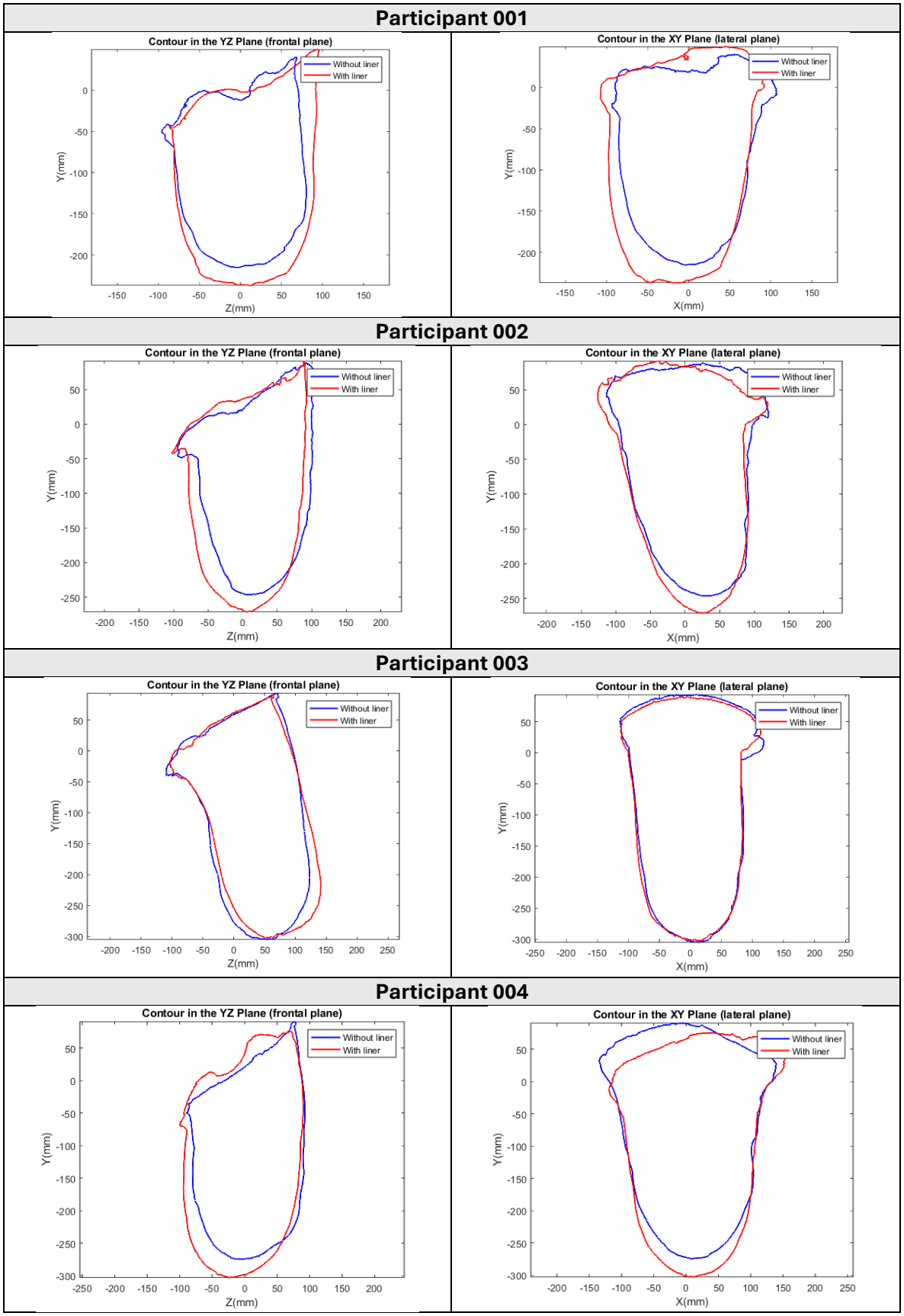


***Figure 17** : Overview of outlines of the scanned plaster casts of each participant for the frontal and lateral view. Outlines in red are the plaster cast with liner, and blue without liner.*

Discussion

The objective of this experimental study was to evaluate the effect of a prosthetic liner on the reproducibility of anthropometric length- and circumference measurements, as well as on the shape and volume of the residual limb. The study explored the added value of introducing a prosthetic liner in the residual limb measurement process applied in a LMIC setting, thereby aiming to reduce operator dependency.

Main findings

Both the inter- and intra-observer agreement of the length-measurements, expressed by the relative differences shown in figures 12B and 14, did neither increase nor decrease systematically for all participants. Additionally, for both the situation with- and without liner, high relative differences were calculated for the length-circumferences with a maximum of 9.1%. This indicated that the utilized method is prone for variation and that the tape measure may not be a suitable instrument for residual limb length.

The reproducibility of the circumference measurements was slightly increased for the situation with liner. The decreased spread and means of the relative differences of both the inter- and intra-observer agreement, shown in figures 12A and 13, point out a reduced measurement variation. This corresponds with the finding in chapter 2 that compression of the prosthetic liner could reduce the influence of the amount of force applied on the measurement tape by the observer during the circumference measurement.

The effect of the liner on the circumferences of the residual limb, estimated with the anthropometric measurements, showed a decrease of residual limb circumferences (figure 13). In the hypothesis a volume decrease was deemed as not possible because of the incompressibility of soft tissue of the residual limb. Proximal movement of the tissue during donning of the liner and by compression of the liner could be a plausible explanation for the observed decrease of the circumference. Additionally, the pattern of decrease of the circumferences from proximal to distal was not consistent between participants. This can be explained by the varying thickness, material, and usage time of the liners of the participants. In contrast with the manual measurements, an increase was measured for all circumferences of participant 1 and the most distal circumferences of participant 3 and 4 (Figure 15B). The deviating results of the plaster casts compared to the anthropometric measurements were not expected and could possibly be explained because of errors that could have occurred during the manual residual limb measurement or pre-processing of the plaster casts.

The volume differences shown in Figure 16 varied considerably between participants. While the observed decrease in residual limb volume following the application of the liner can be attributed to the proximal displacement of soft tissue, the volume increase seen in participants 1 and 4 cannot be similarly explained by the liner's effect on the residual limb. As a result, it is possible that these discrepancies were influenced by errors occurring during the measurement protocol, misalignment in the pre-processing stage, or inaccuracies in estimating the liner's volume. These potential sources of error could not be ruled out as contributors to the observed differences in volume changes.

The plotted outlines of the plaster casts provided more information on possible explanations for the previously observed differences in outlines and volumes. Figure 17 shows that mainly for participant 1,2, and 4, the plaster cast with liner is longer and wider than without liner. This provides an explanation for the increased volume of participant 1 and 4. The decreased volume for participant 2 can still be explained by the thicker liner this participant had. Apart from a smoother surface, no structural effects of the liner on the shape of the residual limb were observed. This can possibly be explained by the different liner types used and the unique characteristics of each participant's residual limb.

Comparison with literature

No studies found in the literature that compare the shape and size of the residual limb with- and without liner or asses the effect of the liner on reproducibility of the residual limb measurements. However, research is done to different techniques to conduct volume measurements of the residual limb.

In the review of Ibrahim et al [51] the use of anthropometric length- and circumference measurements for residual limb measurement was evaluated. Despite that the method emerged as a cost-effective, non-invasive, and straightforward, important limitations were described, namely its inability to accurately assess shape and volume, the potential for unreliable results and the influence of external factors on the measurement process. The discrepancies between operators and the utilisation of disparate protocols may result in unreliable measurement outcomes. Potential inaccuracies may arise due to the variability in patient positioning and the degree of compression applied by the operator to the measuring tape. These reported shortcomings make it plausible that, despite adjustments to the measurement protocol to reduce measurement error, anthropometric measurements always have some extent of bias or inaccuracy.

In the review of Ibrahim et al, plaster casting was not described as a common method to measure residual limb shape and volume. Water displacement was reported as a cost-effective, but time-consuming technique only capable of measuring the residual limb volume. Techniques that were able to measure shape and volume were contact probes, optical scanning, spiral X-ray CT, MRI, ultrasound, and laser scanning.

Limitations & recommendations

The evaluation of the effect of the liner on residual limb measurement was based on a small and non-diverse sample size of four participants. The group consisted of elderly Dutch people with ages ranging from 67 to 86 years and BMI from 24.2 to 25.9, which resulted in low activity levels and comparable residual limb characteristics. Further research should be conducted on a larger and more diverse group of participants to decrease possible influence of coincidence on study outcomes. Additionally, a larger sample size allows the use of agreement parameters like the intraclass correlation coefficient, standard error of measurement and a Bland Altman plot for limits of agreement, to calculate measurement reproducibility [52].

The prosthetic liners used in the study were the ones currently used by the participants, because purchasing a liner for each participant was too cost intensive. The liners of the participants were from different manufacturers and had their own unique specifications, such as liner thickness,

cushioning and material. This could cause differences in the distribution of forces transmitted on the residual limb between the liners of the participants, creating the probability that reproducibility of the anthropometric measurements and residual limb shape and volume is influenced differently. It is recommended to use a set of liners from the same manufacturer and with the same specifications to ensure more consistency in the protocol.

The protocol for plaster casting had several limitations. It consisted of manual steps that could cause measurement error in the volume analysis. Correct alignment of the plaster casts depended on the manual applied markings on the plaster casts by the operator, which were the location of the ischial tuberosity, and the circumference-markings lateral on the residual limb. The applied markings could displace during plaster casting due to movement of the participants ´ pantyhose or the pressure applied by the prosthetist. These factors could result in a translation and rotation error in the aligned plaster casts, making the circumferences and volumes calculated with MATLAB unreliable representations of the residual limb. Another limitation of the use of plaster casting is that the obtained plaster casts gave limited information about tissue volume proximal of the ischial tuberosity, because the lack of anatomical landmarks to compare the plaster volumes above this level. As a result, it could not be determined whether differences in the volumes of the plaster casts could be explained by the displacement of tissue proximally or by measurement error caused by incorrect alignment. For the fourth participant it was tried to mark the proximal edge of the prosthetic liner before plaster casting. However, these markings did not show through on the plaster casts because the correct pencil for the markings was not present during the measurements. A third limitation of the utilized method is that for the situation where the liner is worn the residual limb volume needs to be estimated according to the specifications of the liner. This could cause inaccuracies in the calculated residual limb volume, which creates the uncertainty whether an observed volume difference is caused by the compression of the liner or by an incorrect estimation of the liner volume.

Adaptations to the shape capturing method could be considered to overcome the limitations described for the plaster casting. The area that is casted could be extended to the pelvis of the participant to gather more proximal data of the residual limb. However, still inaccuracies in the alignment of the plaster casts could occur because of the movement of the markers and the application of a varying amount of pressure by the operator. With optical 3D scanning, displacement of markers will not occur, because no contact is made with the residual limb during data collection. 3D scanning still has disadvantages considering the inability to fully map the groin area, which results in a lack of proximal data, and that the liner volume still needs to be estimated. Also, water displacement, which was described as an accurate technique to measure volume differences by Ibrahim et al, is not able to measure proximal of the groin area [51]. However, the method could be an option to calculate the volume of the liner. A combination of optical 3D scanning and water displacement could therefore be considered to evaluate the effect on the liner on the shape and volume of distal residual limb. With this method, there is less chance of measurement error, and it can be determined with more certainty whether a volume change has occurred. However, it does not provide a definitive answer as to whether the volume change was caused by compression or moving the tissue proximally.

Most of the outliers in the results of the anthropometric measurements were caused by large differences between the length measurements. A tool commonly used by prosthetists which

might decrease the variation of these measurements is a transfemoral length gauge (Fillauer, Chattanooga, US). The gauge consists of a calliper which shape matches the distal end of the residual limb and a tip. The tip of the gauge is placed against the ischial tuberosity, while the calliper is shifted to the distal end. Because the calliper can be fixed, it is affected less by the operator. In addition, the fixation of the calliper enables rotation of the gauge to the lateral side to mark the height of the tuber and the location of the circumference measurements. The length gauge was ordered by the prosthetist affiliated with the Radboudumc (Papenburg Orthopedie). However, due to manufacturing delay, the length gauge was not delivered in time for the measurements. If the study is repeated it should be evaluated if less outliers are present when residual limb length is measured with the TF length gauge.

Clinical relevance & future perspective

Given that variability in anthropometric residual limb measurements was observed independent from the circumstances, it would be advantageous to take two measurements per patient when applying the measurement method in an LMIC setting. The average of these measurements could then be used for the design of the TF socket. Additionally, having two observers perform the measurements could further reduce variability, although this approach would necessitate the training and availability of additional local staff. Moreover, this method is more time-consuming, potentially prolonging the overall manufacturing process.

The next step of evaluating the added value of the prosthetic liner to the manufacturing process is to research whether the measurements taken with liner result in a socket design that suffices for application in a LMIC setting. In a subsequent study, designs are tested that implement the suggestions regarding socket design presented in Chapter II, and compare sockets based on measurements with and without liner.

Conclusion

In summary, introduction of a prosthetic liner to the process of anthropometric measurement showed an increased inter- and intra-observer agreement for circumference measurements of the residual limb. However, because of the small sample size these results could not be generalized to draw a firm conclusion. Additionally, no consistent effect of the prosthetic liner on residual limb shape and volume was observed. It could not be ruled out that this result was caused by multiple limitations of the used study protocol. Future research should therefore include a large and diverse group of participants as well as a less operator dependent shape and volume measurement method.

Chapter IV – Socket design: evaluating adjustments to the socket volume

Introduction

In the previous chapter, it was discussed that research is needed to how manual measurements taken with a liner can be translated into an appropriate socket design suitable for LMICs, where the wearing of a liner during prosthesis use is not feasible. Since the focus of this thesis is on socket volume, this chapter will concentrate on the design of the socket volume. Based on the recommendations from the interviews, the design can already be partially specified. First, it was recommended not to deviate from the hybrid socket type used in prior research. Additionally, it was suggested to narrow the mediolateral (ML) dimension of the socket volume. However, it remains unclear to what extent this narrowing should be applied to achieve the optimal cross-sectional shape of the socket volume.

What needs to be clarified is whether the measurements with the liner, obtained in the previous chapter, can be used to design a socket that yields a comparable or better result than one based on measurements taken directly over the skin. Furthermore, the impact of the narrowed ML dimension on the fit and comfort of the socket must be examined. To address these issues, the following two research questions have been formulated:

1. How do patients with a transfemoral amputation and a prosthetist rate the comfort and fit of a hybrid transfemoral prosthetic socket worn without a liner and with Silesian belt suspension, designed based on anthropometric measurements with a liner, compared to a prosthetic socket designed based on measurements without a liner?
2. To what extent does a narrow mediolateral cross-section of the distal part of the transfemoral prosthetic socket affect socket comfort and fit?

The study's hypotheses are as follows:

- As found in Part II of the thesis, the use of a liner during residual limb measurement had a varying effect on the circumference measurements, when compared for the manual measurement and the plaster casts (Figure 15). However, when only the manual measurements are considered, because it was likely that outcomes of the plaster casts were influenced by errors of the protocol, a reducing effect was found. Decreased circumferences will result in a smaller socket volume and consequently a tighter socket fit. A tighter fit may improve suspension but could potentially reduce comfort because of the increased compression of the residual limb.
- Drawing on prosthetists' experience and the literature, it is hypothesized that a narrow mediolateral cross-section of the distal socket enhances prosthesis stability and control, thereby improving socket fit. However, this design may increase pressure on the medial and lateral aspects of the residual limb, potentially leading to discomfort in these regions.

Method

Prior to commencement, the research protocol (file: 2024-17283) was reviewed by the medical ethics review committee Oost-Nederland and ethical approval was obtained on May 13, 2024.

Study design

In this study the effect of adjustments to the measurement and design process of the TF prosthetic sockets was evaluated for both socket comfort and fit. It was therefore an explorative study design.

Participants

Potential participants for the study were the participants measured in the previous study, as the residual limb measurements needed for the socket design were already obtained during the measurement session. Exclusion criteria were a K-level below 2, complaints of the stump or other health issues that limit the mobility of the participants.

Data collection

During the fitting session, the sockets were reviewed by both the participant and the prosthetist using individual questionnaires (Appendices H & I). To assess the perceived socket comfort by the participant, the socket comfort score (SCS) was used [53]. The SCS is a 11-point scale where 0 represents the most uncomfortable and 10 the most comfortable socket imaginable. Subsequent to the SCS, a report was used to assess the level and type and location of discomfort [54]. The level of discomfort was scored with a 11-point scale where 0 represents the most discomfort imaginable and 10 no discomfort. The type of discomfort was categorized into three groups: friction between the residual limb and the socket, specific pressure point, and pain spread out over an area. The participant pinpointed the location of the discomfort experienced in schematic images of the residual limb containing, the frontal, dorsal, medial and lateral view.

Socket fit was evaluated by both the participant and the prosthetist with open ended questions for specific aspects of the socket: the brim, socket volume, and distal end. To quantify socket fit, displacement of the socket in four directions (medial, lateral, anterior, posterior) was measured with a displacement test (Figure 18) [12]. The socket fit is considered too wide when the displacement is more than 0.5 inch (app.1.3cm). Vertical displacement is measured between loading and off-loading of the socket.

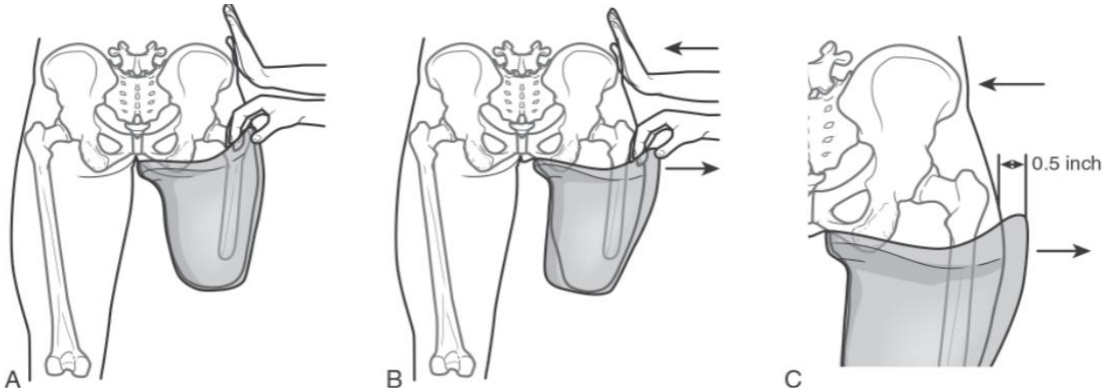


***Figure 18**: Evaluation of the lateral displacement of the socket* [12]. *A) Two hands are used, one is positioned on the iliac crest for stabilization, and one grasps the lateral edge of the socket. B) Both hands are used to give counterpressure to pull the socket laterally. C) The amount of displacement is measured as the distance between the skin and the socket of the participant.*

Procedure

Measurement of current prosthesis

For the design of the socket, the collected manual residual limb measurements of the participants from the study in chapter II were used. The shape, length and orientation of the current socket were collected as well and used in the design process. For the determination of the shape of the brim, an optical handheld 3D scanner (Einscan H2, Shining 3D, Hangzhou, China) was used to scan the texture of the current socket of the participant. Measurement tape was used to measure the length of the socket. The socket length was defined as the distance between the contact point of the ischial tuberosity with the tuber support and the adapter that connects the socket with the prosthetic knee. The orientation of the prosthetic socket was determined in relation to the adapter using a protractor in the frontal and sagittal planes.

Socket design

In this study both the effect of the wearing of a liner and the amount of narrowing of the ML dimension on the fit of the socket was explored. Therefore, different sockets were designed and printed for the participant. Because the investment of time by the participant and prosthetist needed to be reasonable, only a limited amount of designs was tested. Four TF sockets were designed, two are based on the manual measurements with liner and two on the measurements without liner. These manual measurements were the average of all length- and circumference measurements obtained in part II. In addition, both socket duos differed from each other in ML diameter. The amount of narrowing was either a 5% or 10% reduction of the ML diameter of the socket volume. This gives the following variations:

- Socket based on measurements without liner + 5% ML narrowing
- Socket based on measurements without liner + 10% ML narrowing
- Socket based on measurements with liner + 5% ML narrowing
- Socket based on measurements with liner + 10% ML narrowing

The socket design process consisted of four steps which are highlighted below. An overview of the process is given in Figure 19.

Step 1, brim: Instead of the standardised brim set that is developed in the previous study, the design of the brim of the sockets was the same as the brim of the current socket of the participant [35]. The brim was designed by processing an optical 3D scan of the current socket in Meshmixer. The brim was given a thickness of 4.8 mm, which was also used in the previous studies [34, 35].

Step 2, socket volume: The Socket volume was designed with circular rings, which represent the in part II obtained circumference measurements, and a dome-shaped distal end. The objects were loaded in the same workspace as the brim. The rings were positioned distal from the brim at an interval of 5 cm starting from the tuber support. The distal end was positioned distal from the tuber support at a distance that corresponds with the in part II measured residual limb length. The objects were scaled to the desired shape of the socket volume, depending on the socket design variation that is chosen. The ML and AP dimensions of each object were calculated with the following steps:

1. The diameter and the area of the circumference measurements were calculated. If the measurements of the residual limb with the liner were used, the liner thickness was

subtracted from the calculated diameter before the area was calculated. The diameter was divided by either 1,05 or 1,10 depending on the amount of ML narrowing that was used. The diameter of the AP dimension was then calculated with Formula 3 to calculate the surface of an oval to ensure an equal volume despite the different amount of ML narrowing:

Formula 3: $Area = \pi * APradius * MLradius \rightarrow APdiameter = 2 * \frac{Area}{\pi * MLradius}$

2. Both dimensions were reduced with the reduction percentage that corresponds with the reduction profile, which runs from 5% for the first ring distal from the brim to 1% to the distal end.
3. The dome-shaped distal end could not be scaled to a circumference measurement, as no measurement is taken at the distal end of the residual limb. The dimensions of the object were estimated by extrapolating the narrowing of the socket for both the ML and AP dimension.

After scaling, all objects were connected to create the socket volume and a thickness of 4.8 mm is applied. The socket volume was connected with the brim to form the total socket.

Step 3 Alignment and inserts plate: The insert plate formed the bottom of the socket and consisted of several inserts to which the adapter could be attached. The insert plate was positioned distal to the socket at the predetermined distance from the tuber support. The socket was then set in the correct orientation relative to the insert plate by rotating with the pre-measured angles in the frontal and sagittal planes. After rotation, the insert plate and the socket were connected and rotated back into the original orientation.

Step 4, donning sleeve and connection method: At the medio-anterior aspect of the distal socket volume, a hole with a diameter of 30 mm was created in the socket wall to pull the donning sleeve through. The sockets were printed with an Ultimaker S5 3D printer, with printing dimensions of 33x24x30 cm. If the socket exceded these dimensions, the socket was split into two segments, and a connection method was added to join the segments. The connection method used was largely the same as the method developed in one of the earlier studies, but with some modifications that enabled continuation of the conical shape of the socket [34].

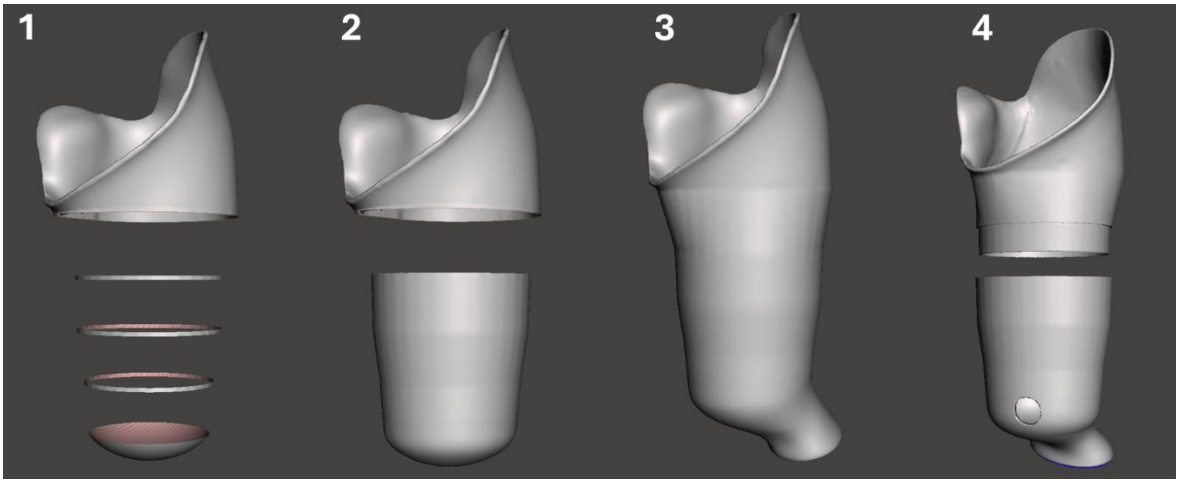


Figure 19: *Steps taken to digitally transform the 3D scan of the brim and the anthropometric measurements into the hybrid TF socket design using Meshmixer.*

Socket manufacturing

The 3D files of the sockets were loaded into the open-source 3D-printer slicing software of Cura (Ultimaker BV, Geldermanlsen, the Netherlands), that creates printable files (g-code). The sockets were 3D-printed with an Ultimaker S5 printer located at Radboudumc. Tough poly Lactic Acid (PLA) from Ultimaker BV was used as print material, and the Fused Filament Fabrication (FFF) modelling technique was used for printing [55]. For the printing process, a 0.8mm print core was used with a layer thickness of 0.2mm, a print speed of 100 mm/sec and an infill of 100%.

Coupling up the prosthesis

The prosthesis consisted of the following parts: the silesian belt, the 3D printed socket, the knee, tube connector, and prosthetic foot of the current prosthesis of the participant (Figure 20). The design of the silesian belt was according to the previous developed silesian belt suspension system that was tested in Sierra Leone [35].

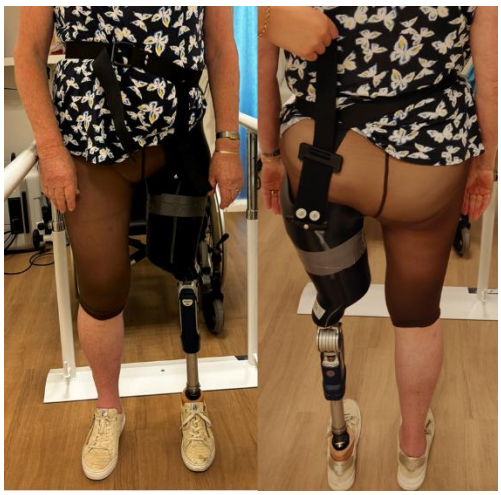


***Figure 20**: The transfemoral prosthesis consisting of the silesian belt suspension, 3D printed socket, and the prosthetic knee as well as the foot of the current prosthesis.*

Fitting assessment

During the fitting session, the fit of the four 3Dprinted sockets was assessed by both the prosthetist and the participant, and the comfort of the socket was assessed by the participant alone. The current socket is also assessed by the participant. The fitting session consisted of six different steps (Figure 21).

Step 1, preparation of the prosthesis: The prosthesis was prepared by removal of the current socket and replacement with one of the 3D-printed prosthetic sockets (Figure 21A). The Silesian belt system was attached to the socket.

Step 2, donning of the prosthesis: The participant was wearing a pantyhose that was shortened at the side of the residual limb to prevent friction between the socket and the skin (Figure 21B). The donning sleeve was pushed over the residual limb and placed in the socket. The socket was donned by pulling the sleeve through the hole in the medio-anterior aspect of the distal socket.

Step 3, safety check by the prosthetist: The participant stood upright in the walking bridge, with support from the horizontal bars (Figure 21C). The prosthetist assessed whether the prosthetic socket provides sufficient stability to safely use the prosthesis. If the socket was approved, the participant was asked to stand upright without leaning on the horizontal bars of the walking bridge. Also, for this situation, the prosthetist assessed if the prosthesis was safe to use.

Step 4, fitting evaluation: The participant was instructed to walk for 2 minutes in the walking bridge (Figure 21D). The exercises were performed under the guidance of the prosthetist and the researcher. After the walking and standing, the prosthetist assessed the fit of the prosthetic socket with the custom-designed questionnaire (Appendix I).

Step 5, displacement tests: The socket displacement was measured in lateral, medial, anterior, and posterior direction with the beforementioned socket displacement test [12]. During the measurements, the participant was standing upright on both the prosthetic and non-prosthetic leg, with support of the horizontal bars of the walking bridge. The vertical displacement was measured after the participant lifted the prosthetic leg and thereby off-loading of the prosthesis. The observations were collected with the questionnaire (Appendix I).

Step 6, pain and comfort evaluation: At last, the custom designed participant questionnaire was administered to the participant to assess the comfort and fit of the socket (Appendix H). Simultaneously, the prosthetist switched the tested socket for one of the other 3D-printed sockets.

***Figure 21A**: preparation of the prosthesis, by replacing the socket with the 3D printed socket, and attachment of the silesian belt.*

***Figure 21B**: donning of the prosthesis by pulling the donning sleeve (blue) through the distal hole in the socket.*

***Figure 21C**: Safety check by the prosthetist; the participant first stands with support of the parallel bars, if safe standing without support is permitted.*

***Figure 21D**: Fitting evaluation by doing a walking exercise in the parallel bars, with supervision of two prosthetists.*

Data analysis

After testing, the socket comfort and discomfort scores, as well as the assessment of the socket fit of the participant were compared among the different 3D-printed sockets. Additionally, the findings of the prosthetist with respect to the socket fit were evaluated for all sockets. Subsequently, differences between the findings of the participant and the prosthetist were identified to check for agreement between both. At last, correspondence between the socket displacement tests and the other assessments was evaluated. The results of the displacement test were interpreted as follows: a displacement of more than 1.3 cm (0.5 inches) indicated a socket that is too wide, and a displacement of less than 1 cm indicates a socket that is too tight [12].

Results

out of the participants of the previous study one participant emerged as most suitable to conduct the tests with. This was participant 3 of the previous study. The participant used a Proseal SIL liner (Ottobock SE & Co. KGaA, Duderstadt, Germany), with a uniform thickness of 3 mm. The averages of the circumference measurements with and without liner differed with the measurements with liner being smaller (Table 5). Therefore, the socket volume of the sockets based on the measurements with liner was smaller compared to the volume of the sockets based on the measurements without liner. This was caused by an initial reduction of the liner for each circumference ranging from 4,7 – 1,4%.

***Table 5**: Mean of the four observations collected in chapter III, calculated at each circumference level for both the situation with- and without liner. The reduction is the percentual difference between both means.*

	circ-1	circ-2	circ-3	circ-4	circ-5
Circumference without liner (mm)	529	516	503	485	430
Circumference with liner (mm)	504	497	492	470	424
Reduction (%)	4,7	3,7	2,2	3,1	1,4

The results of the answered questionnaire by the participant and prosthetist during the session are presented in Table 6 and 7 respectively. Further explanation of the answers can be found in a more detailed table in Appendix J. The first socket was assessed as the poorest design, which manifested as such an amount of pain distal on the residual limb and in the groin area that the participant was unable to walk with the prosthesis. The complaints of discomfort persisted for the other sockets but were less prominent. For socket 2 & 3, the discomfort limited the participant in such a manner that the designs were unsuitable for daily use. For the fourth socket, still some pain and pressure were experienced, but did not limit the participant in walking in the horizontal bars. The assessed comfort during standing and walking was even high as the current socket of the participant. Both the participant and the prosthetist scored the fourth design as the best 3D printed socket.

Table 6: Overview of the answers of the participant for each socket. For the evaluation of the stability and fit of the socket, the participant could choose between bad, insufficient, fair, good, and excellent.

Review by participant	**Socket 1** ***Without liner-5%***	**Socket 2** **Without liner -10%**	**Socket 3** **With liner-5%**	**Socket 4** **With liner-10%**	**Own socket**
Comfort when standing	*6*	*8*	*6*	*9*	*9*
Comfort when walking	*4*	*6*	*6*	*9*	*9*
Discomfort	*4*	*6*	*6*	*8*	*10*
Pain/unease nature	*Pressure point + pain*	*Pressure point + pain*	*Pressure point + pain*	*Pressure point + pain*	-
Pain/unease localisation	*Scar + groin*	*Scar*	*Scar*	*Scar*	-
Stability when standing	*Good*	*Good*	*Good*	*Good*	*Excellent*
Stability when walking	*Insufficient*	*Good*	*Fair*	*Excellent*	*Excellent*
Fit of the brim	*Fair*	*Good*	*Fair*	*Good*	*Excellent*
Fit of the socket volume	*Good*	*Good*	*Fair*	*Good*	*Excellent*
Fit of the distal end	*Good*	*Good*	*Fair*	*Good*	*Excellent*
Difficulty of donning	*None*	*Less than normal*	*Normal*	*More than normal*	*Normal*
Energy/power expenditure	-*	*Normal*	*Normal*	*Normal*	*Normal*

*Note: * Due to the severe discomfort, the first design was unsuitable for walking.*

Table 7: Overview of the answers of the prosthetist for each socket. For subject 1 – 6, the prosthetist could choose between bad, insufficient, fair, good, and excellent to review the prosthesis

Review by prosthetist	**Socket 1** ***Without liner-5%***	**Socket 2** ***Without liner-10%***	**Socket 3** ***With liner-5%***	**Socket 4** ***With liner-10%***
Stability when standing	*Good*	*Good*	*Good*	*Excellent*
Stability when walking	*Good*	*Good*	*Good*	*Excellent*
Suspension	*Fair*	*Fair*	*Fair*	*Good*
Fit of the brim	*Good*	*Good*	*Good*	*Good*
Fit of the socket volume	*Fair*	*Good*	*Fair*	*Good*
Fit of the distal end	*Fair*	*Fair*	*Fair*	*Good*
Possible adjustments	*Tightening + lengthening socket volume*	*Lengthening socket volume*	*Lengthening socket volume*	*Making space at femoral end laterally*

The displacements of the sockets are plotted in the bar chart in Figure 22. Displacement of the sockets in lateral, medial, anterior and posterior direction were comparable between different socket designs. Largest differences were observed for the vertical displacement and the smallest overall and vertical displacement in socket 4.

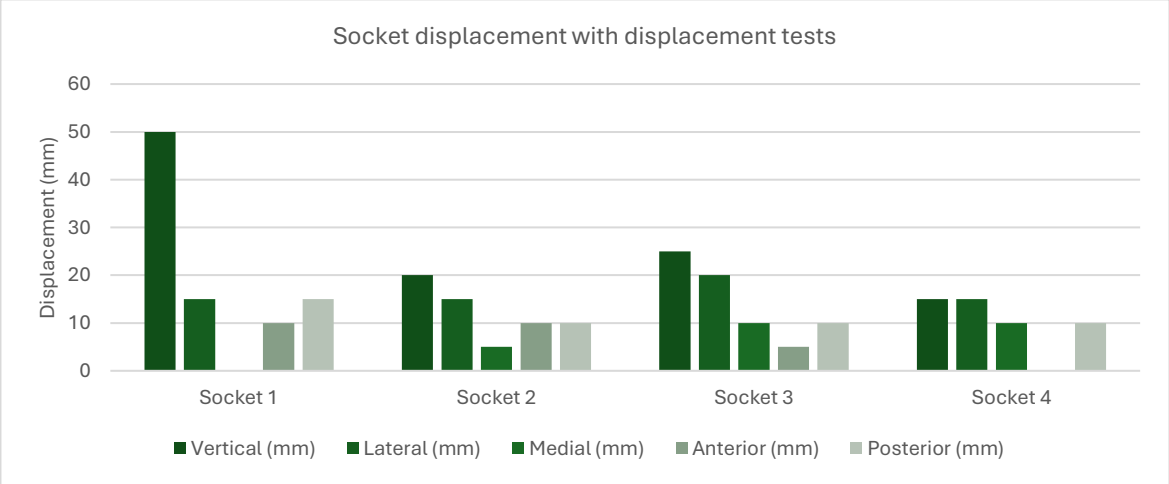


***Figure 22**: Outcomes of the socket displacement test for each socket.*

Discussion

In this study two kinds of variation in TF prosthetic socket design were evaluated: 1) a design based on either anthropometric measurement taken while wearing a prosthetic liner, or without wearing a prosthetic liner. 2) a design with either a narrowing of 5% or 10% of the ML dimension, creating an oval cross section of the socket volume. This resulted in four socket designs tested for one participant during a single fitting session, during which socket comfort as well as socket fit was evaluated by the participant and socket fit by a prosthetist. The design based on measurement while wearing the prosthetic liner and a narrowing of 10% was assessed as the best design by both the participant and the prosthetist.

Main findings

The results for the sockets based on the measurement with liner were better assessed by both the participant and the prosthetist. These sockets had a decreased socket volume because of the smaller measured circumferences obtained in the previous chapter. It was expected that the decrease of the socket volume resulted in an improved socket fit, as more compression is related to better stability and functionality of the socket. However, overachieving of the compression by the socket can cause problems with donning of the socket and a decrease in socket comfort. Except for an increased effort in donning of the last socket, these effects were not observed during the fitting session.

The improved assessment by the participant of both sockets with 10% ML narrowing relative to the sockets with 5% narrowing, was opposite to the hypothesis that an increased ML pressure could lead to discomfort in the compressed areas. The same phenomenon was observed for the evaluation of the prosthetist, but these outcomes show only an improvement between sockets 3 & 4. These results are a sign that a high amount of ML compression is positively assessed by the user and allowed by high deformability of soft tissue of the residual limb. In addition, the results confirm that socket fit and comfort are influenced by both volume and shape.

The complaints of discomfort at the distal tip of the residual limb could be caused by two things, the socket being too wide or too short. If the socket is too wide, the socket volume needs to be comprised. This causes an upward shift of the residual limb in the socket, preventing contact between the distal end of the socket and the residual limb. If socket fit is correct, but discomfort is still present, the length of the socket needs to be increased. For socket one, two, and three, both adjustments could be applied to increase socket fit. In socket four, only the socket length should be increased as the fit was positively assessed. Increasing of the length of the socket, was not a common practice of the previously interviewed prosthetists. However, in the setting of the fitting session, a liner was not used. The complaints at the distal end could be explained by a lack of cushioning of a liner and the difference in donning of the prosthesis. When a liner is worn, the residual limb is pushed in the socket, which can cause a proximal shift of soft tissue. With the donning sack, the soft tissue of the residual limb is pulled distally in the socket, which could explain the high loading of the distal end of the residual limb.

The results of the ML and AP displacement tests were consistent across different sockets but did not align with the participants' or prosthetists' assessments of socket fit and comfort. In contrast, the outcomes of the vertical displacement tests showed better correspondence with the feedback from both the participants and the prosthetists. While ML and AP displacements were

generally low, the vertical displacement was notably higher, which could suggest that the suspension of the socket may be inadequate, leading to greater vertical movement during use. Despite the simplicity and ease of execution of these tests, they are susceptible to variation, particularly in the amount of force applied by the person conducting the test, which may differ between executors. Overall, the added value of these displacement tests as a simple tool for evaluating socket fit remains unproven.

Limitations & recommendations

The 3D printed sockets were tested during a short time frame, which affects reliability of the assessment. For a better understanding of the comfort and fit of the socket, the participant is followed over a longer amount of time, ranging from multiple days to a week. In this manner, the participant has time to get used to the new socket and can test if the socket allows to perform daily tasks. On the other hand, with this study being an explorative study and clear design flaws directly emerged from the tests, long period testing should be applied after adaptations have been made to the design of the socket.

Additionally, the current socket was only used as a reference for the comparison with the 3D printed sockets during the assessment by the participant. Socket fit was not evaluated by the prosthetist and displacement was not measured for the current socket of the participant. This limits interpretation of the results as the performance of the 3D printed sockets cannot be compared with a reference. However, it is arguable how comparable the current socket is for the displacement tests, because it utilized vacuum suspension. The negative pressure of the vacuum could decrease displacement of the socket compared to the pulling forces of the silesian belt.

The assessment of the sockets by the participant could be influenced by habituation to the 3D printed socket designs. The material, shape and volume of the 3D printed sockets differed significantly from the current socket of the participant. This could cause a ´shock effect´ for the first socket that was tested, because of the large change with the normal situation of the participant. The sockets that were tested afterwards were comparable in shape and volume, except for the adjustments, to which the residual limb can adapt over time. The study protocol could be adjusted to prevent the habituation effect from happening by testing the first two sockets again at the end of the session. However, it should be noted that this enlengthens the protocol and therefore asks more effort of the participant.

In future research the design of the TF prosthetic socket should be evaluated with more participants to test whether the design is applicable for different individuals with varying residual limb characteristics. The prosthetic components used during the testing of the socket should be consistent for all participants. If measurements are taken while the participants wear a prosthetic liner, the type of liner should be the same for all individuals.

Clinical relevance

The findings of this study suggested several important adjustments to the existing prosthetic socket design method previously tested in Sierra Leone, with the goal of enhancing its effectiveness in low- and middle-income country settings. The introduction of an oval socket shape with a narrowed ML dimension has demonstrated a positive effect on socket fit and stability. Additionally, the increased reduction resulting from the use of a liner during residual limb

measurement indicates a potential for improved suspension through a tighter socket fit. However, before implementing liners more broadly, further research is needed to assess whether this higher reduction profile indeed enhances socket fit or that the positive results of this study were influenced by the specific characteristics of the participant. An additional recommended modification is to increase the length of the socket, which may increase comfort.

In terms of evaluating socket fit, only the vertical displacements agreed with the assessment of the prosthetist and the participant. The other displacements did not indicate the same outcome of the assessments regarding socket fit. It is therefore questionable if the displacement measurements are an added value for the evaluation of the socket design in LMICs.

Conclusion

In this study, four prosthetic sockets were designed based on anthropometric measurements taken either with or without a liner worn over the residual limb. Additionally, the sockets varied in the degree of mediolateral (ML) narrowing within the cross-sectional volume. The results indicated that sockets designed using measurements taken with a liner were associated with better perceived comfort and fit compared to those designed without a liner. Furthermore, an increased degree of ML narrowing was correlated with higher levels of perceived comfort and fit. However, due to the exploratory nature of this study and the inclusion of only a single participant, these findings cannot be generalized. Future research should validate these design recommendations with a larger sample size and an extended period of socket testing.

Chapter V General discussion

This thesis emerged from previous research of the 3D Sierra Leone project and addresses two problems: 1) a knowledge gap regarding measurement and design of the TF socket volume, and 2) the uncertainty of if current utilised residual limb measurement method is reproducible. The aim of the thesis is therefore to explore possibilities for further standardisation of the measurement and design method of the TF socket volume, to enhance their application in LMIC settings.

The explorative study (Chapter II) mapping the methodologies of the prosthetists confirmed the variety that exist between prosthetists. It also showed that for the manufacturing process of the TF socket manual methods remain dominant, but that no guideline exists on how to execute them. The study therefore tried to evaluate which characteristics influence the design of the socket. Although it was showed that different residual limb and patient characteristics highly influenced the socket design, a quantitative expression of the relationship between each characteristic and the socket remains unknown. Nevertheless, four general suggestions emerged from the interviews regarding the measurement and design of the socket volume in a LMIC setting: 1) Use of the ischial tuberosity as marker for the anthropometric length- and circumference measurements, 2) evaluate if residual limb measurement reproducibility improves due to the usage of a prosthetic liner, 3) the hybrid socket was best applicable on a diverse patient group and required less knowledge and measurements compared to other socket types, and 4) narrow the ML dimension of the socket volume of the hybrid socket.

In the second study (Chapter III) of this thesis, the effect of the prosthetic liner on measurement reproducibility and on shape as well as the volume of the residual limb was evaluated with an experimental study. For the small non diverse sample used in the study, the liner improved measurement reproducibility observed with an increased inter- and intra-observer agreement. Based on varying results between the participants, the study could not find a consistent effect of the liner on residual limb shape and volume. Because of the small sample size, the study cannot give a firm judgement about the added value of a prosthetic liner on the measurement process as the results could not be generalized. Furthermore, the used measurement protocol with plaster casting had a high risk of measurement errors due to the large number of manual operations that were requested from the operator.

In the third study, for one participant it was evaluated if 3D-printed sockets based on measurements with liner, achieve good socket fit and comfort when the socket is used without liner. Besides evaluation of the potential to use the measurements with liner, the socket design was evaluated for two degrees of ML narrowing. Both assessment of the participant and the prosthetist showed best results for the socket based on the measurement with liner and most narrow ML dimension, which could be interpreted that increased compression of the socket volume, caused by an increased reduction profile and ML narrowing of the cross section have positive effect on socket fit and comfort. Yet it needs to be considered that these findings are funded on evaluation of a single participant and could be influenced by individual patient and residual limb characteristics. The result can therefore only be considered as a positive indication of the possibility of designing a socket based on measurements with liner applied in an LMIC setting.

Future work should focus on quantifying the relationship between specific characteristics of the residual limb and the design of the prosthetic socket, as this was not achieved in the current study. This could be achieved by comparison of 3D shapes of the residual limb volume with the corresponding shape of the interior of the hybrid socket. To demonstrate and quantify relationships between characteristics and socket design, gathering of a large dataset from is essential. This research should answer the crucial question whether socket design solely depends on anthropometric measurements or whether specific patient characteristics, such as the amount of soft tissue, must be considered to create a more patient-specific socket. If specific characteristics emerge, a thorough classification method for these characteristics is needed to integrate them in the residual limb measurement process. If future research successfully quantifies the relationships between socket design and specific characteristics, and develops an adequate classification method, the next step should be the integration of the findings in software that automates the design process. This would streamline the manufacturing of transfemoral sockets through standardised residual limb measurement and automated socket design.

The results regarding the effect of the liner observed in this study could be positive indication of its added value to the measurement process. However, the small sample sizes, plausibility of measurement error, and high costs associated with the liners ere limitations that need to be overcome. To justify the investment in prosthetic liners for use in LMIC settings, further research with a larger and more diverse sample is needed to evaluate the effect of the liner on the measurement reproducibility and to determine whether its introduction adds value to the measurement process. Another future direction is testing executability of the adjusted method for manual measurement by local staff in Sierra Leone. The utilization of the ischial tuberosity as anatomical landmark for the length- and circumference measurements was reported as a simple operation by the Dutch prosthetists. However, it is not tested how well the adjusted measurement method can be executed by local staff that had limited educational training.

In conclusion, the exploratory research presented in this thesis highlights the lack of a widely adopted guideline for translating residual limb measurements into the design of transfemoral prosthetic sockets and emphasizes the need for quantitative volumetric data collection to standardize this process. The findings regarding the use of a liner suggest a positive potential for improving measurement reproducibility in LMIC settings. However, due to the limitations of the studies, a definitive conclusion cannot be drawn. Additionally, the work has provided important insights about the complexity of transfemoral socket manufacture process and taught valuable lessons regarding the direction of future research to the effect of the prosthetic liner.

References

1. Organization, W. Health., World Health Organization, ., & World Bank, . (2011). *World Report on Disability 2011*. World Health Organization.
2. McDonald, C. L., Westcott-Mccoy, S., Weaver, M. R., Haagsma, J., & Kartin, D. (2021). Global prevalence of traumatic non-fatal limb amputation. *Prosthetics and Orthotics International*, *45*(2), 105–114. https://doi.org/10.1177/0309364620972258/ASSET/IMAGES/LARGE/10.1177_0309364620972258-FIG5.JPEG
3. *UNDP (United Nations Development Programme). 2024. Human Development Report 2023-24: Breaking the gridlock: Reimagining cooperation in a polarized world. New York.* (n.d.).
4. *Sierra Leone 2015 Population and Housing Census Thematic Report on DISABILITY i*. (n.d.).
5. Allen, A. P. T., Bolton, W. S., Jalloh, M. B., Halpin, S. J., Jayne, D. G., & Scott, J. D. A. (2020). Barriers to accessing and providing rehabilitation after a lower limb amputation in Sierra Leone–a multidisciplinary patient and service provider perspective. *Disability and Rehabilitation*, *0*(0), 1–8. https://doi.org/10.1080/09638288.2020.1836043
6. Yilmaz, M., Gulabi, D., Kaya, I., Bayram, E., & Cecen, G. S. (2016). The effect of amputation level and age on outcome: an analysis of 135 amputees. *European Journal of Orthopaedic Surgery and Traumatology*, *26*(1), 107–112. https://doi.org/10.1007/s00590-015-1709-z
7. Migaou, H., Kalai, A., Hassine, Y. H., Jellad, A., Boudokhane, S., & Salah Frih, Z. Ben. (2019). Quality of Life Associated Factors in a North African Sample of Lower Limbs Amputees. *Annals of Rehabilitation Medicine*, *43*(3), 321. https://doi.org/10.5535/ARM.2019.43.3.321
8. MEDBOX | Standards for Prosthetics and Orthotics Service Provision. 2015-2017… (n.d.). Retrieved March 6, 2023, from https://www.medbox.org/document/standards-for-prosthetics-and-orthotics-service-provision-2015-2017-work-plan#GO
9. Murray, C. D., & Fox, J. (2002). Body image and prosthesis satisfaction in the lower limb amputee. *Disability and Rehabilitation*, *24*(17), 925–931. https://doi.org/10.1080/09638280210150014
10. Esquenazi, A. (2004). Amputation rehabilitation and prosthetic restoration. From surgery to community reintegration. *Disability and Rehabilitation*, *26*(14–15), 831–836. https://doi.org/10.1080/09638280410001708850
11. van der Stelt, M., Verhulst, A. C., Vas Nunes, J. H., Koroma, T. A. R., Nolet, W. W. E., Slump, C. H., … Brouwers, L. (2020). Improving Lives in Three Dimensions: The Feasibility of 3D Printing for Creating Personalized Medical Aids in a Rural Area of Sierra Leone. *The American Journal of Tropical Medicine and Hygiene*, *102*(4), 905. https://doi.org/10.4269/AJTMH.19-0359
12. Muller, M. D. (2016). Chapter 46. *Atlas of amputations and limb deficiencies*, 18–125. https://doi.org/10.1093/oseo/instance.00076343
13. Buzzi, M., Colombo, G., Facoetti, G., Gabbiadini, S., & Rizzi, C. (2012). 3D modelling and knowledge: Tools to automate prosthesis development process. *International Journal on Interactive Design and Manufacturing*, *6*(1), 41–53. https://doi.org/10.1007/S12008-011-0137-5
14. Henao, S. C., Orozco, C., & Ramírez, J. (2020). Influence of Gait Cycle Loads on Stress Distribution at The Residual Limb/Socket Interface of Transfemoral Amputees: A Finite Element Analysis. *Scientific Reports*, *10*(1). https://doi.org/10.1038/S41598-020-61915-1
15. Colombo, G., Filippi, S., Rizzi, C., & Rotini, F. (2010). A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses. *Computers in Industry*, *61*(6), 513–523. https://doi.org/10.1016/J.COMPIND.2010.03.008
16. Kahle, J., Miro, R. M., Ho, L. T., Porter, M., Lura, D. J., Carey, S. L., … Highsmith, M. J. (2020). The effect of the transfemoral prosthetic socket interface designs on skeletal motion and socket comfort: A randomized clinical trial. *Prosthetics and Orthotics International*, *44*(3), 145–154. https://doi.org/10.1177/0309364620913459
17. Jamaludin, M. S., Hanafusa, A., Shinichirou, Y., Agarie, Y., Otsuka, H., & Ohnishi, K. (2019). Analysis of Pressure Distribution in Transfemoral Prosthetic Socket for Prefabrication Evaluation via the Finite Element Method. *Bioengineering 2019, Vol. 6, Page 98*, *6*(4), 98. https://doi.org/10.3390/BIOENGINEERING6040098
18. Ko, S. T., Asplund, F., & Zeybek, B. (2021). A Scoping Review of Pressure Measurements in Prosthetic Sockets of Transfemoral Amputees during Ambulation: Key Considerations for Sensor Design. *Sensors 2021, Vol. 21, Page 5016*, *21*(15), 5016. https://doi.org/10.3390/S21155016

19. Amudhan, K., Vasanthanathan, A., & Anish Jafrin Thilak, J. (2022). An insight into Transfemoral Prostheses: Materials, modelling, simulation, fabrication, testing, clinical evaluation and performance perspectives. *Expert Review of Medical Devices*, *19*(2), 123–140. https://doi.org/10.1080/17434440.2022.2039624
20. Fatone, S., & Caldwell, R. (2017). Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. *Prosthetics and orthotics international*, *41*(3), 237–245. https://doi.org/10.1177/0309364616685229
21. Kapp, S. (2000). Transfemoral Socket Design and Suspension Options. *Physical Medicine and Rehabilitation Clinics of North America*, *11*(3), 569–583.
22. Schuch, C. M., & Pritham, C. H. (1999). Current Transfemoral Sockets : Clinical Orthopaedics and Related Research®. Retrieved from https://journals-lww-com.ezproxy2.utwente.nl/clinorthop/fulltext/1999/04000/current_transfemoral_sockets.7.aspx
23. Edelstein, J. E., & Chui, K. K. (2020). Transfemoral Prostheses. In K. K. Chui, M. "Millee" Jorge, S.-C. Yen, & M. M. Lusardi (Eds.), *Orthotics and Prosthetics in Rehabilitation* (4th ed., pp. 635–653). St. Louis (MO): Elsevier. https://doi.org/https://doi.org/10.1016/B978-0-323-60913-5.00024-6
24. Gholizadeh, H., Abu Osman, N. A. zuan, Eshraghi, A., & Ali, S. (2014). Transfemoral prosthesis suspension systems: a systematic review of the literature. *American journal of physical medicine & rehabilitation / Association of Academic Physiatrists*, *93*(9), 809–823. https://doi.org/10.1097/PHM.0000000000000094
25. Colombo, G., Rizzi, C., Regazzoni, D., & Vitali, A. (2018). 3D interactive environment for the design of medical devices. *International Journal on Interactive Design and Manufacturing*, *12*(2), 699–715. https://doi.org/10.1007/S12008-018-0458-8/FIGURES/22
26. Fatone, S., Johnson, W. B., Tran, L., Tucker, K., Mowrer, C., & Caldwell, R. (2017). Quantification of rectifications for the Northwestern University Flexible Sub-Ischial Vacuum Socket. *Prosthetics and Orthotics International*, *41*(3), 251–257. https://doi.org/10.1177/0309364616684165
27. Gallay, J. F., Gasser, L., Gauthier, P., Joumier, F., Lepetit, J., Matagne, B., … Tarakhchyan, H. (n.d.). *Physical Rehabilitation Programme trans-Femoral Prosthesis Manufacturing guidelines MISSION Acknowledgements*. Retrieved from www.icrc.org
28. Matter, R., Harniss, M., Oderud, T., Borg, J., & Eide, A. H. (2017). Assistive technology in resource-limited environments: a scoping review. *Disability and Rehabilitation: Assistive Technology*, *12*(2), 105–114. https://doi.org/10.1080/17483107.2016.1188170/SUPPL_FILE/IIDT_A_1188170_SM2644.ZIP
29. *CBR Guidelines Community-Based Rehabilitation Introductory booklet*. (2010). Retrieved from www.iniscommunication.com
30. Vitali, A., Regazzoni, D., Rizzi, C., & Colombo, G. (2018). Design and Additive Manufacturing of Lower Limb Prosthetic Socket. *ASME International Mechanical Engineering Congress and Exposition, Proceedings (IMECE)*, *11*. https://doi.org/10.1115/IMECE2017-71494
31. van der Stelt, M., Grobusch, M. P., Koroma, A. R., Papenburg, M., Kebbie, I., Slump, C. H., … Brouwers, L. (2021). Pioneering low-cost 3D-printed transtibial prosthetics to serve a rural population in Sierra Leone – an observational cohort study. *EClinicalMedicine*, *35*, 100874. https://doi.org/10.1016/j.eclinm.2021.100874
32. Ribeiro, D., Cimino, S. R., Mayo, A. L., Ratto, M., & Hitzig, S. L. (2021). 3D printing and amputation: a scoping review. *Disability and Rehabilitation: Assistive Technology*, *16*(2), 221–240. https://doi.org/10.1080/17483107.2019.1646825
33. Radboudumc. (2018). Project 3D Sierra Leone. Retrieved October 12, 2021, from https://www.3dsierraleone.com
34. Toering, T. F. (2022). *Manufacturing 3D-printed Transfemoral Prosthetics for perople in Sierra Leone*.
35. Sterkenburg, I. P. J. (2023). *Simplified Transfemoral Prosthetic Socket Production in Sierra Leone*.
36. Ottobock. (n.d.). *TF Design iFab Order Form*.
37. Friddle's orthopedic appliances, inc. (n.d.). Prosthetic Work Order Trans-Femoral.
38. Streifeneder ortho production. (2023). *Measuring-sheet trans-femoral*.
39. Torres-Moreno, R., Morrison, J. B., Cooper, D., & Foort, J. (1992). A computer-aided socket design procedure for above-knee prostheses. *Journal of Rehabilitation Research and Development*, *29*(3), 35–44. https://doi.org/10.1682/JRRD.1992.07.0035
40. Vitali, A., Regazzoni, D., Rizzi, C., & Colombo, G. (2017). Design and additive manufacturing of lower limb prosthetic socket. In *ASME International Mechanical Engineering Congress and Exposition, Proceedings (IMECE)* (Vol. 11). American Society of Mechanical Engineers (ASME). https://doi.org/10.1115/IMECE2017-71494

41. Amrutsagar, L., Parit, G., Ghyar, R., & Bhallamudi, R. (2020). Parametric Design and Hybrid Fabrication of Above-Knee Prosthesis. *Indian Journal of Orthopaedics*, *54*(3), 381–390. https://doi.org/10.1007/S43465-020-00059-W/TABLES/2
42. Adeoye-Olatunde, O. A., & Olenik, N. L. (2021). Research and scholarly methods: Semi-structured interviews. *JACCP Journal of the American College of Clinical Pharmacy*, *4*(10), 1358–1367. https://doi.org/10.1002/jac5.1441
43. McIntosh, M. J., & Morse, J. M. (2015). Situating and constructing diversity in semi-structured interviews. *Global Qualitative Nursing Research*, *2*. https://doi.org/10.1177/2333393615597674
44. Joshi, A., Kale, S., Chandel, S., & Pal, D. (2015). Likert Scale: Explored and Explained. *British Journal of Applied Science & Technology*, *7*(4), 396–403. https://doi.org/10.9734/bjast/2015/14975
45. Colombo, G., Facoetti, G., Gabbiadini, S., & Rizzi, C. (2013). Socket modelling assistant for prosthesis design. *International Journal of Computer Aided Engineering and Technology*, *5*(2–3), 216–241. https://doi.org/10.1504/IJCAET.2013.052930
46. Li, S., Lan, H., Luo, X., Lv, Y., Gao, L., & Yu, H. (2019). Quantitative compensation design for prosthetic socket based on eigenvector algorithm method. *Review of Scientific Instruments*, *90*(10), 104101. https://doi.org/10.1063/1.5092743/360738
47. Fine, R. A., & Millero, F. J. (1973). Compressibility of water as a function of temperature and pressure. *The Journal of Chemical Physics*, *59*(10), 5529–5536. https://doi.org/10.1063/1.1679903
48. Chagnon, G., Rebouah, M., & Favier, D. (2015). Hyperelastic Energy Densities for Soft Biological Tissues: A Review. *Journal of Elasticity*, *120*(2), 129–160. https://doi.org/10.1007/s10659-014-9508-z
49. Charness, G., Gneezy, U., & Kuhn, M. A. (2012). Experimental methods: Between-subject and within-subject design. *Journal of Economic Behavior and Organization*, *81*(1), 1–8. https://doi.org/10.1016/j.jebo.2011.08.009
50. Cole, T. J., & Altman, D. G. (2017). Statistics Notes: What is a percentage difference? *BMJ*, j3663. https://doi.org/10.1136/bmj.j3663
51. Ibrahim, M. T., Hashim, N. A., Abd Razak, N. A., Abu Osman, N. A., Gholizadeh, H., & Astuti, S. D. (2024). Techniques for Measuring the Fluctuation of Residual Lower Limb Volume in Clinical Practices: A Systematic Review of the Past Four Decades. *Applied Sciences 2024, Vol. 14, Page 2594*, *14*(6), 2594. https://doi.org/10.3390/APP14062594
52. de Vet, H. C. W., Terwee, C. B., Knol, D. L., & Bouter, L. M. (2006). When to use agreement versus reliability measures. *Journal of Clinical Epidemiology*, *59*(10), 1033–1039. https://doi.org/10.1016/j.jclinepi.2005.10.015
53. Hanspal, R. S., Fisher, K., Nieveen, R., Hanspal{, R. S., Fisher{, K., & Nieveen{, R. (2003). Prosthetic socket fit comfort score. *Disability and Rehabilitation*, *25*(22), 1278–1280. https://doi.org/10.1080/09638280310001603983
54. Sabau, P., Chong, J. J., Jafari, A., Agrawal, S., Semasinghe, C., & Etoundi, A. (2020). Application of machine learning towards design optimisation of bio-inspired transfemoral prosthetic socket for robotic leg test rig. In *International Conference on Control, Automation and Systems* (Vol. 2020-October, pp. 396–401). IEEE Computer Society. https://doi.org/10.23919/ICCAS50221.2020.9268404
55. Ultimaker Tough PLA Material: Create Durable Prototypes and Tooling. (2018).
56. Miyata, Y., Sasaki, K., Guerra, G., & Rattanakoch, J. (2022). Sustainable, affordable and functional: reimagining prosthetic liners in resource limited environments. *Disability and Rehabilitation*, *44*(12), 2941–2947. https://doi.org/10.1080/09638288.2020.1844316
57. OPERATION NAMASTE Collaborative Orthotic and Prosthetic Care Alliance. (2021).

Appendix A - CAD-CAM workflows emerging from the scientific literature

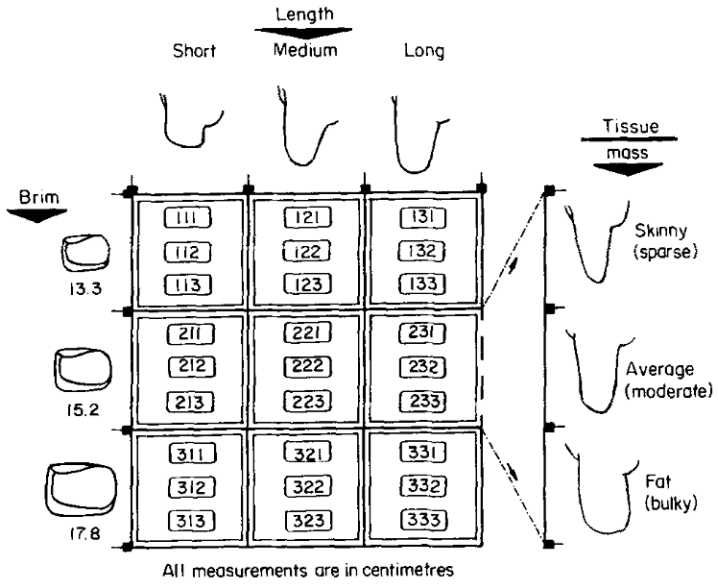
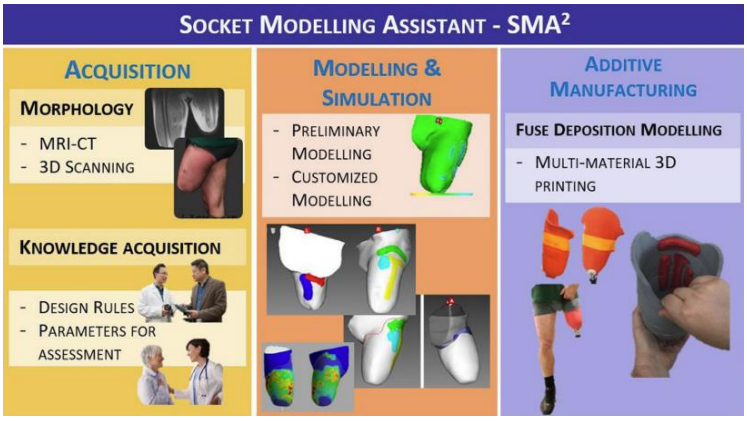


Figure ...: In the work of Torres Moreno et al in 1992, a digital shape library of 27 residual limbs was created that was used to match the residual limb of the patient with one of the reference shapes [39]. *The selection was based on matching anthropometric measurements with variations in skeletal structure (brim size), residual limb length (short, medium, large) and tissue mass (skinny, average, fat). The selected shape is scaled manually to further match the socket design with the skeletal dimensions of the residual limb.*



Firgure ...: In more recent years, Vitali and Colombo et al developed CAD-CAM method where a CAD method, called 'socket modelling assistant, was combined with CAM method of 3D printing [25, 40]. *Based on a 3D model of the residual limb obtained with MRI and residual limb characteristics, automatic and semi-automatic tools are used in the CAD environment to mimic and automize the traditional design process.*

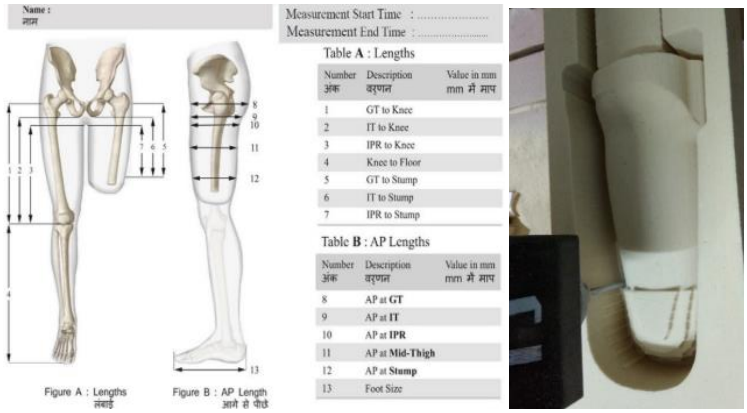


Figure ...: Amrutsagar et al developed an available low-cost production workflow with a semi-automatic CAD design based on 60 parameters derived from 23 anthropometric measurements of the residual limb, and thermoforming over a CAM replica of the designed socket [41].

Appendix B - Interview guide

Introductie

Wij zijn Iris Sterkenburg en Pim de la Fuente, Technisch Geneeskundige en master student Technische Geneeskunde. Vanuit het Radboud UMC Nijmegen doen wij onderzoek naar het ontwikkelen van een gestandaardiseerde workflow voor het maken van transfemorale prothesekokers die toepasbaar is in lage- en middeninkomenslanden.

In de wetenschappelijke literatuur is beperkte informatie te vinden over het productieproces van transfemorale prothesekokers en relaties tussen patiënt-, stomp- en prothesekarakteristieken en het ontwerp van de prothesekoker. Het doel van dit onderzoek is dan ook tweedelig:

- In kaart brengen van bestaande workflows voor het produceren van een transfemorale prothesekoker bij verschillende prothesemakers in Nederland.
- Onderzoeken van de invloed van verschillende patiënt-, stomp- en prothesekarakteristieken op de gebruikte workflow.

Het onderzoek bestaat uit twee delen:

- Observatie van de workflow door een bezoek op de locatie. Idealiter worden het aanmeet-, ontwerp- en productieproces geobserveerd.
- Interview na afloop van de observatie voor aanvullende vragen en het onderzoeken van de invloed van de verschillende karakteristieken op de workflow.

Voor een goede uitwerking van het onderzoek hebben wij het verzoek of tijdens de observaties en interview een audio opname gemaakt kan worden. Dit zal via microsoft teams gebeuren. Daarnaast zouden wij graag foto's willen maken tijdens de observatie, ter ondersteuning van het onderzoek. Op deze foto's zal de patiënt onherkenbaar in beeld zijn. Hiervoor hebben wij uw toestemming en die van de patiënt nodig. Voor de patiënt hebben wij een toestemmingsformulier wat ingevuld kan worden.

Voor het onderzoek zullen een aantal begrippen aan bod komen die wij hiermee nog extra willen uitleggen:

1 Karakteristieken: onderverdeeld in patiënt-, stomp- en prothesekarakteristieken, uitgewerkt in de tabel in Appendix B.
2 Distale deel van de koker: Kokervolume distaal vanaf het laagste deel van de brim
3 Proximale deel van de koker: Kokervolume van meest proximaal tot meest distale punt van de brim.

Vragen voorafgaand aan de observaties

1 Kort uitvragen wat voor patiënt aangemeten gaat worden
2 Welk type koker wordt gebruikt en of andere type kokers ook gemaakt worden. Daarbij of bij andere type kokers ook andere workflows horen.
3 Betreft het een testkoker of een definitieve koker?
    - Wat zijn de verschillen tussen een testkoker en definitieve koker?

Observatie Methodieken/processen

Voorafgaand aan het interview worden het aanmeetproces en, indien mogelijk, het ontwerpproces + productieproces van een transfemorale prothesekoker geobserveerd. Tijdens de observatie kunnen de vragen die in dit deel zijn uitgewerkt gesteld worden, zodat het interview minder uitgebreid is. De reden dat de observatie plaats vindt voor het interview is dat er op deze manier achteraf ruimte is om onbeantwoorde vragen over de methodieken te kunnen stellen.

Tijdens de observatie zullen, na toestemming van de patiënt en de prothesemaker, foto's gemaakt worden ter ondersteuning van de uitgewerkte methodiek/proces. Ook wordt de audio opgenomen en getranscribeerd via Microsoft Teams, zodat alle informatie achteraf terug gevonden kan worden.

Aanmeten

1 Welke aanmeetmethode wordt gebruikt?
   - Is deze verschillend voor de brim en het distale deel?
2 Hoe wordt het aanmeten voorbereid?
3 Welke hulpmiddelen worden gebruikt tijdens het aanmeten?
4 Welke metingen worden gedaan?
5 Hoeveel tijd neemt het aanmeetproces in beslag?

Ontwerpen

Ontwerpproces – algemeen

1 Welke ontwerpmethode gebruikt u?
   - Verschilt de methode voor de brim en het distale deel?
2 Wordt het ontwerpproces ter plekke door uzelf of een collega uitgevoerd, of door een externe partij op een andere locatie?
   - Wanneer de koker extern wordt ontworpen, wie ontwerpt deze dan?
     * Welke data wordt aangeleverd om de koker te kunnen ontwerpen?
     * Is de ontwerpmethode die gebruikt wordt bij jullie bekend?
     * Wordt de koker na het ontwerp door de externe partij nog aangepast?
3 Welke tools/hulpmiddelen gebruikt u tijdens het ontwerpproces?
   - Digitaal: scanner, software, 3D printer en materiaal
   - Handmatig: gereedschap, materiaal
4 Hoeveel tijd neemt het proces in beslag?
5 Hoe wordt de koker gepositioneerd ten opzichte van het distale deel tijdens de bankuitlijing?
   - Waar is deze uitlijning allemaal afhankelijk van? (Div karakeristieken?
   - Hoe wordt hierin rekening gehouden met contracturen?

Ontwerpproces – brim

1 Welk type brim wordt gebruikt?
   - Waarvan is deze keuze afhankelijk?
2 Welke vorm heeft dit type brim?
   - Welke hoogte hebben de trimlijnen?
   - Wat is de vorm van de doorsnede van de brim?

- Gebruikt u standaard vormen voor het ontwerp van de brim?

3 Waarom kiest u voor deze vorm van de brim?
4 In welke mate heeft de vorm van de brim invloed op de koker fit en ophanging van de koker?
- Hoe verhouden koker fit en ophanging zich tot elkaar?

5 In welke mate heeft de vorm van de brim invloed op de vorm van het distale deel van de koker?
6 Wordt de brim circumferentieel gereduceerd?
- Zo ja, waarom en met welk percentage?
- Zo nee, waarom?

7 Worden er specifieke aanpassingen gedaan aan de brim?
- Zo ja, waar worden deze aanpassingen gedaan?
- In welke grootte worden deze aanpassingen gedaan?

Ontwerpproces – distale deel

1 Welke vorm heeft het distale deel van de koker?
- Welke lengte heeft het distale deel van de koker?
  * Hoe verhoudt de lengte van het distale deel zich tot de lengte van de stomp?
- Welke vorm heeft de doorsnede van het distale deel van de koker?
  * Is deze vorm constant of variërend over de lengte van het distale deel?
- Welke vorm heeft het uiteinde van het distale deel van de koker?

2 Waarom kiest u voor deze vorm van het distale deel?
3 In welke mate heeft de vorm van het distale deel invloed op de koker fit en ophanging van de koker?
- Hoe verhouden koker fit en ophanging zich tot elkaar?

4 Wordt het distale deel op basis van de maatname circumferentieel gereduceerd?
- Zo ja, waarom en met welk percentage?
- Zo nee, waarom?

5 Worden er specifieke aanpassingen gedaan aan het distale deel?
- Zo ja, waar worden deze aanpassingen gedaan?
- In welke grootte worden deze aanpassingen gedaan?

Productie

1 Welke productiemethode(s) gebruikt u voor het fabriceren van de prothesekoker?
- Waarom gebruikt u deze methode?

2 Welk materiaal gebruikt u voor de productie?
- Waarom kiest u voor dit materiaal?

3 Hoelang duurt het om de koker te produceren?
4 Wat zijn de kosten van het productieproces?

Data

1 Welke patiëntkarakteristieken worden vastgelegd en opgeslagen?
- Zo ja, welke data en hoe wordt dit vastgelegd en opgeslagen?
- Wie is eigenaar van deze data?

2 Welke stomp-karakteristieken worden vastgelegd en opgeslagen?
- Zo ja, welke data en hoe wordt dit vastgelegd en opgeslagen?
- Wie is eigenaar van deze data?

3 Wordt het kokerontwerp vastgelegd en opgeslagen?

- Zo ja, hoe? (bijvoorbeeld: 3D scan, positieve mal)
- Worden de stappen van het ontwerpproces vastgelegd en opgeslagen?
- Wie is eigenaar van deze data?

4 Wordt de maatname van de stomp vastgelegd en opgeslagen?
- Zo ja, hoe?
- Worden de stappen van het aanmeetproces vastgelegd en opgeslagen?
- Wie is eigenaar van deze data?

5 Zouden jullie ervoor open staan om deze data te delen voor onderzoeksdoeleinden?

Ontwerpoptimalisatie

1 Hoe beoordeelt u de fitting en functionaliteit van de koker wanneer deze wordt aangepast door de patiënt?
- Waar let u specifiek op?
- Gebruikt u hier een standaard methode/protocol voor?

2 Welke aanpassingen worden er achteraf vaak gedaan aan de koker om de fitting en functionaliteit te verbeteren?
- Hoe regelmatig worden dezelfde aanpassingen gedaan?

3 Worden deze aanpassingen vastgelegd en opgeslagen?
- Zo ja, hoe?

Interview: Methodieken

Na afloop van de observaties wordt nagegaan welke vragen al beantwoord zijn en welke vragen aanvullend nog gesteld moeten worden. De aanvullende vragen zijn het eerste onderdeel van het interview.

Indien verschillende workflows worden gebruikt voor het maken van de transfemorale kokers, zullen de verschillen tussen deze workflows uitgevraagd worden als tweede deel van het interview. De open vraag die daarbij centraal staat is:

Waarin verschillen de andere workflows ten opzichte van de geobserveerde workflow?

Doorvragen op het antwoord op deze open vraag kan aan de hand van de vragen in het bovenstaande hoofdstuk van de methodieken en naar eigen invulling.

Interview: Patiënt-, stomp- en prothesekarakteristieken

De karakteristieken die worden nagegaan in dit deel van het interview zijn weergegeven in Appendix B. Bij het uitvragen van de invloed van de karakteristieken wordt gevraagd welke karakteristieken van invloed zijn en in welke mate ze de processen beïnvloeden. Hierbij wordt een scoringsysteem gebruikt van 0 tot 5. 0 voor geen invloed en 1-5 voor het schatten van de invloed van een individuele karakteristiek op het proces.

Aanmeten

1 Welke patiënt-, stomp- en prothesekarakteristieken worden vastgelegd tijdens het aanmeetproces?
2 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de aanmeetmethode?

Ontwerpen

Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de ontwerpmethode?

Ontwerpproces – brim

1 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de vorm van de brim?
   - Is er een duidelijke relatie tussen de karakteristieken en de vorm van de stomp?

2 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de hoeveelheid reductie van de brim?
   - Is er een duidelijke relatie tussen de karakteristieken en de hoeveelheid reductie?

3 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de specifieke aanpassingen aan de brim?
   - Is er een duidelijke relatie tussen de karakteristieken en de specifieke aanpassingen?

Ontwerpproces – distale deel

1 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de vorm van het distale deel?
   - Is er een duidelijke relatie tussen de karakteristieken en de vorm van de stomp?

2 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de hoeveelheid reductie van het distale deel?
   - Is er een duidelijke relatie tussen de karakteristieken en de hoeveelheid reductie?

3 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de specifieke aanpassingen aan het distale deel?
   - Is er een duidelijke relatie tussen de karakteristieken en de specifieke aanpassingen?

4 Hoeveel invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de uitlijning van de koker?
   - Is er een duidelijke relatie tussen de karakteristieken en de uitlijning van de koker?

Produceren

1 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op de productiemethode van de koker?
   - Is er een duidelijke relatie tussen de karakteristieken en de productiemethode van de koker?

Ontwerpoptimalisatie

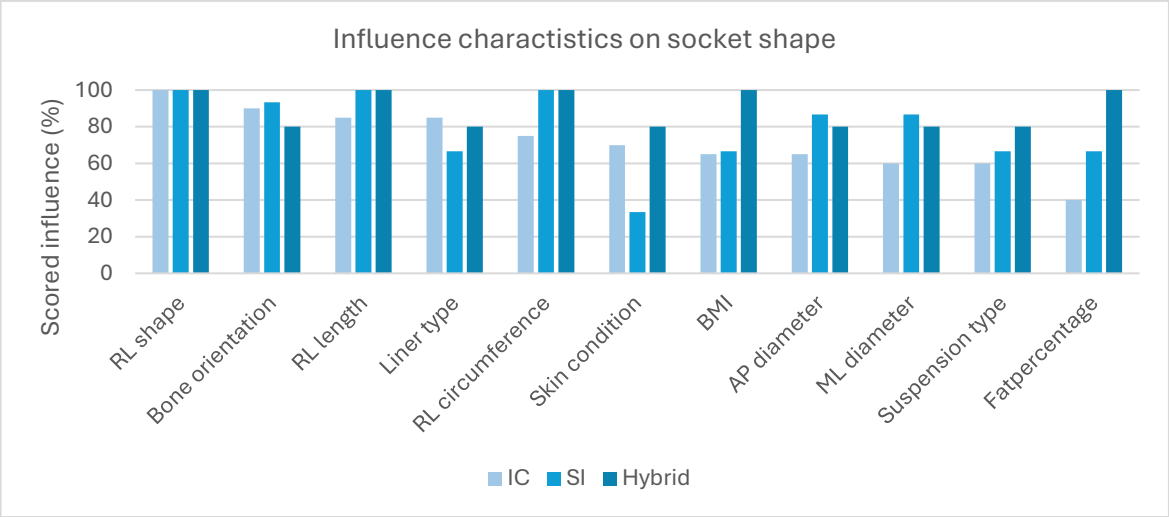
1 Welke invloed hebben specifieke patiënt-, stomp- en prothesekarakteristieken op deze aanpassingen van de koker?
   - Is er een duidelijke relatie tussen de karakteristieken en deze aanpassingen van de koker?

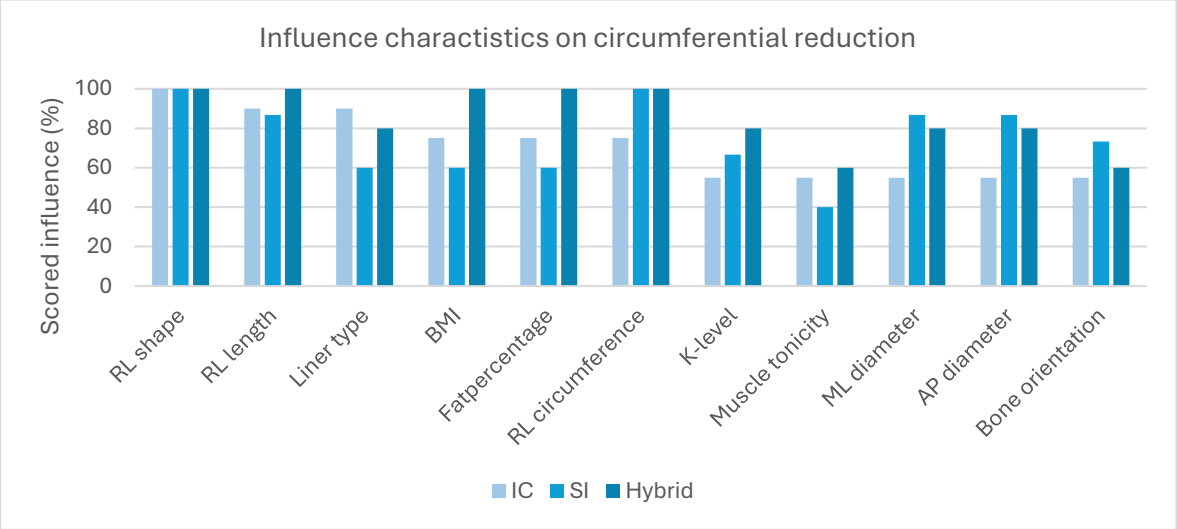
Appendix C - Scoring list with patient-, stump-, and prosthesis characteristics

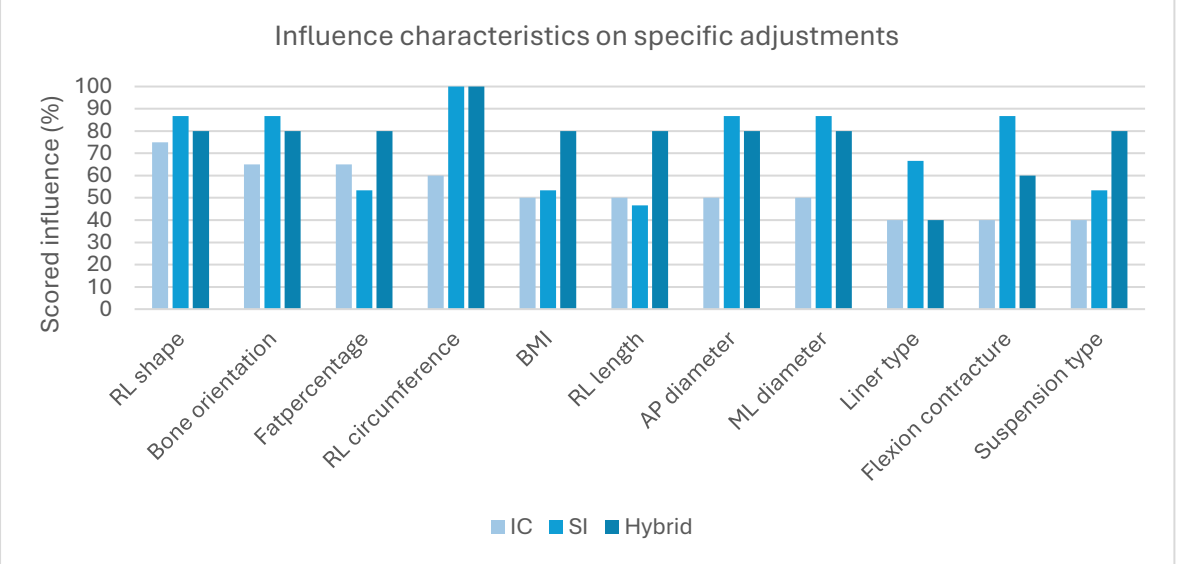
Karateristieken	Wel/niet vastgelegd	Aanmeet-methode	Ontwerpmethode							Productie-methode	Ontwerp-optimalisatie
			Vorm		Circumf. reductie		Specifieke aanpassingen		Uitlijning		
Patiënt			**Brim**	**Dist**	**Brim**	**Dist**	**Brim**	**Dist**			
Geslacht (M/V)											
Leeftijd											
K-Level											
BMI											
Vetpercentage											
Hulpvraag patiënt											
Spierkracht/toniciteit											
Amputatie			**Brim**	**Dist**	**Brim**	**Dist**	**Brim**	**Dist**			
Reden amputatie											
Tijd na amputatie											
Stomplengte											
Stompvorm											
Stompomtrek											
ML diameter											
AP diameter											
Conditie van de huid											
Botoriëntatie											
Kniehoogte											
Heuphoogte											
Heupadductie											
Heupflexie (+contractuur)											
Prothese			**Brim**	**Dist**	**Brim**	**Dist**	**Brim**	**Dist**			
Type + dikte liner											
Type Koker											
Type Brim											
Materiaal koker											
Suspensie											
Type knie											
Type voet											

Appendix D – Influence characteristics on socket design

This appendix gives an overview of the results of the questionnaire regarding each key aspect of socket design.







Appendix E - Questionnaire to obtain participant information

Vragenlijst voor algemene informatie van de deelnemer

Datum: _____

Studienummer: _____

Geboortedatum: _____

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 heeft u de prothese in gebruik? _____(jaren/maanden)

Appendix F - Measurement form for manual measurements

Aanmeetformulier stompvolume metingen

Datum: _____

Studienummer deelnemer: _____

Flexiehoek (graden): _____

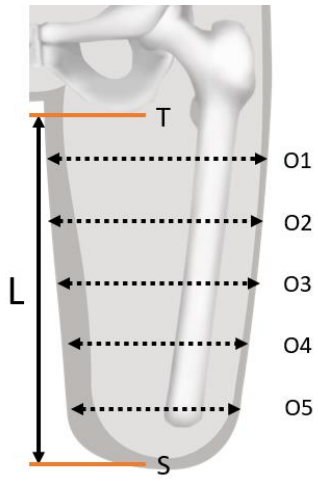
Adductiehoek (graden): _____

Metingen orthopedisch instrumentmaker 1

	Zonder liner 1	Zonder liner 2	Met liner 1	Met liner 2
Lengtemeting (cm)				
Omtrek 1 (cm)				
Omtrek 2 (cm)				
Omtrek 3 (cm)				
Omtrek 4 (cm)				
Omtrek 5 (cm)				

Metingen orthopedisch instrumentmaker 2

	Zonder liner 1	Zonder liner 2	Met liner 1	Met liner 2
Lengtemeting (cm)				
Omtrek 1 (cm)				
Omtrek 2 (cm)				
Omtrek 3 (cm)				
Omtrek 4 (cm)				
Omtrek 5 (cm)				



Figuur 1: Lengte(L) vanaf de tuber(T) tot stomppunt(S) en omtrekmetingen(O) voor het aanmeten van de hybride koker. Omtrekmaat 1 bevindt zicht 3 cm onder de tuber. Omtrekmaten 2 t/m 5 bevinden zich op iedere 5 cm vanaf O1 naar de distale punt.

Appendix G - Matlab code for digital analysis of the plaster casts

Matlab script for the calculation of the circumferences, areas and volumes of both plaster casts. To calculate the variables of the plaster cast without liner, the function plastervolume is made. To calculate the variables for the plaster cast with liner, plastervolume is used combined with either linervolume_uniform or linervolume_nonuniform, based on the specifications of the liner.

```
plaster_skin = 'stl001huid.stl' ;
STL = stlread(plaster_skin);
% Create a figure and plot the STL file
figure;
trisurf(STL,'FaceColor','cyan', 'EdgeColor', 'none');
axis equal;
xlabel('X');
ylabel('Y');
zlabel('Z');
title('3D STL Model');
view(3); % Set the view to 3D
camlight;
lighting phong;
% calculate the circumference and area of each slice, total volume, volume per 50 mm, and the length
of the residual limb
[areas, circumferences, volume_total, volumes, stumplength] = plastervolume(plaster_skin);

liner = 'stl001liner.stl' ;
STL2 = stlread(liner);
% Create a figure and plot the STL file
figure;
trisurf(STL2,'FaceColor','cyan', 'EdgeColor', 'none');
axis equal;
xlabel('X');
ylabel('Y');
zlabel('Z');
title('3D STL Model');
view(3); % Set the view to 3D
camlight;
lighting phong;
% calculate the circumference and area of each slice, total volume, volume per 50 mm, and the length
of the residual limb
[areas2, circumferences2, volume_total2, volumes2, stumplength2] = plastervolume(liner);

% if nonuniform liner thickness apply specifications of the liner:
linerthickness_min = 4;
linerthickness_max = 5;
linerthickness_distal = 15;

% if uniform liner thickness apply specifications of the liner:
%linerthickness = ;
%linercussion = ;

% Repeat the calculation of the plaster cast by compensating for the liner
[volume_total, stump_volume, liner_volume, volumes_stump, liner_areas, adjusted_circumferences,
adjusted_areas] = linervolume_nonuniform(areas2, circumferences2, linerthickness_min,
linerthickness_max, linerthickness_distal);
%[volume_total, stump_volume, liner_volume, volumes_stump, liner_areas, adjusted_circumferences] =
linervolume_uniform(areas2, circumferences2, linerthickness, linercussion);
```

Function: plastervolume

```
function [areas, circumferences, volume_total, volumes, stumplength] = plastervolume(filename)
% Read the STL file
STL = stlread(filename);
% Extract vertices
vertices = STL.Points;
vertices(:,2) = -1*(vertices(:,2));
% Define the range of y-values and the slice thickness
y_min = 0;
y_max = round(max(vertices(:,2)));
y_step = 1;
stumplength = y_max-y_min;
% Initialize an array to store circumferences
circumferences  = zeros((y_max - y_min) / y_step + 1, 2);
```

```
areas           = zeros((y_max - y_min) / y_step + 1, 2);

% Iterate through each slice and 1) find the vertices close to the current slice, 2) project the vertices on
a 2D plane, 3) calculate the convex hull, 4) calculate the circumference, 5) calculate the area of the
circumference, 6) store the area and circumference of the slice in an array
index = 1;
for y_value = y_min:y_step:y_max
    tolerance = 0.5; % Define a small tolerance to create a slice of 1 mm
    slice_vertices = vertices(abs(vertices(:,2) - y_value) <= tolerance, :);

    if isempty(slice_vertices)
        % If no vertices are found in the slice, continue to the next iteration
        continue;
    end
    projected_vertices = slice_vertices(:, [1, 3]);
    k = convhull(projected_vertices);
    circumference = 0;
    for i = 1:length(k)-1
        circumference = circumference + norm(projected_vertices(k(i), :) - projected_vertices(k(i+1), :));
    end
    area = polyarea(projected_vertices(k, 1), projected_vertices(k, 2));
    circumferences(index, :) = [y_value, circumference];
    areas(index, :) = [y_value, area];
    index = index + 1;
end

% Remove unused preallocated rows
circumferences = circumferences(1:index-1, :);
areas = areas(1:index-1, :);

% Calculate the total volume by summing the areas
volume_total    = sum(areas(:,2));

% Sum the circumferences per 50 mm (50 slices)
group_size = 50;
num_groups = ceil((y_max - y_min + 1) / group_size);
volumes = zeros(num_groups, 2);
for i = 1:num_groups
    start_y = y_min + (i-1) * group_size;
    end_y = start_y + group_size - 1;
    group_indices = areas(:, 1) >= start_y & areas(:, 1) <= end_y;
    volumes(i, 1) = (start_y + end_y) / 2; % Midpoint of the y range
    volumes(i, 2) = sum(areas(group_indices, 2));
end
end
```

Function: linervolume_uniform

```
function[volume_total, stump_volume, liner_volume, volumes_stump, liner_areas, adjusted_circumferences,
adjusted_areas] = linervolume_uniform(areas2, circumferences2, linerthickness_min, linerthickness_max,
linerthickness_distal)

y_min = 1;
y_max = max(circumferences2(:,1));
y_step = 1;
% create variables
adjusted_circumferences = zeros((y_max) / y_step + 1, 2);
adjusted_areas          = zeros((y_max) / y_step + 1, 2);
liner_areas             = zeros((y_max) / y_step + 1, 2);
% Iterate through each slice to calculate 1) the adjusted circumference, 2)
% the adjusted area, 3) the area of the liner
index = 1;
for y_value = 1:y_step:nRows
    radius = sqrt(areas2(y_value, 2) / pi);
    adjusted_radius = radius - linerthickness(y_value, 2);
    adjusted_circumference = adjusted_radius * 2 * pi;
    adjusted_area   = adjusted_radius^2 * pi;
    liner_area      = areas2(y_value, 2) - adjusted_area;
    % Store the circumference and area of the volume without liner
    adjusted_circumferences(index,:) = [y_value, adjusted_circumference];
    adjusted_areas(index,:) = [y_value, adjusted_area];
    liner_areas(index, :) = [y_value, liner_area];
    index = index + 1;
end
% Calculate the total voluem with liner, area of the liner at each
% slice, the volume of the liner, and the total volume without liner
volume_total = sum(areas2(:,2));
```

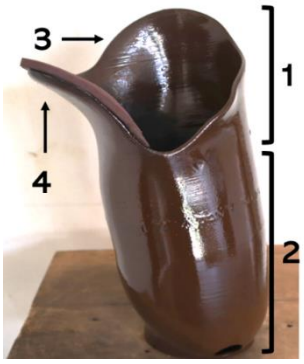
```
liner_areas  = liner_areas(1:(y_max-linerthickness_distal),:); % Volume of liner without distal end
liner_volume = sum(liner_areas(:,2)) + sum(areas2((y_max-linerthickness_distal):y_max,2)); % Volume of liner
with distal end
stump_volume = volume_total - liner_volume;

% calculate the volume per 50 mm (50 slices)
group_size = 50;
adjusted_areas = adjusted_areas((1:y_max-linerthickness_distal),:);
num_groups = ceil((y_max - y_min + 1) / group_size);
volumes_stump = zeros(num_groups, 2);
for i = 1:num_groups
    start_y = y_min + (i-1) * group_size;
    end_y = start_y + group_size - 1;
    group_indices = adjusted_areas(:, 1) >= start_y & adjusted_areas(:, 1) <= end_y;
    volumes_stump(i, 1) = (start_y + end_y) / 2; % Midpoint of the y range
    volumes_stump(i, 2) = sum(adjusted_areas(group_indices, 2));
end
end
```

Function: linervolume_nonuniform

```
function[volume_total, stump_volume, liner_volume, volumes_stump, liner_areas, adjusted_circumferences,
adjusted_areas] = linervolume_nonuniform(areas2, circumferences2, linerthickness_min, linerthickness_max,
linerthickness_distal)

y_min = 0;
y_max = max(circumferences2(:,1));
y_step = 1;
% calculate the course of the linerthickness along the length of the
% residual limb (y axis)
nRows = y_max/y_step + 1;
stepsize = (linerthickness_max - linerthickness_min) / (nRows - 1);
col1 = (y_min:y_max)';
col2 = (linerthickness_min:stepsize:linerthickness_max)';
linerthickness = [col1, col2];
% create variables
adjusted_circumferences = zeros((y_max) / y_step + 1, 2);
adjusted_areas          = zeros((y_max) / y_step + 1, 2);
liner_areas             = zeros((y_max) / y_step + 1, 2);
% Iterate through each slice to calculate 1) the adjusted circumference, 2)
% the adjusted area, 3) the area of the liner
index = 1;
for y_value = 1:y_step:nRows
    radius = sqrt(areas2(y_value, 2) / pi);
    adjusted_radius = radius - linerthickness(y_value, 2);
    adjusted_circumference = adjusted_radius * 2 * pi;
    adjusted_area   = adjusted_radius^2 * pi;
    liner_area      = areas2(y_value, 2) - adjusted_area;
    % Store the circumference and area of the volume without liner
    adjusted_circumferences(index,:) = [y_value, adjusted_circumference];
    adjusted_areas(index,:) = [y_value, adjusted_area];
    liner_areas(index, :) = [y_value, liner_area];
    index = index + 1;
end
% Calculate the total voluem with liner, area of the liner at each
% slice, the volume of the liner, and the total volume without liner
volume_total = sum(areas2(:,2));
liner_areas  = liner_areas(1:(y_max-linerthickness_distal),:); % Volume of liner without distal end
liner_volume = sum(liner_areas(:,2)) + sum(areas2((y_max-linerthickness_distal):y_max,2)); % Volume of liner
with distal end
stump_volume = volume_total - liner_volume;

% calculate the volume per 50 mm (50 slices)
group_size = 50;
adjusted_areas = adjusted_areas((1:y_max-linerthickness_distal),:);
num_groups = ceil((y_max - y_min + 1) / group_size);
volumes_stump = zeros(num_groups, 2);
for i = 1:num_groups
    start_y = y_min + (i-1) * group_size;
    end_y = start_y + group_size - 1;
    group_indices = adjusted_areas(:, 1) >= start_y & adjusted_areas(:, 1) <= end_y;
    volumes_stump(i, 1) = (start_y + end_y) / 2; % Midpoint of the y range
    volumes_stump(i, 2) = sum(adjusted_areas(group_indices, 2));
end

end
```

Appendix H - Assessment form to obtain socket assessment of participant

Vragenlijst beoordeling prothesekoker door deelnemer



Figuur 1: Transfemorale prothesekoker, 1) Brim 2) kokervolume.

Datum: _____

Studienummer deelnemer: _____

3D geprinte koker:

Zonder liner, 5% ovaal	Zonder liner, 10% ovaal	Met liner, 5% ovaal	Met liner, 10% ovaal
○	○	○	○

1. Hoe ervaart u het comfort van de prothesekoker op een schaal van 0-10?

- 0 betekent de meest oncomfortabele pasvorm
- 10 betekent de meest comfortabele pasvorm denkbaar
- Omcirkel het cijfer dat het meest overeenkomt met het ervaren comfort

Meest oncomfortabele pasvorm **Meest comfortabele pasvorm denkbaar**

0 1 2 3 4 5 6 7 8 9 10

2a. Kunt u op een schaal van 0-10 aangeven of u pijn of ongemak van de koker heeft ervaren tijdens de oefeningen?

- 0 betekent ernstige pijn of ongemak waardoor de koker niet te dragen is
- 10 betekent geen pijn of ongemak

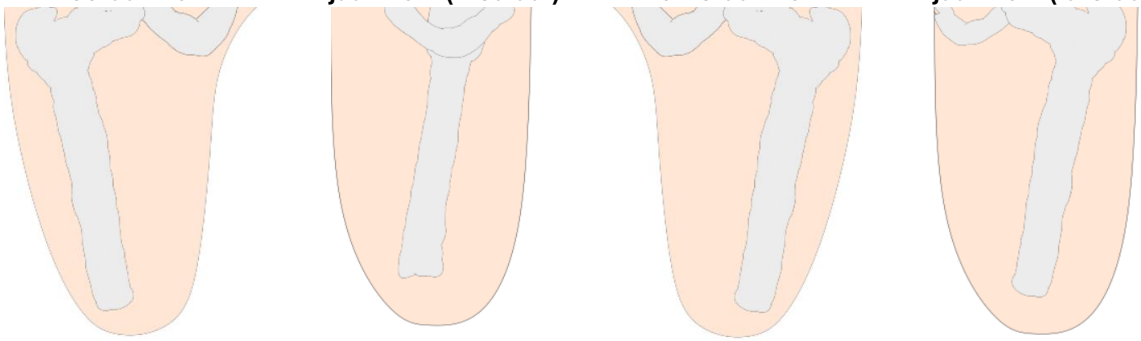
Ernstige pijn of ongemak **Geen pijn of ongemak**

0 1 2 3 4 5 6 7 8 9 10

2b. Kunt u aangeven waar u pijn of ongemak hebt ervaren, en wat de aard is?

- Wrijving tussen de koker en de huid van de stomp
- Drukplek specifiek op de stomp
- Pijn uitgestraald over een gebied

Vooraanzicht **Zijaanzicht (mediaal)** **Achteraanzicht** **Zijaanzicht (lateraal)**



3a. Hoe beoordeelt u de stabiliteit van de prothese tijdens staan?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

3b. Licht uw keuze toe:

_____

_____

4a. Hoe beoordeelt u de stabiliteit van de prothese tijdens lopen?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

4b. Licht uw keuze toe:

_____

_____

5a. Hoe beoordeelt u de pasvorm van de brim (zie onderdeel 1 in Figuur 1) van de koker?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

5b licht uw keuze toe:

_____

_____

6a. Hoe beoordeelt u de pasvorm van het kokervolume (Zie onderdeel 2 in Figuur 1)?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

6b. licht uw keuze toe:

_____

_____

7a. Hoe beoordeelt u de pasvorm van het uiteinde van de koker?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

7b. licht uw keuze toe:

_____

_____

8. Hoeveel moeite kostte het u om de prothesekoker aan te trekken?

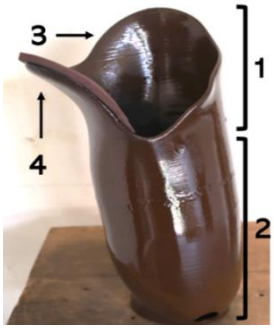
Veel	Meer dan normaal	Normaal	Minder dan normaal	Geen
○	○	○	○	○

9. Hoeveel energie/kracht kostte het u om de oefeningen uit te voeren?

Veel	Meer dan normaal	Normaal	Minder dan normaal	Geen
○	○	○	○	○

Appendix I – Socket fit assessment form for the prosthetist

Scoringslijst beoordeling prothesekoker door instrumentmaker



Figuur 1: Transfemorale prothesekoker, 1) Brim 2) kokervolume.

Datum: _____

Studienummer deelnemer: _____

Naam beoordelaar: _____

3D geprinte koker:

Zonder liner, 5% ovaal	Zonder liner, 10% ovaal	Met liner, 5% ovaal	Met liner, 10% ovaal
○	○	○	○

Verplaatsingstests	Voor loopoefeningen	Na loopoefeningen
Verticaal (mm)	_____	_____
Lateraal (mm)	_____	_____
Mediaal (mm)	_____	_____
Anterior (mm)	_____	_____
Posterior (mm)	_____	_____

1a. Biedt de prothesekoker voldoende stabiliteit tijdens staan?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

1b. Licht uw keuze toe:

_____

_____

2a. Biedt de prothesekoker voldoende stabiliteit tijdens lopen?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

2b. Licht uw keuze toe:

_____

_____

3a. Hoe beoordeelt u de ophanging van de prothesekoker?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

3b. Licht uw keuze toe:

_____

_____

4a. Hoe beoordeelt u de pasvorm van de brim van de koker?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

4b. Licht uw keuze toe:

_____

_____

5a. Hoe beoordeelt u de pasvorm van het kokervolume (Zie onderdeel 2 in Figuur 1)?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

5b. Licht uw keuze toe:

_____

_____

6a. Hoe beoordeelt u de pasvorm van het uiteinde van de koker?

Slecht	Onvoldoende	Redelijk	Goed	Uitstekend
○	○	○	○	○

6b. Licht uw keuze toe:

_____

_____

7. Zijn er mogelijkheden om de prothesekoker aan te passen voor een betere pasvorm?

_____

_____

8. Zijn er tekenen van roodheid, blaarvorming en schuren van de huid?

_____

_____

Appendix J - Assessment of the prosthetist, with substantiation

	Zoner liner, 5%	Zonder liner, 10%	Met liner, 5%	Met liner 10%
Biedt de prothesekoker voldoende stabiliteit tijdens staan?	**Goed;** Mevrouw kan het gewicht goed verdelen. Staat stevig en stabiel zonder steun op de handen	**Goed**; Breekt niet uit. Mevrouw staat stabiel en voelt zich veilig. Kan prothese goed belasten.	**Goed**; Breekt niet uit. Mevrouw kan goed belasten, voelt zich veilig.	**Uitstekend**; Staat stevig en stabiel. Kan goed belasten, voelt zich veilig.
Biedet de prothesekoker voldoende stabiliteit tijdens lopen?	**Goed;** Koker breekt niet uit. Mevrouw heeft voldoende controle voor aansturing van de prothese	**Goed**; Breekt niet uit. Mevrouw kan goed shiften en heeft controle, geen rotatie afwijking.	**Goed**; Breekt niet uit. Kan goed shiften. Voelt zich veilig. Heeft controle	**Uitstekend**; Zeer stabiel. Breekt niet uit. Mevrouw heeft veel vertrouwen. Loopsnelheid is hoog.
Hoe beoordeelt u de ophanging van de prothesekoker?	**Redelijk**; vrij veel op- en neerwaartse verplaatsing van de stomp, maar geen risico op loslaten van de prothese	**Redelijk**; Vrij veel op- en neerwaartse verplaatsing van de stomp in de koker. Wel veilig, geen risico van uit gaan prothese	**Redelijk;** vrij veel verticale verplaatsing, maar wel veilig	**Goed**; Minder verticale verplaatsing. Ook tijdens het zitten blijft de koker goed op zijn plaats.
Hoe beoordeelt u de pasvorm van de brim van de koker?	**Goed**; Randen sluiten netjes aan, tubersteun zit op de juiste plek	**Goed**; Randen sluiten goed aan. Tubersteun op de juiste plaats.	**Goed**; Sluit goed aan. Tubersteun op de juiste plaats.	**Goed**; Sluit goed aan. Tubersteun op de juiste plaats.
Hoe beoordeelt u de pasvorm van het kokervolume?	**Redelijk**; Volumecorrectie niet verkeerd, maar had iets strakker gemogen voor betere drukverdeling	**Goed**; volume correctie is goed.	**Redelijk**; Koker is aan de strakke kant. Mevrouw geeft aan dat dit minder comfortabel is.	**Goed**; Erg strak, maar juist daardoor zeer stabiel en minder druk distaal. Aantrekken wel wat lastiger.
Hoe beoordeelt u de pasvorm van het uiteinde van de koker?	**Redelijk**; Vorm is goed. Te veel druk distaal, maar dit komt meer door de diepte en het volume van de koker	**Redelijk**; Vorm is goed. Uiteinde van de stomp (thv het litteken) blijft wel gevoelig	**Redelijk**; Vorm is goed, maar distaal blijft een gevoelige plek.	**Goed**; Vorm is goed. Nu minder last distaal door meer afsteuning op volume.
Zijn er mogelijkheden om de prothese aan te passen voor een betere pasvorm?	Mevrouw gaf aan last te hebben distaal. Koker iets strakker en iets dieper zou kunnen helpen om de druk distaal te verminderen.	Eventueel koker iets dieper maken ivm gevoeligheid distaal (al is dit wel een bekend probleem bij mevrouw).	Mogelijk wederom iets dieper om uiteinde te ontlasten.	Eventueel ruimte maken t.h.v. het femuruiteinde lateraal.